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[Home](#) > Court Orders

## **Court Orders** <sup>[1]</sup>

04/11/2018	04/11/2018	<a href="#">ORDER</a> <sup>[2]</sup>	Order of Dismissal
07/18/2017	07/17/2017	<a href="#">RULING</a> <sup>[3]</sup> & <a href="#">ORDER</a> <sup>[4]</sup>	Memorandum Ruling (Common Benefit Fees and Allocation) and Order
06/19/2017	06/15/2017	<a href="#">ORDER</a> <sup>[5]</sup>	Order Setting Deadline for Motions for Approval of Settlement in Cases Involving Death or Incapacity of Actos User
07/20/2016	07/18/2016	<a href="#">ORDER</a> <sup>[6]</sup>	Order Rescinding Section II of Second Amended CMO: Direct Filing and Service of Process (Doc. 1538)
04/18/2016	04/15/2016	<a href="#">ORDER</a> <sup>[7]</sup>	Case Management Order Regarding Approval of Settled Actions and Settled Claims Involving Death or Incapacity of a Product User
02/29/2016	02/29/2016	<a href="#">ORDER</a> <sup>[8]</sup>	Case Management Order: Assessment of Common Benefit Fees and Expenses and/or Costs
02/16/2016	02/16/2016	<a href="#">ORDER</a> <sup>[9]</sup>	Case Management Order: Common Benefit Fees and Costs
01/08/2016	01/06/2016	<a href="#">ORDER</a> <sup>[10]</sup>	Order: Cancelling February 18, 2016 Status Conference and Setting April 20-21, 2016 Working Group Meeting
12/16/2015	12/16/2015	<a href="#">ORDER</a> <sup>[11]</sup>	Order Regarding Protocol Involving Disputes Before Other United States District Courts Concerning Enforcement of Subpoenas
12/10/2015	12/09/2015	<a href="#">ORDER</a> <sup>[12]</sup>	Order: Setting Next Status Conference for February 18, 2016

11/17/2015	11/16/2015	<u>ORDER</u> <sup>[13]</sup>	Order Granting a Limited Lift of Stay of Discovery for Issuance of Rule 45 Subpoenas to Healthcare Facilities
09/24/2015	09/21/2015	<u>ORDER</u> <sup>[14]</sup>	Order: Cancelling Status Conferences Through January, 2016
09/02/2015	08/31/2015	<u>ORDER</u> <sup>[15]</sup>	Case Management Order Regarding the Resolution of Cases Involving the Death or Incapacity of a Product User
09/01/2015	09/01/2015	<u>ORDER</u> <sup>[16]</sup>	Case Management Order: Holdback Order
08/21/2015	08/21/2015	<u>ORDER</u> <sup>[17]</sup>	Order: Cancelling September-October, 2015 Status Conferences
08/07/2015	08/07/2015	<u>ORDER</u> <sup>[18]</sup>	Case Management Order: Instructions To Deputy Special Master DeJean
06/19/2015	06/17/2015	<u>ORDER</u> <sup>[19]</sup>	Order: Cancelling July-August, 2015 Status Conferences
05/15/2015	05/14/2015	<u>ORDER</u> <sup>[20]</sup>	Order: Cancelling May-June, 2015 Status Conferences
05/05/2015	05/01/2015	<u>ORDER</u> <sup>[21]</sup>	Order for Limited Stay
04/29/2015	04/29/2015	<u>AGREEMENT</u> <sup>[22]</sup> (Note: This MSA is not an order of the Court, but is produced here for convenience and informational purposes.)	Master Settlement Agreement
04/29/2015	04/28/2015	<u>ORDER</u> <sup>[23]</sup>	Order Regarding Settlement Agreement and Deadlines
04/29/2015	04/28/2015	<u>ORDER</u> <sup>[24]</sup>	Order Regarding Preservation of Records and Prima Facie Evidence of Usage, Injury and Causation Requirements for Pending Cases Not Participating in the Actos ® Resolution Program and Newly Filed or Transferred Cases
04/29/2015	04/28/2015	<u>ORDER</u> <sup>[25]</sup>	Case Management Order: Census of Claims
04/20/2015	04/20/2015	<u>ORDER</u> <sup>[26]</sup>	Order: Suspending Proceedings During Week of April 20, 2015

04/14/2015	04/14/2015	<a href="#">MINUTE ENTRY</a> <sup>[27]</sup>	Minute Entry: Agenda for April 23, 2015 Status Conference
04/09/2015	04/08/2015	<a href="#">ORDER</a> <sup>[28]</sup>	Amended CMO: Protecting the Confidentiality of Discovery Materials
04/09/2015	04/08/2015	<a href="#">ORDER</a> <sup>[29]</sup>	Amended CMO: Motions
03/20/2015	03/20/2015	<a href="#">ORDER</a> <sup>[30]</sup>	Order Designating Potential Trial Cases for May 2, 2016
03/06/2015	03/03/2015	<a href="#">STIPULATED PROTECTIVE ORDER</a> <sup>[31]</sup>	Stipulated Protective Order to Non-Parties Kaiser Foundation Hospitals, et al
02/24/2015	02/23/2015	<a href="#">ORDER</a> <sup>[32]</sup>	Scheduling Order: May 2, 2016 Trial
02/20/2015	02/20/2015	<a href="#">MINUTE ENTRY</a> <sup>[33]</sup>	Minute Entry: Agenda for February 26, 2015 Status Conference
02/10/2015	02/06/2015	<a href="#">ORDER</a> <sup>[34]</sup>	Order: Cancelling March, 2015 Status Conference
02/09/2015	02/06/2015	<a href="#">ORDER</a> <sup>[35]</sup>	Amended CMO: Fact Sheet Analysis
01/21/2015	01/16/2015	<a href="#">ORDER</a> <sup>[36]</sup>	CMO: Fact Sheet Analysis
01/21/2015	01/16/2015	<a href="#">ORDER</a> <sup>[37]</sup>	CMO: Reporting on Ongoing State Court Proceedings
01/21/2015	01/16/2015	<a href="#">ORDER</a> <sup>[38]</sup>	CMO: Reporting on Resolved State Court Proceedings
01/21/2015	01/20/2015	<a href="#">MINUTE ENTRY</a> <sup>[39]</sup>	Minute Entry: Agenda for January 22, 2015 Status Conference
11/18/2014	11/18/2014	<a href="#">MINUTE ENTRY</a> <sup>[40]</sup>	Minute Entry: Agenda for November 20, 2014 Status Conference
10/24/2014	10/21/2014	<a href="#">ORDER</a> <sup>[41]</sup>	Order: Cancelling December, 2014 Status Conference

10/09/2014	10/02/2014	<a href="#">Status Conference Dates for 2015</a> [42]	Status Conference Dates for 2015
10/06/2014	10/02/2014	<a href="#">ORDER</a> [43]	Order: Cancelling October, 2014 Status Conference
09/30/2014	09/30/2014	<a href="#">MINUTE ENTRY</a> [44]	Minute Entry: Second Periodic Review Dates & Deadlines
09/17/2014	09/16/2014	<a href="#">MINUTE ENTRY</a> [45]	Minute Entry: Agenda for September 25, 2014 Status Conference
08/18/2014	08/18/2014	<a href="#">MINUTE ENTRY</a> [46]	Minute Entry: Agenda for August 21, 2014 Status Conference
08/06/2014	07/02/2014	<a href="#">ORDER 1 [ Doc 4535 ]</a> [47]	BCBSMA CASE MANAGEMENT ORDER 1
08/06/2014	08/06/2014	<a href="#">ORDER 2 [ DOC 4536 ]</a> [48]	BCBSMA CASE MANAGEMENT ORDER 2
06/18/2014	06/18/2014	<a href="#">ORDER</a> [49]	Order: Cancelling July, 2014 Status Conference
06/16/2014	06/13/2014	<a href="#">MINUTE ENTRY</a> [50]	Minute Entry: Agenda for June 19, 2014 Status Conference
06/11/2014	06/11/2014	<a href="#">ORDER</a> [51]	ORDER: Second Periodic Review
05/23/2014	05/23/2014	<a href="#">Order Regarding Special Masters</a> [52]	Order appointing Gary J. Russo as Special Master and Kenneth W. DeJean and Carmen M. Rodriguez as Deputy Special Masters.
05/01/2014	05/01/2014	<a href="#">AMENDED ORDER</a> [53]	Amended Order May 22, 2014 Status Conference Is Cancelled and the next Status Conference and Rule 16 Pre-Trial Conference will be held in June 2014
04/24/2014	04/24/2014	<a href="#">ORDER</a> [54]	Order to hold May 22, 2014 Status Conference and Rule 16 Pre-Trial Conference
04/14/2014	04/11/2014	<a href="#">ORDER</a> [55]	Order: Cancelling April, 2014 Status Conference
03/14/2014	03/14/2014	<a href="#">ORDER</a> [56]	Order: Cancelling March, 2014 Status Conference

02/14/2014	02/14/2014	<a href="#">ORDER</a> <sup>[57]</sup>	Order: February, 2014 Status Conference
01/17/2014	01/17/2014	<a href="#">ORDER</a> <sup>[58]</sup>	ORDER: Continuing the Second Pilot Bellwether Trial
01/03/2014	01/03/2014	<a href="#">ORDER</a> <sup>[59]</sup>	Order: January, 2014 Status Conference
12/19/2013	12/19/2013	<a href="#">ORDER</a> <sup>[60]</sup>	Third Amended Court Order: Plaintiffs' Steering Committee
12/11/2013	12/05/2013	<a href="#">MINUTE ENTRY</a> <sup>[61]</sup>	Minute Entry: Agenda for December 11, 2013 Status Conference
11/27/2013	11/27/2013	<a href="#">ORDER</a> <sup>[62]</sup>	Order: December, 2013 Status Conference and Daubert Hearings
09/19/2013	09/19/2013	<a href="#">ORDER</a> <sup>[63]</sup>	Order re: September 26, 2013 Status Conference
08/29/2013	08/29/2013	<a href="#">ORDER</a> <sup>[64]</sup>	CO: Meet and Confer
08/26/2013	08/26/2013	<a href="#">ORDER</a> <sup>[65]</sup>	ORDER: Monthly Status Conference Dates for 2014
08/22/2013	08/22/2013	<a href="#">Minute Entry</a> <sup>[66]</sup>	Minute Entry: Agenda for August 22, 2013 Status Conference
07/24/2013	07/18/2013	<a href="#">Minute Entry</a> <sup>[67]</sup>	Minute Entry: Agenda for July 25, 2013 Status Conference
07/16/2013	07/16/2013	<a href="#">ORDER</a> <sup>[68]</sup>	CMO: Supplemental Order on Expert-Related Issues (First Pilot Bellwether Trial)
06/18/2013	06/18/2013	<a href="#">MINUTE ENTRY</a> <sup>[69]</sup>	Minute Entry: Agenda for June 20, 2013 Status Conference
06/18/2013	06/13/2013	<a href="#">ORDER</a> <sup>[70]</sup>	Second Amended Court Order: Plaintiffs' Steering Committee
05/23/2013	05/23/2013	<a href="#">Minute Entry</a> <sup>[71]</sup>	Minute Entry: Agenda for May 23, 2013 Status Conference

05/23/2013	05/21/2013	<a href="#">ORDER</a> <sup>[72]</sup>	CMO: Motions
05/03/2013	05/03/2013	<a href="#">ORDER</a> <sup>[73]</sup>	Second Amended Scheduling Order: Pilot Bellwether Program (First Trial)
05/03/2013	05/03/2013	<a href="#">ORDER</a> <sup>[74]</sup>	First Amended CMO: Discovery Protocol
05/03/2013	05/03/2013	<a href="#">ORDER</a> <sup>[75]</sup>	CMO: Bellwether Nominations
04/23/2013	04/23/2013	<a href="#">SCHEDULING ORDER</a> <sup>[76]</sup> <a href="#">Attachment 1 - Pre-trial Order Instructions</a> <sup>[77]</sup> <a href="#">Attachment 2 - Pre-trial Order</a> <sup>[78]</sup>	First Amended Scheduling Order: Pilot Bellwether Program (First Trial)
04/23/2013	04/23/2013	<a href="#">ORDER</a> <sup>[79]</sup> <a href="#">Exhibit A - Endorsement of Protective Order</a> <sup>[80]</sup>	First Amended CMO: Protecting the Confidentiality of Discovery Materials
04/18/2013	04/18/2013	<a href="#">MINUTE ENTRY</a> <sup>[81]</sup>	Minute Entry: Agenda for April 25, 2013 Status Conference
04/05/2013	03/27/2013	<a href="#">SCHEDULING ORDER</a> <sup>[82]</sup>	Scheduling Order: Pilot Bellwether Program (Second Trial)
04/03/2013	03/26/2013	<a href="#">ORDER</a> <sup>[83]</sup>	CO: Contact Information
04/03/2013	03/27/2013	<a href="#">MINUTE ENTRY</a> <sup>[84]</sup>	Minute Entry of March 27, 2013
03/27/2013	03/21/2013	<a href="#">ORDER</a> <sup>[85]</sup>	CMO: Select Discovery Issues
03/24/2013	03/21/2013	<a href="#">MINUTE ENTRY</a> <sup>[86]</sup>	UPDATED: Minute Entry: Agenda for March 21, 2013 Status Conference
02/19/2013	02/19/2013	<a href="#">SCHEDULING ORDER</a> <sup>[87]</sup>	Scheduling Order: Pilot Bellwether Program (First Trial)
02/19/2013	02/13/2013	<a href="#">ORDER</a> <sup>[88]</sup>	CMO: Claims for Common Benefit Fees and Expenses

02/13/2013	02/13/2013	<a href="#">MINUTE ENTRY</a> [89]	Minute Entry: Agenda for February 21, 2013 Status Conference
02/04/2013	02/04/2013	<a href="#">ORDER</a> [90]	Amended Court Order: Plaintiffs' Steering Committee
02/04/2013	02/04/2013	<a href="#">MINUTE ENTRY</a> [91]	Minute Entry: Addition to Executive Committe of PSC
01/29/2013	01/29/2013	<a href="#">ORDER</a> [92]	Court Order: Appointment of a Pro Se Liaison
01/23/2013	01/23/2013	<a href="#">Minute Entry: Agenda for January 24, 2013 Status Conference</a> [93]	Minute Entry: Agenda for January 24, 2013 Status Conference
01/16/2013	01/16/2013	<a href="#">MINUTE ENTRY</a> [94]	AGENDA FOR JANUARY 24, 2013 STATUS CONFERENCE
01/09/2013	01/08/2013	<a href="#">ORDER</a> [95]	PROTOCOL FOR IN EXTREMIS DEPOSITIONS
01/02/2013	01/02/2013	<a href="#">ORDER</a> [96]	PERIODIC REVIEW PROCESS
01/02/2013	01/02/2013	<a href="#">MINUTE ENTRY</a> [97]	JANUARY 2013 PERIODIC REVIEW DATES & DEADLINES
12/21/2012	12/21/2012	<a href="#">ORDER</a> [98]	DISCOVERY PROTOCOL
12/13/2012	12/12/2012	<a href="#">MINUTE ENTRY</a> [99]	AGENDA FOR DECEMBER 13, 2012 STATUS CONFERENCE
11/16/2012	11/16/2012	<a href="#">ORDER</a> [100]	DEPUTY SPECIAL MASTER DEJEAN'S FEES AND COSTS
11/13/2012	11/13/2012	<a href="#">CMO: Defendant Fact Sheet (PDF)</a> [101] <a href="#">EXHIBIT A - DEFENDANT FACT SHEET (PDF)</a> [102] <a href="#">EXHIBIT B - PLAINTIFF'S TREATING HEALTH CARE PROVIDER DESIGNATION FOR DEFENDANT FACT SHEETS (PDF)</a> [103]	DEFENDANT FACT SHEETS

11/07/2012	11/07/2012	<a href="#">MINUTE ENTRY</a> [104]	STATUS CONFERENCE SCHEDULED FOR NOVEMBER 15, 2012 IS HEREBY CANCELLED
10/24/2012	10/24/2012	<a href="#">MINUTE ENTRY</a> [105]	AGENDA FOR OCTOBER 25, 2012 STATUS CONFERENCE
10/09/2012	10/09/2012	<a href="#">ORDER</a> [106]	JOINT EXPENSES
10/09/2012	10/09/2012	<a href="#">ORDER</a> [107]	SPECIAL MASTER FEES AND COSTS
09/20/2012	09/20/2012	<a href="#">MINUTE ENTRY</a> [108]	AGENDA FOR SEPTEMBER 20, 2012 STATUS CONFERENCE
07/30/2012	07/30/2012	<a href="#">CMO: Protecting the Confidentiality of Discovery Materials (PDF)</a> [109] <a href="#">EXHIBIT A - Endorsement of Protective Order (PDF)</a> [110]	Protecting the Confidentiality of Discovery Materials
07/27/2012	07/27/2012	<a href="#">2nd AMENDED ORDER</a> [111]	Direct Filing and Service of Process
07/27/2012	07/27/2012	<a href="#">ORDER</a> [112] <ul style="list-style-type: none"> <li><a href="#">EXHIBIT A - NONDISCLOSURE AND CONFIDENTIALITY AGREEMENT</a> [113]</li> </ul>	PROTOCOL RELATING TO THE PRODUCTION OF ELECTRONICALLY STORED INFORMATION ("ESI")
07/13/2012	07/13/2012	<a href="#">ORDER</a> [114]	SCHEDULING ORDER
07/13/2012	07/13/2012	<a href="#">ORDER</a> [115]	DISCOVERY STAY IS LIFTED
07/10/2012	07/08/2012	<a href="#">CMO: Assertions of Attorney-Client Privilege and Work Product Doctrine (PDF)</a> [116]	Assertions of Attorney-Client Privilege and Work Product Doctrine



EXHIBIT 1 - Assertions of Attorney-Client  
Privilege and Work Product Doctrine (PDF)

[117]

07/10/2012	07/10/2012	<u>CMO: PSC's Management of Timekeeping, Cost Reimbursement and Related Common Benefit Issues (PDF)</u> [118]  <u>EXHIBIT A - PSC's Management of Timekeeping (PDF)</u> [119]	PSC'S MANAGEMENT OF TIMEKEEPING, COST REIMBURSEMENT AND RELATED COMMON BENEFITS ISSUES
07/09/2012	07/09/2012	<u>CMO: Plaintiff Fact Sheets (PDF)</u> [120]  <u>EXHIBIT A - ACTOS PLAINTIFF FACT SHEET (PDF)</u> [121] <u>EXHIBIT B - LIMITED AUTHORIZATION TO DISCLOSE AND HEATH INFORMATION (PDF)</u> [122]	PLAINTIFF FACT SHEETS
07/02/2012	07/02/2012	<u>DATES</u> [123]	AMENDED MONTHLY STATUS CONFERENCE DATES
06/20/2012	06/20/2012	<u>MINUTE ENTRY</u> [124]	AGENDA FOR JUNE 21, 2012 STATUS CONFERENCE
05/22/2012	05/22/2012	<u>MINUTE ENTRY</u> [125]	DEADLINE TO FILE ANSWERS
05/22/2012	05/22/2012	<u>MINUTE ENTRY</u> [126]	AGENDA FOR MAY 24, 2012 STATUS CONFERENCE
04/13/2012	04/13/2012	<u>COURT ORDER</u> [127]	PLAINTIFF'S STEERING COMMITTEE
04/13/2012	04/13/2012	<u>MINUTE ENTRY</u> [128]	STATUS CONFERENCES
04/13/2012	04/13/2012	<u>MINUTE ENTRY</u> [129]	COMMUNICATING WITH THE COURT

04/13/2012 04/13/2012 COURT ORDER [130]

DEFENDANT'S LEAD COUNSEL

04/12/2012 04/12/2012 FIRST AMENED CASE MANAGEMENT ORDER [131]

Direct Filing and Service of Process

04/11/2012 04/11/2012 ORDER [132]

ORDER APPOINTING SPECIAL MASTERS

04/09/2012 04/09/2012 ORDER [133]

Direct Filing and Service of Process

02/13/2012 02/13/2012 ORDER [134]

ORDER SETTING INITIAL STATUS CONFERENCE FOR 03/22/2012

01/23/2012 01/23/2012 ORDER [135]

FIRST GENERAL ORDER - ALL ACTIONS

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#### Links

- [1] <http://www.lawd.uscourts.gov/court-orders>
- [2] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.7207.Order%20of%20Dismissal.pdf>
- [3] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6943.Ruling%20Common%20Benefit%20Allocation.pdf>
- [4] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6945.Order%20Common%20Benefit%20Allocation.pdf>
- [5] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6919.Order%20Deadline%20Death%20Incapacity%20Settlement%20Approvals.pdf>
- [6] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6477.Order%20vacating%20direct%20filing.pdf>
- [7] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6314.CMO%20Approval%20of%20Settlements%20Involving%20User%20Death%20or%20Incapacity%20and%20Exhibits.pdf>
- [8] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6238.CMO%20Common%20Benefit%20Assessment.pdf>
- [9] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6215.Common%20Benefit%20Briefing%20Order.pdf>
- [10] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6113.Order%20re%20Feb%20sc%20and%20Apr%20wg.pdf>
- [11] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6078.Order%20re%20Foreign%20Subpoena%20Disputes%20Protocol.pdf>
- [12] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6067.Order%20re%20February%202016%20Status%20Conference.pdf>
- [13] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.6053.Limited%20Lift%20of%20Discovery%20Rule%2045%20Subpoenas%20to%20Facilities.pdf>
- [14] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5967.Order%20re%20Nov-Jan%202016%20Status%20Conferences.pdf>
- [15] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5849.CMO%20Resolution%20of%20Cases%20Involving%20Death%20or%20Incapacity.pdf>
- [16] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5850.CMO%20Holdback%20Order.pdf>
- [17] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5831.Order%20re%20Sept-Oct%20status%20conferences.pdf>
- [18] [http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.080715.CMO\\_SP\\_Dejean.cg.pdf](http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.080715.CMO_SP_Dejean.cg.pdf)
- [19] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5706.Order%20re%20July-Aug%20status%20conferences.pdf>
- [20] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5620.Order%20re%20May-June%20status%20conferences.pdf>
- [21] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5582.Order%20for%20Limited%20Stay.pdf>
- [22] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.Actos%20MDL%20Master%20Settlement%20Agreement.pdf>
- [23] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5552.Order%20re%20Settlement%20Agreement%20and%20Deadlines.pdf>
- [24] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5553.Preservation%20Order.pdf>
- [25] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5551.CMO%20Census%20of%20Claims.pdf>
- [26] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5513.Order%20re%20April%202015%20status%20conference.pdf>

[27] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5491.Status%20Conference%20Agenda%20April%202015.pdf>

[28] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5470.Amended%20CMO%20Protective%20Order.pdf>

[29] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5471.Amended%20CMO%20Motions.pdf>

[30] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5370.Order%20designating%20potential%20May%202016%20trial%20cases.pdf>

[31] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5325.Kaiser%20Protective%20Order.pdf>

[32] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5303.Scheduling%20Order%20May%20202016%20Trial.pdf>

[33] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.Agenda%202-26-15.pdf>

[34] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5259.Order%20re%20March%202015%20Status%20Conference.pdf>

[35] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5246.Amended%20CMO%20Fact%20Sheet%20Analysis.pdf>

[36] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5165.CMO%20Fact%20Sheet%20Analysis.pdf>

[37] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5163.CMO%20Reporting%20on%20Ongoing%20State%20Proceedings.pdf>

[38] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5164.CMO%20Reporting%20on%20Resolved%20State%20Proceedings.pdf>

[39] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.5172.Status%20Conference%20Agenda%20Jan%202015.pdf>

[40] <http://www.lawd.uscourts.gov/sites/default/files/UPLOADS/11-md-2299.11172014.November%20Status%20Conference%20Agenda.pdf>

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UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE) PRODUCTS CIVIL ACTION NO. 11-md-2299  
LITIGATION

VERSUS

JUDGE DOHERTY

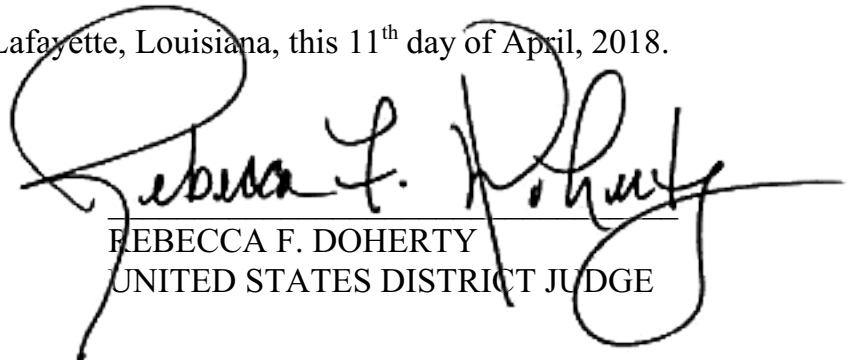
MAGISTRATE JUDGE HANNA

**ORDER OF DISMISSAL**

On December 29, 2011, the Judicial Panel on Multidistrict Litigation assigned this Court with the management of Multidistrict Litigation 2299 (In Re Actos® (Pioglitazone) Products Liability Litigation. All matters pending before this Court having been resolved, remanded through the Panel, or otherwise transferred to the appropriate venue, and all administrative matters addressed, the Court finds it appropriate that this MDL be closed.

**IT IS HEREBY ORDERED** that the case be **DISMISSED**.

THUS DONE AND SIGNED at Lafayette, Louisiana, this 11<sup>th</sup> day of April, 2018.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

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TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

CONTENTS

**I. FACTUAL AND PROCEDURAL BACKGROUND..... 5**

A. Prior to Establishment of MDL 2299..... 5

B. Establishment of MDL 2299..... 7

C. State Court Proceedings..... 11

D. Procedural History Prior to Bellwether Trial..... 13

E. Discovery, Preparation for the Bellwether Trial, *Allen v. Takeda*..... 17

F. The Master Settlement Agreement ..... 30

G. Implementation of the Settlement..... 39

H. The Initial Hold-Back on Settlement Payments..... 43

I. Nationwide Settlements ..... 45

J. Additional Comments on Common Benefit Efforts ..... 45

**II. COMMON BENEFIT FEE AND EXPENSE REVIEW PROCESS ..... 49**

**III. METHODOLOGY FOR CALCULATING AGGREGATE FEE AWARD..... 56**

A. Distinction between Reasonable Hourly Rates in Multidistrict Litigations and Class Actions ..... 56

B. Calculating the Aggregate Fee Award..... 65

**IV. REASONABLENESS ANALYSIS..... 67**

A. Valuation of the Benefit Obtained ..... 67

B. Benchmark Percentage..... 68

C. *Johnson* Factors ..... 71

1. Novelty and Difficulty of the Issues (Factor 2); The Skill Required to Perform the Legal Service Adequately (Factor 3); and The Experience, Reputation, and Ability of the Attorneys (Factor 9)..... 74

2.	Time and Labor Required (Factor 1); Preclusion of Other Employment (Factor 4); Time Limitations Imposed by the Client or the Circumstances (Factor 7).....	75
3.	The Amount Involved and the Results Obtained (Factor 8).....	78
4.	Nature and Length of the Professional Relationship with the Client (Factor 11).....	79
5.	The Customary Fee for Similar Work in the Community (Factor 5), Whether the Fee is Fixed or Contingent (Factor 6), Awards in Similar Cases (Factor 12).....	81
6.	The Undesirability of the Case (Factor 10).....	82
7.	Conclusion: <i>Johnson</i> Factors .....	83
<b>V.</b>	<b>ALLOCATION OF COMMON BENEFIT FEES AND EXPENSES .....</b>	<b>84</b>
<b>VI.</b>	<b>CONCLUSION .....</b>	<b>116</b>

**MEMORANDUM RULING**  
**(Common Benefit Fees and Allocation)**

Early in this MDL, and with the input of the plaintiffs' counsel and the Special Masters, this Court established a system to maintain ongoing records of all common benefit time and expense – *i.e.*, time and expense incurred for the benefit of all plaintiffs, rather than any individual plaintiff alone.<sup>1</sup> According to that protocol, only certain kinds of time and expense would be allowed to be incurred for the common benefit, and any attorney who wished to perform common benefit work was required to submit a request to do so to the Plaintiffs' Steering Committee, which, along with the Court, was vested with the authority to approve or deny such requests with the instruction of the Court that all otherwise qualified attorneys who desired to perform common benefit work be allowed to do so. Furthermore, any approved common benefit time or expense that was incurred, also, would be submitted to Deputy Special Master DeJean, who was tasked with reviewing all such submissions on an ongoing basis, and either approving them, rejecting them, or returning them to the submitter for clarification or to address any deficiencies in the submission. A Master Settlement Agreement (“MSA”)<sup>2</sup> was executed on April 28, 2015, and provided, in part, that participating claimants and their counsel agreed to submit a portion of each of their recoveries to compensate the common benefit expense and fees incurred, respectively.<sup>3</sup> On September 1, 2015, the Court entered a preliminary order setting aside a percentage of all

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<sup>1</sup> See Case Management Order: PSC's Management of Timekeeping, Cost Reimbursement and Related Common Benefit Issues [Rec. Doc. 1357], Case Management Order: Claims for Common Benefit Fees and Expenses [Rec. Doc. 2356].

<sup>2</sup> A copy of the MSA, together with its attachments, may be found at [http://www.lawd.uscourts.gov/resources-state-court-actos-judges#SETTLEMENT\\_PROGRAM](http://www.lawd.uscourts.gov/resources-state-court-actos-judges#SETTLEMENT_PROGRAM).

<sup>3</sup> MSA § 10.04.



recovery in anticipation of a final order establishing a common benefit fund and distribution.<sup>4</sup> Thereafter, by Order dated August 7, 2015,<sup>5</sup> this Court instructed Deputy Special Master DeJean to gather information relevant to this Court's decision of how best to allocate the common benefit fees generated as a result of the MSA and the Assessment Order, among Participating Counsel and the PSC,<sup>6</sup> and to provide that information to the Court. Subsequently, on September 1, 2015, this Court issued a "Case Management Order: Holdback Order" [Rec. Doc. 5850], ordering that funds be withheld from settlement payments in order to compensate common benefit attorneys' fees and expenses and/or costs, should a common benefit fund prove necessary. For the reasons given below, this Court (1) finds that a common benefit fund is necessary, (2) finalizes the amounts provided in the Holdback Order and "Case Management Order: Assessment of Common Benefit Fees and Expenses and/or Costs" [Rec. Doc. 6238], and (3) determines the amounts that will be allocated among participating firms and attorneys. In order to comply with this Court's Order to provide it with the information necessary to make informed allocation decisions, Deputy Special Master DeJean has submitted a Report and Recommendation, which is attached to this Ruling (Attachment A). For the reasons that follow, this Court adopts and incorporates herein Deputy Special Master DeJean's Report and Recommendation, and issues the following ruling on common benefit fees, their necessity, and their allocation, as well as common benefit expenses.

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<sup>4</sup> Rec. Doc. 5850.

<sup>5</sup> Rec. Doc. 5801.

<sup>6</sup> Rec. Doc. 6238.

## I. FACTUAL AND PROCEDURAL BACKGROUND

### A. Prior to Establishment of MDL 2299

This multidistrict litigation concerns Pioglitazone (marketed in several formulations and under several brand names, but known by the commercial name and referred to herein as Actos®), which was approved for sale in the United States in 1999.<sup>7</sup> Actos® was developed and produced by Takeda Pharmaceutical Company Ltd. (a Japanese company with several subsidiaries in the United States, which, here, will be referred to collectively as “Takeda”) and was marketed in the United States for a portion of time by Eli Lilly and Company (“Eli Lilly”); Actos® was available in the United States as early as 1999.<sup>8</sup> The plaintiffs allege that in June, 2011, regulators in Europe, Canada, and the U.S. took action to warn the public that Actos® might increase the risk of bladder cancer in humans.<sup>9</sup> According to the first Motion to Transfer filed with the Judicial Panel on Multidistrict Litigation (“JPML”), as of August 31, 2011, there were at least eleven (11) actions pending in eight (8) district courts alleging injury from usage of Actos® and seeking recovery from Takeda and Eli Lilly.<sup>10</sup>

Shortly after certain governmental warnings were issued, attorneys who would eventually become Lead Counsel, members of the Plaintiffs’ Steering Committee (“PSC”), and other Participating Counsel<sup>11</sup> began to file actions and to coordinate with one another, not only for the

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<sup>7</sup> See Trial Transcript (Vol. II), Rec. Doc. 4173, at 73.

<sup>8</sup> See Trial Transcript (Vol. II), Rec. Doc. 4173, at 73.

<sup>9</sup> See Complaint at 6-7, *Allen, et al. v. Takeda Pharmaceuticals North America, Inc., et al.*, No. 6:12-cv-00064 (W.D.La. July 29, 2011), ECF No. 1.

<sup>10</sup> See Schedule of Actions, *IN RE: Actos (Pioglitazone) Products Liability Litigation*, MDL No. 2299 (JPML August 31, 2011), ECF No. 1-2.

<sup>11</sup> “Participating Counsel” as used herein refers broadly to those counsel who were approved to perform common benefit work, and is defined as “the Court-appointed Plaintiffs’ Steering Committee

protection of their own individual clients, but with an eye towards the advancement and protection of the common and collective interests of others who were likely to become litigants at some point in the future.

Attorneys, many of whom ultimately became members of the PSC, performed extensive legal and factual research in an effort to evaluate potential MDL locations and to prepare to litigate these matters. Counsel, also, poured a great deal of effort, time, and expertise into the extensive and challenging organization required to mount a complex and large, collective of cases, including case and leadership strategy, identification of potential experts, researching case-related science, and documenting potential injuries allegedly associated with the use of Actos®. A group of litigation leaders ultimately stepped forward and made multiple presentations throughout the country to educate and inform other already involved attorneys about Actos® and their theory of causation. As the cases were filed and were being brought to the attention of the JPML, these case leaders engaged in extensive coordination and communication with involved attorneys throughout the country. Thus, the organization and administration skill of the leadership proved of exceptional value to the litigation.

In the meantime, these attorneys, also, had begun the daunting task of learning the complex and extensive science underlying these claims and finding and hiring experts in the scientific, regulatory, and clinical arenas to educate, inform, and in some instances possibly testify on behalf of all plaintiffs. As described below, developing an understanding of the complex scientific aspect of the plaintiffs' theory of the cases required an intensive investment of time, expertise, and effort,

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(along with members of their firm and staff), any other counsel authorized by the Executive Committee or Co-Lead Counsel who desire to be considered for common benefit compensation, or counsel who have been specifically approved by this Court as Participating Counsel prior to incurring any such cost or expense.” Rec. Doc. 1357, p. 1.

on the part of counsel, especially given the very short time frame this MDL followed. Due to the heavy reliance on sophisticated scientific knowledge required to move this litigation forward, those attorneys and firms, who provided the requisite expertise in the sciences, came to provide exceptional value to the PSC.

**B. Establishment of MDL 2299**

Once lawsuits began being filed throughout the country, a number of plaintiffs, through their counsel, together with the defendants, through their counsel, moved to have the JPML consolidate the Actos®-related lawsuits into an MDL; the JPML consolidated the Actos® cases and selected the Western District of Louisiana, Lafayette Division, and Judge Rebecca F. Doherty, to handle all pre-trial matters. The order establishing MDL 2299 (“In Re: Actos® (Pioglitazone) Products Liability Litigation”) was issued by the JPML on December 29, 2011.<sup>12</sup> Just over two years later – on January 27, 2014 – jury selection began in the first, and what ultimately would become the only, bellwether trial conducted in these proceedings. The intervening two years were an incredibly active time for involved counsel and the Court.

On April 11, 2012, this Court appointed a Special Master and two Deputy Special Masters to assist in managing these proceedings, each with his or her specific responsibilities, all designed to avoid any unnecessary overlap of effort or duties. Special Master Gary Russo was appointed with overall responsibility over case management in the MDL; Deputy Special Master Kenneth DeJean was appointed to manage and oversee matters related to the PSC, especially to oversee the ongoing submissions for common benefit fees and expenses; Deputy Special Master Carmen Rodriguez was appointed with primary responsibility over matters related to the law and legal

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<sup>12</sup> Rec. Doc. 1.

analysis, especially with regard to avoiding disputes over or the need for issuing of formal rulings or contested motions.<sup>13</sup> In addition, the parties made the crucial agreement that the Special Masters could communicate *ex parte* with any party or attorney so long as it did not involve substantive legal issues filed and pending before the Court.<sup>14</sup> In combination, these aspects of the team of Special Masters and the agreement of the parties, made it possible for counsel for the parties to work closely with the Special Masters and, ultimately, the Court, to either resolve or avoid many disputes that threatened, and historically within MDLs have acted, to slow or stop the progress of the MDL. For example, no substantive discovery or dispositive motions were *formally* filed until June of 2013, approximately eighteen (18) months after the MDL was created; rather, those disputes were resolved by way of the Court through the Special Masters and the parties' agreement by way of counsels' full involvement, requiring constant, ongoing, and extensive involvement by the PSC leadership and the Court.

Shortly after receiving the MDL assignment, and after having done its due diligence, this Court appointed the PSC by order dated April 13, 2012.<sup>15</sup> The Court assigned the PSC tasks that were both detailed and wide-ranging.

The PSC shall take the lead in litigating these matters on behalf of all plaintiffs, meaning that they shall play the lead role in making strategic, practical, and procedural decisions on behalf of the plaintiffs' counsel and *pro se* plaintiffs.

[T]he PSC shall be responsible for coordinating the plaintiffs' responses to the orders of the Court, for coordinating the presentation of issues to the Court for its consideration, and for overseeing the progress of these proceedings toward final resolution.

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<sup>13</sup> Rec. Doc. 532.

<sup>14</sup> Rec. Doc. 532, at 4-5.

<sup>15</sup> Rec. Doc. 563.

The PSC shall have the responsibility for assigning litigation-related tasks to counsel who provide indication of their willingness to work for the common benefit of all plaintiffs in the case. The committee are encouraged to distribute assignments among counsel who wish to work for the common benefit, taking into consideration the particular strengths and weaknesses of counsel requesting such assignments.

The PSC shall act as the first resource for counsel or parties with questions, comments, concerns, recommendations, or requests, and for transmitting to plaintiffs' liaison counsel or co-lead counsel any such questions, comments, concerns, recommendations, or requests that should come to the attention of the Court.

The PSC shall have responsibility for recommending the approval or denial of any claim made by an attorney for common benefit credit. Specifically . . . the PSC shall review such claims and shall provide guidance to Special Master DeJean with regard to the propriety, fairness and reasonableness of such claims.

In the event of a global settlement, the PSC shall have the primary responsibility, with guidance and oversight by the Court through the Special Masters for management and oversight of the process of distributing funds, reimbursing fees and expenses incurred for the common benefit, and for distributing the remaining fees to all plaintiffs' counsel.<sup>16</sup>

In addition to establishing the PSC, the Court, also, formed an Executive Committee of the PSC and assigned additional duties to the Executive Committee members: co-lead counsel were appointed; liaison counsel was appointed; state court liaison counsel was appointed; and a science coordinator was appointed.<sup>17</sup> Certain additional attorneys were appointed to the PSC as the MDL progressed, or were appointed to the Executive Committee from within the PSC as it became clear that their contributions and/or expertise brought exceptional value to the PSC.<sup>18</sup> For instance, Mark Lanier was appointed to the Executive Committee from the PSC and selected as trial counsel

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<sup>16</sup> Rec. Doc. 560, at 4-6.

<sup>17</sup> Rec. Doc. 560, at 6-7.

<sup>18</sup> Rec. Docs. 2320, 2856.

later in the litigation; the value of his contribution to the collective trial effort is illustrated by the verdict ultimately received.

Even prior to the formal appointment of the PSC, certain counsel – many of whom would ultimately, also, become PSC members – had collected contact information from numerous involved plaintiffs’ attorneys, and had begun to develop e-mail group service lists, which were constantly being tracked, supplemented, and updated.<sup>19</sup> The involved firms established and organized file materials, and began the process of arranging for IT services and personnel, which and who would be necessary in such a far reaching and complex matter. Co-lead counsel and other members of the PSC worked with defense counsel and the Court to lay the foundations for what would become the essential administrative and procedural frameworks for the litigation – this Court having adopted a “bottom up” approach allowing, and at times, requiring, counsel’s involvement in all aspects of the case. The accomplishments obtained and the innovations employed by counsel in this matter – some initiated by this Court and others initiated by the PSC or defense counsel, but all created with active attorney participation – include, but are by no means limited to:

- use of lead counsel for plaintiffs and strategic and managerial leadership, while allocating communication responsibility to liaison counsel; and thus, relieving the Clerk of Court and its servers of part of the burden of disseminating the overwhelming amount of information created;
- allowing all plaintiffs’ counsel who requested to work as Participating Counsel and who were qualified to do the requested work, to work as Participating Counsel;
- establishment of the duties of the Plaintiffs’ Executive Committee (“PEC”);
- adoption of a direct filing order;

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<sup>19</sup> This Court ultimately ordered that all plaintiffs’ counsel maintain current e-mail addresses with the PSC in Court Order: Contact Information [Rec. Doc. 2515].

- adoption of bundled complaints;
- a *workable* remote participation system for status conferences via telephone allowing all counsel and all state court judges who wished to participate to do so;
- adoption and implementation of predictive coding;
- exploration of proposed summary jury trials;
- exploration of a proposed expert round table;
- use of live trial witnesses via satellite transmission;
- creation of a process for selection of and the selection of a bellwether trial that occurred less than 2 years after appointment of PSC;
- a protocol which allowed the Court to preside over perpetuation depositions in a manner that significantly reduced the time required for resolution;
- a remand plan designed to circumvent the common experience of the remand “black hole”;
- a privilege log best practices protocol involving *in camera* review by the Special Master of challenged documents, thus avoiding tremendous time and dispute;
- appointment of a *Pro se* Liaison for unrepresented plaintiffs, including those who are or were incarcerated;
- involvement by plaintiff and defense counsel in the negotiation and drafting of multiple Case Management Orders;
- establishment of document repositories and other file sharing programs; and
- State-Federal liaison efforts that included providing this Court with an overview of trial settings, verdicts, and activity in Actos® cases going forward in state courts across the country, and keeping those state courts apprised of what was occurring in this MDL.

### **C. State Court Proceedings**

In addition to the cases filed in federal courts that were consolidated in the MDL, approximately an equal number of cases were filed in state courts throughout the United States. Particularly large numbers of cases were filed in some states, especially those in Illinois and



California, which raised the possibility of employing those state courts' special procedural devices to manage the caseloads.

The Illinois Supreme Court, in response to a Motion to Transfer and Consolidate, determined the approximately 4,000 Actos® cases filed in Illinois state court would be complex and would share common issues, and recommended they be consolidated before one court for coordinated pretrial proceedings. The Coordinated Proceedings were given the title *In Re Actos® Related Cases*, No 2011 L 010011, and were consolidated in the Circuit Court of Cook County, Illinois, County Department, Law Division, before the Honorable Deborah Dooling as coordinating trial judge (hereinafter "the Illinois coordinated proceeding").

The Los Angeles Superior Court, similarly, conducted a hearing on a Petition for Coordination of the Actos cases filed in California. As a result of that hearing, the Honorable Carl West deemed the Actos® cases to be complex and to share several common issues, and recommended the cases be consolidated before the Los Angeles Superior Court, Central Civil West, pursuant to California Code of Civil Procedure section 404.3 and Rule 3.540 of the California Rules of Court. The Actos® cases filed in California were consolidated under the title *In Re Actos® Product Liability Cases Coordinated Proceedings*, JCCP 4649, before the Honorable Kenneth Freeman (hereinafter "the California coordinated proceeding"). Later in the proceedings, The Honorable William MacLaughlin, also, was appointed to assist the coordinated proceeding with the management of certain specific issues.

The remaining state court Actos® cases, being more widely dispersed among state courts across the country, were handled in their respective courts according to those states' normal procedures. Ultimately, each of the eligible claimants in state court Actos® cases was given the

opportunity to voluntarily participate in the Settlement Program established by the MSA in this MDL, and more than 99% of the eligible claimants chose to do so.

**D. Procedural History Prior to Bellwether Trial**

As early as possible, this Court endeavored to work with counsel to ensure that the extraordinary documentation that was expected to be involved in this MDL would be handled in the most efficient and cost-effective manner possible. To that end, Magistrate Judge Hanna took a primary role working with the Clerk of Court, in coordinating with the PSC, defense counsel, and with Tony Moore, the Clerk of Court for the Western District of Louisiana, to establish special filing procedures to be employed in the Actos litigation. One such procedure, adopted with assurances acquired by agreements between and among the parties, was this Court's order that plaintiffs be allowed to file their Actos® claims in the Western District of Louisiana directly, whatever the district of origin, without requiring each case be transferred through the JPML, within certain stated limitations.<sup>20</sup> Additionally, attorneys with multiple Actos® claims were allowed to file "bundled" complaints, which allowed counsel to drastically reduce expenditures on filing fees.<sup>21</sup> These two protocols allowed for a much more streamlined and efficient filing process, allowing the matter to move forward more rapidly than might otherwise have been the case, and reflected the active negotiation and participation by the PSC and defense counsel.

In order to ease the complexity of any possible, ultimate, remand of any individual case(s), Magistrate Judge Hanna and the Clerk of Court worked with this Court to implement a "spread-texting" protocol for the Western District of Louisiana's CM/ECF system, which required training

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<sup>20</sup> Rec. Doc. 1538.

<sup>21</sup> Id.

and mastery by the PSC and all involved counsel. Under this protocol, the MDL was provided a single “umbrella” civil action number and docket sheet, in addition to each member suit in the MDL having its own separate civil action number and docket history. Any documents that applied only to a member case were filed only in that case’s docket, and any that applied to all cases in the MDL were filed in the umbrella docket and “spread” to the dockets of all member cases. In this way, the filing attorneys and the Clerk of Court could ensure that the docket sheet for any member suit would include only the entries specific to that case, but also, the entries that apply to all cases in the MDL could be found in one central location and could be easily accessed by all counsel and a transferor judge, if remand were required. In this way, a transferor judge who might receive a remanded case could easily access only those docket entries that apply to the remanded case, and not be confronted with the entire MDL docket sheet (which, as of this writing, comprises more than 6,800 entries), but will, also, have ready access to the entire “umbrella” docket. The leadership for the plaintiffs voluntarily took on the task, along with this Court’s Clerk of Court, to train filing attorneys on how to file within and how to navigate within this system.

As the MDL progressed and grew to include more than 4,000 individual member cases, the number of individual counsel involved who might require notice, created extraordinary strain on the ability of this Court’s CM/ECF system to send Notices of Electronic Filing (“NEFs”). To alleviate that strain, the plaintiffs’ leadership agreed, and, thus, this Court ordered, NEFs would be sent only to the Special Masters, the PSC, Defense Lead Counsel, and the leadership, particularly liaison counsel. Liaison Counsel for both sides took on the responsibility to disseminate those entries to all involved attorneys, creating a much greater administrative demand on the PSC, and in particular liaison counsel, Patrick Morrow, as well as upon defense counsel. Liaison counsel for plaintiffs, and defendants, at no small expense, generously agreed to establish their own

systems for forwarding each NEF to all counsel who required notice.<sup>22</sup> To ensure the integrity and transparency of this system, liaison counsel agreed to, and thus, were ordered to, file monthly notices setting out (1) which NEFs had been forwarded in the previous month, and (2) the list of attorneys and email addresses to which each NEF had been sent.<sup>23</sup> These notices have been filed monthly since November, 2013, and each notice is, and has been, made fully available on the MDL 2299 website.<sup>24</sup> Additionally, this Court reminded individual counsel during each monthly status conference – at which all individual counsel could participate, whether in person or by phone by way of the innovative system provided by plaintiffs’ leadership – of their duty to maintain current contact information both with the Court and with liaison counsel to ensure the NEF system remained functional throughout the duration of the MDL.<sup>25</sup> The PSC, and in particular, Liaison Counsel, assured such compliance by following up with contemporaneous notice of all relevant activity and quick response to all inquiries. Each of these systems allowed all plaintiffs’ counsel to more efficiently lodge their cases with this Court, and allowed the Court to receive filings and communicate with the parties much more efficiently than would otherwise have been possible, all acting to benefit the common good of all the plaintiffs, and all as a result of plaintiffs’ leadership, and in this instance, Liaison Counsel, Patrick Morrow.

While discovery went forward in the MDL, and after consultation with the Special Masters and counsel for both parties, this Court, along with the PSC and defense counsel, created a Pilot

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<sup>22</sup> Rec. Doc. 3398.

<sup>23</sup> *Id.*

<sup>24</sup> Copies of the monthly NEF Reports and Service Lists can be viewed online at <http://www.lawd.uscourts.gov/nef-reports-service-lists>. This Court at the outset created a website open to all counsel and has kept the website updated and revised throughout the litigation.

<sup>25</sup> As noted above, this Court ordered that all plaintiffs’ counsel maintain current e-mail addresses with the PSC in Court Order: Contact Information [Rec. Doc. 2515].

Bellwether Program. The PSC and defense counsel worked to adopt an agreeable process and ultimately, the Court fashioned a process under which the parties were to choose at least two cases that would be tried before this Court as bellwether cases. On February 19, 2013, this Court entered a Scheduling Order setting the first bellwether trial, *Allen, et al. v. Takeda Pharmaceuticals North America, Inc., et al.*, for trial on January 27, 2014.<sup>26</sup> The often exhausting and hard work of plaintiffs' and defense counsel, and the unique structure created and employed in this MDL, along with the involvement of the Special Masters, contributed to the extraordinary feat noted above, *i.e.*, coming to a jury verdict within two (2) years of the appointment of the PSC, with few formal substantive discovery or dispositive motions having been filed until June, 2013, when those in preparation for the first bellwether trial were filed. During the roughly six months before the bellwether trial began, a plethora of formal dispositive and discovery motions were filed and resolved, including more than forty (40) motions *in limine*, at least nine (9) formal *Daubert* motions, and a plethora of objections to proposed depositions of experts based not only on *Daubert* but, also, on foundational weakness. Also, exhaustive interaction with the Court and exhaustive discussion and briefing on the application of New York law was had. For the plaintiffs' counsel, the entire human resources of the trial team were brought to bear to obtain this result, and to, at the same time, prepare for the actual trial. Intense judicial involvement and review was required, which, also, necessitated extensive counsel involvement.

An MDL of this scope has many sub-issues that must be managed and resolved while the overall process is ongoing in order for the entire matter to move forward efficiently, and counsel were intimately involved with the Special Master and Deputy Special Masters and the Court in management and resolution of these sub issues. Merely one such exemplary sub-issue was how

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<sup>26</sup> Rec. Doc. 2359.

the claims of litigants appearing *pro se*, and particularly those who were incarcerated, were to be addressed and handled. The Court tasked the PSC, along with Magistrate Judge Patrick Hanna, with taking lead on this task, and a special *Pro se* Liaison was appointed. Thus, a selected member of the PSC was appointed to be the *Pro se* Liaison, and tasked to maintain contact with all of the plaintiffs in the MDL who were or became unrepresented. Pursuant to order of the Court, the *Pro se* Liaison was not to represent any unrepresented litigant, but was to make himself available to provide information, explanation, and any other appropriate assistance needed to *pro se* litigants; especially those who were incarcerated and might have limited access to the internet and, thus, might require additional information. This role, also, included providing information as to possible participation in the Settlement Agreement.<sup>27</sup> By all accounts, the *Pro se* Liaison, Willie Singleton, assisted by Magistrate Judge Hanna and this Court when necessary, has proven to be yet another important contribution of the PSC here, ensuring the informed participation of unrepresented claimants within these MDL proceedings.

**E. Discovery, Preparation for the Bellwether Trial, *Allen v. Takeda***

Discovery in this MDL was dual-tracked and staggered, requiring contemporaneous dual tracking for counsel: one track and group was dedicated to the overall litigation strategy against the defendants, *i.e.*, general causation; the second, and parallel, track and group, was staggered and dedicated to the case specific discovery for the bellwether cases, *i.e.*, individual causation. From March 22, 2012 until the Master Settlement Agreement was executed in April, 2015, the PSC, Participating Counsel, and defense counsel operated on these dual tracks. In order to facilitate this complex tracking, this Court held monthly status and working conference(s) at which PSC

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<sup>27</sup> Rec. Doc. 2294.

members physically appeared and reported to the Court and to all individual plaintiffs' counsel as to the ongoing progress of the matter, and, also, participated in working group meetings with the Special Master(s) and defense counsel and/or the Court in order to keep the litigation moving forward efficiently. Which plaintiffs' counsel, beyond the leadership, participated in the various working group meetings varied according to the issues to be discussed at each meeting, however, trial counsel and lead counsel were required at each meeting in order to create an institutional memory. Other working group meetings were also scheduled and often weekly telephone conferences were conducted as needed, as well. This Court meet weekly with the Special Masters to address and discuss specific issues and for resolution of problems. At the first overall status conference for all, this Court informed all counsel they had four years to complete these MDL pretrial proceedings and, therefore, they should anticipate they should plan to either settle these cases, prepare for their remand, or resolve them by motion or trial, within that time. In an effort to facilitate this deadline, Special Master Russo and Deputy Special Master Rodriguez, also, presided over weekly telephone discovery conferences when needed, where Lead Counsel and other Participating Counsel worked collaboratively with defense counsel to resolve hundreds of scheduling, discovery, privilege, and other pretrial issues and disputes. Counsel wrote scores of letter briefs to Special Master Russo and/or Deputy Special Master Rodriguez and/or opposing counsel; communicated daily with each other and with the Special Masters via e-mail regarding production and other logistical issues; and otherwise worked to either resolve old issues or follow-up on new ones. And, as noted, the Special Masters met weekly or monthly, depending upon need, with the Court in order to obtain the Court's involvement and to keep the Court informed. Additional unscheduled conferences with the Special Masters and/or with the Court, and counsel were held as needed. Thereafter, at the monthly status conferences, involved counsel reported on

their work to the Court, and all counsel received new input and guidance from the Court, were able to raise issues to the Court, and fully report to all plaintiffs' counsel.

With an eye to the necessary resolution, whether by remand or other procedure, counsel, along with the Court considered all viable possibilities for resolution. After fully considering summary jury trials and other innovative approaches for handling these proceedings, the PSC and defense counsel ultimately settled on using bellwether trials as the preferred manner to move forward toward resolution, and began the arduous task of full trial preparation of the bellwether cases. After extensive attorney negotiation and recommendation, this Court ordered two bellwether trials would be held, with the first plaintiff to be chosen by the PSC and the second plaintiff to be chosen by the defendants, and, thereafter, the Court, with full input from counsel, established the process to be used for selection of those two cases.

During the run up to the first bellwether trial, the parties produced and reviewed millions of pages of documents, which were necessary to perform depositions, prepare experts, and conduct the necessary scientific and regulatory research. As noted in Deputy Special Master DeJean's Report and Recommendation, throughout this MDL, with special emphasis on trial preparation, *more than 32 million pages of documents have been produced, organized and reviewed; approximately one hundred and thirty depositions have been taken; plaintiff's leadership designated seventeen experts in their Rule 26 Disclosure, and presented seven at trial; the defendants designated thirteen experts in their Rule 26 Disclosure, and presented five at trial.* As is the case in any litigation, each of the experts offered by the parties needed to be deposed, needed to submit reports, and had to be prepared for trial. Furthermore, as noted by Deputy Special Master DeJean, "the PSC and other Participating Counsel collected, indexed, and produced an incalculable number of articles, science materials, and regulatory documentation, as well as voluminous



scientific and corporate documents, in association with the Phase One expert reports and discovery.” All of this documentary material had to be located, reviewed, processed, organized and stored in a manner to allow ready access, and this daunting task was performed for the plaintiffs, by the PSC and Participating Counsel.

Preparing for the first bellwether trial presented a myriad of complex legal, organizational, logistical, scientific, factual, and discovery-related issues, all of which needed to be addressed simultaneously due to the short trial deadlines this Court had established in its First Scheduling Order.<sup>28</sup> By way of single example, perhaps, the New Drug Application, which, itself, was hundreds of thousands of pages in length, ultimately became a subject of dispute. The original production was done informally, however, objections were made to the first manner of production and were such that in order for a realistic review, this Court ordered a second, formal, production; however, some dispute and further resolution continued among the parties, and, ultimately, some one year after the PSC had begun review of the earlier informal production, the formal production was completed. The unfortunate, “staggered” production created additional work and, to some degree, a more complicated and time consuming review of this one item. As discovery proceeded along the multiple paths noted, simultaneously requiring extensive PSC involvement and extensive man and woman power, counsel were also actively and continuously involved in the work of developing this MDL. The factual and regulatory issues were multitudinous, complicated, and complex, and included such matters as toxicology, pharmacovigilance, marketing, epidemiology, experimental research (pre-clinical trials, clinical trials, and epidemiological/observational studies), regulatory, labeling, general causation, and specific causation, all areas requiring unique expertise and encyclopedic knowledge that the PSC, and particularly all involved trial counsel,

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<sup>28</sup> Rec. Doc. 2359.

would have to master. The parallel track of cases presented as many differing legal issues as there were active cases – the MDL included(s) cases from almost every jurisdiction in the United States, each governed by that state’s substantive law – and thus, required tremendous threshold legal research on a number of legal issues as wide-ranging as service of process, state product liability statutes, punitive damages, attorney-client privilege, causation standards, adequate warning standards, historical development of the defendants’ various associated business entities, spoliation, the impact of *Lexecon, Inc. v. Milberg, Weiss, Bershad, Hynes & Lerach*<sup>29</sup> on this Court’s jurisdiction, and the scope of authority of this Court for contempt of court, and preemption, among others. All, again, requiring extensive and exhaustive work by the PSC, and calling upon the unique expertise of the PSC and Participating Counsel.

As foreshadowed, discovery in these proceedings was extremely intense and involved a plethora of legal and factual questions – both general and specific in nature. Also, the tremendous number of documents involved created the need for an in-depth scientific understanding, as well as an efficient factual focus and organization, requiring counsel to create a document repository, and to develop creative analytics and unique search algorithms, as well as other advanced technological mechanisms, to organize the plethora of information into a useable and meaningful repository. In part, in response to this daunting task, counsel set about to adopt and implement predictive coding for application and use in this MDL, which will be discussed in greater detail below.

The PSC, also, worked tirelessly to control the scope and pace of discovery along with defense counsel and the Court – working toward a balance that allowed all to prepare for the first bellwether trial, while also, discovering the general corporate causation information, with an eye

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<sup>29</sup> 523 U.S. 26, 118 S.Ct. 956, 140 L.Ed.2d 62 (1998).

to the *Allen* trial, as well as later trials to come. Intense coordination and co-operative scheduling among all involved counsel was required to keep the general causation discovery ever moving forward, all the while proceeding toward the specific discovery required for the bellwether trials, all under a schedule designed to keep the matter moving ever forward. Plaintiffs' leadership took on the tasks for plaintiffs required to develop, not only, the law and evidence to prove general causation, but also, the law and facts inherent in proving specific causation within the first bellwether case, with an eye to the second bellwether case, as well as to develop defendants, Takeda's and Eli Lilly's knowledge concerning the alleged increased cancer risk associated with Actos® generally, and as to the specific individual claimants, all simultaneously – no small feat. The task undertaken was at times daunting and at all times challenging. The PSC's efforts, it should be noted, were at all times being opposed by an equally resolute and vigorous defense team, large in number and unflinching in determination, who provided an aggressive defense of their clients at every turn, led by Sara Gourley. The multiple tracks of discovery and the vigorous responses and defenses mounted by defense counsel, required not only the time, but also, the expertise of the PSC to effectively meet. Often multiple assignments within the PSC were required and often the process consumed all available man and woman power, and all of a firm's resources; the process becoming all consuming, thus, severely limiting or prohibiting the PSC firms from taking on other cases or certainly from taking on leadership roles in other large cases. As noted, once discovery was sufficiently completed in order to mount their case in the first bellwether trial, the PSC, also, began preparing for the specific tasks involved in mounting and trying the first bellwether trial, *i.e.*, finalizing and preparing their experts for producing reports and testifying at trial, preparing to defend experts' depositions and trial testimony, and preparing to introduce their experts' opinions at trial, as well as preparation of and for factual and medical witnesses, all the

while responding to this Court's orders as to substantive legal issues, and mounting a full attack on spoliation. Again, the tasks were demanding and, at times, all consuming.

This Court notes there were several other tangential issues that could have caused significant delay and could have negatively impacted the expected timeframe for the MDL to be completed, which the PSC and defense counsel, along with the Special Masters and the Court, met head on and ultimately resolved efficiently. Principal among those was the historically daunting issue of privilege, which has proven to be an inescapable morass in past MDLs. As the immense amount of discovery became clear, the parties suggested there might, ultimately, be more than 100,000 privilege claims. Considering the extraordinarily large number of privileges that might be asserted – a number that admittedly seemed to grow and contract over time and with the telling – no matter the actual number, the privilege issue had the potential to derail or cause a significant delay in the bellwether trial and thus, the overall litigation. The Court, consequently, instructed the parties to confer with Special Master Russo to determine if a more reasonable manner to resolve the massive number of privilege claims could be devised. The PSC and defense counsel spent much time and energy on this issue along with Special Master Russo, and ultimately, guided by Special Master Russo, negotiated and agreed to a new and unique privilege review process that involved submission by the defendants of select, specific documents for *in camera* review by the Special Master, allowing for due process review and appeal to the Court, and integrating a random selection of the remaining privilege claims for *in camera* review by the Special Master, again, allowing for due process review and appeal to the Court. The process created by Special Master Russo and the parties' counsel provided a truncated but, also, meaningful process to address this possibly overwhelming issue, and the possible privilege issue was managed and addressed, causing no undue delay in the process.

Specifically, the parties set up, with the Special Master, a process whereby the Special Master was provided two hundred (200) allegedly privileged documents at a time, with a spreadsheet designed specifically for this privilege resolution process. The Special Master issued preliminary rulings as to privilege assertions, and provided a period for the parties to respond with additional argument before making final rulings as to the assertions. The evolving predictive information created by this process allowed the Court and the parties to facilitate a negotiated resolution of the entire privilege process in a relatively short time. The PSC worked tirelessly along with discovery counsel to resolve this seemingly insurmountable privilege review on a very timely basis, ultimately resolving *more than 22,000 assertions* of privilege in a manner that allowed the litigation and the bellwether trial to move forward as scheduled.

The PSC and defense counsel, also, devoted a significant amount of time, energy, and expertise to setting up the systems that were used for document production. This MDL was one of the first to allow the use of a “predictive coding”<sup>30</sup> system to aid the discovery process and the production of relevant documents.<sup>31</sup> The predictive coding process required a significant amount of attorney time at the outset to devise and implement, and required the creation of an agreed to strict set of procedural and process safeguards, due to its relative novelty. Despite the initial “front loaded” investment of time required, the predictive coding system provided a unique way to, in part, realistically manage the immense amount of information needed to be produced and reviewed

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<sup>30</sup> Predictive coding refers to the use of dynamic algorithms which are trained to review electronically stored information (“ESI”) and to pick out which of it is likely relevant to requested discovery. Such algorithms are trained by human programmers, who provide collections of ESI that is known to be relevant and irrelevant, then who monitor the algorithm’s attempts to sort relevant from irrelevant information when given unsorted ESI, and to adjust the algorithm with each attempt creating a collective working memory. Over time, predictive coding algorithms can learn to find relevant documents within a given percentage range of reliability, upon which the parties must agree. *See* Rec. Doc. 1539.

<sup>31</sup> Rec. Doc. 1539.

in this MDL. The predictive coding system, although not perfect or fully realized, nonetheless, provided an innovative efficiency to the discovery process when compared to the existing, prevailing methods of review. Although a process not yet fully mature, the PSC and defense counsel expended tremendous time, and computer and legal expertise, to harness this technological possibility with quite positive, if not complete, result. As this area involved cutting edge technology, those counsel who could bring their unique expertise and skill to the task were exceptionally valuable to the PSC.

While the journey through discovery and pre-trial preparation was smoother than expected (there were a few *sets* of significant and aggressively disputed discovery-related cross-motions prior to the bellwether process), the parties, nonetheless, in conjunction with the bellwether trial, filed a plethora of pre-trial motions addressing both specific and general causation, including motions *in limine*, *Daubert* motions, motions for summary judgment, and motions for editing of and challenges to experts' depositions, and arguments of spoliation, all of which inured to the benefit of all plaintiffs and required tremendous attorney time and resource on the part of the PSC.

The PSC and defense counsel, also, met the strict standards established and expected by the Court as to trial preparation, including direct involvement with each other and the Court in producing proposed jury instructions as to applicable New York law – an area of law not fully resolved by the New York Courts. The parties – with the plaintiffs led by the PSC – poured considerable effort into producing, discussing with the Court, and exploring, along with defense counsel, proposed jury instructions that met this Court's high expectations. The selected bellwether case, as was ultimately determined, was to apply New York law to each of the substantive legal issues, spawning a variety of legal issues, which, as noted, many were not clear or fully resolved under New York law. All such questions had to be fully briefed to the Court

before jury instructions could be determined by the Court. The legal research and briefing required from counsel were both extensive and complex.

The PSC's efforts to vet and identify their first bellwether case – a process that had involved a great deal of discussion, evaluation, review of medical records, conferences with prescribing physicians, etc. – ultimately led to the trial of *Allen, et al. v. Takeda Pharmaceuticals North America Inc., et al.*, which began on January 27, 2014 and ended on April 7, 2014.<sup>32</sup> Preparation for this trial, as noted, was an exhaustive, and demanding process for all; trial of this matter was even more so given the vigorous and aggressive defense mounted by defense counsel. The PSC and the trial team utilized focus groups, mock trials, and planned a trial strategy which called upon almost the entirety of all of the PSC firms' human resources, as well as the full support capabilities of those firms. The PSC and defense counsel each set up a "war room" in the courthouse and manned their respective war rooms continuously, almost 24 hours a day, and 7 days a week, throughout the trial; a trial process which brought to bear the entire human resource and collective expertise of the PSC – their firms' support staff – and all counsel of the trial team and their firms' support staff.

Additionally, and simultaneously, requiring yet another PSC task force, on the basis of information revealed during the discovery process, the PSC mounted a concerted effort to present and pursue a motion for sanctions against the defendants for alleged spoliation of evidence – an issue that, also, impacted the impending trial strategy. The PSC vigorously pursued and defendants vigorously defended, the spoliation issue, and ultimately, this Court determined spoliation had

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<sup>32</sup> See Rec. Docs. 4171, 4210.

occurred, thus requiring a time consuming and expertise intensive shift in the final trial strategy,<sup>33</sup> again requiring all the trial team to re-evaluate and, perhaps, adjust their trial preparation.

As noted above, the trial, itself, was an intense and exhaustive process for all involved. In order to facilitate the efficient trial of the matter, this Court established a contemporaneous process for the speedy resolution of any, heretofore, unexpected factual trial deposition objections, which could not have been resolved before trial – experts having for the most part already been preliminarily addressed by counsel and the Court – including those disputes over how depositions that had been videotaped ahead of time and now would have to be used at trial, should be edited for presentation at trial. Defense counsel and the PSC appointed Sherry Knutson for the defendants, and Neil Overholtz for the plaintiffs, to contemporaneously address the large number of deposition objections made and anticipated at or during trial, but not within the trial proceeding, and thus, to address the contested admissibility of certain deposition testimony contained within the depositions the parties now sought to admit at trial. Consequently, these objections could be determined in a manner so as not to delay the trial. The PSC and defense counsel, with the Special Master presiding and with ready access and contemporaneous input from the Court, worked through a multitude of objections to a multitude of depositions, again, with full and contemporaneous input from the Court, before, and in some instances when required by time and circumstances, during the trial. These disputes continued to arise and to be decided up to and actually through the first several weeks of the bellwether trial. The extensive time and energy committed by the PSC, the trial team, defense counsel, Special Masters, and the Court to the resolution of these disputes allowed the bellwether trial to proceed without delay. The same procedure utilizing PSC representatives, defense counsel, and the Special Master, with review to

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<sup>33</sup> Rec. Doc. 4330.



the Court, was utilized in resolving several late arising motions *in limine*. Also, the innovation of plaintiffs' counsel to employ a recently added rule to the Federal Rules of Civil Procedure allowing for live transmission of remote witnesses during the trial, under specific circumstances, similarly, illustrated the expertise of the PSC, and the trial team in particular, and allowed the case to move forward without undue delay. Again, all involved counsel had to work with the Court to ensure all safeguards were met, and the unique process required counsel's technological expertise to work with this Court's capable information technology staff to set up the necessary technological requirements for real time remote transmission of the live testimony.

During thirty-seven days of actual trial, the PSC trial team presented eighteen witnesses, the defendants presented eleven witnesses, and more than four hundred exhibits were admitted. The jury's deliberations led to a verdict for Mr. and Mrs. Allen in the amount of \$1.5 million in compensatory damages, and \$9 billion in punitive damages.<sup>34</sup> Post-trial motions were filed by the defendants and responded to by the PSC; the Court denied in part, and the Court granted in part.<sup>35</sup> The defendants appealed the *Allen* judgment to the Fifth Circuit<sup>36</sup> requiring the PSC to prepare appellate briefing and cross appeals;<sup>37</sup> however, ultimately, the appeal(s) was/were withdrawn in conjunction with the global settlement reflected in the MSA process.

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<sup>34</sup> Jury Verdict, *Allen, et al. v. Takeda Pharmaceuticals North America, Inc., et al.*, No. 6:12-cv-00064 (W.D.La. April 7, 2014), ECF No. 639.

<sup>35</sup> See Final Amended Memorandum Ruling: Defendants' Rule 50(B) Motion for Judgment as a Matter of Law, *Allen, et al. v. Takeda Pharmaceuticals North America, Inc., et al.*, No. 6:12-cv-00064 (W.D.La. September 5, 2014), ECF No. 716; Memorandum Ruling: Defendants' Rule 59 Motion for New Trial, *Allen, et al. v. Takeda Pharmaceuticals North America, Inc., et al.*, No. 6:12-cv-00064 (W.D.La. October 27, 2014), ECF No. 729.

<sup>36</sup> Rec. Doc. 4884.

<sup>37</sup> The parties ultimately withdrew all appeals in light of settlement agreement.

Almost immediately after the *Allen* trial was completed, and contemporaneously with the appellate process in *Allen*, members of the PSC and other Participating Counsel shifted focus to begin preparing for the expected second bellwether trial – a process that included additional case specific discovery and new legal research as New York law no longer would be the applicable law – and addressing a number of issues that had become relevant during and after the *Allen* trial (*e.g.*, new scientific developments, discovery as against Eli Lilly, in-depth legal research as to a different state’s law, strategic discussions, restoration of backup tapes inherent in the spoliation issues, and potential trial strategy for a new litigation). After the *Allen* verdict was rendered, serious settlement negotiations began, in conjunction with and under the guidance of Special Master Russo, and upon request, the Court, at that point, suspended further bellwether trials and thus, suspended the case specific discovery in order to provide the opportunity for settlement success. Thus, the PSC and defense counsel, at that point, had to again shift their focus, now to the equally complex task of settlement negotiations and creation of the MSA document and Settlement Program – again, no small task.

Thus, this Court notes that throughout this entire process, in addition to the rigorous in-court and out-of-court trial demands, the PSC teams and their staffs, also, provided logistical and administrative assistance for the collective plaintiff effort, for the Clerk of Court, and for the parties as a whole as discussed earlier. Also, in addition to fully staffing a trial “War Room” almost twenty-four hours a day, and almost seven days a week, for and during the entire *Allen* trial, the PSC tracked the admission status of all exhibits and demonstrative aids for future use, and coordinated with all counsel and the Court regarding all submissions. During the trial, the PSC trial team participated in nightly conferences to review admitted evidence needed for and to be produced each day, and took lead responsibility for conferences with the Court on unanticipated

evidentiary disputes. As noted, the PSC created a multilayered, expertise diverse trial team to assist the two trial co-counsel and the team, along with co-trial counsel and their firms' staff, spent extensive time revising, updating, assimilating, and indexing the significant evidence to be used in the *Allen* trial, and for potential use as a "Trial Package" and resource, for test cases in the MDL or for any possible unresolved transferred or remanded cases. Thus, the expenditure in time, effort, and resources by the PSC, trial co-counsel, and the trial team and their firms was extensive and at times, all consuming.

#### **F. The Master Settlement Agreement**

After the defendants filed their appeal of the *Allen* judgment and various related orders of the Court, as noted, with the help of the Special Master and Magistrate Judge Hanna – this Court being of the opinion that to avoid any possible future conflict, it should not be intimately involved in the forging of a settlement the Court might be called upon to interpret or enforce - the parties entered into extremely complicated, multi-sided settlement negotiations. The MSA that was ultimately agreed to, drafted, and executed was negotiated by Doug Marvin, representing Takeda ("settlement counsel") and various plaintiffs' counsel that ultimately became the Plaintiffs' Settlement Review Committee ("PSRC").

As noted, in order to avoid the possibility of future conflict were this Court to have to address interpretation of, or enforcement of the settlement itself, this Court distanced itself from settlement negotiations, and instructed Special Master Russo and Magistrate Judge Hanna to assist the parties in their efforts to obtain a global settlement agreement, if possible or if needed. Both Magistrate Judge Hanna and Special Master Russo have reported to this Court that the time, expertise, and commitment of the PSC leadership was exemplary, extensive, and, again, at times all consuming. It is of note that the initial status conference the Court conducted with counsel was

on March 22, 2012; the Master Settlement Agreement (“MSA”) that ultimately resulted in the global settlement of approximately 11,000 claims for \$2.4 billion was signed and submitted to the Court by the parties on April 28, 2015; an, heretofore, unheard of accomplishment in an MDL of this size. This result is due in no small part to the commitment and work of all involved, and in particular the PSC and its leadership, and co-lead counsel, Richard Arsenault and Paul Pennock.

The MSA, itself, was the product of extensive, complex, and intensive negotiations among counsel and was executed by representatives of the PSC and the defendants. Although the MSA, itself, did not settle any claims outright, it did create a complete Settlement *Program* whereby all aspects of all the individual claims and claimants, who could provide sufficient documentation of a history of Actos® usage and a proper diagnosis of bladder cancer, would be eligible to apply to receive compensation, and would agree to dismiss any pending Actos®-related suits they might have against the defendants if their claim was accepted.

The Settlement Program was intended, and was designed to be, global in nature, or, at least, to be available to as many claimants in the United States as possible – state and federal. To that end, the Settlement Program was made open to enrollment to two broad groups of claimants or potential claimants nationwide: (1) claimants who had filed a case – whether in federal or state court – as of the date the MSA was executed, alleging (a) use of Actos® prior to December 1, 2011, and (b) a diagnosis of bladder cancer; and (2) claimants with no case pending as of the date the MSA was executed, but (a) a retainer agreement to receive representation in an Actos® suit signed on or before May 1, 2015, and (b) allegations of Actos® usage prior to December 1, 2011 and diagnosis of bladder cancer prior to the date the MSA was executed.<sup>38</sup> As a result, as of this writing, approximately 99.4% of the approximate 11,000 claimants known to have cases alleging

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<sup>38</sup> MSA, § 2.01.

bladder cancer across the United States due to Actos® usage – or who have representation to bring such a case – have voluntarily agreed to and are participating in the Global Settlement Program created by the MSA.<sup>39</sup>

The global acceptance of the negotiated Settlement Program was vital to the success of the MSA; the MSA provided the defendants would have the right not to participate in the Settlement Program unless certain thresholds of participation were met. These thresholds included 95% of all “Eligible Enrollees” (*i.e.*, claimants either with a suit alleging bladder cancer caused by Actos® pending as of April 28, 2015, or with a retainer agreement for such a suit signed as of May 1, 2015).<sup>40</sup> Furthermore, while the MSA called for aggregate settlement funds of \$2.37 billion, the agreed to settlement, also, provided the defendants would increase the total to \$2.4 billion should the participation threshold exceed 97% of all Eligible Enrollees.<sup>41</sup> Thus, the created MSA was intended to be global in scope, included both “a carrot and a stick,” and was designed to encourage the maximum level of participation.

The procedural aspects of the MSA settlement were and remain complex and involved. Thus, Claims Administrators were selected, have worked with all, and have reported to the Court and the parties, throughout the process as to the administration involved, and reported in April,

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<sup>39</sup> 10,782 claimants alleged that they developed bladder cancer caused by Actos. Of this number, 10,722 enrolled in the Settlement Program, or nearly 99.45% of those eligible. Most of the claimants who did not enroll in the settlement have since voluntarily dismissed their claims, ostensibly because they were unable to produce evidence of Actos use or bladder cancer as an injury. Indeed, only a handful of individual claimants remain. Accordingly, as the Settlement Program winds down, more than 99.99% of the claims have been resolved. And, as of this date, approximately \$2,300,000,000, or more than 96% of the settlement funds, has been paid out or is in the process of being paid. The remaining less than 4% is earmarked for (a) claimants who are resolving issues involving the authorization to receive funds (*e.g.*, securing releases, obtaining clearances from bankruptcy trustees), (b) payments to lienholders, or (c) the Extraordinary Injury Fund.

<sup>40</sup> MSA, § 5.02.

<sup>41</sup> MSA, § 10.01.

2016 that not only had the 95% participation threshold been met – guaranteeing that the Settlement Program would go into effect – but the 97% participation threshold had also been met and surpassed, ensuring the increased funding of the settlement fund. This remarkable rate of participation is a testament to the ability and hard work of all involved, especially the PSC and co-leadership and their firms’ work explaining the benefits, transparency, and operation of the Settlement Program to all plaintiffs’ counsel, so those counsel could fully inform their clients and meet their ethical responsibilities. Also of note is the expertise of the Program’s Administrators to oversee a large and complex claims evaluation process efficiently and transparently, and the ongoing involvement of the Special Masters, Magistrate Judge Hanna and the PSC leadership, co-lead counsel, and defense counsel.

As the PSC and defendants, with help from Special Master Russo and Magistrate Judge Hanna, had created an MSA that had created an opt-in Settlement Program, claimants were required, through their attorneys, to affirmatively choose to take part in the process by providing a Notice of Intent to Opt-in, a release of all related Actos® claims, and a signed Stipulation of Dismissal.<sup>42</sup> In this way, the MSA addressed the possibilities of spurious claims attempting to enroll and diminishing the results for the legitimate claimants, eliminating such claims. Also, once enrolled, claimants were required, again, through their attorneys, to submit Claim Packages containing the relevant medical records for review by the Claims Administrator. The parties selected the firm of BrownGreer PLC to be the Claims Administrator, and by all accounts BrownGreer has done excellent, and outstanding work in that role. Per the terms of the MSA, part of the duties of the Claims Administrator is to review all provided documentation, to determine whether that documentation is complete or deficient, and to provide an opportunity for claimants,

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<sup>42</sup> MSA, § 2.02.

through their attorneys, to correct any deficiencies found. The Claims Administrator, upon review, either rejected or accepted the claim as eligible and issued a Points Award for each claim. In the event a claim was determined to be ineligible by the Claims Administrator, the claimant had the right to appeal that decision to an Eligibility Committee (“EC”) composed of members of the Plaintiffs’ Settlement Review Committee (“PSRC”) and counsel for Takeda. The regular meetings of the Eligibility Committee, and the assistance of the PSC leadership, were instrumental in resolving these eligibility appeals. At the direction of this Court, Special Master Russo attended these EC meetings in order to ensure the Settlement Program did not become unnecessarily slowed by this appeal process or reflect bias of any nature. This Court received regular updates from Special Master Russo, which made clear the PSRC and/or members of their firms regularly attended these EC meetings, and were thoroughly prepared in order to resolve all appeals of eligibility decisions in an efficient, unbiased and timely fashion.

Once review and approval of a claim were completed, the Claims Administrator assigned each claimant a number of points, according to a matrix agreed to by the parties.<sup>43</sup> The Points Matrix allotted points according to the level of injury and age of the claimant, with adjustments according to cumulative dosage and a set of agreed risk factors.<sup>44</sup> The value of each point would ultimately depend on the total number of points, compared against the total amount of funding provided. The total dollar value of each point could not be determined until the enrollment and evaluation processes had been completed, however, because total settlement funding was dependent on reaching certain participation thresholds, as noted above, and the final valuation could not be ascertained until the total settlement funding was final.

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<sup>43</sup> MSA, § 6.02.

<sup>44</sup> *See* MSA, App’x. J.

In addition to regularly attending and participating in meetings of the EC, members of the PSRC, also, participated in the process devised to address certain claimants seeking extraordinary injury fund (“EIF”) payments, pursuant to Section 7.02 of the MSA. The EIF was established to enhance payments for claimants with minor children, substantial economic loss attributable to their injury, or medical complications from bladder cancer not otherwise covered by the Master Settlement Program. The same group of PSRC members who attended the EC meetings, also, attended these EIF meetings. At the request of this Court, Special Master Russo, also, attended these EIF meetings, and/or had Ms. Katie Darden attend on his behalf. Special Master Russo and Ms. Darden provided periodic reports to the Court on the progress of the EIF meetings, and again it was clear to this Court that PSRC members regularly attended the meetings, were prepared, and were instrumental in determining whether or not claimants were eligible for EIF payments in an unbiased fashion.

Because the MSA created by the parties, by necessity, included full due process review and the time delay a due process review entails, the MSA created additional procedures to ensure claimants received proper, efficient, but also, timely compensation. The Settlement Program included a system of interim payments, which could be and were made prior to the final completion of the Program, based on estimated point valuations.<sup>45</sup> As noted above, the MSA, also, created an Extraordinary Injury Payments procedure, whereby certain qualifying claimants were found to be entitled to additional recovery based on the severity of their injury.<sup>46</sup> Additionally, a procedure designed to find, evaluate, and satisfy private and public liens was put into place, which will be

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<sup>45</sup> MSA, § 7.01.

<sup>46</sup> MSA, § 7.02.



discussed in greater detail below.<sup>47</sup> Thus, the input and value brought to the benefit of all by those involved PSC members, again, cannot be understated.

The MSA, also, took special care to ensure claimants had recourse to challenge the decisions being made regarding their cases as the Settlement Program carried forward, in light of their agreement not to further pursue their cases in court. At every stage of the submission and evaluation process, each claimant had the right to request reconsideration by the Claims Administrator, ask that the Administrator's decision be reviewed by a body created by the parties' counsel comprised of counsel selected by and from both parties, as discussed above, and/or ask the Special Master of the MDL to review those decisions.<sup>48</sup> All challenged decisions by the Claims Administrator were appealable to Special Master Russo and/or Katie Darden, and have been reviewed and disposed of. These due process procedures were built into the process and guaranteed that claimants and their counsel had multiple opportunities to contest decisions they might think improper, and to have full, adequate, impartial, and almost contemporaneous review of all decisions.

Pursuant to the operation of the MSA and this Court's orders, as of this date, approximately 90% of the money set aside to satisfy claims in the Settlement Program has been paid. Again, the breadth, completeness, and success of the MSA, also, reflect the superior expertise of those involved in its creation.

Especially relevant to this ruling, the created and agreed to MSA, also, required all claimants – as to expenses – and their counsel – as to fees – to agree to relinquish a portion of their respective recoveries to compensate the expenses – as to claimants – and fees – as to attorneys –

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<sup>47</sup> MSA, Art. XIII.

<sup>48</sup> See MSA, Secs. 3.01, 3.05, 4.02, 6.02, 7.02, 9.01, 9.03, and 14.03.

that were incurred in the MDL on behalf of all plaintiffs; counsel to relinquish common benefit fees from their fees; **claimants to be responsible only for a percentage of the common benefit expenses.** Section 10.04 of the MSA is entitled “Common Benefit Fees and Reimbursement of Litigation Costs,” and reflects the following agreement:

10.04 To ensure that common benefit attorneys (hereinafter referred to as “Common Benefit Attorneys”) are fairly compensated and that their fees are reasonable, an assessment of Common Benefit Attorneys’ fees will be imposed on counsel for each Claimant in accordance with the amount set by Order of the Honorable Rebecca F. Doherty to be entered in the MDL (“Assessment”). By opting into the Program, Program Participants and their counsel agree to, and waive, the right to any appeal of any order entered by the MDL court associated with the settlement. Any sum paid as a common benefit fee shall be deducted from the total amount of counsel fees payable under individual plaintiffs’ counsel’s retainer agreement.

- (A) In addition to those amounts provided above, Common Benefit Attorneys shall also be entitled to reimbursement of their reasonable common benefit expenses. Reimbursement of these expenses shall be deducted from the clients’ net recovery. The amount of common benefit expenses shall be determined by Order and entered in the MDL, which sum will be deducted from the Settlement Funds deposited into the QSF.<sup>49</sup>

Pursuant to this portion of the MSA, each *claimant* who agrees/agreed to participate in the Settlement Program agrees/agreed to submit a portion of his or her recovery under the program to compensate for only, *expenses* incurred on behalf of all claimants, and agrees/agreed not to appeal this Court’s orders related to the settlement. Also, each claimant’s *counsel*, furthermore, agrees/agreed to submit a portion of **his or her fees** to compensate for a percentage of the *fees* incurred on behalf of all claimants, and, also, agrees/agreed not to appeal this Court’s orders related to the settlement. **It should not be overlooked that any amount this Court might allocate as**

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<sup>49</sup> MSA, at 35-36.

common benefit fees, does not come from any individual claimants' recovery, rather it *comes from the amount the claimant had already agreed to pay to his or her attorney when he or she agreed to representation*. Thus, common benefit fees are taken from the original attorneys' compensation – not the claimants' MDL recovery. Expenses, however, are taken from the *claimant's recovery – much as with any single claim which is not within an MDL*.

As is reflected in this Court's orders this Court has, from the outset of this MDL, expected to compensate common benefit work, and early on established procedures designed to keep ongoing records of approved common benefit work and common benefit expenses and for regular and ongoing review and evaluation of that work and those expenses within the MDL.<sup>50</sup> Therefore, claimants now choosing to participate in the Settlement Program, and their counsel, have had full knowledge and notice from the outset of what would be required from them should they wish to participate in a global settlement and equally so, any attorney who might have desired to perform or claim compensation for work performed was given full notice of the applicable requirements. By voluntarily participating in the MSA, all have voluntarily agreed to abide by the procedures established and decisions made by this Court governing the compensation for common benefit work, *i.e.*, fees and expenses.

As noted above, many of the participants in the *global* Settlement Program do not, and did not, have cases pending in the MDL, rather had cases pending in various state courts. However, by virtue of the choice to participate in the Settlement Program, each individual claimant and his or her respective counsel, agreed to abide by this Court's decisions as to the amounts that might be retained to compensate the work done for common benefit of all and the expenses incurred for

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<sup>50</sup> See Rec. Doc. 2356.

the benefit of all, as well as to this Court's decisions determining allocation of any amount among counsel.

**G. Implementation of the Settlement**

As described above, the MSA included an enhanced recovery for all participants in the settlement if 95% or more of those eligible to participate agreed to do so. Once the MSA was agreed to, the PSC leadership spent significant time and resource traveling around the country to explain the terms of the MSA to all involved counsel, meeting with various individual plaintiffs' counsel in the MDL, as well as meeting with those plaintiffs' counsel who had cases filed in state courts across the United States. The Special Master attended at least one of those meetings, held in California, and reported to the Court. The Special Master, also, received reports on a regular basis concerning other meetings that were being conducted throughout the country and reported to this Court on those meetings as well. These educational meetings, although both time consuming and perhaps costly, provided the needed detailed information to individual claimants' counsel to allow for informed consent, fulfillment of their ethical responsibilities, and for the extraordinary success of the Settlement Program. The success of the settlement program and almost complete participation is due in large part to the work and expertise of the PSC leadership, Special Master Russo, and settlement counsel for the defendants. Additionally, and perhaps uniquely, the PSC leadership has continued to lend their time, expertise, and finances to preparing and presenting the program even after the MSA has been executed and it is in no small part due to their time and commitment to the MSA and settlement process that has made it an unqualified success.

As a result, the Settlement Program has been extremely and uniquely successful. At this writing, approximately 99.4% of the eligible claimants, nationwide, have opted into the

settlement.<sup>51</sup> The percentage is expected to increase once the settlement process is fully completed and approach the unheard of 100% of all eligible individual claimants nation-wide, once all ineligible claims are removed. This rather unprecedented settlement success on the part of plaintiff participation, in part, is, again, a direct result of the PSC leadership's continued vigilance in handling issues arising after creation of the MSA process, as they have arisen, whether of the MSA, or other residual matters, along with the Special Masters' continued facilitation. Here, the PSC leadership did not abandon the process once the MSA was signed, which can so often, and regrettably, be the case. Their continued commitment and work has acted to the tremendous benefit of all.

The first interim payment made to any claimants elected by the Settlement Process through the Claims Administrator, was announced on June 30, 2016, and the payment process began with the first payment being made to a claimant on July 20, 2016. The settlement process, much like the litigation, has been efficiently handled by the PSC leadership, along with the administrators, the Special Masters and defense settlement counsel – again, not without great expenditure of time and resource. This Court has kept in close communication with the Special Master and continued to monitor, guide, and oversee the progress of this matter, and is convinced that due, in large part, to the continuing administration, oversight, and management by the Special Master, PSC leadership and defense settlement counsel, all working closely with BrownGreer, that the settlement process has been a model of efficiency. The Special Master has reported that calls have been conducted each week by all involved, *i.e.*, select PSC members, Takeda, and the Settlement Program's Administrators to make sure any issues which arose were and are resolved promptly. This dedication of continuing time and resources by the PSC leadership and defense settlement

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<sup>51</sup> See fn 37.

counsel to the settlement process, even after the MSA was entered, has contributed in large part to the unprecedented success of the MSA.

Also, as a part of the implementation of the MSA, it was necessary to work with and address parties who withheld or had legal claims to liens, *i.e.*, primarily, both public and private medical providers. This Court requested Magistrate Judge Hanna take the lead to assist the parties and settlement administrators with addressing those liens as he has developed a special expertise in this area. Magistrate Judge Hanna met regularly with the PSC leadership and defense counsel and the Lien Resolution Administrator<sup>52</sup> to create a fair and effective lien resolution process, and to help resolve all issues that have arisen in moving the settlement forward on this front. As with the Claims Administration process, the Lien Resolution Administration process was negotiated, and agreed to by the parties, here with the help of Magistrate Judge Hanna and, again, is unique and has proven quite effective. The medical lien resolution in all personal injury cases has proven, historically, to be problematic. With Magistrate Judge Hanna's leadership, the expertise of the counsel involved, and the operation of the Lien Resolution Administrator, resolution of all liens has progressed at an extraordinary pace.<sup>53</sup> The created process has employed unique and creative solutions heretofore not employed in an MDL of this size and has been, and continues to be, effective, transparent, and fair. According to all sources, the Garretson Group ("Garretson"),

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<sup>52</sup> Per the terms of the MSA, the Claims Administrator was not to serve as the Qualified Settlement Fund Administrator (whose duties are to oversee the receipt, maintenance, and distribution of settlement funds paid by the defendants). MSA, § 8.02. In this MDL, BrownGreer was selected to be the Claims Administrator, and the Garretson Group, who was selected to be the Lien Resolution Administrator, who was selected and agreed to, also, administer the Qualified Settlement Fund.

<sup>53</sup> As of this writing, more than 98% of the 18,671 liens initially identified have been resolved. The remaining liens are unresolved only due to data discrepancies or to the time it takes for plans and agencies to communicate with Garretson. Garretson is expeditiously addressing the remaining liens on a case-by-case basis.

which was selected by the PSC and defense counsel to be the Lien Resolution Administrator, also, has been integral to the success, not only of the lien resolution program, but, also, integral to the success of the Settlement Program as a whole, as the settlement could not go forward without resolution of all outstanding liens. Thus, again, the expertise of involved counsel has acted to the benefit of all.

In connection with Magistrate Judge Hanna, counsel, and Garretson, a lien resolution protocol was created, which, again, the parties negotiated and agreed to, under which Garretson has reached out to all private and public medical providers that had asserted liens on payments to claimants in the Settlement Program. Garretson has successfully reached agreements with each of the identified lienholders for resolution of their liens. The Court understands Garretson did most, if not all, of the work of locating, auditing, and valuing the liens in conjunction with the PSC, defense counsel, and Magistrate Judge Hanna. This process, while exhaustive and quite involved, was necessary to make it possible for Garretson, BrownGreer, and counsel to estimate the amount that would be needed to be withheld from each claimant's recovery and to ultimately facilitate pay outs to the individual claimants. This, in turn, again, helped ensure individual plaintiffs' counsel could have the necessary information required to engage in a thorough and meaningful discussion of the costs and benefits of the Settlement Program with their clients, before each client made his or her choice to enter or reject the proposed settlement. Thus, the work of the PSC leadership, again, allowed all counsel to meet their ethical obligations to their clients and the Court. This process operated with full transparency which, also, has helped the parties reach the required participation thresholds to allow the Settlement Program to proceed. Finally, and in some instances related to the lien resolution process, special attention has been paid to create an additional process for addressing those claims which might be affected by ongoing bankruptcies,

and the specialized interaction with bankruptcy trustees and courts. Those counsel who lent their expertise to this issue have, also, been of great value to the litigation.

Altogether, the MSA created by counsel using their expertise, the tremendous effort and commitment of time and resource involved by counsel, BrownGreer, Garretson, the Special Master, and Magistrate Judge Hanna, and the oversight of the Court has created a model of efficiency in the advancement of the Settlement Program, and have kept this matter moving ever forward to final completion at an unprecedented pace. According to estimates now available, at the current rate of progress, final payments could be completed as early as the end of 2017, which would represent approximately six years from inception of this MDL to resolution of the Settlement Program, resolving more than 99% of all cases in the MDL, and, also, resolving almost 11,000 eligible claims nationwide, which, in and of itself, is an extraordinary feat within the world of MDLs. This success is in large part attributable to the involvement of the Special Masters, the PSC leadership and defense settlement counsel involved, and to the PSC's able leadership, exceptional expertise, and the tireless work done on behalf of all plaintiffs.

#### **H. The Initial Hold-Back on Settlement Payments**

From the inception of these proceedings, based on historical precedent, this Court had anticipated that, in the event of a global settlement, those attorneys who had worked for the common benefit of all plaintiffs would need to be compensated for their work.<sup>54</sup> As noted above, the parties' counsel – out of whose recovery the fees will come – themselves, anticipated this Court would award common benefit fees and expenses and agreed to that award.<sup>55</sup> After the MSA was

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<sup>54</sup> Rec. Doc. 1357.

<sup>55</sup> MSA, § 10.04.



executed, this Court was repeatedly urged to give the participants in the Settlement Program a *preliminary indication* of the amount that *might be used* to compensate the PSC and Participating Counsel, so that individual counsel could effectively communicate with and inform their clients, as part of their ethical responsibilities; for that reason, this Court entered *the preliminary* Holdback Order on September 1, 2015, instructing the Settlement Program Administrators to, at that time, withhold 8.6% of any payments made pursuant to the terms of the MSA in order to have a preliminary amount available to compensate for common benefit fees, and to withhold \$25 million to address common benefit expenses.<sup>56</sup> By Order dated February 16, 2016, the Court notified counsel and all parties to this proceeding that it would issue a *final assessment* order for common benefit fees and expenses in the amounts described in its Holdback Order, and provided full opportunity for all to object to any such assessment.<sup>57</sup> No objection(s) were lodged.<sup>58</sup> Thereafter, the Court entered its Case Management Order: Common Benefit Fees and Costs, assessing the amounts described in the Holdback Order.<sup>59</sup> The hold-back amount remains available for release, and this Court now enters its final Common Benefit Ruling allocating those amounts.

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<sup>56</sup> Rec. Doc. 5850.

<sup>57</sup> Rec. Doc. 6215.

<sup>58</sup> While no objections were lodged within the deadline provided therefor, this Court received a notice of comment or opposition by a claimant to the amount assessed for common benefit attorneys' fees by a plaintiff *on December 27, 2016*, through that claimant's counsel. The Court would point out that the "objection" is not timely, and that the Court's final decision to compensate common benefit attorneys' fees requires a reduction in **only** the fees awarded to each original **counsel** pursuant to each claimant's individual retainer agreement **and does not act to reduce a given claimant's award**. However, the Court, also, would draw the involved claimant's attention to this ruling, which lays out the reasoning behind this Court's decision to assess part of the attorney's fees for compensation of common benefit work.

<sup>59</sup> Rec. Doc. 6238.

**I. Nationwide Settlements**

There were approximately 4,500 Actos®-related lawsuits filed in (or removed to) federal district courts throughout the nation, that were transferred into (or filed in) these proceedings. Another approximately, 6,500 were filed in (and remained pending in) state court systems throughout the country. As noted above, the MSA specifically permitted plaintiffs whose claims were in state court to participate in the MDL Settlement Program, should they so desire, and they have done so in almost all cases. This exemplary result is in no small part the result of the expertise, work, and time expended by the PSC leadership and defense settlement counsel; thus, the PSC has performed the extraordinary service of, also, providing settlement opportunities to more than twice as many state court claimants, a group above and beyond whose interests they were explicitly and formally obligated to protect, thus, providing exemplary benefit to all claimants and to the public.

**J. Additional Comments on Common Benefit Efforts**

The descriptions provided above address many, but certainly not all, of the common benefit services provided by the PSC and Participating Counsel; this Court should, also, note, it does not, however, address several discrete aspects of these proceedings that might help to further illuminate the full scope of the common benefit delivered to all of the claimants participating in the Settlement Program.

First, the very large number of cases in this MDL, together with the large number of cases filed in state court, required an extraordinary level of organization, coordination, and cooperation among the PSC and all plaintiffs' counsel, *i.e.*, among MDL plaintiffs' attorneys *as well as* between MDL plaintiffs' attorneys and plaintiffs' attorneys in the thousands of state court matters, and that cooperation, coordination, and expertise was supplied by the leadership of the PSC and

the plaintiffs' state court liaison, Dawn Barrios, and defense team state court liaison, Sherry Knutson. The fact that the MDL cases did not overtake, step on, or otherwise interfere with the state court cases (including the Illinois and California coordinated proceedings), *and* that defendants were not overwhelmed by the sheer number of cases that might have remained in state courts throughout the country, is due in large part to the tremendous effort of the PSC and defense counsel – for the plaintiffs, by co-lead counsel, Richard Arsenault and Paul Pennock, by the state court liaison, Dawn Barrios, and their coordination with the Special Master and the Court. The ability to keep all sets of cases proceeding in parallel, without each tripping over the other, contributed immensely to the common benefit of all MDL plaintiffs and the public at large, and this Court wishes to acknowledge that fact. Co-lead counsel, Richard Arsenault and Paul Pennock, displayed an extraordinary talent and ability for organizational and administrative skill underlying true leadership ability. State court liaison for the PSC, Dawn Barrios, along with the state court liaison for defendants, Sherry Knutson, kept not only this Court, but all state courts, updated and informed as to the plethora of issues and matters involved as this MDL and those in the state courts as those cases moved forward, with full respect shown and given to all courts involved. Such coordination and communication were often nuanced, complex, and time intensive and were integral to the overall success achieved, as illustrated by the level of participation reached among claimants with cases in state courts.

Second, a very important aspect of this litigation that might not be obvious to the casual observer is this: the PSC and Participating Counsel were working within cutting edge science, requiring rigorous research and investigative science; counsel education and mastery, and specialized expertise and training were required at every step along the way to resolution; thus, requiring highly capable counsel with unique and specialized talents working in tandem with

highly capable staff and with identified outside medical and regulatory experts. The breadth of the necessary scientific knowledge required to identify the biological mechanisms that might contribute to the argued elevated carcinogenic risk alleged, required mastery of and development of multiple scientific theories across many scientific disciplines and within multiple regulatory environments. The grasp of the discrete subject matter required not only review of hundreds of thousands of scientific articles and treaties and documents, but, also, innumerable tutorials in order to understand, yield, and present in a manner lay jurors could grasp, what the PSC and their experts believed to be the three plausible biological mechanisms for Actos®-induced cancer ultimately presented at trial, within the complex and idiosyncratic regulatory context of those theories. Additionally, one must always be aware the PSC, at every step, had to meet an equally vigorous, and scientifically prepared, defense mounted by an equally prepared and aggressive defense team. Thus, in an area of cutting edge science and great regulation, extensive and specialized expertise, education, and research were required and presented a particular challenge for counsel; one, the trial result and settlement amount would argue, the PSC met. These efforts – developing *de novo* theories of general causation and applying those general causation theories to specific cases, and exploring and understanding the complex regulatory apparatus involved over some twenty plus years, made possible the result(s) obtained and came at a documented and expensive cost in time, resource, and expertise.

Furthermore, those counsel who had the needed organizational, administrative and leadership skills, as well as those who had the needed specialized scientific expertise, along with those with the needed technological expertise, proved of immense value to the process.

Additionally, the ability to translate a complex, nuanced, body of evidence into an understandable whole capable of being presented to and swaying lay jurors cannot be understated.

The trial counsel – Mark Lanier and Richard Arsenault, supported by an ever present PSC trial team, performed in exemplary fashion, all the while being met and challenged by an aggressive defense trial team. The trial result is a testament to the work expended and the ability of the PSC trial team.

Finally, as noted above, this Court – at the outset – imposed on all Participating Counsel the obligation to monthly submit fee and expense claims to the PEC and the Deputy Special Master and imposed on the PEC, particularly, the obligation to audit those time and expense claims before allowing them to be submitted to Deputy Special Master DeJean. The PEC's willingness to perform this auditing service added an entirely new layer of responsibility on top of the customary obligations of PSC and PEC attorneys. A task in large part assumed by Richard Arsenault's firm through the ever available attorney, Jennifer Hoekstra, as overseen by Richard Arsenault, which and who acted to make the final resolution of these proceedings significantly more efficient than might otherwise have been the case. The regular and ongoing submission and review of time and expenses submitted by all Participating Counsel, *i.e.*, Participating Counsel and the PSC, to both the PEC and the Deputy Special Master, has been pivotal to the success of the unique process instituted by this Court to deal with the historically thorny problem of common benefit compensation and has acted to avoid the historical delay and, often conflict ridden process, inherent in common benefit fee allocation. Without the PSC, PEC, and all Participating Counsels' agreement to and actual participation in and compliance with this rather unique approach to time and expense accountability, the superb work of Richard Arsenault's firm, and in no small part Jennifer Hoekstra, as well as the capable and even-handed review of Deputy Special Master DeJean, the more transparent and more objective process of fee allocation could not have existed, moved forward as timely, accurately, or fairly as it has, nor could it have addressed the thorny

issue of common benefit award in as transparent and efficient manner as it has. Thus, the PSC, PEC and Participating Counsel, again, expended considerable time, and expense, to the benefit of all.

## II. COMMON BENEFIT FEE AND EXPENSE REVIEW PROCESS

As noted above, and referenced by the Report and Recommendation of Deputy Special Master DeJean, at the outset, this Court chose to approach one of the most problematic aspects of an MDL – common benefit determination and allocation among attorneys – in a unique and more objective and transparent fashion and, thus, instituted a policy, procedure, and organizational process, to attack this historically problematic aspect of MDLs. The Court, with hands-on input from the PSC leadership, and with the input of the Special Masters, issued multiple orders to create and implement a new and unique approach to common benefit allocation, requiring all who wished to contribute or become Participating Counsel to obtain prior approval for work from the PSC, PEC, or co-lead counsel, within the context of this Court’s order that all who requested work and were qualified, should receive work; for all those accepted as Participating Counsel and for the PSC to maintain current records of their time and expenses for each approved task; having the PEC review those submissions, and thereafter, having Deputy Special Master DeJean review all submissions; and establishing a due process review by the Special Master and, ultimately, by the Court for all objections. *See* Rec. Docs. 1357, 2356. In conjunction with the noted orders of the Court, Deputy Special Master DeJean was tasked with the initial Court oversight of all submissions for common benefit time and expense made by the PSC and other Participating Counsel, with opportunity for objection and appeal by counsel to the Special Master and, ultimately, the Court.<sup>60</sup>

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<sup>60</sup> *See* Rec Docs. 532, 1357, & 2356.

As noted, the actual process Deputy Special Master DeJean was to follow for receiving common benefit time and expense was established by this Court, but was implemented through the submission and review of time and expense records of all Participating Counsel.<sup>61</sup> Initially, also, in conjunction with this Court's orders, the PSC was tasked with instituting a specific procedure whereby all common benefit work was to be assigned by co-leads and/or the PEC to all qualified attorneys who either were assigned work as members of the PSC, or who applied for and received prior approval to and performed work as, "Participating Counsel."<sup>62</sup> The PSC was directed to set up a procedure whereby all PSC members and/or Participating Counsel who performed common benefit work and/or who incurred approved common benefit expense would monthly submit their time and expense to the PEC for initial compilation and approval. Upon completion of this task, the protocol set up by the Court required the audited compilation of time and expense to be sent to Deputy Special Master DeJean for review to either accept, reject, or request additional information to cure any deficiencies he might find, and allowed for a multilayered due process appeal to Special Master Russo and ultimately to the Court.<sup>63</sup>

If deficiencies were found in any of the submissions for common benefit time and/or expense, Deputy Special Master DeJean was to issue a deficiency notice to the attorney submitting the claim. To date, Deputy Special Master DeJean has reviewed approximately 4,500 pages of submissions for common benefit time and expense, has sent out more than 13,000 common benefit time deficiency inquiries, and has sent out more than 30 common benefit expense deficiency notices since he began his review of common benefit claims, ultimately omitting certain time and

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<sup>61</sup> See Rec Docs. 560, 1357, & 2356.

<sup>62</sup> Rec Docs. 1357 & 2356.

<sup>63</sup> See Rec Docs. 560, 1357, & 2356.

expense requests. The issued notices granted their recipients fourteen (14) days to correct deficiencies or to request additional time to respond. Upon receipt of all necessary information and documentation, Deputy Special Master DeJean then made a determination as to whether the expense and/or time had been approved by the PEC, PSC, co-lead counsel, or the Court, as required by the process,<sup>64</sup> whether the deficiencies had been corrected, and whether the common benefit time and expense was or was not presumed sufficiently reasonable and thus, was approved or disapproved by Deputy Special Master DeJean. By the agreed to Order of the Court, once this determination was made, a period for appeal to Special Master Russo was allowed and full opportunity to be heard by Special Master Russo was provided, and thereafter, ultimately, full review by and full opportunity to be heard by this Court. If no appeals were taken, by the agreed to Order of the Court, a presumption as to the validity and reasonableness of the submission operated as to the final determination of the Court.<sup>65</sup> To date, there are no remaining objections to decisions on common benefit time and expenses made by any Participating Counsel.

Deputy Special Master DeJean has performed the explained audit procedure throughout the life of this MDL and now, as this matter approached its final resolution, was authorized by the Court to, also, conduct interviews, make inquiry, and gather the information necessary for this Court to make its determination as to the total of the reported submissions for common benefit fees and expense approved and/or requested to the Court and to recommend as to the allocation among counsel.<sup>66</sup> During May and June of 2016, pursuant to the directive of the Court, Deputy Special Master DeJean conducted sworn interviews of all counsel who had submitted common

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<sup>64</sup> See Rec Doc. 2356.

<sup>65</sup> See Rec Docs. 1357 & 2356.

<sup>66</sup> See Rec Doc 5801.



benefit time and expense claims and who wished to be heard. The interviews addressed the nature of the work and contribution performed by the submitting attorney and/or firm, as well as a review guided to some degree by those factors enumerated in *Johnson v. Ga. Highway Express, Inc.*, 488 F.2d 714, 717-19 (5<sup>th</sup> Cir. 1974)<sup>67</sup> as they might have related to the work of the submitting attorney and/or firm. During the interviews, each PSC member, PEC member, and/or Participating Counsel, who elected to be interviewed, had full opportunity to comment on the work done by others, explain the nature and perceived value of the work done by him or her or their firm and to, also, comment on what, if any, resources and work might have been used in bringing this matter to resolution or had to be foregone in order to serve this MDL. All who were interviewed verified that the only resources, information, or results used in the management, trial, and settlement of these proceedings, were those of the PSC, PEC, and Participating Counsel who had followed this Court's ordered protocol; in other words, all verified the PSC used no attorney work product or input beyond that created within the MDL, to move this matter forward to its ultimate resolution.

Although, perhaps, adding time and expense for Participating Counsel, the PSC, and PEC, at the early stages and along the progression of the case, the described protocol has proven wonderfully effective in removing the often extensive unwarranted time, expense, and dissonance of fee allocation, by documenting the time and expense incurred on an ongoing basis throughout the litigation, and thus, provided a valuable objective foundational platform for one of the most contentious aspects of MDLs – namely, fee allocation. Furthermore, the PEC, through Richard

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<sup>67</sup> As will be discussed in greater detail below, the *Johnson* factors are: (1) the time and labor required; (2) the novelty and difficulty of the issues; (3) the skill required to perform the legal service adequately; (4) the preclusion of other employment by the attorney because he accepted this case; (5) the customary fee for similar work in the community; (6) whether the fee is fixed or contingent; (7) time limitations imposed by the client or the circumstances; (8) the amount involved and the results obtained; (9) the experience, reputation, and ability of the attorneys; (10) the undesirability of the case; (11) the nature and length of the professional relationship with the client; and (12) awards in similar cases.

Arsenault's firm, the selected accounting firm of Arsement, Redd, and Morella, and Deputy Special Master DeJean performed ongoing and final cross checking of all submitted requests, approvals and costs to ensure accuracy and transparency – all at no small cost in time and expenditure. Again, note should be made of the unyielding work of Jennifer Hoekstra of Richard Arsenault's firm and Deputy Special Master DeJean and his staff in implementing and facilitating the complex and comprehensive process employed.

It is, also, of note that this Court instructed the co-lead counsel and the PSC that *all attorneys who requested work and who were qualified and capable to do that work, were to receive work*, and the submission process and Deputy Special Master DeJean's Report and Recommendation, reflect this to have been the case; the process requiring pre-approval of all work by the PSC, PEC, or co-lead counsel, with appeal available to the Court, therefore worked to the benefit of all plaintiffs. The interview process conducted by Deputy Special Master DeJean, overall, confirmed the PSC was a well-organized, well led, and efficiently functioning group, and that all outside counsel who followed the established protocol and submitted official requests to the PSC to perform common benefit work were provided with the opportunity. Further, Deputy Special Master DeJean's Report and Recommendation shows the interviews established that the structure of the PSC was such that not only were members of the PSC, but also, all plaintiffs' counsel throughout the country, given full notice of the process in time to fully comply with it, but that all attorneys were kept informed of all developments in the MDL by either co-lead and/or liaison counsel. Again, Deputy Special Master DeJean's Report and Recommendation shows there was unanimity in all interviews conducted that the duties and work of the co-lead and liaison counsel were extremely beneficial to not only the PSC, but, also, to all individual counsel involved in these proceedings.

The foregoing procedures resulted in attorneys' fee claims being submitted in regularly as the litigation progressed and approved, clarified, or rejected on a regular and ongoing basis by Deputy Special Master DeJean, with appeal rights to Special Master Russo and ultimately to this Court. With this unique innovation, once the case has been settled, plaintiffs' counsel are better able to turn their attention away from the often lengthy and contentious matter of fees, to the equally necessary, but often neglected, task of assisting in the administration of the settlement and making the settlement process more effective and efficient. Again, counsels' time and focus throughout the litigation upon documentation of their time and expense expended have allowed counsel, at this stage, to turn their attention to full and effective completion of the core matters at hand. Counsel were freed from the time consuming task of attempting to recreate and to evaluate their past time and resources expended, all of which would have occurred much earlier, in order to make an effective and supportable claim for attorneys' fees and expenses and/or costs. Under the protocol in place, and due in no small matter to the work of counsel, the Neblett, Beard and Arsenault firm, and Deputy Special Master DeJean, that task of *reporting* has already been completed and this Court has already approved objective data from which to work.

Additionally, in an MDL of this size and complexity, the obligation to keep all counsel contemporaneously informed of all processes and relevant developments is taxing; one requiring tremendous time and computer expertise and capacity, and in this matter the Court was relieved of that almost overwhelming task by the PSC beautifully, in particular by liaison counsel Patrick Morrow, through tremendous time and effort, and at no small expense. Liaison Counsel Patrick Morrow embraced an, heretofore, undefined new role of liaison counsel and performed this demanding role seamlessly. The contemporaneous notice and reporting to all counsel was instrumental to the transparency of the process and thus, to the involvement of all counsel and,

also, merits special note. Only with transparency and understanding could all involved counsel meet their ethical responsibilities to their clients, respond to the Court, and work toward and not against the collective good.

It should, also, be noted, the PSC leadership expended significant time, resources, effort, and expertise negotiating a settlement and establishing a settlement process that is global in nature, embracing not only all MDL, but also, state court litigants. The able assistance and involvement of the state courts involved, also, cannot be understated. The Honorable Kenneth Freeman and the Honorable William MacLaughlin in California and the Honorable Deborah Dooling in Illinois in particular, contributed greatly to the efficient resolution and management of the global resolution of these claims and of issues related to attorneys' fees and expenses, thus inuring to the benefit of all the claimants whether federal or state. This Court wishes to take this opportunity to express its genuine appreciation to all the state court judges who helped to resolve these cases, and in particular, to Judges Dooling, Freeman, and MacLaughlin for their exceptional cooperation and professional skill.

This Court was advised certain agreements as to the distribution of common benefit fees and expenses and/or costs, separate from the MSA, were entered into between the PSC and the lead counsel of the Illinois and California coordinated proceedings with the oversight of Judges Dooling and Freeman or MacLaughlin.<sup>68</sup> This Court was not privy to the details or formation of any such agreements, as this Court played no role in their negotiation, nor has this Court reviewed nor been asked to review the language of any such agreements. As such, the existence of any such agreements rests with those courts, and will not impact this Court's decisions as to the allocation

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<sup>68</sup> The process embraced to address amicable resolution of common benefit distribution for the consolidated state court cases remained available to resolve any other such disputed claims, if any arose.

of common benefit fees and expenses and/or costs pursuant to the MSA; however, pursuant to the MSA, this Court will allow the effect of those agreements to be realized within the MSA. This Court, also, has been advised that Judge Dooling and Judge Freeman have established common benefit protocols in their respective proceedings to address individual attorney allocation in those proceedings, and this Court has been provided copies of the orders establishing Qualified Settlement Fund (“QSF”) accounts within those respective coordinated proceedings; this Court leaves to those capable judges the decisions as to the individual allocation of common benefit fees within those proceedings, with the Court’s appreciation of and for their able involvement.

To date, from June 2012 until June 2016, a total of thirty one firms have submitted claims for common benefit time and/or expense within the federal MDL, resulting in review and approval of over 200,000 hours in audited common benefit time expended in this MDL.

### **III. METHODOLOGY FOR CALCULATING AGGREGATE FEE AWARD**

#### **A. Distinction between Reasonable Hourly Rates in Multidistrict Litigations and Class Actions**

At the outset, this Court wishes to note that much of the jurisprudence concerning common fund and/or common benefit cases arises within the context of class actions, a procedural vehicle similar to, but not the same as, the procedural vehicle of a Multidistrict Litigation. First, it bears noting multidistrict cases flow from a completely separate and distinct statutory origin. The authority to create an MDL flows from 28 U.S.C. § 1407, while class actions are governed by Fed.R.Civ.P. 23 and have roots in the English common law. Although somewhat similar in certain aspects, the two are quite different and distinct in other, fundamental aspects. Whereas, in class actions one attorney or firm represents all claimants and the class action is one case – governed by certain qualifying requirements – in an MDL there are as many separate counsel as there are separate claims, and each claim retains its own independent procedural vehicle, and identity, as

well as its own home venue for *resolution* – the location and venue of the MDL court being only temporary in time, and limited in scope.<sup>69</sup>

The Supreme Court highlighted these statutory limitations in *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 118 S. Ct. 956, 140 L. Ed. 2d 62 (1998); there, the U.S. Supreme Court reversed a Ninth Circuit affirmation of an MDL district court’s transfer to itself – under the transfer provision of 28 U.S.C. § 1404 – of a suit the district court deemed sufficiently related to the MDL which had been assigned to it by the JPML. The Supreme Court determined the transfer was improper, basing its decision on a strict reading of 28 U.S.C. § 1407, and noting that the statute “not only authorizes the Panel to transfer [cases] for coordinated or consolidated pretrial proceedings, but obligates the Panel to remand any pending case to its originating court when, at the latest, those pretrial proceedings have run their course.” *Lexecon*, 523 U.S. at 34. Furthermore, the Court noted the statute requires that the Panel “shall” remand cases, unless it “shall have been previously terminated” and therefore, held that remand is not subject to judicial discretion. *Lexecon*, 523 U.S. at 34-35.

Other notable distinctions exist between MDLs and class actions, which will be discussed in full detail below. After a full review of all the applicable statutory, jurisprudential and procedural provisions, and with an eye to the existing practical realities existing in an MDL, it is the opinion of this Court that sufficient distinctions exist between the two procedural vehicles – *i.e.*, a class action and a MDL - to warrant review, and that those distinctions should be taken into account and should guide a court when establishing a common benefit award in an MDL. Other

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<sup>69</sup> Each action transferred by the JPML “shall be remanded by the panel at or before the conclusion of such pretrial proceedings **to the district from which it was transferred unless it shall have been previously terminated.**” 28 U.S.C § 1407 (emphasis added). *See also Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26, 118 S. Ct. 956, 140 L. Ed. 2d 62 (1998).

district courts addressing this issue have suggested a similar conclusion. *See, e.g., In re Vioxx Prod. Liab. Litig.*, 760 F. Supp. 2d 640, 660 (E.D. La. 2010) (electing to use a reasonable hourly rate for the lodestar that is the average of the billing rates for all submitters of common benefit time and/or expense, to reflect the national nature of the plaintiffs' counsels' practice in the MDL, rather than limiting the decision to a reasonable hourly rate within *the court's* locality, as required for class actions); *In Re: Oil Spill by the Oil Rig "Deepwater Horizon" in the Gulf of Mexico, on Apr. 20, 2010*, No. 2179, 2016 WL 6215974, at \*19 (E.D. La. Oct. 25, 2016) (using an average or blended rate for the purposes of conducting a lodestar analysis).

Within the more homogeneous class action, as noted, a reasonable hourly rate arguably should be determined with reference to the legal community in the locality in which the district court sits<sup>70</sup> – which, also, with a class action will be the proper venue for that matter, as well; that is not the case for an MDL. Rather, in MDLs the venue *for resolution of each case* remains the venue of original filing for that case. There is no *collective venue* but for the *temporary* venue of

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<sup>70</sup> The Court in *In re Enron Corp. Sec., Derivative & ERISA Litig.*, 586 F. Supp. 2d 732, 754-55 (S.D. Tex. 2008), presented a review of certain relevant common fund jurisprudence within *class actions*, which indicated

[a] reasonable hourly rate should be in accord with rates “prevailing in the community for similar services by lawyers of reasonably comparable skill, experience and reputation.” *Blum v. Stenson*, 465 U.S. 886, 895–96 n. 11, 104 S.Ct. 1541, 79 L.Ed.2d 891 (1984). “A reasonable hourly rate is determined with reference to the prevailing market rate in the *relevant legal community for similar work*.... While the hourly rate must be ‘adequate to attract competent counsel,’ the ‘measure is not the rates which lions at the bar may command.’” *Coleman v. Houston Independent School District*, 202 F.3d 264, 1999 WL 1131554 (5th Cir.1999), *citing Leroy v. City of Houston*, 906 F.2d 1068, 1079 (5th Cir.1990). The relevant legal community is the one in which the district court sits, no matter how much of the work is done elsewhere. *Green v. Administrators of Tulane Educational Fund*, 284 F.3d 642, 662 (5th Cir.2002), *abrogated on other grounds, Burlington N. & Santa Fe Ry. Co. v. White*, 548 U.S. 53, 126 S.Ct. 2405, 165 L.Ed.2d 345 (2006). In addition to the community rate, the district court must also consider the attorneys' regular rates. *Louisiana Power & Light Co. v. Kellstrom*, 50 F.3d 319, 328 (5th Cir.1995)(emphasis added).

the court, *temporarily* empowered to handle *pretrial* matters, with ultimate resolution to occur in the original court of proper venue, unless previously terminated within the MDL.

In determining a reasonable hourly rate within that *class action*, the court in *In re Enron* looked, in part, to the typical hourly rates charged in the Houston/Dallas area, as that was where *the single class action had been filed and where venue was proper*.<sup>71</sup> Looking to local Houston rates to assist in the determination of a reasonable hourly rate for a class action filed in that locality was the method chosen by the court for *that class action* and not without good reason – the matter was a *single case, filed against a defendant located in the Houston area, pursued by a single attorney or firm, under the normal venue allowed for under the federal rules of civil procedure*. As mandated by the class action venue provisions, *the court handling the matter would be situated in the proper venue for the case*, there, Houston. Thus, Houston was the proper venue for the *single case – a class action. Lead Counsel were located in Houston, the suit concerned actions taken by Enron (a corporation located in Houston), and venue was proper in Houston*. Consequently, much as in any other *single case*, the hourly rates charged should reflect those factual realities. There, Houston offered the truest picture of the reasonable rates for the work done in that suit, no matter where the work might have been performed - *just as in any non-class action case*.

MDLs, by contrast, are not one case, rather they are *a loose collective of separate cases temporarily* brought together by a specific statute for a limited purpose, *only for the handling of pretrial matters for a limited duration* destined to return to their proper venue if not previously terminated.<sup>72</sup> Each individual case is unique as to its specific individual claim, and *the collective*

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<sup>71</sup> *In re Enron*, 586 F. Supp. 2d at 778-86.

<sup>72</sup> 28 U.S.C. § 1407.



*is only a temporary creation of statute.*<sup>73</sup> MDLs are, by statutory creation, only *a temporary forced gathering of a plethora of separate cases, which were originally filed in courts found within their proper venues (across the United States) and destined for final resolution in those courts (across the United States) within those venues, brought together for collective handling before another court for only pre-trial matters and only until those pretrial matters are completed.* Under the MDL statute, it is contemplated that cases *are to be tried in the original courts and districts in which they were filed*, but are consolidated before a selected MDL judge for *pre-trial* purposes only, and only if the JPML determines such temporary consolidation “will be for *the convenience of parties and witnesses* and will *promote the just and efficient conduct* of such actions.”<sup>74</sup> Thus, with an MDL, there is no inherent requirement that the transferee district(s) be the situs of the conduct complained of, nor the district where any party is located, nor where any counsel is located, nor where any acts might have occurred, nor where the work should or might be done. In fact, as a practical matter, often no party is a resident of the district selected for the MDL court, and it is not at all unusual that none of the counsel serving for the common benefit is from the location of the MDL court, nor is any of the discovery or pretrial work performed in that venue. Indeed, the selection of the MDL judge and court location historically has had little to do with the location of the defendant or the location of the plaintiffs, or where original venue is proper for the many cases involved – venue being suspended by the statute – rather, that selection is made by the panel with an eye to “the convenience of the parties and witnesses” and to the “just and efficient conduct” of such actions, and historically has keyed more to the capability of the judge and the

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<sup>73</sup> 28 U.S.C. § 1407.

<sup>74</sup> 28 U.S.C. § 1407. See also *Lexecon, Inc. v. Milberg, Weiss, Bershad, Hynes & Lerach*, 523 U.S. 26, 118 S.Ct. 956, 140 L.Ed.2d 62 (1998).

judge's court's ability to handle such a large collective of cases, and practical considerations such as ease of transportation for *the expected* out of state counsel, witnesses, and parties when working in a given court. Thus, to tie the allowable fee *for out of state counsel* representing clients *in individual suits filed throughout the country and destined to be resolved in courts throughout the country* to the fees prevalent in *the locality of the court selected to handle the temporary collective*, does not support or display the same logic as with class actions. Rather, such a requirement in an MDL, in fact, could have unintended negative and harmful consequences, by having the locations which might support a higher hourly rate being favored by counsel over locations which might reflect a lower hourly rate, and act to bypass courts which might be well suited to the task at hand and bypass a judge who might be highly capable, and thus, handicap the sought judicial efficiency. Requiring common benefit fees in MDLs to be determined by the typical hourly rates charged *in the locality of the transferee court – which might have little if any connection or relationship to the parties, the counsel, the claims made, or proper venue of the many cases involved* – does not hold the same compelling logic as it does with a class action.

Indeed, the Actos® MDL provides a prime example of the incongruity of which this Court speaks. While the JPML chose the Western District of Louisiana, Lafayette Division as the transferee court to handle the pre-trial matter of MDL 2299, Lafayette bears no inherent relation to the dispute, the parties, the many original venues, or the involved counsel – the chief Takeda entities are located in Japan and Illinois; the plaintiffs and plaintiffs' counsel span the entire United States of America; the venue proper as to each individual claim spans the entire United States, and the PSC, PEC, and Participating Counsel comprise attorneys whose practices span the entire United States. Indeed, the “relevant legal community,” as defined in *In re Enron*,<sup>75</sup> and referenced

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<sup>75</sup> *In re Enron*, 586 F. Supp. 2d at 754.

by Judge Fallon in *In re: Vioxx Prod. Liability Litigation*, supra, in the Actos® MDL is that reflected by the plethora of counsel having claims in the multidistrict litigation, and the proper venues of those claims. In this instance, as in many MDLs, that of the United States; thus, the relevant legal community is comprised of counsel who practice within a unique MDL bar and whose practice, as Judge Fallon recognized in *Vioxx*, is national in nature.<sup>76</sup>

The counsel in this MDL span the entire United States; the original and proper venues span the entire United States; the work done spanned both the entire United States and international locations; and the defendants are international and national corporations that bear no relation to the MDL court location. While this MDL court is located in Lafayette, Louisiana, only a portion of the work in the MDL was performed by attorneys in the physical area of Lafayette, Louisiana and that work, for the most part, was tied directly to participation in Court matters. Rather, the legal community of the attorneys who prosecuted the MDL, quite literally, spans the nation, conducting work across the nation and outside the United States, for the collective benefit of cases properly filed across the nation, and destined, by statute, to be returned to and resolved in courts located across the nation.<sup>77</sup> While the legal community of Lafayette, Louisiana is no less skilled or professional than those of, perhaps, San Francisco or New York, in an MDL of this nature, the differing local rates that might prevail in San Francisco or New York or in Lafayette, Louisiana should not by themselves determine the rates of counsel from all across the nation who did work for the benefit of cases from across the nation, destined to be resolved in courts across the nation. To use the typical hourly rates charged in the area which happens to be where the selected and

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<sup>76</sup> “In *Vioxx*...the attorneys come from states across the country. Thus a more national rate is the appropriate pole star to guide the Court.” *In re Vioxx Prod. Liab. Litig.*, 760 F. Supp. 2d 640, 660 (E.D. La. 2010).

<sup>77</sup> 28 U.S.C. § 1407.

temporary MDL Court sits – which, again, almost always is not where all of the parties reside, or where the majority of counsel practice, or the proper venue for every member case – such as here, Lafayette, Louisiana, to calculate the lodestar, again, clearly lacks the compelling logic found in a class action and as noted, would result in an arbitrary determination, higher or lower than that which should be proper for compensation, either for the time expended, or for the caliber of work produced. Again, MDLs, by their statutory creation, represent a *temporary*<sup>78</sup> *collective of cases from across the nation*, pursued by a *nationwide collective* of counsel, who engage in a *national practice*, for the common benefit of a *collection of nationwide claimants*. In reality, with an MDL, the “relevant legal community,”<sup>79</sup> is, in fact, as the Honorable Eldon Fallon noted in *In re: Vioxx Prod. Liab. Litig.*, 760 F. Supp. 2d 640, 660 (E.D. La. 2010) that *collective of counsel from the collective of the proper venues* temporarily brought together for pre-trial purposes – here, a *national collective*. Additionally, there is no indication in the MDL statute or the actions of the JPML that either intends or suggests that the choice of which judge, or whatever location might be selected for the MDL, is to determine the attorney rate for common fund recovery evaluation; to the contrary, the statute is silent as to that discrete issue and the JPML criteria for selection of the MDL venue are geared more to the practicality of the court’s capacity and ability and the convenience of those attorneys, witnesses, and parties involved. Therefore, this Court is of the opinion a broader view of what constitutes the “relevant legal community”<sup>80</sup> when dealing with an

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<sup>78</sup> This Court notes that statutorily MDLs are created for pre-trial purposes only, but is fully cognizant the practical reality is that once pre-trial matters are resolved, the path often, is cleared for settlement – however, this occurs by agreement of all parties and is contemplated by the statute by its reference to return “unless previously terminated.”

<sup>79</sup> *In re Enron*, 586 F. Supp. 2d at 754.

<sup>80</sup> *In re Enron*, 586 F. Supp. 2d at 754.

MDL of this size is appropriate to address a lodestar evaluation, rather than the locality found in single class actions.

Additionally, considering the immense expense that must be outlaid to conduct an MDL, tying the evaluation of compensation to the location of the judge and court selected by the Panel, rather than having it reflect the more relevant practical realities and factors of the venue of the cases, recognition of the national nature of the matter, and the unique expertise involved, and costs across the country could, also, result in an egregious over-compensation, or under-compensation, of counsel depending upon the circumstances present. Again, it cannot be overlooked that the selections of the court and judge by the JPML have little, if any, consideration of or relationship to the compensation possible for collective and common benefit work. Therefore, this Court is, again, of the opinion that a broader scope, acknowledging the immense breadth of location and experience represented by plaintiffs' counsel in this case, is required to adequately determine a lodestar for use in addressing the common benefit fee in this case. That, however, is not to say that the location of the presiding court should never have bearing on the calculation or should never be one of several factors considered, particularly in smaller more geographically compact cases. Certainly, this factor should, when relevant, be considered and given weight. This Court can envision circumstances where the location of the MDL Court could, and perhaps should, be given great weight. However, under the facts of this case, this Court remains of the opinion that with the national and international nature of this multidistrict litigation, the locale of the presiding court should not be the determinative factor. Thus, in this matter the Court will follow the lead established by my capable and experienced colleague, the Honorable Eldon Fallon and find, in *this* MDL – the “relevant legal community”<sup>81</sup> is one national in nature, but will, also, be cognizant of

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<sup>81</sup> *In re Enron*, 586 F. Supp. 2d at 754.

and certainly consider those rates selected in similar MDLs in this area when evaluating an applicable lodestar.<sup>82</sup>

### **B. Calculating the Aggregate Fee Award**

In determining *the analysis* to employ in determining fees in those type cases which contemplate “common funds,” the Courts, again, have more often borrowed from class action cases. In the more generalized “common fund” cases, the Fifth Circuit has noted the court has an independent duty to the plaintiffs and to the public to ensure that amounts paid as common benefit are reasonable, as noted in, *In re High Sulfur Content Gasoline Prods. Liab. Lit.*, 517 F.3d 220, 227-28 (5<sup>th</sup> Cir. 2008), a class action case. This Court finds the Fifth Circuit’s instruction in that case equally applicable to MDLs. In all common fund cases, courts have typically used one of two methods for calculating attorneys’ fees: (1) the percentage method, where fees are based on a reasonable percentage of the common fund; or (2) the lodestar method, where fees are computed by multiplying the number of hours reasonably expended on the litigation by a reasonable hourly rate and, in the court’s discretion, applying an upward or downward multiplier. *See Union Asset Mgmt. Holding A.G. v. Dell, Inc.*, 669 F.3d 632, 642-43 (5<sup>th</sup> Cir. 2012). In *Union Asset*, a securities fraud class action, the Fifth Circuit “join[ed] the majority of circuits in allowing our district courts the flexibility to choose between the percentage and lodestar methods in common fund cases, with their analysis under either approach informed by the *Johnson* considerations.” *Id.* at 644.

Virtually all of the recent common fund fee awards by district courts in the Fifth Circuit – whether MDL or class action – have used the percentage method, with an overlay analysis of reasonableness, using the *Johnson* factors. *See In Re: Oil Spill by the Oil Rig “Deepwater Horizon” in the Gulf of Mexico, on Apr. 20, 2010*, No. 2179, 2016 WL 6215974, at \*15 (E.D. La.

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<sup>82</sup> *In re Vioxx Prod. Liab. Litig.*, 760 F. Supp. 2d at 640.

Oct. 25, 2016); *In re FEMA Trailer Formaldehyde Prod. Liab. Litig.*, No. 07-1873, 2013 WL 1867117, \*3 (E.D.La. May 2, 2013); *In re Vioxx Prods. Liab. Litig.*, 760 F.Supp.2d 640, 652 (E.D.La. 2010); *Burford v. Cargill, Inc.*, No. 05-0283, 2012 WL 5471985, \*1 (W.D.La. Nov. 8, 2012); *In re OCA, Inc. Sec. & Derivative Litig.*, No. 05-2165, 2009 WL 512081, at \*19 (E.D.La. Mar. 2, 2009); *In re Enron Corp. Sec., Derivative & ERISA Litig.*, 586 F.Supp.2d 732, 766 778 (S.D.Tex. 2008); *Turner v. Murphy Oil USA, Inc.*, 472 F.Supp.2d 830, 860-81 (E.D.La. 2007). Also finding the noted method of analysis appropriate for this MDL, this Court will determine the valuation of the benefit received by the Settlement claimants, and also, set the benchmark percentage to be applied to the total value of the settlement, following which the Court will test the reasonableness of that percentage by consideration of the *Johnson* factors.

By way of context, in *Johnson v. Ga. Highway Express, Inc.*, plaintiffs had prevailed in a class action asserting violations of Title VII of the Civil Rights Act of 1964, and challenged the adequacy of the District Court's award of attorneys' fees for plaintiff's counsel. After describing factors that must be considered as part of the determination of the reasonableness of any award of attorneys' fees – which factors are listed and discussed below – the Fifth Circuit vacated the District Court's award of attorneys' fees and remanded for reconsideration in light of certain factors. *Johnson v. Georgia Highway Exp., Inc.*, 488 F.2d 714, 720 (5th Cir. 1974). *Johnson* was overruled to a very narrow extent by the United States Supreme Court in *Blanchard v. Bergeron*, 489 U.S. 87, 109 S. Ct. 939, 103 L. Ed. 2d 67 (1989). There, the Supreme Court considered the Fifth Circuit's statement in *Johnson* that, while “whether the fee is fixed or contingent” is one factor to consider when determining whether a fee is reasonable, a litigant should never “be awarded a fee greater than he is contractually bound to pay, if indeed the attorneys have contracted

as to amount.” *Johnson v. Georgia Highway Exp., Inc.*, 488 F.2d at 718.<sup>83</sup> The Supreme Court reversed only that portion of the *Johnson* decision in the context of determining the reasonableness of a fee awarded pursuant to 42 U.S.C. § 1988, stating that in that context “[t]he *Johnson* contingency-fee factor is simply that, a factor,” and “a contingent-fee contract does not impose an automatic ceiling on an award of attorney’s fees.” *Blanchard v. Bergeron*, 489 U.S. 87, 93, 109 S. Ct. 939, 944, 103 L. Ed. 2d 67 (1989). Thus, the list of factors provided in *Johnson*, that must be considered when determining the reasonableness of attorneys’ fees, in a *class action*, were not disturbed. Those factors are: (1) the time and labor required; (2) the novelty and difficulty of the issues; (3) the skill required to perform the legal service adequately; (4) the preclusion of other employment by the attorney because he accepted this case; (5) the customary fee for similar work in the community; (6) whether the fee is fixed or contingent; (7) time limitations imposed by the client or the circumstances; (8) the amount involved and the results obtained; (9) the experience, reputation, and ability of the attorneys; (10) the undesirability of the case; (11) the nature and length of the professional relationship with the client; and (12) awards in similar cases. *Johnson v. Ga. Highway Express, Inc.*, 488 F.2d 714, 717-19 (5<sup>th</sup> Cir. 1974), *overruled on other grounds*, *Blanchard v. Bergeron*, 489 U.S. 87 (1989).

#### IV. REASONABLENESS ANALYSIS

##### A. Valuation of the Benefit Obtained

First, this Court will determine the value of the benefit obtained; to a certain extent this Court addressed that issue above and references and incorporates that discussion herein as well. The Court, also, notes the monetary value of a settlement fund includes all monetary amounts

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<sup>83</sup> As explained, any award of common benefit fees to be awarded pursuant to the MSA in this matter, **are to come from the attorney’s fees already having been agreed to by the attorney and his of her client at the outset.**



actually paid (or irrevocably deposited into a fund for payment) to or for the benefit of plaintiffs pursuant to the terms of the global settlement. *See, e.g., Murphy Oil*, 472 F.Supp.2d at 861; *Vioxx*, 760 F.Supp.2d at 652. Under the terms of the MSA in this matter, in light of the level of participation, this Court finds the total value of the settlement to be \$2.4 billion; and the award given by the jury in the bellwether case, which was awarded by the Court, ultimately, was \$1.5 million in compensatory damages, and \$36.875 million in punitive damages. The awarded \$9 billion in punitive damages having been reduced by this Court to \$36.875 million<sup>84</sup>, over and above the global settlement amount. Undeniably, great financial benefit has been obtained. Additionally, there are other non-monetary benefits which flow from the resolution obtained; those national/global non-monetary benefits were discussed above, and should be incorporated herein, and will, also, to some extent, be further addressed below.

#### **B. Benchmark Percentage**

The next step this Court will address, is to determine the benchmark percentage for the common benefit award. To do this, the Court will first look to awards for common benefit work in comparable cases. This Court finds instructive its fellow courts' suggestions. *See Enron*, 586 F.Supp.2d at 745 n.12; *Murphy Oil*, 472 F.Supp.2d at 862 (“[T]he percentage should not be completely arbitrary, devoid of reality, or inconsistent with the usual fees for the type of case involved. In short, there is no one percentage that should apply to all cases. Each case should be analyzed on its own basis.”). Global recoveries of \$100 million or less are ubiquitous, and the case law readily establishes a customary or benchmark percentage-of-benefit award of 25%. *See Enron*, 586 F.Supp.2d at 745 n.12; *Murphy Oil*, 472 F.Supp.2d at 863-64. However, in the “mega-fund” cases, (recoveries exceeding \$100 million) or “super-mega-fund” cases (recoveries

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<sup>84</sup> *See* Rec. Doc. 729 in civil action 6:12-cv-00064.

exceeding \$1 billion), such as this, whether in class actions or MDLs, there are fewer pure percentage awards to serve as a benchmark; consequently, there is variability in the percentages awarded in these cases. *See In re Prudential Ins. Co.*, 148 F.3d 283, 339 (3<sup>rd</sup> Cir. 1998) (“The district court also examined the fee awards in *class actions* with recoveries exceeding \$100 million and found the fee percentages ranged from 4.1% to 17.92%.”); *In re Diet Drugs Prods. Liability Litig.*, 553 F.Supp.2d 442, 480 (E.D.Pa. 2008) (noting percentages ranging from 4.8% to 15% where the fund exceeded \$1 billion). It, also, appears that as the size of the recovery increases, the percentage tends to decrease. *See Vioxx*, 760 F.Supp.2d at 652. Nevertheless, a review of the relevant jurisprudence indicates awarding courts have rejected a blanket rule that would automatically cap the fee percentage at a low figure even when the total recovery is quite high. *See Enron*, 586 F.Supp.2d at 753. The settlement in this MDL clearly qualifies as a “super-mega-fund” recovery and, thus, the opportunities for comparison are relatively few. Accordingly, it is perhaps more illuminating to consider *the range or average of percentages* in other *super-mega-fund* cases. This Court has reviewed those super mega-fund cases and found that if one averaged the average fee awards, approximately 9.9% of the total settlement value would be that average. However, this Court cautions that **every case** – whether super mega-fund or not, whether a class action or MDL – **is unique and should be treated as such**. Thus, any attempt to discuss a black letter percentage is illusory. Rather, a court such as this one, it would seem, is better served to *be guided* by its independent duty owed to plaintiffs and to the public to ensure amounts paid as common benefit are reasonable,<sup>85</sup> based upon all hard data available, along with the more subjective concerns explored in other similar cases.<sup>86</sup>

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<sup>85</sup> *See In re High Sulfur Content Gasoline Prods. Liab. Lit.*, 517 F.3d 220, 227-28 (5<sup>th</sup> Cir. 2008)

<sup>86</sup> *See In re Enron Corp. Sec., Derivative & ERISA Litig.*, 586 F. Supp. 2d 732 (S.D. Tex. 2008); *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Products Liab. Litig.*, 553 F. Supp. 2d 442

Considering the information uniquely available to this Court, *i.e.*, hard data available from the timekeeping process put in place at the outset, the insight of the Deputy Special Master who was put in place at the outset and reviewed all work done within the context of his review and observation of the trial, and the insight provided by this Court's extensive hands on involvement in this case, and from input from all of the Special Masters, and upon request of plaintiffs' counsel to declare a preliminary amount, this Court previously ordered a preliminary *holdback* of 8.6% of the total settlement value, to be available to fund any possible compensation of the PSC and Participating Counsel for their common benefit services,<sup>87</sup> with full recognition the declared percentage could change once the Court had all of the available data and information available that would exist at the resolution of the case. This preliminary holdback was determined using *an approximation* of the *expected amount and value* of the attorney's fee claims and expense claims, based on those claims for fees and expenses that had been received at that time, as informed by the *Johnson* factors ascertained by this Court's extensive hands on participation. Again, this Court

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(E.D.Pa. 2008); *In re WorldCom, Inc. Sec. Litig.*, 388 F. Supp. 2d 319 (S.D.N.Y. 2005); *In re Payment Card Interchange Fee & Merch. Disc. Antitrust Litig.*, 991 F. Supp. 2d 437 (E.D.N.Y. 2014); *In re Visa Check/Mastermoney Antitrust Litig.*, 297 F. Supp. 2d 503 (E.D.N.Y. 2003); *In re Tyco Int'l, Ltd. Multidistrict Litig.*, 535 F. Supp. 2d 249 (D.N.H. 2007); *In re Cendant Corp. Litig.*, 243 F. Supp. 2d 166 (D.N.J. 2003); *In re AOL Time Warner, Inc. Sec.*, 2006 WL 3057232 (S.D.N.Y. Oct. 25, 2006); *In re Bank of America Corp. Sec., Derivative, and ERISA Litig.*, No. 09-md-2058 (S.D.N.Y., Apr. 8, 2013); *Shaw v. Toshiba Am. Info. Sys., Inc.*, 91 F. Supp. 2d 942 (E.D. Tex. 2000); *In re Toyota Motor. Corp. Unintended Acceleration Marketing, Sales Practices, and Products Liab. Litig.*, No. 10-ml-2151 (C.D. Cal., June 17, 2013); *In re Prudential Ins. Co. of Am. Sales Practice Litig.*, 106 F. Supp. 2d 721, 736 (D.N.J. 2000); *In re Black Farmers Discrimination Litig.*, 953 F. Supp. 2d 82 (D.D.C. 2013); *DeLoach v. Phillip Morris Cos.*, 2003 WL 23094907 (M.D.N.C. Dec. 19, 2003); *In re TFT-LCD (Flat Panel) Antitrust Litig.*, 2013 WL 1365900 (N.D. Cal. Apr. 3, 2013); *In re Nortel Networks Corp. Sec. Litig.*, No. 01-cv-1855 (S.D.N.Y., Jan. 29, 2007); *In re Nortel Networks Corp. Sec. Litig.*, No. 04-cv-2115 (S.D.N.Y., Dec. 26, 2006); *In re Royal Ahold N.V. Sec. & ERISA Litig.*, 461 F. Supp. 2d 383 (D. Md. 2006); *Allapattah Servs., Inc. v. Exxon Corp.*, 454 F. Supp. 2d 1185 (S.D. Fla. 2006); *In re NASDAQ Mkt.-Makers Antitrust Litig.*, 187 F.R.D. 465, 489 (S.D.N.Y. 1998); *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig.*, 268 F. Supp. 2d 907, 939 (N.D. Ohio 2003).

<sup>87</sup> Rec. Doc. 5850.

now has available more complete information and the experience of presiding over a trial and all pretrial matters, and now considering the additional information available to the Court provided by the Deputy Special Master, the recent settlement, and being informed as to other “super-mega-fund” cases now being available, and, in particular, now having benefit of Deputy Special Master DeJean’s Report and Recommendation, as well as benefit of the value of a global resolution and the value of counsels’ full participation in this matter, and for the full reasons noted above and incorporated by reference here, as well as those reasons to follow, this Court finds the 8.6% – the percentage established by this Court in its Holdback Order – is reasonable and, also, in line with the common benefit award percentages in other super-mega-fund cases and likely a proper starting point for this Court’s analysis.

**C. *Johnson* Factors**

However, a finding of reasonableness does not, in and of itself, necessarily, end the inquiry or the analysis. The relevant jurisprudence instructs the Court’s analysis should, also, be informed by the *Johnson* factors. Therefore, the Court will now consider the *Johnson* factors in order to address the reasonableness of the percentage. The Fifth Circuit advises that it does “not require the trial court’s findings to be so excruciatingly explicit in this area of minutiae that decisions of fee awards consume more paper than did the cases from which they arose.” *In re High Sulfur Content Gasoline Prods. Liab. Litig.*, 517 F.3d 220, 228-29 (5<sup>th</sup> Cir. 2008). The Court is mindful of this instruction and will reflect that instruction in its review, but, also, is mindful of its obligation to protect the plaintiffs and the public in any award made and the need for full and complete transparency in the area of such great possible contention.

To begin, as part of the reasonableness analysis, *Johnson* suggests consideration of a lodestar amount. As noted above, this Court is mindful of the instruction provided by the jurisprudence, but, also, notes that uniquely, this Court has benefit of an objective history and

actual accounting and review of the actual work performed by all counsel or their firms, the location and the nature of the work performed, and the impact or value of that work in this case, that might not have been available in other MDLs or class actions. The Deputy Special Master reports that Participating Counsel have submitted approved claims for more than 200,000 hours of common benefit work on behalf of the respective firms. The audited number of hours each firm has submitted is found in the incorporated Deputy Special Masters' Report and Recommendation and this Court accepts and adopts the Deputy Special Master's recommendation as to the number and nature of compensable hours expended.

Courts with MDLs of similar size *within this area* and the recent past have used \$450 as an appropriate average/blended hourly rate for work performed. *See Enron*, 586 F.Supp.2d at 779-80 (a class action, approving an average/blended rate of \$456 in 2008); *Vioxx*, 760 F.Supp.2d at 660 (an MDL, approving an average/blended rate of \$443.29 in 2010); *Deepwater Horizon*, 2016 WL at \*19 (an MDL, approving an average/blended hourly rate of \$450 in 2016).<sup>88</sup> Again, the rate reflective of the area where the presiding Court sits, although certainly informative, should not, in a case such as this one, necessarily be wholly determinative. However, neither is it always irrelevant to the inquiry, thus, this Court notes those rates as reflective of the locales and times involved, and includes them as a factor to be considered when evaluating the reasonableness of the amount assessed to compensate common benefit fees.

Again, this Court notes the potential rate as discussed above is only one factor to be considered for the purpose of evaluating the reasonableness of the total amount to be withheld in

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<sup>88</sup> The Court, for instance, notes that a reasonable hourly rate of approximately \$450 has been referenced in previous Fifth Circuit cases but has not necessarily been adjusted over time. *See, e.g., In re Enron* (in which proceedings began in 2001, at the latest); *Vioxx*, (in which the earliest state proceedings began in 2002, and an MDL was created in 2005); *Deepwater Horizon* (initiated following an oil spill that occurred in 2010).

order to compensate common benefit fees. *The jurisprudence suggests that the average rate is not necessarily reflective of the rate ultimately used to calculate any firm's award, rather it is used as an additional evaluation of the reasonableness of a total common benefit fee award.* This Court notes, as did the Common Benefit Fee and Cost Committee in *In re: Oil Spill by the Oil Rig "Deepwater Horizon" in the Gulf of Mexico, on April 20, 2010*, that many Participating Counsel in personal injury cases, typically work on contingency basis, and therefore, as a practical reality, do not have established hourly rates.<sup>89</sup> Therefore, an hourly rate should only be considered one factor among several when determining the reasonableness of a fee award, rather than determinative of the hourly rate awarded to any individual attorney.

Furthermore, this Court has the unique advantage of having hard data, generated throughout the litigation, as to the number of hours worked by counsel, as discussed above, to consider as to a reasonable rate; however, the raw data of hours actually worked is, also, merely a starting point for a meaningful evaluation. Neither an hourly rate nor the number of hours expended by a firm for the common benefit necessarily reflects *the value of or the quality of the work performed, nor the benefit obtained* from that work; other "intangible" factors (*e.g.*, the import of the work to the outcome of the MDL or to the negotiation of the MSA, the expertise in a certain field) might have greatly affected the benefit generated. Consequently, the Court will briefly evaluate the work done in light of the *Johnson* factors in light of the analysis suggested by applicable jurisprudence.<sup>90</sup>

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<sup>89</sup> Fee and Cost Committee Recommendation for Proposed Cost Reimbursement and Fee Allocation, 2:10-md-02179-CJB-JCW, Rec. Doc. 22628, 5 n. 11 (E.D. La. April 11, 2017).

<sup>90</sup> This Court is not unaware that certain pending cases have not participated in the Settlement Program, and that those matters will ultimately be resolved separately. Consequently, this Court finds the common benefit discussion in this ruling would not necessarily be entirely reflective of those remaining matters, nor will work done for the benefit of those remaining matters be attributable to those cases which have participated in this Settlement Program. Consequently, this ruling addresses the common benefit for

First, again it should be noted, full discussion of the history and nature of this case has been laid out above and acts also, to inform this analysis, but for purposes of brevity will not be repeated below, rather will be incorporated by this internal reference.

1. Novelty and Difficulty of the Issues (Factor 2); The Skill Required to Perform the Legal Service Adequately (Factor 3); and The Experience, Reputation, and Ability of the Attorneys (Factor 9)

In this case, the plaintiffs sought to prove a novel, scientifically obtuse, and extremely document intensive and difficult case founded on a not before legally established link between a drug, Actos<sup>®</sup> and a certain type of bladder cancer. In so doing, the PSC was required to develop a sophisticated expertise in medical science, the scientific method, an encyclopedic knowledge of vast scientific and medical publications; an understanding and historical knowledge and understanding of broad regulatory action(s) nationally and in the European Union; while also, engaging superb organizational and administrative skill by mastering enormous amounts of technical and regulatory knowledge in order to be able to pull together, into a coherent and meaningful whole, all the information available, while meeting a vigorous, well-funded defense mounted by large corporate defendants with able and aggressive attorneys. This task, while daunting in its own right, was made more difficult by the novelty of the science, the difficulty inherent in proving up cutting edge science and the optimistic time frame imposed by the Court. All these factors argue the 8.6% is reasonable.

The *Johnson* court indicated that, in order to evaluate the skill required to perform the legal service properly, the trial judge should closely observe the attorney's work product, his or her preparation, and general ability before the court. The trial judge's expertise gained from past

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only those cases which participated in the present Settlement Program – any remaining matters will be addressed in a separate and independent process, and the court will address any possible common benefit issues among those remaining cases separately and apart from this ruling.

experience as a lawyer and his or her observation from the bench of the lawyers at work become(s) highly important in this consideration. This Court was hands-on on a daily basis throughout the case's progression, and presided over the extensive trial preparation and ten week trial of the bellwether trial and, therefore, has been able to observe the legal skill displayed and expertise required to develop and present to a lay jury both the facts and the law in these proceedings, particularly necessary while contending with an often equally motivated set of counsel for the defense mounting an equally vigorous defense. This Court found plaintiffs' counsels' skill and expertise displayed to have been superb in all respects. The PSC, Participating Counsel, co-lead counsel, liaison counsel, trial counsel, and the trial team performed exceptionally, and at the highest level, and the work performed throughout the litigation, *i.e.*, in discovery, in written submissions, trial preparation, trial performance, and settlement negotiations and in the creation of the MSA and implementations of the settlement process, was of equal excellence. The attorneys involved were highly experienced, displayed a broad panoply of unique expertise, and performed at the top of their profession. Their tireless efforts and the quality of their work was readily apparent to the Court. The experience, expertise, skill, ability and reputations of the PSC, co-lead counsel, liaison counsel, and trial counsel are reflective of their mastering of a specialized area of practice, national both in scope and level of performance. These factors, also, support a finding the 8.6% is reasonable.

2. Time and Labor Required (Factor 1); Preclusion of Other Employment (Factor 4); Time Limitations Imposed by the Client or the Circumstances (Factor 7)

As indicated by my able colleague, “[C]ollectively, these three factors require the Court to give appropriate credit to the intensive and sustained efforts of Participating Counsel to bring this litigation to a timely resolution.” *Vioxx*, 760 F.Supp.2d at 656. The “time and labor required” factor not only helps the Court to evaluate the work done, but also, serves the injured claimants



and, also, can help guard against spurious claims and counsel rushing cases to settlement to obtain a fee that might not reflect the actual work done.

Criticism, perhaps not unjustified, of the overall MDL process has been found within the attorneys' belief they would lose control of the destiny of their cases, if a part of an MDL process, and that the MDL process would take too long to complete. With mindfulness of these criticisms, this Court, as explained above, at the outset, offered counsel the opportunity to be active participants in molding the litigation process from a "bottom up" and not a "top down" basis – an opportunity they readily embraced – and the Court, also, established the goal of four year completion – a goal counsel, perhaps, less enthusiastically than the former, embraced. Nonetheless, counsel rose to the challenge and the occasion and diligently worked toward both goals with true commitment and with significant demonstrable success. Therefore, from the outset, the goals of handling this MDL from a "bottom up" and counsel hands on perspective and of completing this MDL in four years were embraced, implemented, and ultimately substantially reached by counsel. From the initial status conference until announcement of the settlement, at each meeting between the Court and various counsel, counsel were reminded the goal remained to conclude this MDL within four years. The importance of this four-year timeframe and hands on approach by counsel was reflected in every case management order negotiated by the parties and submitted to the Court, and in the challenging pace at which counsel worked. The practical impact of the ambitious timeframe and the hands-on involvement of counsel, became the practical reality. In order to meet those dual goals, the PSC, co-lead counsel, liaison counsel, and Participating Counsel dedicated the bulk of their and their firm's time and resources to this MDL, often effectively limiting their ability to participate in other MDLs in any leadership capacity, if at all; and with several counsel having to limit their and their firm's ability to accept other work,

especially larger cases of any nature. Thus, select members of the PSC, in particular, often found themselves and their firms severely limited in their ability to accept other employment for much, if not all, of their time within this MDL, and thus, also, as a practical reality limited their and their firms' income during that period, all the while having to incur time and expense within the MDL, placing not only time, but also, real financial constraints upon them and their firms.

The PSC have performed an immense amount of work in this MDL. The PSC and Participating Counsel's firms expended over 200,000 hours of approved common benefit work; counsel took approximately 130 depositions and analyzed more than 32 *million pages* of documents; furthermore, the PSC mounted a complete, ten-week bellwether trial against a vigorous defense that required nearly 24 hour and 7 days a week involvement for over 10 weeks focus and work. The involved lawyers spent days, weeks, and months away from their practices, their homes, and their families over the course of this case at no small expense and sacrifice. Throughout the litigation, the PSC performed with an extremely high level of expertise, collaboration, and agreement, often unique in large multi-counsel matters, which benefitted not only the plaintiffs in the MDL, but all plaintiffs across the country, as evidenced by the success of the Global Settlement Program.

Furthermore, the Settlement, Settlement Process, and written MSA, which were devised, negotiated, and implemented by certain of the PSC leadership and defendants' settlement counsel, required an unprecedented level of expertise, experience, skill, effort and talent to negotiate, create and implement. The issues involved included a comprehensive and complex set of claimants, circumstance, and legal issues. The MSA is a comprehensive and complex document that was so well conceived and constructed almost all of the Actos<sup>®</sup> cases filed *in the United States* in both state and federal courts, have voluntarily joined in the process created therein. Historically, and

regrettably often, after the settlement is negotiated, the PSC feels itself largely discharged of their responsibilities. Here, however, the co-leads and certain PSC members have continued to devote much time and effort implementing the settlement and settlement process, working with the Claims Administrator, program vendors, defendants' settlement counsel, and the Court on administrative and interpretive implementation issues – no small matter in a nationwide global settlement such as this and their commitment is reflected in the success of the program created.

Therefore, this Court finds the PSC have expended an incredible amount of time, effort, and expense and have reflected clear expertise in their leadership and representation. The PSC have responded to motions, injunctions, prepared for and engaged in a ten week trial, and met an equally aggressive defense team. The PSC, also, have responded to an initial appeal filed by Takeda, and implemented a nationwide settlement process, all of which could not have been contemplated by this Court at the time the initial holdback was created. The results obtained, and the PSC's involvement, leadership, and participation since that initial holdback only serve to further validate the reasonableness of the percentage ordered withheld, and all support and further validate the reasonableness of the 8.6 percentage.

3. The Amount Involved and the Results Obtained (Factor 8)

The Supreme Court, the Fifth Circuit, and the district courts addressing this matter have held that the most critical factor in determining the reasonableness of a fee award is the “degree of the success obtained.” *Enron Corp.*, 586 F.Supp.2d at 796-97 (citing *Farrar v. Hobby*, 506 U.S. 103 (1992); *Migis v. Pearle Vision, Inc.*, 135 F.3d 1041, 1047 (5<sup>th</sup> Cir. 1998)). Success, however, is determined not only by the gross amount of the recovery, but also, by the number of individuals who benefit from the settlement, the degree to which it provides them with full compensation for their injuries, and the extent to which the settlement benefits the public at large. As noted in *Vioxx*,

760 F.Supp.2d at 657-68; *Murphy Oil*, 472 F.Supp.2d at 866; *In re Diet Drugs*, 553 F.Supp.2d 442, 472-73 (E.D.Pa. 2008).

In this matter, the parties chose to participate in a bellwether process; one bellwether case was ultimately selected and tried to completion. That case originated in New York; was tried pursuant to New York substantive law; the claimants resided in New York; the actual trial involved counsel from across the nation. The jury verdict included both substantial general damages of \$1.5 million and a substantial punitive damage award of \$9 billion (ultimately reduced by this Court to \$36.875 million). While this Court did reduce the punitive damages award, the award, nonetheless, remains substantial. The substantial recovery obtained in the bellwether case may be assumed to have prompted or at least influenced the parties to negotiate the agreed to collective settlement totaling \$2.4 billion; a sum sufficiently large to provide an adequate pool for recovery for all individual claimants, and an amount sufficient that close to one hundred percent of the plaintiffs, *throughout the entire United States* in state courts as well as the MDL, who were eligible to participate in the settlement program, have voluntarily chosen to join the settlement process. As of this writing, approximately 11,000 claimants, across the United States, are participating in the Settlement Program, and, thus, approximately 11,000 claimants from around the nation are participating in a settlement valued at \$2.4 billion, and thus, have benefitted from the work done by the PSC and Participating Counsel. This factor supports a finding the 8.6% is reasonable.

4. Nature and Length of the Professional Relationship with the Client (Factor 11)

The professional relationship between the PSC and Participating Counsel, and the individual MDL plaintiffs, generally did not antedate the litigation, nor will it likely continue beyond the closure of this MDL. However, in this MDL setting, the PSC, through its leadership, contemporaneous communication, and consistent work to keep all individual claimant's counsel

fully informed, provided great benefit to all of the claimants involved in the MDL, if reflected nowhere else than in the almost 100% voluntary participation in the Settlement Process. To the extent one could argue the plethora of individual attorneys around the country and, thus, their clients, were served by the PSC, the PSC did an exemplary job of developing, maintaining, and supporting their relationship with those counsel and of providing the information necessary for those individual attorneys to develop, maintain, and support their relationship with their respective individual clients. In its purest form, the Court finds that the “nature and length of the professional relationship” as to the Participating Counsel and the PSC might have little impact here; however, it should not be overlooked that the PSC was instrumental in keeping all plaintiffs’ counsel, nationwide, informed, contemporaneously, as to the progress of the MDL so that those attorneys could tend to, not only, their ethical responsibilities, but also, their attorney/client relationships. Without the constant and transparent flow of information, individual claimant counsel could not have maintained and fostered a meaningful, professional relationship with their clients. Additionally, worthy of mention was the attorney client relationship reflected in the bellwether case *Allen, et al. v. Takeda Pharmaceuticals North America Inc., et al.*; counsel representing the Allens, clearly, had fostered a strong and meaningful professional relationship with the entire Allen family – a relationship that was reflected in the tenor of the interaction between and among the family and counsel during the trial, and given the trial’s result, clearly this close client relationship benefited all. Therefore, this Court finds this factor to be less of a factor within this MDL setting, but, nonetheless, one worthy of mention. *See Murphy Oil*, 472 F.Supp.2d at 866-67 (finding that the “nature and length of the professional relationship with the client” factor did not warrant an increase in the benchmark percentage because class counsel and the class members did not have a professional relationship before the litigation commenced, and were unlikely to continue to have

one after the litigation was complete). This factor, however, is of mention to support the reasonableness of the 8.6%.

5. The Customary Fee for Similar Work in the Community (Factor 5), Whether the Fee is Fixed or Contingent (Factor 6), Awards in Similar Cases (Factor 12)

These factors were largely covered in this Court's discussion of the benchmark percentage and possible lodestar. *See* Part IV.B, *supra*, and this Court adopts and incorporates that discussion herein. However, this Court, also, notes plaintiffs' counsel worked on contingency in this MDL, as is the case in nearly every MDL involving personal injury claims. Each of the Participating Counsel who was appointed to the PSC undertook his or her task(s) (along with their financial commitment to fund the substantial expenses in these proceedings) based upon an initial contingency contract with their individual clients with little, if any, guarantee of success or return on their investment. Large MDLs such as this one are expensive to mount, sustain, and bring to conclusion, and require a continuous influx of capital. The PSC invested, collectively, millions of dollars, and more than 200,000 hours' work was performed not only by counsel themselves, but not reflected in this number is the time and work performed by support staff who must be paid by the firm each pay period, with no assurance the named attorney or firm would receive any remuneration whatsoever, and with no assurance the expenses they, also, incurred would be, in any way, reimbursed. In light of the significant medical and scientific questions inherent in this case, the risk taken was great and the contingent nature of their recovery uncertain. The initial contingency contract is a matter of contract as between counsel and the parties and remains in place and it is of note, that it is from this contingency fee the common benefit fees will be taken. Also, as to *allocation of the common benefit recovery* among the Participating Counsel and the PSC, the Court is informed as to each attorney/firm's attorneys' *actual work performed, its nature, the amount of hours expended, and that work's value*. In this case, the protocol established by the

Court for regular submission of time and expenses allows this Court to have available a more objective set of data to inform its analysis of the risks taken than that offered by a purely contingent fee protocol. Furthermore, this Court's extensive, daily, and hands-on involvement, as well as having presided over the bellwether trial, along with extensive input from the Special Masters and Magistrate Judge Hanna, grant this Court a unique vantage point for determining the value of the work performed and the value received by all.

Again, it bears repeating that any award of common benefit fees *will come from the original attorney fee contract amount or percentage, agreed to by the attorney and client within their original contract of employment*, and will therefore, act to reduce the amount received by the original contracting attorney *and not the claimant*, as those attorneys have benefited from the work provided by the PSC and Participating Counsel required to reach the favorable resolution, and thus, was done for the benefit of all claimants.

The factors of the customary fee for similar work in the community has been fully discussed above and will not be repeated here, but that discussion is incorporated herein. Equally so, the factor of awards in similar cases has been fully discussed above and will not be repeated here, but is incorporated herein.

6. The Undesirability of the Case (Factor 10).

The courts have noted that in certain types of cases the attorney faces hardships in his or her communities because of his or her desire to help the litigant. For instance, oftentimes the decision to help eradicate discrimination in civil rights cases has not and is not pleasantly received by the community. This can have an economic impact on the attorney's practice which, also, can be considered by the Court.<sup>91</sup> Other factors can, also, argue that a case might be deemed

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<sup>91</sup> *Johnson v. Georgia Highway Express, Inc.*, 488 F.2d 714, 719 (1974).

“undesirable.” For instance, “[c]ases may be deemed ‘undesirable’ when ‘the defendant is a large corporation with substantial resources, financial and otherwise, for a vigorous defense; and the legal and factual issues presented risks to recover absent settlement.’”<sup>92</sup>

Here, the defendants are without question large multinational corporations with substantial resources, financial and otherwise, who mounted an exceedingly vigorous and aggressive defense. The science involved was cutting edge and proof of the plaintiff’s scientific and medical theories was in no way certain. Discovery with non-domestic corporations can present its own unique practical and procedural challenges; Takeda’s parent company is a Japanese corporation and much of the development, also, took place in the European Union. Both defendants, Takeda and Eli Lilly, mounted a very aggressive and at times, perhaps, difficult resistance to discovery. To successfully mount a prosecution of the plaintiff’s claims under these circumstances, was not a given, and required great time and expense and involved substantial risk. Thus, this Court finds this factor weighs in favor of finding the 8.6% reasonable.

7. Conclusion: Johnson Factors

Taken together, the *Johnson* factors indicate the amount determined to be set aside to compensate attorneys for work done for the common benefit of all is reasonable; in fact, the percentage is, arguably, well within the reasonable range that could have been awarded in similar super mega-sized cases. Thus, this Court finds a common benefit fee award of 8.6% of the settlement amount is reasonably supported.

As a final step in the cross-check process, some cases suggest the Court perform a comparison between the reasonable percentage and the reasonable lodestar amount. *See, e.g.*,

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<sup>92</sup> *The City of Omaha Police & Fire Retirement Systems v. LHC Group*, 2015 WL 965696, \*8 (W.D.LA. 2015).



*Deepwater Horizon*, 2016 WL at \*20 (E.D. La. Oct. 25, 2016) (citing *Vioxx*, 760 F. Supp. 2d. at 661). This Court has given full discussion of the lodestar considerations above, and incorporates that discussion herein. This Court's process has identified the numbers of hours expended – to date – as over 200,000 approved hours. A review of a possible reasonable lodestar, when viewed on a national level, and applied to the number of hours of work performed, also, argues the percentage selected – for all the reasons noted above and incorporated herein – is reasonable.

#### V. ALLOCATION OF COMMON BENEFIT FEES AND EXPENSES

This Court looked to the *Johnson* factors to evaluate the reasonableness of the overall amount to be awarded as to all claims for common benefit work and found the percentage award reasonable. Because of the somewhat unique protocol instituted at the outset to approve and track work done for the benefit of all on an ongoing basis, and this Court's hands on involvement, as well as Deputy Special Master DeJean's involvement, this Court has, perhaps, a unique opportunity to engage in a more objective and refined analysis of the allocation *among the involved counsel* and therefore, this Court finds certain of the *Johnson* factors, perhaps, may continue to enlighten.

Historically, courts in MDLs have utilized a Plaintiff's Fee Committee to provide portions, if not all, of the information to be considered and to provide the recommendations to be used by the Court to make individual allotments – a method which, at times, has presented certain challenges, become contentious, and significantly extended the life of the MDL. As noted, in this MDL prior approval for, and identification of the nature of, all common benefit work was required; such work needed to be submitted and reviewed on an ongoing basis; all expenses and time were subject to review by the PEC and Deputy Special Master DeJean, performed regularly as the litigation progressed; thus, perhaps, a more objective basis for this Court's review exists when

considering allocation of common benefits among Participating Counsel and the PSC. This Court, also, has benefited from the Deputy Special Master's institutional memory obtained from his review of all work done, and by the Court ordered interview process in which he engaged, as well as Special Master Russo's input and this Court's hands on experience with the MDL and the *Allen* trial.

This Court tasked Deputy Special Master DeJean with providing the court with a review and Report and Recommendation as to allocation among Participating Counsel and the PSC of the common benefit amount awarded, and suggested certain *Johnson* factors, where applicable, might provide some insight when evaluating an attorney's participation *within the confines of the collective amount awarded and available (and only if relevant and applicable)*. In other words, when making allocation to specific attorneys/firms, *within the amount available*, the Court suggested the *Johnson* factors, only where relevant and appropriate, might be enlightening. Consequently, this Court instructed Deputy Special Master DeJean to "amass and gather the facts and information necessary for this Court's analysis, decision, and ruling on the question of whether a common benefit assessment should be made in this case and allocation therein."<sup>93</sup>

This Court has fully reviewed and evaluated Deputy Special Master DeJean's Report and Recommendation, which is based on his ongoing review of submitted hours and expenses, his observations of Participating Counsel in this MDL and the diverse kinds of benefits obtained by their work, and his interviews of those Participating Counsel who wished to be heard. The Court notes however, that it has not reviewed, nor has it requested access to, any raw data underlying as to the hours and expenses reflected in the Report and Recommendation, but relies only on the aggregated summaries as made a part of Deputy Special Master DeJean's Report and Recommendation.

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<sup>93</sup> Rec. Doc. 5801.

As this Court is in the unique position of, also, having followed the work done by Participating Counsel and by the PSC, by, *e.g.*, having had hands-on involvement from the beginning, having heard a bellwether trial, resolved numerous motions, held weekly meetings with the Special Masters, held monthly meetings with lead counsel for all parties, and maintained an ongoing discourse with Magistrate Judge Hanna, as to those areas of his involvement. Therefore, in keeping with this Court's orders and with the procedure established at the beginning of this MDL for the purpose of tracking the common benefit fees and expenses incurred, Deputy Special Master DeJean has reviewed all submitted common benefit hours and expenses on an ongoing basis, and has conducted interviews with all Participating Counsel who wished to give them. This Court has, separately, also, been in a position to evaluate the type and quality of common benefit work performed, and Deputy Special Master DeJean has conferred with Special Master Russo, who along with Magistrate Judge Hanna was tasked with overseeing the settlement process, and therefore who had the ability to evaluate some common benefit work performed outside this Court's direct supervision. It is of note Magistrate Judge Hanna, nor Special Master Russo, has reviewed any possible raw data as to the hours performed by Participating Counsel. Finally, this Court has conferred separately with Magistrate Judge Hanna, who has been involved with the noted nuanced aspects of this complex litigation. This Court has compared the contents of Deputy Special Master DeJean's Report and Recommendation to its own observations and knowledge of this MDL and finds them to be harmonious, and hereby adopts and incorporates Deputy Special Master DeJean's Report and Recommendation as to the allocation of common benefit fees among individual firms. It is of note, Deputy Special Master DeJean's recommendation was in harmony with the Court's evaluation – an occurrence which might not be unexpected as we each were actively involved in evaluation and observation, albeit from differing vantage points and

perspectives. Finally, as noted above and as found in Deputy Special Master DeJean's Report and Recommendation, the aggregate numbers of approved hours listed by Deputy Special Master DeJean reflect contributions by various levels of counsel and/or staff within the noted firms. For the reasons given in the Factual and Procedural Background (Sec. I, *supra*), and as supplemented by the information given below, this Court makes the following fee awards:

1. Aylstock, Witkin, Kreis & Overholtz, PLLC (PSC) (Neil Overholtz)

As Deputy Special Master DeJean notes, Mr. Overholtz is a member of the law firm of Aylstock, Witkin, Kreis & Overholtz, PLLC. Mr. Overholtz was appointed to the PSC by the Court. Although Mr. Overholtz did not initially start out in a leadership role with the PSC, his work dedication provided great support skills and eventually he evolved into more of a leadership role. Deputy Special Master DeJean notes that "[a]lthough Mr. Overholtz began his service on the PSC in a support role, he ultimately became a valued member of the PSC leadership. He participated in almost every aspect of the case beginning prior to the formation of the MDL through settlement and implementation of the settlement process. He is unequivocally one of the major contributors to the success of the MDL. He was instrumental in setting up predictive coding, the predictive coding process, assisting experts in preparing their reports, document review and prepared for and took depositions of both lay and expert witnesses. He maintained an active role in the MDL from its inception and maintained that role through the settlement and disbursement process and continues in that role today.

Mr. Overholtz, although not in a leadership position, worked tirelessly on Actos matters and had many attorneys and staff from his firm devote numerous

hours for the various tasks he was assigned and undertook. He was present for almost the entire trial. Mr. Overholtz and his firm paid all assessments.

Mr. Overholtz and his firm accumulated 18,767.65 hours of audited Common Benefit time. Mr. Overholtz accumulated \$1,177,326.60 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$16,130,795.18 for Common Benefit fees and \$1,177,326.60 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

2. Andrews Thornton Higgins Razamara LLP (Non PSC) (Anne Andrews)

As Deputy Special Master DeJean notes, “Ms. Andrews is not a member of the PSC. Ms. Andrews did qualify as ‘participating counsel’ and was thus authorized to perform certain Common Benefit work and incur Common Benefit expenses. She is a member of the firm, Andrews Thornton and performed work on various projects as directed by the PSC.

Ms. Andrews elected to waive her appearance at the interview process and elected to rely solely upon the firm hours submitted for Common Benefit fees and her submissions for expenses.

All assignments given to the firm were performed in a timely manner by either Ms. Andrews or a junior associate, Lauren Davis.

Ms. Andrews and her firm accumulated 244.58 hours of audited Common Benefit time. Ms. Andrews accumulated \$0.00 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean's recommendation, and awards \$93,551.85 for Common Benefit fees.

3. Andrus Wagstaff, PC (PSC) (Vance Andrus)

As Deputy Special Master DeJean notes, "Mr. Andrus is a partner in Andrus, Hood and Wagstaff, PC. He is a member of the PSC and was involved in the MDL even prior to his appointment to the PSC. Mr. Andrus received various assignments, which included document review, legal research, opinions on discovery practices and procedures and suggestions as to experts and trial procedure as requested by co-leads or the PEC.

Mr. Andrus elected not to participate in the interview process regarding Common Benefit time and expense. All assignments given to Mr. Andrus were performed in a timely and exemplary manner reflecting his high degree of skill and expertise in complex litigation. Mr. Andrus and his firm paid all assessments.

Mr. Andrus and his firm accumulated 1,024.90 hours of audited Common Benefit time. Mr. Andrus accumulated \$588,880.27 in Common Benefit audited expenses."

This Court hereby adopts Deputy Special Master DeJean's recommendation, and awards \$479,653.20 for Common Benefit fees and \$588,880.27 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

4. Barrios Kingsdorf & Casteix, LLP (PSC and State Court Liaison) (Dawn Barrios)

As Deputy Special Master DeJean notes, "Ms. Barrios is a partner in the law firm of Barrios, Kingsdorf and Casteix, LLP. She was appointed as a member

of the Actos PSC. Additionally, the Court appointed Ms. Barrios to the Executive Committee and also appointed her as State and Federal Court Liaison for the plaintiffs.

Ms. Barrios maintained exceptional contact and communication with her defense counterpart, Sherry Knutson and State and Federal Judges as directed by the court. Additionally, Ms. Barrios participated in the Bellweather vetting interviews and coordinated well with state court counsel who had potential Bellweather cases. Likewise, as State and Federal Court Liaison, Ms. Barrios coordinated Sherry Knutson on behalf of the defendants concerning all new state court cases, the status of state court trials and corresponded appropriately with State and Federal Judges as directed by Judge Rebecca F. Doherty regarding events taking place on their respective Actos dockets.

All assignments given to Ms. Barrios were performed in a timely and exemplary manner reflecting her high degree of skill and expertise in complex litigation, especially in the management of the difficult State/Federal relationships that are ever present in complex litigation.

Ms. Barrios and her firm accumulated 1,937.70 hours of audited Common Benefit time. Ms. Barrios accumulated \$423,498.90 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$985,320.45 for Common Benefit fees and \$423,498.90 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

5. Baum Hedlund Aristei Goldman, PC (Non PSC) (Michael Baum)

As Deputy Special Master DeJean notes, “Mr. Baum is a partner in the firm of Baum Hedlund. He was not on the PSC, but did qualify as “participating counsel” and performed all assignments from the PSC. Additionally, Mr. Baum represented Dr. Helen Gee, a one-time potential key witness and whistleblower plaintiff regarding Actos. Mr. Baum acted as liaison between the PSC and Dr. Gee and maintained coordination with the PSC regarding her deposition testimony. Mr. Baum participated in document review at the direction of the PSC.

Mr. Baum and his firm accumulated 2,953.55 hours of audited Common Benefit time. Mr. Baum accumulated \$27,560.14 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$797,458.50 for Common Benefit fees and \$27,560.14 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

6. Beasley Allen Law Firm (PSC) (Andy Birchfield)

As Deputy Special Master DeJean notes, “Mr. Birchfield is a member of the PSC. He is a partner in the firm of Beasley Allen. Mr. Birchfield performed Common Benefit work on projects as directed by the PSC and in fact took a lead role in deposition preparation, taking depositions, the predictive coding process, discovery and motion practice. He was heavily involved in settlement negotiations and in fact his involvement was critical in settling the case and developing the settlement matrix used with the Actos defendants. Subsequent to settlement, Mr.



Birchfield remained active in the settlement process through disbursement. He was a great credit to the overall success of the settlement program and its implementation through BrownGreer and/or Garretson Resolution Group. All assignments given to Mr. Birchfield were performed in a timely and exemplary manner reflecting his high degree of skill and expertise in complex litigation. Mr. Birchfield and his firm paid all assessments.

Mr. Birchfield and his firm accumulated 8,398.45 hours of audited Common Benefit time. Mr. Birchfield accumulated \$681,099.90 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$5,668,953.75 for Common Benefit fees and \$681,099.90 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

7. Climaco, Wilcox, Peca & Garofoli Co., LPA (Dawn Chmielewski – Former PSC member from Climaco Law Firm)

As Deputy Special Master DeJean notes, “Ms. Chmielewski was appointed to the PSC while a member of the Climaco Law Firm. During her time on the PSC, she received many assignments which were all performed in an exemplary manner. She was involved in document review, predictive coding, various research and writing projects and was a valuable asset to the PSC through her work efforts. She eventually began employment with Noblett, Beard and Arsenault and withdrew from the PSC. Her Common Benefit time thereafter was submitted through Neblett, Beard and Arsenault. Her Common Benefit Time in this award only

reflects those hours while she was a member of what was previously known as the Climaco Law Firm.

Ms. Chmielewski and the Climaco Law Firm accumulated 1,862.10 hours of audited Common Benefit time. Ms. Chmielewski and the Climaco Law Firm accumulated \$25,669.43 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$628,458.75 for Common Benefit fees and \$25,669.43 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

8. Derriel McCorvey (Non PSC) (McCorvey Law, LLC)

As Deputy Special Master DeJean notes, “Mr. McCorvey is a sole practitioner in Lafayette, Louisiana. He is not a member of the PSC, but did apply for and was qualified by the PSC as ‘participating counsel’ to perform Common Benefit work in accord with the case management orders of the court. He was assigned one work task by the PSC which was completed in a timely manner.

Mr. McCorvey accumulated 19 hours of audited Common Benefit time. Mr. McCorvey accumulated \$0.00 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$6,412.50 for Common Benefit fees.

9. Douglas & London, PC (PSC) (Stephanie O’Connor)

As Deputy Special Master DeJean notes, “Ms. O’Connor is a partner at the law firm of Douglas and London. She was appointed by the Court to the PSC. She was also appointed to the Plaintiff Executive Committee and was named as the

Science Coordinator for the PSC. The work performed by Ms. O'Connor represents a tireless and exemplary effort associated with the serious undertaking of responsibilities as Science Coordinator. Ms. O'Connor created a Science Committee and was in fact named the head of that committee. Ms. O'Connor was extensively involved in verification of information and content of expert reports and meeting experts. She also participated extensively in preparing experts for depositions and for trial, as well as having participated in the science aspects of the case in preparation for trial and document review. Her work in preparation for trial received accolades from many of the PSC members in their interviews. She developed a great working relationship with the experts. Her efforts resulted in a seamless presentation of expert testimony at trial and provided experts that survived pre-trial motions and cross examination by the defendants. She was instrumental in making sure that the PSC was in compliance with all of the deadlines established by the Court. Likewise, she reviewed documents, performed research, was actively involved in preparing and defending motions in limine and was a key member of the trial team in preparation for trial and continued in her preparation and observations during the trial. She remained active after trial in preparation for the second Bellweather. Her work was invaluable to the orderly development of presentation of trial materials and the acceptance of experts by the Court.

Ms. O'Connor and her firm accumulated 15,783.21 hours of audited Common Benefit time. Ms. O'Connor accumulated \$865,941.67 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean's recommendation, and awards \$13,139,522.33 for Common Benefit fees \$865,941.67 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

10. Drakulich Firm (PSC) (Nick Drakulich)

As Deputy Special Master DeJean notes, "Mr. Drakulich is a partner in the Drakulich Law Firm, APLC. He was appointed as a member of the PSC at the beginning of the MDL. Mr. Drakulich, as exhibited by his hours, performed work almost daily in most aspects of the Actos MDL litigation up through settlement. Mr. Drakulich was tasked with reviewing many documents, preparing witnesses for depositions, attending depositions, and in fact took depositions both in the United States and in England. Mr. Drakulich provided much oversight and input to the trial team throughout the trial. He was instrumental in the development of the case against Eli Lilly & Co. He attended the trial and was relied upon heavily for his advice and counsel through settlement due to his extensive experience in complex litigation. Mr. Drakulich maintained a day to day overview of most MDL activities and was literally consumed with the litigation. Co-lead counsel each verified the extent and quality of his involvement and the very important contribution he made to the overall success of the Actos MDL.

Mr. Drakulich and his firm accumulated 8,533.18 hours of audited Common Benefit time. Mr. Drakulich accumulated \$406,324.46 in Common Benefit audited expenses."

This Court hereby adopts Deputy Special Master DeJean's recommendation, and awards \$7,103,872.35 for Common Benefit fees and \$406,324.46 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

11. Girard Gibbs, LLP (PSC) (A.J. DeBartolomeo)

As Deputy Special Master DeJean notes, "Ms. DeBartolomeo was a partner in the law firm of Girard Gibbs, LLP at the beginning of the MDL. She was appointed to the PSC. Eventually, Ms. DeBartolomeo became a member of the Gibbs Law Group, as well as remaining of counsel to Girard Gibbs, LLP. Ms. DeBartolomeo has extensive experience in complex litigation and has previously served as lead counsel, co-lead counsel and as a member of the PSC in various complex litigation cases. Ms. DeBartolomeo was added to the PSC as a result of her complex trial litigation experience and expertise in science," which contributed toward the seamless presentation of the science aspect of the case at trial. "Ms. DeBartolomeo completed all work assignments in a timely and exemplary manner. Ms. DeBartolomeo worked primarily on the science aspect regarding the theory of causation, worked with experts on their reports and conducted document review. She also coordinated with other attorneys and experts to prepare for trial and develop strategies for trial presentation. Ms. DeBartolomeo and her firm paid all assessments.

Ms. DeBartolomeo and her firm accumulated 4,293.10 hours of audited Common Benefit time. Ms. DeBartolomeo accumulated \$559,720.79 in Common Benefit audited expenses."

This Court hereby adopts Deputy Special Master DeJean's recommendation, and awards \$2,018,830.28 for Common Benefit fees and \$559,720.79 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

12. Kershaw Cutter & Ratinoff (Non PSC) (Brooks Cutter) (Cutter Law)

As Deputy Special Master DeJean notes, "Mr. Cutter is not a member of the PSC, but did qualify as 'participating counsel' and was thus allowed to perform Common Benefit work and incur Common Benefit expenses. He has vast experience in complex litigation and was assigned various work projects as directed by the PSC. Each of these projects were performed in a timely manner, which included document review, research and various strategies to be used in preparation for trial.

Mr. Cutter and his firm accumulated 916.70 hours of audited Common Benefit time. Mr. Cutter accumulated \$5,426.26 in Common Benefit audited expenses."

This Court hereby adopts Deputy Special Master DeJean's recommendation, and awards \$309,386.25 for Common Benefit fees and \$5,426.26 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

13. Lanier Law Firm (PSC) (Mark Lanier)

As Deputy Special Master DeJean notes, "Mr. Lanier is the owner of the Lanier Law Firm in Houston, Texas. He was appointed to the PSC and served as lead trial counsel for the first Bellweather trial. Mr. Lanier is deserving of many

accolades for his exemplary presentation and performance at trial, resulting in a nine billion dollar verdict for the plaintiffs. Mr. Lanier was the sole presenter of witnesses and cross examined all defense witnesses. Mr. Lanier's presentation of testimony and evidence at trial with the assistance of the PSC trial team was seamless. Mr. Lanier was instrumental in providing the trial presentation that was critical to obtaining the plaintiff verdict in the Bellweather trial. Mr. Lanier is known throughout the country for his trial skills and presentation of evidence. Mr. Lanier has extensive expertise in complex litigation, trial management and presentation of trial evidence through verdict. Mr. Lanier is considered to be one of the leading trial lawyers in America. Mr. Lanier was assisted by members of his firm and the work effort and work product of an exceptional PSC and participating counsel who were also able to provide the necessary support for a seamless trial presentation. Mr. Lanier participated in focus groups and mock trials and set up an extensive jury selection evaluation system. Mr. Lanier and his firm paid all assessments.

Mr. Lanier and his firm accumulated 15,742.38 hours of audited Common Benefit time. Mr. Lanier accumulated \$888,718.82 in Common Benefit audited expenses."

This Court hereby adopts Deputy Special Master DeJean's recommendation, and awards \$15,230,752.65 for Common Benefit fees and \$888,718.82 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

14. Levin Papantonio Thomas Mitchell Rafferty & Proctor, PA (PSC) (Troy Rafferty)

As Deputy Special Master DeJean notes, “Mr. Rafferty is a partner at Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, PA. He is a member of the PSC. Mr. Rafferty was extensively involved in the preparation for depositions, taking of depositions, document review and was assigned various special projects by the PSC. He has extensive experience in complex litigation. He was actively involved in the preparation for trial. All assignments were performed in an exemplary manner. Mr. Rafferty and his firm paid all assessments.

Mr. Rafferty and his firm accumulated 5,870.66 hours of audited Common Benefit time. Mr. Rafferty accumulated \$673,483.85 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$2,905,976.70 for Common Benefit fees and \$673,483.85 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

15. Lief Cabraser Heimann & Bernstein, LLP (PSC) (Don Arbitblit)

As Deputy Special Master DeJean notes, “Mr. Arbitblit is a partner at Lief, Cabraser, Herman and Bernstein, LLP. He is a member of the PSC and has remained very active in this litigation from the early stages through time of settlement. Mr. Arbitblit and other members of the firm played a significant role in developing and preparing this matter for trial. He has an extensive science background and was able to work closely with various experts in preparing their reports and opinions. He participated in expert depositions and was particularly important in managing the relationship of the PSC with various key plaintiff



experts. His involvement with and management of expert witnesses and the information upon which they based their opinion greatly contributed to a seamless presentation of expert testimony of these experts at trial.

Mr. Arbitblit was of particular importance to the PSC in the development of the science aspect of the case and worked closely with Stephanie O'Connor to develop and coordinate expert reports and testimony.

Mr. Arbitblit and members of his firm are nationally recognized experts in complex litigation whose presence in the MDL contributed heavily towards a successful trial presentation of evidence in the first Actos Bellweather case. The firm also had many plaintiff cases enrolled in the Actos settlement program. All assignments given to Mr. Arbitblit and his firm were performed in a timely and exemplary manner reflecting his and his firm's high degree of skill and expertise in complex litigation. Mr. Arbitblit and his firm paid all assessments.

Mr. Arbitblit and his firm accumulated 3,936.30 hours of audited Common Benefit time. Mr. Arbitblit accumulated \$630,848.62 in Common Benefit audited expenses."

This Court hereby adopts Deputy Special Master DeJean's recommendation, and awards \$2,479,869.00 for Common Benefit fees and \$630,848.62 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

16. Morrow, Morrow, Ryan, Bassett & Haik (PSC and Liaison Counsel) (Patrick Morrow)

As Deputy Special Master DeJean notes, "Mr. Morrow is a senior partner in the law firm of Morrow, Morrow, Ryan and Bassett. He is a member of the PSC.

The Court appointed Mr. Morrow to the Executive Committee and also appointed him as Liaison Counsel for the Actos MDL. Mr. Morrow was central to the effective communication, transparency and management of this MDL and plaintiff counsel throughout the country who had claims in the MDL. Mr. Morrow was instrumental in resolving many issues and answering questions with individual plaintiff counsel and the PSC. Mr. Morrow was active in the MDL from inception throughout settlement and has remained so through this day. He was also a member of the Plaintiff Settlement Resolution Committee. Mr. Morrow played a key role in managing issues that arose during the course of the litigation with various plaintiff counsel across the country and was responsible for sending extensive email blasts which provided updates to all plaintiff counsel across the country having claims in the MDL. Mr. Morrow attended almost every status conference in person and/or had a representative of his firm present. During the numerous interviews conducted by the undersigned, Mr. Morrow received accolades from many individuals during the interview process regarding his communication skills and the timeliness of communications to all involved counsel in his position as Liaison Counsel. He later served as local counsel at the request of the Court for filing of all requests for court approval in death cases. His work was performed in a timely and exemplary manner.

Likewise, Jeff Bassett, a senior partner in the firm, took a lead role in the development of the spoliation issues, which eventually became a heated and critical area of development in this litigation in preparation for trial and after trial. Mr. Bassett took the lead in the spoliation arguments, prepared briefing, personally

performed extensive and detailed document review associated with spoliation issues and provided an exemplary display of his legal abilities in the spoliation hearings which ultimately was successful. Mr. Morrow and his firm paid all assessments.

Mr. Morrow and his firm accumulated 9,235.02 hours of audited Common Benefit time. Mr. Morrow accumulated \$1,018,334.79 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$12,051,701.10 for Common Benefit fees and \$1,018,334.79 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

17. Murray Law Firm (PSC) (Steven Murray)

As Deputy Special Master DeJean notes, Mr. Murray is a member of the Murray Law Firm and was appointed to serve on the PSC by this Court. Mr. Murray provided valuable experience in complex litigation, was assigned various tasks by the PSC, and played various nuanced roles within the litigation. He and his firm, specifically, also, participated in document review, and undertook specific projects such as punitive damages, research, briefing review and comment. Mr. Murray attended almost every status conference in person, and, as reflected in Deputy Special Master DeJean’s Report and Recommendation, was able to bring his “experience and counsel in complex litigation to the making of strategic decisions during development of the case for trial. Mr. Murray and his firm paid all assessments.

Mr. Murray and his firm accumulated 3,072.70 hours of audited Common Benefit time. Mr. Murray accumulated \$567,901.59 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$2,488,887.00 for Common Benefit fees and \$567,901.59 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

18. NastLaw LLC (PSC) (Dianne Nast)

As Deputy Special Master DeJean notes, “Ms. Nast is a partner at Nast Law. She was previously a partner at the firm of Roda Nast. She was appointed to the PSC by the Court. Ms. Nast provided document review and performed all assignments by the PSC. She was relied upon for counsel and advice throughout the litigation due to her knowledge and expertise in complex litigation.

Ms. Nast and her firm accumulated 455.90 hours of audited Common Benefit time. Ms. Nast accumulated \$211,947.64 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$133,350.75 for Common Benefit fees and \$211,947.64 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

19. Neblett, Beard & Arsenault (PSC and Co-Lead Counsel) (Richard Arsenault)

As Deputy Special Master DeJean notes, “Mr. Arsenault is a member of the Neblett, Beard and Arsenault firm. He is a member of the PSC. The Court

appointed Mr. Arsenault and Mr. Paul Pennock as Co-Lead Counsel and appointed each of them as members of the Plaintiff Executive Committee (PEC). Even prior to their appointment as co-lead counsel, Mr. Arsenault and Mr. Pennock were both central to the effective organization, development and management of the potential Actos litigation leading to the formation of the Actos MDL. Mr. Arsenault participated in every aspect of the litigation both pre-MDL and continues through settlement and implementation of the settlement program. Mr. Arsenault sat as trial counsel through the entire trial alongside trial counsel Mark Lanier and attended trial every day. Mr. Arsenault worked closely with his co-lead, Mr. Pennock at every step of the litigation. Their teamwork, organizational activity and case development and preparation of the first Bellweather case for trial was performed in a seamless and exemplary manner.

Mr. Arsenault devoted all necessary resources of his firm to complete the demands of the litigation. Jennifer Hoekstra, an attorney with his firm contributed greatly to the organizational effort and seamless organization of resources from inception of the MDL through conclusion.” Ms. Hoekstra was an invaluable resource in the auditing of time and expense.

Mr. Arsenault remains extremely active since the settlement process began, and has played a key role in the successful implementation of the Settlement Program. Mr. Arsenault continues to work tirelessly to close out all MDL outstanding issues. Mr. Arsenault and Mr. Pennock were of critical importance to the overall operation of the PSC and in their leadership roles. As Deputy Special Master DeJean notes, “Mr. Arsenault has extensive experience in complex

litigation and has served as lead and/or co-lead counsel in numerous cases involving complex litigation. He is a frequent lecturer and presenter at seminars and other educational efforts involving complex litigation across the nation.

Mr. Arsenault also contributed to the organizational and efficient operation of the Actos Resolution Program and maintained consistent and frequent contact with BrownGreer, the Actos claims administrator, and the Garretson Resolution Group on lien resolution. Mr. Arsenault also set up and conducted regular conference calls, as needed, for the Plaintiff Settlement Resolution Committee (PSRC) subsequent to settlement and maintained day to day contact and supervision to ensure the smooth and efficient operation of the settlement program that began making disbursements to claimants earlier rather than later.

In short, under the leadership of Mr. Arsenault and Mr. Pennock, they were at the forefront of the Actos MDL litigation from the filing of the earliest lawsuits, to the formation of the MDL, through the Bellweather process, the settlement process, and they continue to work tirelessly to close all MDL outstanding cases. All assignments given to Mr. Arsenault were performed in a truly timely and exemplary manner reflecting his high degree of skill and expertise in complex litigation. He was critical to the formation of the highly organized structure of the PSC, the seamless trial preparation and the implementation and oversight of the settlement program. Mr. Arsenault and his firm paid all assessments.

Mr. Arsenault and his firm accumulated 37,658.30 hours of audited Common Benefit time. Mr. Arsenault accumulated \$1,231,864.62 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean's recommendation, and awards \$37,281,717.00 for Common Benefit fees and \$1,231,864.62 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

20. Oliver Law Group, PC (Non PSC) (Alyson Oliver)

As Deputy Special Master DeJean notes, "Ms. Oliver is not a member of the PSC, but was qualified as 'participating counsel' through the PSC. She was primarily assigned duties in potential Bellweather selection. Her duties included gathering of information as requested by PSC members.

Ms. Oliver and her firm accumulated 21.50 hours of audited Common Benefit time. Ms. Oliver accumulated \$866.13 in Common Benefit audited expenses."

This Court hereby adopts Deputy Special Master DeJean's recommendation, and awards \$6,288.75 for Common Benefit fees and \$866.13 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

21. Parker Waichman, LLP (PSC) (Jerrold Parker)

As Deputy Special Master DeJean notes, "Mr. Parker is a senior partner at Parker Waichman, LLP. He was appointed as a member of the PSC by the Court. Mr. Parker played a significant role in the early stages of the MDL through document review as well as having been instrumental in setting up and monitoring the predictive coding process used by the PSC to enhance the reliability of document production. He and members of his office performed document review,

research, proofreading of briefs and provided input into jury selection, witness testimony and cross examination points throughout trial. Mr. Parker has extensive experience in the management of complex litigation. Mr. Parker was instrumental in the development, monitoring and oversight of predicting coding. Mr. Parker attended many of the trial days. Mr. Parker provided valuable support during trial regarding technical matters and cross-examination of witnesses. Mr. Parker and his firm paid all assessments.

Mr. Parker and his firm had 3,788.05 hours of audited Common Benefit time. Mr. Parker had \$625,356.67 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$3,494,476.13 for Common Benefit fees and \$625,356.67 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

22. Pennock Law Firm, LLC (Non PSC) (Shannon Pennock)

As Deputy Special Master DeJean notes, “Ms. Pennock is not a member of the PSC, but did apply for and receive qualification as ‘participating counsel.’ She was assigned certain research tasks by the PSC and performed all tasks in an exemplary manner.

Ms. Pennock and her firm accumulated 164.50 hours of audited Common Benefit time. Ms. Pennock accumulated \$0.00 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$55,518.75 for Common Benefit fees.



23. Robinson Calcagnie, Inc. (PSC) (Mark Robinson)

As Deputy Special Master DeJean notes, “Mr. Robinson is a shareholder in Robinson Calcagnie, Inc. He is a member of the PSC. He was appointed by the Court to the Executive Committee. Mr. Robinson has vast experience in managing and trying complex cases and was heavily involved in the California Actos proceedings. He and/or members of his firm performed document review, prepared for depositions, attended and took depositions and were involved in the Bellweather vetting process. Dan Robinson, a member of the firm, attended the trial and provided information and assistance leading to the successful trial of this matter and performed all work in an exemplary manner. Mark Robinson was designated as the liaison between the Actos MDL and the California Actos proceedings and maintained oversight of the California proceedings.

Mr. Robinson and his firm accumulated 7,126.90 hours of audited Common Benefit time. Mr. Robinson accumulated \$612,282.57 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$2,309,115.60 for Common Benefit fees and \$612,282.57 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

24. Searcy Denney Scarola Barnhart & Shipley, PA (Non PSC) (Calvin Warriner)

As Deputy Special Master DeJean notes, “Mr. Warriner is not a member of the PSC. He performed work on projects as directed by the PSC. He did qualify as ‘participating counsel’ pursuant to the case management orders of the Court. Mr.

Warriner has experience in complex litigation matters and provided timely work on all projects assigned.

Mr. Warriner and his firm accumulated 112.10 hours of audited Common Benefit time. Mr. Warriner accumulated \$0.00 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$37,833.75 for Common Benefit fees.

25. Seeger Weiss, LLP (Chris Seeger) (PSC)

As Deputy Special Master DeJean notes, “Mr. Seeger is a partner in the law firm of Seeger Weiss, LLP. He is a member of the PSC. He is a highly experienced member of the complex litigation bar and has managed and/or participated as lead counsel, co-lead counsel and served on many steering committees in his career. Mr. Seeger and his firm were assigned certain work projects by the PSC and performed all of these projects in a timely and exemplary manner. He did not attend the trial. He and members of his firm have been active in post-settlement implementation of the Master Settlement Agreement and working with the Claims Administrator.

Mr. Seeger and his firm accumulated 2,185.70 hours of audited Common Benefit time. Mr. Seeger accumulated \$524,504.15 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$983,565.00 for Common Benefit fees and \$524,504.15 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

26. Sill Law Group, PLLC (PSC) (Tara Tabatabaie)

As Deputy Special Master DeJean notes, “Ms. Tabatabaie is an attorney and Ph.D. with the Sill Law Group, PLLC. She is a member of the PSC. Ms. Tabatabaie has an extensive background in science and played an important role in developing the science relating to Actos. Likewise, Ms. Tabatabaie spent an extensive amount of time developing experts and their reports and was central to providing the PSC with information regarding defense experts. She performed all tasks requested by the PSC in an exemplary manner. She was also involved in document review, assessment and analysis of various studies on Actos and was important to the development of the scientific evidence used in direct and cross examination of experts.

Ms. Tabatabaie and her firm accumulated 2,122.70 hours of audited Common Benefit time. Ms. Tabatabaie accumulated \$561,192.42 in Common Benefit audited expenses. Ms. Tabatabaie and her firm paid all assessments.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$1,002,975.75 for Common Benefit fees and \$561,192.42 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

27. Simmons, Hanly & Conroy, LLC (PSC) (Jayne Conroy)

As Deputy Special Master DeJean notes, “Ms. Conroy is currently a partner at Simmons, Hanly and Conroy. By way of history, she was previously appointed to the PSC while a partner at Hanly Conroy. Hanly Conroy subsequently merged with Simmons Law Firm, to now be known as Simmons, Hanly Conroy. Ms.

Conroy engaged in extensive document review and assisted with the preparation of expert reports and providing invaluable advice to the PSC based on her extensive experience in complex litigation. All assignments given to Ms. Conroy were performed in a timely and exemplary manner reflecting her high degree of skill and expertise in complex litigation. Ms. Conroy and her firm paid all assessments.

Ms. Conroy and her firm accumulated 5,090.34 hours of audited Common Benefit time. Ms. Conroy accumulated \$572,722.19 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$2,634,250.95 for Common Benefit fees and \$572,722.19 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

28. Singleton Law Firm, PC (PSC) (James “Willie” Singleton)

As Deputy Special Master DeJean notes, “Mr. Singleton is the owner of the Singleton Law Firm in Shreveport, Louisiana. He is a member of the PSC. He has extensive experience in complex litigation cases. The Court appointed him as Pro Se Liaison. Mr. Singleton performed his job in a timely and exemplary manner in both managing issues relating to Pro Se plaintiffs as well as communicating with Pro Se plaintiffs extensively and maintaining open lines of communication with Pro Se Plaintiffs. Mr. Singleton worked closely with Magistrate Judge Patrick Hanna to ensure orderly and timely communication with transparency of the court proceedings to Pro Se Plaintiffs. He was assigned numerous projects and did an exemplary job on every project. Mr. Singleton attended every status conference in

person and reported the status of his work to the Court at almost all of the status conferences. Mr. Singleton was always available for phone calls, conferences, and assignments and performed all tasks within the given timetable assigned. Mr. Singleton and his firm paid all assessments.

Mr. Singleton and his firm accumulated 1,421.92 hours of audited Common Benefit time. Mr. Singleton accumulated \$565,214.69 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$799,830.00 for Common Benefit fees and \$565,214.69 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

29. Skikos, Crawford, Skikos, & Joseph, LLP (Non PSC) (Steven Skikos)

As Deputy Special Master DeJean notes, “Mr. Skikos is not a member of the PSC but did qualify as participating counsel and was in a leadership role in the California JCCP. Mr. Skikos was instrumental in having the California JCCP participate in the Actos MDL settlement program.

Mr. Skikos performed exemplary work through his valued assistance in developing the MSA and seeing it through implementation.”

Mr. Skikos and his firm accumulated 108.90 hours of audited Common Benefit time. Skikos Crawford & Skikos accumulated \$8,621.13 in Common Benefit audited expenses.

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$53,905.50 for Common Benefit fees and \$8,621.13

for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

30. Wagstaff & Cartmell (Non PSC) (Thomas Cartmell)

As Deputy Special Master DeJean notes, “Mr. Thomas Cartmell is not a member of the PSC but did qualify as ‘participating counsel.’ Mr. Cartmell was assigned various tasks such as research and document review and performed these tasks in a timely and thorough manner.

Mr. Cartmell and his firm accumulated 50.10 hours of audited Common Benefit time. Wagstaff Law accumulated \$75.00 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$14,654.25 for Common Benefit fees and \$75.00 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

31. Weitz & Luxenberg, PC (PSC and Co-Lead Counsel) (Paul Pennock)

As Deputy Special Master DeJean notes, “Mr. Pennock is a partner at Weitz and Luxenberg and is member of the PSC. The Court appointed Mr. Arsenault and Mr. Paul Pennock as Co-Lead Counsel and approved each of them as members of the Plaintiff Executive Committee (PEC). Even prior to their appointment as co-lead counsel, Mr. Arsenault and Mr. Pennock were both central to the effective organization, development and management of the potential Actos litigation leading to the formation of the Actos MDL. Mr. Pennock participated in every aspect of the litigation both pre-MDL and continues through settlement and

implementation of the settlement program. Mr. Pennock sat as trial counsel through many days of the trial. Mr. Pennock worked closely with his co-lead, Mr. Arsenault at every step of the litigation. Their teamwork, organizational activity and case development and preparation of the first Bellweather case for trial was performed in a seamless and exemplary manner. Mr. Pennock devoted the necessary resources of his firm to complete the demands of the litigation.

Mr. Pennock remains extremely active since settlement playing a key role in the successful implementation of the settlement program. Mr. Pennock continues to work tirelessly to close out all MDL outstanding issues. Mr. Pennock and Mr. Arsenault were of critical importance to the overall structuring of the PSC. Mr. Pennock has extensive experience in complex litigation and has served as lead and/or co-lead counsel in numerous cases involving complex litigation. He is a frequent lecturer and presenter at seminars and other educational efforts involving complex litigation across the nation.

Mr. Pennock also contributed to the organizational and efficient operation of the Actos Resolution Program.

In short, under the leadership of Mr. Pennock and his firm, he was at the forefront of the Actos MDL litigation from the filing of the earliest lawsuits, to the formation of the MDL, through the Bellweather process, the settlement process, and continues to work tirelessly to close all MDL outstanding cases. All assignments given to Mr. Pennock were performed in a truly timely and exemplary manner reflecting his high degree of skill and expertise in complex litigation. He was critical to the seamless trial presentation.

Even prior to their appointment as co-lead counsel, Mr. Pennock and Mr. Arsenault were central to the effective organization, development and management of the potential Actos litigation leading to the formation of the Actos MDL. His work began prior to the formation of the MDL and his efforts were represented by substantial expenditures and expenses. Mr. Pennock was involved on almost a daily basis in every aspect of this litigation along with Mr. Arsenault. Mr. Pennock and Mr. Arsenault provided exemplary management styles and techniques, though different from each other, which resulted in the success of the Actos MDL. Mr. Pennock attended many days of trial in Lafayette, Louisiana and constantly provided input throughout those days. He remained actively involved in all aspects of the case after trial and remained actively involved through settlement and distribution of funds. Mr. Pennock worked closely with his co-lead, Mr. Arsenault, at every step of the litigation. The collaboration effort between the two was extraordinary and was performed in an exemplary manner. All of his tasks were performed in an exemplary manner in preparation for trial and post-trial implementation of the MSA. He has maintained an active role in the disbursement process.

Jonathan Sedge, a member of the firm provided valued assistance in the organizational structure of the case and provided research for various legal issues. His work and dedication were important to the success of the MDL.

Mr. Pennock and his firm paid all assessments.



Mr. Pennock and his firm accumulated 39,523.56 hours of audited Common Benefit time. Mr. Pennock accumulated \$1,400,502.07 in Common Benefit audited expenses.”

This Court hereby adopts Deputy Special Master DeJean’s recommendation, and awards \$35,571,204.00 for Common Benefit fees and \$1,400,502.07 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

This Court, also, understands there remain outstanding invoices for expert fees owed to the firm Law & Forensics. This Court hereby adopts Deputy Special Master DeJean’s recommendation and orders that \$259,635.00 be paid, from the amounts retained to compensate common benefit expenses, to the PSC account from which shared expenses are paid, and that the PSC pay such amount to the firm Law & Forensics.

## VI. CONCLUSION

This Court has determined, on the basis of its above noted evaluation of various aspects of the proceedings of MDL 2299, that it is appropriate to compensate Participating Counsel for the common benefit work they have performed. This Court further determines that 8.6% of the total Qualified Settlement Fund is a reasonable amount to allocate to compensate common benefit fees, and that \$25 million is an appropriate amount to retain to compensate common benefit expenses and/or costs. This Court, additionally, for the reasons given above, and with the adoption of Deputy Special Master DeJean’s Report and Recommendation, has determined that reasonable amounts should be awarded to each firm that performed common benefit work, both for fees and for expenses and/or costs, as shown above.

Furthermore, as this Court has paid tremendous deference to the rights of the PSC and Participating Counsel and their due process rights throughout this matter, in keeping with those concerns, the Court grants the PSC and any Participating Counsel the opportunity to be heard. The Court will allow any member of the PSC and/or Participating Counsel to make comment or provide any information of which this Court currently does not have benefit. Each firm may, *but is in no way required*, to submit any such comment or evidence, the comment **limited to two pages**, with **an additional limit of three pages of exhibits**, if counsel feel compelled to comment or to submit exhibits. Such comments shall be filed, with a copy provided to chambers, no later than **5:00 pm (central time) on Thursday, July 27, 2017**. In the event no comments are received by that time, this ruling shall become effective as of **5:00 pm (central time) on Thursday, July 27, 2017**. If any comments are received, this Court will review them in the manner appropriate to each as expeditiously as possible, and this ruling shall go into effect immediately upon final issuance.<sup>94</sup>

*The Court cautions counsel that this opportunity to submit comment is not an invitation for random response, nor is it an invitation to rehash time or expense claims that have already been submitted, reviewed, and approved or denied*, with all due process protection, such opportunity to comment or object having already been provided (*see* Rec. Doc. 2356, which provides an opportunity to challenge determinations as to time and expense made by Deputy Special Master DeJean and Special Master Russo, with full due process rights to review and appeal). Rather, it is the opportunity to be heard and to present relevant information or perspective not currently before the Court that counsel might believe the Court might be unaware of or might

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<sup>94</sup> Pursuant to Fed.R.Civ.P. 53(f)(1), Participating Counsel are hereby given notice of Deputy Special Master DeJean's Report and Recommendation and a chance to be heard regarding its content, in addition to the chances they have been given to be heard throughout the review and approval process. Pursuant to Fed.R.Civ.P 53(f)(2), the time to respond is reduced by this Court from 21 days to 10.

be beneficial for the Court to consider when determining the compensation of common benefit fees and expenses is contemplated. Again, *no counsel should feel he or she is obligated to file*, rather an opportunity to be heard is being provided. Therefore,

IT IS HEREBY ORDERED the Special Master will notify the Garretson Group when the Memorandum Ruling has become effective; immediately thereafter, the Garretson Group is ORDERED to distribute from the amounts previously withheld, the amounts identified as common benefit fees and expenses (inclusive of assessments, held expenses, and held shared expenses) awarded, to the firms and/or accounts as described above. The Garretson Group is, also, ordered to pay \$259,635.00 to the PSC account, and the PSC is ORDERED to pay that amount to Law & Forensics as soon as reasonably possible thereafter.

The Garretson Group is, also, ORDERED to distribute the agreed upon amounts set out in any separate agreements, *i.e.*, state court or other Actos® matters, that will be identified by the Special Master, which might have been submitted to BrownGreer and/or the Garretson Group by way of independent agreement.

Any funds that remain for the purpose of compensating common benefit fees and expenses and/or costs in excess of the distributions described above shall continue to be retained for the purpose of compensating any further common benefit fees and expenses and/or costs incurred through the final resolution of the Settlement Program. The Garretson Group is to retain these remaining funds pending further order of this Court, and is to provide weekly updates on the status of the common benefit distributions to Special Master Russo and/or Deputy Special Master DeJean.

Upon the final resolution of the Settlement Program, any remaining funds retained to compensate common benefit *expenses and/or costs* shall be paid to those claimants who received

payments under the Settlement Program, on a *pro rata* basis. Any funds retained to compensate common benefit work that might remain at the conclusion of this matter will be addressed by the Court at that time.

SIGNED this 17 day of July, 2017.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

# **ATTACHMENT A**

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE- \* MDL NO. 6:11-md-02299  
PRODUCTS LIABILITY LITIGATION) \*  
\* JUDGE REBECCA F. DOHERTY  
\*  
\* MAGISTRATE JUDGE HANNA

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REPORT AND RECOMMENDATION ON  
COMMON BENEFIT ALLOCATION OF FEES AND EXPENSES

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I was appointed as Deputy Special Master in Actos MDL 2299 by Honorable Rebecca F. Doherty. [Rec. Doc. 532] My duties assigned by the Court primarily involved the management and general oversight of matters related to the Plaintiff's Steering Committee, including monitoring the assignment of duties and tasks that inure to the Common Benefit of all plaintiffs, making adjudicative reports and recommendations for those attorneys seeking reimbursement for costs incurred and work performed for the Common Benefit of all plaintiffs. Additional duties included submitting periodic motions to the Court, review of approval and/or denial of summary descriptions of allocations of work, making recommendations for distribution of fees and/or reimbursement or payment of costs incurred and performing such other duties as might be requested of me by the Court or by the Special Master.

The Court appointed the Plaintiff's Steering Committee (PSC) on April 13, 2012 [Rec. Doc. 560] for MDL No. 6:11-MD 02299. The PSC was required to take the lead in litigating matters on behalf of all plaintiffs. A significant responsibility of the PSC, among others, was to manage Common Benefit Expenses and Fees and is stated as follows:

The PSC shall have the responsibility for assigning litigation-related tasks to counsel who provide some indication of their willingness to work for the common

benefit of all plaintiffs and the case. The committee are encouraged to distribute assignments among counsel who wish to work for the common benefit, taking into consideration the particular strengths and weaknesses of counsel requesting such assignments...

The PSC shall have responsibility for recommending the approval or denial of any claim made by an attorney for common benefit credit. Specifically, with regard to any claim that an attorney is entitled to be compensated or reimbursed for fees or costs incurred for the common benefit of the plaintiffs, the PSC shall review such claims and shall provide guidance to Special Master DeJean with regard to the propriety, fairness and reasonableness of such claims. The PSC is encouraged to create a formal process by which claims for compensation or reimbursement may be presented either before or shortly after being incurred. In doing so, they are to coordinate their efforts with Special Master DeJean, whose responsibilities, in part, encompass formal oversight of the approval process, imposing reasonable limits on such fees and costs, and making recommendations to the Court for approval or denial of any such request. The Court shall rule on any such requests periodically throughout the litigation.

In the event of a global settlement, the PSC shall have the primary responsibility, with guidance and oversight by the Court through the Special Masters, for management and oversight of the process of distributing funds, reimbursing fees and expenses incurred for the common benefit, and for distributing the remaining fees to all plaintiffs' counsel. [Rec. Doc. 560]

The Court adopted guidelines for the management of Common Benefit time keeping, cost reimbursement and related Common Benefit issues to be supplemented and enforced together with the Court's Case Management Order of February 13, 2013 [Rec. Doc. 1357 and 2356].

I.

OVERVIEW

A brief review of the litigation is appropriate to establish the accomplishments of the Court, the parties to the litigation, the attorneys and their staff members representing the parties in the litigation, as well as the efforts of the PSC members and of "participating counsel" who contributed to the forward progress of the litigation.

A.

Actos Litigation Bellweather Trials and Settlement

This MDL arises out of a product liability claim regarding the prescription drug Actos, also known as Pioglitazone. The drug was primarily prescribed in connection with individuals being treated for certain types of diabetes. Various Takeda entities manufactured and/or marketed the drug and distributed it in the United States along with Eli Lilly and Company pursuant to a contractual agreement. Many Takeda entities were named as defendants in this litigation as well as Eli Lilly and Company.

In considering the success of this MDL it is appropriate to keep in mind that Actos has remained on the market in the United States through this date.

Eventually, thousands of lawsuits were filed in State and Federal Courts regarding Actos throughout the country.

During the initial stages of the MDL, Judge Rebecca F. Doherty created a website accessible by all counsel and the public at large. All motions, court orders, opinions, recent developments, a calendar of scheduled events and various other matters were posted on this website. Throughout the litigation, the court held monthly status conferences in open court with mandatory appearances for all counsel speaking at the status conference and phone attendance being allowed for those who had no speaking part in the status conference. Notice of each status conference was posted on the website. The Court and Co-Lead counsel established a call-in number for those unable to attend in person. Logs were kept of all persons participating in each status conference either attending in person and/or attending by phone.

Judge Rebecca F. Doherty set up an extremely aggressive timeline for the trial of the first Bellweather case. The MDL in Lafayette, Louisiana was established on December 29, 2011 and as a result of the aggressive trial schedule and timeline established by the Court, the first



Bellweather trial took place in Lafayette, Louisiana beginning on January 27, 2014 and ending April 7, 2014.

Discovery commenced immediately with Common Benefit attorneys being responsible for all aspects of pretrial preparation including document production, discovery, the taking of depositions, hiring and preparation of experts, motion practice and coordination of federal and state court proceedings. Over 32 million documents were discovered and collated.

A brief review of the accomplishments of the PSC and participating counsel in preparing for the first Bellweather trial is necessary at this point.

During the preparation for the first bellwether trial, literally millions of pages of documents were produced and reviewed for and from depositions, expert preparation, and scientific and regulatory research. Over the course of the entire litigation, more than 32 million pages of documents were produced, organized and reviewed; approximately one hundred and thirty (130) depositions were taken; plaintiff's leadership designated seventeen (17) experts in their Rule 26 Disclosure, and presented seven (7) at trial; the defendants designated thirteen (13) experts in their Rule 26 Disclosure, and presented five (5) at trial, all experts for both sides requiring deposition, reports and full development for trial. In addition, the PSC and other Participating Counsel collected, indexed, and produced an incalculable number of articles, scientific materials, and regulatory information and documentation, as well as voluminous scientific and corporate documents, in association with the Phase One expert reports and discovery.

The first Bellweather trial resulted in a combined compensatory and punitive damage verdict in favor of the sole plaintiffs, Mr. and Mrs. Terrance Allen, in the excess of nine billion dollars. The verdict was appealed by the defendants to the U.S. Fifth Circuit Court of Appeals.

During the pendency of the appeal, the Court issued another very aggressive scheduling

order for the second Bellweather trial. Parties began preparation for the second Bellweather Trial, including taking of depositions, etc. Spoliation depositions began shortly after the verdict in the initial Bellweather trial. Various motions were filed in preparation for the second Bellweather trial by the parties. The litigation moved forward on several different tracks at the same time the appeal was pending including multiple depositions, motions and development of experts. This placed a burden on the resources of all parties.

During late March 2015, plaintiffs and defendants formally announced that they had reached a tentative settlement agreement dependent on a certain participation level of claimants being met. A private settlement agreement, known as the Master Settlement Agreement (MSA) was prepared by the parties, without court involvement, that established a voluntary opt-in program for claimants and their counsel involving pending Actos claims. The agreement was signed by the parties, without court involvement, on April 28, 2015. Takeda and Lilly reserved walk-away rights so as to terminate the settlement program and agreement if too few eligible participants enrolled in the program.

The aggressive trial schedule set by the court placed demands upon the PSC and participating counsel resulting in many firms having to forego taking on other cases and performing other work.

The settlement agreement or MSA was designed to provide a fair and efficient means to compensate qualifying claimants. The program was available for claimants who could qualify by establishing the required evidence of Actos usage and development of the requisite medical conditions as set forth in the settlement program requirements for participants. After enrolling, claimants and/or their primary attorneys gathered and submitted medical records to the claims administrator for processing and review as set forth in the agreement. There were multiple layers

of review for eligibility, including initial review by the claims administrator, an opportunity to submit additional records, an appeal and in certain cases the opportunity to seek additional compensation from the Extraordinary Injury Fund (EIF). If, after that process, it was determined that a particular claim did not meet the criteria established in the MSA, the claimant could appeal to the Special Master for a final and binding review. Claimants who qualified for the settlement program were assigned points based upon objective risk factors and the nature and extent of the injury and were entitled to a similar review process for their point calculations. Thus, the settlement program included an exit opportunity for each qualifying claimant and multiple additional layers of review to ensure that claims received ample due process consideration before awards were made final to those claimants participating in the private settlement program.

During the course of the litigation various case management orders issued by the Court to establish a procedure whereby as Deputy Special Master, I was in charge of the management and oversight of matters related to the Plaintiff's Steering Committee, including monitoring the assignment of duties and tasks that inure to the Common Benefit of all plaintiffs, making adjudicative reports and making recommendations to Special Master Russo for approval of claims for those attorneys seeking credit for expenses incurred and work performed for the common benefit of all plaintiffs, submitting periodic motions to the Court seeking review and approval or denial of summary descriptions of allocations of work, distribution of fees and reimbursement of costs incurred and performing such other duties as might be requested by the Court or the Special Master. [Rec. Doc. 532, 1357 and 2356]

Takeda and Lily formally announced that they were satisfied that the thresholds necessary to trigger funding of the Actos settlement program had been met. Takeda and Lily also formally waived their walk-away privileges and announced that they would commence funding of the Actos

settlement program, thus enabling and clearing the way for distribution of interim payments to eligible claimants. Eventually, in the excess of 99.5% of all eligible claimants enrolled in the program.

The implementation of the settlement program proceeded at a very rapid rate. Takeda and Lilly made payments quickly in order to ensure that claimants would receive funds in a timely fashion. The first interim payments were made on July 20, 2016. Thus, in a very short period of time, the parties to this MDL were able to bring the first Bellweather case to trial, reach a settlement agreement and begin interim distribution of monies to claimants.

The efficiency demonstrated by the case management orders of the Court from inception of this MDL through the date of the first distribution and thereafter is virtually unprecedented in mass tort settlements of this size. It was due in large part to the ability, industry and professionalism of Judge Rebecca Doherty, Magistrate Judge Patrick Hanna, plaintiff and defense attorneys, their offices and staff, BrownGreer, Garretson Resolution Group, Co-Lead counsel, Liaison counsel, Pro-Se Liaison counsel and the use of a Special Master and two Deputy Special Masters.

## II.

### Procedures for Performing and Documenting Common Benefit Work

From the very beginning of the Actos MDL, steps were taken by Judge Rebecca Doherty, and Magistrate Judge Patrick Hanna, through extensive and detailed case management orders, to create a fair, transparent, innovative and open protocol for all interested attorneys to perform work for the Common Benefit of the Actos plaintiffs and to create a transparent factual record for application for Common Benefit fees and expenses. The procedures were set up in various case management orders. [Rec. Doc. 532, 560, 1357 and 2356]

Through the innovative procedures established and implemented by the Court as Deputy Special Master I was assigned to review time and expense submissions as opposed to having a fee committee review time and expense submissions, as was previously done in other complex litigation cases.

The Court, through the various case management orders, set up a protocol whereby any attorney seeking to perform Common Benefit work or seeking to be reimbursed for Common Benefit expenses was required to comply with the protocol set forth in the various case management orders before performing any Common Benefit work or incurring any Common Benefit costs.

Under the protocol, Common Benefit work was to be assigned by Co-Leads and/or the Plaintiff Executive Committee (PEC) members. If attorneys outside of the PSC wanted to perform Common Benefit work and/or seek Common Benefit expenses, they were required to comply with the protocol so as to qualify as “participating counsel”. In other words, no Common Benefit work could be performed or Common Benefit expenses incurred unless there was approval and/or qualification to perform such work or incur the expenses in compliance with the protocol set forth in the case management orders issued by the Court prior to performing the work or incurring the expense. The Court specifically disallowed any requests for Common Benefit time and expense reimbursement that were not authorized and/or approved in advance of the work being performed or the expenses being incurred in accord with the protocol set forth by the Court.

The protocol set in place by the Court had me, as Deputy Special Master, appointed to perform the duties that have been traditionally performed by the “fee committee” so as to avoid the appearance of a fee committee being appointed whose members may have a financial interest

in the setting of fees and reimbursement of expenses for those attorneys performing Common Benefit work and incurring Common Benefit expenses.

Approximately thirty-one firms or individuals, inclusive of PSC members, availed themselves of the opportunity to perform Common Benefit work through the qualification process. Anyone authorized to perform Common Benefit work and incur Common Benefit expenses was required under the protocol to report their hours and expenses to the undersigned for review and eventual reporting to the Court. [Rec. Doc. 560, 1357 & 2356] All attorneys who applied for and were qualified as members of the PSC and/or "participating counsel" were authorized to perform Common Benefit work or incur Common Benefit expense in varying degrees based on experience, expertise, and capability, size of firm and their specialty.

Each entry submitted seeking Common Benefit time and expense was reviewed by the undersigned pursuant to the Court established protocol and was either approved or labeled deficient. The submitting attorney or firm would receive a deficiency notice for deficient entries and was allowed fourteen days within which to correct those deficiencies. Due to the innovative procedures and protocol set in place by the Court in the case management orders pertaining to Common Benefit time and expense, deficiencies were corrected and/or withdrawn.

Additionally, the early appointment of a Deputy Special Master with the specific task of reviewing Common Benefit time and expense submissions allowed for a review of time and expense in relatively close proximity to the dates those services were performed. During the course of my review of time and expense, I reviewed thousands of Common Benefit time submission entries and thousands of Common Benefit expense submission entries. The majority of Common Benefit expenses were paid out of assessments funded by PSC members. Payment was authorized only after approval by the PEC, myself and/or the court.

The Court issued a Common Benefit assessment order for Common Benefit attorney fees. [Rec. Doc. 6215] The Court also ordered that \$25,000,000.00 would be withheld from all claimants participating in the MSA for Common Benefit expenses and further, that any balance of that amount not taxed as expenses would be refunded to the various claimants. [Rec. Doc. 6215]

Judge Rebecca F. Doherty requested that I prepare a Report and Recommendation for Allocation of Attorney Fees and Expenses based upon the results of my duties set forth in Rec Doc 5801 and other relevant case management orders. I was tasked with specific instructions from the Court to amass and gather the facts and information necessary for the court's analysis, decision, and ruling on the question of whether a Common Benefit assessment should be made in this case and allocation thereof. [Rec. Doc. 5801] Specifically, I was instructed to amass and gather information as to:

1. the lodestar determination, including the hours, expenses, and costs actually incurred by the PSC and other participating common benefit attorneys in this case;
2. reasonable hourly fee rates for attorneys and paralegals;
3. the time and labor reasonably required to protect the plaintiffs' common interests;
4. the novelty and difficulty of the questions raised by the claims in these proceedings;
5. the skill requisite to perform the legal service properly;
6. the preclusion of other employment by the attorney due to acceptance of the case;
7. the customary fee;
8. whether the fee is fixed or contingent;
9. time limitations imposed by the client or the circumstances;
10. the amount involved and the results obtained;
11. the experience, reputation, and ability of the attorneys;

12. the “undesirability” of the case;
13. information as to the nature and length of the professional relationship with the client;  
and
14. any and all other factual information as a result of this fact-gathering process, which might be of benefit to the Court.

Pursuant to that order, the undersigned set up in person interviews to be conducted under oath during May and June of 2016 with any attorney authorized to seek payment for and/or reimbursement for Common Benefit time and expense pursuant to the case management order protocol and who wanted to appear for the interview process.

During the interviews, I questioned each member of the PSC who submitted a request for Common Benefit time and expense as well as questioning “participating counsel” who chose to appear, regarding their Common Benefit time and expense and contribution to the MDL. Almost all members of the PSC and some participating counsel elected to attend the interviews. The interviews were conducted under oath by the undersigned in the courtroom of Magistrate Judge Patrick Hanna. The interviews included inquiry into areas of professional qualification, size of firm, type of practice of the firm, number of members in the firm and their experience in handling complex litigation and in some instances, experience or expertise in managing complex litigation and the contribution each made to the MDL and value of their work.

During the interviews, I questioned each person appearing regarding the relevant Johnson<sup>1</sup> factors and the particular applicability of those factors to their work and the work of the MDL. The Johnson factors were reviewed for applicability to the Actos MDL as well as how those factors

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<sup>1</sup> *Johnson v. Georgia Highway Exp., Inc.*, 488 F.2d 714, 715 (5th Cir. 1974)



applied to that person or firm's work and the contribution that person felt that they made to the overall success of the MDL as well as the overall applicability of the factors to the PSC and participating counsel.

The functioning of the Plaintiff's Steering Committee was also discussed. During the interview, I questioned each person appearing as to whether there was ever a need for the Plaintiff's Steering Committee to use the work product of other attorneys who were not on the PSC and/or were not "participating counsel". Unanimously, all persons interviewed stated that the PSC and/or "participating counsel" performed all of the work necessary in this Actos MDL in an exemplary manner and that there was no need for the PSC to look to the work product of other counsel outside of the PSC and/or "participating counsel" to reach the successful result of this MDL. The PSC was described unanimously by all persons interviewed as being self-sufficient and as not having to use any work product other than that generated by the Plaintiff's Steering Committee and/or by authorized "participating counsel" from inception through trial and conclusion of this matter.

The interviews confirmed to the undersigned that the PSC and "participating counsel" were a well-functioning and highly skilled group that met all of the aggressive and demanding deadlines imposed by the Court. The PSC did not make a request for any extensions of and/or set forth a need for additional time to meet any deadlines set by the court through time of settlement. There was diversity among assignments of work with best talents being used for a specific assignment which ultimately led to the success of the Actos MDL.

I explored each of the applicable Johnson<sup>2</sup> factors in depth with each attorney appearing for the interviews. I also allowed each person being interviewed to be given the opportunity for

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<sup>2</sup> *Johnson v. Georgia Highway Exp., Inc.*, 488 F.2d 714, 715 (5th Cir. 1974)

open discussion and comment regarding the MDL settlement. All persons interviewed thoroughly supported the settlement.

During each of the interviews, all attorneys appearing were allowed the opportunity to make a presentation and/or make any submission to the undersigned which they felt established the value of their work and/or their contribution for the Common Benefit to the MDL, as opposed to relying only on submitted hours of work and/or evidence of expenses.

Each person interviewed was also invited to make additional submissions, if they desired, to the undersigned after the interview to provide any additional evidence of their contribution and/or effort to the success of the Actos MDL.

No one availed themselves of the appellate process who had applied for Common Benefit work and for authority to incur Common Benefit expenses by the Plaintiff's Steering Committee as "participating counsel".

In addition, the undersigned, pursuant to the instructions from Judge Rebecca F. Doherty in Rec. Doc. 5801, interviewed Special Master Gary Russo in great detail regarding his invaluable insight as to the MDL involvement of various attorneys, the work they performed, the specific duties or unique duties performed by certain counsel, their participation in trial and the attorneys who were actively involved in the trial preparation process and settlement process. Of utmost value was his insight into settlement negotiations and the participation of counsel in the settlement process, including the drafting of the settlement agreement or Master Settlement Agreement (MSA) and the development of the matrix system for case evaluation presented to the claims administrator and/or the lien resolution administrator.

Each of the interviews also functioned as an overall cross check regarding the time submissions reviewed by the undersigned when compared to the observations of Special Master Russo during trial and settlement.

The PSC and participating counsel accumulated a total of 202,421.65 audited hours and accumulated a total of \$14,855,885.37 in audited expenses. The audited hours for each firm include hours for the various levels of participation and contribution of counsel and/or their staff. These levels of participation and contributions are reflected in the specific allocations to each firm established by the varying degrees of participation or contribution of members of the firm and their staff. The PSC members paid \$12,238.00.00 in assessments. All time and expense submissions ended March 17, 2017. Thereafter, all common benefit work or expenses had to be approved by Special Master Russo.

#### ALLOCATION OF FEES AND EXPENSES

My allocation recommendation for each Common Benefit applicant is as follows, in alphabetical order, for Common Benefit fees and expenses (including assessments, held expenses and held shared expenses):

1. Aylstock, Witkin, Kreis & Overholtz, PLLC (PSC) (Neil Overholtz) (AWKO ACTOS 2016 QSF Trust)

Mr. Overholtz is a member of the law firm of Aylstock, Witkin, Kreis & Overholtz, PLLC. Mr. Overholtz was appointed to the PSC by the Court. Although Mr. Overholtz did not initially start out in a leadership role with the PSC, his work dedication provided great support skills and eventually he evolved into a leadership role. The value of Mr. Overholtz to the PSC grew with time and he was eventually involved in many of the strategic planning sessions and played a major role in

developing many of the aspects of the case for trial. Although Mr. Overholtz began his service on the PSC in a support role, he ultimately became a valued member of the PSC leadership. He participated in almost every aspect of the case beginning prior to the formation of the MDL through settlement and implementation of the settlement process. He is unequivocally one of the major contributors to the success of the MDL. He was instrumental in setting up predictive coding, the predictive coding process, assisting experts in preparing their reports, document review and prepared for and took depositions of both lay and expert witnesses. He maintained an active role in the MDL from its inception and maintained that role through the settlement and disbursement process and continues in that role today.

Mr. Overholtz, although not in a leadership position, worked tirelessly on Actos matters and had many attorneys and staff from his firm devote numerous hours for the various tasks he was assigned and undertook. He was present for almost the entire trial. Mr. Overholtz and his firm paid all assessments.

Mr. Overholtz and his firm accumulated 18,767.65 hours of audited Common Benefit time. Mr. Overholtz accumulated \$1,177,326.60 in Common Benefit audited expenses.

I recommend an award of \$16,130,795.18 for Common Benefit fees and an award of \$1,177,326.60 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

2. Andrews Thornton Higgins Razamara LLP (Non PSC) (Anne Andrews) (Andrews & Thornton Attorneys at Law State Bar of California)

Ms. Andrews is not a member of the PSC. Ms. Andrews did qualify as “participating counsel” and was thus authorized to perform certain Common Benefit work and incur Common Benefit expenses. She is a member of the firm, Andrews Thornton and performed work on various projects as directed by the PSC.

Ms. Andrews elected to waive her appearance at the interview process and elected to rely solely upon the firm hours submitted for Common Benefit fees and her submissions for expenses.

All assignments given to the firm were performed in a timely manner by either Ms. Andrews or a junior associate, Lauren Davis.

Ms. Andrews and her firm accumulated 244.58 hours of audited Common Benefit time. Ms. Andrews accumulated \$0.00 in Common Benefit audited expenses.

I recommend an award of \$93,551.85 for Common Benefit fees and an award of \$0.00 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

3. Andrus Wagstaff, PC (PSC) (Vance Andrus) (Andrus Wagstaff P.C.)

Mr. Andrus is a partner in Andrus, Hood and Wagstaff, PC. He is a member of the PSC and was involved in the MDL even prior to his appointment to the PSC. Mr. Andrus received various assignments, which included document review, legal research, opinions on discovery practices and procedures and suggestions as to experts and trial procedure as requested by co-leads or the PEC.

Mr. Andrus elected not to participate in the interview process regarding Common Benefit time and expense. All assignments given to Mr. Andrus were performed in a timely and exemplary manner reflecting his high degree of skill and expertise in complex litigation. Mr. Andrus and his firm paid all assessments.

Mr. Andrus and his firm accumulated 1,024.90 hours of audited Common Benefit time. Mr. Andrus accumulated \$588,880.27 in Common Benefit audited expenses.

I recommend an award of \$479,653.20 for Common Benefit fees and an award of \$588,880.27 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

4. Barrios Kingsdorf & Casteix, LLP (PSC and State Court Liaison) (Dawn Barrios) (Barrios, Kingsdorf & Casteix, LLP)

Ms. Barrios is a partner in the law firm of Barrios, Kingsdorf and Casteix, LLP. She was appointed as a member of the Actos PSC. Additionally, the Court appointed Ms. Barrios to the Executive Committee and also appointed her as State and Federal Court Liaison for the plaintiffs.

Ms. Barrios maintained exceptional contact and communication with her defense counterpart, Sherry Knutson and State and Federal Judges as directed by the court. Additionally, Ms. Barrios participated in the Bellweather vetting interviews and coordinated well with state court counsel who had potential Bellweather cases. Likewise, as State and Federal Court Liaison, Ms. Barrios coordinated Sherry Knutson on behalf of the defendants concerning all new state court cases, the status of state court trials and corresponded appropriately with State

and Federal Judges as directed by Judge Rebecca F. Doherty regarding events taking place on their respective Actos dockets.

All assignments given to Ms. Barrios were performed in a timely and exemplary manner reflecting her high degree of skill and expertise in complex litigation, especially in the management of the difficult State/Federal relationships that are ever present in complex litigation.

Ms. Barrios and her firm accumulated 1,937.70 hours of audited Common Benefit time. Ms. Barrios accumulated \$423,498.90 in Common Benefit audited expenses.

I recommend an award of \$985,320.45 for Common Benefit fees and an award of \$423,498.90 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

5. Baum Hedlund Aristei Goldman, PC (Non PSC) (Michael Baum) (Baum, Hedlund, Aristei & Goldman PC)

Mr. Baum is a partner in the firm of Baum Hedlund. He was not on the PSC, but did qualify as “participating counsel” and performed all assignments from the PSC. Additionally, Mr. Baum represented Dr. Helen Gee, a one-time potential key witness and whistleblower plaintiff regarding Actos. Mr. Baum acted as liaison between the PSC and Dr. Gee and maintained coordination with the PSC regarding her deposition testimony. Mr. Baum participated in document review at the direction of the PSC.

Mr. Baum and his firm accumulated 2,953.55 hours of audited Common Benefit time. Mr. Baum accumulated \$27,560.14 in Common Benefit audited expenses.

I recommend an award of \$797,458.50 for Common Benefit fees and an award of \$27,560.14 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

6. Beasley Allen Law Firm (PSC) (Andy Birchfield) (Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.)

Mr. Birchfield is a member of the PSC. He is a partner in the firm of Beasley Allen. Mr. Birchfield performed Common Benefit work on projects as directed by the PSC and in fact took a lead role in deposition preparation, taking depositions, the predictive coding process, discovery and motion practice. He was heavily involved in settlement negotiations and in fact his involvement was critical in settling the case and developing the settlement matrix used with the Actos defendants. Subsequent to settlement, Mr. Birchfield remained active in the settlement process through disbursement. He was a great credit to the overall success of the settlement program and its implementation through BrownGreer and/or Garretson Resolution Group. All assignments given to Mr. Birchfield were performed in a timely and exemplary manner reflecting his high degree of skill and expertise in complex litigation. Mr. Birchfield and his firm paid all assessments.

Mr. Birchfield and his firm accumulated 8,398.45 hours of audited Common Benefit time. Mr. Birchfield accumulated \$681,099.90 in Common Benefit audited expenses.



I recommend an award of \$5,668,953.75 for Common Benefit fees and an award of \$681,099.90 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

7. Climaco, Wilcox, Peca & Garofoli Co., LPA (Dawn Chmielewski – Former PSC member from Climaco Law Firm) (Climaco, Wilcox, Peca & Garofoli Co., LPA)

Ms. Chmielewski was appointed to the PSC while a member of the Climaco Law Firm. During her time on the PSC, she received many assignments which were all performed in an exemplary manner. She was involved in document review, predictive coding, various research and writing projects and was a valuable asset to the PSC through her work efforts. She eventually began employment with Noblett, Beard and Arsenault and withdrew from the PSC. Her Common Benefit time thereafter was submitted through Neblett, Beard and Arsenault. Her Common Benefit Time in this award only reflects those hours while she was a member of what was previously known as the Climaco Law Firm.

Ms. Chmielewski and the Climaco Law Firm accumulated 1,862.10 hours of audited Common Benefit time. Ms. Chmielewski and the Climaco Law Firm accumulated \$25,669.43 in Common Benefit audited expenses.

I recommend an award of \$628,458.75 for Common Benefit fees and an award of \$25,669.43 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

8. Derriel McCorvey (Non PSC) (McCorvey Law, LLC)

Mr. McCorvey is a sole practitioner in Lafayette, Louisiana. He is not a member of the PSC, but did apply for and was qualified by the PSC as

“participating counsel” to perform Common Benefit work in accord with the case management orders of the court. He was assigned one work task by the PSC which was completed in a timely manner.

Mr. McCorvey accumulated 19 hours of audited Common Benefit time. Mr. McCorvey accumulated \$0.00 in Common Benefit audited expenses.

I recommend an award of \$6,412.50 for Common Benefit fees and an award of \$0.00 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

9. Douglas & London, PC (PSC) (Stephanie O’Connor) (Douglas & London P.C.)

Ms. O’Connor is a partner at the law firm of Douglas and London. She was appointed by the Court to the PSC. She was also appointed to the Plaintiff Executive Committee and was named as the Science Coordinator for the PSC. The work performed by Ms. O’Connor represents a tireless and exemplary effort associated with the serious undertaking of responsibilities as Science Coordinator. Ms. O’Connor created a Science Committee and was in fact named the head of that committee. Ms. O’Connor was extensively involved in verification of information and content of expert reports and meeting experts. She also participated extensively in preparing experts for depositions and for trial, as well as having participated in the science aspects of the case in preparation for trial and document review. Her work in preparation for trial received accolades from many of the PSC members in their interviews. She developed a great working relationship with the experts. Her efforts resulted in a seamless presentation of expert testimony at trial and provided experts that survived pre-trial motions and cross examination by the defendants.

She was instrumental in making sure that the PSC was in compliance with all of the deadlines established by the Court. Likewise, she reviewed documents, performed research, was actively involved in preparing and defending motions in limine and was a key member of the trial team in preparation for trial and continued in her preparation and observations during the trial. She remained active after trial in preparation for the second Bellweather. Her work was invaluable to the orderly development of presentation of trial materials and the acceptance of experts by the Court.

Ms. O'Connor and her firm accumulated 15,783.21 hours of audited Common Benefit time. Ms. O'Connor accumulated \$865,941.67 in Common Benefit audited expenses.

I recommend an award of \$13,139,522.33 for Common Benefit fees and an award of \$865,941.67 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

10. Drakulich Firm (PSC) (Nick Drakulich) (Drakulich Firm A Professional Law Corp.)

Mr. Drakulich is a partner in the Drakulich Law Firm, APLC. He was appointed as a member of the PSC at the beginning of the MDL. Mr. Drakulich, as exhibited by his hours, performed work almost daily in most aspects of the Actos MDL litigation up through settlement. Mr. Drakulich was tasked with reviewing many documents, preparing witnesses for depositions, attending depositions, and in fact took depositions both in the United States and in England. Mr. Drakulich provided much oversight and input to the trial team throughout the trial. He was instrumental in the development of the case against Eli Lilly & Co. He attended the

trial and was relied upon heavily relied upon for his advice and counsel through settlement due to his extensive experience in complex litigation. Mr. Drakulich maintained a day to day overview of most MDL activities and was literally consumed with the litigation. Co-lead counsel each verified the extent and quality of his involvement and the very important contribution he made to the overall success of the Actos MDL.

Mr. Drakulich and his firm accumulated 8,533.18 hours of audited Common Benefit time. Mr. Drakulich accumulated \$406,324.46 in Common Benefit audited expenses.

I recommend an award of \$7,103,872.35 for Common Benefit fees and an award of \$406,324.46 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

11. Girard Gibbs, LLP (PSC) (A.J. DeBartolomeo) (Girard Gibbs LLP)

Ms. DeBartolomeo was a partner in the law firm of Girard Gibbs, LLP at the beginning of the MDL. She was appointed to the PSC. Eventually, Ms. DeBartolomeo became a member of the Gibbs Law Group, as well as remaining of counsel to Girard Gibbs, LLP. Ms. DeBartolomeo has extensive experience in complex litigation and has previously served as lead counsel, co-lead counsel and as a member of the PSC in various complex litigation cases. Ms. DeBartolomeo was added to the PSC as a result of her complex trial litigation experience and expertise in science which contributed towards the seamless presentation of the science aspect of the case at trial. Ms. DeBartolomeo completed all work assignments in a timely and exemplary manner. Ms. DeBartolomeo worked

primarily on the science aspect regarding the theory of causation, worked with experts on their reports and conducted document review. She also coordinated with other attorneys and experts to prepare for trial and develop strategies for trial presentation. Ms. DeBartolomeo and her firm paid all assessments.

Ms. DeBartolomeo and her firm accumulated 4,293.10 hours of audited Common Benefit time. Ms. DeBartolomeo accumulated \$559,720.79 in Common Benefit audited expenses.

I recommend an award of \$2,018,830.28 for Common Benefit fees and an award of \$559,720.79 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

12. Kershaw Cutter & Ratinoff (Non PSC) (Brooks Cutter) (Cutter Law)

Mr. Cutter is not a member of the PSC, but did qualify as “participating counsel” and was thus allowed to perform Common Benefit work and incur Common Benefit expenses. He has vast experience in complex litigation and was assigned various work projects as directed by the PSC. Each of these projects were performed in a timely manner, which included document review, research and various strategies to be used in preparation for trial.

Mr. Cutter and his firm accumulated 916.70 hours of audited Common Benefit time. Mr. Cutter accumulated \$5,426.26 in Common Benefit audited expenses.

I recommend an award of \$309,386.25 for Common Benefit fees and an award of \$5,426.26 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

13. Lanier Law Firm (PSC) (Mark Lanier) (The Lanier Law Firm PC)

Mr. Lanier is the owner of the Lanier Law Firm in Houston, Texas. Mr. Lanier was selected as trial counsel for the first Bellweather. Mr. Lanier was subsequently appointed as a member of the PSC. His appointment to the PSC was after the original PSC had been appointed and was in conjunction with Mr. Lanier being selected as actual trial counsel. Mr. Lanier is deserving of many accolades for his exemplary presentation and performance at trial, resulting in a nine billion dollar verdict for the plaintiffs. Mr. Lanier was the sole presenter of witnesses and cross examined all defense witnesses. Mr. Lanier's presentation of testimony and evidence at trial with the assistance of the PSC trial team was seamless. Mr. Lanier was instrumental in providing the trial presentation that was critical to obtaining the plaintiff verdict in the Bellweather trial. Mr. Lanier is known throughout the country for his trial skills and presentation of evidence. Mr. Lanier has extensive expertise in complex litigation, trial management and presentation of trial evidence through verdict. Mr. Lanier is considered to be one of the leading trial lawyers in America. Mr. Lanier was assisted by members of his firm and the work effort and work product of an exceptional PSC and participating counsel who were also able to provide the necessary support for a seamless trial presentation. Mr. Lanier participated in focus groups and mock trials and set up an extensive jury selection evaluation system. Mr. Lanier and his firm paid all assessments.

Mr. Lanier and his firm accumulated 15,742.38 hours of audited Common Benefit time. Mr. Lanier accumulated \$888,718.82 in Common Benefit audited expenses.

I recommend an award of \$15,230,752.65 for Common Benefit fees and an award of \$888,718.82 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

14. Loeff Cabraser Heimann & Bernstein, LLP (PSC) (Don Arbitblit) (Loeff Cabraser Heimann & Bernstein LLP)

Mr. Arbitblit is a partner at Loeff, Cabraser, Heimann and Bernstein, LLP. He is a member of the PSC and has remained very active in this litigation from the early stages through time of settlement. Mr. Arbitblit and other members of the firm played a significant role in developing and preparing this matter for trial. He has an extensive science background and was able to work closely with various experts in preparing their reports and opinions. He participated in expert depositions and was particularly important in managing the relationship of the PSC with various key plaintiff experts. His involvement with and management of expert witnesses and the information upon which they based their opinion greatly contributed to a seamless presentation of expert testimony of these experts at trial.

Mr. Arbitblit was of particular importance to the PSC in the development of the science aspect of the case and worked closely with Stephanie O'Connor to develop and coordinate expert reports and testimony.

Mr. Arbitblit and members of his firm are nationally recognized experts in complex litigation whose presence in the MDL contributed heavily towards a successful trial presentation of evidence in the first Actos Bellweather case. The firm also had many plaintiff cases enrolled in the Actos settlement program. All assignments given to Mr. Arbitblit and his firm were performed in a timely and

exemplary manner reflecting his and his firm's high degree of skill and expertise in complex litigation. Mr. Arbitblit and his firm paid all assessments.

Mr. Arbitblit and his firm accumulated 3,936.30 hours of audited Common Benefit time. Mr. Arbitblit accumulated \$630,848.62 in Common Benefit audited expenses.

I recommend an award of \$2,749,869.00 for Common Benefit fees and an award of \$630,848.62 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

15. Levin Papantonio Thomas Mitchell Rafferty & Proctor, PA (PSC) (Troy Rafferty)  
(Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.)

Mr. Rafferty is a partner at Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, PA. He is a member of the PSC. Mr. Rafferty was extensively involved in the preparation for depositions, taking of depositions, document review and was assigned various special projects by the PSC. He has extensive experience in complex litigation. He was actively involved in the preparation for trial. All assignments were performed in an exemplary manner. Mr. Rafferty and his firm paid all assessments.

Mr. Rafferty and his firm accumulated 5,870.66 hours of audited Common Benefit time. Mr. Rafferty accumulated \$673,483.85 in Common Benefit audited expenses.

I recommend an award of \$2,905,976.70 for Common Benefit fees and an award of \$673,483.85 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).



16. Morrow, Morrow, Ryan, Bassett & Haik (PSC and Liaison Counsel) (Patrick Morrow)  
(Morrow, Morrow, Ryan & Bassett)

Mr. Morrow is a senior partner in the law firm of Morrow, Morrow, Ryan and Bassett. He is a member of the PSC. The Court appointed Mr. Morrow to the Executive Committee and also appointed him as Liaison Counsel for the Actos MDL. Mr. Morrow was central to the effective communication, transparency and management of this MDL and plaintiff counsel throughout the country who had claims in the MDL. Mr. Morrow was instrumental in resolving many issues and answering questions with individual plaintiff counsel and the PSC. Mr. Morrow was active in the MDL from inception throughout settlement and has remained so through this day. He was also a member of the Plaintiff Settlement Resolution Committee. Mr. Morrow played a key role in managing issues that arose during the course of the litigation with various plaintiff counsel across the country and was responsible for sending extensive email blasts which provided updates to all plaintiff counsel across the country having claims in the MDL. Mr. Morrow attended almost every status conference in person and/or had a representative of his firm present. During the numerous interviews conducted by the undersigned, Mr. Morrow received accolades from many individuals during the interview process regarding his communication skills and the timeliness of communications to all involved counsel in his position as Liaison Counsel. He later served as local counsel at the request of the Court for filing of all requests for court approval in death cases. His work was performed in a timely and exemplary manner.

Likewise, Jeff Bassett, a senior partner in the firm, took a lead role in the development of the spoliation issues, which eventually became a heated and critical area of development in this litigation in preparation for trial and after trial. Mr. Bassett took the lead in the spoliation arguments, prepared briefing, personally performed extensive and detailed document review associated with spoliation issues and provided an exemplary display of his legal abilities in the spoliation hearings which ultimately was successful. Mr. Morrow and his firm paid all assessments.

Mr. Morrow and his firm accumulated 9,235.02 hours of audited Common Benefit time. Mr. Morrow accumulated \$1,018,334.79 in Common Benefit audited expenses.

I recommend an award of \$12,051,701.10 for Common Benefit fees and an award of \$1,018,334.79 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

17. Murray Law Firm (PSC) (Steven Murray) (Stephen B. Murray d/b/a Murray Law Firm)

Mr. Murray is a member of the Murray Law Firm. He was appointed to serve on the PSC by the Court. Mr. Murray provided his vast experience in complex litigation over the years and he was assigned various tasks by the PSC. He and his firm participated in document review, specific projects such as punitive damages, research, briefing review and comment. Mr. Murray attended most every status conference in person and was able to apply his experience and counsel in complex litigation to the making of strategic decisions during development of the case for trial. Mr. Murray and his firm paid all assessments.

Mr. Murray and his firm accumulated 3,072.70 hours of audited Common Benefit time. Mr. Murray accumulated \$567,901.59 in Common Benefit audited expenses.

I recommend an award of \$2,488,887.00 for Common Benefit fees and an award of \$567,901.59 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

18. NastLaw LLC (PSC) (Diane Nast) (NastLaw LLC/Dianne M. Nast)

Ms. Nast is a partner at Nast Law. She was previously a partner at the firm of Roda Nast. She was appointed to the PSC by the Court. Ms. Nast provided document review and performed all assignments by the PSC. She was relied upon for counsel and advice throughout the litigation due to her knowledge and expertise in complex litigation.

Ms. Nast and her firm accumulated 455.90 hours of audited Common Benefit time. Ms. Nast accumulated \$211,947.64 in Common Benefit audited expenses

I recommend an award of \$133,350.75 for Common Benefit fees and an award of \$211,947.64 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

19. Neblett, Beard & Arsenault (PSC and Co-Lead Counsel) (Richard Arsenault) (Neblett, Beard & Arsenault)

Mr. Arsenault is a member of the Neblett, Beard and Arsenault firm. He is a member of the PSC. The Court appointed Mr. Arsenault and Mr. Paul Pennock as Co-Lead Counsel and appointed each of them as members of the Plaintiff

Executive Committee (PEC). Even prior to their appointment as co-lead counsel, Mr. Arsenault and Mr. Pennock were both central to the effective organization, development and management of the potential Actos litigation leading to the formation of the Actos MDL. Mr. Arsenault participated in every aspect of the litigation both pre-MDL and continues through settlement and implementation of the settlement program. Mr. Arsenault sat as trial counsel through the entire trial alongside trial counsel Mark Lanier and attended trial every day. Mr. Arsenault worked closely with his co-lead, Mr. Pennock at every step of the litigation. Their teamwork, organizational activity and case development and preparation of the first Bellweather case for trial was performed in a seamless and exemplary manner.

Mr. Arsenault devoted all necessary resources of his firm to complete the demands of the litigation. Jennifer Hoekstra, an attorney with his firm contributed greatly to the organizational effort and seamless organization of resources from inception of the MDL through conclusion. Ms. Hoekstra was a valuable resource in the auditing of time and expense.

Mr. Arsenault remains extremely active since settlement playing a key role in the successful implementation of the settlement program. Mr. Arsenault continues to work tirelessly to close out all MDL outstanding issues. Mr. Arsenault and Mr. Pennock were of critical importance to the overall structuring of the PSC. Mr. Arsenault has extensive experience in complex litigation and has served as lead and/or co-lead counsel in numerous cases involving complex litigation. He is a frequent lecturer and presenter at seminars and other educational efforts involving complex litigation across the nation.

Mr. Arsenault also contributed to the organizational and efficient operation of the Actos Resolution Program and maintained consistent and frequent contact with BrownGreer, the Actos claims administrator, and the Garretson Resolution Group on lien resolution. Mr. Arsenault also set up and conducted regular conference calls, as needed, for the Plaintiff Settlement Resolution Committee (PSRC) subsequent to settlement and maintained day to day contact and supervision to ensure the smooth and efficient operation of the settlement program that began making disbursements to claimants earlier rather than later.

In short, under the leadership of Mr. Arsenault and Mr. Pennock, they were at the forefront of the Actos MDL litigation from the filing of the earliest lawsuits, to the formation of the MDL, through the Bellweather process, the settlement process, and they continue to work tirelessly to close all MDL outstanding cases. All assignments given to Mr. Arsenault were performed in a truly timely and exemplary manner reflecting his high degree of skill and expertise in complex litigation. He was critical to the formation of the highly organized structure of the PSC, the seamless trial preparation and the implementation and oversight of the settlement program. Mr. Arsenault and his firm paid all assessments.

Mr. Arsenault and his firm accumulated 37,658.30 hours of audited Common Benefit time. Mr. Arsenault accumulated \$1,231,864.62 in Common Benefit audited expenses.

I recommend an award of \$37,281,717.00 for Common Benefit fees and an award of \$1,231,864.62 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

20. Oliver Law Group, PC (Non PSC) (Alyson Oliver) (Oliver Law Group P.C.)

Ms. Oliver is not a member of the PSC, but was qualified as “participating counsel” through the PSC. She was primarily assigned duties in potential Bellweather selection. Her duties included gathering of information as requested by PSC members.

Ms. Oliver and her firm accumulated 21.50 hours of audited Common Benefit time. Ms. Oliver accumulated \$866.13 in Common Benefit audited expenses.

I recommend an award of \$6,288.75 for Common Benefit fees and an award of \$866.13 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

21. Parker Waichman, LLP (PSC) (Jerrold Parker) (Parker Waichman LLP)

Mr. Parker is a senior partner at Parker Waichman, LLP. He was appointed as a member of the PSC by the Court. Mr. Parker played a significant role in the early stages of the MDL through document review as well as having been instrumental in setting up and monitoring the predictive coding process used by the PSC to enhance the reliability of document production. He and members of his office performed document review, research, proofreading of briefs and provided input into jury selection, witness testimony and cross examination points throughout trial. Mr. Parker has extensive experience in the management of complex litigation. Mr. Parker was instrumental in the development, monitoring and oversight of predicting coding. Mr. Parker attended many of the trial days. Mr.

Parker provided valuable support during trial regarding technical matters and cross-examination of witnesses. Mr. Parker and his firm paid all assessments.

Mr. Parker and his firm had 3,788.05 hours of audited Common Benefit time. Mr. Parker had \$625,356.67 in Common Benefit audited expenses.

I recommend an award of \$3,494,476.13 for Common Benefit fees and an award of \$625,356.67 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

22. Pennock Law Firm, LLC (Non PSC) (Shannon Pennock) (Pennock Law Firm LLC)

Ms. Pennock is not a member of the PSC, but did apply for and receive qualification as “participating counsel”. She was assigned certain research tasks by the PSC and performed all tasks in an exemplary manner.

Ms. Pennock and her firm accumulated 164.50 hours of audited Common Benefit time. Ms. Pennock accumulated \$0.00 in Common Benefit audited expenses.

I recommend an award of \$55,518.75 for Common Benefit fees and an award of \$0.00 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

23. Robinson Calcagnie, Inc. (PSC) (Mark Robinson) (Robinson Calcagnie, Inc.)

Mr. Robinson is a shareholder in Robinson Calcagnie, Inc. He is a member of the PSC. He was appointed by the Court to the Executive Committee. Mr. Robinson has vast experience in managing and trying complex cases and was heavily involved in the California Actos proceedings. He and/or members of his firm performed document review, prepared for depositions, attended and took

depositions and were involved in the Bellweather vetting process. Dan Robinson, a member of the firm, attended the trial and provided information and assistance leading to the successful trial of this matter and performed all work in an exemplary manner. Mark Robinson was designated as the liaison between the Actos MDL and the California Actos proceedings and maintained oversight of the California proceedings.

Mr. Robinson and his firm accumulated 7,126.90 hours of audited Common Benefit time. Mr. Robinson accumulated \$612,282.57 in Common Benefit audited expenses.

I recommend an award of \$2,309,115.60 for Common Benefit fees and an award of \$612,282.57 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

24. Searcy Denney Scarola Barnhart & Shipley, PA (Non PSC) (Calvin Warriner) (Searcy Denney Scarola Barnhart & Shipley, PA)

Mr. Warriner is not a member of the PSC. He performed work on projects as directed by the PSC. He did qualify as “participating counsel” pursuant to the case management orders of the Court. Mr. Warriner has experience in complex litigation matters and provided timely work on all projects assigned.

Mr. Warriner and his firm accumulated 112.10 hours of audited Common Benefit time. Mr. Warriner accumulated \$0.00 in Common Benefit audited expenses.



I recommend an award of \$37,833.75 for Common Benefit fees and an award of \$0.00 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

25. Seeger Weiss, LLP (Chris Seeger) (PSC) (Seeger Weiss LLP)

Mr. Seeger is a partner in the law firm of Seeger Weiss, LLP. He is a member of the PSC. He is a highly experienced member of the complex litigation bar and has managed and/or participated as lead counsel, co-lead counsel and served on many steering committees in his career. Mr. Seeger and his firm were assigned certain work projects by the PSC and performed all of these projects in a timely and exemplary manner. He did not attend the trial. He and members of his firm have been active in post-settlement implementation of the Master Settlement Agreement and working with the Claims Administrator.

Mr. Seeger and his firm accumulated 2,185.70 hours of audited Common Benefit time. Mr. Seeger accumulated \$524,504.15 in Common Benefit audited expenses.

I recommend an award of \$983,565.00 for Common Benefit fees and an award of \$524,504.15 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

26. Sill Law Group, PLLC (PSC) (Tara Tabatabaie) (Sill Law Group, PLLC)

Ms. Tabatabaie is an attorney and Ph.D. with the Sill Law Group, PLLC. She is a member of the PSC. Ms. Tabatabaie has an extensive background in science and played an important role in developing the science relating to Actos. Likewise, Ms. Tabatabaie spent an extensive amount of time developing experts

and their reports and was central to providing the PSC with information regarding defense experts. She performed all tasks requested by the PSC in an exemplary manner. She was also involved in document review, assessment and analysis of various studies on Actos and was important to the development of the scientific evidence used in direct and cross examination of experts.

Ms. Tabatabaie and her firm accumulated 2,122.70 hours of audited Common Benefit time. Ms. Tabatabaie accumulated \$561,192.42 in Common Benefit audited expenses. Ms. Tabatabaie and her firm paid all assessments.

I recommend an award of \$1,002,975.75 for Common Benefit fees and an award of \$561,192.42 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

27. Simmons Hanly & Conroy, LLC (PSC) (Jayne Conroy) (Simmons Hanly Conroy)

Ms. Conroy is currently a partner at Simmons, Hanly and Conroy. By way of history, she was previously appointed to the PSC while a partner at Hanly Conroy. Hanly Conroy subsequently merged with Simmons Law Firm, to now be known as Simmons, Hanly Conroy. Ms. Conroy engaged in extensive document review and assisted with the preparation of expert reports and providing invaluable advice to the PSC based on her extensive experience in complex litigation. All assignments given to Ms. Conroy were performed in a timely and exemplary manner reflecting her high degree of skill and expertise in complex litigation. Ms. Conroy and her firm paid all assessments.

Ms. Conroy and her firm accumulated 5,090.34 hours of audited Common Benefit time. Ms. Conroy accumulated \$572,722.19 in Common Benefit audited expenses.

I recommend an award of \$2,634,250.95 for Common Benefit fees and an award of \$572,722.19 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

28. Singleton Law Firm, PC (PSC) (James “Willie” Singleton) (The Singleton Law Firm)

Mr. Singleton is the owner of the Singleton Law Firm in Shreveport, Louisiana. He is a member of the PSC. He has extensive experience in complex litigation cases. The Court appointed him as Pro Se Liaison. Mr. Singleton performed his job in a timely and exemplary manner in both managing issues relating to Pro Se plaintiffs as well as communicating with Pro Se plaintiffs extensively and maintaining open lines of communication with Pro Se Plaintiffs. Mr. Singleton worked closely with Magistrate Judge Patrick Hanna to ensure orderly and timely communication with transparency of the court proceedings to Pro Se Plaintiffs. He was assigned numerous projects and did an exemplary job on every project. Mr. Singleton attended every status conference in person and reported the status of his work to the Court at almost all of the status conferences. Mr. Singleton was always available for phone calls, conferences, and assignments and performed all tasks within the given timetable assigned. Mr. Singleton and his firm paid all assessments.

Mr. Singleton and his firm accumulated 1,421.92 hours of audited Common Benefit time. Mr. Singleton accumulated \$565,214.69 in Common Benefit audited expenses.

I recommend an award of \$799,830.00 for Common Benefit fees and an award of \$565,214.69 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

29. Skikos, Crawford, Skikos, & Joseph, LLP (Non PSC) (Steven Skikos) (Skikos, Crawford, Skikos & Joseph)

Mr. Skikos is not a member of the PSC but did qualify as participating counsel and was in a leadership role in the California JCCP. Mr. Skikos was instrumental in having the California JCCP participate in the Actos MDL settlement program.

Mr. Skikos performed exemplary work through his valued assistance in developing the MSA and seeing it through implementation.

Mr. Skikos and his firm accumulated 108.90 hours of audited Common Benefit time. Skikos Crawford & Skikos accumulated \$8,621.13 in Common Benefit audited expenses.

I recommend an award of \$53,905.50 for Common Benefit fees and an award of \$8,621.13 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

30. Wagstaff & Cartmell (Non PSC) (Thomas Cartmell) (Wagstaff & Cartmell, LLP)

Mr. Thomas Cartmell is not a member of the PSC but did qualify as participating counsel. Mr. Cartmell was assigned various tasks such as research and document review and performed these tasks in a timely and thorough manner.

Mr. Cartmell and his firm accumulated 50.10 hours of audited Common Benefit time. Wagstaff Law accumulated \$75.00 in Common Benefit audited expenses.

I recommend an award of \$14,654.25 for Common Benefit fees and an award of \$75.00 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

31. Weitz & Luxenberg, PC (PSC and Co-Lead Counsel) (Paul Pennock) (Weitz & Luxenberg PC)

Mr. Pennock is a partner at Weitz and Luxenberg and is member of the PSC. The Court appointed Mr. Arsenault and Mr. Paul Pennock as Co-Lead Counsel and approved each of them as members of the Plaintiff Executive Committee (PEC). Even prior to their appointment as co-lead counsel, Mr. Arsenault and Mr. Pennock were both central to the effective organization, development and management of the potential Actos litigation leading to the formation of the Actos MDL. Mr. Pennock participated in every aspect of the litigation both pre-MDL and continues through settlement and implementation of the settlement program. Mr. Pennock sat as trial counsel through many days of the trial. Mr. Pennock worked closely with his co-lead, Mr. Arsenault at every step of the litigation. Their teamwork, organizational activity and case development and preparation of the first

Bellweather case for trial was performed in a seamless and exemplary manner. Mr. Pennock devoted the necessary resources of his firm to complete the demands of the litigation.

Mr. Pennock remains extremely active since settlement playing a key role in the successful implementation of the settlement program. Mr. Pennock continues to work tirelessly to close out all MDL outstanding issues. Mr. Pennock and Mr. Arsenault were of critical importance to the overall structuring of the PSC. Mr. Pennock has extensive experience in complex litigation and has served as lead and/or co-lead counsel in numerous cases involving complex litigation. He is a frequent lecturer and presenter at seminars and other educational efforts involving complex litigation across the nation.

Mr. Pennock also contributed to the organizational and efficient operation of the Actos Resolution Program.

In short, under the leadership of Mr. Pennock and his firm, he was at the forefront of the Actos MDL litigation from the filing of the earliest lawsuits, to the formation of the MDL, through the Bellweather process, the settlement process, and continues to work tirelessly to close all MDL outstanding cases. All assignments given to Mr. Pennock were performed in a truly timely and exemplary manner reflecting his high degree of skill and expertise in complex litigation. He was critical to the seamless trial presentation.

Even prior to their appointment as co-lead counsel, Mr. Pennock and Mr. Arsenault were central to the effective organization, development and management of the potential Actos litigation leading to the formation of the Actos MDL. His

work began prior to the formation of the MDL and his efforts were represented by substantial expenditures and expenses. Mr. Pennock was involved on almost a daily basis in every aspect of this litigation along with Mr. Arsenault. Mr. Pennock and Mr. Arsenault provided exemplary management styles and techniques, though different from each other, which resulted in the success of the Actos MDL. Mr. Pennock attended many days of trial in Lafayette, Louisiana and constantly provided input throughout those days. He remained actively involved in all aspects of the case after trial and remained actively involved through settlement and distribution of funds. Mr. Pennock worked closely with his co-lead, Mr. Arsenault, at every step of the litigation. The collaboration effort between the two was extraordinary and was performed in an exemplary manner. All of his tasks were performed in an exemplary manner in preparation for trial and post-trial implementation of the MSA. He has maintained an active role in the disbursement process.

Jonathan Sedge, a member of the firm provided valued assistance in the organizational structure of the case and provided research for various legal issues. His work and dedication were important to the success of the MDL.

Mr. Pennock and his firm paid all assessments.

Mr. Pennock and his firm accumulated 39,523.56 hours of audited Common Benefit time. Mr. Pennock accumulated \$1,400,502.07 in Common Benefit audited expenses.

I recommend an award of \$35,571,204.00 for Common Benefit fees and an award of \$1,400,502.07 for Common Benefit expenses (inclusive of assessments, held expenses and held shared expenses).

#### OVERALL OBSERVATIONS

As a result of my appointment and assignment by the court, I have been given a unique opportunity that has allowed me to experience hands on an overview as to the organization, work effort and resources which must be employed to develop the seamless trial presentation and successful settlement that occurred in the Actos MDL. The MDL represents an extraordinary example of a Court engaging in new and innovative techniques for the management of an MDL. Both plaintiff and defense attorneys were able to perform their work in an efficient and thorough manner so that they could achieve a swift and conclusive result for their respective clients.

Every firm and attorney who was on the PSC and/or who was designated as “participating counsel” was provided a full and transparent opportunity to perform Common Benefit work and incur Common Benefit expenses and to have their work product submissions reviewed in close proximity to its performance of the task. Thirty-one firms consisting of the PSC and firms who applied to be qualified as “participating counsel” submitted Common Benefit time and expense. Although the submission of time and expense as required by the case management orders required additional work effort by attorneys and their staff, it has provided a thorough, transparent and full opportunity to all interested attorneys to perform work in a controlled environment. This ultimately led to a very successful settlement and most of all it ultimately provided relatively quick resolution for claimants.



CONCLUSIONS

For the foregoing reasons, I recommend the Common Benefit attorney fees be allocated and paid in the following amounts:

1) Alystock Witkin Kreis Overholtz (AWKO Actos 2016 QSF Trust)	\$16,130,795.18
2) Andrews Thornton (Andrews & Thornton Attorneys at Law State Bar of California)	\$93,551.85
3) Andrus Hood & Wagstaff (Andrus Wagstaff P.C.)	\$479,653.20
4) Barrios Kingsdorf & Casteix (Barrios, Kingsdorf & Casteix, LLP)	\$985,320.45
5) Baum Hedlund (Baum, Hedlund, Aristei & Goldman PC)	\$797,458.50
6) Beasley Allen (Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.)	\$5,668,953.75
7) Climaco Wilcox Peca Tarantino (Climaco, Wilcox, Peca & Garofoli Co., LPA)	\$628,458.75
8) Derriel C. McCorvey (McCorvey Law, LLC)	\$6,412.50
9) Douglas & London (Douglas & London P.C.)	\$13,139,522.33
10) Drakulich Law Firm (Drakulich Firm A Professional Law Corp.)	\$7,103,872.35
11) Girard Gibbs (Girard Gibbs LLP)	\$2,018,830.28
12) Kershaw Cutter & Ratinoff (Cutter Law)	\$309,386.25
13) Lanier Law Firm (The Lanier Law Firm PC)	\$15,230,752.65

14) Lief Cabraser Heimann & Bernstein (Lief Cabraser Heimann & Bernstein LLP)	\$2,479,869.00
15) Levin Papantonio Thomas Mitchell Rafferty & Proctor (Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.)	\$2,905,976.70
16) Morrow Morrow Ryan & Bassett (Morrow, Morrow, Ryan & Bassett)	\$12,051,701.10
17) Murray Law Firm (Stephen B. Murray d/b/a Murray Law Firm)	\$2,488,887.00
18) Nast Law (NastLaw LLC/Dianne M. Nast)	\$133,350.75
19) Neblett Beard & Arsenault (Neblett, Beard & Arsenault)	\$37,281,717.00
20) Oliver Law (Oliver Law Group P.C.)	\$6,288.75
21) Parker Waichman (Parker Waichman LLP)	\$3,494,476.13
22) Pennock Law Firm (Pennock Law Firm LLC)	\$55,518.75
23) Robinson Calcagnie Robinson Shapiro Davis (Robinson Calcagnie, Inc.)	\$2,309,115.60
24) Searcy Denney Scarola Barnhart & Shipley (Searcy Denney Scarola Barnhart & Shipley, PA)	\$37,833.75
25) Seeger Weiss (Seeger Weiss LLP)	\$983,565.00
26) Sill Law Group (Sill Law Group, PLLC)	\$1,002,975.75
27) Simmons Hanly Conroy (Simmons Hanly Conroy)	\$2,634,250.95
28) Singleton Law Firm (The Singleton Law Firm)	\$799,830.00

29) Skikos Crawford & Skikos (Skikos, Crawford, Skikos & Joseph)	\$53,905.50
30) Wagstaff Law (Wagstaff & Cartmell, LLP)	\$14,654.25
31) Weitz & Luxenberg (Weitz & Luxenberg PC)	\$35,571,204.00

For the foregoing reasons, I recommend Common Benefit expenses be allocated and paid in the following amounts:

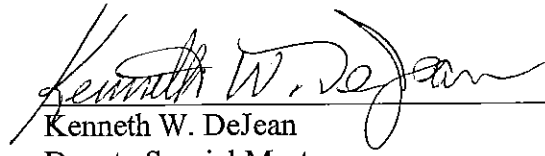
1) Alystock Witkin Kreis Overholtz (AWKO Actos 2016 QSF Trust)	\$1,177,326.60
2) Andrews Thornton (Andrews & Thornton Attorneys at Law State Bar of California)	\$0.00
3) Andrus Hood & Wagstaff (Andrus Wagstaff P.C.)	\$588,880.27
4) Barrios Kingsdorf & Casteix (Barrios, Kingsdorf & Casteix, LLP)	\$423,498.90
5) Baum Hedlund (Baum, Hedlund, Aristei & Goldman PC)	\$27,560.14
6) Beasley Allen (Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.)	\$681,099.90
7) Climaco Wilcox Peca Tarantino (Climaco, Wilcox, Peca & Garofoli Co., LPA)	\$25,669.43
8) Derriel C. McCorvey (McCorvey Law, LLC)	\$0.00
9) Douglas & London (Douglas & London P.C.)	\$865,941.67
10) Drakulich Law Firm (Drakulich Firm A Professional Law Corp.)	\$406,324.46

11) Girard Gibbs (Girard Gibbs LLP)	\$559,720.79
12) Kershaw Cutter & Ratinoff (Cutter Law)	\$5,426.26
13) Lanier Law Firm (The Lanier Law Firm PC)	\$888,718.82
14) Lieff Cabraser Heimann & Bernstein (Lieff Cabraser Heimann & Bernstein)	\$630,848.62
15) Levin Papantonio Thomas Mitchell Rafferty & Proctor (Levin, Papantonio, Thomas, Mitchell, Rafferty & Proctor, P.A.)	\$673,483.85
16) Morrow Morrow Ryan & Bassett (Morrow, Morrow, Ryan & Bassett)	\$1,018,334.79
17) Murray Law Firm (Stephen B. Murray d/b/a Murray Law Firm)	\$567,901.59
18) Nast Law (NastLaw LLC/Dianne M. Nast)	\$211,947.64
19) Neblett Beard & Arsenault (Neblett, Beard & Arsenault)	\$1,231,864.62
20) Oliver Law (Oliver Law Group P.C.)	\$866.13
21) Parker Waichman (Parker Waichmann LLP)	\$625,356.67
22) Pennock Law Firm (Pennock Law Firm LLC)	\$0.00
23) Robinson Calcagnie Robinson Shapiro Davis (Robinson Calcagnie, Inc.)	\$612,282.57
24) Searcy Denney Scarola Barnhart & Shipley (Searcy Denney Scarola Barnhart & Shipley, PA)	\$0.00
25) Seeger Weiss (Seeger Weiss LLP)	\$524,504.15


26) Sill Law Group (Sill Law Group, PLLC)	\$561,192.42
27) Simmons Hanly Conroy (Simmons Hanly Conroy)	\$572,722.19
28) Singleton Law Firm (The Singleton Law Firm)	\$565,214.69
29) Skikos Crawford & Skikos (Skikos, Crawford, Skikos & Joseph)	\$8,621.13
30) Wagstaff Law (Wagstaff & Cartmell, LLP)	\$75.00
31) Weitz & Luxenberg (Weitz & Luxenberg PC)	\$1,400,502.07

It is further recommended that the outstanding invoices to the PSC from Law & Forensics be paid in the sum of \$259,635.00 representing expert fees that remain due and owing and further that this amount be paid to the PSC account from which shared expenses are paid and that the PSC be directed to pay Law & Forensics.

Signed this 14<sup>th</sup> day of July, 2017 at Lafayette, Louisiana.

  
Kenneth W. DeJean  
Deputy Special Master

RECEIVED

JUL 17 2017 

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

**IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION**

**MDL No. 6:11-md-2299**

**JUDGE DOHERTY**

**This Document Applies to:  
All Cases**

**MAGISTRATE JUDGE HANNA**

**ORDER**

In consideration of this Court's Memorandum Ruling of July 17, 2017,

IT IS HEREBY ORDERED the Special Master will notify the Garretson Group when the Memorandum Ruling has become effective; immediately thereafter, the Garretson Group is ORDERED to distribute from the amounts previously withheld, the amounts identified as common benefit fees and expenses (inclusive of assessments, held expenses, and held shared expenses) awarded, to the firms and/or accounts as described in the Memorandum Ruling. The Garretson Group is, also, ordered to pay \$259,635.00 to the PSC account, and the PSC is ORDERED to pay that amount to Law & Forensics as soon as reasonably possible thereafter.

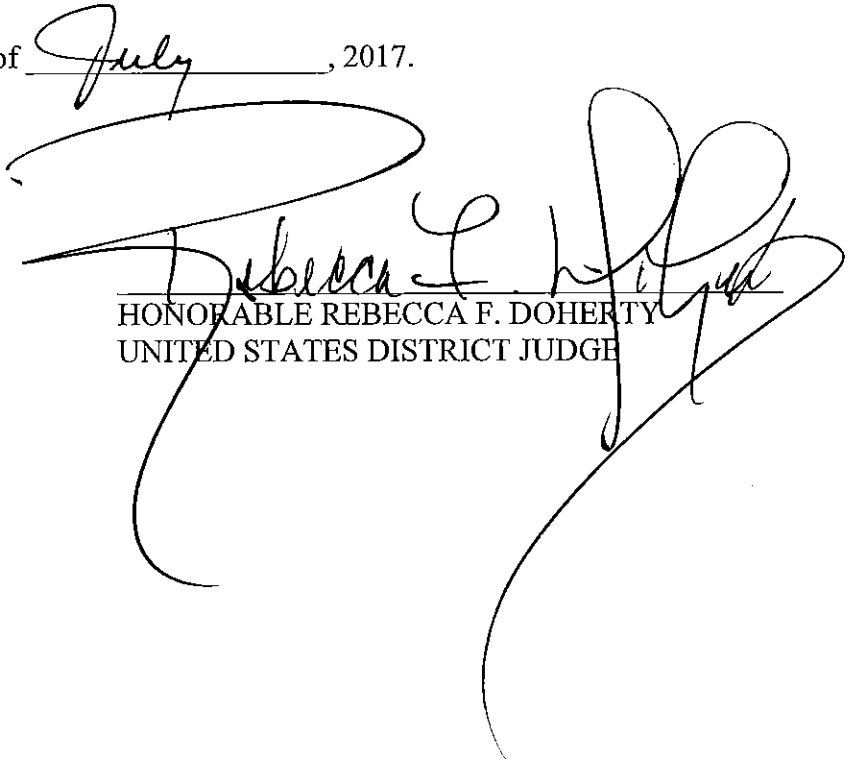
The Garretson Group is, also, ORDERED to distribute the agreed upon amounts set out in any separate agreements, *i.e.*, state court or other Actos® matters, that will be identified by the Special Master, which might have been submitted to BrownGreer and/or the Garretson Group by way of independent agreement.

Any funds that remain for the purpose of compensating common benefit fees and expenses and/or costs in excess of the distributions described above shall continue to be retained for the purpose of compensating any further common benefit fees and expenses and/or costs incurred through the final resolution of the Settlement Program. The Garretson Group is to retain these

remaining funds pending further order of this Court, and is to provide weekly updates on the status of the common benefit distributions to Special Master Russo and/or Deputy Special Master DeJean.

Upon the final resolution of the Settlement Program, any remaining funds retained to compensate common benefit *expenses and/or costs* shall be paid to those claimants who received payments under the Settlement Program, on a *pro rata* basis. Any funds retained to compensate common benefit work that might remain at the conclusion of this matter will be addressed by the Court at that time.


SIGNED this 17 day of July, 2017.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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JUN 15 2017



TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

This Document Applies To:  
*All Cases*

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**ORDER**

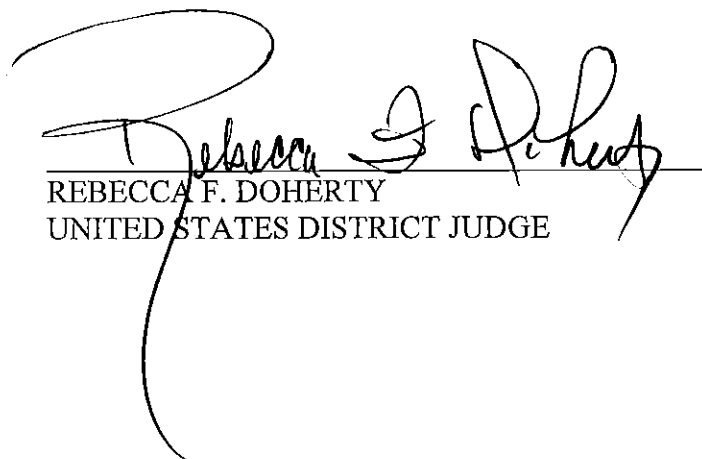
On April 15, 2016, this Court issued a “Case Management Order Regarding Approval of Settled Actions and Settled Claims Involving Death or Incapacity of a Product User” [Rec. Doc. 6314] (“the CMO”). The CMO established procedures whereby a claimant can both notify the Court that a settlement had been reached in a case involving the death or incapacity of an Actos® user and request a report and recommendation on approval by this Court of the terms of that settlement. This procedure has proved to be quite efficient, with more than 100 claimants having moved for approval of their settlements, and this Court has adopted Magistrate Judge Hanna’s recommendations that each of them be approved. Counsel for all parties have indicated to this Court that it is expected all or nearly all claimants in cases involving the death or incapacity of an Actos® user have reached settlements with the defendants, and either have filed or shortly will file motions for approval thereof. Consequently, the Court hereby sets the following deadline for any remaining such motions.

IT IS HEREBY ORDERED any motion for approval of settlement terms in a case involving the death or incapacity of an Actos® user, submitted pursuant to “Case Management Order Regarding Approval of Settled Actions and Settled Claims Involving Death or Incapacity



of a Product User" [Rec. Doc. 6314], must be filed with the Court no later than **4:00 p.m. (central time) on July 31, 2017.**

THUS DONE AND SIGNED in Lafayette, Louisiana, this 15 day of June, 201~~6~~<sup>7</sup>.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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JUL 18 2016

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TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER**

IT IS HEREBY ORDERED Section II of this Court's Second Amended Case Management Order: Direct Filing and Service of Process [Rec. Doc. 1538], addressing and allowing the direct filing of cases in these MDL proceedings, is hereby RESCINDED and VACATED, and is therefore no longer applicable.

IT IS FURTHER ORDERED this Court's Order of May 10, 2016 [Rec. Doc. 6369] shall be STRICKEN.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 18<sup>th</sup> day of July, 2016.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

U.S. DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
RECEIVED

APR 15 2016

TONY R. MOORE, CLERK  
BY  DEPUTY

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE: ACTOS (PIOGLITAZONE) )  
PRODUCTS LIABILITY )  
LITIGATION )

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

This Document Applies to: )  
)  
ALL CASES )  
/

**CASE MANAGEMENT ORDER REGARDING APPROVAL OF  
SETTLED ACTIONS AND SETTLED CLAIMS INVOLVING  
DEATH OR INCAPACITY OF A PRODUCT USER**

This Cause comes before the Court upon the Parties Joint Motion for Entry of a Case Management Order Relating to Approval and Dismissal of Settled Actions and Settled Claims Involving Death or Incapacity of a Product User (DE 6305). The Court has reviewed the Motion and is otherwise fully informed of the premises. Accordingly, it is

ORDERED and ADJUDGED that the Motion be and is hereby  
GRANTED as follows:

The purpose of this Order is to establish modified procedures for ensuring timely Court notification and prompt approval and dismissal of claims involving deceased or incapacitated claimants. These comprehensive procedures will allow the Court to exercise appropriate control of its docket while aiding the Parties' ability to complete the settlement process. This Order applies to all Parties as defined by the Actos (Pioglitazone) Product Liability Litigation Master Settlement Agreement ("Actos Resolution Program").

When all claims of a deceased or incapacitated Actos<sup>1</sup> user in a particular action settle, Plaintiff may file a Motion for Report and Recommendation to Approve Settlement attached as Exhibit B with Magistrate Judge Hanna. Upon review of the Motion, Magistrate Judge Hanna will issue a Report and Recommendation attached as Exhibit C. If no objection to the Report and Recommendation is filed within 10 days of entry, the Report and Recommendation will become an Order. Any objections to the Report and Recommendation shall be referred to Judge Doherty. Any objections shall be submitted, in writing, directly to Chambers and not into the record, no later than ten (10) days after entry of Magistrate Judge Hanna's Report and Recommendation.

DONE AND ORDERED in Chambers, at Lafayette, Louisiana, this 15 day of April, 2016.



REBECCA J. DOHERTY  
UNITED STATES DISTRICT JUDGE

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<sup>1</sup> Actos®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, or pioglitazone (“Actos”)

**EXHIBIT B**

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

**IN RE: ACTOS (PIOGLITAZONE)** )  
**PRODUCTS LIABILITY** )  
**LITIGATION** )

**MDL No. 6:11-md-2299**

**JUDGE DOHERTY**

**MAGISTRATE JUDGE HANNA**

This Document Applies to: )

ALL CASES )

**UNOPPOSED MOTION FOR REPORT AND RECOMMENDATION APPROVING  
SETTLEMENT AS TO CLAIMS OF DECEDENT,**

Plaintiffs, [all derivative claimants and PR], individually and as legal heirs of the Estate of Actos User, and Defendants Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals U.S.A., Inc. (collectively, "Takeda"), have reached a settlement agreement as to any and all claims of [all derivative claimants and PR], related in any way to the [Name of Decedent]'s use of Actos<sup>1</sup>.

The law of Plaintiffs' decedent's domicile requires that a compromise of the type of claims asserted by the Plaintiffs in this case be approved by a court of competent jurisdiction. Because this Court has specific knowledge as to (1) the status of the Actos Multi District Litigation generally, (2) the claims raised in this individual case, and (3) the parties' efforts to settle Actos actions in these proceedings, Plaintiffs assert that this Court

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<sup>1</sup> Actos®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, or pioglitazone ("Actos")

is best situated to approve the settlement of the Administrator's claims. As a result, Plaintiffs now request that this Court approve the settlement and issue the attached Order.

Specifically, Plaintiffs [all derivative claimants and PR], have executed a Release, Indemnity and Assignment Agreement ("Agreement") in which each settled all claims brought on behalf of the Estate of DECEDENT. Plaintiffs, through their undersigned counsel, represent to the Court that each was fully advised of the risks and benefits of pursuing these claims to trial and, after due consideration, Plaintiffs voluntarily entered into the Agreement.

The settlement reached herein between [all derivative claimants and PR] and Takeda, is just, fair, and reasonable, and in the best interests of all persons entitled to pursue an action for injury or wrongful death under the circumstances.

Proper notice has been given to all eligible persons entitled to recovery of damages for the death of Decedent.

WHEREFORE, Plaintiffs respectfully request that the Court order them to collect and receipt for payment of the settlement proceeds; to deduct and pay the expenses of recovery and collection of the settlement proceeds and the attorney's fees as contracted; to acknowledge satisfaction in whole for the settlement proceeds; and to distribute the net proceeds as ordered by the Court.

The attorneys' fees are fair and reasonable under the circumstances.

WHEREFORE, Plaintiffs pray this Court enter its Order

(a) approving the settlement between [all derivative claimants and PR] and Takeda as being fair and reasonable and in the best interest of the beneficiaries;

(b) approving the settlement as full and complete settlement between [all derivative claimants and PR] and Takeda;

(c) distributing the proceeds of the settlement to [all derivative claimants and PR];  
and

(d) distributing attorney's fees pursuant to the agreement entered into between [all derivative claimants and PR] and their attorneys.

As required by this Court's Local Rules, counsel for Plaintiffs hereby certify that counsel for Plaintiff conferred in good faith with counsel for all parties who may be affected by the relief sought in the motion, and has been advised that this motion is unopposed.

Dated:

**EXHIBIT C**

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

<b>IN RE: ACTOS (PIOGLITAZONE)</b>	)	
<b>PRODUCTS LIABILITY</b>	)	<b>MDL No. 6:11-md-2299</b>
<b>LITIGATION</b>	)	
	)	<b>JUDGE DOHERTY</b>
	)	
	)	<b>MAGISTRATE JUDGE HANNA</b>
This Document Applies to:	)	
	)	
<b>ALL CASES</b>	)	
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**REPORT AND RECOMMENDATION ON UNOPPOSED MOTION FOR APPROVAL OF SETTLEMENT AS TO CLAIMS OF DECEDENT.**

This Court, having reviewed Plaintiff's Unopposed Motion To Approve Settlement as to Claims of [all derivative claimants and PR] [DE XYZ], the parties having received due notice and having had the opportunity to be heard, and this Court having considered all submissions made, I recommend to the Court that the Motion be

**GRANTED, and**

The settlement by and between the Plaintiffs, [all derivative claimants and PR], individually and as legal heirs to the Estate of Decedent and Defendants Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals U.S.A., Inc. (collectively, "Takeda"), as noticed to the Court on \_\_\_\_\_, be

**APPROVED.**

**ANY PARTY OBJECTING TO THIS RECOMMENDATION SHALL SUBMIT OBJECTIONS, IN WRITING, DIRECTLY TO JUDGE DOHERTY'S CHAMBERS – AND SHALL NOT FILE THE OBJECTION INTO THE RECORD – NO LATER THAN TEN (10) DAYS AFTER ENTRY OF THIS RECOMMENDATION.**



If there is no objection within ten (10) days of entry of this Recommendation, the Recommendation will become an Order.

This is DONE AND SIGNED in Lafayette, Louisiana, this \_\_\_\_\_ day of \_\_\_\_\_, 2016.

\_\_\_\_\_  
HONORABLE PATRICK J. HANNA  
UNITED STATES MAGISTRATE JUDGE

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FEB 29 2016

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**ASSESSMENT OF COMMON BENEFIT FEES AND EXPENSES AND/OR COSTS**

On September 1, 2015, this Court issued its Case Management Order: Holdback Order (“Holdback Order”).<sup>1</sup> In that Order, the Court laid out the contractual and jurisprudential bases for its authority to impose an assessment on payments made pursuant to the Master Settlement Agreement (“MSA”) to compensate the common benefit fees and expenses and/or costs that have been incurred in the MDL. The Holdback Order also described the procedural devices that were established at the beginning of this MDL to maintain accurate records of all common benefit work properly performed. Based on an evaluation of aggregate information as to common benefit fees and expenses and/or costs – provided by counsel in accordance with the aforementioned procedural devices, and collected by Deputy Special Master DeJean<sup>2</sup> – the Court created holdback funds in amounts sufficient to reimburse the common benefit fees and expenses and/or costs incurred since inception of this MDL through the administration of the Master Settlement Agreement.

On February 16, 2016, this Court issued its Case Management Order: Common Benefit Fees and Costs.<sup>3</sup> There, based on further evaluation of the information available, this Court indicated its intent to impose assessments, in the amount and percentage given in the Holdback

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<sup>1</sup> Rec. Doc. 5850.

<sup>2</sup> See Case Management Order: Instructions to Deputy Special Master DeJean. Rec. Doc. 5801

<sup>3</sup> Rec. Doc. 6215.

Order, on all payments made pursuant to the MSA and on the Qualified Settlement Fund itself, to compensate common benefit fees and expenses and/or costs. The Order, furthermore, provided an opportunity for Plaintiffs and Counsel to file briefs laying out any meaningful objections to such an assessment. The deadline for filing any such objections has passed, and none were received by this Court, nor conveyed to this Court by way of the Special Masters.

Considering this Court's authority to impose an assessment to compensate common benefit attorneys' fees and expenses and/or costs in this MDL, the information provided to the Court detailing the common benefit fees and expenses and/or costs incurred to this point and estimations of those to be incurred in the future, and the lack of objection to this Court's stated intent to impose such an assessment at specified levels,

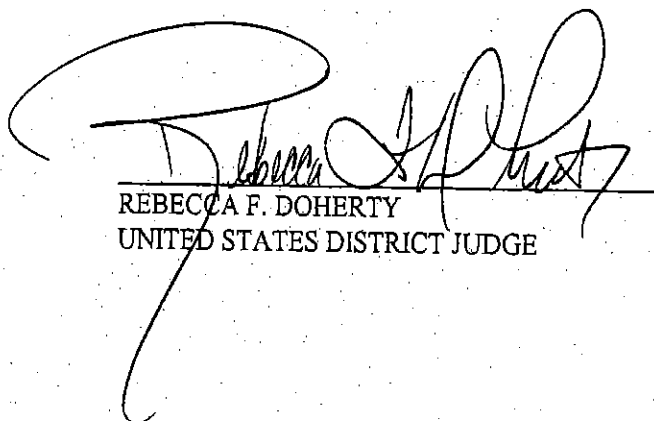
IT IS HEREBY ORDERED 8.6% of any payments made pursuant to the terms of the Master Settlement Agreement shall be retained for the purposes of compensating common benefit attorneys' fees. Such funds shall be maintained in the manner contemplated by the MSA and related agreements.

These funds shall not constitute the separate property of any party or attorney, or be subject to garnishment or attachment for the debts of any party or attorney, and will not be distributed or disbursed except when and as so directed by court order. None of such funds may be disbursed, expended, withdrawn, removed, or released for any purpose whatsoever without written permission of this Court. All funds shall be held in such a fashion that the source of each amount withheld can be readily identified.

IT IS HEREBY FURTHER ORDERED \$25,000,000.00 shall be retained from the Qualified Settlement Fund for the purpose of compensating common benefit expenses and/or costs. That amount shall be maintained in the manner contemplated by the MSA and related agreements.

These funds shall not constitute the separate property of any party or attorney, or be subject to garnishment or attachment for the debts of any party or attorney, and will not be distributed or disbursed except when and as so directed by court order. None of such funds may be disbursed, expended, withdrawn, removed, or released for any purpose whatsoever without written permission of this Court. All funds shall be held in such a fashion that the source of each amount withheld can be readily identified.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 29 day of February, 2016.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

FEB 16 2016

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

This Document Applies To:  
*All Cases*

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**COMMON BENEFIT FEES AND COSTS**

By Order dated September 1, 2015, this Court issued its Case Management Order: Holdback Order ["Holdback Order"].<sup>1</sup> In the Holdback Order, this Court:

- conducted a preliminary analysis of the jurisprudence that authorizes courts overseeing complex litigation in which a large group of plaintiffs receive significant benefits as a result of the efforts of counsel who do not represent them individually, and authorizes such courts to provide remuneration to those attorneys whose efforts have resulted in such common benefits;
- evaluated the aggregate common fees and costs information that had, by that point, been collected by Special Master DeJean pursuant to this Court's program of instructions related to common benefit fees and costs,<sup>2</sup> estimated the amount of funds that would be required to reimburse common benefit work done in the MDL through the administration of the Master Settlement Agreement, and
- established two holdback orders:

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<sup>1</sup> Rec. Doc. 5850.

<sup>2</sup> See "Order Appointing Special Masters" [Rec. Doc. 532], "Case Management Order: PSC's Management of Timekeeping, Cost Reimbursement and Related Common Benefit Issues" [Rec. Doc. 1357], "Case Management Order: Claims for Common Benefit Fees and Expenses" [Rec. Doc. 2356], and "Order Regarding Special Masters" [Rec. Doc. 4264].

- a holdback of 8.6% from any payments made to any party pursuant to the terms of the Master Settlement Agreement for the purpose of establishing a fund from which to compensate counsel (i) whose efforts resulted in common benefits to the claimants participating in the Settlement Process and (ii) who have complied with this Court's orders for making a claim for such remuneration, and
- a holdback of \$25,000,000 from those payments subject to an MDL expense and/or cost assessment for the purpose of establishing a fund from which to reimburse expenses and/or costs incurred by counsel (i) whose efforts resulted in common benefits to the claimants participating in the Settlement Process and (ii) who have complied with this Court's orders for making a claim for such reimbursement.

At this Court's request, Special Master DeJean has recently provided updated aggregate information about fee claims and expenses/cost claims he has evaluated to date. It appears to this Court that the amounts established in the Holdback Order – 8.6% for payment of fee claims and \$25,000,000 to pay expense/cost claims – will establish sufficient funds to provide the reimbursement and compensation goals discussed in the Holdback Order.

Having reviewed additional relevant facts and jurisprudence, this Court intends to issue a final order allocating 8.6% of all payments made pursuant to the Master Settlement Agreement for use to compensate attorneys whose efforts have yielded common benefits to the larger group of plaintiffs and who have complied with this Court's orders for making a claim for such remuneration. Moreover, this Court intends to issue a final order allocating \$25,000,000 of the settlement funds paid by the Defendants pursuant to the Master Settlement Agreement for use in reimbursing costs and/or expenses incurred by counsel for the common benefit of the larger

group of plaintiffs if, but only if, counsel have complied with this Court's instructions for submitting such reimbursement claims.

Considering the foregoing,

IT IS HEREBY ORDERED that any Counsel or Plaintiff who has a *meaningful objection* to the entry of such a Common Benefit Order in this matter shall be permitted to brief such objection. Any such brief is limited to 10 pages in length and must be filed *no later than ten (10) days after the date this Order is entered*. Counsel are advised that no extensions of this deadline will be granted absent good cause shown. For purposes of such extensions, the failure to read and calendar the deadline in this Order will not be deemed "good cause." No responsive brief or reply brief will be permitted; should the Court find a response is necessary, an opportunity to respond will be afforded by the Court.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 16<sup>th</sup> day of February, 2016.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
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JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**ORDER**

Pursuant to consultation with the Special Master, and by the request of both parties, the Plaintiffs' Steering Committee and Defendants,

IT IS HEREBY ORDERED the status conference scheduled for February 18, 2016 is **CANCELLED**. The Court will, however, schedule meetings of a select working group for **the afternoon of Wednesday, April 20 and all day Thursday, April 21, 2016**. The parties required to attend will be notified by the Special Master after consultation with the parties and with the Court. Attendees should anticipate being available for the afternoon of Wednesday, April 20, and the entirety of Thursday, April 21, into the evening should it be required. An agenda for the meetings will be determined by the Court in consultation with the Special Master and will be provided to the parties a reasonable time before the scheduled meetings.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 6 day of January, 2016.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE



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DEC 16 2015



TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER REGARDING PROTOCOL INVOLVING DISPUTES  
BEFORE OTHER UNITED STATES DISTRICT COURTS  
CONCERNING ENFORCEMENT OF SUBPOENAS**

The Court, having been made aware of issues concerning objections to, or enforcement of, certain Rule 45 subpoenas issued by other United States District Courts, hereby ORDERS as follows:

In the event that a Party to the above-captioned litigation pursues an enforcement action in the district where the subpoena was issued; the Party seeking to enforce compliance with the subpoena is directed by this Court to reference this Order in its own filing made in the district where the subpoena was issued, and attach a copy of this Order to said filing. The purpose of this Order is to ensure that any District Court where a Party to the Actos (Pioglitazone) Products Liability Litigation seeks to enforce a subpoena issued by that Court is informed that:

1. The subpoena in dispute was issued in connection with the cases comprising the Actos (Pioglitazone) Products Liability Litigation consolidated for pretrial purposes in this Court by Order of the Judicial Panel on Multidistrict Litigation dated December 29, 2011.

2. The discovery disputes that arise in connection with the Actos (Pioglitazone) Products Liability Litigation involve complex issues whose resolution by various district courts risks inconsistent results and frustration of the goals of judicial economy and efficiency served by consolidation for pretrial purposes.

3. This Court is not only willing but prefers to hear and resolve all discovery disputes that arise in any other United States District in connection with the Actos (Pioglitazone)

Products Liability Litigation. This Court can accomplish this in accordance with the provisions of Rule 45(f), through its authority as a transferee court under 28 U.S.C. § 1407, or by working cooperatively and in conjunction with the District Court in which any discovery dispute involving a non-party was issued. *See e.g., United States, ex rel. A. Scott Pogue v. Diabetes Treatment Centers of America, Inc., et al.*, 238 F.Supp.2d 270 (D.C. 2002) (discussing the authority of transferor courts in connection with non-party discovery disputes in other districts).

4. This Court respectfully requests that District Courts faced with discovery disputes related to the Actos (Pioglitazone) Products Liability Litigation consider referring such disputes to the undersigned for handling and resolution.

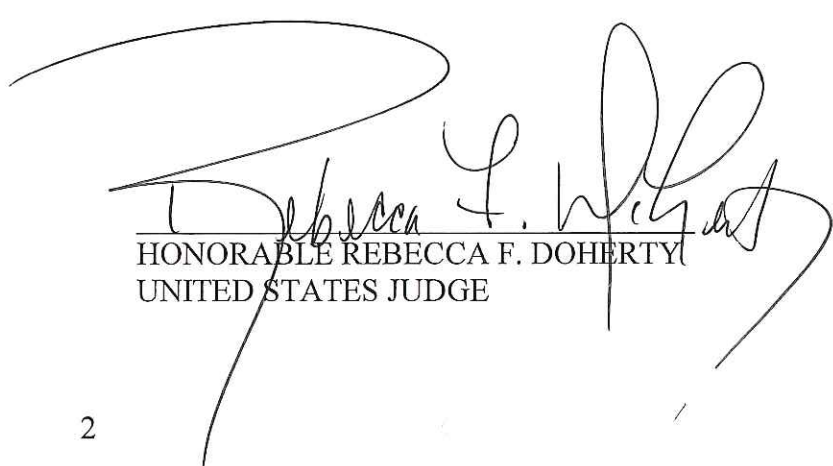
5. Questions regarding this request maybe directed to the undersigned either at the United States District Courthouse, 800 Lafayette Street, Suite 4900, Lafayette, LA, 70501 or by telephone to chambers at (337) 593-5050.

6. This Court will make every effort to prevent undue hardship to non-parties in other districts and their counsel, including the avoidance of unnecessary travel and expense, and will make every effort to resolve disputes by telephone whenever possible.

7. The Actos (Pioglitazone) Products Liability Litigation is a priority matter for this Court and, as such, the Court is committed to addressing discovery disputes related thereto as expeditiously as possible in light of the aggressive discovery schedule and settlement posture of this matter.

IT IS SO ORDERED.

THUS DONE AND SIGNED at Lafayette, Louisiana this 16 day of December, 2015.

  
HONORABLE REBECCA F. DOHERTY  
UNITED STATES JUDGE

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TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER**

As the Settlement Program contemplated by the Master Settlement Agreement is proceeding in due course, and it is expected the Claim Package submission process will be substantially complete within several weeks,

IT IS HEREBY ORDERED this Court will hold a status conference as to the MDL proceedings at open court on **Thursday, February 18, 2016 at 10:30 am**, to be held in **Courtroom 2**. No further status conferences will be held without notice of the Court.

THUS DONE AND SIGNED in Lafayette, Louisiana, this <sup>9<sup>th</sup></sup> day of December, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE



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SEP 21 2015



TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

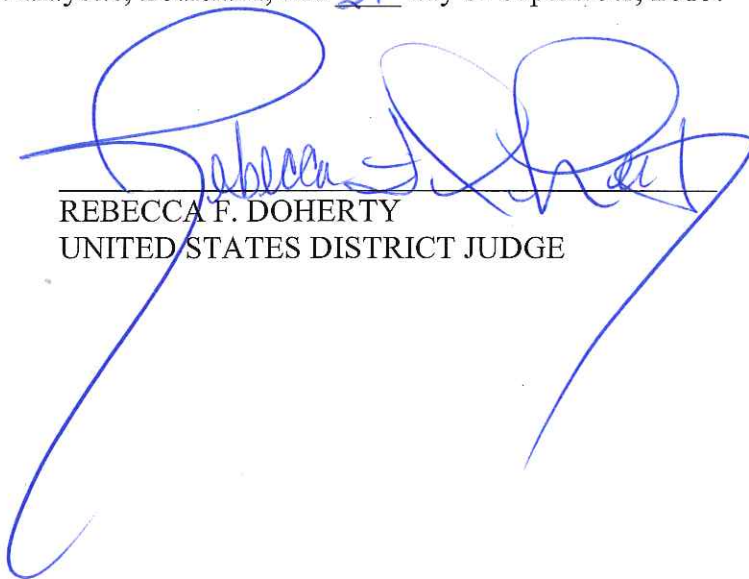
**ORDER**

Whereas, the Settlement Program contemplated by the Master Settlement Agreement is now moving forward, and the parties, therefore, wish to turn their attention to the submission and evaluation of Claim Packages for those claims included in the Settlement Program;

IT IS HEREBY ORDERED the working group meetings and monthly status conferences are CANCELLED through January, 2016, unless this Court orders otherwise.

The Court will issue an order setting the dates of the status conferences and working group meetings that are to take place during the remainder of 2016 in due course, however, counsel can assume the conferences and meetings will follow the same general scheduling pattern as utilized in the past.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 21 day of September, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)	)	
PRODUCTS LIABILITY LITIGATION	)	MDL NO. 6:11-MD-2299
	)	
THIS DOCUMENT APPLIES TO:	)	JUDGE DOHERTY
<i>ALL CASES</i>	)	MAGISTRATE JUDGE HANNA
	)	
	)	

**CASE MANAGEMENT ORDER REGARDING THE RESOLUTION OF CASES INVOLVING THE DEATH OR INCAPACITY OF A PRODUCT USER**

As designed, the settlement program for this litigation (the ACTOS Resolution Program) addresses cases and claims involving deceased claimants and incapacitated claimants. This Case Management Order applies to the resolution of wrongful death cases (including any survival action components), pure survival actions (i.e., the claimant passed away from something other than injuries allegedly caused by ACTOS Products), and cases involving living, yet incapacitated, claimants.

The Court recognizes that the resolution of these cases implicates varying state law distribution schemes and approval requirements. As the Court maintains authority to direct and control the pretrial proceedings for all cases before it pursuant to 28 U.S.C. § 1407, the Court sets forth the below protocol and requirements for finalizing the claims submitted to BrownGreer PLC as the Claims Administrator (“Claims Administrator”) under the ACTOS Master Settlement Agreement that involve deceased or incapacitated claimants.

1. **Claimant Definitions.** In this Order, the term “Deceased Claimant” refers to any person who ingested ACTOS Products (as defined in the Master Settlement Agreement) and asserted a claim under the Master Settlement Agreement by opting into the ACTOS Resolution

Program, or on whose behalf a claim was submitted, who is deceased at the time payment is to be distributed by the Claims Administrator on the claim. The term “Incapacitated Claimant” refers to any person who ingested ACTOS Products and asserted a claim under the Master Settlement Agreement by opting into the ACTOS Resolution Program, or on whose behalf a claim was submitted, who is legally incapacitated at the time payment is to be distributed from the Qualified Settlement Fund (“QSF”) on the claim. The term “Representative Claimant” refers to the person who has asserted a claim on behalf of a Deceased Claimant or Incapacitated Claimant and has authority to act on behalf of a Deceased Claimant and the Deceased Claimant’s estate, heirs and beneficiaries in connection with the ACTOS Resolution Program.

2. **Applicable Law.** For purposes of this Order, the Court deems the state law regarding the proof of capacity of a Representative Claimant to act on behalf of a Deceased Claimant and his/her estate, heirs and beneficiaries or Incapacitated Claimant regarding the execution of a Release and the receipt and distribution of the proceeds of any payment received under the Master Settlement Agreement shall be the law of the state (or district, territory or other jurisdiction) of the Deceased Claimant’s domicile at the time of his or her death or, in the case of an Incapacitated Claimant, the state (or district, territory or other jurisdiction) of the Incapacitated Claimant’s domicile as of the date of initial submission of an Opt In Package to the Claims Administrator under the Master Settlement Agreement.

3. **Proof Required of Authority Required for Claims Involving Deceased Claimants.** The Representative Claimant of a Deceased Claimant shall submit one of the following to the Claims Administrator before the Claims Administrator may authorize any payment on the claim of the Deceased Claimant from the QSF:

- (a) If the Representative Claimant has been appointed the personal representative, administrator, or other position with the authority to act on behalf of the Deceased Claimant and his or her estate under applicable state law, the Representative Claimant shall submit to the Claims Administrator a copy of the court order, letters of administration, letters testamentary or other document evidencing such appointment, issued by a court or other appropriate official;
- (b) If the Representative Claimant has not been appointed as described in Paragraph 3(a), the Representative Claimant shall submit to the Claims Administrator a copy of the last will and testament (or such other document sufficient under applicable state law to effect the disposition of a decedent's property upon death) of the Deceased Claimant that named the Representative Claimant as the executor or executrix (or comparable position under applicable state law) of the Deceased Claimant's estate, **and** the Representative Claimant shall submit to the Claims Administrator a sworn declaration, in the form attached to this Order as Attachment 1 (which will be made available electronically on the website of the Claims Administrator), executed by the Representative Claimant that contains substantially all of the following:
1. The name and address of every person who has a legal right potentially to share in the proceeds of any settlement payment on the claim of the Deceased Claimant and a certification that each such person has been notified of the settlement and the method of notification, or the reason why such person cannot be notified;
  2. A certification from the Representative Claimant that:



- i. No person notified under paragraph 3(b)(i) objects to the declarant serving as the Representative Claimant and taking such steps as required by the Actos Resolution Program to resolve all claims related to the Deceased Claimant's use of an Actos Product, including signing a Release required by the Program to release all claims of the Deceased Claimant's estate, heirs and beneficiaries.
  - ii. The Representative Claimant will:
    1. Comply with any and all provisions of the state law applicable to the claim regarding the compromise and distribution of the proceeds of the settlement of a survival or wrongful death claim to the appropriate heirs or other beneficiaries and any other parties with any right to receive any portion of any payments; and
    2. Indemnify and hold harmless Takeda, Eli Lilly and any other Defendants and their attorneys and insurers, the Claims Administrator, the Special Master(s), the Plaintiffs' Settlement Review Committee ("PSRC"), and the agents and representatives of any of the foregoing, from any and all claims, demands, or expenses of any kind arising out of the compromise and distribution of the proceeds of the settlement of such a survival or wrongful death claim.
- (c) If neither Paragraph 3(a) nor Paragraph 3(b) applies, the Representative Claimant shall submit to the Claims Administrator a sworn declaration, in the form attached

to this Order as Attachment 1, executed by the Representative Claimant that contains substantially all of the following:

1. The Representative Claimant's relationship to the Deceased Claimant;
2. The basis of the Representative Claimant's authority to act on behalf of the Deceased Claimant and his/her estate, heirs and beneficiaries;
3. The name and address of every person who has a legal right potentially to share in the proceeds of any settlement payment on the claim of the Deceased Claimant and a certification that each such person has been notified of the settlement and the method of notification, or the reason why such person cannot be notified;
4. A certification from the Representative Claimant that:
  - i. No person notified under paragraph 3(c)(3) objects to the declarant serving as the Representative Claimant and taking such steps as required by the Actos Resolution Program to resolve all claims related to the Deceased Claimant's use of an Actos Product, including signing a Release required by the Program to release all claims of the Deceased Claimant's estate, heirs and beneficiaries.
  - ii. The Representative Claimant will:
    1. Comply with any and all provisions of the state law applicable to the claim regarding the compromise and distribution of the proceeds of the settlement of a survival or wrongful death claim to the appropriate heirs or other

beneficiaries and any other parties with any right to receive any portion of any payments; and

2. Indemnify and hold harmless Takeda, Eli Lilly and any other Defendants and their attorneys and insurers, the Claims Administrator, the Special Master(s), the PSRC, and the agents and representatives of any of the foregoing, from any and all claims, demands, or expenses of any kind arising out of the compromise and distribution of the proceeds of the settlement of such a survival or wrongful death claim.

4. **Proof Required of Authority Required for Claims Involving Incapacitated Claimants.** The Representative Claimant of an Incapacitated Claimant shall submit one of the following to the Claims Administrator before the Claims Administrator may authorize any payment on the claim of the Incapacitated Claimant from the QSF:

- (a) If the Representative Claimant has been appointed the guardian, conservator, curator, personal representative or other position with the authority to act on behalf of the Incapacitated Claimant under applicable state law, the Representative Claimant shall submit to the Claims Administrator a copy of the court order, certification, or other document evidencing such appointment, issued by a court or other appropriate official;
- (b) If the Representative Claimant has not been appointed as described in Paragraph 4(a), the Representative Claimant shall submit to the Claims Administrator a copy of an appropriate and legally sufficient, under applicable state law, Power of

Attorney executed by the Incapacitated Claimant at a time when the Incapacitated Claimant possessed the legal capacity to do so;

(c) If neither Paragraph 4(a) nor Paragraph 4(b) applies, the Representative Claimant shall submit to the Claims Administrator a sworn declaration, in the form attached to this Order as Attachment 2 (which will be made available electronically on the website of the Claims Administrator), executed by the Representative Claimant that contains substantially all of the following:

1. The Representative Claimant's relationship to the Incapacitated Claimant;
2. The basis of the Representative Claimant's authority to act on behalf of the Incapacitated Claimant;
3. The nature of the Incapacitated Claimant's incapacity;
4. A certification from the Representative Claimant that he or she will:
  - i. Comply with any and all provisions of the state law applicable to the claim regarding the compromise and distribution of the proceeds of the settlement of a claim by an Incapacitated Claimant; and
  - ii. Indemnify and hold harmless Takeda, Eli Lilly and any other Defendants and their attorneys and insurers, the Claims Administrator, the Special Master(s), the PSRC, and the agents and representatives of any of the foregoing, from any and all claims, demands, or expenses of any kind arising out of the compromise and distribution of the proceeds of the settlement of such a claim.

5. **Initial Submission Deadline.** The Representative Claimant must present documentation as set forth in Paragraphs 3 or 4 within 30 days after final Opt In Deadline Applicable to any claimant under the MSA.

6. **The Procedure for Review of Materials Submitted Under this Order.** The materials submitted by a Representative Claimant under this Order shall be reviewed as follows:

- (a) *Review by the Claims Administrator:* Within five business days after its receipt of the materials, the Claims Administrator shall review the materials and determine whether they satisfy the terms of this Order.
- (b) *Opportunity to Cure Deficient Materials.* If the Claims Administrator determines under Paragraph 6(a) that the materials do not satisfy the terms of this Order, the Claims Administrator shall promptly notify the Representative Claimant of any deficiency in the materials and shall allow the Representative Claimant the opportunity to submit additional materials in an effort to satisfy the terms of this Order and to inform the Claims Administrator that the Representative Claimant does not intend to submit any further materials. The Claims Administrator shall review any additional materials within five business days after receipt and determine whether they satisfy the terms of this Order. The Claims Administrator's determination that the materials satisfy the terms of this Order shall be final.
- (c) *Appeal to the Special Master.* If after the submission of additional materials (or indication from the Representative Claimant that no additional materials will be submitted) pursuant to Paragraph 6(b) the Claims Administrator determines that the materials submitted by the Representative Claimant do not satisfy the terms of

this Order, the Claims Administrator shall promptly notify counsel for the Representative Claimant (or the Representative Claimant, if unrepresented). Within five business days after the date of such notice, the Representative Claimant shall notify the Claims Administrator whether the Representative Claimant wishes to appeal that determination to the Special Master. If there is an appeal, the Special Master shall review the appeal on the record before the Claims Administrator and no additional materials may be submitted by the Representative Claimant. The Special Master shall determine whether the materials submitted satisfy the terms of this Order. The decision of the Special Master on an appeal shall be final and not subject to further review. The Special Master shall be paid a fee of \$300 for each such appeal. If the appeal is resolved in favor of the Representative Claimant, Takeda shall pay the Special Master fee. If the appeal is resolved against the Representative Claimant, the Representative Claimant shall pay the Special Master fee.

**7. Payment on a Claim Subject to This Order.**

- (a) After the process set forth in Paragraph 6, as applicable, if the Representative Claimant is found to have failed to submit materials in satisfaction of this Order, the claim presented by the Representative Claimant shall not be paid unless and until satisfactory materials have been submitted.
- (b) If the Representative Claimant is found to have submitted materials in satisfaction of this Order, the Claims Administrator shall, subject to and in accordance with the terms of the Master Settlement Agreement, authorize payment(s) on the claim from the QSF to the Representative Claimant, who shall be entitled to receive any

settlement funds without further action from the Court and shall hold the settlement funds in trust, pending the Representative Claimant's compliance with applicable state law governing the disposition of the proceeds, including obtaining court approval of the settlement, by a court of competent jurisdiction, if necessary.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 31<sup>ST</sup> day of AUGUST, 2015.



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HONORABLE PATRICK J. HANNA  
UNITED STATES MAGISTRATE JUDGE







NAME		INFORMATION	
3.		Address	
		Relationship to Deceased Claimant	
		Notified of Settlement?	<input type="checkbox"/> Yes. How Notified: _____ <input type="checkbox"/> No. Why Not: _____
4.		Address	
		Relationship to Deceased Claimant	
		Notified of Settlement?	<input type="checkbox"/> Yes. How Notified: _____ <input type="checkbox"/> No. Why Not: _____
5.		Address	
		Relationship to Deceased Claimant	
		Notified of Settlement?	<input type="checkbox"/> Yes. How Notified: _____ <input type="checkbox"/> No. Why Not: _____

**D. CERTIFICATION**

By signing this Sworn Statement, I certify and declare under penalty of perjury pursuant to 28 U.S.C. Section 1746 that:

- (a) I have authority to sign any forms or other documents required in connection with the submission and review of any claim under the ACTOS Resolution Program on behalf of the Deceased Claimant identified in Section A and the estate of such claimant (if applicable), and to receive any payment issued on the claim of the Deceased Claimant in that Program, subject to state law provisions regarding distribution [see subparagraph (c)], if applicable;
- (b) The information I have provided in this Sworn Statement is true and correct;
- (c) I will comply with any and all provisions of state estate law and all other state law applicable to the Deceased Claimant's claim regarding the compromise and distribution of the proceeds of the settlement of a survival or wrongful death claim to the appropriate heirs or other beneficiaries and any other parties with any right to receive any portion of any payments;
- (d) Every person who has a legal right potentially to share in the proceeds of any settlement payment on the claim of the Deceased Claimant has been notified of the settlement; the method of notification, or the reason why such person cannot be notified, is listed above; and none of these persons objects to my appointment as Representative Claimant and signing a Release in the Program to release all claims of the Deceased Claimant's estate, heirs, and beneficiaries;
- (e) I will indemnify and hold harmless Takeda, Eli Lilly, and any other Defendants and their attorneys and insurers, the Claims Administrator, the Special Master(s), the Plaintiffs' Settlement Review Committee, and the agents and representatives of any of the foregoing, from any and all claims, demands, or expenses of any kind arising out of the compromise and distribution of the proceeds of the settlement of such a survival or wrongful death claim.

I understand that the Claims Administrator will rely on this Certification and that false statements or claims made in connection with this Sworn Statement may result in fines, imprisonment, and/or any other remedy available by law to the federal government.

**E. SIGNATURE BY REPRESENTATIVE CLAIMANT**

<b>Signature</b>		<b>Date</b>	____/____/____ (Month/Day/Year)
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TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**HOLDBACK ORDER**

**Introduction**

By Order dated April 13, 2012, this Court appointed a Plaintiffs' Steering Committee ("PSC") and assigned it the duty of representing the common interests of all plaintiffs and their counsel in these proceedings.<sup>1</sup> Additionally, this Court created an administrative process by which counsel providing legal services for the common benefit of all plaintiffs were under an ongoing obligation to submit claims for common benefit fees and common benefit expenses and/or costs incurred. This process included ongoing review of such claims by Deputy Special Master Kenneth W. DeJean ("DSM DeJean"), and required limited reporting by DSM DeJean to this Court about such claims.<sup>2</sup>

Thereafter, and as a result of negotiations among the signatories to the "Master Settlement Agreement" ("MSA"), a document entitled "Master Settlement Agreement" was created and signed, which provides, in relevant part, that, for those who choose to participate in the Settlement Program established by the MSA, "an assessment of common benefit attorneys'

<sup>1</sup> Rec. Doc. 560.

<sup>2</sup> Pursuant to this Court's "Order Appointing Special Masters" [Rec. Doc. 532], "Case Management Order: PSC's Management of Timekeeping, Cost Reimbursement and Related Common Benefit Issues" [Rec. Doc. 1357], "Case Management Order: Claims for Common Benefit Fees and Expenses" [Rec. Doc. 2356], and "Order Regarding Special Masters" [Rec. Doc. 4264], Deputy Special Master DeJean reviews all claims of common benefit time spent and expense and/or cost incurred on an ongoing basis to determine whether they are reasonable. This process ultimately will include completion of the due process review. See Rec. Doc. 532, at 1; Rec. Doc. 137, at 1-2, 5-9, Exhibit A; Rec. Doc. 2356, at 1-9; Rec. Doc. 4264, at 1.

fees will be imposed on each Claimant in accordance with the amount set by Order entered in the MDL,” and that “[t]he amount of common benefit expenses shall be determined by Order entered in the MDL, which will be deducted from the Settlement Funds deposited into the [Qualified Settlement Fund].” MSA, § 10.04-(A).<sup>3</sup> The deadline for “opting in” to the proposed settlement process is now September 11, 2015. In light of this development, this Court has concluded now is an appropriate time to impose a holdback obligation on the Defendants in order to create a holdback of funds necessary to meet approved common benefit fees and expenses and/or costs, which will be used to compensate attorneys who provided approved common benefit legal services and/or incurred approved common benefit expenses and/or costs in accordance with the terms established in this Court’s prior orders.

In making rulings concerning common benefit issues in these proceedings, this Court is bound by Fifth Circuit jurisprudence. *See, e.g., In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1176 (D.C. Cir. 1987), *aff’d sub nom. Chan v. Korean Air Lines, Ltd.*, 490 U.S. 122, 109 S. Ct. 1676, 104 L. Ed. 2d 113 (1989). The Fifth Circuit approves the use of the percentage method *or* the lodestar method, but either (or both) must be accompanied by a Johnson cross-check. *See Union Asset Management Holding A.G. v. Dell, Inc.*, 669 F.3d 632 (5<sup>th</sup> Cir. 2012); Johnson v. Georgia Highway Express, 488 F.2d 714, 717-19 (5<sup>th</sup> Cir. 1974). The Johnson factors include (1) the time and labor required; (2) the novelty and difficulty of the questions; (3) the skill requisite to perform the legal service properly; (4) the preclusion of other employment by the attorney due to acceptance of the case; (5) the customary fee; (6) whether the fee is fixed or contingent; (7) time limitations imposed by the client or the circumstances; (8) the amount involved and the results obtained; (9) the experience, reputation, and ability of the attorneys; (10) the “undesirability” of the case; (11) the nature and length of the professional

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<sup>3</sup> For the MSA lien resolution process, see MSA, Art. XIII.

relationship with the client; and (12) awards in similar cases. *Id.* The information necessary for the Court to conduct a final analysis for and of approved common benefit fees and approved common benefit expenses and/or costs does not yet fully exist.<sup>4</sup> Nonetheless, the parties' movement toward possible settlement makes it prudent for this Court to impose a holdback obligation at this time.

This Court finds that it does have the authority to create a holdback from payments to be made by the Defendants to any plaintiff participating in the Settlement Program. *See, e.g., In re Oil Spill by the Oil Rig DEEPWATER HORIZON in the Gulf of Mexico on April 20, 2010*, 2011 WL 6817982 (E.D.La. 12/28/2011) (*citing In re Air Crash Disaster at Florida Everglades on Dec. 29, 1972*, 549 F.2d 1006, 1017-18 (5<sup>th</sup> Cir. 1977); *In re Zyprexa Products Liability Litigation*, 594 F.3d 113, 128-30 (2<sup>nd</sup> Cir. 2010) (Kaplan, J., concurring); *In re Genetically Modified Rice Litigation*, 2010 WL 716190, at \*4 & n.2 (E.D.Mo. 2/24/2010)); and *In re Vioxx Products Liability Litigation*, 2012 WL 1448135, \*1 (E.D.La. 4/25/2012) (Fallon, J.). *See, also, Downing v. Goldman Phipps, PLLC*, 764 F.3d 906, 909-10 (8<sup>th</sup> Cir. 2014); *In re Guidant Corporation Implantable Defibrillators Products Liability Litigation*, 2010 WL 145278, \*1 (D.Minn. 1/8/2010) (Frank, J.); *In re Zyprexa Products Liability Litigation*, 451 F.Supp.2d 458, 479 (E.D.N.Y. 9/11/2006). This holdback order will remain in place until this Court has the complete information required to complete its deliberations concerning a common benefit assessment and a determined assessment amount.

This order addresses both approved common benefit expenses and/or costs and approved common benefit fees – two separate, distinct, but also, to some degree overlapping

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<sup>4</sup> For instance, the total amount of the Qualified Settlement Fund has not yet been determined and likely will not be known until the end of the opt-in period, and possibly as late as the Effective Date defined in the MSA. *See* MSA, §§ 5.02, 10.01. Moreover, this Court has not yet received evidence as to the Johnson factors.

considerations.<sup>5</sup> Expenses and/or costs are finite, determinable, and complete in and of themselves. Furthermore, approved common benefit expenses and/or costs are treated differently than approved common benefit attorneys' fees within the MSA.<sup>6</sup> Thus, this holdback order will address the two categories separately.

### **Holdback for Assessment of Approved Common Benefit Fees**

At this juncture, the Court is without the required information to make a final and finite determination as to approved common benefit fees. In the interim, however, this Court must rely on its personal knowledge of the history of this case, along with its extensive, hands-on involvement with this matter, as well as its observations of the conduct and work done by the PSC, and the other approved common benefit counsel.

This Court's knowledge is derived through its hands-on involvement with every aspect of this MDL, including both direct observations and numerous reports made by Magistrate Judge Hanna and the Special Masters whom this Court has appointed to certain tasks in these proceedings. This Court has met weekly with the Special Masters, has met monthly with counsel, has participated in working group meetings, as well as, in Court status conferences open to all counsel, for over three years, has presided over extensive discovery, as well as a 37-day bellwether trial, and has considered and ruled on numerous pre-trial and post-trial motions.

These many opportunities to interact with, and observe, counsel in this case have provided this Court with ample evidence to determine the PSC and other approved common benefit counsel took their obligations very seriously, and that they vigorously promoted and protected the common interests of the plaintiffs in these proceedings. This Court is aware of the quality of both the approved common benefit work provided by the numerous plaintiffs' counsel,

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<sup>5</sup> See Rec. Doc. 532, at 1; Rec. Doc. 137, at 1-2, 5-9, Exhibit A; Rec. Doc. 2356, at 1-9; Rec. Doc. 4264, at 1.

<sup>6</sup> See MSA, § 10.04-(A).

as well as the unique difficulties presented in this MDL. This Court relies on its personal knowledge of the history of these proceedings to conclude that it will, at the appropriate time, issue a common benefit assessment order. At this time, therefore, the Court will issue a holdback order merely to attempt to ensure that sufficient funds will exist to cover the common benefit assessment once determined and issued.

In order to address the underlying purpose or benefit of issuing a holdback order, this Court has reviewed all available information in an effort to withhold an amount sufficient to cover an assessment of approved common benefit fees. However, the Court cautions and reminds that, at this point, the Court does not have all the information necessary to make a final considered determination of the common benefit assessment amount.

The Court finds, based upon the information now available to the Court, that there currently is a rational basis to issue a holdback order requiring, 8.6% be withheld from payments made by Defendants by way of settlement.

#### **Holdback for Approved Common Benefit Expenses and/or Costs**

As noted above, early in the MDL, this Court established an ongoing process by which Deputy Special Master DeJean, also, reviewed and audited claims of common benefit expense and/or cost incurred. Furthermore, also, as noted above, the nature of common benefit expenses and/or costs is such that the amount can be known with certainty only once the review and auditing process is complete. However, at this juncture, the Court can approximate an interim amount and attempt to extrapolate from that amount.

Consequently, based upon the limited information available to the Court, this Court finds that the Defendants should withhold a total of \$25 million from those payments subject to an MDL expense assessment. This sum will be used to cover approved common benefit expenses

and/or costs. Should the amount withheld for this purpose exceed the final total of approved common benefit expenses and/or costs, the remainder, if administratively possible, will be reimbursed to Claimants against whom those expenses and/or costs were assessed.

For the foregoing reasons,

**Holdback – Fees**

IT IS HEREBY ORDERED that, with regard to the Qualified Settlement Fund described in the Master Settlement Agreement, Defendants shall retain and protect 8.6% of any payments made to any party pursuant to the terms of the Master Settlement Agreement, and shall maintain custody of those funds in the manner contemplated by the MSA and related agreements.

These holdback funds will not constitute the separate property of any party or attorney or be subject to garnishment or attachment for the debts of any party or attorney, and will not be distributed or disbursed except when and as so directed by court order. None of such funds may be disbursed, expended, withdrawn, removed, or released for any purpose whatsoever without written permission of this Court. All holdback funds shall be held by Defendants (or their designee) in such a fashion that the source of each amount withheld can be readily identified.

**Holdback – Expenses and/or Costs**

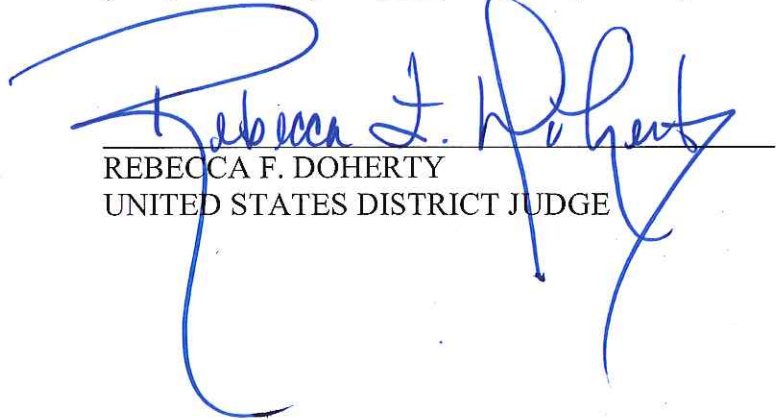
IT IS HEREBY FURTHER ORDERED that, with regard to the Qualified Settlement Fund described in the Master Settlement Agreement, Defendants shall retain and protect \$25,000,000.00 from those payments subject to an MDL expense and/or cost assessment, and shall maintain custody of those funds in the manner contemplated by the MSA and related agreements.

These holdback funds will not constitute the separate property of any party or attorney or be subject to garnishment or attachment for the debts of any party or attorney, and will not be



distributed or disbursed except when and as so directed by court order. None of such funds may be disbursed, expended, withdrawn, removed, or released for any purpose whatsoever without written permission of this Court. All holdback funds shall be held by Defendants (or their designee) in such a fashion that the source of each amount withheld can be readily identified.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 1 day of September, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

AUG 21 2015 *JS*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA**

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

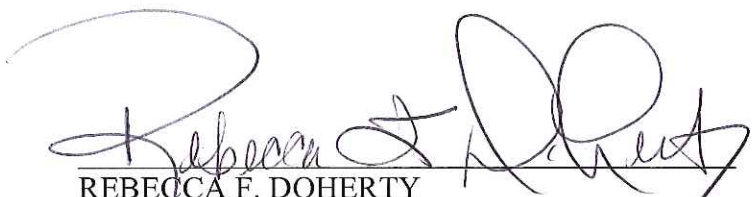
This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER**

IT IS HEREBY ORDERED the working group meetings and monthly status conferences scheduled for September and October, 2015 are CANCELLED. The Court will give notice as to whether they will go forward in November.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 21<sup>st</sup> day of August, 2015.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

AUG - 7 2015

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**INSTRUCTIONS TO DEPUTY SPECIAL MASTER DEJEAN<sup>1</sup>**

By Order dated April 11, 2012, this Court appointed Deputy Special Master DeJean and assigned him the duties, *inter alia*, of conferring with the Court and performing such “duties as might be requested of him by the Court.”<sup>2</sup> Pursuant to this appointment, this Court now instructs Deputy Special Master DeJean as follows:

IT IS HEREBY ORDERED that Deputy Special Master DeJean amass and gather the facts and information necessary for this Court’s analysis, decision, and ruling on the question of whether a common benefit assessment should be made in this case and allocation therein. Specifically, Deputy Special Master DeJean is instructed to amass and gather information now needed by the Court, such as:

- information as to the lodestar determination, including the hours, expenses, and costs actually incurred by the PSC and other common benefit attorneys in this case;
- information as to reasonable hourly fee rates for attorneys and paralegals;

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<sup>1</sup> This Order will be filed in the MDL Docket (11-md-2299) and applies to all cases in the MDL, but will not be spread to all cases.

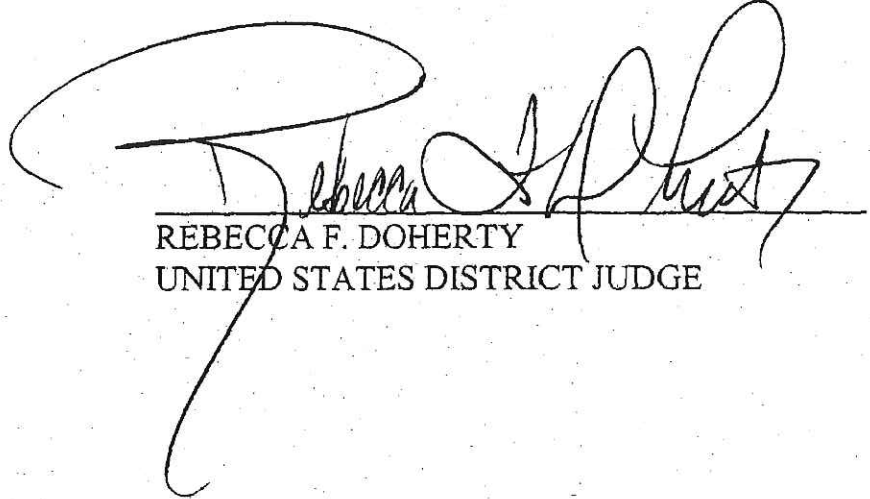
<sup>2</sup> Rec. Doc. 532, at 1.

- information as to the time and labor reasonably required to protect the plaintiffs' common interests;
- information as to the novelty and difficulty of the questions raised by the claims in these proceedings;
- information as to the skill requisite to perform the legal service properly;
- information as to the preclusion of other employment by the attorney due to acceptance of the case;
- information as to the customary fee;
- information as to whether the fee is fixed or contingent;
- information as to time limitations imposed by the client or the circumstances;
- information as to the amount involved and the results obtained;
- information as to the experience, reputation, and ability of the attorneys;
- information as to the "undesirability" of the case;
- information as to the nature and length of the professional relationship with the client; and
- any and all other factual information that Deputy Special Master DeJean concludes, as a result of this fact-gathering process, which might be of benefit to the Court.

IT IS HEREBY FURTHER ORDERED that Deputy Special Master DeJean shall provide this Court with informal updates about the status of his efforts every 30 days, beginning August 31, 2015, so as to keep this Court apprised of the progress he is making. Once the necessary

information has been amassed and gathered, Deputy Special Master DeJean shall inform the Court that he has completed his task.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 7<sup>th</sup> day of August, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

JUN 17 2015



TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

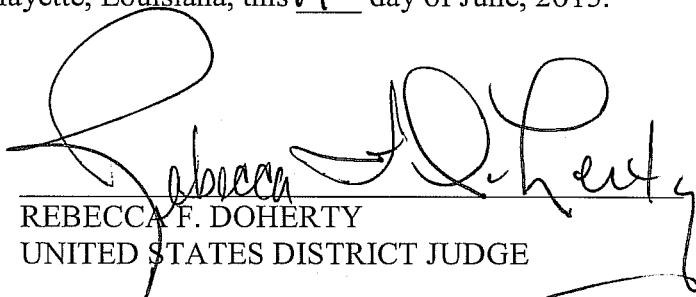
This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER**

IT IS HEREBY ORDERED the Working Group meetings and monthly status conferences scheduled for July and August, 2015 are CANCELLED. The Court will give notice as to whether they will go forward in September.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 17<sup>th</sup> day of June, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

MAY 14 2015 *ms*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

This Document Applies To:  
*All Cases*

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**ORDER**

IT IS HEREBY ORDERED the Working Group meeting and monthly status conference scheduled for May and June, 2015 are CANCELLED. The Court will give notice as to whether they will go forward in July.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 14 day of May, 2015.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

MAY - 1 2015 *MS*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER FOR LIMITED STAY**

Plaintiffs and Defendants have advised the Court that an agreement has been reached to establish a settlement program for the resolution of bladder cancer claims (“Actos Resolution Program”). Toward this end, the parties are working together to implement a settlement that will be open to certain plaintiffs who allege a bladder cancer injury in this Court as well as in other courts in the United States.

The parties, therefore, jointly seek to stay discovery in this matter and adjourn all deadlines in the above-captioned cases, until further notice, to allow the parties to proceed with the Actos Resolution Program, and to allow the parties to avoid incurring the costs of further proceedings that may be unnecessary as cases are resolved.

IT IS HEREBY ORDERED discovery in this matter is stayed, and all deadlines are adjourned in the above-captioned cases, unless otherwise specified within the “Master Settlement Agreement.”

IT IS FURTHER ORDERED this Court’s Order for Limited Stay [Rec. Doc. 5554] is STRICKEN FROM THE RECORD.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 1<sup>st</sup> day of May, 2015.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE



## **MASTER SETTLEMENT AGREEMENT**

This Master Settlement Agreement, dated April 28, 2015 (the “Execution Date”), is entered into by and between (i) Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals U.S.A., Inc. (collectively, “Takeda”), and (ii) the plaintiffs’ counsel listed in the signature pages hereto under the heading “Plaintiffs’ Settlement Review Committee” (“PSRC”). Takeda and the PSRC have agreed to establish a private settlement program intended to resolve the claims of all persons who are eligible to enroll into the private settlement program, as set forth by the terms of this Agreement.

All capitalized terms used herein shall have the meanings ascribed to them, respectively, either where they appear in this Agreement set off in parentheses and quotations and underscored, or as set forth in Article XVI below.

### **RECITALS**

**A.** This Master Settlement Agreement establishes a private settlement program (the “ACTOS Resolution Program” or the “Program”) for the purpose of resolving certain Claims alleging a personal injury involving bladder cancer resulting from the use of an ACTOS Product pending against Takeda, Eli Lilly & Company (“Lilly”), and other Defendants, as defined in Article XVI, in the following proceedings on the Execution Date: (1) *In Re: Actos (Pioglitazone) Products Liability Litigation*, MDL No. 2299 (the “MDL”), a federal multi-district litigation venued in the United States District Court for the Western District of Louisiana (the “MDL Court”); (2) any other federal court proceedings, either pending in that court or awaiting transfer to the MDL (collectively, the “Other Federal Court Proceedings”); (3) *In re Actos Related Cases*, No. 2011 L 010011 (the “Illinois Coordinated Proceedings”), venued in the Circuit Court of Cook County, Illinois, County Department, Law Division (the “Illinois Coordinated Court”); (4) *In Re Actos Product Liability Cases Coordinated Proceeding*, JCCP No. 4696 (the “California Coordinated Proceedings”), venued in the California Superior Court, Los Angeles County, California (the “California Coordinated Court”); and (5) any and all other state court proceedings (the “Other State Court Proceedings”).

**B.** Members of the PSRC and Takeda have agreed to establish this Program to resolve such Claims that involve an Alleged Injury of Bladder Cancer resulting from the use of ACTOS Products, as specified in this Agreement.

**C.** Claimants with Claims that have not yet been filed in any jurisdiction are also eligible to participate in the Program, provided that the Claims involve an Alleged Injury of Bladder Cancer occurring in the United States prior to the Execution Date, allegedly resulting from the use of ACTOS Products, and who duly execute and serve the Notice of Intent to Opt In Form for Unfiled Claims and Declaration of Counsel in accordance with Section 2.04 of this Agreement.

**D.** Takeda, Lilly, and all other Released Persons deny any liability or wrongdoing, and Takeda asserts that it, and the other Released Persons, have meritorious affirmative defenses to these lawsuits and claims. This Agreement and the Program, accordingly, will not be construed as evidence of, or as an admission by Released Persons of, any fault, liability,

wrongdoing, or damages whatsoever, or as an admission by any Claimant who enrolls in the Program of a lack of merit in their claims.

**E.** The Parties agree and understand that this Agreement shall not be used, cited, or relied upon in any manner in any future cases or settlements without the express approval of PSRC and Takeda, other than as necessary to enforce this Agreement.

**F.** All sums awarded under this Agreement constitute damages on account of personal physical injuries or sickness, within the meaning of §104(a)(2) of the Internal Revenue Code.

Takeda and the PSRC hereby agree as follows:

## **ARTICLE I. CASE REGISTRATION**

### **Section 1.01 Registration of All Filed and Unfiled ACTOS Products-related Claims**

The purposes of the registration requirements set forth in this Article I are to allow the Parties and the Courts to identify the filed and unfiled cases and claims connected to ACTOS Products, to create a joint database of such cases and claims which will help the MDL Court and the Illinois and California Coordinated Courts cooperatively manage this litigation, and to assist the Parties with effectuating the provisions of this Agreement.

### **Section 1.02 Case Census Orders**

- (A)** PSRC and Takeda will jointly petition the MDL Court, the Illinois Coordinating Court, and the California Coordinating Court for a case management order (“Case Census Order(s)”), substantially in the form of Appendix A (as modified in the Illinois and California Coordinated Courts to conform to state practice), to be entered in each jurisdiction within three (3) days following the Execution Date, requiring any plaintiffs’ counsel representing clients with ACTOS Products-related Claims pending in the respective court to identify to PSRC, Takeda and Claims Administrator all clients with ACTOS Products-related claims, whether their claims are filed or unfiled, and regardless of whether such claims are eligible for enrollment into the ACTOS Resolution Program or if that plaintiffs’ counsel intends to enroll the claims of any such clients into the ACTOS Resolution Program. The Case Census Orders shall require online submission of claims information in accordance with the instructions of the Claims Administrator at [www.actosofficialsettlement.com](http://www.actosofficialsettlement.com) for the accurate and efficient transfer of the required information about each Claimant and Claim to the Claims Administrator and the Parties.
- (B)** Primary Counsel (as defined in the Case Census Order) must make online submission of all information required by the Case Census Order within ten (10) days following the entry of such orders. As set forth in Case Census Orders, Primary Counsel must certify, pursuant to 28 U.S.C. § 1746, that the information submitted in response to the Case Census

Orders is true, complete and correct to his or her knowledge, and submission of such information constitutes a representation to the Court that the list of claimants and information provided therein is true, complete and correct.

### **Section 1.03 Claims Database**

The Claims Administrator will maintain a joint database of all cases filed in any court and all unfiled claims identified pursuant to the Case Census Orders and in connection with enrollments of Claims in the Program, which database shall be made available to the MDL Court, the Illinois Coordinating Court, and the California Coordinating Court, Takeda and the PSRC. The database may include for every registered ACTOS-related claim, *inter alia*, the current venue, case number, alleged injury, date of alleged injury, alleged duration of ACTOS Products use, the identity of the Primary Counsel responsible for the Claim, state where alleged injury occurred, and filing jurisdiction, as well as other claim specific information. Nothing herein prevents either Takeda or the PSRC from maintaining their own separate database of all registered plaintiffs and unfiled Claims. The Claims Administrator may consult with Takeda and the PSRC regarding the accuracy of the information in the Case Census.

## **ARTICLE II. PROGRAM ENROLLMENT**

### **Section 2.01 Eligible Enrollees and Program Participants**

- (A) Only Eligible Enrollees may participate in the Program. “Eligible Enrollee” means all Claimants (including Representative Claimants) who:
1. have cases filed, as of the Execution Date, in (i) the MDL Court; (ii) any Other Federal Court Proceeding; (iii) the Illinois Coordinated Proceedings; (iv) the California Coordinated Proceedings; or (v) any Other State Court Proceeding, in each case alleging (i) the use of ACTOS Products prior to December 1, 2011, and (ii) an Eligible Injury resulting from the alleged use of ACTOS Products; or
  2. did not have a case pending against Defendants in state or federal court on or before the Execution Date but who (i) allege (a) the use of ACTOS Products prior to December 1, 2011, and (b) an Eligible Injury occurring in the United States resulting from the alleged use of ACTOS Products prior to the Execution Date; (ii) provide an attorney affirmation that the Claimant (or the Claimant’s Personal Representative) had signed a retainer agreement with an attorney or with his or her law firm on or before the third (3rd) day following the Execution Date for legal representation of said Claimant relating to an Eligible Injury allegedly resulting from the use of ACTOS Products; and (iii) provide a properly executed and

timely Opt In Package for Unfiled Claims to Takeda pursuant to the procedures set forth in this Section.

- (B) “Eligible Injury” means a diagnosis of Bladder Cancer. Only Claimants alleging an Eligible Injury may participate in the Program. “Bladder Cancer” shall be defined as cancer that formed in the urothelial lining of the urinary bladder, the renal pelvis or the ureter.
- (C) Those Claimants who become finally enrolled in the Program pursuant to the provisions of this Article II are “Program Participants.” To the extent this Agreement refers to a Program Participant’s use of ACTOS Products, where the Claim is being brought in a representative capacity by a Program Participant who was not the Product User, such reference shall refer to Product User.

## **Section 2.02 Enrollment Procedures for Claimants with Cases Pending in Federal or State Court**

- (A) Enrollment in the Program is *not* automatic for any Eligible Enrollee with a pending lawsuit. Such Eligible Enrollees may take steps to enroll in the Program as set forth herein.
- (B) Claimants who, on or prior to the Execution Date, have cases that allege usage of ACTOS Products prior to December 1, 2011 and involve an alleged Eligible Injury resulting from the use of ACTOS Products pending in (i) the MDL (“MDL Claimants”), (ii) the Illinois Coordinated Proceedings (“Illinois Coordinated Proceeding Claimants”), or (iii) the California Coordinated Proceedings (“California Coordinated Proceeding Claimants”) (collectively, the “State Court Coordinated Proceeding Claimants”), (iv) in federal courts other than the MDL Court, including all cases subject to a Conditional Transfer Order or otherwise awaiting transfer to the MDL (“Other Federal Court Claimants”), or (v) in state courts other than in the Illinois Coordinated Proceedings or the California Coordinated Proceedings (“Other State Court Claimants”) ((i) – (v) collectively, “Filed Claimants”) may take steps as outlined below to enroll in the Program. Such Claimants whose cases have been dismissed with prejudice prior to the Execution Date are not eligible to participate in the Program, unless on the Execution Date, (i) the time for such Claimant to appeal has not run, (ii) the Claimant’s case is pending appeal, (iii) the Claimant’s time for filing a motion for reconsideration has not run; or (iv) the Claimant’s motion for reconsideration is pending. Such Claimants whose cases have been dismissed without prejudice prior to the Execution Date are eligible to enroll in the Program, unless such claims are barred from re-filing by the applicable statute of limitations, as determined by Takeda, but subject to the reconsideration procedures of Section 2.05(C), below.

- (C) Such Filed Claimants who wish to enroll in the Program must submit the following on or before the Opt In Deadline in accordance with the provisions of Section 2.03:
- a. a “Notice of Intent to Opt In Form for Filed Claims” contained in Appendix B, executed by Signature of Claimant;
  - b. a “Release” contained in Appendix C, to be executed by Personal Signature by the Claimant or the Personal Representative of Claimant, and all Persons having or asserting the right to bring claims, including future wrongful death claims, by reason of their relationship with the Product User, including, without limitation, the Product User’s spouse or surviving spouse, representatives, and/or heirs, concerning the Product User’s alleged use of ACTOS Products; and
  - c. a “Stipulation of Dismissal,” for each case wherein the Product User or a representative of the Product User is named as a plaintiff, executed by Signature of the counsel of record, for the applicable Court, as follows:
    1. MDL Claimants must submit an executed stipulation of dismissal in the form contained in Appendix D-1 (the “MDL Stipulation of Dismissal”);
    2. Illinois Coordinated Proceeding Claimants must submit an executed stipulation of dismissal in the form contained in Appendix D-2 (the “Illinois Stipulation of Dismissal”);
    3. California Coordinated Proceeding Claimants must submit an executed stipulation of dismissal in the form contained in Appendix D-3 (the “California Stipulation of Dismissal”);
    4. Other Federal Court Claimants must submit an executed stipulation of dismissal for federal court that abides by all applicable federal and local rules for effectuating the dismissal, with prejudice, of the Federal Case against all Defendants (each a “Federal Stipulation of Dismissal”); and
    5. Other State Court Claimants must submit an executed stipulation of dismissal for state court that abides by all

applicable state and local rules for effectuating the dismissal, with prejudice, of the State Case against all Defendants (each a “State Stipulation of Dismissal”).

The Notice of Intent to Opt In Form for Filed Claims, the Release, and the applicable Stipulation(s) of Dismissal are referred to collectively herein as the “Opt In Package for Filed Claims.” Failure to timely submit an Opt In Package for Filed Claims in the manner required bars such Claimant from enrollment and potential recovery of an award under the Program.

Subject to the requirements of Section 11.03 below, for Claims involving Product Users who are deceased or incapacitated, if a Release cannot be executed prior to the Opt In Deadline because the process of appointment of the necessary legal representative for the Product User has not been completed, such Claimants may be permitted to opt in to the Program without providing the Release, provided that the proceeding necessary to obtain the necessary appointment is initiated prior to the Opt In Deadline.

- (D) Submission of the Opt In Package for Filed Claims (i) is irrevocable; (ii) binds the Claimant submitting the forms to the terms and conditions of this Agreement; and (iii) constitutes affirmative acceptance of the jurisdiction of the Special Master and the MDL Court (or of the applicable state court should the MDL Court lack subject matter jurisdiction) for all matters and decisions relative to this Agreement.
- (E) Filed Claimants who properly and timely submit an Opt In Package for Filed Claims are enrolled Program Participants, and must submit a Claim Package on or before the Claim Package Deadline.

### **Section 2.03 Implementing Case Management Orders and Deadlines for Enrollment by Claimants with Pending Cases**

- (A) PSRC and Takeda will jointly petition the MDL Court, the Illinois Coordinating Court, and the California Coordinating Court for a case management order in each of those jurisdictions to implement certain deadlines and other provisions of this Agreement and to provide notice of this Agreement, in the form attached hereto as Appendix E (“Implementing CMO”), as modified in the Illinois and California Coordinated Courts to conform to state practice.
- (B) The Implementing CMO will also set forth 11:59 p.m. C.T. on the later of the following dates as the time and date by which Eligible Enrollees must submit the Opt In Package for Filed Claims or Opt In Package for Unfiled Claims, as applicable (“Opt In Deadline”): (x) July 13, 2015; or (y) if, on or before July 13, 2015, an Eligible Enrollee provides to the Claims Administrator a reasonable justification for requiring more than a 75-day period to opt in (as determined by the Claims Administrator in good faith)

the Opt In Deadline pertaining to that Eligible Enrollee shall be extended to August 12, 2015; or (z) if the Claims Administrator shall determine that, for any reason in its discretion, any Eligible Enrollee needs an additional thirty (30) days to opt in, the Opt In Deadline applicable to all Eligible Enrollees shall be September 11, 2015. Upon agreement by Takeda and the PSRC, or at the discretion of the Eligibility Committee, the Opt In Deadline may be further extended as to any Claimant to an agreed-upon date.

- (C) The Opt In Package for Filed Claims and Opt In Package for Unfiled Claims, as applicable, must be timely submitted in accordance with instructions provided by the Claims Administrator, including making such submission online where specified. *See* [www.actosofficialsettlement.com](http://www.actosofficialsettlement.com).

#### **Section 2.04 Enrollment Procedures for Qualifying Unfiled Claimants**

- (A) Claimants who did not have a case pending against Defendants in state or federal court on or before the Execution Date, but who allege (i) usage of ACTOS Products prior to December 1, 2011, and (ii) an Eligible Injury resulting from the use of ACTOS Products occurring in the United States prior to the Execution Date, and who provide a properly executed and timely Opt In Package for Unfiled Claims pursuant to the procedures set forth in this Section, are “Qualifying Unfiled Claimants,” and may be enrolled in the Program as Program Participants, if it can be affirmed that the Claimant (or the Claimant’s Personal Representative) signed a retainer agreement with an attorney or with his or her law firm on or before the third (3rd) day following the Execution Date for legal representation of said Claimant relating to an Alleged Injury allegedly resulting from the use of ACTOS Products. Accordingly, Claimants who have not been represented by Counsel on or before the third (3rd) day following the Execution Date in relation to personal injury claims alleged to have resulted from the use of ACTOS Products and who do not have a case against Defendants that was pending in state or federal court on the Execution Date are not eligible for enrollment in the Program.
- (B) The “Opt In Package for Unfiled Claims” must include the following:
  - a. A “Notice of Intent to Opt In Form for Unfiled Claims,” executed by Signature of the Claimant, in the form contained in Appendix F;
  - b. A “Declaration of Counsel,” in the form contained in Appendix G, executed by Signature of the Claimant’s counsel, affirming that the Claimant (or the Claimant’s Personal Representative) had signed a retainer agreement with that attorney or with his or her law firm on or before the third (3rd) day following the Execution Date for legal representation of said Claimant

relating to an Eligible Injury allegedly resulting from the use of ACTOS Products; and

- c. A Release contained in Appendix C, to be executed by Personal Signature by the Claimant or the Personal Representative of Claimant, and all Persons having or asserting the right to bring claims, including future wrongful death claims, by reason of their relationship with the Product User, including, without limitation, the Product User's spouse or surviving spouse, representatives, and/or heirs, concerning the Product User's alleged use of ACTOS Products.

Subject to the requirements of Section 11.03 below, for Claims involving Product Users who are deceased or incapacitated, if a Release cannot be executed prior to the Opt In Deadline because the process of appointment of the necessary legal representative for the Product User has not been completed, such Claimants may be permitted to opt in to the Program without providing the Release, provided that the proceeding necessary to obtain the necessary appointment is begun prior to the Opt In Deadline.

- (C) The Opt In Package for Unfiled Claims must be submitted on or before the Opt In Deadline, as may be extended in accordance with Section 2.03(B) above.
- (D) The Opt In Package for Unfiled Claims must be timely submitted in accordance with instructions provided by the Claims Administrator, including making such submission online where specified. *See* [www.actosofficialsettlement.com](http://www.actosofficialsettlement.com).
- (E) Submission of the Opt In Package for Unfiled Claims is irrevocable. Qualifying Unfiled Claimants who properly and timely submit an Opt In Package for Unfiled Claims are (i) enrolled Program Participants bound by the terms of this Agreement; (ii) agree to submit to the jurisdiction of the Special Master and the MDL Court (or, if the MDL Court does not have subject matter jurisdiction, to the jurisdiction of the Illinois Coordinated Court or the California Coordinated Court), and (iii) must submit a Claim Package on or before the Claim Package Deadline.

## **Section 2.05 Notification of Enrollment Status and Program Participation**

- (A) The Claims Administrator will provide notice to all Eligible Enrollees who have cases pending in a state or federal court and/or whose claims are identified by Plaintiffs' counsel in the Case Census, of their "Final Enrollment Status," meaning their status as either a Program Participant or Unenrolled Claimant (as defined in Paragraph 2.05(B) below), on a rolling basis and no later than ten (10) days after the latest Opt In Deadline applicable to such Claimant.



- (B) An “Unenrolled Claimant” is an Eligible Enrollee who (as may be applicable to them pursuant to Section 2.01 through Section 2.04) fails to serve: (a) a complete and timely Opt In Package for Filed Claims, if a Filed Claimant; or (b) a complete and timely Opt In Package for Unfiled Claims, if a Qualifying Unfiled Claimant.
- (C) Within seven (7) days of receiving notice of his or her Final Enrollment Status, an Eligible Enrollee may seek reconsideration of his or her status as an Unenrolled Claimant from the Claims Administrator, which reconsideration will be decided by the Claims Administrator within seven (7) days of such reconsideration request. Eligible Enrollees may submit Opt In Package documentation or other additional materials to the Claims Administrator in connection with such reconsideration request. The Claims Administrator’s reconsideration decision regarding Final Enrollment Status is binding and Non-Appealable.

### **Section 2.06 Program Participation is Exclusive and Irrevocable**

By submitting a Notice of Intent to Opt In Form for Filed Claims or a Notice of Intent to Opt In Form for Unfiled Claims, as applicable, all enrolled Program Participants covered by such Opt In Forms, and their counsel, shall be deemed to have agreed to be bound by all of the terms and conditions of this Agreement. A Program Participant may only pursue his or her claim in the Program and may not pursue her claim in any court of law or other proceeding. In no event may Claimants whose cases are dismissed in connection with this ACTOS Resolution Program resubmit their Claims for enrollment in the Program. No enrolled Program Participant may under any circumstances or reason, regardless of the amount of any individual Settlement Payment, withdraw an Opt In Package, request the return of his or her Release or Stipulation of Dismissal, or otherwise unilaterally exit the Program.

### **Section 2.07 Provision of Opt In Forms to Takeda and PSRC**

The Claims Administrator shall make the Notice of Intent to Opt In Forms for Filed Claims, the Notice of Intent to Opt In Forms for Unfiled Claims and the Declarations of Counsel that it receives pursuant to this Article II available to Takeda or the PSRC upon request by either Party.

## **ARTICLE III. CLAIM PACKAGE SUBMISSION**

### **Section 3.01 Claim Package Deadline**

- (A) Program Participants may submit Claim Packages after receipt of a Notice of Final Enrollment Status confirming that the Program Participant has successfully enrolled. Program Participants, by and through their counsel if represented, must submit a complete Claim Package, together with all Supporting Documentation, no later than 11:59 p.m. C.T. on the ninetieth (90th) day following the Effective Date (the “Claim Package Deadline”)

or, as applicable and subject to the terms of Section 3.05, the Cure Deadline. As set forth further in this Article, if certain Supporting Documentation is not available for submission, a Program Participant may submit a No Records Statement to that effect, as set forth in Section 3.03(A)(3), or seek relief from the Eligibility Committee, as described in Section 4.02.

- (B) In the event that a Program Participant fails to submit a complete Claim Package on or before the Claim Package Deadline or Cure Deadline, as applicable, Takeda shall have the right to file the Stipulation(s) of Dismissal provided in the Opt In Package, or file a motion to dismiss the Program Participant's case, if one is pending, with prejudice, and/or to act to enforce the Program Participant's Release, subject to the resolution of any appeals to the Eligibility Committee and/or Special Master pursuant to Sections 4.02 and 9.03.

### **Section 3.02 Consent to Review of Medical Records**

Program Participants are responsible for obtaining and submitting, through their counsel, if represented, the Core Medical Records and other Supporting Documentation required for a Claim Package. Program Participants consent to review of such records by the Claims Administrator (and those employed, or engaged by, the Claims Administrator), PSRC, Takeda, Takeda's counsel, Takeda's insurers, Lien resolution personnel, the Special Master, and the courts.

### **Section 3.03 Complete Claim Package Requirements**

- (A) A complete Claim Package must include the following "Supporting Documentation":
- (1) A completed Claim Form contained in Appendix H, executed by Personal Signature, to include the Program Participant's election of Injury Level;
  - (2) A complete but undated Authorization to Release Records and Other Information contained in Appendix I, executed by Personal Signature. When executing this document, the Program Participant shall not specify particular healthcare providers for the collection of records, but shall leave the provider field of the form blank so that it may be utilized for collection of any necessary records in accordance with the audit provisions set forth in Section 8.05;
  - (3) The following "Core Medical Records," certified by the Program Participant as Complete or unavailable. If any of the following Core Medical Records are unavailable, a certified No Records Statement from the pertinent provider

must be included in the Claim Package.

- i. Records of Bladder Cancer diagnosis, to include:
  1. A pathology report finding the existence of cancerous cells in the urothelial lining of the urinary bladder, the renal pelvis or the ureter; or
  2. If it is determined by the Claims Administrator or the Eligibility Committee, as applicable, that no pathology report is available, despite diligent efforts by the Program Participant to obtain it, provision of other contemporaneous medical records referencing a pathology report containing a diagnosis of Bladder Cancer that, in both instances, are determined by the Claims Administrator or Eligibility Committee, as applicable, to be sufficient to establish a diagnosis of Bladder Cancer.
- ii. Proof of ACTOS Products usage, to include:
  1. Contemporaneous Prescription Records from all pharmacies that dispensed ACTOS Products to the Product User for the period spanning first alleged use of ACTOS Products through the last use of ACTOS Products or June 1, 2012, whichever is earlier; and
  2. Contemporaneous Medical Records documenting Product User's usage of ACTOS Products.
- iii. Complete medical records from all healthcare providers who:
  1. diagnosed the Product User's Bladder Cancer; and/or
  2. provided treatment for the Product User's Bladder Cancer.
- iv. If not otherwise included in the above-listed records, medical records from all healthcare providers who prescribed ACTOS Products to the Product User, for the period spanning first alleged use of ACTOS Products through the last use of ACTOS products.
- v. If not otherwise included in the above-listed records, medical records from all healthcare providers who served

as the Product User's primary care provider, for the period spanning three years prior to the diagnosis of Bladder Cancer through the time of the diagnosis of Bladder Cancer.

- vi. If not otherwise included in the above-listed records, and if Program Participant is alleging Bladder Cancer involving the urothelial lining of the renal pelvis, complete medical records from any nephrologist(s) who treated the Product User.
- vii. If death due to Bladder Cancer is alleged, a Death Certificate or an Autopsy Report.

(4) A Payment Election Form, as required by the Claims Administrator, to indicate the Qualified Settlement Fund ("QSF") Administrator is to issue any Settlement Payment to such Program Participant through his or her counsel, if represented, subject to and in accordance with the terms of this Agreement and the Qualified Settlement Fund Agreement. If payments are to be made by wire, the Payment Election Form shall include the wire instructions for use by the QSF Administrator. Primary Counsel representing more than one Program Participant may provide one Payment Election Form applicable to all such Program Participants.

(5) Where the Claim is being brought in a representative capacity by a Program Participant who is not the Product User, documentation, such as letters of administration, sufficient to establish that the Program Participant is the duly authorized legal representative for the Product User or the Product User's estate. The Claims Administrator, with the approval of the PSRC and Takeda, may adopt a procedure specifying the proof required of the authority of a Representative Claimant to act on behalf of a deceased or incapacitated or incompetent Product User.

(6) A W-9 Form, which will be made available by the Claims Administrator, providing the information required by such form for Primary Counsel. Each Primary Counsel shall provide only one W-9 Form.

**(B)** Program Participants may submit additional records to the Claims Administrator, beyond those that are required, if reasonably related to the Program Participant's Alleged Injury or to a Derivative Claim. All Derivative Claims must be included as a part of the Claim Package

submitted by or on behalf of the Product User. Persons who did not use ACTOS Products may not submit a separate Claim Package under the Program.

#### **Section 3.04 Claim Package Submission**

Claim Packages must be submitted to the Claims Administrator on or before the Claim Package Deadline in accordance with instructions provided by the Claims Administrator, including making such submission online where specified. *See* [www.actosofficialsettlement.com](http://www.actosofficialsettlement.com).

#### **Section 3.05 Determination of Adequacy and Completeness of Claim Packages**

- (A) The Claims Administrator shall review all Claim Packages submitted to the Program to determine whether a Claim Package is complete and meets the requirements of Section 3.03. A Claimant whose Claim Package for any reason does not meet the requirements of Section 3.03 shall be considered incomplete, shall fail to establish an Eligible Claim, and will subject the Claim to dismissal with prejudice, as described below, without compensation, absent timely cure as set forth herein. The decision as to the completeness and adequacy of the Claim Package is in the sole discretion of the Claims Administrator, subject to review by the Eligibility Committee and the Special Master to the extent provided for by this Agreement, in accordance with Sections 4.02 and 9.03 below.
- (B) As part of the Claims Administrator's determination of the adequacy and completeness of the Claim Package, the Claims Administrator will determine whether the Program Participant's alleged diagnosis of Bladder Cancer is substantiated by a pathology report finding the existence of cancerous cells in the urothelial lining of the urinary bladder, the renal pelvis or the ureter after the Program Participant was first prescribed or provided ACTOS Products, or, if it is determined by the Claims Administrator that no pathology report is available, other contemporaneous medical records referencing a pathology report containing a diagnosis of Bladder Cancer that, by the determination of the Claims Administrator, are sufficient to establish the diagnosis of Bladder Cancer. If the Claims Administrator does not find that the Claim Package supports a diagnosis of Bladder Cancer after the Program Participant was first prescribed or provided ACTOS Products, the Claim Package will be determined to be deficient by the Claims Administrator.
- (C) The Claims Administrator shall inform the Program Participant's counsel, or the Program Participant, if not represented by counsel, within thirty (30) days (unless the Claims Administrator provides notice that additional time is required) after submission of the Claim Package or, in the case of a Program Participant who fails to submit any Claim Package, within fifteen (15) days (unless the Claims Administrator provides notice that additional

time is required) after the Claim Package Deadline (each a “Notice of Claim Package Deficiency”), whether any or all of the Supporting Documentation is missing, inadequate or incomplete. Failure to correct the deficiencies on or before the later of (x) the thirtieth (30th) day following the date of the Notice of Claim Package Deficiency or (y) if the Program Participant on or before the thirtieth (30th) day following the date of the Notice of Claim Package Deficiency has provided to the Claims Administrator a reasonable justification for requiring more than a 30-day cure period (as determined by the Claims Administrator in good faith), the sixtieth (60th) day following the date of the Notice of Claim Package Deficiency (as applicable, the “Cure Deadline”), will result in rejection of the Claim Package. The Claims Administrator shall provide notice of the rejection of the Claim Package to Claimant’s counsel within ten (10) days following the expiration of the Cure Deadline (“Notice of Rejection”).

“Reasonable justification” with respect to the foregoing shall include substantiation to the Claims Administrator that any missing Core Medical Records have been appropriately requested from the relevant provider, and that such request is pending. Any issues regarding such pending records requests after the Cure Deadline may be addressed to the Eligibility Committee pursuant to Article IV below who may authorize the Claims Administrator to provide further additional reasonable extensions to the Cure Deadline as necessary with respect to such pending records requests.

- (D) Within ten (10) days following the issuance of a Notice of Rejection to a Program Participant, or, within ten (10) days following the last affirmance of such a Notice of Rejection after any available review by the Eligibility Committee and/or appeal to the Special Master has been sought to the extent provided for by this Agreement, the Claims Administrator shall deliver the Release and the Stipulation(s) of Dismissal provided with the Opt In Package, to Takeda. Takeda, or, if Takeda is not a Defendant in the case, any Defendant in such case, may thereupon file the Stipulation(s) of Dismissal with the appropriate court. If necessary to effectuate dismissal of the Program Participant’s claim, Takeda may also seek dismissal by motion made in the appropriate court.
- (E) The Claims Administrator shall provide monthly updates to Takeda and PSRC as to the submission, review and approval process for Claim Packages. Takeda or PSRC may request copies of any Claim Package or any other documentation submitted with such Claim Package from the Claims Administrator, with the expense of such copies, if any, to be borne by the requesting Party.

## ARTICLE IV. ELIGIBLE CLAIMS AND ELIGIBILITY COMMITTEE

### Section 4.01 Eligible Claims

Only “Eligible Claims” may be compensated in the Program. An Eligible Claim requires the following:

- (1) The Claimant has received notification of her Final Enrollment Status as a Program Participant; and
- (2) The Claimant has timely submitted a complete Claim Package as set forth in Article III.

### Section 4.02 Review by the Eligibility Committee

(A) If any Claim Package is determined to be deficient by the Claims Administrator because it does not include each of the Core Medical Records, as set forth in Section 3.03(A)(3) above, or does not otherwise constitute an Eligible Claim, the Claimant may request determination by the Eligibility Committee as to whether his or her Claim Package nonetheless establishes an Eligible Claim.

- (1) The “Eligibility Committee” shall consist of the following committee members:

a. **MDL Plaintiffs’ Counsel:**

- i. Richard J. Arsenault
- ii. Andy D. Birchfield, Jr.
- iii. W. Mark Lanier
- iv. Patrick C. Morrow
- v. Neil D. Overholtz
- vi. Paul J. Pennock

b. **Illinois Coordinated Proceedings Plaintiffs’ Counsel:**

- i. Tommy Fibich
- ii. Peter Flowers
- iii. Tor Hoerman

**c. Takeda Counsel:**

- i. Three members, to be designated by Kenneth D. Greisman, Senior Vice President, General Counsel and Secretary, Takeda Pharmaceuticals International, Inc. and Takeda Pharmaceuticals U.S.A., Inc.

In any vote on an issue before the Eligibility Committee, each of the three above-listed groups shall have one vote. In the event of a 2-to-1 vote on any issue, the group in the minority shall have the right to appeal the issue to the Special Master.

- (2) Program Participants seeking review by the Eligibility Committee must submit a request for Eligibility Committee review within ten (10) days following the issuance of a Notice of Rejection of the Program Participant's Claim Package by the Claims Administrator.
  - (3) For each Claim Package submitted to them, the Eligibility Committee will determine whether the medical records provided establish sufficient proof of (1) Claimant's usage of ACTOS Products, and (2) Claimant's diagnosis of Bladder Cancer following the initiation of his or her usage of ACTOS Products. If, in their discretion the Eligibility Committee determines that the records provided by Claimant constitute sufficient proof of these two criteria, such Claimant will be deemed to have established an Eligible Claim, notwithstanding the deficiencies in the Claim Package.
  - (4) The determination of the Eligibility Committee shall be appealable by the Program Participant to the Special Master, in accordance with Section 9.03 below, within ten (10) days of the issuance of the Eligibility Committee's determination. The Special Master's determination of whether a deficient Claim Package nonetheless can establish an Eligible Claim shall be final, binding and Non-Appealable.
- (B)** If, by the determination of the Eligibility Committee, or by the determination of the Special Master if appealed, a Claim Package does not establish sufficient proof of (1) Claimant's usage of ACTOS Products, and (2) Claimant's diagnosis of Bladder Cancer following the initiation of his or her usage of ACTOS Products, and is therefore deemed not to established an Eligible Claim, the Claims Administrator shall deliver the Release and the Stipulation(s) of Dismissal to Takeda within thirty (30) days from the determination and Takeda may thereupon file the Stipulation(s) of Dismissal with the appropriate court.



## ARTICLE V. TERMINATION RIGHT

### Section 5.01 PSRC Efforts

The Parties to this Agreement believe that this Agreement represents a fair, just and efficient method for resolving ACTOS Products claims. The PSRC will use their best efforts to achieve sufficient participation to meet the participation benchmarks necessary to effectuate the Program.

### Section 5.02 Walk Away Right

- (A) Takeda shall have the option, in its sole discretion, to terminate the Program and this Agreement if, but only if, in Takeda's determination, certain thresholds of participation ("Required Participation Thresholds") in the Program are not met, as set forth in Paragraph (B) below (the "Walk Away Right").
- (B) Takeda's Walk Away Right may be overcome only if each of the following Required Participation Thresholds is satisfied by the enrollment of Program Participants:
- (1) **Overall Participation:** No less than ninety-five percent (95%) participation of all Eligible Enrollees;
  - (2) **Wrongful Death:** No less than ninety-five percent (95%) participation of all Eligible Enrollees alleging wrongful death;
  - (3) **Cystectomy:** No less than ninety-five percent (95%) participation of all Eligible Enrollees alleging a Cystectomy;
  - (4) **Age Less Than 60 Years Old:** No less than ninety-five percent (95%) participation of all Eligible Enrollees who were less than 60 years of age at the time of their diagnosis of Bladder Cancer; and
  - (5) **Use of ACTOS Products for More Than 24 Months:** No less than ninety-five percent (95%) participation of all Eligible Enrollees who allege more than 24 months of ACTOS Products usage prior to their diagnosis of Bladder Cancer.
- (C) For purposes of determining whether each of the foregoing Required Participation Thresholds have been met:
- (1) The denominator for each respective category set forth in Paragraph (B)(1)-(5) above will include all Eligible Enrollees in each such category with cases pending as of

the Execution Date in the MDL, the State Coordinated Proceedings, any Other Federal Court Proceedings, and any Other State Court Proceedings, as well as any additional unfiled claims as identified in the Case Census, as well as all Eligible Enrollees who assert unfiled claims as Qualifying Unfiled Claimants in this Program that were not included in the Case Census.

- (2) The denominator for the Overall Participation category set forth in Paragraph (B)(1) above shall be adjusted for accuracy using the information available from the Case Census, Plaintiff Fact Sheets, Complaints, and/or other available case information, prior to the determination of whether each of the foregoing Required Participation Thresholds have been met.
- (3) The numerator for each respective category set forth in Paragraph (B)(1)-(5) above will include all Eligible Enrollees in each such category who are Program Participants.

(D) Takeda may exercise the Walk Away Right, if available, on or before 11:59 p.m. C.T. on the forty-fifth (45<sup>th</sup>) day following the last Opt In Deadline attributable to any Eligible Enrollee, subject to Section 15.01(B). Takeda shall exercise its Walk Away Right by filing notice through the MDL Court’s Electronic Case Filing System. Takeda also shall provide written notice of its exercise of the Walk Away Right, as applicable, to the state court judges presiding over the Illinois Coordinated Proceedings and California Coordinated Proceedings, with a copy to state-court liaison counsel. The date on which Takeda’s Walk Away Right expires without previously having been exercised, or any previous date agreed upon by Takeda and the PSRC, shall be the “Effective Date.”

### **Section 5.03 Consequences of Exercise of Walk Away Right**

Upon exercising the Walk Away Right, the Program shall immediately terminate and this Agreement becomes null and void, Takeda shall not be obligated to deposit any Settlement Funds into the Qualified Settlement Fund, and all Releases and Stipulations of Dismissal or Motions to Dismiss shall promptly be returned to PSRC, the Program Participant’s counsel, or the *pro se* Program Participant, as appropriate. Takeda shall be responsible for payment of any Administrative Expenses incurred through the termination date.

## **ARTICLE VI. CLAIMS VALUATION**

### **Section 6.01 General**

- (A) If the Claims Administrator, Eligibility Committee, or Special Master, as applicable, determines that a Program Participant's Claim is an Eligible Claim under the terms of the Agreement, the Claims Administrator will determine the amount of each such individual Program Participant's settlement award (which may be paid as an Interim Payment, Final Payment and/or EI Payment, as set forth below, referred to collectively herein as "Settlement Payment(s)"), consistent with the terms of this Agreement. Each Program Participant who is determined to have an Eligible Claim under the terms of the Agreement shall be deemed to be a "Qualifying Program Claimant." The Claims Administrator shall have the responsibility to allocate the Settlement Funds among all Qualifying Program Claimants, consistent with the terms of this Agreement.
- (B) Each Qualifying Program Claimant shall receive Interim Payments and/or Final Payments based on the number of "Points" awarded to such Qualifying Program Claimant during the Claim Assessment process described in Section 6.02 (including Appendix J) (the "Points Award Process") and the value of those Points as determined after all Qualifying Program Claimants have completed the Points Award Process and EI Payment Process, as applicable. The Points Award Process, together with the EI Payment Process set forth in Section 7.02, may be referred to collectively herein as the "Claims Valuation Process."
- (C) For purposes of conducting the Claims Valuation Process, in addition to the Supporting Documentation submitted as part of a Qualifying Program Claimant's Claim Package, the Claims Administrator may also consider medical and employment records, if any, relating to such Qualifying Program Claimant that were obtained by Takeda in connection with the litigation of such Qualifying Program Claimant's Claim.
- (D) No Program Participant shall be entitled to any Settlement Payment other than in accordance with the terms of this Agreement, nor shall any Program Participant be entitled to pursue any claim for any other injury allegedly resulting from the use of ACTOS Products. Except in the event that the Walk Away Right is exercised pursuant to Article V, Program Participants disclaim any claim to receive any punitive, exemplary, or emotional damages and understand and agree that no payment made hereunder is or shall be deemed to be attributable to punitive, exemplary, or emotional damages. All Settlement Payments made pursuant to the Program constitute damages on account of personal injuries or physical injuries or physical sickness within the meaning of Section 104 of the Internal Revenue Code of 1986, as amended, arising from the physical injuries alleged to have resulted from the use of ACTOS Products. The presence of any Derivative Claimants who assert claims relating to the Alleged Injuries of any Program Participants shall not affect the valuation of such Program Participants' claims, and there shall be no separate settlement awards made to any Derivative Claimants.

## Section 6.02 The Points Award Process

- (A) After a Program Participant has timely submitted a complete Claim Package that meets all the requirements of Section 3.03, or alternatively if such Program Participant's Claim Package has otherwise been determined by the Eligibility Committee or Special Master to establish an Eligible Claim, and such Program Participant has been determined or deemed to be a Qualifying Program Claimant, the Claims Administrator shall determine the number of Points ("Points Award") that should be awarded to the Qualifying Program Claimant. The criteria, methodologies, formulae, guidelines and other terms and conditions for determining Points Awards (collectively, the "Point Awards Criteria") are set forth in the "Points Matrix," attached as Appendix J to this Agreement. The Points Award analysis performed by the Claims Administrator shall be based solely on the terms and conditions of the Points Matrix and this Section 6.02.
- (B) As outlined in Appendix J, assessment of Points shall consider (without limitation and among other factors as set forth in Appendix J) the extent of injury and treatment, age, duration and dosage of ACTOS Products usage, timing of ACTOS Products usage, and risk factors for development of Bladder Cancer.
- (C) The Claims Administrator shall notify each Qualifying Program Claimant, Takeda, and the PSRC of such Qualifying Program Claimant's Points Award using a form developed for such purpose by the Claims Administrator ("Notice of Points Award"). A Point Award is not final and is subject to revision at any time until Final Payment. Such Points Award shall be subject to reconsideration by the Claims Administrator and appeal to the Special Master as set forth in Sections 6.02(D) and (E), and Section 9.03, but otherwise shall be final, binding and Non-Appealable.
- (D) A Qualifying Program Claimant Participant may seek reconsideration by the Claims Administrator of such Qualifying Program Claimant's Points Award by filing a request for reconsideration with the Claims Administrator within fifteen (15) days of the Notice of Points Award. The Claims Administrator will respond to any such request for reconsideration within thirty (30) days ("Notice of Reconsideration Determination"). Appeals to the Special Master pursuant to this Section may be taken only from the Claims Administrator's decision after a request for reconsideration, not from the initial decision of the Claims Administrator. If a timely request for reconsideration is not made, no appeal may be brought. The Special Master may at his discretion consult with the Eligibility Committee regarding any appeals made under this Section.
- (E) In accordance with Section 9.03, a Qualifying Program Claimant may appeal his or her Points Award determination of the Claims Administrator to the Special Master by submitting a notice to such effect to the Claims

Administrator and the Special Master within fifteen (15) days of the Notice of Reconsideration Determination, in accordance with procedures established by the Claims Administrator. The Special Master thereupon shall review such Points Award determination *de novo*. If, upon any such timely appeal, the Special Master determines that a Points Award determination of the Claims Administrator was in error, the Special Master either may return the matter to the Claims Administrator for a further determination (which itself may be appealed in the same manner as specified above) or may substitute its own Points Award determination for that of the Claims Administrator. All such Points Award determinations of the Special Master shall be final, binding and Non-Appealable. The Special Master shall notify the Claims Administrator of its determination, and the Claims Administrator shall, promptly following receipt of such notice, notify Counsel for the relevant Qualifying Program Claimant (or, if such Qualifying Program Claimant is without counsel, such Qualifying Program Claimant), Takeda and the PSRC of the Special Master's determination.

## **ARTICLE VII. PAYMENTS TO QUALIFYING PROGRAM CLAIMANTS**

### **Section 7.01 Interim Settlement Payments**

- (A) Pursuant to procedures to be established by the Claims Administrator, subject to agreement by Takeda and the PSRC, and at a time agreed upon by Takeda and the PSRC, the Claims Administrator shall make an estimated interim determination of the dollar value that is expected to be assigned per Point in the Program after all final Point Awards have been determined for each Qualifying Program Claimant ("Estimated Points Valuation").
- (B) Within 45 days after the Claims Administrator has made the Estimated Points Valuation, interim settlement payments ("Interim Payments") shall be made to Qualifying Program Claimants from the QSF in an amount to be determined and approved by the Claims Administrator and by the Lien Resolution Administrator in accordance with Article XIII, pursuant to procedures to be established by the Claims Administrator and subject to agreement by Takeda and the PSRC, subject to the provisions of Section 11.03 regarding Releases, and in accordance with the Medicare, Medicaid, and SCHIP Extension Act of 2007 ("MMSEA") and all other applicable laws relating to Lien satisfaction and reporting. No part of any Interim Payment shall be reimbursement for costs of medical care.

### **Section 7.02 Extraordinary Injury Fund Payments**

- (A) Qualifying Program Claimants may apply to receive additional payments from an Extraordinary Injury Fund ("EI Payments") in addition to the Interim Payments and Final Payments made to them in accordance with

their Point Awards pursuant to Sections 7.01 above and 7.03 below. The Claims Administrator's determination of EI Payments as set forth in this Section 7.02 may be referred to as the "EI Payment Process." A \$1,000 Administrative Application Fee, payable to the Claims Administrator, will be charged for all Extraordinary Injury applications. Applications for EI Payments shall be made in good faith. Any dispute regarding whether an application is made in good faith is to be determined by the Special Master. The failure to exercise good faith may result in a de novo review of the Claimant's Points Award determined under Section 6.02 above and a potential reduction of same.

- (B) EI Payments for all Qualifying Program Claimants cannot in the aggregate exceed \$50 million (the "EI Fund Cap Amount"), which amount shall initially be earmarked for EI Payments within the Settlement Funds deposited by Takeda pursuant to Article X. Following the completion of the EI Payment Process for all applicable Qualifying Program Claimants, any remaining funds initially earmarked for EI Payments that have not been distributed as part of the EI Payment Process shall be included with the balance of the Settlement Funds for the determination of the Final Point Value, as set forth below.
- (C) Each Qualifying Program Claimant that desires to seek an EI Payment shall have the burden of proving to the Claims Administrator's satisfaction such Qualifying Program Claimant's eligibility for such EI Payment, and, in that connection, may be required by the Claims Administrator to produce further documentation.
- (D) To be eligible to be considered for an EI Payment, a Qualifying Program Claimant must (i) have (or be a Qualifying Program Claimant in respect of a Product User that has) Specified Documented Economic Damages of not less than \$200,000; (ii) establish an injury of Bladder Cancer and have minor children at the time of the Product User's alleged injury; and/or (iii) establish extenuating circumstances relative to the Product User's alleged injury warranting compensation that are not otherwise addressed by the Points Award Process. The Claims Administrator shall consult with the Eligibility Committee to determine the factors for evaluating whether a Claimant has shown extenuating circumstances.
  - a. "Specified Documented Economic Damages" means, in relation to any Product User, (i) such Product User's past out-of-pocket medical expenses and (ii) such Product User's past lost wages or future lost wages, through a date to be determined by the Claims Administrator, in each case to the extent that such expenses or lost wages, as the case may be, are (x) a result of such Product User's Eligible Injury, (y) Documented, and (z) have neither been reimbursed nor are eligible for reimbursement.

- b. “Documented” means established by medical records, billing records, tax returns, social security earnings statements or any other documentation or evidence requested, or otherwise found acceptable, by the Claims Administrator.
- (E) Each Qualifying Program Claimant that is eligible for, and properly and timely applies for, an EI Payment shall (subject to Article XIII and to all of the other terms and conditions of this Agreement) receive an EI Payment according to criteria to be determined by the Claims Administrator.
- (F) Determinations concerning a Qualifying Program Claimant’s eligibility for an EI Payment, and the amount thereof, shall be made by the Claims Administrator. The Claims Administrator shall promptly notify each Qualifying Program Claimant, Takeda and the PSRC of such Qualifying Program Claimant’s EI Payment determination. All EI Payment determinations of the Claims Administrator shall be made according to guidelines to be established by the Claims Administrator in consultation with Takeda and the PSRC.
- (G) The Claims Administrator’s determination concerning a Qualifying Program Claimant’s eligibility for an EI Payment, and the amount thereof, shall be appealable by either Takeda or the Program Participant to the Special Master, in accordance with Section 9.03 below, within fifteen (15) days of the issuance of the Claims Administrator’s determination. The Special Master’s resolution of all appeals relating to EI Payments shall be final, binding and Non-Appealable.
- (H) EI Payment awards shall be determined in the first instance without regard to the EI Fund Cap Amount, but EI Payment shall be made until all possible EI Payment eligibility and awards determinations have been made, and any Special Master Appeals thereof resolved. However, any term of this Agreement to the contrary notwithstanding, if, after such process has been fully completed, the total aggregate EI Payments so awarded in the first instance would (but for this sentence) exceed the EI Fund Cap Amount, all such initial EI Payment awards shall be reduced pro rata to the extent necessary so that such aggregate EI Payment awards exactly equal the EI Fund Cap Amount. After completion of the entire process set forth in this Section 7.02 with respect to EI Payments, the final EI Payment awards shall be paid no earlier than thirty (30) days following the Claims Administrator’s Final Points Valuation, in accordance with Article XIII, and subject to the provisions of Section 11.03 regarding Releases.

### **Section 7.03 Final Settlement Payments**

- (A) No final settlement payments (“Final Payments”) may be made to any Qualifying Program Claimant from the QSF until final Point Awards have been established for each enrolled Claimant, and all EI Payment eligibility and awards determinations for any applicable Claimant have been made, and any Special Master Appeals thereof resolved, and a final dollar value per Point (“Final Point Value”) has been calculated by the Claims Administrator (“Claims Administrator’s Final Points Valuation”).
- (B) Final Payments shall be paid to each Qualifying Program Claimant from the QSF in an amount equal to (x) the product of such Qualifying Program Claimant’s Points Award multiplied by the Final Point Value, minus (y) the amount of any Interim Payment made to such Qualifying Program Claimant, subject to the provisions of Article XIII, and in accordance with MMSEA and all other applicable laws relating to Lien satisfaction and reporting.
- (C) Subject to the provisions of Section 11.03 regarding Releases, the Claims Administrator shall give notice to the QSF Administrator of the amount of the Final Payment to be made to each Qualifying Program Claimant within 45 days following the later of: (1) the Claims Administrator’s Final Points Valuation, or (2) notification given from the Lien Resolution Administrator to the Claims Administrator and Takeda that such Claimant’s outstanding Liens have been satisfied or otherwise resolved in accordance with Article XIII, and payment shall be made from the QSF within fifteen (15) days of the Claims Administrator’s notification of the amount of the Final Payment for the applicable Qualifying Program Claimant. If Claimant has no outstanding Liens, Final Payment shall be made from the QSF within 60 days following the Claims Administrator’s Final Points Valuation.

#### **Section 7.04 Satisfaction of Liens**

For the avoidance of doubt, this Article VII is subject in all respects to Article XIII.

### **ARTICLE VIII. CLAIMS ADMINISTRATOR**

#### **Section 8.01 Claims Administrator Selection**

- (A) This Agreement is a private agreement.
- (B) A Claims Administrator shall be selected by Takeda, subject to agreement by PSRC.
- (C) At the request of PSRC and Takeda, BrownGreer PLC has agreed to preside over the Program as the initial Claims Administrator.



- (D) Any successor to the initial Claims Administrator shall fulfill the same functions from and after the date of its succession and shall be bound by the determinations made by its predecessor(s) to date.
  - (1) In the event that PSRC and Takeda are unable to agree upon the appointment of a mutually agreeable successor Claims Administrator, PSRC and Takeda's counsel will each present two (2) candidates to the MDL Court.
  - (2) The MDL Court will, in consultation with the judges presiding over the California and Illinois Coordinated Proceedings, interview the candidates in camera to determine who will serve as the successor Claims Administrator. The order of the MDL Court will be final and Non-Appealable.

### **Section 8.02 Responsibilities and General Authority**

- (A) The Claims Administrator shall carry out the responsibilities for Program enrollment and claim administration and review set forth in this Agreement as well as any additional responsibilities, if any, set forth in any subsequent amendments to this Agreement.
- (B) The Claims Administrator shall have the authority to perform all actions, to the extent not expressly prohibited by, or otherwise inconsistent with, any provision of this Agreement, deemed by the Claims Administrator to be reasonably necessary for the efficient and timely administration of this Agreement. For the avoidance of doubt, the Claims Administrator shall not serve as the QSF Administrator under the terms of the Qualified Settlement Fund Agreement.
- (C) The Claims Administrator may create administrative procedures, supplementary to (and not inconsistent with) those specified herein or in the Appendices hereto, that provide further specific details about how the Program is to be administered, and/or other aspects of the Program, including, but not limited to, procedures regarding submission of documents, procedures regarding execution and signature of documents, and procedures regarding determination of timeliness of submissions; provided, however, that such procedures comply, or otherwise are not in conflict, with the terms of this Agreement, and to which PSRC and Takeda agree.
- (D) Without limitation of the foregoing, the Claims Administrator shall have the authority to modify and/or supplement the Claim Form and any other form or Appendix required by this Agreement to provide for more efficient administration of the Program, subject to prior written consent by Takeda and PSRC, provided that no Program Participant who previously

completed an earlier iteration of the Claim Form shall be required to submit a new Claim Form.

- (E) Without limitation of the foregoing, the Claims Administrator will:
- (1) determine whether a Claimant is enrolled as a Program Participant;
  - (2) review and make determinations of whether a Claimant's Claim Package is timely and complete in accordance with the provisions of Section 3.03 and Section 3.05;
  - (3) determine whether a Claimant has an Eligible Claim and is a Qualifying Program Claimant under the terms of the Agreement, pursuant to Sections 4.01 and 6.01, and subject to Section 4.02;
  - (4) determine the number of Points to be awarded to each Qualifying Program Claimant in the Points Award Process, in accordance with Sections 6.01 and 6.02 and the Points Matrix (Appendix J);
  - (5) make an Estimated Points Valuation, in accordance with Section 7.01(A);
  - (6) determine the amount of any Interim Payment to be made to each Qualifying Program Claimant, subject to the approval of the Lien Resolution Administrator, in accordance with Section 7.01(B);
  - (7) determine the Final Point Value, pursuant to Section 7.03(A);
  - (8) determine the amount of all Final Payments to be made to each Qualifying Program Claimant, and give notice to the QSF Administrator of such Final Payment amounts, in accordance with Sections Section 7.03(B) and Section 7.03(C);
  - (9) make all determinations concerning each Qualifying Program Claimant's eligibility for an EI Payment and the amount thereof, in accordance with Section 7.02;
  - (10) Facilitate audits of Claim Packages in accordance with Section 8.05; and
  - (11) Deliver Stipulations of Dismissal and Releases provided by Program Participants in their Opt In Packages to Takeda, in accordance with the terms of this Agreement.
- (F) The Claims Administrator, the QSF Administrator, and the PSRC shall cooperate with Takeda in providing to Takeda any information that is necessary to comply with reporting obligations under the MMSEA, or other applicable laws.

- (G) A time period prescribed in this Master Settlement Agreement for the Claims Administrator to take action on a matter may be extended at the request of the Claims Administrator only if the volume of submissions relating to that matter warrants an extension and such extension is approved by the PSRC and Takeda.

### **Section 8.03 Liability of Administrative Personnel**

No Claims Administrator, Claims Administrator Liaison, or Special Master, or employee or agent thereof, shall be liable to any Claimant, Eligible Enrollee, Program Participant, or their respective counsel for his acts or omissions, or those of any agent or employee thereof, in connection with the Program except, with respect to each such Person, for such Person's own willful misconduct. Nothing in this Section confers on any Claimant, Eligible Enrollee, Program Participant, or their respective counsel any privity of contract with, or other right to institute any action against, any Claims Administrator, Claims Administrator Liaison, or Special Master. In the event that the Claims Administrator, Claims Administrator Liaison, or Special Master must comply with any discovery obligations related to its work under this Agreement, the requesting party bears the cost of complying with such discovery obligation and such work and costs are expressly excluded from this Agreement.

### **Section 8.04 Method of Notification**

All notifications required to be sent by the Claims Administrator under this Agreement shall be provided by a method selected by the Claims Administrator as the most efficient. The use of electronic mail to an address supplied by counsel for the Program Participant, or the Program Participant directly if not represented by counsel, shall be sufficient for all notifications required to be sent by the Claims Administrator. Notice may also be served by any other reasonable method determined by the Claims Administrator. If there is more than one counsel of record on the complaint, the notice shall be given to the counsel listed first. If the Claimant is *pro se*, notice shall be provided directly to the *pro se* Claimant.

### **Section 8.05 Takeda/Lilly/PSRC Audit Right**

- (A) In accordance with the terms of this Section, Takeda, Lilly and PSRC shall each have the right and discretion, at each's own expense, to itself conduct, or have conducted by an independent auditor, audits to verify Claims submitted by Program Participants or any aspect thereof. Such audits may include individual Claim Packages or groups of Claim Packages. To this end, Takeda, Lilly and PSRC shall each have the right to submit additional records that it has gathered on individual Program Participants that are reasonably related to the Program Participant's Alleged Injury. For any such additional records, the submitting Party shall

provide full copies to the other Party. The Claims Administrator shall fully cooperate with any such audit.

- (B) Takeda, Lilly or the PSRC shall notify the other (and the Claims Administrator) of any audit that it is planning to conduct or to have conducted pursuant to this Section and which Claim Packages (if any in particular) are to be audited. Upon receiving notification that an audit is being initiated under this Section 8.05, if Takeda or the PSRC's position is that such audit should not be conducted, such objecting party may address the issue with the Special Master, who will make a determination regarding whether good cause exists to limit the right to audit. The Special Master shall have discretion to determine whether fees in connection with addressing the issue shall be paid by the non-prevailing party, and the amount of such fees.
- (C) If following completion of its audit of a Claim Package, Takeda, Lilly or PSRC is of the view that any reasonable indicia of deception, dishonesty, or fraud relating to any Claim Package or in any way to the Program exist, Takeda, Lilly or PSRC, as the case may be, may petition the Special Master, under seal, with copies being provided to Program Participant's counsel (or, if *pro se*, to the Program Participant) and Takeda's or Lilly's counsel or PSRC (depending on who may file) pursuant to Section 15.01. Any ruling of the Special Master may be appealed to the MDL Court or, should the MDL Court lack subject matter jurisdiction, to the California or Illinois Coordinated Courts or the court in which the case was filed.
- (D) Without limitation of the foregoing, and any term in this Agreement to the contrary notwithstanding, in the event that the Special Master upon motion by the Claims Administrator, Takeda, Lilly or the PSRC determines that a Program Participant, or Counsel for such Program Participant, has used, or that there is substantial evidence that a Program Participant, or Counsel for such Program Participant, has used, deception, dishonesty or fraud in connection with the Claim of such Program Participant:
  - (1) such Program Participant's Claim shall be denied and such Program Participant immediately shall cease to have any further rights under the Program, but such Program Participant's Stipulation(s) of Dismissal and Release shall be delivered to Takeda and Lilly (and, without limitation, Takeda and Lilly shall be free to file or cause to be filed such Stipulation of Dismissal and/or Release in any relevant action or proceeding);
  - (2) each of such Program Participant (if the Special Master makes such determination in respect of such Program Participant) and such Counsel (if the Special Master makes such determination in respect of such Counsel) shall be fully liable (i) for the costs and expenses (including legal costs and expenses) incurred by the

Claims Administrator, Takeda, Lilly and/or the PSRC in connection with any related audit and/or any related proceedings (including MDL Court, or other court, proceedings) under this Section, and (ii) if applicable, to repay to the QSF any Settlement Payment previously paid to or with respect to such Program Participant (and any such repayment of such Settlement Payment in whole or in part shall be disregarded for purposes of Article XIII); and

- (3) such Program Participant, such Counsel and/or such Counsel's other Program Participants shall be subject to such further sanctions or other penalties as the Special Master may impose, including (i) in the case of such Counsel (and/or such Counsel's other Program Participants), raising the level of scrutiny of (including conducting audits, incremental to those conducted pursuant to Section 8.05(A)) of, modifying the timing of the review of, and/or requiring such Counsel to pay the costs and expenses associated with any future audits (including any such incremental audits) of, any other Claim of any or all of the other Program Participants for which it is Counsel, (ii) suspension of any Interim Payments to all other Program Participants of such Counsel and/or (iii) referral of the matter to the United States Attorney or other appropriate law enforcement officials for possible criminal prosecution, provided that no such further sanctions or other penalties shall affect the status of any other Program Participant or his or her Claim unless such sanction or other penalty is consented to by Takeda and Lilly.

(E) The Claims Administrator shall have the authority and obligation to adopt reasonable procedures to detect deception, dishonesty or fraud in relation to any Claim. In the event that the Claims Administrator determines that any Person (other than a Program Participant or Counsel) has engaged or participated in, or that there is substantial evidence that such Person has engaged or participated in, deception, dishonesty or fraud in relation to any Claim, then, without limitation of the foregoing:

- (1) the Claims Administrator shall refer such matter for possible action by the Special Master pursuant to Section 8.05(C);
- (2) pending resolution by the Special Master of such matter pursuant to Section 8.05(C), the Claims Administrator shall suspend further consideration of any documentation from such Person; and
- (3) the Claims Administrator may raise the level of scrutiny of (including conducting audits, incremental to those conducted pursuant to Section 8.05(A), of), and/or modify the timing of the

review of, any other Claim Package that includes documentation from such Person.

- (F) No Settlement Payment may be paid in respect of any Program Participant while that Claim is the subject of any audit under this provision.
- (G) All audits shall be initiated in good faith.

## **ARTICLE IX. SPECIAL MASTER**

### **Section 9.01 Special Master Appointment**

For the sake of uniformity in rulings and efficiency, PSRC and Takeda agree (a) to recommend to the respective courts that each court appoint Gary J. Russo as Special Master for the purpose of making recommendations on certain motions, as described in Section 9.02, and any petitions brought under Section 8.05, and (b) to privately appoint Gary J. Russo as Special Master for the purpose of hearing appeals of the Claims Administrator's determinations, as described in Section 9.03. The individual initially appointed as Special Master, as well as any successor thereto, is referred to herein as the "Special Master." Any successor to the initial Special Master shall fulfill the same functions from and after the date of his succession and shall be bound by the determinations made by his predecessor(s) to date.

### **Section 9.02 Motions to Dismiss**

The Special Master will (a) hear all motions to dismiss claims that fail to comply with the terms of this Agreement, and (b) recommend to the MDL Court or to the respective federal court or state court Judge, as the case may be, a ruling on each of the motions to dismiss. If the Judge presiding over any specific case has not appointed the Special Master, any motion to dismiss shall be made to the presiding Judge in the jurisdiction where the case is pending.

### **Section 9.03 Appeals to the Special Master from Claims Administrator and Eligibility Committee Determinations**

- (A) The Special Master shall hear appeals from decisions of the Claims Administrator regarding Points Awards pursuant to Sections 6.02(D) and (E). Appeals to the Special Master under this section may be taken only from the Claims Administrator's decision after a request for reconsideration, not from the initial decision of the Claims Administrator. If a timely request for reconsideration is not made, no appeal may be brought.

- (B) The Special Master shall hear timely appeals from decisions of the Eligibility Committee pursuant to Section 4.02.
- (C) Notice of any permitted appeal (each a “Notice of Appeal”) must be sent to the Claims Administrator, on behalf of the Special Master, within the time permitted for appeals as set forth in Sections 4.02(A)(4) or 6.02(E), as applicable.
- (D) The Special Master shall hear timely appeals from the determinations of the Claims Administrator regarding EI Payments pursuant to Section 7.02.
- (E) The Special Master shall hear disputes regarding the scope of Release required under Section 11.03.
- (F) The Special Master’s consideration of any such appeals or disputes shall be limited to the record evidence that was before the Claims Administrator or the Eligibility Committee, as applicable.
- (G) The Special Master must render a decision within thirty (30) days of receipt of the appeal.
- (H) The decision of the Special Master shall itself be final, binding and Non-Appealable (*i.e.*, it shall not be subject to further appeal, either within the Program or to any court or arbitrator). If a Program Participant fails to timely request reconsideration or to meet the Notice of Appeal deadline set forth herein, as applicable, the Program Participant’s right to appeal shall be extinguished and the Claims Administrator’s or Eligibility Committee’s decisions, as applicable, shall be final, binding and Non-Appealable.

**Section 9.04 Petitions to the Special Master Relating to Claim Audits**

The Special Master may hear petitions from the Claims Administrator, Takeda, Lilly (as set forth in Section 15.06) or PSRC regarding deception, dishonesty, or fraud relating to any Claim Package or in any way to the Program, in accordance with Sections 8.05.

**Section 9.05 Special Master’s Costs**

The Party appealing a decision of the Claims Administrator or Eligibility Committee to the Special Master pursuant to Section 9.03 shall be required to pay the costs of the Special Master in considering the appeal. The costs of the Special Master relating to disputes heard pursuant to Section 9.04 shall be assessed in accordance with the provisions of Section 8.05. With respect to all other motions, petitions, or appeals to the Special Master, the non-prevailing Party with respect to such motion, petition, or appeal shall pay the costs of the Special Master for his

consideration of the same.

### **Section 9.06 Submissions to the Special Master**

In any instance in which this Agreement provides for submission of any notice or materials to the Special Master, the submission shall be made to the Claims Administrator and the Claims Administrator shall provide such materials to the Special Master.

## **ARTICLE X. FUNDING OBLIGATIONS**

### **Section 10.01 Settlement Funds**

(A) Subject to the Walk Away Right, as set forth in Article V, Takeda shall pay funds in the aggregate amount of \$2,370,000,000, and, in the event that the Overall Participation rate as set forth in Section 5.02(B)(1) above exceeds ninety seven percent (97%) of all Eligible Enrollees, Takeda shall pay an additional amount of \$30,000,000 (the “Settlement Funds”). The Settlement Funds shall be deposited into the QSF as follows:

1. Within thirty (30) days after the Claims Administrator has made the Estimated Points Valuation, Takeda shall deposit into the QSF such funds as are necessary for the payment of Interim Payments pursuant to Section 7.01; and
2. Within thirty (30) days after the Claims Administrator has made the Claims Administrator’s Final Points Valuation, Takeda shall deposit into the QSF the remaining balance of the Settlement Funds, after deducting any funds previously deposited by Takeda into the QSF following the Estimated Points Valuation for the payment of Interim Payments under paragraph 10.01(A)1 above.

For the avoidance of doubt, under no circumstances shall Takeda or any other Defendant be obligated for the payment of any monies more than the aggregate amount of \$2,370,000,000 in the event of an Overall Participation rate of up to 97%, except that, if the Overall Participation rate exceeds 97%, an additional \$30,000,000 shall be payable, for a total aggregate amount of \$2,400,000,000, as set forth above, nor for any additional monies associated with the Program (including but not limited to additional monies for EI Payments, attorneys’ fees or expenses, or Common Benefit Fund payments), with the exception of the payment obligations relating to Administration Expenses set forth in Section 10.05 (E) and any expenses for audits and appeals, where applicable, as explicitly provided for in Sections 8.05(A) and 9.05.

(B) The PSRC agree that the amount of the Settlement Funds is fair and reasonable under the circumstances.



- (C) Any term of this Agreement, or of the Qualified Settlement Fund Agreement, to the contrary notwithstanding, in no event shall Takeda have any obligation to make payment of the Settlement Funds into the Qualified Settlement Fund unless and until (i) the Qualified Settlement Fund shall have been duly approved by the MDL Court, and (ii) the Effective Date shall have occurred. No Settlement Payments shall be made pursuant to Article VII unless and until Takeda's Walk Away Right as set forth in Article V has expired without being exercised.
- (D) Any term of this Agreement, or of the Qualified Settlement Fund Agreement, to the contrary notwithstanding, neither the PSRC, the Program Participants, the Special Master, the Claims Administrator, the QSF Administrator, nor any other Person is entitled under this Agreement or the Qualified Settlement Fund Agreement to collect any amount from any of the Defendants or any other Released Persons other than from Takeda pursuant to Takeda's express obligations to make payments into the Qualified Settlement Fund, to pay Administrative Expenses, and to pay any expenses relating to motions, appeals, or audit(s), as dictated by this Agreement. For the avoidance of doubt, neither Takeda nor any other Released Persons shall have any obligation to pay (or to make any payment on account of), or reimburse, any Persons for any attorneys' fees or costs or expenses incurred by any Claimant in connection with the Program. Released Persons also shall have no responsibility for the management of the Qualified Settlement Fund or any Liability to any Persons arising from the handling of Claim Packages by the Claims Administrator.

#### **Section 10.02 Qualified Settlement Fund**

- (A) In accordance with the terms of this Agreement, the Settlement Funds shall be deposited into the Qualified Settlement Fund and shall remain the property of the Qualified Settlement Fund. The Settlement Funds within the Qualified Settlement Fund will be held in a fiduciary capacity. The Qualified Settlement Fund shall comply with the Treasury Regulations Section 1.468B-1 *et seq.* regarding taxation and tax reporting obligations. The Qualified Settlement Fund shall be deemed to be in the custody of the MDL Court. The Qualified Settlement Fund shall remain subject to the jurisdiction of the MDL Court until such Settlement Funds are distributed in their entirety or upon further order of the MDL Court.
- (B) Takeda and PSRC wish to have the Qualified Settlement Fund maintained in as secure a manner as possible so that the Settlement Funds will be available to be paid to those who qualify for a Settlement Payment under the Program. The PSRC will select a financial institution within seven (7) days of the Execution Date, and Takeda and the PSRC agree that this designated financial institution shall hold the Settlement Funds. Takeda and PSRC will consult as to the form of prudent investment vehicles to be

used for investment of the funds. Once a tentative decision as to the form of investment has been made, Takeda and PSRC shall jointly move the MDL Court for approval of the Qualified Settlement Fund.

- (C) The “QSF Administrator” shall be the Person selected by the PSRC to administer the Qualified Settlement Fund. PSRC is solely responsible for securing the QSF Administrator’s execution and delivery of the Qualified Settlement Fund Agreement and such Person’s consent to the jurisdiction of the MDL Court, acknowledging that the chosen financial institution and the QSF Administrator alone have the obligation to manage the Settlement Funds. Monthly reports shall be made to the MDL Court of the interest earned, distributions made, and other matters involving the status of administration. Its management shall thereafter be subject to review by the MDL Court.
- (D) Takeda shall in no way be responsible for the expenses of the QSF Administrator or the administration of the Qualified Settlement Fund. Takeda shall in no way be associated with the administration of the Qualified Settlement Fund or be liable in respect of any dispute between or among any Program Participants and their respective counsel in respect of any costs, expenses, legal fees, or litigation costs to be deducted from the Qualified Settlement Fund.

### **Section 10.03 Tax Treatment of the Qualified Settlement Fund**

- (A) Treatment. To the fullest extent allowable under applicable law, the Qualified Settlement Fund shall be treated as being at all times a “qualified settlement fund” within the meaning of Treasury Regulation §1.468B-1 *et seq.* The QSF Administrator and, as required, PSRC and Takeda, shall timely make such elections as are necessary or advisable to carry out the provisions of this Section, including the “relation-back election” as defined in Treasury Regulation §1.468B-1, back to the earliest permitted date. Such elections shall be made in compliance with the procedures and requirements contained in such regulation. It shall be the sole responsibility of the QSF Administrator to timely and properly prepare and deliver the necessary documentation for signature by all necessary parties, and thereafter to cause the appropriate filing to occur.
- (B) Tax Returns. For the purpose of Section 468B of the Internal Revenue Code, the “administrator” shall be the QSF Administrator. The QSF Administrator shall timely and properly file all informational and other tax returns necessary or advisable with respect to the Qualified Settlement Fund and the amounts held in the Qualified Settlement Fund including the returns described in Treasury Regulation §1.468B-2(k)(l). Such returns (as well as the election described in Section 468B) shall be consistent with Section 468B and in all events shall reflect that all taxes (including any estimated taxes, interest or penalties, or tax detriments) on the income

earned by the Qualified Settlement Fund shall be paid exclusively out of the Qualified Settlement Fund, in accordance with Section 468B.

- (C) Taxes and Tax Expenses. All (i) federal, state, or local taxes (including any estimated taxes, interest or penalties, or tax detriments) arising with respect to the income earned on or by the Qualified Settlement Fund, including any taxes, interest penalties, or tax detriments, that may be imposed upon Defendants with respect to any income earned on or by the Qualified Settlement Fund for any period during which the Qualified Settlement Fund (or any portion thereof) does not qualify as a “qualified settlement fund” for federal or state income tax purposes (hereafter referred to as “Taxes”), and (ii) expenses and costs incurred in connection with the administration of tax matters for the Qualified Settlement Fund and the operation and implementation of this Section (including expenses of tax attorneys or accountants and mailing and distribution costs and expenses relating to filing (or failing to file) the returns described in this Section) (hereinafter referred to as “Tax Expenses”), shall be paid exclusively out of the Qualified Settlement Fund. The QSF Administrator shall notify PSRC and Takeda in writing of the fact and amount of any such payment of Taxes or Tax Expenses out of the Qualified Settlement Fund (and any withholding pursuant to this Section).
- (D) Cooperation. PSRC and Takeda hereto agree to cooperate with the QSF Administrator, Claims Administrator, each other, and their tax attorneys and accountants to the extent reasonably necessary to carry out the provisions of this Section. The QSF Administrator shall be empowered to take all such actions, including such actions as may be inconsistent with those expressly set forth in this Article 10, as he deems necessary to ensure that the Trust is treated as a “Qualified Settlement Fund” under Section 468B of the Internal Revenue Code and the Regulations promulgated pursuant thereto. The overarching purpose of the Qualified Settlement Fund is to at all times be in compliance with Internal Revenue Code Section 468B and all administrative authority and announcements thereunder.

#### **Section 10.04 Common Benefit Fees and Reimbursement of Litigation Costs**

To ensure that common benefit attorneys (hereinafter referred to as “Common Benefit Attorneys”) are fairly compensated but that their fees are in conformance with reasonable rates, an assessment of common benefit attorneys’ fees will be imposed on each Claimant in accordance with the amount set by Order entered in the MDL (“Assessment”). Any sum paid as a common benefit fee shall be deducted from the total amount of counsel fees payable under individual plaintiffs’ counsel’s retainer agreement.

- (A) In addition to those amounts provided above, Common Benefit Attorneys shall also be entitled to reimbursement of their reasonable common benefit expenses. Reimbursement of these expenses shall be deducted from the

clients' net recovery. The amount of common benefit expenses shall be determined by Order entered in the MDL, which sum will be deducted from the Settlement Funds deposited into the QSF.

- (B) Takeda takes no position regarding, and has no responsibility or Liability for, the award of common benefit attorneys' fees and the reimbursement of costs under this Section, or the allocation of the same, and waives the right to contest these matters.

#### **Section 10.05 Claims Administration Expenses**

- (A) The fees and expenses incurred by the Claims Administrator or the Special Master in administering the Program (the "Administrative Expenses") shall be paid by Takeda, except as otherwise set forth herein in Articles VIII and IX. Any invoice for the Claims Administrator's or Special Master's fees and costs payable by Takeda shall be submitted to Takeda..
- (B) Within ten (10) Business Days after the end of each full calendar month following the Execution Date, the Claims Administrator shall submit to Takeda, in such form and in such detail as Takeda reasonably from time to time may specify, a report (each an "Expenses Report"), itemizing and certifying a list of all Administrative Expenses incurred during such calendar month.

### **ARTICLE XI. DISMISSALS, DISCLAIMERS, AND RELEASES**

#### **Section 11.01 Dismissals**

- (A) Following the Effective Date, the Defendants are entitled to dismissal with prejudice of the Claims of all Filed Claimants that opt in to the Program in accordance with the provisions of Article II.
- (B) Takeda and Lilly are entitled to file with the relevant court the Stipulation(s) of Dismissal submitted with the Opt In Package of any such Claimant at any time following the Effective Date, or if there is an uncured deficiency relating to the Stipulation(s) of Dismissal, Takeda and Lilly are entitled to move to dismiss the Claimant's case with prejudice, pursuant to Section 9.02.

#### **Section 11.02 Disclaimers**

Program Participants, their counsel, Takeda, Lilly and the PSRC are bound by decisions made by the Special Master, the Eligibility Committee and the Claims Administrator, including ones with which they may disagree. This eventuality is part of the Program and is accepted by Program Participants, subject to the limited right of appeal set forth in Sections 3.05, 4.02, 6.02(D) and (E), 7.02(G), 9.03, and 11.03.

### **Section 11.03 Releases**

Program Participants shall execute the Release, Indemnity and Assignment appended to this Agreement at Appendix C, the terms of which are incorporated herein by reference.

Without limitation, Takeda and Lilly shall be free to file or cause to be filed the Releases in any relevant action or proceeding at any time following the Effective Date. To the extent necessary to effectuate the release of all Settled Claims against the Released Persons by all Program Participants, and their heirs, beneficiaries, agents, estate, executors, administrators, personal representatives, successors and assigns, Takeda and Lilly, at each of their discretion, may require a different form of Release, in substitution for the form of Release required to be submitted with the Opt In Packages, that conforms with the requirements of applicable state law, including if necessary Releases executed by the Claimant's heirs or legal representatives. If required by Takeda or Lilly for a particular Program Participant, such Releases must be submitted to the Claims Administrator prior to the payment of any Settlement Payment(s) to such Program Participant from the QFS, and such Releases also constitute consideration for Takeda's agreement to deposit the Settlement Funds pursuant to Section 10.01 above and Lilly's participation in the ACTOS Resolution Program.

If, pursuant to Section 2.02(C) or 2.04(C) above for Claims involving Product Users who are deceased or incapacitated, a Release was not executed prior to the Opt In Deadline because the process of appointment of the necessary legal representative for the Product User had not been completed, but the proceeding necessary to obtain the necessary appointment was begun prior to the Opt In Deadline, payment of any Settlement Payment(s) to such Claimants shall be conditioned upon their submission of a Release executed by the duly appointed legal representative of the deceased Claimant. In addition, if a Claimant who has executed a Release in connection with this program subsequently dies and a representative for such Claimant continues his or her participation in the Program, Takeda or Lilly may require the submission of a Release executed by the duly appointed legal representative of the deceased Claimant, and/or the deceased Claimant's heirs, prior to the payment of any Settlement Payment(s). In both such circumstances, Takeda shall be free to file the Stipulation(s) of Dismissal with respect to any such Claimant at any time following the Effective Date. Any dispute regarding the scope of Release required under this provision from any Program Participant shall be resolved by the Special Master.

### **Section 11.04 Unknown Facts**

Program Participants shall agree, and by executing the Releases do agree, that the Releases are intended to and do cover any and all losses, injuries, damages and claims of every kind and nature whatsoever, whether direct or indirect, known or unknown, including any future wrongful death claim, and suspected or unsuspected. Program Participants shall acknowledge, and by executing the

Releases do acknowledge, that they may hereafter discover facts different from, or in addition to, those which they now know to be, or believe to be, true with respect to their alleged injuries, losses and claims, including, but not limited to, other diagnoses of other cancers, recurrences of Bladder Cancer, and/or future complications or other injuries relating to Bladder Cancer or other cancers or the treatment of Bladder Cancer or other cancers. Program Participants shall acknowledge, and by executing the Releases do acknowledge, that they may learn of additional facts as those facts relate to ACTOS Products and the Released Persons' activities as those facts relate to ACTOS Products. Program Participants shall agree, and by executing the Releases do agree, that the Releases, and the specific releases contained therein, shall be and remain effective in all respects, notwithstanding such different or additional facts and the subsequent discovery thereof. Program Participants shall, and by executing the Releases do, expressly waive any and all rights they may have under any statute, code, regulation, ordinance or the common law, which may limit or restrict the effect of a general release as to claims, including claims that Program Participants do not know or suspect to exist in their favor at the time of the Releases. Specifically, Program Participants shall acknowledge, and by executing the Releases do acknowledge, that they have been advised by their attorneys concerning, and are familiar with, the California Civil Code Section 1542, and Program Participants shall, and by executing the Releases do, expressly waive any and all rights under California Civil Code Section 1542 and under any other federal or state statute or law of similar effect.

#### **Section 11.05 No Admission of Liability or Lack of Merit**

- (A) Neither this Agreement nor any exhibit, document or instrument delivered hereunder nor any statement, transaction or proceeding in connection with the negotiation, execution or implementation of this Agreement, is intended to be or shall be construed as or deemed to be evidence of an admission or concession by Takeda, Lilly, or any other Released Person, of any fault, Liability, wrongdoing or damages or of the truth of any allegations asserted by any Plaintiff or Claimant against it, or as an admission by any Claimant of any lack of merit in their claims.
- (B) No Party, no Claimant, and no counsel for any Claimant, shall seek to introduce and/or offer the terms of this Agreement, any statement, transaction or proceeding in connection with the negotiation, execution or implementation of this Agreement, or any statements in the documents delivered in connection with this Agreement, or otherwise rely on the terms of this Agreement, in any judicial proceeding, except insofar as it is necessary to enforce the terms of this Agreement (or in connection with the determination of any income tax Liability of a party) or any instrument executed and delivered pursuant to this Agreement (including any Enrollment Form and the executed attachments thereto). If a Person seeks to introduce and/or offer any of the matters described herein in any proceeding against Takeda, Lilly, or any other Released Person, the

restrictions of this Section 11.05 shall not be applicable to Takeda, Lilly, or any other Released Person with respect to that Person.

## **ARTICLE XII. COURT APPROVAL AND OTHER DOCUMENTATION**

### **Section 12.01 Survival and Wrongful Death Claims**

If required by applicable state law, a Program Participant's counsel or a Person authorized by a Program Participant's counsel will seek court approval of the settlement of the case brought on behalf of a decedent or others authorized under applicable state law to advance survival or wrongful death claims, and will obtain any additional Releases or documentation required therefore. Program Participants' counsel will assume responsibility for all necessary filings relating to notice and approval of the settlement and the Program Participants will be responsible for all associated costs and expenses.

### **Section 12.02 Claims Involving Minors**

If required by applicable state law, a Program Participant's counsel or a Person authorized by a Program Participant's counsel will seek court approval of the settlement of the case brought on behalf of a minor. Program Participants' counsel will assume responsibility for all necessary probate and guardianship filings, all filings relating to court approval of settlement, and all issues or rulings arising therefrom or related thereto.

### **Section 12.03 Other Documents**

Takeda, Program Participants, and their counsel if represented, agree to cooperate in acquiring or executing any other documents necessary to finalize an individual Program Participant's settlement.

## **ARTICLE XIII. LIENS**

### **Section 13.01 Medical Bills, Liens, and Other Potential Rights for Reimbursement**

The PSRC and Takeda shall jointly select a Lien Resolution Administrator to assist Program Participants in resolving Liens that are or may be asserted by Governmental Payors or Private Payors against Settlement Payments made to Program Participants in connection with the Program, and to provide assurances to Takeda that such Liens have been resolved prior to Settlement Payments. Any dispute between the PSRC and Takeda regarding the selection of a Lien Resolution Administrator under this provision shall be resolved by Magistrate Judge Patrick J. Hanna of the United States District Court for the Western District of Louisiana.

Each Program Participant and his or her counsel agree that an amount equal to the total determined in accordance with Section 13.01(B)(2)(d) and Section 13.01(C)(2), as each such Section may apply, will be withheld from the Program

Participant and maintained within the Qualified Settlement Fund. The funds withheld from the Program Participant's Settlement Payment(s) in accordance with the foregoing sentence shall only be released from the Qualified Settlement Fund to the Program Participant (a) when there is an agreement from all Governmental and/or Private Payors evidencing the final amount needed to satisfy amounts owed to all such Payors that provides for a full release of any and all entities, including the Released Persons, by all such Payors with regard to the Program Participant, or (b) to the extent the total amount withheld is reduced by applying the calculations in accordance with Section 13.01(B)(2)(d) and Section 13.01(C)(2), as each may apply. The funds withheld in the Qualified Settlement Fund may be paid from the Qualified Settlement Fund directly to the Lien Resolution Administrator's trust for payment to the Governmental and/or Private Payor to the extent of such Payor's interests.

**(A) Responsibility for Satisfaction of All Medical Expenses and Liens**

- (1) Each Program Participant agrees that it is his or her sole responsibility to pay, have paid or otherwise discharge and satisfy all past and present bills, costs, or Liens resulting from or arising out of the Program Participant's Alleged Injury from use of ACTOS Products. Each Program Participant agrees that the Released Persons shall have no responsibility to pay or have paid any future bills, costs, or Liens resulting from or arising out of the Program Participant's alleged use of ACTOS Products. Each Program Participant further represents and warrants that he or she will not seek from any Released Person any compensation for any future bills, costs, or Liens resulting from or arising out of the Program Participant's alleged use of ACTOS Products. Each Program Participant agrees that the Released Persons shall have no responsibility whatsoever for satisfaction of any and all Liens, of any kind, that arise from or are related to payments made or services provided to such Program Participant, or on such Program Participant's behalf, and past, present, or future bills, costs or Liens incurred in connection with the claims asserted by such Program Participant related to such Program Participant's alleged use of ACTOS Products. Further, each Program Participant agrees that the Released Persons shall have no responsibility to pay or have paid any bills, costs or expenses arising out of or in connection with the actions of the Lien Resolution Administrator or the Private Lien Resolution Program (also referred to herein as the "PLRP") contemplated by this Agreement.
- (2) Each Program Participant shall indemnify, repay and hold the Released Persons harmless from any and all such bills, costs or Liens, known or unknown, and whether existing as of the date of becoming a Program Participant or arising thereafter. Specifically, and without limitation, if any governmental entity, or anyone



acting on behalf of any governmental entity, seeks penalties, damages, multiple damages (including double damages), or any other amounts from any Released Person relating to payments by such governmental entity, or anyone acting by contract or otherwise on behalf of such governmental entity, arising from or relating to the Program Participant's alleged use of ACTOS Products, then the Program Participant shall indemnify, repay, and hold the Released Persons harmless from any and all such penalties, damages, claims, and rights to payment, including any attorneys' fees, from such entities.

**(B) Procedure Regarding Payments by Governmental Payors**

With respect to potential payments made on a Program Participant's behalf by the Medicare Program, the Medicaid Program, or any Other Governmental Payor (collectively "Governmental Payors"), then as conditions precedent to the distribution of any Final Payment from the Qualified Settlement Fund to the Claimant, each Program Participant and his or her counsel agree as follows:

- (1) Identification of Governmental Payors. The Lien Resolution Administrator will affirmatively verify which Program Participants are or were entitled to benefits pursuant to the Medicare Program or the Medicaid Program. Each Program Participant and his or her counsel agree to identify every Other Governmental Payor that may have made any payments on behalf of such Program Participant in any way related to such Program Participant's alleged use of ACTOS Products from the time the Program Participant alleges he or she first suffered injury from the alleged use of ACTOS Products through the Execution Date. Each Program Participant and his or her counsel represent and warrant they will use best efforts and reasonable diligence to identify such Other Government Payors.
- (2) Satisfaction of Governmental Payors' Interests. Each Program Participant and his or her counsel agree, either directly or through the Lien Resolution Administrator, to provide to Takeda's counsel written documentation demonstrating that each Governmental Payor identified pursuant to Section 13.01(B)(1) either:
  - (a) holds no interest, including any Liens, in the Settlement Payment(s); or
  - (b) expressly releases any and all entities from any liability whatsoever for any interest, including any Liens, in the Settlement Payment(s); or

- (c) agrees any interest, including any Liens, in the Settlement Payment(s) has been finally and completely satisfied; or
- (d) has reached a binding agreement with the Program Participant, either directly or through the Lien Resolution Administrator setting forth in detail a specific dollar amount or percentage of the Settlement Payment(s) that the Governmental Payor agrees is the maximum amount it will seek to resolve any interest, including any Liens, in the Settlement Payment(s).

(C) Procedure Regarding Payments by Private Payors

With respect to potential payments made on a Program Participant's behalf by any for-profit or not-for-profit, non-governmental healthcare plan, health insurer, managed care organization, labor union welfare plan, joint union and employer welfare plan, self-funded employer plan or any other non-governmental organization, including any entity operating under a contract with any of the foregoing (collectively "Private Payors"), then as conditions precedent to the distribution of any Final Payment from the Qualified Settlement Fund to the Claimant, each Program Participant and his or her counsel agree as follows:

- (1) Identification of Private Payors. Each Program Participant and his or her counsel agree to identify every Private Payor that may have made any payments on behalf of such Program Participant in any way related to such Program Participant's injury from the alleged use of ACTOS Products from the time the Program Participant alleges she first suffered injury from the alleged use of ACTOS Products through the Execution Date. Each Program Participant and his or her counsel represent and warrant they will use best efforts and reasonable diligence to identify such Private Payors.
- (2) Satisfaction of Private Payors' Interests Each Program Participant and his or her counsel agree to comply with the requirements of one of the two options below relating to protecting the interests of Private Payors:
  - (a) Option 1: The Program Participant, through his or her counsel, is (1) processed through the PLRP administered by the Lien Resolution Administrator and (2) his or her counsel identifies to the Lien Resolution Administrator all Private Payors pursuant to Section 13.01(C)(1).
    - i. If each and every Private Payor identified pursuant to Section 13.01(C)(1) participate in the PLRP administered by the Lien Resolution Administrator

or no Private Payors are identified, then the PLRP shall dictate the amount to be withheld in the Qualified Settlement Fund, but in no event will that holdback exceed 30% of the gross settlement proceeds.

- ii. If at least one of the Private Payors identified pursuant to Section 13.01(C)(1) does not participate in the PLRP (“Non-Participating Private Payor”) based on the Lien Resolution Administrator’s good faith effort in making such categorization and the Program Participant provides notice of this settlement to each such Non-Participating Private Payor, then such Program Participant and his or her counsel agree: (1) 30% of the gross settlement proceeds (or such other amount that Judge Hanna shall set (“Other Lien Amount”)) shall be withheld in the Qualified Settlement Fund; (2) the 30% (or Other Lien Amount) shall be eligible for release 45 days after notice is given unless any Non-Participating Private Payor asserts a right to a portion of the settlement proceeds during these 45 days (assertion of a right shall be defined as the provision of itemized medical claims); and (3) if any Non-Participating Private Payor asserts a right to a portion of the settlement proceeds during these 45 days, the 30% (or Other Lien Amount) shall be released only when the Program Participant has reached a binding agreement with such Non-Participating Private Payors as set forth in Section 13.01(B)(2)(d). If all such Non-Participating Private Payors agree to participate in the PLRP, then the procedures set forth in Section 13.01(C)(2)(b) shall govern. NOTE: The 30% (or Other Lien Amount) holdback in this section is inclusive of the PLRP holdback referenced in the previous section. The 30% (or Other Lien Amount) holdback may not be able to be released under this section if the PLRP process is not yet complete for the Participant.
- b. Option 2: The Program Participant, through their counsel, opts out of the PLRP and 30% (or Other Lien Amount) of the gross settlement proceeds shall be withheld in the Qualified Settlement Fund until the Participant satisfies each and every requirement of Section 13.01(B) above with respect to all Private Payors identified pursuant to Section 13.01(C)(1) or if a Program Participant did not have a

Private Payor or governmental benefits that paid for his or her treatment, he or she shall provide an affidavit stating so.

For the avoidance of doubt, the conditions precedent in this Section are not conditions precedent to Takeda's funding obligations into the Qualified Settlement Fund under Section 10.01, but are only conditions precedent to the distribution of any funds withheld from the Program Participant's Settlement Payment(s) from the Qualified Settlement Fund to the Program Participant.

### **Section 13.02 Attorney Liens**

Each Program Participant shall represent and warrant that all legal expenses, bills, costs or contingency fee agreements resulting from or arising out of representation of such Program Participant by any attorney in relation to such Program Participant's alleged use of ACTOS Products have been paid or will be paid out of the Settlement Payments and are the Program Participant's responsibility to pay, and that any Liens based on any legal expenses, bills, costs or contingency fee agreements incurred as a result of the Program Participant's alleged use of ACTOS Products will be satisfied by such Program Participant. Each Program Participant will indemnify, repay and hold the Released Persons harmless from any and all such claims.

### **Section 13.03 Other Liens**

If Takeda, Lilly, the Claims Administrator, the Lien Resolution Administrator or the PSRC receives notification of any other Lien asserted against any Settlement Payments to be made to any Program Participant, including but not limited to tax Liens and child support Liens, an amount sufficient for the satisfaction of such Liens may be withheld from such Program Participant's Settlement Payments by the Claims Administrator, in consultation with the Lien Resolution Administrator, until each such Lien has been finally and completely satisfied. Each Program Participant will indemnify, repay and hold the Released Persons harmless from any and all such claims.

## **ARTICLE XIV. WARRANTY OF CAPACITY TO ENTER INTO THE AGREEMENT**

### **Section 14.01 PSRC**

Each Person comprising PSRC represents and warrants that such Person has all requisite power and authority to execute, deliver and perform this Agreement and to consummate the transactions contemplated hereby. The execution, delivery, and performance of this Agreement and the consummation by such Person of the actions contemplated hereby will be, upon delivery, duly and validly executed and delivered by such Person and will constitute its legal, valid, and binding obligation.

## **Section 14.02 Takeda**

Takeda represents and warrants that it has all requisite power and authority to execute, deliver, and perform this Agreement and to consummate the transactions contemplated hereby. The execution, delivery, and performance of this Agreement and the consummation by it of the actions contemplated hereby will be, upon delivery, duly and validly executed and delivered by Takeda and will constitute its legal, valid, and binding obligation.

## **Section 14.03 Additional Agreement and Acknowledgements of Program Participants**

- (A) Each Program Participant, on his or her own behalf and on behalf of his or her heirs, beneficiaries, agents, estates, executors, administrators, personal representatives, successors and assigns, shall be deemed to have agreed, and by executing the Release does agree, to resolve his or her Claims with Defendants and, if represented, to have granted his or her counsel the authority to resolve his or her Claims with Defendants in accordance with the terms of this Agreement. Each Program Participant further represents and warrants that he or she has the sole right and exclusive authority to enter into this Agreement and to submit a Claim Package under it; that neither his or her Claim nor any of the claims, demands or obligations referred to in this Agreement have been sold, assigned, subrogated, transferred, or otherwise disposed of by him or her; and that he or she is the sole Person who may have a potential cause of action against Defendants relative to his or her Claim. Each Program Participant shall further represent and warrant, and by executing the Release does represent and warrant, that no other Person or entity has any right, title or interest in his or her Claim, any of the demands, obligations, or causes of action referred to in this Agreement, or any Settlement Payment to him or her, and that there are no other Liens (except as may be disclosed in accordance with Article XIII herein) other than the actual or potential attorneys liens of the Program Participant's counsel to the extent such attorneys liens have been perfected. Private funding agreements are not Liens under this Agreement, and are not the responsibility of Takeda. To the extent any Program Participant has received any funding or other consideration from any third party, including any private litigation funding, such Program Participant shall represent and warrant, and by executing the Release does represent and warrant, that such third party has no Lien or other claim that can be asserted against any of the Released Persons or the Qualified Settlement Fund or any portion thereof. Each Program Participant shall agree, and by executing the Release does agree, that he or she will indicate on his or her Claim Form whether a bankruptcy action is currently pending in which he or she is seeking bankruptcy protection.

- (B) Each Program Participant, by participating in the Program as provided for herein, and his or her counsel, if represented, acknowledge and agree that they are contractually bound by the terms of this Agreement.
- (C) Each Program Participant, by participating in the Program as provided herein, and his or her counsel, if represented, acknowledge and agree that they are waiving all rights to pursue their claims in court, and any further claims, appeals, or objections shall be resolved by the Eligibility Committee or the Special Master as set forth herein, and such decisions shall be final and binding upon each Program Participant and his or her counsel, if represented. Further, each Program Participant, by opting into participation in the Program, acknowledges and agrees to this method of alternative dispute resolution.

## **ARTICLE XV. MISCELLANEOUS**

### **Section 15.01 Notice**

- (A) Any notice, request, instruction or other document to be delivered pursuant to this Agreement shall be sent to the appropriate Party as follows, unless otherwise instructed by the terms of this Agreement, by a notice delivered to the other Party pursuant to this Section 15.01(A). Notice may be provided by (i) United States mail, return receipt requested; (ii) to the extent specified hereunder, electronic mail; (iii) facsimile, with a confirming copy sent within one day by regular United States Mail; (iv) prepaid courier; (v) Federal Express; or (vi) personal delivery:

- (1) If to Takeda:

Attn: Global General Counsel  
Takeda Pharmaceutical Company Limited  
12-10, Nihonbashi 2-chome, Chuo-ku  
Tokyo 103-8668, Japan  
Fax: +81-3-3278-2222

Attn: General Counsel  
Takeda Pharmaceuticals U.S.A., Inc.,  
One Takeda Parkway  
Deerfield, IL 60015  
Fax: 224-554-7831

- (2) If to Lilly:

Attn: General Counsel  
Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285

- (3) If to any Program Participant represented by counsel:

To such Program Participant's counsel as reflected on such Program Participant's Claim Form, or, if such Program Participant has not provided a Claim Form with the necessary contact information, then to the first-listed counsel for such Program Participant, listed on such Program Participant's Complaint, or if such Program Participant has not filed a Complaint, then to the first-listed counsel for such Program Participant, listed on such Program Participant's Notice of Intent to Opt In Form for Filed Claims or Notice of Intent to Opt In Form for Unfiled Claims. In addition, the Claims Administrator may provide notice to Program Participants and their counsel through the online portal established by the Claims Administrator at [www.actosofficialsettlement.com](http://www.actosofficialsettlement.com).

- (4) If to the PSRC:

Richard J. Arsenault  
Neblett, Beard & Arsenault  
2220 Bonaventure Court  
P.O. Box 1190  
Alexandria, LA 71309  
Fax: 318.561.2592

- (5) If to a Program Participant who is not represented by counsel:

To such Program Participant's address as reflected on such Program Participant's Claim Form, or, if such Program Participant has not provided a Claim Form with the necessary contact information, then to such Program Participant's address as reflected on such Program Participant's Complaint, or if such Program Participant has not filed a Complaint, then to such Program Participant's address as reflected on such Program Participant's Notice of Intent to Opt In Form for Filed Claims. In addition, the Claims Administrator may provide notice to Program Participants through the online portal established by the Claims Administrator at [www.actosofficialsettlement.com](http://www.actosofficialsettlement.com).

- (B) If the date or deadline for any notice, request, instruction or other document to be delivered or given pursuant to this Agreement falls on a day that is not a Business Day, such notice, request, instruction or other document shall be deemed due under this Agreement on the next following Business Day.
- (C) Any notice, request, instruction or other document to be given by any Party or any Claims Administrator to any Program Participant or his or her

counsel hereunder, shall be in writing and delivered in accordance with the terms of Section 15.01(A), and such Party or Claims Administrator may rely on the contact information last provided by the Program Participant or his or her counsel to such party or Claims Administrator, as applicable, and no party nor any Claims Administrator shall have any obligation to (but in its sole and absolute discretion may) take other steps to locate Program Participants or counsel as to whom notices, requests, instructions or other documents have been returned as undelivered or undeliverable. Each Program Participant and (if applicable) his or her counsel shall have the responsibility to keep the Claims Administrator informed of the correct contact information for both such Program Participant and such counsel.

- (D) Any such notice, request, instruction or other document shall be deemed to have been given as of the date so transmitted by facsimile or electronic mail, on the next Business Day when sent by Federal Express, or five Business Days after the date so mailed, provided that if any such date on which any such notice or other communication shall be deemed to have been given is not a Business Day, then such notice or other communication shall be deemed to have been given as of the next following Business Day and, provided, further, that delivery otherwise shall be deemed to occur upon tender and rejection by the intended recipient.

### **Section 15.02 Governing Law**

The provisions of this Agreement, appendices, and the individual Releases shall be interpreted in accordance with, and governed by, the laws of the State of Illinois (or United States federal law, to the extent applicable), including any applicable statutes of limitation, without regard to any otherwise applicable principles of conflicts of law or choice of law rules (whether of the State of Illinois or any other jurisdiction) that would result in the application of the substantive or procedural rules or law of any other jurisdiction. The Parties and any Program Participant or Claimant who seeks to opt-in to the Program irrevocably submit to the jurisdiction of the Special Master and (i) the MDL Court as to any claim that was pending in federal court as of the Execution Date, (ii) the respective state court as to any claim that was pending in that court as of the Execution Date or (iii) the Illinois Coordinated Court as to any unfiled claim, with respect to any suit, action, proceeding, or dispute arising out of or relating to the Program, the applicability or enforceability of the Program, or any document relating to the Program, including the Agreement, any of its Appendices, or the individual Releases.

### **Section 15.03 Waiver of Inconsistent Provisions of Law; Severability**

- (A) To the fullest extent permitted by applicable law, each Party waives any provision of law (including the common law), which renders any



provision of this Agreement invalid, illegal or unenforceable in any respect.

- (B) Any provision of this Agreement which is prohibited or unenforceable to any extent or in any particular context shall be ineffective, but such ineffectiveness shall be limited as follows: (i) if such provision is prohibited or unenforceable only in or as it relates to a particular jurisdiction, such provision shall be ineffective only in or as it relates to (as the case may be) such jurisdiction and only to the extent of such prohibition or unenforceability, and such prohibition or unenforceability in or as it relates to (as the case may be) such jurisdiction shall not otherwise invalidate or render unenforceable such provision (in such or any other jurisdiction); (ii) if (without limitation of, and after giving effect to, clause (i)) such provision is prohibited or unenforceable only in a particular context (including only as to a particular Person or Persons or under any particular circumstance or circumstances), such provision shall be ineffective, but only in such particular context; and (iii) without limitation of clauses (i) or (ii), such ineffectiveness shall not invalidate any other provision of this Agreement. In any event, upon any such determination that any term or other provision is invalid, illegal or unenforceable, PSRC and Takeda shall negotiate in good faith to modify this Agreement so as to effect the original intent of PSRC and Takeda as closely as possible to the fullest extent permitted by applicable law. Nothing in this Section 15.03(B) is intended to, or shall, limit (1) Section 15.03(A) or (2) the intended effect of Section 15.02.

#### **Section 15.04 Good Faith Negotiations**

PSRC and Takeda each acknowledge that: the negotiations leading up to this Agreement were conducted regularly and at arm's length; this Agreement is made and executed by and of each such executing Party's own free will; each such executing Party knows all of the relevant facts and its rights in connection therewith; and such Party affirms that it has not been improperly influenced or induced to make this settlement as a result of any act or action on the part of any other Party or employee, agent, attorney or representative of any other Party. The Parties hereby acknowledge that they entered into this Agreement to compromise permanently and settle the claims between any Program Participant, on the one hand, and the Released Persons, on the other hand, settled by the execution of this Agreement and the Program Participant's individual Release.

#### **Section 15.05 Construction**

- (A) With regard to each and every term and condition of this Agreement, the Agreement has been negotiated, prepared and drafted by PSRC and counsel for Takeda, and if at any time any Party desires or is required to interpret or construe any such term or condition or any agreement or instrument subject hereto, no consideration shall be given to the issue of

which Party hereto, or its counsel, actually prepared, drafted or requested any term or condition hereof.

- (B) The headings of the Articles, Sections, paragraphs and subsections herein are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement. Any reference to an Appendix shall be deemed to refer to the applicable Appendix attached hereto. The words “include” and “including” and words of similar import when used in this Agreement or any Appendix attached hereto are not limiting and shall be construed to be followed by the words “without limitation,” whether or not they are in fact followed by such words. The definitions contained in this Agreement or any Appendix attached hereto are applicable to the singular as well as the plural forms of such terms. Words of any gender (masculine, feminine, neuter) mean and include correlative words of the other genders. As used herein or in any Appendix hereto, the term “dollars” and the symbol “\$”, shall mean United States dollars. References herein to instruments or documents being submitted “by” any Person include (whether or not so specified) submission of the same on behalf of such Person by her counsel whether or not so specified, provided that if any particular instrument or document is required herein to be executed by a particular Person, it must (unless otherwise expressly specified herein) be so executed by such Person. References herein to any particular Section (such as, for example, Section 15.01) shall be deemed to refer to all sub-Sections of such Section (such as, for example, Section 15.01(A), 15.01(B), etc.), all sub-sub-Sections of such sub-Sections, and so on; the corresponding principle applies to all references herein to any particular sub-Section, sub-sub-Section and so on. The words “this Agreement”, “herein”, “hereof”, “hereby”, “hereunder” and words of similar import refer to this Agreement as a whole (together with any Appendices attached hereto) and not to any particular subdivision unless expressly so limited or the context requires otherwise. Any reference herein to this Agreement shall be deemed to include this Agreement as it may be modified, varied, amended or supplemented from time to time.

### **Section 15.06 Lilly's Rights as a Third Party Beneficiary**

It is the parties' intent that Lilly shall be a third party beneficiary only to the extent of being able to enforce the obligations of this Agreement as against the PSRC or any Program Participant as set forth in the following sections of this Agreement: Recitals A and D, and Sections 2.02(D), 2.04, 2.06, 3.05(D), 6.01(D), 8.05, 9.02, 9.03 (E-H), 9.04, 9.06, 10.01(A)(2) second paragraph, 10.01(D), 11.01, 11.03-11.05, 13.01(A)(1), 13.01(A)(2), 13.02, 14.03, and 15.07, 15.10, Appendix C, and Article XII. This Agreement is not intended to supersede or otherwise modify any agreements between Takeda and Lilly.

### **Section 15.07 No Other Third Party Beneficiaries; No Right of Assignment**

- (A) With the exception of Lilly as set forth in Section 15.06 above, no provision of this Agreement or any Appendix attached hereto is intended to create any other third-party beneficiary hereto or thereto. For the avoidance of doubt, nothing in this Section 15.07 limits or modifies the third-party beneficiary provisions of any Opt In Form, Claim Form, Release or Stipulation of Dismissal. This Agreement and all of the provisions hereof shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns; provided, however, that neither this Agreement nor any of the rights, interests or obligations hereunder may be assigned by the PSRC or any Program Participant without the prior written consent of Takeda. Any assignment in violation of this Section 15.07(A) shall be null and void *ab initio*. No right to receive a Settlement Payment pursuant to this Program may be assigned – at any time, including but not limited to prior to the Execution Date – by any Claimant or their counsel without prior written consent of Takeda. Any assignment in violation of this Section 15.07 shall be null and void *ab initio*, and if such assignment is not null and void *ab initio* for any reason, payment of any Settlement Payments under the Program to such Claimants shall be precluded until such time as assignments in violation of this Section 15.07 have been nullified and voided and the Claims Administrator has been provided proof of such nullification.
- (B) No Program Participant shall have any right to institute any proceeding, judicial or otherwise, against any of Released Persons (including Takeda), any Special Master, or any Claims Administrator to enforce, or otherwise with respect to, this Agreement.

### **Section 15.08 Further Assurances**

From time to time following the Execution Date, (i) each Party shall take such reasonable actions consistent with the terms of this Agreement as may reasonably be requested by any other Party, and otherwise reasonably cooperate with each other Party in a manner consistent with the terms of this Agreement as reasonably

requested by each such other Party, and (ii) each Program Participant and his or her counsel, if any, shall take such reasonable actions consistent with the terms of this Agreement as may reasonably be requested by Takeda or by the PSRC, and otherwise reasonably cooperate with Takeda and the PSRC in a manner consistent with the terms of this Agreement as reasonably requested by Takeda or the PSRC, in the case of each of (i) and (ii) as may be reasonably necessary in order further to effectuate the intent and purposes of this Agreement and to carry out the terms hereof. To the extent such actions shall be made by counsel, such actions shall be consistent with their duties to their clients who are parties to this Agreement.

### **Section 15.09 Specific Performance**

It is understood and agreed by the Parties that money damages would not be a sufficient remedy for any breach of this Agreement by any Party and each non-breaching Party shall be entitled to specific performance and injunctive or other equitable relief as a remedy of any such breach in addition to any other remedy available at law or in equity, without the necessity of demonstrating the inadequacy of money damages.

### **Section 15.10 Confidentiality and Public Communications**

Takeda, the PSRC, and Lilly shall cooperate in the public description of this Agreement and the Program established herein and shall agree upon the timing of distribution.

### **Section 15.11 Private Agreement**

This is a private agreement and not subject to court approval.

### **Section 15.12 No Misrepresentation of Program**

Counsel for each Program Participant opting to enroll in this Program hereby covenants not to make any misrepresentation with respect to the ACTOS Resolution Program or the terms and conditions of this Agreement to any Person, for example by leading Persons who are not Eligible Enrollees to believe that they are, or may become, eligible to receive any Settlement Payment under the Program. The Parties agree that the provisions of this Section 15.11 are an essential element of this Agreement and that a breach of any such provision shall constitute a material breach of this Agreement entitling Takeda to an immediate remedy against any counsel who breached such provision, including injunctive relief and attorneys' fees as determined by the applicable court.

### **Section 15.13 Entire Agreement**

This Agreement, including the Appendices hereto, constitutes the complete and entire agreement of the Parties with respect to the subject matter hereof. This Agreement and the Appendices hereto may not be modified, contradicted, added to or altered in any way by previous written or oral agreements, nor by any

contemporaneous or subsequent oral agreements. All antecedent or contemporaneous extrinsic representations, warranties or collateral provisions concerning the negotiation and preparation of the Agreement and the Appendices hereto are intended to be discharged and nullified. In any dispute involving the Agreement or the Appendices hereto, no signatory shall introduce evidence of or seek to compel testimony concerning any oral or written communication made prior to the Effective Date with respect to the negotiation and preparation of the Agreement. Any change, modification, deletion or addition to this Agreement, including the Appendices hereto, must be agreed to by all Parties and in writing and executed with the same formalities as this Agreement.

#### **Section 15.14 Counterparts; Facsimile Signature**

This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which shall together constitute one and the same instrument. It shall not be necessary for any counterpart to bear the signature of all parties hereto. This Agreement and any amendments hereto, to the extent signed and delivered by means of a facsimile machine or electronic scan (including in the form of an Adobe Acrobat PDF file format), shall be treated in all manner and respects as an original agreement and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person.

#### **Section 15.15 Recitals**

All recitals are incorporated herein as material provisions of this Agreement.

### **ARTICLE XVI. DEFINED TERMS**

“ACTOS Products” means Products manufactured, distributed, marketed or sold by or for Takeda containing the active pharmaceutical compound pioglitazone, including, but not limited to, ACTOS, ACTO*plus* met, ACTO*plus* met XR, and *Duetact*.

“ACTOS Resolution Program” has the meaning ascribed thereto in Recital A.

“Administrative Expenses” has the meaning ascribed thereto in Section 10.05.

“Agreement” or “Master Settlement Agreement” means this Master Settlement Agreement, including any and all Exhibits, Appendices, and Schedules attached hereto, as the same may be amended or modified from time to time in accordance with the terms hereof.

“Alleged Injury” means an injury alleged by a Claimant to have been caused by ACTOS Products as set forth in a Complaint, Plaintiff Fact Sheet, Notice of Intent to Opt In Form for Filed Claims, Notice of Intent to Opt In Form for Unfiled Claims or Case Census.

“Assessment” has the meaning ascribed thereto in Section 10.04.

“Authorization to Release Records and Other Information” means the Form contained in Appendix I that must be submitted as part of the Claim Package.

“Bladder Cancer” has the meaning ascribed thereto in Section 2.01.

“Business Day” means any day other than a Saturday, a Sunday, or a day on which banking institutions in New York City, New York, are authorized or obligated by law or executive order to remain closed.

“California Coordinated Court” has the meaning ascribed thereto in Recital A.

“California Coordinated Proceeding Claimant” has the meaning ascribed thereto in Section 1.02.

“California Coordinated Proceedings” has the meaning ascribed thereto in Recital A.

“California Stipulation of Dismissal” has the meaning ascribed thereto in Section 2.02(C).

“Case Census” means the report, and any updates thereto, by Plaintiffs’ counsel of all filed and unfiled personal injury claims relating to ACTOS Products produced pursuant to the Case Census Orders.

“Case Census Orders” means the Case Management Orders to be entered by the MDL Court, Illinois Coordinated Court, and the California Coordinated Court, substantially in the form attached as Appendix A, requiring the registration by Plaintiffs’ counsel of all filed and unfiled personal injury claims relating to ACTOS Products.

“Census Order Deadline” means the date by which Primary Counsel shall provide the information required by the Case Census Order, which shall be ten (10) days after the entry of such Order, as may be extended by order of the courts or by agreement of Takeda and the PSRC.

“Claimants” includes MDL Claimants, State Court Coordinated Proceeding Claimants, Other Federal Court Claimants, and Other State Court Claimants and Qualifying Unfiled Claimants who allege a Claim.

“Claim” and “Claims”, as the context may require, means any actions, disputes, and claims asserted against Defendants that constitute: (i) part of the MDL; (ii) part of any Other Federal Court Proceeding; (iii) part of the California Coordinated Proceedings; (iv) part of the Illinois Coordinated Proceedings; or (v) part of any Other State Court Proceeding, in each case asserting an Alleged Injury resulting from the use of ACTOS Products, as well as (vi) claims asserted against Defendants by Qualifying Unfiled Claimants in a Notice of Intent to Opt In Form for Unfiled Claims.

“Claims Administrator” means the Person appointed by Takeda with the agreement of PSRC to fulfill the functions of the “Claims Administrator,” as provided for in Article VIII, (for so long as such Person or Persons continues to serve in such capacity).

“Claims Administrator’s Final Points Valuation” has the meaning ascribed thereto in Section 7.03(A).

“Claim Form” means the Form contained in Appendix H that must be submitted as part of the Claim Package.

“Claim Package” means a Program Participant’s request for compensation under the Program, which includes the required Supporting Documentation set forth in Section 3.03.

“Claim Package Deadline” has the meaning ascribed thereto in Section 3.01.

“Claims Valuation Process” has the meaning ascribed thereto in Section 6.01(B).

“CMO” means a Case Management Order entered by the MDL Court, the California Coordinated Court, the Illinois Coordinated Court, a Federal Court or a State Court.

“Common Benefit Attorneys” has the meaning ascribed thereto in Section 10.04.

“Complete” means the entire set of records produced by, or obtained from, a healthcare provider, pharmacy, or other provider of records.

“Contemporaneous Medical Records” means records reflecting medical care, including, but not limited to diagnosis, treatment, or examination, of a Product User that were created at, or about, the time the medical care was given.

“Contemporaneous Prescription Records” means records documenting medications prescribed or provided to a Product User that were created at, or about, the time the prescription(s) were written.

“Core Medical Records” has the meaning ascribed thereto in Section 3.03.

“Cure Deadline” has the meaning ascribed thereto in Section 3.05.

“Declaration of Counsel” means the form attached as Appendix G and referenced in Section 2.04.

“Defendants” means any and all defendants in any of the MDL cases, the Other Federal Court Proceedings, the California Coordinated Proceedings, the Illinois Coordinated Proceedings, or any Other State Court Proceedings.

“Derivative Claim” means a claim of a Person other than the Person who allegedly used ACTOS Products, which claim derives from the Claim alleged by the Person who allegedly used ACTOS Products.

“Documented” has the meaning ascribed thereto in Section 7.02(D).

“Effective Date” has the meaning ascribed thereto in Section 5.02(D).

“EI Payment Process” has the meaning ascribed thereto in Section 7.02(A).

“EI Payment” has the meaning ascribed thereto in Section 7.02(A).

“EI Fund Cap Amount” has the meaning ascribed thereto in Section 7.02(B).

“Eligibility Committee” means the committee with responsibility for reviewing determinations of Claim Package deficiencies made by the Claims Administrator, as set forth in Section 4.02.

“Eligible Claim” has the meaning set forth in Section 4.01.

“Eligible Enrollee” has the meaning ascribed thereto in Section 2.01.

“Eligible Injury” has the meaning ascribed thereto in Section 2.01.

“Estimated Points Valuation” has the meaning ascribed thereto in Section 7.01(A).

“Execution Date” has the meaning ascribed thereto in the Preamble.

“Expenses Report” has the meaning ascribed thereto in Section 10.05.

“Federal Cases” means any Claims constituting part of the MDL or the Other Federal Court Proceedings (including any such Claim that has been removed from state court and any such claim that is awaiting transfer to the MDL Court) that have been filed as of the Execution Date.

“Federal Stipulation of Dismissal” has the meaning ascribed thereto in Section 2.02(C).

“Filed Claimants” has the meaning ascribed thereto in Section 2.02(B).

“Final Enrollment Status” has the meaning ascribed thereto in Section 2.05.

“Final Payment(s)” has the meaning ascribed thereto in Section 7.03(A).

“Final Point Value” has the meaning ascribed thereto in Section 7.03(A).

“Governmental Payors” has the meaning ascribed thereto in Section 13.01(B).

“Illinois Coordinated Court” has the meaning ascribed thereto in Recital A.

“Illinois Coordinated Proceeding Claimant” has the meaning ascribed thereto in Section 1.02.

“Illinois Coordinated Proceedings” has the meaning ascribed thereto in Recital A.

“Illinois Stipulation of Dismissal” has the meaning ascribed thereto in Section 2.02(C).

“Implementing CMO” has the meaning ascribed thereto in Section 2.03.

“Interim Payment(s)” has the meaning ascribed thereto in Section 7.01(B).



“Internal Revenue Code” means the Internal Revenue Code of 1986, as amended, and the regulations promulgated thereunder.

“Liability or Liabilities” means any and all debts, liabilities, covenants, promises, contracts, agreements and/or obligations of whatever kind, nature, description or basis, whether fixed, contingent or otherwise, whether presently known or unknown, developed or undeveloped, discovered or undiscovered, foreseen or unforeseen, matured or unmatured, or accrued or not accrued.

“Lien” means any lien, claim, mortgage, hypothecation, encumbrance, assignment, subrogation right, reimbursement claim, right of indemnity, right to payment, third-party interest or adverse claim of any nature whatsoever, pledge, security interests or charges of any kind, in each case whether statutory or otherwise, including any of the foregoing relating to medical treatment or lost wages, based on any legal expenses, bills, or costs that have been or may be asserted by any health care provider, insurer, governmental entity, employer, any other Person operating under contract with any of the previously mentioned entities, or any other Person.

“Lien Resolution Administrator” means an entity chosen by the PSRC subject to approval by Takeda to assist Program Participants in resolving Liens that are or may be asserted by Governmental Payors or Private Payors.

“Lilly” has the meaning ascribed thereto in Recital A.

“MDL” has the meaning ascribed thereto in Recital A.

“MDL Claimant” has the meaning ascribed thereto in Section 2.02.

“MDL Court” has the meaning ascribed thereto in Recital A.

“MDL Stipulation of Dismissal” has the meaning ascribed thereto in Section 2.02(C).

“Medicaid Program” shall mean the federal program administered by the states under which certain medical items and services are furnished to Medicaid beneficiaries under Title XIX of the Social Security Act, 42 U.S.C. § 1396-1, et seq., as amended from time to time.

“Medicare Program” shall mean the federal Medicare fee-for-service Parts A and B program administered by CMS under which certain medical items and services are furnished to Medicare beneficiaries under Title XVIII of the Social Security Act, 42 U.S.C. § 1395, et seq., as amended from time to time.

“MMSEA” has the meaning ascribed thereto in Section 7.01(B).

“Non-Appealable” means not subject to (i) any further right of appeal to the Claim Administrator, Eligibility Committee, Special Master or otherwise within the Program or (ii) any right of appeal to the MDL Court, Illinois Coordinated Court, California Coordinated Court, or any other court.

“Non-Participating Private Payor” has the meaning ascribed thereto in Section 13.01(C)(2).

“Notice of Appeal” has the meaning ascribed thereto in Section 9.03.

“Notice of Claim Package Deficiency” has the meaning ascribed thereto in Section 3.05.

“Notice of Intent to Opt In Form for Filed Claims” has the meaning ascribed thereto in Section 2.02.

“Notice of Intent to Opt In Form for Unfiled Claims” has the meaning ascribed thereto in Section 2.04.

“Notice of Points Award” has the meaning ascribed thereto in Section 6.02(C).

“Notice of Reconsideration Determination” has the meaning ascribed thereto in Section 6.02(D).

“Notice of Rejection” has the meaning ascribed thereto in Section 3.05.

“Opt In Deadline” has the meaning ascribed thereto in Section 2.03.

“Opt In Package For Filed Claims” has the meaning ascribed thereto in Section 2.02(C).

“Opt In Package For Unfiled Claims” has the meaning ascribed thereto in Section 2.04(B).

“Other Federal Court Claimant” has the meaning ascribed thereto in Section 2.02.

“Other Federal Court Proceedings” has the meaning ascribed thereto in Recital A.

“Other Governmental Payor” shall mean shall mean certain other governmental health care programs with statutory reimbursement or subrogation rights, limited to the Defense Health Agency (formally known as TRICARE), Department of Veterans Affairs, and Indian Health Services benefits.

“Other Lien Amount” has the meaning ascribed thereto in Section 13.01(C).

“Other State Court Claimant” has the meaning ascribed thereto in Section 2.02.

“Other State Court Proceedings” has the meaning ascribed thereto in Recital A.

“Party” means, individually, and “Parties” means, collectively, PSRC, Takeda, Program Participants and their counsel.

“Person” means a natural person, corporation, limited liability company, other company, trust, joint venture, association, partnership, or other enterprise or entity, or the legal representative of any of the foregoing.

“Personal Representative” means a Person duly authorized to represent the legal interests of a living Claimant, or the estate of a deceased Claimant.

“Personal Signature” means the actual signature by the person whose signature is required on the document. Unless otherwise specified in this Agreement, a document requiring a Personal Signature may be submitted by an actual original “wet ink” signature on hard copy, or a PDF or other electronic image of an actual signature, but cannot be submitted by an electronic signature within the meaning of the Electronic Records and Signatures in Commerce Act, 15 U.S.C. §§7001, et seq., the Uniform Electronic Transactions Act, or their successor acts.

“Points” has the meaning ascribed to such term in Section 6.01 and Appendix J (the Points Matrix).

“Points Award” has the meaning ascribed thereto in Section 6.02(A).

“Points Award Criteria” has the meaning ascribed thereto in Section 6.02(A).

“Points Award Process” has the meaning ascribed thereto in Section 6.01(B).

“Points Matrix” has the meaning ascribed thereto in Section 6.02(A) and is attached hereto as Appendix J.

“Primary Counsel” has the meaning ascribed thereto in the Case Census Orders.

“Private Lien Resolution Program” or “PLRP” means a program administered by the Lien Resolution Administrator to address private Liens.

“Private Payors” has the meaning ascribed thereto in Section 13.01(C).

“Product User” means, in relation to any particular Claimant, the natural person (including the deceased natural person) person who alleges, or is alleged, to have suffered losses or damages as a result of such natural person’s own Alleged Injury alleged to have been caused (in whole or in part) by such natural person’s alleged ingestion of ACTOS Products (as opposed to any Legal Representative in respect of such natural person).

“Program” has the meaning ascribed thereto in Recital A.

“Program Participant(s)” has the meaning ascribed thereto in Section 2.01.

“PSRC” has the meaning ascribed thereto in the Preamble.

“QSF Administrator” has the meaning ascribed thereto in Section 10.02(C).

“Qualified Settlement Fund” or “QSF” means the settlement fund established pursuant to Section 10.02 in which Takeda will deposit the Settlement Funds.

“Qualified Settlement Fund Agreement” means the agreement entered into between the PSRC and an appropriate financial agreement establishing and governing the Qualified Settlement Fund.

“Qualifying Program Claimant” has the meaning ascribed thereto in Section 6.01.

“Qualifying Unfiled Claimant” has the meaning ascribed thereto in Section 2.04.

“Release” means the form of release of claims attached hereto as Appendix C, and any substituted form of release of claims necessary to conform with applicable state law as required by Takeda in accordance with Section 11.03.

“Released Persons” means:

- (1) Takeda Development Center Americas, Inc., formerly known as Takeda Global Research & Development Center, Takeda Development Centre Europe Ltd., formerly known as Takeda Global Research & Development Centre – Europe, Takeda Pharmaceuticals America, Inc., Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals International, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda Pharmaceuticals North America, Inc., Takeda California, Inc., formerly known as Takeda San Francisco and Takeda San Diego, Inc., Takeda Ventures, Inc., Takeda America Holdings, Takeda Industries, Inc., Lilly, and/or other Defendants;
- (2) Any and all past or present suppliers or manufacturers of materials, components, and services used in the manufacture of ACTOS Products, including the labeling and packaging thereof;
- (3) Any and all past or present distributors of ACTOS Products, including wholesale distributors, retail distributors, private label distributors, pharmacists, pharmacies, hospitals, and clinics, with respect to their distribution of ACTOS Products, and sale representatives;
- (4) All health care providers, whether entities or individuals, including without limitation physicians, pharmacists, nurses, pharmacies, hospitals, and medical centers who provided treatment in any way related to any Claimant’s alleged use of ACTOS Products, all health care providers who prescribed ACTOS Products for any Claimant, all pharmacists and pharmacies who dispensed ACTOS Products to any Claimant;
- (5) Any direct or indirect parent, subsidiary, affiliate, sister entity, shareholder, predecessor or successor of any of the Persons identified in subparagraphs (1)-(4) above.
- (6) Any other Person against whom any Claimant has asserted or could attempt to assert any claim, liability, or right to payment arising out of or related in any way to any Claimant’s alleged use of ACTOS Products, whether as a joint tortfeasor or otherwise, under any theory of law or equity, including any person or entity named as a defendant in any pending litigation relating to ACTOS Products;

- (7) Any attorney, law firm, and its employees representing the Defendants or other Released Persons in regard to any Claimant's alleged use of ACTOS Products and any Claimant's asserted claims against the Defendants or other Released Persons;
- (8) Any insurer of any of the Persons identified in subparagraphs (1)-(7) above in its capacity as such (and any reinsurer of such insurer in its capacity as such); and
- (9) Any past, present or future officers, directors, board members, employees and shareholders, and past, present and future parents, subsidiaries, affiliates, controlling persons, suppliers, vendors, distributors, contractors, agents, assigns, servants, counsel, and insurers of any of the Persons identified in subparagraphs (1)-(8) above in his or her capacity as such, and all of their officers, directors, employees, shareholders, predecessors, successors, assigns, heirs, executors, estate administrators, and personal representatives (or the equivalent thereto).

"Representative Claimant" means a person authorized by a court or other official of competent jurisdiction under applicable state law, to act on behalf of a deceased or legally incapacitated or incompetent Product User.

"Required Participation Thresholds" has the meaning ascribed thereto in Section 5.02.

"Settled Claims" means any and all claims, causes of action, demands, damages, costs, expenses, liabilities or other losses, whether in law or in equity, including assigned claims, whether known or unknown, asserted or unasserted, regardless of the legal theory, existing now or arising in the future, arising out of or relating to the purchase, use, manufacture, sale, design, distribution, promotion, marketing, clinical investigation, testing, administration, regulatory approval, and/or labeling of ACTOS Products, alone or in combination with any other substance, or any other transaction between any Claimant and Released Persons relating to such Claimant's alleged use of ACTOS Products. The term "Settled Claims" also includes any claims, causes of action, demands, damages, costs, expenses, liabilities or other losses, whether in law or in equity, including assigned claims, whether known or unknown, asserted or unasserted, regardless of the legal theory, existing now or arising in the future, arising directly or indirectly out of or in any way related to, this Release and the events surrounding its negotiation and execution. These "Settled Claims" also include any cause of action that a Claimant may attempt to assert against any attorney, law firm, or its employees as it relates to their representation of any Defendant and/or other Released Person in connection with this settlement or the defense of Takeda and/or other Released Persons as that defense relates to ACTOS Products claims asserted by any plaintiff or claimant. These "Settled Claims" include, without limitation and by way of example, all ACTOS Products -related claims for damages or remedies of whatever kind or character, known or unknown, that are now recognized by law or that may be created or recognized in the future by statute, regulation, judicial decision, or in any other manner, including but not limited to:

- a. Personal injury and/or bodily injury, damage, death, fear of disease or injury, including without limitation reduced future medical treatment options, mental or physical pain or suffering, emotional or mental harm, or loss of enjoyment of life;
- b. Compensatory damages, punitive, exemplary, statutory and other multiple damages or penalties of any kind;
- c. Loss of wages, income, earnings, and earning capacity, medical expenses, medical benefits, including rights to future Medicare or Medicaid benefits, doctor, hospital, nursing, and drug bills;
- d. Loss of support, services, consortium, companionship, society or affection, or damage to familial relations, by spouses, surviving spouses, former spouses, parents, children, other relatives or “significant others” of Claimants;
- e. Consumer fraud, refunds, unfair business practices, deceptive trade practices, unfair and deceptive acts and practices, fraudulent inducement, and other similar claims whether arising under statute, regulation, or judicial decision;
- f. Wrongful death and survival actions; including any future wrongful death claim;
- g. Medical screening and monitoring, injunctive and declaratory relief;
- h. Economic or business losses or disgorgement of profit;
- i. Prejudgment or post-judgment interest;
- j. Spoliation causes of action, whether negligent, intentional or otherwise; and
- k. Sanctions of any kind, whether monetary or non-monetary, against any Released Persons, under any potentially applicable rule or law including but not limited to Fed. R. Civ. P. 37 and Ill. S. Ct. Rule 219(c); this includes enforcement of existing orders and pursuit of any deferred sanctions in the MDL against any Released Persons.

“Settlement Funds” has the meaning ascribed thereto in Section 10.01.

“Settlement Payment(s)” has the meaning ascribed thereto in Section 6.01.

“Signature” means the actual signature by the person whose signature is required on the document, or on behalf of such person by a person authorized by a power of attorney or equivalent document to sign such documents on behalf of such person. Unless otherwise specified in this Agreement, a document requiring a Signature may be submitted by: (i) an actual

original “wet ink” signature on hard copy; (ii) a PDF or other electronic image of an actual signature; or (iii) an electronic signature within the meaning of the Electronic Records and Signatures in Commerce Act, 15 U.S.C. §§7001, et seq., the Uniform Electronic Transactions Act, or their successor acts.

“Special Master” has the meaning ascribed thereto in Section 9.01.

“Specified Documented Economic Damages” has the meaning ascribed thereto in Section 7.02(D).

“State Cases” means any Claims constituting part of the California Coordinated Proceedings, Illinois Coordinated Proceedings, or the Other State Court Proceedings that have been filed as of the Execution Date.

“State Court Coordinated Proceeding Claimant” has the meaning ascribed thereto in Section 2.02.

“State Stipulation of Dismissal” has the meaning ascribed thereto in Section 2.03.

“Stipulation of Dismissal” means, as the context may require, an MDL Stipulation of Dismissal, a California Stipulation of Dismissal, an Illinois Stipulation of Dismissal, a Federal Stipulation of Dismissal, or a State Stipulation of Dismissal.

“Supporting Documentation” means any and all of the various documents and information required pursuant to Section 3.03(A) of the Agreement.

“Takeda” has the meaning ascribed thereto in the Preamble.

“Tax Expenses” has the meaning ascribed thereto in Section 10.03.

“Taxes” has the meaning ascribed thereto in Section 10.03.

“Unenrolled Claimant” has the meaning ascribed thereto in Section 2.05.

“United States” as used herein means the fifty states of the United States of America, the District of Columbia, Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, Guam and the U.S. Minor Outlying Islands. Any reference herein to a “state” shall be interpreted to refer to the states and territories as set forth in this definition.

“Walk Away Right” has the meaning ascribed thereto in Section 5.02.

**ARTICLE XVII. APPENDICES**

<b>Appendix A</b>	Case Census Order
<b>Appendix B</b>	Notice of Intent to Opt In Form for Filed Claims
<b>Appendix C</b>	Release
<b>Appendix D-1</b>	MDL Stipulation of Dismissal
<b>Appendix D-2</b>	Illinois Stipulation of Dismissal
<b>Appendix D-3</b>	California Stipulation of Dismissal
<b>Appendix E</b>	Implementing CMO
<b>Appendix F</b>	Notice of Intent to Opt In Form for Unfiled Claims
<b>Appendix G</b>	Declaration of Counsel
<b>Appendix H</b>	Claim Form
<b>Appendix I</b>	Authorization to Release Records and Other Information
<b>Appendix J</b>	Points Matrix



IN WITNESS WHEREOF, PSRC and Takeda have executed this Agreement effective as of the Execution Date.

**Takeda Pharmaceutical Company Limited**

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Christophe Weber  
President and Chief Executive Officer

April \_\_, 2015

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Yoshihiro Nakagawa  
Global General Counsel

April \_\_, 2015

**Takeda Pharmaceuticals U.S.A., Inc.**

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Kenneth D. Greisman  
Senior Vice President, General Counsel and Secretary

April \_\_, 2015

**Plaintiffs' Settlement Review Committee**

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Richard J. Arsenault  
Neblett, Beard & Arsenault  
2220 Bonaventure Court  
P.O. Box 1190  
Alexandria, LA 71309

April \_\_, 2015

[Signatures continued on next page]

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Beasley, Allen, Crow, Methvin, Portis & Miles, P.C.  
218 Commerce Street  
Montgomery, AL 36104

April \_\_, 2015

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Tommy Fibich  
Fibich, Leebron, Copeland, Briggs, & Josephson  
1150 Bissonnet Street  
Houston, TX 77005

April \_\_, 2015

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April \_\_, 2015

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Tor Hoerman  
Tor Hoerman Law LLC  
234 S. Wabash – 7<sup>th</sup> floor  
Chicago, IL 60604

April \_\_, 2015

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W. Mark Lanier  
The Lanier Law Firm, P.C.  
6810 FM 1960 West  
Houston, TX 77069

April \_\_, 2015

[Signatures continued on next page]

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Patrick C. Morrow  
Morrow Morrow Ryan & Bassett  
324 W. Landry Street  
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April \_\_, 2015

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Neil D. Overholtz  
Aylstock, Witkin, Kreis & Overholtz, PLLC  
17 E. Main Street, Suite 200  
Pensacola, FL 32502

April \_\_, 2015

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Paul J. Pennock  
Weitz & Luxenberg P.C.  
700 Broadway  
New York, NY 10003

April \_\_, 2015

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

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IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT APPLIES TO:  
*ALL CASES*

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)  
) MDL NO. 6:11-MD-2299  
)  
) JUDGE DOHERTY  
)  
) MAGISTRATE JUDGE HANNA  
)  
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**ORDER REGARDING SETTLEMENT AGREEMENT AND DEADLINES**

This Court is advised that Takeda and a committee of plaintiffs' counsel ("Plaintiffs' Settlement Review Committee" or "PSRC") have negotiated a Master Settlement Agreement ("Agreement") to resolve claims against Takeda and/or other defendants in the above matters ("Defendants") involving Bladder Cancer injuries alleged to have resulted from the use prior to December 1, 2011 by claimants of ACTOS® Products.

The Agreement, which will be made available online at [www.actosofficialsettlement.com](http://www.actosofficialsettlement.com), is a private settlement agreement to establish a program (the "ACTOS Resolution Program" or "Program") for the settlement of cases alleging a personal injury involving bladder cancer pending, as of April 28, 2015, in this MDL No. 2299, in other federal courts but not yet transferred into MDL No. 2299 ("Other Federal Court Cases"), in the Illinois Coordinated Proceeding ("Illinois Coordinated Cases"), in the California Coordinated Proceeding ("California Coordinated Cases"), or in any state court ("Other State Court Cases"), and any unfiled claims for which there is no case pending against Takeda and/or other Defendants in federal or state court on or before April 28, 2015, but for which claimants provide notice to Defendants and the PSRC in accordance with the terms of the Agreement, in which claimant alleges the use of ACTOS® Products prior to December 1, 2011, and a Bladder Cancer

resulting from the use of such ACTOS® Products, provided that such claimants with unfiled claims must have signed a retainer agreement with an attorney for legal representation relating to that claim on or before 12:00 noon Eastern Daylight Time on May 1, 2015 (“Unfiled Claims”).

#### **I. AUTHORITY OF COURT TO OVERSEE SETTLEMENT**

This Court has authority to enter Orders establishing time frames for the completion of acts defined in the Agreement. Fed. R. Civ. P. 16(a)(5), (d); *In re Vioxx Prods. Liab. Litig.*, 650 F. Supp. 2d 549 (E.D. La. 2009); *In re Propulsid Prods. Liab. Litig.*, 2004 WL 305816 (E.D. La. 2004). The instructions herein are to be construed as the orders of this Court.

#### **II. NOTICE TO MDL PLAINTIFFS**

All plaintiffs with cases pending in MDL No. 2299 on the date of the entry of this Order shall be given notice of this Order and of the Agreement.

#### **III. CASE MANAGEMENT ORDER REGARDING CENSUS OF CLAIMS**

As defined in this Court’s Case Management Order Regarding Census of Claims, on or before ten (10) days from the date of that Order, responses shall be served to provide the required Census of all filed and unfiled claims in which Primary Counsel has an Interest, as those terms are defined in that Order.

#### **IV. ENROLLMENT OF PLAINTIFFS WITH PENDING CLAIMS**

Under the terms of the Agreement establishing the ACTOS Resolution Program, Plaintiffs with claims pending in this MDL No. 2299, Other Federal Court Cases, Illinois Coordinated Cases, California Coordinated Cases, or Other State Court Cases on or prior to April 28, 2015 who allege an injury of Bladder Cancer resulting from the use of ACTOS® Products taken by such plaintiffs prior to December 1, 2011 (collectively, “Eligible Plaintiffs”) are permitted to enroll in, and be bound by the terms of, the ACTOS Resolution Program. Plaintiffs with cases that were dismissed with prejudice prior to April 28, 2015 are not Eligible Plaintiffs.

Eligible Plaintiffs who intend to participate in the ACTOS Resolution Program must submit an “Opt In Package for Filed Claims,” which includes a “Notice of Intent to Opt In Form for Filed Claims,” a Stipulation of Dismissal of the plaintiff’s pending claim, and a Release of claims, as set forth in the Agreement, by the “Opt-In Deadline” set forth in this Order (and extended as applicable under the terms of the Agreement).

**Pursuant to the terms of the Agreement, Eligible Plaintiffs who elect to enroll in the Program and submit an Opt In Package for Filed Claims shall submit a complete Claim Package, as detailed in the Agreement, by the Claim Package Deadline, extended as appropriate to the Cure Deadline, to be eligible for an award under the ACTOS Resolution Program. Enrollment in the Program is irrevocable, and the claims of Eligible Plaintiffs who submit Opt In Package for Filed Claims, but who do not timely submit a complete Claim Package, will not be eligible to receive any compensation under the Program and such plaintiffs’ cases will be subject to dismissal with prejudice by the filing of the Stipulation of Dismissal submitted with the Opt In Package for Filed Claims, or by a motion by Defendants for dismissal with prejudice, following the Cure Deadline as set forth in the Agreement.**

Each judge presiding over the claims of such Eligible Plaintiffs shall retain jurisdiction over those cases, including jurisdiction over the termination of Plaintiffs’ rights to sue Defendants in those cases.

#### **V. ENROLLMENT OF UNFILED CLAIMS**

As set forth in the Agreement, any person who alleges a Bladder Cancer injury occurring prior to April 28, 2015 resulting from the use of ACTOS® Products taken by such person prior to December 1, 2011, and who retained counsel for legal representation relating to such alleged injury prior to 12:00 noon Eastern Daylight Time on May 1, 2015, but who did not have a case

pending against Defendants in state or federal court on or before April 28, 2015, shall be eligible for participation in the ACTOS Resolution Program upon timely submission to Takeda of an “Opt In Package for Unfiled Claims” Agreement (“Unfiled Claimants”). As detailed in the Agreement, the Opt In Package for Unfiled Claims must include: (i) a notification of the claimant’s unfiled claim and intent to opt in to the Program (“Notice of Intent to Opt In Form for Unfiled Claims”), (ii) a declaration signed by the claimant’s counsel affirming that the claimant (or the claimant’s personal representative) had signed a retainer agreement with that attorney or with his or her law firm prior to 12:00 noon Eastern Daylight Time on May 1, 2015 for legal representation of said claimant relating to a Bladder Cancer injury allegedly resulting from the use of ACTOS® Products (“Declaration of Counsel”), and (iii) a Release of claims in the form attached to the agreement. Opt In Packages for Unfiled Claims must be submitted by the “Opt In Deadline” set forth in this Order (and extended as applicable under the terms of the Agreement).

**All Unfiled Claimants (as defined above and set forth in the terms of the Agreement) who timely submit an Opt In Package for Unfiled Claims pursuant to the Agreement are enrolled in, and bound by the terms of, the ACTOS Resolution Program. Under the terms of the Agreement, Unfiled Claimants enrolled in the Program shall submit a complete Claim Package, as detailed in the Agreement by the Claim Package Deadline, extended as may be appropriate to the Cure Deadline, both set forth in this Order, to be eligible for an award under the ACTOS Resolution Program.**

Pursuant to the terms of the Agreement, enrollment in the Program is irrevocable, and Unfiled Claimants who do not timely submit a complete Claim Package will not be eligible to receive any compensation under the Program.

**VI. ACTOS RESOLUTION PROGRAM DEADLINES**

<p><b><u>11:59 p.m. C.T. on the tenth (10th) day following the entry of this Court's Case Management Order Regarding Census of Claims (the "Census Order Deadline")</u></b></p>	<p>Date by which Primary Counsel shall serve responses regarding filed and unfiled claims in accordance with this Court's Case Management Order Regarding Census of Claims.</p>
<p><b><u>July 13, 2015 (by 11:59 p.m. C.T.) (the "Opt In Deadline")</u></b></p>	<p>Date by which Eligible Plaintiffs and Unfiled Claimants may elect to participate in the ACTOS Resolution Program by submitting the Opt In Package for Filed Claims or the Opt In Package for Unfiled Claims, as applicable, pursuant to the terms of the Agreement.</p> <p>An extension of thirty (30) days to the Opt In Deadline may be sought from the Claims Administrator in accordance with the terms of the Agreement. In addition to such thirty (30) day extension for individual plaintiffs seeking such an extension, the Claims Administrator, in the Claims Administrator's discretion, may allow an additional thirty (30) days for plaintiffs to opt in to the ACTOS Resolution Program under the terms of the Agreement. This date may be further extended by written agreement of the PSRC and Defendants.</p>
<p><b><u>11:59 p.m. C.T. on the 45th day following the last day of the final extension of the Opt-In Deadline attributable to any Program Participant (the "Effective Date")</u></b></p>	<p>Date by which Takeda may exercise its termination right under the Agreement. If Takeda's termination right under the Agreement expires without previously having been exercised, this date shall become the Effective Date of the Agreement.</p>
<p><b><u>11:59 p.m. C.T. on the ninetieth (90th) day following the Effective Date (the "Claim Package Deadline")</u></b></p>	<p>Date by which ACTOS Resolution Program Participants may submit Claim Packages seeking an award under the ACTOS Resolution Program.</p>
<p><b><u>Thirty (30) days after Notice sent by Claims Administrator notifying of Claims Package deficiencies (the "Cure Deadline")</u></b></p>	<p>Date by which an ACTOS Resolution Program Participant must cure deficiencies in his or her Claim Package. Program Participants may seek an extension of an additional 30 days from the Claims Administrator in accordance with the terms of the Agreement.</p>



**VII. FORM SUBMISSION**

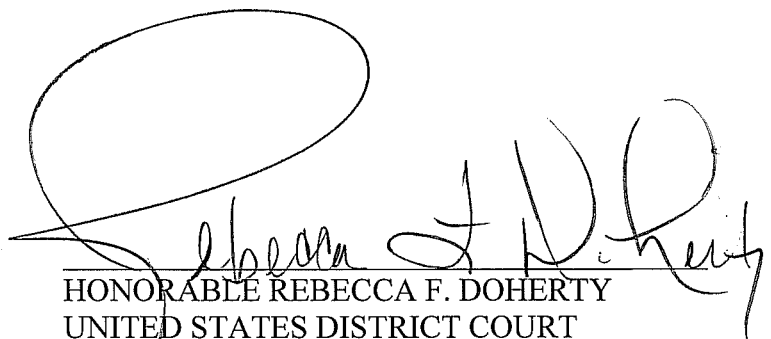
Notice of Intent to Opt In Packages for Filed Claims, Opt In Packages for Unfiled Claims and Claim Packages must be submitted online at [www.actosofficialsettlement.com](http://www.actosofficialsettlement.com), in accordance with instructions provided therein by the Claims Administrator. Counsel and Claimants shall use the forms provided by the Claims Administrator to submit Enrollment and Claim Package materials and shall not attempt to use any of the sample forms attached as appendices to the Master Settlement Agreement.

**VIII. APPOINTMENT OF SPECIAL MASTER**

The Court, by this Order, appoints Gary J. Russo as Special Master to hear motions to dismiss claims that fail to comply with the terms of the Agreement, and to recommend to this Court rulings on those and any other motions, as specified in the Agreement.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 28 day of

April, 2015.

  
HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT COURT

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

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IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

This Document Applies To:  
*All Cases*

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)  
) MDL No. 6:11-md-2299

)  
) JUDGE DOHERTY

)  
) MAGISTRATE JUDGE HANNA  
)  
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**ORDER REGARDING PRESERVATION OF RECORDS AND *PRIMA FACIE*  
EVIDENCE OF USAGE, INJURY AND CAUSATION REQUIREMENTS FOR  
PENDING CASES NOT PARTICIPATING IN THE ACTOS® RESOLUTION  
PROGRAM AND NEWLY FILED OR TRANSFERRED CASES**

**I. INTRODUCTION**

This Order applies to all Plaintiffs with personal injury claims pending as of April 28, 2015 in these cases, or subsequently filed or transferred into this proceeding. This Order requires such Plaintiffs to produce certain specified information regarding their personal injury claims. The Order does not apply to any Plaintiff whose claim is eligible for, and has been submitted to, the ACTOS® Resolution Program. Moreover, if a Plaintiff has already undertaken to meet any of the obligations set forth in this Order pursuant to this Court's previous case management orders, that Plaintiff is not required under this Order to duplicate any of those actions already undertaken. Persons who represent themselves *pro se* in this proceeding shall comply fully with all obligations required of counsel by this Order, unless otherwise stated.

**II. PRESERVATION NOTICE REQUIREMENT**

- A. Counsel for Plaintiff or Plaintiff *pro se* shall notify the following individuals or entities, by registered mail (with return receipt) (each, a "Notice"), that the individual or entity may have records relevant to the Plaintiff's claim in these cases ("Claim") and that any records relating to the Plaintiff must be preserved as directed herein, pending collection by the Plaintiff or Defendant:
1. All Pharmacies that dispensed any medications to the Plaintiff for the period from three years prior to the date of the first diagnosis of the alleged personal injury to the present;
  2. All Physicians, Medical Facilities, other Healthcare Providers and/or other persons ("Other Providers") who prescribed ACTOS® Products for the Plaintiff, or provided any samples of ACTOS® Products to the Plaintiff;

3. For the period of three years prior to the date of the first diagnosis of the alleged personal injury to the present, if not already included in Paragraphs 1 or 2 above:
  - (i) Plaintiff's primary care physician(s);
  - (ii) Plaintiff's endocrinologist(s);
  - (iii) Plaintiff's urologist(s);
  - (iv) Plaintiff's oncologist(s) or any other medical provider who provided treatment to Plaintiff for cancer;
  - (v) Any hospital who treated Plaintiff for any reason; and
  - (vi) Any other healthcare provider who treated Plaintiff for the personal injury alleged in his or her case.
- B. The Notices set forth in Paragraph A above, shall be sent within sixty (60) days after the final Opt-In Deadline, as may be extended under the terms of the ACTOS® Resolution Program Master Settlement Agreement, for cases that were pending as of April 28, 2015, or, for cases filed on or after April 28, 2015, within sixty (60) days from the date the case is filed in or transferred into this proceeding,
- C. A copy of this Order shall be attached to the Notice sent pursuant to this Section, and copies of all such Notice(s) shall be preserved by counsel for Plaintiff or Plaintiff *Pro Se* for so long as the Claim remains pending in this proceeding.
- D. Plaintiffs shall serve on Defendants a statement listing the names and addresses of all individuals or entities to which Notices were sent, along with copies of the Notices and a signed certification that the Notices were sent as required by this Order, within sixty (60) days after the final Opt-In Deadline, as may be extended under the terms of the ACTOS® Resolution Program Master Settlement Agreement, if their case was pending prior to April 28, 2015, or for cases filed on or after April 28, 2015, within sixty (60) days from the date the case is filed in or transferred into this proceeding. Service of the Notice on Defendants by Plaintiffs shall be made by email to Sherry A. Knutson, Esq. at [SidleyActos@Sidley.com](mailto:SidleyActos@Sidley.com).
- E. Plaintiffs who fail to fully comply with the requirements of Paragraphs A through D above shall be given notice of such failure by e-mail or fax from Defendants' Lead Counsel or her designee and shall be provided thirty (30) additional days to cure such deficiency ("Cure Period"). No other extensions will be granted unless agreed to by all Parties in writing. If Plaintiff fails to cure the deficiency within the Cure Period, Defendants' Lead Counsel or her designee may file a Motion to Show Cause why that case should not be dismissed with prejudice. Plaintiff shall thereupon have sixty (60) days to respond to the Notice to Show Cause. Any

failure to respond to the Motion within the required period of time shall lead to the dismissal of the case with prejudice, except for good cause shown.

- F. Absent good cause shown for the failure to comply with the requirements of the Preservation Notice Order, the parties agree, a Plaintiff may not seek to introduce into evidence at trial any document or information from a Pharmacy, Physician, other Healthcare Provider and/or Other Provider, if a Notice was required by Paragraph A of this Order and such Notice was not sent to the Pharmacy, Physician, other Healthcare Provider and/or Other Provider from whom such document or information was obtained.

### **III. DISCOVERY REQUIREMENTS**

- A. Within sixty (60) days after the final Opt-In Deadline, as may be extended under the terms of the ACTOS® Resolution Program Master Settlement Agreement, or, for cases filed on or after April 28, 2015, within sixty (60) days from the date the case is filed in or transferred into this proceeding, Plaintiffs who are subject to this Order shall produce all of the documents and/or information described in this Section III.
1. All pharmacy records regarding the dispensing of drugs to the Plaintiff for the period from three years prior to the date of the first diagnosis of the alleged personal injury to the present;
  2. A Plaintiff Fact Sheet (“PFS”) that complies with the requirements of the MDL Case Management Order governing submission of Plaintiff Fact Sheets, entered by this Court on July 9, 2012 (the “MDL PFS Order”), and authorizations in the forms previously approved by the Court;
  3. Medical records as follows for the period of three years prior to the date of the first diagnosis of the alleged personal injury to the present:
    - (i) All Physicians, Medical Facilities, other Healthcare Providers and/or Other Providers who prescribed ACTOS® Products for the Plaintiff, or provided any samples of ACTOS® Products to the Plaintiff;
    - (ii) All medical records relating to the Plaintiff from Plaintiff’s primary care physician(s);
    - (iii) All medical records relating to the Plaintiff from Plaintiff’s endocrinologist(s);

- (iv) All medical records relating to the Plaintiff from Plaintiff's urologist(s);
  - (v) All medical records relating to the Plaintiff from Plaintiff's oncologist(s) or any other medical provider who provided treatment to Plaintiff for cancer;
  - (vi) All medical records relating to the Plaintiff from any hospital who treated Plaintiff; and
  - (vii) All medical records relating to the Plaintiff from any other healthcare provider who treated Plaintiff for the personal injury alleged in his or her case;
4. A certification signed by Plaintiff or his or her counsel (i) attesting that records have been collected from all pharmacies that dispensed drugs to, or for, the Plaintiff, as described in subparagraph A(1) above; (ii) attesting that all medical records described in subparagraph A(3) above have been collected; and (iii) attesting that all records collected pursuant to subparagraphs A(1) and A(3) have been produced, pursuant to this Order. If any of the documents described in subparagraphs A(1) and (3) above do not exist, Plaintiff or his or her counsel shall state that fact and the reason, if known, why they do not exist in this certification, and provide a "No Records Statement" from the pharmacy or healthcare provider;
  5. A report complying with Rule 26(a)(2) on general causation for the injury alleged by Plaintiff from a medical expert opining to a degree of medical or scientific certainty that ACTOS® Products pose an increased risk for the development of the type of injury alleged by Plaintiff; and
  6. A report complying with Rule 26(a)(2) from a medical expert opining to a reasonable degree of medical certainty, that the use of ACTOS® Products caused or substantially contributed to the personal injury alleged by Plaintiff.
- B. Service on Defendants by Plaintiff or his or her counsel of items set forth above shall be made by email to Sherry A. Knutson, Esq. at [SidleyActos@Sidley.com](mailto:SidleyActos@Sidley.com).
- C. Plaintiffs who fail to fully comply with the requirements of this Order shall be given notice of such failure by e-mail or fax from Defendants' Lead Counsel or her designee and shall be provided thirty (30) additional days to cure such deficiency ("Cure Period"). If a Plaintiff fails to cure the deficiency within the Cure Period, Defendant's Lead Counsel or her designee shall meet and confer with Plaintiff, and if that does not result in a cure then Defendant's Liaison Counsel may file a Motion to Show Cause why that case should not be dismissed with prejudice. Plaintiffs shall thereupon have thirty (30) days to respond to the Motion to Show Cause. Any failure to respond to the Motion within the required

period of time shall lead to the dismissal of the case with prejudice, except for good cause shown.

- D. To the extent not expressly stated herein, nothing in this Order abrogates or replaces each Plaintiff's obligation to submit the PFS, authorizations, and other materials required under the MDL Orders. The Plaintiff need not re-submit a PFS if one has already been submitted with respect to his or her claim.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 28 day of April, 2015.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT COURT

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

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IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT APPLIES TO:  
*ALL CASES*

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)  
) MDL NO. 6:11-MD-2299

)  
) JUDGE DOHERTY

)  
) MAGISTRATE JUDGE HANNA  
)  
)

**CASE MANAGEMENT REGARDING CENSUS OF CLAIMS**

In the management of this litigation as the transferee District, it is necessary to have a more accurate census of the cases, as well as claims of putative plaintiffs, represented by Counsel with cases pending before this Court. To that end, this Order requires the registration of all cases and unfiled claims of putative plaintiffs who are represented by Counsel and who allege a personal injury as a result of the use of an ACTOS Product. “ACTOS® Product” means a Product manufactured, distributed, marketed or sold by or for Takeda containing the active pharmaceutical compound pioglitazone, including, but not limited to, ACTOS, ACTO*plus* met, ACTO*plus* met XR, and *Duetact*.

This Order applies to all Counsel who represent one or more plaintiffs in this Multidistrict Litigation No. 2299 (“Plaintiffs”).

The Court hereby orders the registration of claims as follows:

1. Primary Counsel, defined below, shall register all claims alleging a personal injury relating to ACTOS® Products, in which they have an Interest (as defined below in Paragraph 2), whether (a) pending in this proceeding, (b) pending in any other jurisdiction or tribunal in the United States, or (c) not yet filed in any jurisdiction,. If a

case has been filed by one law firm, Primary Counsel shall be the Counsel of Record. If a case has been filed by one or more firms, the firms filing such a case shall designate one firm among them as Primary Counsel. All Counsel in this proceeding shall be responsible for ensuring that all claims relating to ACTOS® Products in which they have an Interest are registered by Primary Counsel in accordance with this Order, and shall coordinate with Primary Counsel to avoid submission of the same claim by multiple Primary Counsel.

2. Counsel shall be deemed to have an “Interest” in a ACTOS® Claim if Counsel or any person affiliated with, or related in any way to, Counsel: (a) has an engagement or retainer agreement with a person to represent that person in relation to ACTOS® Products; (b) is listed as the counsel of record for a Plaintiff in filed pleadings related to ACTOS® Products; (c) has entered an appearance for a Plaintiff in any legal action related to ACTOS® Products; (d) would benefit directly or indirectly from any payment to settle any claim connected with ACTOS® Products; or (e) otherwise has any financial interest of any kind whatsoever in any claim of such Plaintiff connected with ACTOS® Products.

3. Primary Counsel shall fully comply with this Order, and shall provide the information required by this Order completely and accurately, by no later than ten (10) days after entry of this Order. The census submission from each Primary Counsel shall provide the information required current as of the time of the submission.

4. Primary Counsel shall register claims by using the online Registration function at [www.actosofficialsettlement.com](http://www.actosofficialsettlement.com), either by providing the information required by that function for each claim individually or by completing and uploading the Census

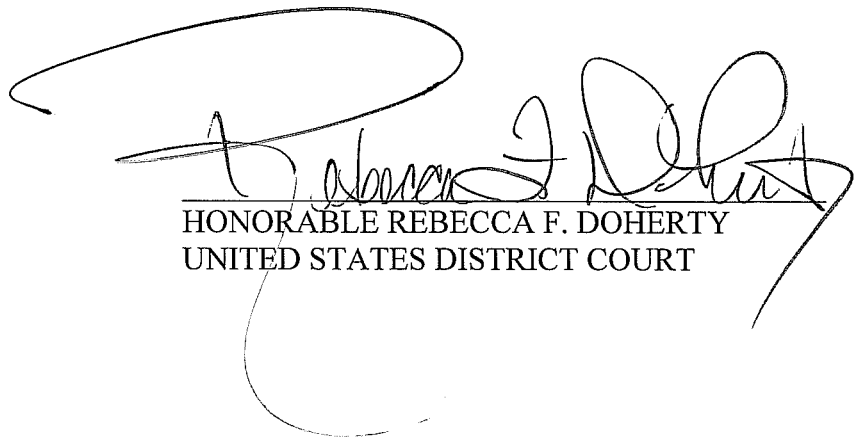


Spreadsheet available at that website for this purpose. Primary Counsel shall not modify the format or fields required by the Census Spreadsheet. The Claims Administrator promptly shall make all registration information available to Lead Counsel for the Plaintiffs Steering Committee and Lead Counsel for the Defendants in Adobe pdf format and Excel format.

5. When registering claims in accordance with this Order, Primary Counsel must certify, pursuant to 28 U.S.C. § 1746 and using the online function for this purpose, that all information provided to register claims is true, complete and correct, to the best of his or her knowledge. Submission of registration information under Paragraph 4 constitutes a representation to the Court that the information provided is true, complete and correct.

6. The Court expects all Counsel to comply with this Order. Failure to meet the requirements of this Order by the deadlines set within the “Order Regarding Settlement Agreement and Deadlines” will subject non-compliant Counsel to a show cause hearing as to why they have not complied with this Order.

April ~~THUS~~ DONE AND SIGNED in Lafayette, Louisiana, this 28 day of \_\_\_\_\_, 2015.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT COURT

RECEIVED

APR 20 2015 *OM*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

This Document Applies To:  
*All Cases*

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA


ORDER

IT IS HEREBY ORDERED the proceedings in this MDL scheduled for the week of April 20, 2015 week shall be **SUSPENDED** and rescheduled by the Court at a later date.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 20 day of April, 2015.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

APR 14 2015 

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone) Products Liability Litigation  
MDL No. 11-md-2299, All Cases

Date: April 14, 2015

**MINUTE ENTRY:**  
**AGENDA FOR APRIL 23, 2015 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, April 23, 2015:

- I. Report on developments in the MDL since the February 26, 2015 status conference
- II. Status of federal and state court filings
- III. Discovery plan
- IV. Report on status of outstanding motions
- V. Report on status of outstanding orders
- VI. Common benefit claims process update
- VII. Report on *pro se* process
- VIII. State court update
- IX. PSC liaison update
- X. Next status conference date - May 21, 2015

RECEIVED

APR - 8 2015

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

6-11-md-2299

JUDGE DOHERTY

This Document Applies to  
*All Cases*

MAGISTRATE JUDGE HANNA

**AMENDED CASE MANAGEMENT ORDER:  
Protecting the Confidentiality of Discovery Materials<sup>1</sup>**

For good cause shown, the Court issues the following Protective Order:

**1. Discovery Material.**

(a) This Order applies to all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise (collectively “discovery material”), by any party to this proceeding (the “Producing Party”) to any other party (the “Receiving Party”).

(b) At the time this Order is entered in the *In re Actos (Pioglitazone) Products Liability Litigation* (W.D. La., MDL No. 2299), it becomes binding upon all parties presently involved, or who are later named, in these proceedings including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, experts, consultants, representatives, directors, officers, employees, and others as set forth in this Order.

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<sup>1</sup> The only amendment to this Order is found on page 12, Section 8(a), paragraph 3. All other aspects of this Order remain unchanged.

(c) If additional parties are added other than parents, subsidiaries or affiliates of current parties to this litigation, their ability to receive Confidential Information as set forth in this Order will be subject to their being bound, by agreement or Court Order, to this Order.

(d). The entry of this Protective Order does not prevent any party from seeking a further order of this Court regarding Discovery Materials.

(e) Nothing herein shall be construed to affect in any manner the admissibility at trial or hearings before this Court of any document, testimony, or other evidence.

**2. Confidential Discovery Material.** “Confidential Discovery Material,” as used herein, means information of any type, kind or character that the Producing Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Rule 26(c)(1)(G), whether it is a document, information contained in a document, information revealed during a deposition or other testimony, information revealed in an interrogatory response, or information otherwise revealed. Discovery material containing trade secrets, or other confidential or proprietary research, development, manufacturing or commercial or business information may be designated by the Producing Party as “Confidential.” Without prejudice to the right of a Producing Party to object to the production of the following information or of a party to seek production and/or de-designation, examples of the information that may be alleged to be subject to such designation include but are not limited to the Producing Party’s:

a. Customer names and compilations of information related to opinion leaders and other consultants;

b. Proprietary licensing, distribution, marketing, design, development, research and manufacturing information regarding products and medicines, whether previously or currently marketed or under development (not to include disseminated marketing materials or materials that, on its face, was published to the general public);

c. Unpublished clinical studies, scientific literature, and related documents;

d. Information concerning competitors;

e. Production information;

f. Personnel records and information;

g. Financial information not publicly filed with any federal or state regulatory authorities or not contained within any publicly available quarterly or annual reports;

h. Private medical information that identifies a person unless such identifying information is redacted; and

i. Information submitted to any governmental or regulatory agency, which information is exempt from public disclosure.

**3. Discovery Material and Foreign Law.** Any entity organized under the laws of a country other than the United States, including but not limited to Japan, France, Germany, and the United Kingdom, that produces information in this litigation may designate as confidential those documents in any form (including electronic or paper

form) containing “Protected Data” within the meaning of the applicable data protection or privacy laws, if any.<sup>2</sup>

#### **4. Use of Confidential Discovery Material.**

(a) Any discovery material that is designated as “Confidential” in accordance with Paragraph 2 above, along with any copies, abstracts, summaries, excerpts, compilations thereof, or information derived from such discovery material, and any notes or other records regarding the contents of such discovery material (collectively “confidential discovery material”), shall not be used for any business or competitive purpose, except by the Producing Party, or for any other purposes whatsoever, other than the litigation of cases in this MDL, including post-MDL proceedings in transferor courts (hereinafter referred to collectively as “this litigation”), and for any other action brought by or on behalf of a former pioglitazone user alleging injuries or other damages therefrom (“Other Actos Lawsuits”), so long as all parties are bound by and subject to this Order or another judicially approved order that is identical to or the substantial equivalent to this Order. Confidential discovery material will not be disclosed except in accordance with paragraphs 4(b), 7, 10, and 11.

(b) Prior to being given access to confidential discovery material, any person falling within subparagraphs 7(a)(vi) or 7(a)(vii) shall be provided with a copy of

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<sup>2</sup> “Protected Data” shall refer to any information that a party believes in good faith to be subject to foreign data protection laws. Protected Data constitutes highly sensitive materials requiring special protection. Examples of such data protection laws include but are not limited to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L281/31) (European Union personal information); Data Protection Act 1998 (c. 29) (United Kingdom personal information); the German Federal Data Protection Act (Germany personal information); French Data Protection Act. Law No. 78-17 of January, 6, 1978, J.C.P. 1978, III, No. 44692; and The Personal Information Protection Act (Law No. 57 of 2003) (Japan personal information).

this Order and shall execute a copy of the Endorsement of Protective Order, attached as Exhibit A. Counsel providing such access to confidential discovery material shall retain copies of the Endorsement(s) of Protective Order and shall provide them to counsel producing confidential discovery materials as provided below. For testifying experts, a copy of the Endorsement of Protective Order executed by the testifying expert shall be furnished to counsel for the party who produced the confidential discovery material to which the expert has access.

**5. Designation of Confidential Discovery Material.**

(a) Confidential discovery material, if in writing, shall have the following language stamped on the face of the writing, or shall otherwise have such language clearly marked in the margins:

**“CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER”**

Such stamping or marking will take place prior to production by the Producing Party, or subsequent to selection by the Receiving Party for copying but prior to the actual copying if done expeditiously. The stamp shall be affixed in such manner in the margins as not to obliterate or obscure any written matter.

(b) To the extent that confidential discovery material is stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) (“Computerized Material”) is produced by any party in such form, the Producing Party may designate such matters as confidential by a designation of **“CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER”** on the media. Whenever any Receiving Party reduces such material to



hardcopy form, that party shall mark the hardcopy form with the corresponding “**CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER**” designation.

(c) In the case of deposition testimony relating to documents designated as confidential, the portion of the transcript in which confidential writings are offered, identified or discussed shall also be designated as confidential. Any additional confidentiality designations shall be made within thirty (30) calendar days after the transcript has been received by counsel making the designation, and shall specify the testimony being designated confidential by page and line number(s). Until the expiration of such thirty (30) day period, the entire text of the deposition, including exhibits, shall be treated as confidential under this Order.

(d) In the event that the Producing Party inadvertently fails to designate discovery material as confidential in this or any other litigation, it may make such a designation subsequently by notifying all parties to whom such discovery material was produced, in writing as soon as practicable. After receipt of such notification, the Receiving Party shall treat the designated discovery material as confidential, subject to that party’s right to dispute such designation in accordance with Paragraph 8.

**6. Consent to Jurisdiction.** All persons receiving or given access to confidential discovery material in accordance with the terms of this Order consent to the continuing jurisdiction of the Court for the purposes of enforcing this Order and remedying any violations thereof.

**7. Disclosure of Confidential Discovery Material.**

(a) Confidential discovery material shall not be disclosed to anyone other than the following categories of persons:

i. The Court (and any appellate court), including court personnel, Special Masters and members of their staffs, jurors, and alternate jurors only in the manner provided in paragraph 10 below.

ii. If produced by Plaintiffs, Defendants' in-house counsel, paralegals and clerical support staff, and outside counsel, including any attorneys employed by or retained by Defendants' outside counsel who are assisting in connection within this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel or retained by the attorneys employed by or retained by Defendants' outside counsel. To the extent a Defendant does not have in-house counsel, it may designate two individuals employed by each Defendant (in addition to outside counsel) to receive Confidential Discovery Materials produced by Plaintiffs.

iii. If produced by any Defendant, a Plaintiff in this litigation, Plaintiff's attorneys in this litigation, including the paralegal, clerical, secretarial and other staff employed or retained by such counsel. Additionally, confidential discovery material produced by any defendant in this MDL may be disclosed to the named plaintiff(s) in Other Actos Lawsuits, and their counsel, including paralegal, clerical, secretarial and other staff employed or retained by such other plaintiffs' counsel if: (a) the lawsuit alleges or involves injuries or damages resulting from the use of pioglitazone; and (b) an order identical to or the substantial equivalent to this Order has been entered in such lawsuit or all counsel for plaintiff who receive the documents agree to be governed by the terms of this Order and shall sign an Endorsement of Protective Order, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms. Further, confidential discovery material produced

by any defendant in this MDL may be disclosed to counsel representing an Actos claimant with an unfiled claim, if: (a) the claim alleges or involves injuries or damages resulting from the use of pioglitazone; and (b) all counsel for claimant who receive the documents agree to be governed by the terms of this Order and shall sign an Endorsement of Protective Order, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms.

iv. If produced by any Defendant, clients of Plaintiff's attorneys in this litigation, including those with unfiled claims, if those clients agree to be governed by the terms of this Order and shall sign a Confidentiality Agreement, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms.

v. If produced by any Defendant, outside counsel for any other Defendant, including any attorneys employed by or retained by any other Defendant's outside counsel who are assisting in connection with this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel.

vi. Any Defendant's insurer or counsel for its insurer provided that prior to receiving confidential discovery materials a person with sufficient authority to bind each insurer and its counsel executes the Endorsement of Protective Order and provides a copy to the Producing Party on behalf of the insurer or law firm. Any materials provided to an insurer or its counsel shall not be used for any purpose other than evaluation of the claims asserted in this litigation and shall not be used outside the claims asserted in this litigation.

vii. Court reporters (including persons operating video recording equipment at depositions) and persons preparing transcripts of testimony to the extent necessary to prepare such transcripts.

viii. Retained experts, advisors and consultants, including persons directly employed by such experts, advisors and consultants (collectively "Experts"), but only to the extent necessary to perform their work in connection with this litigation or Other Actos Lawsuits in which an order that is identical to or the substantial equivalent of this Order has been entered.

ix. The persons who authored the confidential discovery material, were a source of the confidential discovery material, are in good faith believed to be referenced in the confidential discovery material and already familiar with the subject-matter of the confidential discovery material or who received such confidential discovery material.

(b) All parties and their respective counsel, paralegals and the employees and assistants of all counsel receiving discovery material shall take all steps reasonably necessary to prevent the disclosure of confidential discovery material other than in accordance with the terms of this Order.

(c) A plaintiff's current or former healthcare provider who has agreed on the record at deposition to maintain the confidentiality of any document intended to be used at the deposition may be shown or questioned about Confidential Discovery Material at the deposition, provided that no copies of the Confidential Discovery Material shall be left in the possession of the healthcare provider witness and copies of that Confidential Discovery Material shall not be attached to or included with any original or

copy of the transcript of that deposition provided to the healthcare provider; however, copies of the Confidential Discovery Material shall be attached to the deposition transcript and made available for the use of the deponent in the event he or she testifies at trial. Counsel present at the deposition should make a good faith effort to obtain the healthcare provider's agreement on the record to maintaining confidentiality and no counsel shall make efforts to dissuade the healthcare provider from refusing to agree on the record to maintaining the confidentiality of any such documents. Regardless of whether any deponent signs the Endorsement of Protective Order attached as Exhibit A, this Order will apply to any deponent who is shown or examined about Confidential Discovery Material and the deponent cannot take any exhibits with them nor can he/she reveal any information learned from the confidential materials shown to them. This paragraph is not intended to prevent any deponent from seeking other relief from this Court.

(d) Except for plaintiff's current or former healthcare provider (who are subject to the foregoing sub-section) and current employees and consultants of the defendants or the producing party, each person who is permitted to see confidential documents shall first be shown a copy of this Order and shall further be advised of the obligation to honor the confidentiality designation.

(e) Disclosure of confidential discovery material other than in accordance with the terms of this Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate, including without limitation, contempt, injunctive relief and damages.

**8. Disputes concerning designation of Confidential Discovery Material.**

a) If at any time a Receiving Party wishes in good faith to dispute a designation of discovery material as confidential hereunder, such party shall notify the designating party of such dispute in writing (Dispute Notice), specifying by exact document numbers the discovery material in dispute and providing a brief explanation of the basis of the dispute with regard to each such document or other discovery material. No more than 50 documents shall be challenged in a single Dispute Notice, and only one Dispute Notice may be sent within a three-week period. If no change in designation is offered by the Producing Party, the Producing Party must provide within fourteen (14) calendar days a written explanation of the good faith basis for the designation(s) at issue.

If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, the Receiving Party shall, in writing (Challenge Notice), notify the Producing Party that a resolution cannot be reached regarding the confidentiality designation of a document or, the Receiving Party may elect to file and serve a motion that identifies the challenged material and sets forth the basis for the challenge to the confidentiality designation. Any such motion shall be accompanied by a Motion for Leave to File Under Seal (“Sealing Motion”), in accordance with this Court’s order concerning Sealing Motions. On such motion, the Producing Party shall have the burden of proving that the material is entitled to protection, as if this Order has not been entered, pursuant to Rule 26(c)(1)(G). On such a motion by the Receiving Party, the Producing Party shall have no less than fifteen (15) calendar days to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief.<sup>3</sup> The Opposition shall be accompanied by a Sealing Motion.

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<sup>3</sup> If the number of pending challenges becomes burdensome, the parties agree to alter the schedule to provide sufficient time for an Opposition.

Notwithstanding the procedure described above, no motion affecting information provided pursuant to this Order may be filed without prior consultation with the Special Masters. The Court strongly suggests genuine consideration of any guidance the Special Masters might offer be given by the parties before filing any such motion.

If the Receiving Party elects to serve a Challenge Notice rather than move, the Producing Party shall, within twenty-one (21) calendar days of receiving such notice from the Receiving Party, file and serve a motion that identifies the challenged material and sets forth in detail the basis for the confidentiality designation. Any such motion shall be accompanied by Sealing Motion. The Producing Party shall have the burden of proof on such motion to establish the propriety of its confidentiality designation. The time allotted under this paragraph for a Producing Party to respond in writing to a Challenge Notice or to file and serve a motion setting forth the basis of a challenged confidentiality designation shall not be shortened except upon a showing of good cause.

(b) All discovery material designated as confidential under this Order, whether or not such designation is in dispute pursuant to subparagraph 8(a) above, shall retain that designation and be treated as confidential in accordance with the terms hereof unless and until:

- i. the Producing Party agrees in writing that the material is no longer confidential and subject to the terms of this Order; or
- ii. fourteen (14) calendar days after the expiration of the appeal period of an Order of this Court that the matter shall not be entitled to confidential status (or such longer time as ordered by this Court) if the Order on appeal is not subject to a stay; or

- iii. the Producing Party does not respond as set forth above within fourteen (14) calendar days of service of the Dispute Notice; or
- iv. the Producing Party does not serve a motion within twenty-one (21) days of receiving a Challenge Notice.

9. **Designation by Non-Parties.** Any non-party who is producing discovery materials in this litigation may subscribe to and obtain the benefits of the terms and protections of this Order by designating pursuant to the terms of this Order as “Confidential” the discovery materials that the non-party is producing. Such subscription shall be through a Notice filed with this Court and such Notice shall indicate that the Non Party agrees to this Order in its entirety.

10. **Filing with the Court.** The parties will use the following procedure for submitting to the Court papers consisting of, relating to, containing, incorporating, reflecting, describing, or attaching Confidential Information: Other than motion practice relating to disputes concerning designation of Confidential Discovery Material which shall be filed, together with a Sealing Motion, pursuant to paragraph 8 of this order. All papers consisting of, relating to, containing, incorporating, reflecting, describing, or attaching Confidential Information shall be timely served upon opposing counsel pursuant to Court Ordered deadlines or agreements by the parties. A courtesy copy of such papers shall simultaneously be provided to the Deputy Special Master. Following service of Reply papers upon opposing counsel, the parties shall meet and confer in good faith for up to twenty-one (21) days to resolve objections of the use of any confidential information or confidential documents in the briefs (Confidential Document Review Period or CDRP). During the CDRP, any party objecting to the use of any information or



documents in the briefs must contact the filing party and both sides must attempt in good faith to resolve the objection(s). If no resolution is achieved within the CDRP and the objecting party is not waiving its objection, then the objecting party must file a Sealing Motion no later than the last day of the CDRP. The objecting party shall refrain from filing any papers that are the subject of the objection until either Sealing Motion is resolved or, if no Sealing Motion has been filed with the Court, the expiration of the CDRP.

**11. Use of Confidential Discovery Material at Hearings or Trial.** This Order does not restrict or limit the use of confidential discovery material at any trial. However, prior to any hearing that is held other than a trial at which the use of confidential discovery material is anticipated, the parties shall meet and confer regarding the use of the confidential discovery material. If the parties cannot agree, the parties shall request the Court to rule on such procedures.

**12. Responses to Subpoenas or Other Process.** If a Receiving Party or its counsel or expert is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization which calls for production of any confidential discovery material produced by another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such document or information until fourteen (14) calendar days after notifying counsel for the producing party in writing of all of the following: (1) the information and documentation which is requested for production in the subpoena; (2) the date on which compliance with the subpoena is requested; (3) the location at which compliance with the subpoena is requested; (4) the identity of the party serving the

subpoena; and (5) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena has been issued. The party, counsel or expert receiving the subpoena or other process shall cooperate, to the extent reasonably possible, with the Producing Party in any proceeding relating thereto.

**13. Return or Destruction of Confidential Discovery Materials.** Within thirty (30) calendar days of the conclusion of any attorney's last case in this proceeding, including any appeals related thereto, at the written request and opinion of the Producing Party, such attorney and any persons to whom he or she disclosed confidential discovery material under this Order shall return and surrender or destroy any such material or copies thereof to the Producing Party at the Producing Party's expense. Such persons shall return or surrender any discovery materials produced by the Producing Party and any and all copies (electronic or otherwise), summaries, notes, compilations, and memoranda related thereto; provided, however, that counsel may retain their privileged communications, work product, Endorsements of Protective Order, materials required to be retained by applicable law, and all court-filed documents even though they contain discovery materials produced by the Producing Party, but such retained privileged communications and work product shall remain subject to the terms of this Order. At the written request of the Producing Party, any person or entity having custody or control of recordings, notes, memoranda, summaries or other written materials, and all copies thereof, relating to or containing discovery materials produced by the Producing Party shall deliver to the Producing Party an affidavit certifying that reasonable efforts have

been made to assure that all such discovery materials produced by the Producing Party and any copies thereof, any and all records, notes, memoranda, summaries, or other written material regarding the discovery materials produced by the Producing Party (except for privileged communications, work product and court-filed documents as stated above) have been delivered to the Producing Party in accordance with the terms of this Order or destroyed. In lieu of returning the materials, the Producing Party may direct that the materials be destroyed in a manner that will protect the confidential discovery materials and the destroying party shall certify that it has done so.

**14. Reservation of Rights.**

(a) Except as provided for herein, nothing in this Order shall prevent or restrict counsel for any party in any way from inspecting, reviewing, using or disclosing any discovery material produced or provided by that party, including discovery materials designated as confidential.

(b) Nothing shall prevent disclosure beyond that required under this Order if the producing party consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders such disclosure and that Order is not subject to an appellate stay within twenty-one (21) calendar days after it is issued.

(c) No disclosure pursuant to this Paragraph shall waive any rights or privileges of any party granted by this Order.

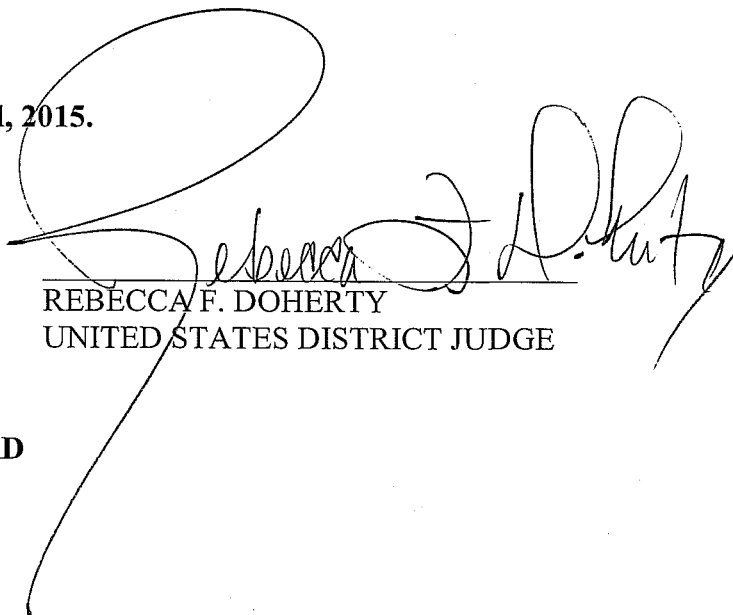
**15. No Effect on Other Obligations.** This Order shall not enlarge or affect the proper scope of discovery in this or any other litigation, nor shall this Order imply that confidential discovery material is properly discoverable, relevant, or admissible in this or any other litigation. Each party reserves the right to object to any disclosure of

information or production of any documents that the Producing Party designates as confidential discovery material on any other ground it may deem appropriate. The actions of the parties and their counsel in designating (or de-designating) discovery material as confidential pursuant to this Order shall not constitute evidence that is admissible to a jury at trial.

**16. Obligation of Good Faith.** All parties and counsel for such parties in this litigation shall make a good faith effort to ensure that their experts, employees, and agents comply with this Order. In the event of a change in counsel, retiring counsel shall fully instruct new counsel of their responsibilities under this Order.

**17. Modifications/Continuing Effect.** By written agreement of the parties, or upon motion and order of the Court, the terms of this Order may be amended or modified. This Order shall continue in force until amended or superseded by express order of the Court, and shall survive any final judgment or settlement in this litigation.

**SO ORDERED, this 8 day of April, 2015.**



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

**AGREED TO BY COUNSEL OF RECORD**

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

6-11-md-2299

JUDGE DOHERTY

This Document Applies to  
*All Cases*

MAGISTRATE JUDGE HANNA

**ENDORSEMENT OF PROTECTIVE ORDER**

I hereby attest to my understanding that information or documents designated Confidential are provided to me subject to the Protective Order regarding confidential information produced in discovery, entered \_\_\_\_\_, (the "Protective Order"), in the above-captioned litigation; that I have been given a copy of and have read the Protective Order, and that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Protective Order, indicating my agreement to be bound by the Protective Order, is a prerequisite to my review of any information or documents designated as confidential pursuant to the Protective Order.

I further agree that I shall not disclose to others, except in accord with the Protective Order, any confidential discovery material, in any form whatsoever, and that such confidential discovery material and the information contained therein may be used only for the purposes authorized by the Protective Order.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such discovery material and further information will continue even after this litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Protective Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court for the Western District of Louisiana, to the full extent allowed by law and to the full extent determined by the United States Court(s), for the purposes of any proceedings relating to enforcement of the Protective Order.

I further agree to be bound by and to comply with the terms of the Protective order as soon as I sign this Agreement, whether or not the Protective Order has yet been entered as an Order of Court.

Date:

By: \_\_\_\_\_

Subscribed and sworn to before me this

\_\_\_\_ day of \_\_\_\_\_, 20\_\_

\_\_\_\_\_  
NOTARY PUBLIC

RECEIVED

APR - 8 2015

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

6-11-md-2299

This Document Applies to  
*All Cases*

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**AMENDED CASE MANAGEMENT ORDER: MOTIONS<sup>1</sup>**

The submission to this Court of contested motions in the captioned proceedings shall be made in accordance with the following instructions.

**I. SCOPE OF ORDER**

This Order shall apply to all contested motions in the captioned proceedings. It shall not apply to unopposed motions, which the parties may continue to file as they have been doing. The stay on filing contested motions shall remain in place except for the categories of motions described herein.<sup>2</sup>

**II. MOTIONS**

The parties will be permitted to file the following categories of contested motions within the following timeframes.

**A. DISCOVERY**

Discovery motions may be filed at any time prior to the discovery deadline in the action in which the motion is filed. *However, no discovery motion may be filed without prior*

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<sup>1</sup> The only amendments to this Order are found on page 1, adding fn. 2, and page 4, changing the language of Section III(A). All other aspects of this Order remain unchanged.

<sup>2</sup> As to the six cases chosen by this Court for consideration for trial beginning May 2, 2016, which are listed in Rec. Doc. 5370, the procedure outlined in the Court's Scheduling Order: May 2, 2016 Trial [Rec. Doc. 5303] will supersede this more general Order in case of conflict.

*consultation with the Special Masters; the Court strongly suggests genuine consideration of any guidance the Special Masters might offer be given by the parties before filing any such motion.* This Court has issued instructions to the Special Masters to assist the parties, to the fullest extent possible, to resolve discovery disputes without the need for formal motions and briefing. Any motion filed without prior consultation with the Special Masters will be denied summarily.

**B. CLASS ACTION ISSUES**

**Deadline: May 31, 2013**

The parties may file motions by this deadline that are related to the class action allegations asserted in any case in these proceedings. However, should any party take the position that further discovery is required before a motion challenging class allegations or supporting class certification may be filed, the party shall provide notice of this fact to this Court, *via* the Special Masters. The Special Masters will assist the parties in addressing issues raised with the Court.

**C. CHOICE OF LAW ISSUES**

**Deadline: June 28, 2013**

The parties shall notify the Court, through the Special Masters, of their conclusion(s) as to the applicable law to each claim made against each defendant in each of the bellwether cases. In the event that the parties disagree as to any conclusion as to a bellwether case(s), the Special Masters will consult with this Court and briefing deadlines will be set to allow an early determination to be made on any disputed choice of law question.

**D. DISPOSITIVE MOTIONS, MOTIONS IN *LIMINE*<sup>3</sup>**

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<sup>3</sup> Please see this Court's Scheduling Order: Pilot Bellwether Program (First Trial) (Rec. Doc. 2359) and Scheduling Order: Pilot Bellwether Program (Second Trial) (Rec. Doc. 2520) for additional briefing deadlines associated with dispositive and *limine* motions.



**Deadline, 1<sup>st</sup> Pilot Bellwether Trial:            October 14, 2013**

All dispositive motions and *limine* motions associated with the *First Pilot Bellwether Trial* shall be filed no later than this deadline. Prior to this deadline, the Special Masters will solicit from counsel (confidentially, if preferred) lists of *limine* motions that the parties intend to file and will follow up with discussions with counsel as to the filing of those identified motions. The purpose of these consultations will be for the Special Masters to provide guidance to counsel with regard to the necessity of filing and response to *limine* motions.

**Deadline, 2<sup>nd</sup> Pilot Bellwether Trial:            January 13, 2014**

All dispositive motions and *limine* motions associated with the *Second Pilot Bellwether Trial* shall be filed no later than this deadline. Prior to this deadline, the Special Masters will solicit from counsel (confidential, if preferred) lists of *limine* motions the parties intend to file and will follow up with discussions with counsel as to the filing of those identified motions. The purpose for these consultations will be for the Special Masters to provide guidance to counsel with regard to the necessity of filing and response to *limine* motions.

**F.     *DAUBERT*<sup>4</sup>**

**Deadline, 1<sup>st</sup> Pilot Bellwether Trial:            October 21, 2013**

All *Daubert* motions associated with the *First Pilot Bellwether Trial* shall be filed no later than this deadline.

**Deadline, 2<sup>nd</sup> Pilot Bellwether Trial:            January 20, 2014**

All *Daubert* motions associated with the *Second Pilot Bellwether Trial* shall be filed no later than this deadline.

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<sup>4</sup> Please see this Court's Scheduling Order: Pilot Bellwether Program (First Trial) (Rec. Doc. 2359) and Scheduling Order: Pilot Bellwether Program (Second Trial) (Rec. Doc. 2520) for additional briefing deadlines, as well as an evidentiary hearing, associated with *Daubert* motions.

### III. GUIDELINES

A. Should any party wish to file a contested motion that is not addressed by a more particularized Order lifting this requirement, counsel are to contact the Special Masters for guidance as to how and when to bring the issue to the attention of the Court.

B. All motions must comply with this Court's standard rules, except to the extent waived or modified by orders issued in these proceedings. Counsel are encouraged to consult the local rules before filing any motion; they may be found on this Court's website, at <http://www.lawd.uscourts.gov/local-rules>. To the extent that counsel have any questions, they are strongly encouraged to contact any of the Special Masters in this matter, all of whom have extensive experience of, and familiarity with, the local rules.

C. Counsel are cautioned that this Court does not automatically grant leave to file reply briefs. Any party wishing to file a reply brief must first consult with the Special Masters and if necessary, thereafter, seek leave to file, making sure to attach a copy of the proposed brief to the motion for leave.<sup>5</sup> Any motion for leave that has not been discussed with the Special Masters will be summarily denied for failure to comply with this Order. Any proposed motion for leave to file a reply brief and attached proposed reply brief that merely reiterate argument, instead of responding to unanticipated opposition argument, will not be permitted to be filed.

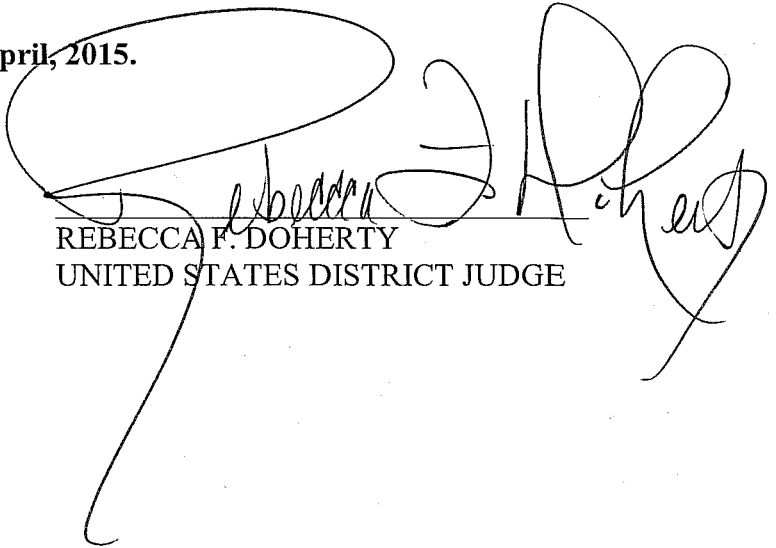
D. The Plaintiffs' Steering Committee will take the lead on facilitating briefing on behalf of all Plaintiffs, except where the PSC explicitly refuses to make arguments with regard to a motion or issue. Where non-PSC counsel intend to present separate argument on a given motion, Counsel are required to coordinate their efforts with the PSC to avoid unnecessary duplication.

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<sup>5</sup> See Local Rules for additional instructions concerning the filing of reply briefs.

E. All parties should be aware that, with regard to motions, this Court does not grant oral argument merely as a matter of course. Should oral argument be required on any given motion, counsel will be notified by the Court or the Special Masters, and oral argument will be scheduled by the Court.

**SO ORDERED, this 8 day of April, 2015.**



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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MAR 20 2015

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
Case Nos. 3:11-cv-01651, 6:11-cv-01590,  
6:11-cv-01593, 6:11-cv-01648,  
6:12-cv-01332, 6:13-cv-00325

MAGISTRATE JUDGE HANNA

**ORDER**

This Court, in the Scheduling Order of February 23, 2015 (Rec. Doc. 5305), having indicated its intent to try several direct-filed Louisiana Western District cases beginning May 2, 2016, issues the following order designating the cases which might be tried on that date.

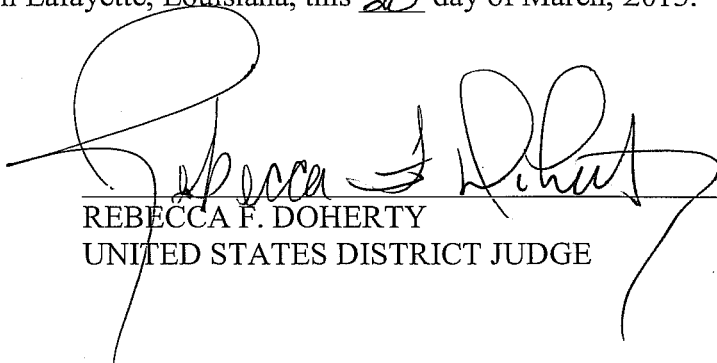
This Court will consider using the May 2, 2016 trial date established in the Scheduling Order to try one or more of the following cases:

Boyd et al v. Takeda Pharmaceuticals America Inc. et al	3:11-cv-01651
Jones et al v. Takeda Pharmaceuticals North America Inc. et al	6:11-cv-01590
Schwing et al v. Takeda Pharmaceuticals North America Inc. et al	6:11-cv-01593
Eddie et al v. Takeda Pharmaceuticals America Inc. et al	6:11-cv-01648
Bynum v. Takeda Pharmaceuticals America Inc. et al	6:12-cv-01332
Richard et al v. Takeda Pharmaceuticals USA Inc. et al	6:13-cv-00325

The parties are instructed to conduct discovery, motion practice, and the mandatory settlement conferences on all of the cases noted above.

On or after the deadline for filing responses to dispositive motions set in the Scheduling Order, the Court will determine which of the above cases will be set for trial. At that time, counsel will be given full opportunity to raise any objections they might wish to make as to any then contemplated joinder for trial and/or consolidation.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 20 day of March, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

MAR - 3 2015

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY  
LITIGATION

MDL Docket No. 2299

6:11-MD-2299

-----  
**This Document Relates to All Cases**  
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Hon. Rebecca F. Doherty  
United States District Judge

Plaintiffs' Steering Committee on Behalf of All  
Plaintiffs Herein,

Plaintiffs

v.

Takeda Pharmaceuticals America, Inc.; Takeda  
Pharmaceuticals North America, Inc.; Takeda  
California, Inc.; Takeda Pharmaceutical  
Company Limited; and Eli Lilly and Company

Defendants.

**STIPULATED PROTECTIVE ORDER TO NON-PARTIES KAISER FOUNDATION  
HOSPITALS, THE PERMANENTE MEDICAL GROUP, INC. AND KAISER  
FOUNDATION HEALTH PLAN, INC.'S ANALYTICAL FILES AND OTHER HIGHLY  
CONFIDENTIAL INFORMATION**

Pursuant to paragraph 17 of the Court's Case Management Order: Protecting the  
Confidentiality of Discovery Materials in Civil Action No. 06-11-MD-2299 (W.D. La.) (the  
"MDL Confidentiality Order"), Rule 26(c) of the Federal Rules of Civil Procedure and 45 C.F.R.  
§ 164.512(e)(1), Plaintiffs' Steering Committee ("PSC") and non-parties Kaiser Foundation  
Hospitals, The Permanente Medical Group, Inc. and Kaiser Foundation Health Plan, Inc.  
(together "Kaiser") stipulate to a Protective Order as follows:

## I. RECITALS

1. The PSC served a subpoena upon non-party Kaiser Foundation Hospitals in the above-entitled action on about September 2, 2014 ("September 2014 Subpoena.").

2. Thereafter, on February 19, 2015, the PSC filed certain motions to compel.

3. In response to the September 2014 Subpoena and the PSC's motion to compel, Kaiser has agreed to permit the PSC to designate certain individuals to access certain highly confidential and proprietary analytical files that contain portions of Kaiser's research data (the "Analytical Files") pertaining to the cohort study and nested case control study of Pioglitazone and bladder cancer in patients with diabetes mellitus (the "Actos-Bladder Cancer Study"), the manuscript prepared by researchers at Kaiser concerning the Actos-Bladder Cancer Study that has been submitted for publication, including drafts of the manuscript (collectively referred to as the "Manuscript"), and internal and external communications concerning the Manuscript (collectively the "Manuscript Communications") for the limited and exclusive purpose of litigating this MDL action.

4. In response to the Subpoena and the PSC's motion to compel, Kaiser, also, will provide responsive, non-privileged documents from custodial files of five Kaiser employees; Kaiser has advised that such documents have already been gathered through early November 2014 and can be promptly provided; responsive documents from November 2014 to the present will be provided on a rolling basis within 30 days from the signing of this Order.

5. The parties agree, the Analytical Files, as well as other materials requested by the September 2014 Subpoena, specifically including, but not limited to the nested cohort study questionnaires, contain personal and protected health information regarding or relating to individuals who have a privacy interest in such information and public disclosure thereof would

be contrary to the law and public interest. The PSC and Kaiser, also, understand and agree that such documents and information are subject to the Standards of Privacy of Individually Identifiable Health Information, 45 C.F.R. Parts 160 and 164, promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"); California Civil Code §§ 56 et seq.; or other similar statutory or regulatory privacy protections. The PSC and Kaiser agree that Kaiser may redact the Analytical Files and any other materials requested by the September 2014 Subpoena to the extent necessary to protect personal health information in accordance with HIPAA and that the PSC shall reimburse Kaiser's reasonable costs in providing access to and redacting the materials requested by the September 2014 Subpoena.

6. The PSC and Kaiser agree that once adopted this Stipulated Protective Order will constitute a "qualified protective order" under 45 C.F.R. 164.512(e).

7. The parties agree that Paragraph 17 of the MDL Confidentiality Order provides that its terms may be "amended or modified" "[b]y written agreement".

8. The parties agree that under Rule 26(c) of the Federal Rules of Civil Procedure, the Court may upon good cause issue protective orders.

9. The parties further agree such good cause exists for this Stipulated Protective Order given the highly confidential and proprietary nature of the Analytical Files, the Manuscript, the Manuscript Communications and the privacy interests of the patients whose information is contained therein.

10. The parties agree, that the PSC will submit this Stipulated Protective Order to the Court and request its entry before Kaiser must grant the PSC's designees access to the Analytical Files, the Manuscript or the Manuscript Communications. However, in order to promote expedient access to the Analytical Files, the Manuscript or the Manuscript Communications in



light of current litigation deadlines in this action, the PSC agrees to be bound by the terms of the Stipulated Order upon executing it by and through counsel and Kaiser may, therefore, permit access to the Analytical Files, the Manuscript or the Manuscript Communications before the Court formally enters this Stipulated Protective Order.

11. This Stipulated Protective Order hereby incorporates the terms and conditions of the Court's MDL Confidentiality Order such that all discovery materials Kaiser has produced and may further produce in this action may have at least the same protections as the "Confidential Discovery Materials" subject to that previous order. However, with regard to the Analytical Files, the Manuscript or the Manuscript Communications (sections II and III below) and discovery materials that Kaiser designates as "Attorneys' Eyes Only" (section IV below), the terms of this Stipulated Protective Order will govern and supersede the provisions of the MDL Confidentiality Order, and in the case of any conflict as between the two, this Order, Stipulated Protective Order to Non-Parties Kaiser Foundation Hospitals, the Permanente Medical Group, Inc. and Kaiser Foundation Health Plan, Inc.'s Analytical Files and Other Highly Confidential Information, shall govern.

12. The Takeda defendants may enter into a parallel Stipulated Protective Order with Kaiser that permits the Takeda Defendants to access the Analytical Files, the Manuscript or the Manuscript Communications in the same manner and under the same terms and conditions as the PSC's access to those files, and restricts the Takeda defendants' ability to disclose Kaiser's "Attorneys' Eyes Only" discovery materials.

## **II. ACCESS TO KAISER ANALYTICAL FILES AND WORK-PRODUCT ANALYSES AND REPORTS DERIVED THEREFROM**

13. In order to protect against any unnecessary use or disclosure of the Analytical Files and the work-product analyses and aggregated data reports derived therefrom (the “Work-Product Files”), the PSC and Kaiser agree to the following terms and conditions:

14. The PSC may designate no more than four individuals from among its retained consultants or attorneys (the “Analytical-File Users”) to access Kaiser’s Analytical Files.

15. Kaiser shall develop a Remote Access Protocol that permits the Analytical-File Users to securely access and perform statistical analyses of the Analytical Files through the Internet. Kaiser shall not require the Analytical-File Users to disclose their identities to Kaiser in order to access the Analytical Files. Additional details of Kaiser’s Remote Access Protocol are set forth in the attached Exhibit 1. Up to two Analytical-File Users may simultaneously access the Analytical Files. Kaiser shall make the Analytical Files accessible to the PSC-designated persons at the earliest feasible time, and in no case longer than eighteen (18) days after entry of this Stipulated Protective Order by the Court.

16. Before Kaiser makes the Analytical Files available to the Analytical-File Users, Kaiser may remove any non-essential, individually-identifiable health information from the Analytical Files, including but not limited to, first name, last name and medical record number of individuals, so long as the integrity of the Analytical Files is sufficiently preserved for the Analytical-File Users to examine or analyze the Actos-Bladder Cancer Study. Kaiser must assign a unique numeric code to each unique patient in the Analytical Files, and ensure a basis of comparison and/or identification of these redactions against the original documents.

17. Kaiser’s Remote Access Protocol shall include the following features for handling Work-Product Files:

- a. the ability to create or modify user accounts;

- b. the ability to set file or folder permissions; and
- c. a file-zip program that can be used to encrypt and password-protect

designated files.

18. When an Analytical-File User has generated Work-Product Files and wishes to obtain them from Kaiser, the PSC's counsel shall notify Kaiser's counsel or other Kaiser designee via email. Upon receiving such notification, Kaiser shall have until 5 p.m. PST the next business day to email the designated work-product files to the PSC's counsel. Kaiser shall permanently destroy all copies of the designated Work-Product Files after emailing them to the PSC's counsel.

19. Kaiser shall not in any circumstance attempt to decrypt or otherwise view the contents of any Work-Product Files.

20. The PSC shall reimburse Kaiser its reasonable costs in preparing the Analytical Files and the Remote Access Protocol.

### **III. LIMITATIONS ON ACCESS, USE AND DISCLOSURE OF ANALYTICAL FILES, WORK-PRODUCT FILES, MANUSCRIPT AND MANUSCRIPT COMMUNICATIONS**

21. The Analytical Files, the Work-Product Files, the Manuscript and Manuscript Communications, or any portions of any thereof, shall not be used or disclosed for any purpose other than litigation of this MDL action such as sales, marketing, research and development, contract negotiations, or any other commercial, competitive or business purpose.

22. The PSC shall not permit anyone other than their respective designated Analytical-File Users to access the Analytical Files through Kaiser's Remote Access Protocol and pending publication of the Manuscript the PSC will limit access to the Manuscript and the Manuscript Communications to members of the PSC and their testifying experts.

23. Prior to permitting the respective designated Analytical-File Users to access the Analytical Files through Kaiser's Remote Access Protocol, or prior to permitting anyone access to the Manuscript or Manuscript Communications, the PSC must provide those individuals with copies of this Stipulated Protective Order, the MDL Confidentiality Order and the applicable Attorneys' -Eyes-Only Notice and obtain their signatures on the Certificate of Confidentiality Obligation ("Certificate") attached here as Exhibit 2. For testifying experts, copies of any such Certificate executed by a testifying expert that accessed the Analytical Files, the Manuscript, or the Manuscript Communications shall be furnished to Kaiser upon request. The PSC shall take all other reasonable steps to ensure that the Analytical-File Users, or anyone with access to the Manuscript or Manuscript Communications do not use or disclose such information for any purpose other than litigation of this MDL action.

24. The Analytical-File Users shall not, in any circumstance:

- a. print or photograph the Analytical Files or any portions thereof;
- b. transfer or save the Analytical Files or any portions thereof to a CD, DVD, USB drive, hard drive or any other recordable device or medium; or
- c. attempt to re-identify the Analytical Files or any portions thereof.

Nothing in this paragraph shall prohibit the Analytical-File Users from performing statistical analyses of the Analytical Files or generating aggregated data reports from the Analytical Files.

25. Any use or disclosure of the Analytical Files to any person or entity other than to the Analytical-File Users for the purpose of this litigation as specified in paragraphs 14, 20 and 21 above is strictly prohibited unless:

- a. Kaiser consents to such use or disclosure; or
- b. the Court orders such use or disclosure.

Similarly, any use or disclosure of the Manuscript or Manuscript Communications to any person or entity other than to the PSC and its testifying experts for the purpose of this litigation as specified in paragraphs 15, 21 and 22 above is strictly prohibited unless:

- c. Kaiser consents to such use or disclosure; or
- d. the Court orders such use or disclosure.

26. Kaiser shall terminate its Remote Access Protocol upon the earlier of:

a. written notification from the PSC's counsel that the Analytical-File Users have completed their work with the Analytical Files; or

b. 180 calendar days from the date the Analytical-File Users first access the Analytical Files.

27. Should circumstances arise in the course of litigating this MDL action which requires the Analytical-File Users to regain access to the Analytical Files after Kaiser terminates its Remote Access protocol pursuant to paragraph 26 above, the PSC's counsel will advise Kaiser's counsel of those circumstances and request additional Remote Access to the Analytical Files for the Analytical-File Users. Kaiser will not unreasonably withhold such access and will arrange to provide access to the Analytical Files via the Remote Access Protocol for a mutually agreeable period of time. The PSC's counsel shall give Kaiser at least 5 business-days' notice of its request for additional access to allow Kaiser sufficient time to re-establish the Remote Access Protocol for the Analytical-File Users. However, Kaiser shall not under any circumstances be required to permit additional access to its Analytical Files beyond the end of the next trial proceeding in the MDL.

28. To the extent there exist any documents that contain or reflect the Analytical Files or portions thereof in Kaiser's production of documents and/or custodian-level ESI to the PSC,

Kaiser may designate those files as “HIGHLY CONFIDENTIAL ANALYTICAL FILES.” Similarly, Kaiser may designate the Manuscript and any Manuscript Communications in Kaiser’s production of documents and/or custodian-level ESI to the PSC as “HIGHLY CONFIDENTIAL MANUSCRIPT FILES.” All documents so designated shall be subject to the limitations on use and disclosure set forth in paragraphs 22 to 26 of this Stipulated Protective Order.

29. The Work-Product Files, or any portions thereof, shall be entitled to the same protections as materials designated “ATTORNEYS’ EYES ONLY” pursuant to the MDL Confidentiality Order and section IV below.

**IV. LIMITATIONS ON ACCESS, USE AND DISCLOSURE OF KAISER’S ATTORNEYS’-EYES-ONLY DISCOVERY MATERIALS**

30. “ATTORNEYS’ EYES ONLY” information is defined as follows and shall include any information, document, or thing, or portion of any document or thing that Kaiser in good faith believes contains trade secrets, competitively sensitive technical, marketing, financial, sales, research and development, or other confidential business information not publicly filed with any federal or state regulatory authorities or not contained within any publicly available quarterly or annual reports, or other highly sensitive business or personal information, or unpublished manuscripts awaiting peer review and publication and communications related thereto, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of Kaiser.

31. “ATTORNEY’S EYES ONLY” information shall be afforded the same protections afforded to “Confidential Discovery Material” in the MDL Confidentiality Order.

32. In addition, discovery materials produced and marked as “ATTORNEYS’ EYES ONLY” may be disclosed only to outside counsel for the parties and their staff, and to the

persons identified in paragraphs 7(a)i, 7(a)vii and 7(a)viii of the MDL Confidentiality Order, except that such “ATTORNEYS’ EYES ONLY” materials may NOT be disclosed to any Plaintiff, or any other persons, or in any Other Actos Lawsuits outside of this MDL, or to counsel representing an Actos claimant with an unfiled claim, unless counsel for Kaiser agrees in advance or as ordered by the Court. Before disclosing “ATTORNEYS’ EYES ONLY” information to any Plaintiff, or any other persons, or in any Other Actos Lawsuits outside of this MDL, or to counsel representing an Actos claimant with an unfiled claim, the party making the disclosure must identify that person to Kaiser and either: (a) obtain Kaiser’s written approval, which must not be unreasonably withheld, and also (b) obtain each such person's execution of the non-disclosure agreement in the form attached to the MDL Confidentiality Order as Exhibit A after copies of the MDL Confidentiality Order and this Stipulated Protective Order is provided to such individuals; or (c) seek an order from the Court authorizing the disclosure.

33. Absent written consent from Kaiser, any person who receives access to “ATTORNEYS’ EYES ONLY” information shall not be involved in the prosecution of patents or patent applications relating to Pioglitazone or the methods, procedures, subjects, results or conclusions of the preclinical and clinical research or studies performed by Kaiser Permanente Northern California studying Pioglitazone, before any foreign or domestic agency, including the United States Patent and Trademark Office (“the Patent Office”). For purposes of this paragraph, “prosecution” includes directly or indirectly drafting, amending, advising, or otherwise affecting the scope or maintenance of patent claims. To avoid any doubt, “prosecution” as used in this paragraph does not include representing a party challenging a patent before a domestic or foreign agency (including, but not limited to, a reissue protest, ex parte reexamination or inter partes reexamination). This Prosecution Bar shall begin when access to “ATTORNEYS’ EYES

ONLY” information is first received by the affected individual and shall end two (2) years after final termination of this action.

34. If Kaiser discovers that it has inadvertently or mistakenly disclosed information, documents or tangible items protected by attorney-client privilege or work product immunity, and brings that discovery to the attention of the Receiving Party, Kaiser and the Receiving Party's treatment of such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5). Such inadvertent or mistaken disclosure of such information shall not by itself prejudice or otherwise constitute a waiver of any claim of attorney-client privilege or work product immunity for such information. However, this does not restrict the right of the Receiving Party to challenge Kaiser's claim of privilege or work product protection if appropriate within a reasonable time after receiving notice of the inadvertent or mistaken disclosure.


Under Paragraph 8 concerning disputes to the designation of Confidential Discovery Material, if a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by Kaiser, the Receiving Party and Kaiser shall meet and confer to attempt to resolve the issue. If the Receiving Party and Kaiser are unable to reach an agreement as to the designation of the discovery material, the Receiving Party shall not have the right to serve a Challenge Notice as set forth in Paragraph 8 of the MDL Confidentiality Order with respect to the discovery materials produced by Kaiser. Instead, the Receiving Party shall file and serve a motion that identifies the challenged material and sets forth the basis for the challenge to the confidentiality designation. Any such motion shall be accompanied by a Motion for Leave to File Under Seal (“Sealing Motion”), in accordance with this Court's order concerning Sealing Motions. On such motion, Kaiser shall have the burden of proving that the material is entitled to protection, as if this Order has not been entered, pursuant to, Rule



26(c)(1)(G). On such a motion by the Receiving Party, Kaiser shall have no less than fifteen (15) calendar days to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief. The Opposition shall be accompanied by a Sealing Motion.

Dated: March 2, 2015

Respectfully submitted,

By:   
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26(c)(1)(G). On such a motion by the Receiving Party, Kaiser shall have no less than fifteen (15) calendar days to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief. The Opposition shall be accompanied by a Sealing Motion.

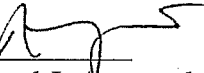
Dated: March 2, 2015

Respectfully submitted,

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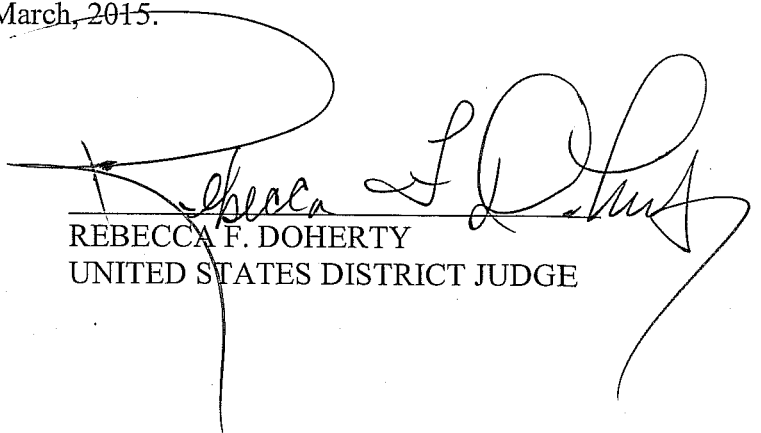
*Attorneys for non-parties Kaiser Foundation  
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*On behalf of the Plaintiffs' Steering  
Committee*

SO ORDERED, this 3 day of March, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

**EXHIBIT 1 WAS FILED UNDER SEAL  
ATTACHED TO REC. DOC. 5325 (6:11-MD-2299)**

**IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY  
LITIGATION

MDL Docket No. 2299

6:11-MD-2299

-----  
**This Document Relates to All Cases**  
-----

Hon. Rebecca F. Doherty  
Unites States District Judge

Plaintiffs' Steering Committee on Behalf of All  
Plaintiffs Herein,

Plaintiffs

v.

Takeda Pharmaceuticals America, Inc.; Takeda  
Pharmaceuticals North America, Inc.; Takeda  
California, Inc.; Takeda Pharmaceutical  
Company Limited; and Eli Lilly and Company

Defendants.

**CERTIFICATE OF CONFIDENTIALITY OBLIGATION**

I hereby attest to my understanding that I am being permitted access to one or more of the following: (1) a highly confidential and proprietary manuscript ("Manuscript"), (2) highly confidential communications relating to or concerning the Manuscript ("Manuscript Communications"), (3) highly confidential and proprietary research data analytical files (the "Analytical Files") and may generate statistical analyses and aggregated data from those analytical files (the "Work-Product Files") that contain information pertaining to patients, subject

to the terms and conditions of the following attached documents in the above-captioned litigation:

- Stipulated Protective Order Regarding the Plaintiffs' Steering Committee's Access to Non-Parties Kaiser Foundation Hospitals, The Permanente Medical Group, Inc. and Kaiser Foundation Health Plan, Inc.'s Analytical Files and Other Highly Confidential Information; and;
- Case Management Order: Protecting the Confidentiality of Discovery filed July 30, 2012. (together, the "Confidentiality Obligation Documents")

I have read the attached Confidentiality Obligation Documents and agree to be bound by their terms. I understand that my execution of this Certification is a prerequisite to my review and use of Kaiser's Analytical Files, the Manuscript and the Manuscript Communications. I agree that I shall not use or disclose the Analytical Files, Work-Product Files, the Manuscript and the Manuscript Communications or portions thereof, to others in any form whatsoever, except in accord with the terms and conditions of the attached, and that those files and the information contained therein may be used only for the purposes authorized by the Confidentiality Obligation Documents.

I further agree and attest to my understanding that my obligation to honor the confidentiality of the Analytical Files, Work-Product Files, the Manuscript and the Manuscript Communications and portions thereof will continue even after this litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Confidentiality Obligation Documents, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court for the Western District of Louisiana, to the full extent allowed by law and to the full extent

determined by the United States Courts, for the purposes of any proceedings relating to enforcement of the Protective Order.

I further agree to be bound by and to comply with the terms of the attached Confidentiality Obligation Documents as soon as I sign this Agreement, whether or not any of them have been entered as an Order of Court.

Date:

By: \_\_\_\_\_

Subscribed and sworn to before me this

\_\_\_\_\_ day of \_\_\_\_\_, 20 \_\_\_\_

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FEB 23 2015 

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS® (PIOGLITAZONE  
PRODUCTS LIABILITY LITIGATION

6:11-md-02299

JUDGE DOHERTY

This Document Applies to  
All Cases Listed in Attachment A<sup>1</sup>

MAGISTRATE JUDGE HANNA

**SCHEDULING ORDER: MAY 2, 2016 TRIAL<sup>2</sup>**

This Court hereby sets the following trial date and associated deadlines:

**JURY TRIAL:** May 2, 2016 at 9:30 AM in Lafayette before Judge REBECCA F. DOHERTY. Counsel are to be present in Courtroom 2 at 9:00 AM.

**PRETRIAL CONFERENCE:** April 11, 2016 at 10:00 AM in Lafayette before Judge REBECCA F. DOHERTY

***DEADLINES***

**NOTICE:** The parties are placed on notice this Court expects timely and full compliance with the following deadlines. This Court's previous approach of allowing the parties to grant each other informal extensions will not apply. No extension of any deadlines set forth in this scheduling order may be granted by counsel or the Special Masters without prior and informed consent of the Court.

**February 20, 2015**

**10 Status Reports Due**

Using the form previously provided by the Special Masters, the parties shall produce Status Reports on 10 of the 61 Louisiana, Western District, direct-filed cases identified in the verified, agreed-

<sup>1</sup> Attachment A reflects a list of the docket numbers of cases included in the agreed to verified list of direct-filed cases Louisiana Western District cases provided by the parties.

<sup>2</sup> Counsel are expected to schedule and sequence discovery so as to permit all deadlines to be met. This Court's Special Masters, as well as the Court, will be available to assist the parties in such scheduling should it prove necessary. Moreover, if a separate Discovery Order is necessary, counsel should notify this Court immediately, through the Special Masters.



to list produced on February 6, 2015 (hereafter the “Louisiana Western” cases).

No later than February 23, 2015, and each Monday thereafter

**Identification of Anticipated Discovery**

The parties shall identify the specific discovery they propose to propound, conduct, or schedule, in which Louisiana Western case or cases, within the next week(s), and request leave to do so. **These identifications are due February 23, 2015, and each subsequent Monday until discovery is complete.**

Discovery anticipated should be identified in the Status Reports as they are filed; however, the parties must obtain leave of Court by way of the Special Masters before engaging in any specific discovery. The parties shall submit specific requests to conduct specifically- identified discovery to the Special Masters, who will consider those requests and recommend approval or disapproval of them at this juncture as soon as possible. *Within four calendar days of issuance of the Special Masters’ recommendation*, a party aggrieved by the Special Masters’ determination may request an immediate appeal to this Court.

March 6, 2015

**20 Status Reports Due**

Using the form previously provided by the Special Masters, the parties shall produce Status Reports on an additional 20 of the Louisiana Western cases.

March 9, 2015

**Defendants’ Nomination of Primary Case in First Trial Group**

Deadline for the Defendants to nominate the primary case for the first trial grouping.

The Court intends to designate a group of approximately 5 Louisiana Western cases to be tried together beginning May 2, 2016. Defendants will nominate the primary case from among the Louisiana Western cases, with the sole limitation being that the **Plaintiff or decedent must have had significant exposure to Actos during the period from 2006 through 2011.**

Once this case has been nominated by the Defendants, the Plaintiffs’ Steering Committee and the Defendants will each nominate 3 additional cases to be added to the trial nomination pool.

March 11, 2015

**Parties’ Nomination of Additional Cases for First Trial Group**

Deadline for the Plaintiffs’ Steering Committee and the Defendants to each nominate 3 additional cases for the first trial grouping.

The Court intends to designate a group of approximately 5 Louisiana Western Cases to be tried together beginning May 2, 2016.

The parties should consider several important factors in making their nominations:

- All Plaintiffs/decedents should have significant exposure to Actos in the period from 2006 through 2011.
- If possible, the selected grouping should include at least one smoker and one non-smoker.
- If possible, the selected grouping should include at least one person with a known genetic tendency toward bladder cancer and at least one person without such a known tendency.
- If possible, the selected grouping should include at least one person with industrial exposure known to increase the risk of bladder cancer and at least one person without such known exposure.

Should the trial nomination pool fail to reflect the desired factual dichotomy, or should any of the nominated cases be dismissed for any reason prior to final case designation, the Court may adjust the grouping as it deems advisable.

At the earliest opportunity, but *no later than June 1, 2015*, this Court intends to select 5 cases from the pool to be tried together, beginning May 2, 2016. Thus, the parties are cautioned to keep their Status Reports current, as this Court will rely heavily on those Reports in making its selection. All deadlines falling after the date on which the cases are designated for trial shall apply to only those cases designated, unless noted otherwise, for the first trial fixing.

Discovery and pre-trial preparation on the remaining Louisiana Western cases shall proceed, however, on separate tracks, and will be addressed in separate orders of this Court.

*After the parties have submitted their nominees for the first trial group*

#### **First Formal Settlement Negotiations**

The parties are encouraged to begin, immediately, and to continue thereafter to explore and engage in ongoing settlement negotiations as to the Louisiana Western cases. *After the parties have submitted their nominees for the first trial group*, Special Master Russo shall schedule a formal settlement conference and/or mediation regarding *the cases included in the first trial nomination pool*. Magistrate Judge Hanna will be available for mediation on any one case, or group of cases, where appropriate. Counsel will be required to make themselves, and their clients, available to participate, in person, in good faith negotiations as ordered by this Court.

Plaintiffs' and Defendants' counsel will be required to file into the record a formal certification of settlement efforts in a form that will be provided by the Court and in part reflective of this Court's standard certification. Such certification will be governed by the requirements of Fed.R.Civ.P. 11.

March 20, 2015

**Remaining Status Reports Due**

Using the form previously provided by the Special Masters, the parties shall produce Status Reports on the remaining Louisiana Western cases.

March 26, 2015

**Deadline to Seek Leave to Amend Pleadings**

Deadline for the parties to file motions for leave to file amendments adding claims to their pleadings in the Louisiana Western cases.<sup>3</sup>

April 15, 2015

**Identification of General Causation Experts**

Plaintiffs and Defendants shall identify *general* causation experts, by name, address, and area of expertise, providing such identification to opposing counsel and to the Special Masters. Such designations shall not be changed without good cause being shown.

April 16, 2015

**Deadline for Requests to File Defense/Threshold Motions**

Deadline for submitting formal requests for leave to file defense/threshold motions for the first trial grouping. For any motion permitted to be filed at this juncture, the Court will set a filing and/or briefing schedule, after conferring with the Special Masters.

Two separate and staggered motion deadlines shall apply. No motion shall be filed without first requesting leave to file from this Court. As to defense/threshold motions, the defendants may seek leave to file pleadings-based motions or other threshold motions challenging the Louisiana Western plaintiffs' right to proceed to trial, by submitting descriptions of their proposed motions (each no longer than 1 page in length) to the Special Masters. The Special Masters will make a recommendation of approval or disapproval on the request as soon as possible. *Within 4 calendar days of issuance of the Special Masters' recommendation*, any party aggrieved by the Special Masters' recommendation will be permitted an immediate appeal to this Court.

After defense/threshold motion requests have been submitted

**First Formal Settlement Negotiations**

The parties are encouraged to begin, immediately, and to continue thereafter to explore and engage in ongoing settlement negotiations as to the Louisiana Western cases. *After the parties have submitted*

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<sup>3</sup> In filing any motion for leave to amend, counsel are cautioned to comply with Local Rule 7.6.

*their nominees for the first trial group*, Special Master Russo shall schedule a formal settlement conference and/or mediation regarding *the cases included in the first trial nomination pool*. Magistrate Judge Hanna will be available for mediation on any one case, or group of cases, where appropriate. Counsel will be required to make themselves, and their clients, available to participate, in person, in good faith negotiations as ordered by this Court.

Plaintiffs' and Defendants' counsel will be required to file into the record a formal certification of settlement efforts in a form that will be provided by the Court and in part reflective of this Court's standard certification. Such certification will be governed by the requirements of Fed.R.Civ.P. 11.

No later than June 1, 2015

**Final Designation of Cases for Trial**

Final designation by the Court of cases for trial beginning May 2, 2016.

July 1, 2015

**Defendants' Certification of Identification, Location, and Production of All Responsive Documents**

Defendants' counsel shall certify that they have engaged in good faith and best efforts to identify, locate and produce all responsive documents and electronically-stored information requested by the Plaintiffs' Steering Committee and/or the Louisiana Western plaintiffs approved by this Court. Such certification will be subject to the obligations and requirements of Fed.R.Civ.P. 11.

July 1, 2015 and the 1<sup>st</sup> of each month thereafter, until March 23, 2016

**Exchange of Witness and Exhibit Lists**

The parties shall exchange *witness and exhibit lists* for the cases designated for the first trial fixing. **No witness or exhibit may be added without good cause shown and leave of Court once the discovery deadline of September 11, 2015 has passed** (except for experts identified, and reports produced, in accordance with this order); *however*, witnesses and exhibits may be removed at any time prior to March 23, 2016. All exhibits must be identified with particularity and not by an *in globo* designation. Each witness' contact information must be included, along with a declaration of whether the witness is expected to testify live at trial or will require a video deposition, or deposition transcript.

July 1, 2015

**Plaintiffs' General Causation Expert Identification**

Deadline for Plaintiffs to identify all general causation experts and produce background information (*See Fed.R.Civ.Pro.26(a)(1)(B)(iv-vi)*).

July 8, 2015

**Plaintiffs' General Causation Expert Reports**

Deadline for Plaintiffs to produce general causation expert reports.

July 22, 2015

**Defendants' General Causation Expert Identification**

Deadline for Defendants to identify all general causation experts and produce background information (*See Fed.R.Civ.Pro.26(a)(1)(B)(iv-vi)*).

July 29, 2015

**Defendants' General Causation Expert Reports**

Deadline for Defendants to produce general causation expert reports.

August 10 through  
September 14, 2015

**Expert Depositions**

All expert depositions, other than trial video depositions, must be completed in this period, unless leave of Court is obtained.<sup>4</sup>

August 10, 2015

**Plaintiffs' Specific Causation Expert Identification**

Plaintiffs to identify all specific causation experts and produce background information (*See Fed.R.Civ.Pro.26(a)(1)(B)(iv-vi)*).

No later than  
August 10, 2015

**Second Formal Settlement Negotiations**

The parties are strongly encouraged to continue all settlement negotiations throughout this process. *On or before August 10, 2015*, Special Master Russo will schedule a second settlement conference and mediation with Magistrate Judge Hanna if deemed appropriate, *as to the cases included in the trial nomination pool, or, if final case designation has been completed, as to the cases that have been designated for trial beginning May 2, 2016*. Counsel will be required to make themselves, and their clients, available to participate, in person, in any negotiations ordered by this Court.

Plaintiffs' and Defendants' counsel will be required to file into the record a certification of settlement efforts in a form that will be provided by the Court and that will contain requirements beyond the Court's standard certification, and such certification will be governed by the requirements of Fed.R.Civ.P. 11.

August 17, 2015

**Plaintiffs' Specific Causation Expert Reports**

Plaintiffs to produce specific causation expert reports.

August 31, 2015

**Defendants' Specific Causation Expert Identification**

Defendants to identify all specific causation experts and produce background information (*See Fed.R.Civ.Pro.26(a)(1)(B)(iv-vi)*).

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<sup>4</sup> Unless agreed to by all parties or by order of this Court, deposition of Plaintiffs' experts shall occur before deposition of Defendants' experts within the same discipline.

September 8, 2015

**Defendants' Specific Causation Expert Reports**

Defendants to produce specific causation expert reports.

September 11, 2015

**Deadline for Completion of Discovery**

September 18, 2015

**Plaintiffs' Certification of Remaining Claims**

In the interest of minimizing the amount of time spent, by the parties and by this Court, in testing, briefing, considering, and ruling on the viability and effect of claims that are not expected to be tried, *Plaintiffs will be required to certify* each of the claim(s) made they intend to pursue at trial, and to dismiss those claim(s) they do not intend to present at trial.

Counsel for each of the Plaintiffs shall file into the record a Certification: (a) that he or she has reviewed each claim asserted in the Complaint (as amended, if relevant); (b) that he or she has considered the evidence available to support each and every such claim; (c) that he or she has conferred with the client(s), and (d) he or she has made a good faith effort to identify those claims that will be pursued at trial and will take prompt action to dismiss those which will not be pursued at trial. This certification shall be signed by trial counsel, lead counsel, and, where relevant, the attorney who represents the Plaintiff individually, and be governed by Fed.R.Civ.P. 11. Plaintiffs shall move to dismiss each claim originally asserted in the Plaintiffs' complaints that is not listed in the certification.

September 25, 2015

**Deadline for Submitting Requests to File Daubert Motions**

Counsel are encouraged to submit such requests earlier (and may do so piecemeal as to any issue they wish to adopt from their filing in Allen v. Takeda), as soon as they develop an intent to file a Daubert motion on any given issue as to any given expert. The Special Masters will make a recommendation on the requests for leave as soon as possible. *Within 4 calendar days of issuance of that recommendation*, any party aggrieved by it will be permitted an immediate appeal to this Court.

The parties will be required to obtain leave prior to filing any Daubert motion at this juncture. Such leave may be requested by submitting descriptions of the proposed motions (each no longer than 1 page in length) to the Special Masters identifying which of the issues already presented to the Court in Allen they wish to re-urge by adoption, identified by page, paragraph, and document number, within the document where those issues were urged. The parties shall, also, identify what, if any, issues were not addressed by

this Court in Allen or which are impacted by the application of Louisiana law, or new facts, or a change in otherwise applicable law which they wish to challenge pursuant to Daubert, Fed.R.Civ.P. 26(b)(4), or Fed.R.Evid. 702. The Special Masters will make a recommendation on the request as soon as possible. *Within 4 calendar days of issuance of the Special Masters' recommendation*, any party aggrieved by the Special Masters' recommendation will be permitted an immediate appeal to this Court.

October 2, 2015

**Deadline for Submitting Requests to File Dispositive Motions**

Counsel are encouraged to submit such requests earlier (and may do so piecemeal as to any issue they wish to adopt from their filing in Allen), as soon as they develop an intent to file a dispositive motion on any given issue. The Special Masters will make a recommendation on the requests for leave as soon as possible. *Within 4 calendar days of issuance of that recommendation*, any party aggrieved by it will be permitted an immediate appeal to this Court.

The parties will be required to obtain leave prior to filing any dispositive motion at this juncture. Such leave may be requested by submitting descriptions of the proposed motions (each no longer than 1 page in length) to the Special Masters identifying which of the issues already presented to the Court in Allen they wish to re-urge, identified by page, paragraph, and document number within the document where those issues were urged and what, if any, issues were not addressed by this Court in Allen or which are impacted by the application of Louisiana law or new facts, or a change in otherwise applicable law they now wish to address. The Special Masters will make a recommendation on the request as soon as possible. *Within 4 calendar days of issuance of the Special Masters' recommendation*, any party aggrieved by the Special Masters' recommendation will be permitted an immediate appeal to this Court.

October 16, 2015

**Deadline for Filing Daubert Motions**

The parties should have already, at this juncture, obtained leave. Such leave should have been requested as noted above.

October 23, 2015

**Deadline for Filing Dispositive Motions**

The parties should have already, at this juncture, obtained leave. Such leave should have been requested as noted above.

After dispositive motions have been filed

**Third Formal Settlement Negotiations**

*After the parties have filed dispositive motions*, Special Master Russo shall schedule a third formal settlement conference as to *the cases designated to commence trial on May 2, 2016*. Magistrate Judge Hanna will be available for mediation on any one case, or group of cases, where appropriate. Counsel will be required to make themselves, and their clients, available to participate, in person, in any negotiations ordered by this Court.

Plaintiffs' and Defendants' counsel will be required to file into the record a certification of settlement efforts in a form that will be provided by the Court and that will contain requirements beyond the Court's standard certification and such certification will be governed by the requirements of Fed.R.Civ.P. 11.

November 6, 2015

**Deadline for Filing Oppositions to Daubert Motions**

Any Daubert motion or issue re-urged by adoption from Allen should be responded to by way of adoption of the response filed in Allen, identified by paragraph, page, and document number. Thus, opposition to issues raised by adoption of arguments in Allen should be identified by reference to page, paragraph, and document number of the opposition filed as to that issue in Allen, unless the opposition is impacted by the application of Louisiana law, new facts, or a change in otherwise applicable law. Any issue raised not by way of adoption, should be responded to in the normal fashion.

November 13, 2015

**Deadline for Filing Motions for Leave to File Reply Briefs in Support of Daubert Motions<sup>5</sup>**

November 13, 2015

**Deadline for Filing Oppositions to Dispositive Motions**

Opposition to issues raised by adoption of arguments in Allen should be identified by reference to page, paragraph, and document number of the opposition filed as to that issue in Allen, unless the opposition is impacted by the application of Louisiana law or new facts, or a change in otherwise applicable law. Any issues not raised by adoption, should be responded to in the normal fashion.

November 20, 2015

**Deadline for Filing Motions for Leave to File Reply Briefs in Support of Dispositive Motions**

December 1, 2015

**Dispositive Motions Ripe for Ruling**

All dispositive motions must be fully ripe for ruling (*i.e.*, all motions, oppositions, and any allowed replies must have been filed).

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<sup>5</sup> The parties shall have 21 days following service of oppositions or reply briefs, if any, to resolve any matters concerning privilege or confidentiality pursuant to paragraph 10 of the Protective Order (*i.e.*, Case Management Order: Protecting the Confidentiality of Discovery Materials).



No later than  
January 10, 2016

**Fourth Formal Settlement Negotiations**

*On or before January 10, 2016*, Special Master Russo shall schedule a fourth settlement conference *as to the cases designated to commence trial on May 2, 2016*. Magistrate Judge Hanna will be available for mediation on any one case, or group of cases, where appropriate. Counsel will be required to make themselves, and their clients, available to participate, in person, in face to face negotiations.

Plaintiffs' and Defendants' counsel will be required to file into the record a certification of settlement efforts in a form that will be provided by the Court. That form will contain requirements beyond the Court's standard certification, and will be governed by Fed.R.Civ.P. 11.

Month of February,  
2016

**Trial Depositions**

Trial video depositions must be scheduled to occur this month, where possible.

With regard to trial video depositions, the Court intends to preside over those depositions in person and encourages the parties to schedule them, where possible, in the State of Louisiana. For those depositions that cannot be scheduled within Louisiana, the Court will make itself available to travel for that purpose, travel costs to be borne by the party noticing the depositions. The parties should be prepared to engage in full contemporaneous objections, and will receive immediate rulings on all objections that will carry over for use at trial.

**Editing Video Depositions**

Editing of video trial depositions should begin immediately. There will be no formal briefing on disputes. Instead, the parties shall succinctly identify any disputes in a manner to be identified by this Court, as will be explained by the Special Masters, and provided to this Court along with the Pre-Trial Order, if not before. Hearings on excerpt disputes will be held, in open Court, during the week of the pre-trial conference. The parties are strongly urged to reach equitable resolution of all issues, before hearings of this Court.

February 1, 2016

**Deadline for Submitting Requests to File Motions *in Limine***

Counsel are encouraged to submit such requests earlier (and may do so piecemeal as to any issue they wish to adopt from their filing in Allen), as soon as they develop an intent to file a motion *in limine* on any given issue. The Special Masters will make a recommendation on the requests as soon as possible. *Within 4 calendar days of*

*issuance of the Special Masters' recommendation*, any party aggrieved by the Special Masters' recommendation will be permitted an immediate appeal to this Court.

Such leave may be requested by submitting descriptions of the proposed motions (each no longer than 1 page in length) to the Special Masters identifying which of the issues already presented to the Court in Allen they wish to re-urge, identified by page, paragraph, and document number within the document where those issues were urged. The parties shall, also, identify what, if any, issues were not addressed by this Court in Allen or which are impacted by the application of Louisiana law, new facts, or a change in otherwise applicable law they now wish to address. The Special Masters will make a recommendation on the request as soon as possible. *Within 4 calendar days of issuance of the Special Masters' recommendation*, any party aggrieved by the Special Masters' recommendation will be permitted an immediate appeal to this Court. The parties are strongly urged to reach equitable resolution of remaining issues before hearings by this Court.

**February 18, 2016**

**Deadline for Filing Motions *in Limine***

Motions *in limine* will be addressed and ruled upon in open Court the week of the pre-trial conference. The parties are strongly encouraged to resolve any disputes before such hearings of the Court.

**March 7, 2016**

**Deadline for Filing Oppositions to Motions *in Limine***

Any motion *in limine* or issue included therein that is re-urged by adoption from Allen should be responded to by way of adoption of the response filed in Allen, identified by paragraph, page, and document number. Thus, opposition to issues raised by adoption of arguments in Allen should be identified by reference to page, paragraph, and document number of the opposition filed as to that issue in Allen, unless the opposition is impacted by the application of Louisiana law, new facts, or a change in otherwise applicable law. Any issue raised not by way of adoption, should be responded to in the normal fashion.

**March 14, 2016**

**Deadline for Filing Motions for Leave to File Reply Briefs in Support of Motions *in Limine***

**March 15, 2016**

**Plaintiffs' Inserts**

Plaintiffs shall submit to Defendants inserts for proposed pre-trial order, *voir dire*, jury interrogatories, and jury instructions.

March 18, 2016

**Defendants' Inserts**

Defendants shall submit to Plaintiffs inserts for proposed pre-trial order, *voir dire*, jury interrogatories, and jury instructions.

Before the parties submit a joint proposed Pre-Trial Order

**Final Formal Settlement Negotiations**

*Before the parties have submitted their proposed joint Pre-Trial Order*, or earlier, as deemed appropriate, Special Master Russo shall schedule a final settlement conference *as to the cases designated to commence trial on May 2, 2016*. Magistrate Judge Hanna will be available for mediation on any one case, or group of cases, where appropriate. Counsel will be required to make themselves, and their clients, available to participate, in person, in any face to face negotiations ordered by this Court.

Plaintiffs' and Defendants' counsel will be required to file into the record a certification of settlement efforts as to each case, in a form that will be provided by the Court, and will be governed by Fed.R.Civ.P. 11. That certification must include a general description of the good-faith efforts to settle and a statement of counsel's good-faith conclusion that the case will not settle, and must be signed by a member of the Plaintiff's Steering Committee, the attorney who represents the Plaintiff individually, and lead and trial counsel for the Defendants. The certification must be submitted prior to trial, **as the case will not proceed to trial without this certification.**

March 24, 2016 or earlier

**Counsel Conference**

Counsel for the parties shall confer, preferably in person, to create the Pre-Trial Order, joint jury instructions, joint jury interrogatories, proposed *voir dire* requests, and identify and discuss any possible objections to each party's final will call witness and exhibit list. Once submitted, witnesses may not be omitted from this list without good cause shown and agreement of the opposing party. No witness may be added at this late date without a showing of extreme good cause.

March 28, 2016

**Pre-Trial Order**

Deadline to file proposed joint Pre-trial Order, together with proposed *voir dire* requests, joint jury interrogatories, joint jury instructions, and final will call witness and exhibit lists.

Counsel should look to the Pre-Trial Order which governed the Allen case. However, counsel are strongly encouraged to consult with the Special Masters for guidance, instructions, and assistance in preparing the proposed Pre-Trial Order.

April 11, 2016

Pre-Trial Conference.<sup>6</sup>

April 11-15, 2016

Hearings and Rulings on Excerpts and Motions *in Limine*

In Court hearings and rulings on video deposition excerpts and any possible remaining *in limine* issues.

April 25, 2016

**Bench Books** (that have not already been provided).

**Glossary** (provided to Court Reporter).

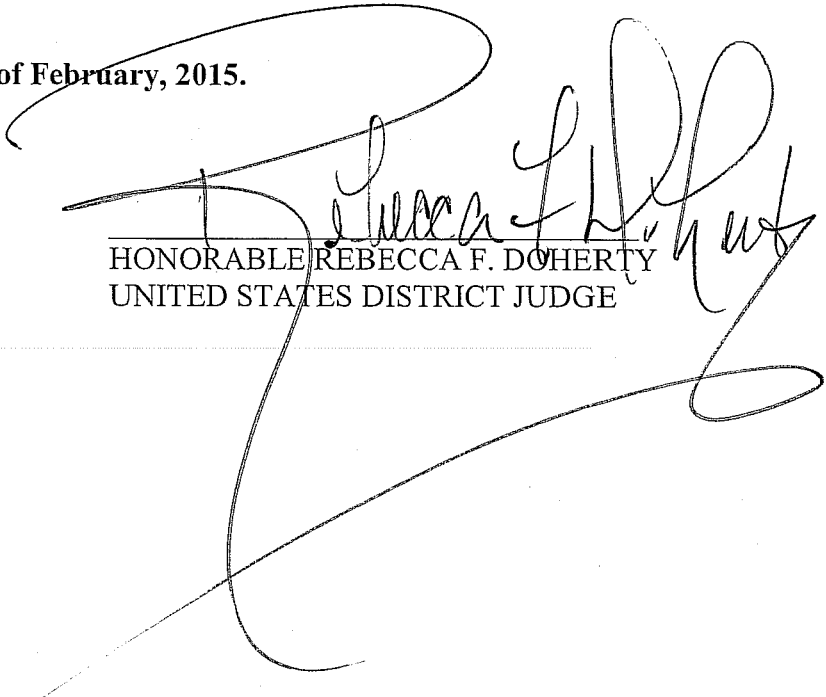
**Training for electronic courtroom.**<sup>7</sup>

May 2, 2016

**Trial**

Trial to begin and continue to completion.<sup>8</sup>

SO ORDERED, this 23 day of February, 2015.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

<sup>6</sup> This Court's pre-trial conferences are extensive and address both substantive and procedural issues at great length. Counsel should expect that the pre-trial conference will be lengthy, and make their travel plans accordingly.

<sup>7</sup> This is the deadline by which training must be completed, however counsel are encouraged to schedule such training earlier than the deadline, if possible. Counsel must bring to the training the laptops they intend to use for the presentation of exhibits at trial.

<sup>8</sup> Trial will proceed unless *all* cases set to be tried are dismissed, settled, or otherwise incapable of being tried. Settlement or dismissal of fewer than all cases will not result in a continuance of those cases remaining. Counsel should engage in trial preparation with this in mind.

~~ATTACHMENT A~~

2:11-cv-02007	6:12-cv-01608
2:12-cv-00641	6:12-cv-01641
3:11-cv-01647	6:12-cv-01647
3:11-cv-01651	6:12-cv-01648
3:11-cv-01751	6:12-cv-01649
5:12-cv-00005	6:12-cv-01650
5:12-cv-00010	6:12-cv-01651
5:12-cv-00398	6:12-cv-01652
6:11-cv-01590	6:12-cv-01683
6:11-cv-01593	6:12-cv-01685
6:11-cv-01624	6:12-cv-01696
6:11-cv-01625	6:12-cv-01701
6:11-cv-01626	6:12-cv-01803
6:11-cv-01627	6:12-cv-01953
6:11-cv-01642	6:12-cv-02144
6:11-cv-01646	6:12-cv-02575
6:11-cv-01648	6:13-cv-00240
6:11-cv-01653	6:13-cv-00325
6:11-cv-01654	6:13-cv-00614
6:11-cv-01656	6:13-cv-02020
6:11-cv-01660	6:14-cv-00321
6:11-cv-01677	6:14-cv-00726
6:11-cv-01997	6:14-cv-00794
6:12-cv-00527	6:14-cv-01040
6:12-cv-00640	6:14-cv-01042
6:12-cv-00643	6:14-cv-01055
6:12-cv-00644	6:14-cv-01569
6:12-cv-00877	6:14-cv-03291
6:12-cv-00878	
6:12-cv-00879	
6:12-cv-00981	
6:12-cv-01291	
6:12-cv-01332	
6:12-cv-01460	
6:12-cv-01600	

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone) Products Liability Litigation  
MDL No. 11-md-2299, All Cases

Date: February 20, 2015

**MINUTE ENTRY:**  
**AGENDA FOR FEBRUARY 26, 2015 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, February 26, 2015:

- I. Report on developments in the MDL since the January 22, 2015 status conference
- II. Status of federal and state court filings
- III. Discovery plan
- IV. Report on status of outstanding motions
- V. Report on status of outstanding orders
- VI. Common benefit claims process update
- VII. Report on *pro se* process
- VIII. State court update
- IX. PSC liaison update
- X. Next status conference date - April 23, 2015

RECEIVED

FEB - 5 2015 *mo*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

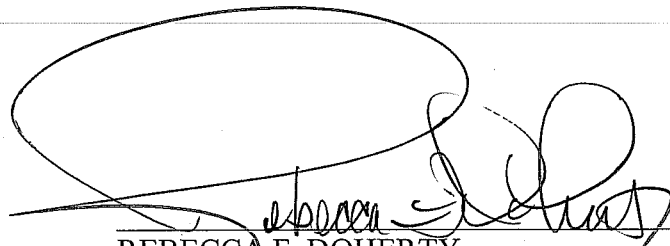
This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER**

Considering the obligations imposed on the parties by the ongoing litigation plan in these MDL proceedings, as well as this Court's calendar, this Court has determined that the monthly status conference scheduled for March 26, 2015 shall be **CANCELLED**. The meeting of the Working Group scheduled for March 25, 2015 shall continue as planned.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 5 day of February,  
2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

FEB - 6 2015

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

This Document Applies To:  
*All Cases*

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**AMENDED CASE MANAGEMENT ORDER:**  
**FACT SHEET ANALYSIS**

The Fact Sheet process having advanced substantially, this Court issues the following orders related to the use of information disclosed in the Fact Sheets to further these proceedings.

IT IS ORDERED, the **Defendants** shall provide the following particularized information, relating to each Plaintiff in the MDL, if contained in the relevant Plaintiff Fact Sheet, to the Special Masters and the Plaintiffs Steering Committee, who shall treat the information as confidential, subject to CASE MANAGEMENT ORDER: Protecting the Confidentiality of Discovery Materials (Rec. Doc. 1540). The Defendants shall produce the information in a manner and timeframe as ordered by the Court and conveyed to the Defendants by way of the Special Masters:

I. Actos User Background Information

- Name.
- Date of birth.
- Gender.
- Race.
- If applicable, date of death and cause of death as noted in the death certificate.



## II. Exposure to Actos

- The date Actos use began, and in what dose.
- The date Actos use ceased.
- Total duration of Actos use.
- Any change made to the dosage of Actos over the course of its use, including the date any change was made.
- Cumulative Actos dose at the time of diagnosis of bladder cancer.
- Whether any generic Actos alternative was used, and if so, the date(s) of use of that alternative.

## III. Medical History

- Any recurrent chronic infection or irritation of the urinary tract, and if known, the date(s) and duration of such infection or irritation.
- The date bladder cancer was diagnosed, according to a pathology report, and the type of cancer (e.g., muscular invasive or superficial).
- Any medically documented symptoms of bladder cancer occurring prior to diagnosis, and when medically noted.

## IV. Treatment

- Any treatment for bladder cancer administered (e.g., TURBT/TURP, cystectomy, BCG), including the date(s) of treatment.
- Whether the bladder cancer recurred, and if so, the date(s) of recurrence; any treatment administered in response, including the date(s) of treatment and the nature of the recurrence (e.g., muscular invasive or superficial).

## V. Risk/Causative Factors

- Smoking history, including secondhand smoke.
- Environmental exposures that the medical community agrees present a risk factor of bladder cancer (e.g., parasites, aristolochic acid), and if known, the date(s) and duration of exposure.
- Occupational exposures that the medical community agrees present a risk factor of bladder cancer (e.g., aromatic amines, arsenic), and if known, the date(s) and duration of exposure.
- Any medical history of genetic abnormality or history of hereditary predisposition presenting a risk factor for bladder cancer.
- Any other medically accepted risk factors for bladder cancer.<sup>1</sup>

IT IS FURTHER ORDERED, the **Plaintiffs' Steering Committee** shall provide the following particularized information, relating to each Plaintiff's case in the MDL, if contained in the relevant Defendant Fact Sheet, to the Special Masters in a manner and timeframe as ordered by the Court and conveyed to the Plaintiffs' Steering Committee by way of the Special Masters:

I. Actos User Background Information

- The Plaintiff's name.
- The Actos user's name (if different than the Plaintiff).
- The name of any physician who prescribed Actos to the Actos user.

II. Sales Representative Information

- The name of any Takeda or Eli Lilly sales representative who contacted a prescribing physician.

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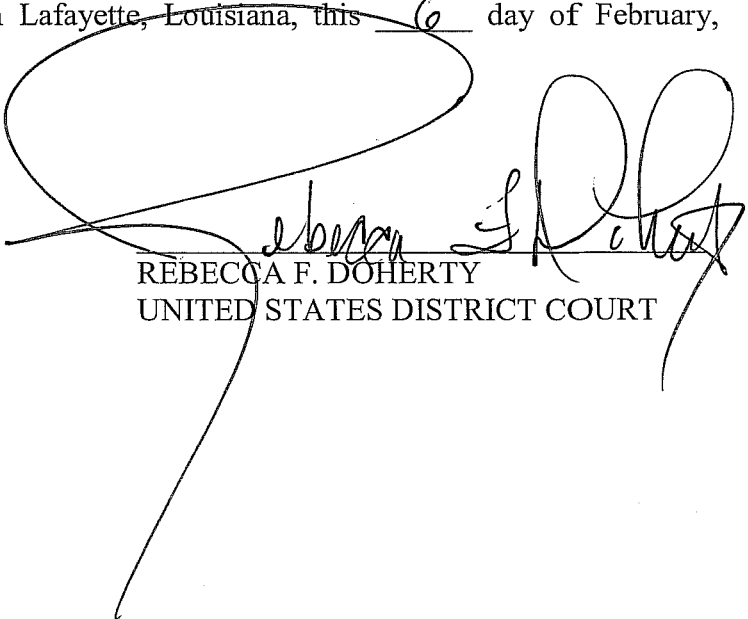
<sup>1</sup> Diabetes, while a disputed potential risk factor, need not be included in this list, as the Court assumes that every case in these MDL proceedings involves a Plaintiff or Decedent who has or had diabetes. If that assumption is incorrect as to any case in these proceedings, that fact should be noted.

- Whether the contacting sales representative was employed by a Takeda entity or Eli Lilly during the time of contact.

III. Contact with a Prescribing Physician

- Whether any “Dear Doctor” letter, or a document similar in purpose, was sent to a prescribing physician, and the date any such document was sent.
- Whether a “PIR” was received from a prescribing physician by any Takeda entity or Eli Lilly, and if so, from whom it was received and the date it was received; whether any response to a PIR was sent to a prescribing physician by a Takeda entity or Eli Lilly, and if so, the date it was sent.
- Whether any promotional material was provided to a prescribing physician by a Takeda or Eli Lilly sales representative, the nature of the material, and the date it was provided.
- Any other contact between a prescribing physician and Takeda or Eli Lilly or their sales representatives, the nature of the contact, and the date of the contact.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 6 day of February, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT COURT

RECEIVED

JAN 16 2015 *MS*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

This Document Applies To:  
*All Cases*

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**FACT SHEET ANALYSIS**

The Fact Sheet process having advanced substantially, this Court issues the following orders related to the use of information disclosed in the Fact Sheets to further these proceedings.

IT IS ORDERED, the **Defendants** shall provide the following particularized information, relating to each Plaintiff in the MDL, if contained in the relevant Plaintiff Fact Sheet, to the Special Masters in a manner and timeframe as ordered by the Court and conveyed to the Defendants by way of the Special Masters:

I. Actos User Background Information

- Name.
- Date of birth.
- Gender.
- Race.
- If applicable, date of death and cause of death as noted in the death certificate.

II. Exposure to Actos

- The date Actos use began, and in what dose.
- The date Actos use ceased.

- Total duration of Actos use.
- Any change made to the dosage of Actos over the course of its use, including the date any change was made.
- Cumulative Actos dose at the time of diagnosis of bladder cancer.
- Whether any generic Actos alternative was used, and if so, the date(s) of use of that alternative.

### III. Medical History

- Any recurrent chronic infection or irritation of the urinary tract, and if known, the date(s) and duration of such infection or irritation.
- The date bladder cancer was diagnosed, according to a pathology report, and the type of cancer (e.g., muscular invasive or superficial).
- Any medically documented symptoms of bladder cancer occurring prior to diagnosis, and when medically noted.

### IV. Treatment

- Any treatment for bladder cancer administered (e.g., TURBT/TURP, cystectomy, BCG), including the date(s) of treatment.
- Whether the bladder cancer recurred, and if so, the date(s) of recurrence; any treatment administered in response, including the date(s) of treatment and the nature of the recurrence (e.g., muscular invasive or superficial).

### V. Risk/Causative Factors

- Smoking history, including secondhand smoke.

- Environmental exposures that the medical community agrees present a risk factor of bladder cancer (e.g., parasites, aristolochic acid), and if known, the date(s) and duration of exposure.
- Occupational exposures that the medical community agrees present a risk factor of bladder cancer (e.g., aromatic amines, arsenic), and if known, the date(s) and duration of exposure.
- Any medical history of genetic abnormality or history of hereditary predisposition presenting a risk factor for bladder cancer.
- Any other medically accepted risk factors for bladder cancer.<sup>1</sup>

IT IS FURTHER ORDERED, the **Plaintiffs' Steering Committee** shall provide the following particularized information, relating to each Plaintiff's case in the MDL, if contained in the relevant Defendant Fact Sheet, to the Special Masters in a manner and timeframe as ordered by the Court and conveyed to the Plaintiffs' Steering Committee by way of the Special Masters:

I. Actos User Background Information

- The Plaintiff's name.
- The Actos user's name (if different than the Plaintiff).
- The name of any physician who prescribed Actos to the Actos user.

II. Sales Representative Information

- The name of any Takeda or Eli Lilly sales representative who contacted a prescribing physician.

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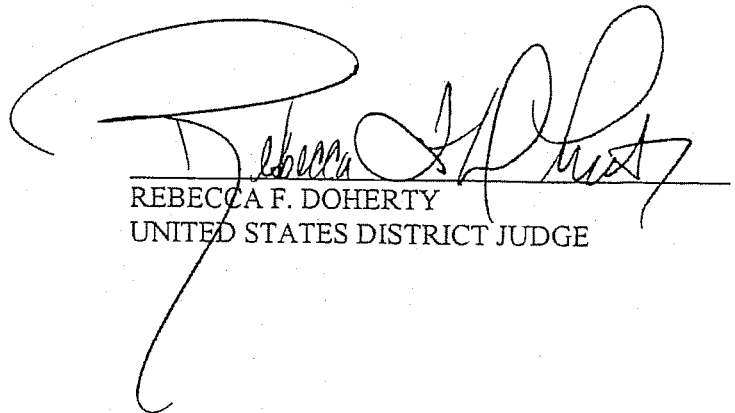
<sup>1</sup> Diabetes, while a disputed potential risk factor, need not be included in this list, as the Court assumes that every case in these MDL proceedings involves a Plaintiff or Decedent who has or had diabetes. If that assumption is incorrect as to any case in these proceedings, that fact should be noted.

- Whether the contacting sales representative was employed by a Takeda entity or Eli Lilly during the time of contact.

III. Contact with a Prescribing Physician

- Whether any “Dear Doctor” letter, or a document similar in purpose, was sent to a prescribing physician, and the date any such document was sent.
- Whether a “PIR” was received from a prescribing physician by any Takeda entity or Eli Lilly, and if so, from whom it was received and the date it was received; whether any response to a PIR was sent to a prescribing physician by a Takeda entity or Eli Lilly, and if so, the date it was sent.
- Whether any promotional material was provided to a prescribing physician by a Takeda or Eli Lilly sales representative, the nature of the material, and the date it was provided.
- Any other contact between a prescribing physician and Takeda or Eli Lilly or their sales representatives, the nature of the contact, and the date of the contact.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 16 day of January, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

JAN 16 2015

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**REPORTING ON ONGOING STATE COURT PROCEEDINGS**

The effective and efficient management of these MDL proceedings requiring that this Court and the parties remain timely apprised of the status and progress of all Actos-related proceedings, including those in State courts, this Court orders the following information to be provided as described below in the time frame as ordered below or conveyed to the parties by the Special Masters.

IT IS ORDERED, any Plaintiff's counsel who is counsel of record in these MDL proceedings and who is involved in any Actos-related State court proceeding, shall, through the Plaintiffs' Steering Committee:

- for any proceeding filed prior to the date of this Order, provide a copy of the Petition filed in the State court proceeding to the designated State Court Liaison, Dawn Barrios, this Court assuming Defense counsel representative Sherry Knutson already has notice of said Petition, **WITHIN THIRTY CALENDAR DAYS OF THE DATE OF THIS ORDER;**
- for any proceeding filed on or after the date of this Order, provide a copy of the Petition filed in the State court proceeding to the designated State Court Liaison, Dawn Barrios, **WITHIN SEVEN CALENDAR DAYS OF THE FILING OF**



**THE PETITION**, again assuming Defense counsel representative Sherry Knutson already has notice of said Petition.

IT IS FURTHER ORDERED that for any Actos-related State court proceeding filed on or after the date of this Order in which any Takeda entity or Eli Lilly is named as a Defendant, counsel for Takeda and Eli Lilly in this MDL shall provide the information noted below, **WITHIN SEVEN CALENDAR DAYS OF FILING AND/OR ENTRY OR NOTICE BEING GIVEN IN THE STATE COURT PROCEEDING**, to Dawn Barrios, the State Court Liaison (again assuming Defense counsel representative Sherry Knutson already has notice of each filing), and the Special Masters simultaneously, both of whom shall provide notice to this Court in the manner outlined and previously ordered by this Court:

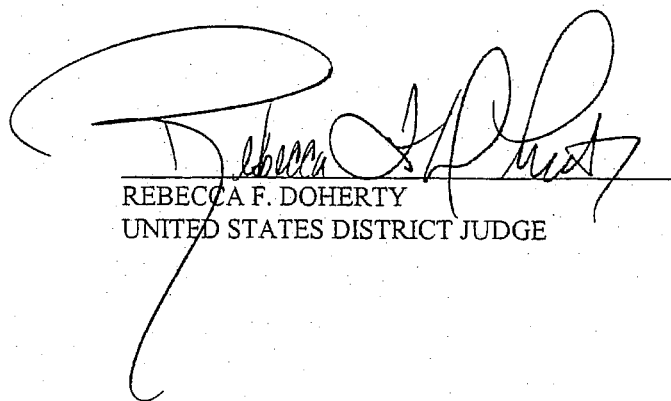
- The filing of an Actos-related suit, including in which court the suit was filed and by what counsel.
- Whether the Petition contains a claim for punitive damages.
- The filing of any dispositive motion.
- The entry of any ruling on a dispositive motion.
- The setting of a hearing for oral argument.
- The ruling, if any, made by the Court at oral argument, or thereafter.
- The dismissal and/or settlement of a suit.
- The setting of a suit for trial.
- A trial verdict and/or judgment, and a copy of the verdict form, if available.
- The filing of any post-trial motion.
- The setting of any post-trial motions for oral argument.

- The ruling, if any, made by the Court at oral argument on any post-trial motion, or thereafter.
- The entry of any ruling or judgment on a post-trial motion.
- The filing of a notice of appeal.
- The filing of an appeal.
- The resolution of an appeal, and a copy of the appellate ruling, once available.
- The filing of an application for review by a State Supreme Court, and that Court's response.
- The opinion of a State Supreme Court or applicable appellate court.

The Special Masters shall coordinate with counsel for Defendants and the Plaintiffs' Steering Committee to establish a schedule for providing the information noted above related to any Actos-related State court proceeding filed prior to the date of this Order.

Counsel are reminded this Court anticipates prompt compliance with all deadlines delineated herein, or later delineated by the Court through the Special Masters and will fully enforce those deadlines.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 16 day of January, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

JAN 16 2015 *NY*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**REPORTING ON RESOLVED STATE COURT PROCEEDINGS**

The effective and efficient management of these MDL proceedings requiring that this Court and the parties remain timely apprised of the resolution of all Actos-related proceedings, including those in State courts, this Court orders the following information to be provided as described below in the time frame as ordered by the Court below or conveyed to the parties by the Special Masters.

IT IS ORDERED that, should an Actos-related State court proceeding be resolved in any fashion, whether by trial, settlement, motion, or otherwise, the involved parties and/or Plaintiffs' and/or Defendants' counsel who are before this Court in these MDL proceedings shall provide the following information relating to the resolved proceeding to the Special Masters **WITHIN FOURTEEN CALENDAR DAYS OF ENTRY OF INITIAL JUDGMENT**. The Special Masters shall compile the information and provide it to the Court in a manner that ensures no information is disclosed that is indicative of strategy or violative of privilege.

I. Court Information

- The court before which the case proceeded.
- Plaintiffs' Counsel.
- Defendants' Counsel.
- What law applied.

## II. Resolution

- The manner of resolution.
- If resolved by dispositive motion, a copy of the ruling thereon, if available.
- If resolved by trial,
  - The type of trial (e.g., judge or jury).
  - The verdict and/or judgment, with a copy of verdict form, if available, if not already provided to the Court.
- If resolved by settlement, the amount of the settlement, if not subject to a confidentiality order.

## III. Plaintiff

- If Plaintiff is not the Actos user, Plaintiff's name.
- Relationship to the Actos user.

## IV. Actos User's Background Information

- Name.
- Date of birth.
- Gender.
- Race.
- If applicable, date of death and cause of death as noted in the death certificate.

## V. Actos User's Exposure to Actos

- The date Actos use began, and in what dose.
- The date Actos use ceased.
- Total duration of Actos use.

- Any change made to the dosage of Actos over the course of its use, including the date any change was made.
- Cumulative Actos dose at the time of diagnosis of bladder cancer.
- Whether any generic Actos alternative was used, and if so, the date(s) of use of that alternative.

#### VI. Actos User's Medical History

- Any recurrent chronic infection or irritation of the urinary tract, and if known, the date(s) and duration of such infection or irritation.
- The date bladder cancer was diagnosed, according to a pathology report, and the type of cancer (e.g., muscular invasive or superficial).
- Any medically documented symptoms of bladder cancer occurring prior to diagnosis, and when medically noted.

#### VII. Actos User's Treatment for Bladder Cancer

- Any treatment for bladder cancer administered (e.g., TURBT/TURP, cystectomy, BCG), including the date(s) of treatment.
- Whether the bladder cancer recurred, and if so, the date(s) of recurrence; any treatment administered in response, including the date(s) of treatment and the nature of the recurrence (e.g., muscular invasive or superficial).

#### VIII. Actos User's Risk/Causative Factors of Bladder Cancer

- Smoking history, including secondhand smoke.
- Environmental exposures that the medical community agrees present a risk factor of bladder cancer (e.g., parasites, aristolochic acid), and if known, the date(s) and

duration of exposure.

- Occupational exposures that the medical community agrees present a risk factor of bladder cancer (e.g., aromatic amines, arsenic), and if known, the date(s) and duration of exposure.
- Any medical history of genetic abnormality or history of hereditary predisposition presenting a risk factor for bladder cancer.
- Any other medically accepted risk factors for bladder cancer.<sup>1</sup>

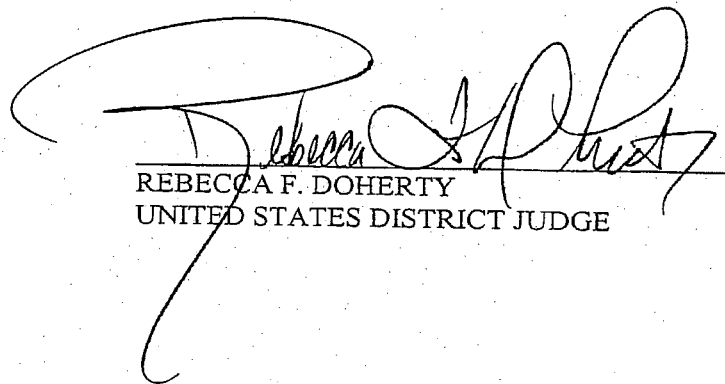
IX. Other Information

- Any other unprivileged, disclosable information counsel believes impacted the resolution of the case.

X. Appeal

- Whether an appeal, if any, is to be or has been filed.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 16 day of January, 2015.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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<sup>1</sup> Diabetes, while a disputed potential risk factor, is not included in this list, as the Court assumes that every Plaintiff or Decedent in an Actos-related proceeding has or had diabetes. If that assumption is incorrect as to any proceeding, that fact should be noted.

RECEIVED

JAN 20 2015



UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone) Products Liability Litigation  
MDL No. 11-md-2299, All Cases

Date: January 20, 2015

**MINUTE ENTRY:**  
**AGENDA FOR JANUARY 22, 2015 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, January 22, 2015:

- I. Report on developments in the MDL since the November 20, 2014 status conference
- II. Status of federal and state court filings
- III. Discovery plan
- IV. Report on status of outstanding motions
- V. Report on status of outstanding orders
- VI. Common benefit claims process update
- VII. Report on *pro se* process
- VIII. State court update
- IX. PSC liaison update
- X. Next status conference date - February 26, 2015

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NOV 17 2014



TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone) Products Liability Litigation  
MDL No. 11-md-2299, All Cases

Date: November 17, 2014

**MINUTE ENTRY:**  
**AGENDA FOR NOVEMBER 20, 2014 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, November 20, 2014:

- I. Report on developments in the MDL since the September 25, 2014 status conference
  - A. Periodic Review
- II. Status of federal and state court filings
- III. Discovery plan
  - A. Plan to be finalized in January
  - B. Most outstanding privilege disputes have been resolved
- IV. Report on status of outstanding motions
- V. Report on status of outstanding orders
- VI. Common benefit claims process update
- VII. Report on *pro se* process
- VIII. State court update
- IX. PSC liaison update
- X. Next status conference date - January 22, 2015



RECEIVED

OCT 21 2014 

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER**

Considering the present posture of this matter and this Court's trial calendar, this Court has determined that the Working Group meeting and monthly status conference scheduled for the week of December 15, 2014 shall be **CANCELLED**.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 21 day of October, 2014.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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OCT -2 2014

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

MONTHLY STATUS CONFERENCE DATES FOR 2015

This Court will conduct Status Conferences on the following dates for the 2015 calendar year:

- January 22, 2015
- February 26, 2015
- March 26, 2015
- April 23, 2015
- May 21, 2015
- June 25, 2015
- July 23, 2015
- August 20, 2015
- September 24, 2015
- October 22, 2015
- November 19, 2015
- December 17, 2015

Status Conferences will be held in open court beginning at 10:30 a.m. On the day before each Status Conference, this Court will conduct a pre-conference Working Group meeting at 2:00 p.m., unless notice otherwise is issued.

Defendants' and Plaintiffs' lead and co-lead counsel and the Plaintiffs' Steering Committee members are asked to anticipate their participation in each Status Conference.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 2 day of October, 2014.

COPY SENT

DATE 10-2-14

BY CS

TO CO | RJH | JGA

REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

cb OCT - 2 2014

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

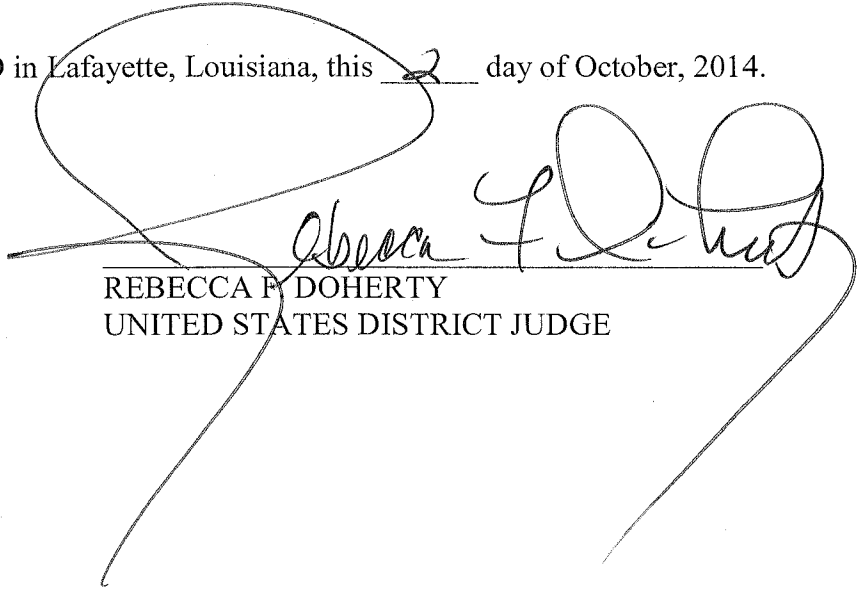
This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER:**  
**OCTOBER 2014 STATUS CONFERENCE**

Considering the present posture of this matter, this Court has determined that the Working Group meeting and Monthly Status Conference scheduled for October 22-23, 2014 shall be **CANCELLED**. All counsel are reminded that the Periodic Review will be conducted on November 19, 2014.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 2 day of October, 2014.



REBECCA P. DOHERTY  
UNITED STATES DISTRICT JUDGE

COPY SENT  
DATE 10-3-14  
BY CS  
TO cb/RJA/efc

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone) Products Liability Litigation  
MDL No. 11-md-2299, All Cases

Date: September 30, 2014

**MINUTE ENTRY:  
NOVEMBER 2014 PERIODIC REVIEW DATES & DEADLINES**

Pursuant to the Case Management Order: Periodic Review Process issued by this Court, this Minute Entry sets out the dates, times, deadlines, and procedural information that will govern the November 2014 Periodic Review:

**Dates & Times:**

The date of the in-person Review Session with Defendants' Lead Counsel and the PSC's Executive Committee will be **Wednesday, November 19, 2014 at 2:00 pm**. The Review Session will follow a meeting of the Working Group which will begin at 10:00 am on the same day. A monthly Status Conference will be held the following day, Thursday, November 20, 2014 at 10:30 am.

**Deadlines:**

All comments by MDL attorneys are due no later than **Monday, November 3, 2014 at 12:00 pm**.

The PSC's Executive Committee Report is due no later than **Monday, November 3, 2014 at 12:00 pm**.

**Procedural Information:**

The PSC Executive Committee Report, as well as comments regarding the administration of these MDL proceedings, shall be addressed to Special Master Russo and shall be sent via email with a request for delivery confirmation to: **grusso@joneswalker.com**.


Comments regarding the PSC shall be addressed to Deputy Special Master DeJean and shall be sent via email with a request for delivery confirmation to: **kwdejean@kwdejean.com**.

Comments regarding the Special Masters shall be addressed to this Court and shall be sent via email with a request for delivery confirmation to: **Hanna\_MDL\_orders@lawd.uscourts.gov**.

The next Periodic Review will be held approximately one year from the date of the November Periodic Review.

RECEIVED

SEP 16 2014



TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone) Products Liability Litigation  
MDL No. 11-md-2299, All Cases

Date: September 16, 2014

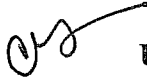
**MINUTE ENTRY:**  
**AGENDA FOR SEPTEMBER 25, 2014 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, September 25, 2014:

- I. Report on developments in the MDL since the August 21, 2014 status conference
- II. Status of federal and state court filings
- III. Discovery plan
- IV. Report on status of outstanding motions
- V. Report on status of outstanding orders
- VI. Common benefit claims process update
- VII. Report on *pro se* process
- VIII. State court update
- IX. PSC liaison update
- X. Next status conference date - October 23, 2014

RECEIVED

AUG 18 2014



UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone) Products Liability Litigation  
MDL No. 11-md-2299, All Cases

Date: August 18, 2014

**MINUTE ENTRY:**  
**AGENDA FOR AUGUST 21, 2014 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, August 21, 2014:

- I. Report on developments in the MDL since the June 19, 2014 status conference
- II. Status of federal and state court filings
- III. Discovery plan
- IV. Report on status of outstanding motions
- V. Report on status of outstanding orders
- VI. Common benefit claims process update
- VII. Report on *pro se* process
- VIII. State court update
- IX. PSC liaison update
- X. Next status conference date - September 25, 2014

RECEIVED

JUL - 2 2014



TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE)

MDL NO. 6:11-md-02299

This document applies to:

JUDGE DOHERTY

Case Nos: 14-1149, 14-1151, 14-1152,  
14-1154, 14-1155, 14-1156, 14-1157,  
14-1158, 14-1159, 14-1160, 14-1161

MAGISTRATE JUDGE HANNA

BCBSMA CASE MANAGEMENT ORDER

The plaintiffs, Blue Cross and Blue Shield of Massachusetts, Inc. and its subsidiary, Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc., (collectively BCBSMA) have directly filed the following eleven bundled complaints in this MDL:

14-cv-1149	14-cv-1157
14-cv-1151	14-cv-1158
14-cv-1152	14-cv-1159
14-cv-1154	14-cv-1160
14-cv-1155	14-cv-1161
14-cv-1156	

These complaints are brought by BCBSMA entities. Given the nature of the complaints, this Court in the management of its docket, enters the following orders that are applicable to these specific cases until further order of this Court:

IT IS ORDERED that any motions or pleadings that are intended to be applicable to any or all of these cases shall be so designated in the caption filed in case number 11-md-2299.

IT IS FURTHER ORDERED that all counsel are to direct any filings intended to be

applicable to these cases by way of the spread text function in CM/ECF. Counsel are NOT to spread text any filings to all of the member cases as that function is performed solely by the Clerk of Court personnel. BCBSMA shall direct ALL persons involved in filing documents in this MDL to undergo the training provided by the Clerk of Court for the operation of the spread text function in CM/ECF.

IT IS FURTHER ORDERED that, until further order of this Court, these cases shall remain bundled.

IT IS FURTHER ORDERED that only lead counsel for BCBSMA shall be served with Notice of Electronic Filings by the Court as well as documents filed by the other parties. Lead counsel for BCBSMA shall serve liaison counsel for the Plaintiff's Steering Committee, Patrick C. Morrow, electronically at [actosliason@mmrblaw.com](mailto:actosliason@mmrblaw.com), and the defendants' counsel, Dlesli Davis, electronically at [Dlesli.davis@nortonrosefulbright.com](mailto:Dlesli.davis@nortonrosefulbright.com), with any documents required to be served after summons and service have been accomplished on the defendants. Designated counsel for the defendants shall be responsible for service to all of its co-counsel. Lead counsel for BCBSMA shall be responsible for service to all of its co-counsel. Lead counsel for BCBSMA is to provide the Clerk of Court, liaison counsel for the Plaintiffs' Steering Committee and lead counsel for the defendants with current contact information for electronic service.

Thus done and signed this 2 day of July, 2014 at Lafayette, La.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE



UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE)

MDL NO. 6:11-md-02299

This document applies to:

JUDGE DOHERTY

Case nos: 14-1149, 14-11151,  
14-1152, 14-1154, 14-1155  
14-1156, 14-1157, 14-1158,  
14-1159, 14-1160 and 14-1161

MAGISTRATE JUDGE HANNA

**BCBSMA CASE MANAGMENT ORDER 2**

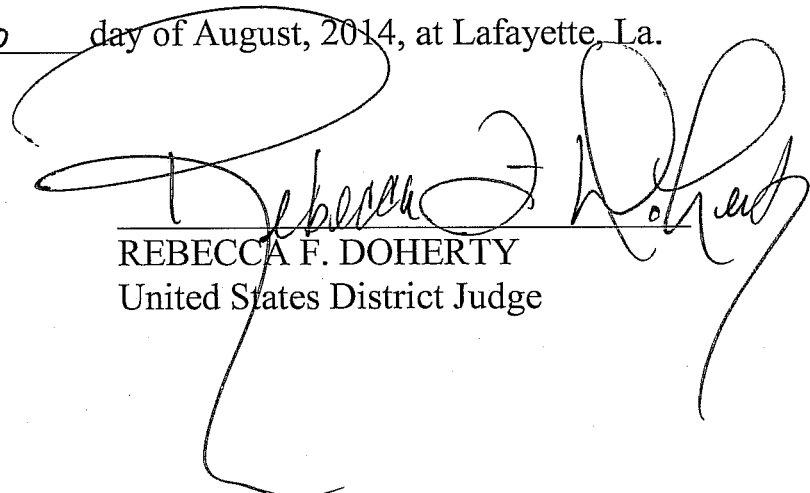
In order to provide for the efficient administration of the Court's docket and address concerns raised over compliance with the privacy requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), this Court enters the following orders that will apply to all cases brought by Plaintiffs, Blue Cross and Blue Shield of Massachusetts, Inc. and its subsidiary, Blue Cross and Blue Shield of Massachusetts HMO Blue, Inc. (collectively BCBSMA) in this MDL, whether pending now or brought in the future.

IT IS ORDERED that BCBSMA will communicate with the Court through its designated PSC member for the State of Massachusetts in accordance with the guidance provisions of this Court's Minute Entry: Communicating with the Court, of April 13, 2012.

IT IS FURTHER ORDERED that BCBSMA shall provide to Magistrate Judge Hanna in a single document that is NOT to be filed into the record at this juncture, the names of all of the members, with their corresponding member numbers, the state in which they reside, and the identity of any pending litigation in any jurisdiction which the member may have brought on his or her own behalf to recover damages arising out of the alleged use of Actos in order to provide a means to accomplish effective administration of the cases through the Court's docketing system.

IT IS FURTHER ORDERED that the Defendants who have been served are granted an extension of time to file any responsive pleadings of 120 days from the date of service without BCBSMA cases being subject to dismissal pursuant to LR 41.3.

Signed this 6 day of August, 2014, at Lafayette, La.

A large, stylized handwritten signature in black ink, appearing to read 'Rebecca F. Doherty', is written over a horizontal line. The signature is highly cursive and loops around the line.

REBECCA F. DOHERTY  
United States District Judge

RECEIVED

JUN 18 2014

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE  
PRODUCTS LIABILITY LITIGATION)

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

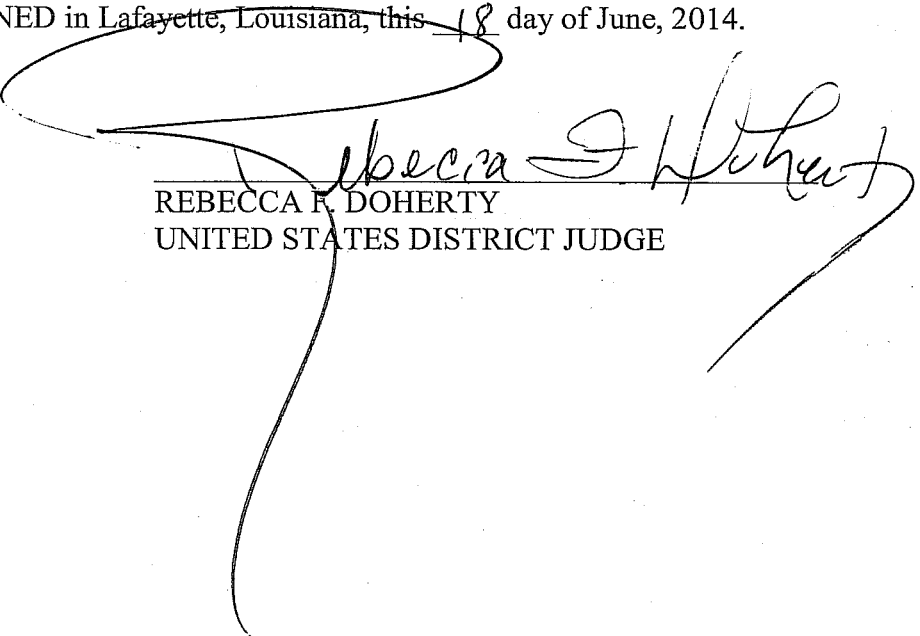
MAGISTRATE JUDGE HANNA

**ORDER:**  
**JULY, 2014 STATUS CONFERENCE**

Considering the current status of filings and the motions that are expected to be filed shortly,

IT IS HEREBY ORDERED the Monthly Status Conference scheduled for July 24, 2014 is **CANCELLED**.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 18 day of June, 2014.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

JUN 13 2014



UNITED STATES DISTRICT COURT

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

WESTERN DISTRICT OF LOUISIANA

LAFAYETTE DIVISION

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: June 13, 2014

**MINUTE ENTRY:**  
**AGENDA FOR JUNE 19, 2014 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, June 19, 2014:

- I. Report on developments in the MDL since the December 11, 2013 status conference
- II. Status of federal and state court filings
- III. Discovery Plan
- IV. Bellwether trials update – Judge Doherty to address
- V. Report on status of outstanding motions
- VI. Report on status of outstanding orders
- VII. Common benefit claims process update
- VIII. Report on *pro se* process - Magistrate Judge Hanna and Mr. Singleton (prisoner litigation)
- IX. State court update
- X. PSC liaison update
- XI. Next status conference date

RECEIVED

JUN 11 2014

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS® (PIOGLITAZONE  
PRODUCTS LIABILITY LITIGATION)

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:

*All Cases*

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**SECOND PERIODIC REVIEW**

Pursuant to the Case Management Order: Plaintiffs' Steering Committee [Rec. Doc. 560] issued by this Court on April 13, 2012, wherein this Court reserved the right to "determine whether the membership of the Plaintiffs' Steering Committee ("PSC") should remain in place or should be adjusted to allow better, or more efficient, performance of the duties assigned herein . . .," the Second Periodic Review will take place over the next two months and will culminate in this Court meeting with lead counsel for the defense and with the PSC Executive Committee *on the afternoon of Wednesday, August 20<sup>th</sup>, 2014 beginning at 2:00 p.m.*

**I. Scope**

This Order will govern the procedures affording MDL attorneys a mechanism to present any concerns, comments, or suggestions they might have about the administration of this MDL, the PSC, or the Special Masters.

**II. Comment by MDL Attorneys**

Any MDL attorney who wishes to communicate any comments, concerns, or suggestions concerning the PSC, the administration of this MDL, or any aspect of the Special Masters' appointment and functioning in these proceedings must do so *in writing*. All writings shall be

*submitted no later than August 1, 2014.* Written responses to this Order shall be submitted as follows:

- Where the subject matter of concern is the PSC, an attorney comment must be submitted to Deputy Special Master DeJean. Such comments shall be sent via email with a request for delivery confirmation to: **kwdejean@kwdejean.com**.
- Where the subject matter of concern is the administration of these MDL proceedings, an attorney comment must be submitted to Special Master Russo. Such comments shall be sent via email with a request for delivery confirmation to: **grusso@joneswalker.com**.
- Where the subject matter of concern is the Special Masters, an attorney comment must be submitted directly to this Court. Such comments shall be sent via email with a request for delivery confirmation to: **Hanna\_MDL\_orders@lawd.uscourts.gov**.

Special Master Russo and Deputy Special Master DeJean will remove from any comments submitted to them anything that has the potential to adversely affect the impartiality of the Court. Once this process has been completed, both Deputy Special Master DeJean and Special Master Russo will present all comments to the Court for review. At that time, this Court will review the written comments and thereafter, address any issues or concerns that need to be addressed.

### **III. PSC Executive Committee Report**

The Executive Committee of the PSC will prepare a PSC Executive Committee Report (“Report”) that will be submitted to this Court through Special Master Russo addressing the following particulars: (a) outlining workflow (*i.e.*, how much work is allocated to the PSC, how much work is being completed by attorneys outside the PSC, etc.); (b) discussing the cohesiveness of the PSC membership; (c) addressing the PSC’s efficiency in steering the MDL; and (d) any concerns that the Executive Committee has regarding any issue related to the administration of these proceedings. All information in this Report is to be prepared generally so as to **not** convey substantive or strategic information about the case. The Report submitted by

the Executive Committee in response to this Court's request during the first periodic review contained precisely the type of information that should be included once again.

This Report shall be submitted to Special Master Russo *no later than Monday, August 4, 2014*.

#### **IV. In-Person Review Sessions**

This Court and Magistrate Judge Hanna, on August 20, 2014, shall hold closed discussion sessions individually, with the Defendants' Lead Counsel, and thereafter the PSC's Executive Committee. ("Review Session")

##### **A. Structure**

The Court will meet with counsel from each side individually and hold frank, closed-door conversations to evaluate the administrative elements of this MDL. The Court will begin the breakout sessions with the Defendants' Lead Counsel, and finish with the PSC's Executive Committee.

##### **B. Time**

The Review Session will last as long as necessary to allow counsel to discuss freely any concerns, comments, or suggestions they may have regarding the level of this Court's involvement in day-to-day management of these proceedings, the Special Masters' functioning, the PSC's structure and membership, the Defendants' Lead Counsel, and interaction with the Court.

##### **C. Tone**

The Review Session is intended to be an open session where counsel can freely and candidly discuss with the Court and Magistrate Judge Hanna any concerns, suggestions, or comments they may have regarding the MDL and its administration.

**D. Substance**

Any administrative concerns counsel wish to discuss with the Court shall be discussed in the Review Session. However, counsel are cautioned and warned that only discussions on **administrative matters** will be allowed. Any reference to, or substantive discussion of, any substantive matter will not be allowed, and will be vigorously addressed by the Court. The process will be conducted with the utmost fairness to both the Defendants and the Plaintiffs.

**CONFIDENTIALITY:** All materials submitted in accordance with this Order are for the **exclusive use** of this Court and shall not be seen by any other party. Once the Review Process is complete, all information will be shredded and disposed of.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 11<sup>th</sup> day of June, 2014.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE



**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA**

IN RE ACTOS® (PIOGLITAZONE  
PRODUCTS LIABILITY LITIGATION)

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER REGARDING SPECIAL MASTERS<sup>1</sup>**

The parties having had notice that the Court was considering the appointment of special masters in this matter, and having had an opportunity to be heard and make suggestions and objections concerning the naming of the special masters; with the advice and consent of the parties, the Court has APPOINTED:

- Gary J. Russo as Special Master, with overall responsibility for the case management duties described below;
- Kenneth W. DeJean as Deputy Special Master, with responsibility solely for management and oversight of matters related to the Plaintiffs' Steering Committee, especially the assignment of duties and tasks that inure to the common benefit of all plaintiffs, making adjudicative reports and recommendations to Special Master Russo for approval of claims for those attorneys seeking credit for costs incurred and work performed for the common benefit of all plaintiffs, submitting periodic reports to the Court of the status of his efforts, assisting the Court in the distribution of fees and reimbursement of costs (if any), and performing such other duties as might be requested of him by the Court or by the Special Master; and
- Carmen M. Rodriguez, as Deputy Special Master, with primary responsibility for matters related to the law and legal analysis, especially considering contested motions and issuing

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<sup>1</sup> In an effort to clarify and simplify this Court's findings regarding the rules and conditions that apply to the Special Masters' appointments, the instant Order Regarding Special Masters replaces and supercedes the following orders previously issued in this matter: Order Appointing Special Masters [Doc. 532], Case Management Order: Joint Expenses [Doc. 1906], Case Management Order: Special Master Fees and Costs [Doc. 1907], Case Management Order: Deputy Special Master DeJean's Fees and Costs [Doc. 2072], Amended Case Management Orders: Order Appointing Special Masters, Special Master Fees and Costs, and Deputy Special Master DeJean's Fees and Costs [Doc. 3089], and Supplemental Case Management Order: Joint Expenses [Doc. 3369]. The only substantive change made by this Order is the explicit recognition that the Special Masters are authorized to obtain assistance from attorneys, paralegals, and staff within their firms in order to complete the tasks assigned the Special Masters in this Order and otherwise.

reports and recommendations on same, as well as drafting orders and minute entries as might be requested by the Court, together with responsibility for any and all matters delegated by Special Master Russo.

These appointments were made pursuant to Fed. R. Civ. P. 53 and the inherent authority of the Court. The Special Masters' duties, and terms of their service, along with the reasons for their appointment are set forth below.

### **BACKGROUND**

This Court was appointed as the transferee court in these proceedings on December 29, 2011. At the time that the Special Masters were originally appointed, this Court had received over 200 transferred cases and a number of cases had been filed directly in the Western District of Louisiana. This Court had been informed by counsel that the number of claims which could be expected to be joined in these proceedings was in the thousands. History has proven those predictions correct, as there currently are more than 3,000 cases pending in, or related to, these proceedings. In addition to its size, this MDL presents many difficult issues, including international involvement. It has required – and will continue to require – a substantial amount of attention and oversight from the Court.

Other MDL courts, facing similar challenges, have easily concluded that the appointment of Special Masters was appropriate to help the Court with various pretrial, trial, and post-trial tasks. Indeed, the appointment of a Special Master or Masters in cases such as this is common. As this Court has continued to carry a full docket of civil cases, and with the benefit of other Courts' experience, this Court concluded that it was necessary to appoint three individuals, each to assist the Court with select aspects of case management. Collectively, the Special Masters' areas of responsibility cover all aspects of case management, including the claims process, discovery, experts, legal issues, contested motions, bellwether trials, settlement efforts, etc. The 2003 amendments to Rule 53 specifically recognize the pretrial, trial, and post-trial functions of

masters in contemporary litigation. Thus, the Court has concluded it is necessary to appoint Special Masters to assist the Court in both effectively and expeditiously moving these disputes toward their final resolution or remand to the transferor courts.

The appointment of the Special Masters has been extraordinarily helpful to this Court and to the parties, yielding palpable benefits and significant cost savings. For instance, the Special Masters' management of discovery and other pre-trial issues, together with their role as liaison between the Court and counsel, has led to the successful resolution of a plethora of disputes informally, such that only two formal discovery motions were filed during the entire discovery and pre-trial period that preceded the first bellwether trial. Furthermore – as counsel and the parties are aware – this Court made an early decision to use an innovative and creative approach of party involvement to this litigation, using certain traditional and time-tested procedures, while also remaining committed to considering innovative alternatives, and testing and modifying assumptions and choices against the reality of those choices and assumptions while evaluating the best way to accomplish the statutory goal of promoting the just and efficient conduct of these proceedings.<sup>2</sup> This Court (and these proceedings) have benefitted greatly from both the willing and professional participation of counsel in this creative process, and the presence and work of the Special Masters, who have provided invaluable oversight, guidance, and instruction to counsel, and who, also, have consulted with the Court to provide valuable feedback on those innovations. This feedback has allowed for real-time adjustments when procedural innovations have proven not to be beneficial.

Because the early appointment of Special Masters was one of the innovations selected, this Court established a Periodic Review Process initiated in January, 2013, to evaluate the Special Masters' performance and validity, as well as their evolving role in this litigation. This

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<sup>2</sup> 28 U.S.C. § 1407.

Court elicited reports and evaluations from counsel, and also conducted in-person interviews with counsel for both parties, at length and outside the presence of the Special Masters. Details of that review remain confidential. However, generally, counsel provided glowing reports about the Special Masters and the benefits they have brought and bring to this large and complex litigation.

During the course of these meetings, it has become and remains abundantly clear the Special Masters are and will remain invaluable to the efficient progress of this litigation and their efforts have and continue to yield benefits, not the least of which is illustrated by the amicable resolution of almost all discovery disputes and related issues, and the bare minimum of formal discovery motions filed to date. Furthermore, the parties agree, the guidance provided to counsel to assist in progressing toward and during the first pilot bellwether trial was of significant value and has and continues to result in significant cost savings to the parties. Additionally, the forewarning provided to this Court as to issues and disputes that can be expected to arise, and, thus, can be addressed and resolved early, has been and continued to be of great value to this Court and the parties. Thus, this Court's actual experience over the 24 months since the Special Masters were appointed reinforces the positive information and responses received from counsel during the Periodic Review Process.

In short, this Court's conclusion – based on its own insight, comparison of statistics in these proceedings with other multi-district proceedings of comparable size, and feedback received from counsel – is that the early appointment of the Special Masters early in these proceedings has been an important, successful innovation that has benefitted the parties, this Court, and the efficient operation of justice, and has resulted in significant savings in time and money to the parties. Now that the first bellwether trial has been completed and these proceedings are moving into the next phase of litigation, this Court fully expects this trend to

continue and these proceedings (together with this Court and the parties) to continue benefitting from the assistance provided by the capable Special Masters.

## **I. Masters' Duties**

The Special Masters will generally be assigned to (1) assist the Court with managing the litigation, including the claims process, discovery, experts, legal analysis, settlement efforts, communication with counsel, and any and all pretrial and post-trial matters that cannot be addressed effectively and timely by an available district judge or magistrate judge of the district, as well as (2) perform any and all other duties assigned to them by the Court (as well as any ancillary acts required to carry out those duties) as permitted by both the Federal Rules of Civil Procedure and Article III of the Constitution. However, the Court retains sole authority to issue final rulings on all decisions made by the Special Masters, specifically including all matters formally submitted for adjudication.

This Court has reviewed recent legal authority addressing the duties of a Special Master that are permitted under the Federal Rules of Civil Procedure and Article III of the Constitution. Consonant with the foregoing findings and these general parameters, the currently-anticipated needs of the court, and the parties' consent, the Special Masters in these proceedings shall have the authority to:

- A. assist the court with preparation for attorney conferences (including formulating agendas), court scheduling, and negotiating changes to orders of this Court;
- B. supervise discovery, establish discovery and schedules, and review and attempt to resolve informally any and all discovery conflicts;
- C. oversee management of docketing, including the identification and processing of matters requiring court rulings;
- D. compile data and assist with, or make findings and recommendations with regard to, interpretation of scientific and technical evidence;

- E. assist with legal analysis of the parties' motions or other submissions, whether made before, during, after, or in place of, trials, hearings, or oral argument, and make recommended findings of fact and conclusions of law;
- F. assist with responses to media inquiries;
- G. help to coordinate federal, state and international aspects of this litigation;
- H. direct, supervise, monitor, and report upon implementation and compliance with this Court's orders, and make findings and recommendations on remedial action if required;
- I. interpret any agreements reached by the parties, and require clarification of same, if necessary;
- J. propose structures and strategies for settlement negotiations on the merits, and on any subsidiary issues, and evaluate parties' class and individual claims, as may become necessary;
- K. propose structures and strategies for attorney fee issues and fee settlement negotiations, review fee and cost applications, and evaluate counsel's individual claims for fees, as may become necessary;
- L. administer, allocate, and distribute funds and other relief, if necessary;
- M. adjudicate eligibility and entitlement to funds and other relief, if necessary;
- N. monitor compliance with structural injunctions, if necessary;
- O. make formal or informal recommendations and reports to the parties, and make recommendations and reports to the Court, regarding any matter pertinent to these proceedings; and
- P. communicate with parties and attorneys as needs arise in order to permit the full and efficient performance of these duties.

The Court shall retain sole authority to issue final rulings on matters formally submitted for adjudication, unless otherwise agreed by the parties, and subject to waiver of objection to written orders or recommendations.

The Special Masters may, at their discretion, obtain assistance from personnel within their firms (including lawyers, paralegals, and clerical staff) to facilitate the timely execution of the above duties, or any other duty or task assigned to the Special Masters by the Court.

## **II. Communication with the Parties and the Court**

The Special Masters may communicate *ex parte* with the Court at their discretion, without providing notice to the parties, as necessary, in order to fulfill their duties. Moreover, the Special Masters may communicate *ex parte* with any party or attorney, as the Special Masters deem appropriate, for the purpose of ensuring the efficient administration and management of these proceedings. However, the Special Masters may not engage in *ex parte* communications with any party or attorney concerning any substantive legal issue filed and pending before the Court.

## **III. Masters' Record**

The Special Masters shall maintain normal billing records of their time, as well as time spent on this matter by personnel within their firms, with reasonably detailed descriptions of their activities and matters worked upon. With regard to any contested motion, or upon any other special request by the Court, the Special Masters shall (i) submit such report or recommendation to the Court in writing, as well as (ii) filing such report and recommendation into the record electronically. The Special Masters shall preserve for the record any document received from counsel or parties to this case that are not docketed in this or another court, but need not preserve for the record any document (whether created by a Special Master or anyone else) that is docketed in this or any other court.

## **IV. Review of the Special Masters' Orders**

The Special Masters shall either: (1) reduce any formal order, finding, report, or recommendation to writing and file it electronically via Electronic Case Filing ("ECF"); or (2) issue any formal order, finding, report, or recommendation on the record, before a court reporter. When making a report and recommendation to this Court, the Special Master and/or Deputy Special Masters shall submit to the Court a proposed order adopting the report and

recommendation. Any party may file an objection to an order, instruction, finding, report, or recommendation by a Special Master within *14 calendar days* of the date it was electronically filed, within *14 calendar days* of the time the order or instruction was issued, or within the time frame authorized by Fed. R. Civ. P. 6(d). **The failure to meet this deadline or to timely request an extension of the deadline shall result in permanent waiver of any objection to a Special Masters' orders, instructions, findings, reports, or recommendations.**

**A. Recommended Conclusions of Law**

The Court shall decide *de novo* all objections to conclusions of law made or recommended by a Special Master.

**B. Procedural Rulings**

The Court shall set aside a ruling by a Special Master on a procedural matter only for an abuse of discretion.

**C. Recommended Factual Findings**

To the extent a Special Master enters an order, finding, report, or recommendation regarding an issue of fact, the Court shall review such issue *de novo*.

**V. Compensation**

The Special Masters shall be compensated at the following rates:

- \$425 per hour for the Special Masters' services;
- \$275 per hour for service provided by firm partners;
- \$200 per hour for service provided by firm associates;
- \$95 per hour for paralegal services.

With regard to the services provided by, or at the behest of, Deputy Special Master DeJean, the Plaintiffs shall bear the cost of his fees and expenses unless agreed or ordered otherwise. With regard to all other fees and expenses incurred by the Special Masters, the parties



shall bear this cost equally (50% by the Plaintiffs and 50% by the Defendants). The Special Masters shall incur only such fees and expenses as may be reasonably necessary to fulfill their duties under this Order, or such other orders as the Court may issue.

The Special Masters in this case are excused from the obligation of providing detailed descriptions of their activities, and the activities of other personnel in their firms, in their billing statements. This unusual provision is necessary and appropriate because: (a) the Special Masters have been granted express authority to participate in *ex parte* contact with counsel for all parties in these proceedings; (b) this Court and all parties are aware that, in the months since the Special Masters have been appointed, counsel have freely exercised their right to engage in *ex parte* contact with the Special Masters; (c) the parties and the Special Masters agree these *ex parte* exchanges have been extremely helpful to the Special Masters' ability to assist the parties and this Court in managing these proceedings much more efficiently than would have been the case without them; and (d) this Court wishes to ensure that the Special Masters' records (including their billing records) are not used by any party or counsel to render non-confidential that which was discussed with a well-founded expectation of confidentiality.

Because a complete description of the Special Masters' activities has the potential to render public confidential communications between the Special Masters and the Court or between the Special Masters and counsel or parties, the Special Masters are instructed to maintain their records of billing statements that reflect normal, reasonably-detailed descriptions of their activities and do not contain any authorized *ex parte* information unless notified to the contrary by the Court to address specific issues.

## **VI. Payment of Special Masters' Fees**

### **A. Joint Expenses**

As instructed by this Court, Special Master Russo has opened a checking account (named "In re Actos (Pioglitazone) Products Liability Litigation Joint Expenses Account") in Mid-South Bank, NA, whose home office is in Lafayette, Louisiana (the "Joint Expense Account"), for the purpose of serving as holder of funds collected from the parties until such time as funds are disbursed. Additionally, Special Master Russo has engaged the accounting firm of Arsement, Redd, and Morella, LLC for the purpose of auditing and administering the Joint Expense Account pursuant to the terms of this Order. Funds in the Joint Expense Account will be used to pay Special Masters' fees and costs, banking fees, and accounting fees, with full and transparent notice given by the Court and/or the Special Masters.

The Plaintiffs and Defendants are instructed to make quarterly deposits into the Joint Expense Account in the amount of \$200,000 each. These deposits are due to be paid no later than 15 days after each quarter has ended. This schedule shall remain in place until further notice. The deposit amount will be adjusted (either increased or decreased) as necessary.

Should the Defendants and Plaintiffs, by way of co-lead counsel or their designee, wish to use the Joint Expense Account to fund joint expenses such as a court reporting firm hired on behalf of all parties in the case, or for any other expenses incurred jointly, they should jointly draft an agreed amendment to this Order for signature by the Court, prior to submission of funds to cover such expenses.

At the end of these proceedings, any funds remaining in the Joint Expense Account shall be returned, 50% to the Plaintiffs and 50% to the Defendants.

## **B. Special Masters' Requests for Distribution of Funds**

The Special Masters shall submit monthly statements, dated no later than 30 days after the end of each month, reflecting the time they have expended fulfilling their duties (in one-tenth hour increments), together with out-of-pocket expenses they have incurred.

## **C. Distribution of Funds**

Funds in the Joint Expense Account shall be distributed in accordance with the following procedures:

- The Special Masters Requests for Distribution of Funds shall be submitted to Magistrate Judge Hanna. For any Request submitted by Special Master Russo and Deputy Special Master Rodriguez, a copy shall be provided to Lead Counsel for both parties. If the Request is submitted by Deputy Special Master DeJean, a copy shall be provided only to Co-Lead Counsel for the Plaintiffs. The Request shall be accompanied by a billing statement that contains brief summaries of their daily activities, together with a recap of the fees and expenses reflected in the billing statement.
- Magistrate Judge Hanna shall review the itemized billing statements *in camera* for the purpose of determining the reasonableness of the Special Masters' fees and costs. The itemized statements shall not be made available to the public or counsel, other than Lead Counsel, except as expressly ordered by this Court.
- The parties shall have seven (7) days to file objections with Magistrate Judge Hanna to any Request for Distribution of Funds. Magistrate Judge Hanna shall review each such Request, together with any objection filed.
- After considering each Request together with any objections submitted by the parties, the Court will determine whether the itemized statement is regular and reasonable and will issue a Report and Recommendation on the Request. After The Report and Recommendation shall be filed into the record, with a copy of the entire packet received from the Special Masters filed into the record under seal. The Report and Recommendation shall recommend payment in full, partial payment, or denial of the request in its entirety.
- The parties shall have fourteen (14) days to file objections to Magistrate Judge Hanna's Report and Recommendation. Any such objections shall be submitted directly and solely to Judge Doherty's Chambers, and shall not be filed into the record. This Court shall consider Magistrate Judge Hanna's recommendation, together with all objections made to such recommendation, and thereafter order payment, modified payment, or denial of payment. This Court's order shall include, as appropriate, instructions to the accounting firm to issue payment.

- Only upon order issued by this Court shall the accounting firm issue payment and only in the amount ordered by the Court.

The Special Masters' billing statements will not be distributed to counsel (other than Lead Counsel for both parties), except upon timely and proper request by an appropriate party made in writing, and submitted to the Court through the co-lead counsel(s) for Plaintiffs and Defendants, or their designee, *and* such distribution will be ordered by this Court only if any objection by an appropriate opposing party submitted through the co-lead counsel(s) for Plaintiffs or Defendants, or their designee, is overruled.

No funds shall be distributed, except upon order of this Court for any purpose, whatsoever.

The accounting firm shall issue to this Court, directed to Magistrate Judge Hanna with a copy to this Court, a quarterly report of the activity in the account since the last report, including the current balance and all distributions made and to whom.

## **VII. Other Matters**

### **A. Affidavits**

The Special Masters have submitted affidavits to the Court by the Special Masters in accordance with Rule 53(b)(3). The affidavits are attached to Rec. Doc. 532.

### **B. Cooperation**

The Special Masters shall have the full cooperation of the parties and their counsel. As agents and officers of the Court, the Special Masters, and any personnel to whom they might delegate one or more tasks assigned them by the instant Order or by this Court, shall enjoy the same protections from being compelled to give testimony and from liability for damages as those enjoyed by other federal judicial adjuncts performing similar functions. The parties will make readily available to the Special Masters any and all facilities, files, databases, and documents necessary to fulfill the duties and functions described in this Order.

**C. Effective Date**

The Court notified the Special Masters they would be appointed, and requested they commence work on this matter, on Friday, March 16, 2012, which shall be the effective date of their appointment.

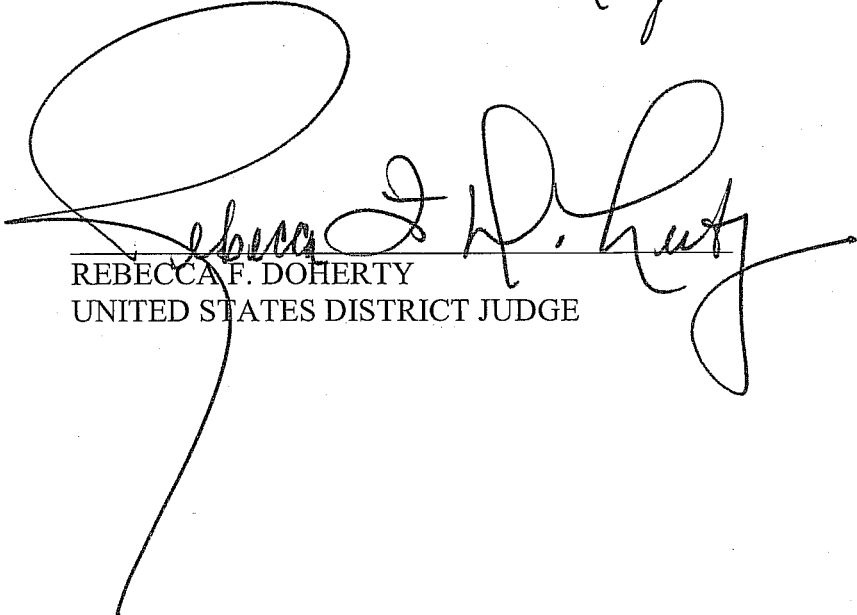
**D. Reasonable Diligence**

The Special Masters appointed herein are ordered to proceed with all reasonable diligence in fulfilling their duties.

**VIII. Periodic Review**

Pursuant to Case Management Order: Periodic Review Process [Doc. 2208] the Court implemented a periodic review process whereby the Court requests comments, concerns, or suggestions concerning, *inter alia*, any aspect of the Special Masters' appointment and/or functioning in these proceedings. Consequently, this Court may, consistent with this review, or otherwise, amend this Order.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 23 day of May,  
2014.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

APR 30 2014

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**AMENDED ORDER: MAY, 2014 AND JUNE, 2014 STATUS CONFERENCES  
AND RULE 16 PRE-TRIAL CONFERENCE**

In its ongoing management of the Multidistrict Litigation, the Court issues the following  
ORDERS:

The Monthly Status Conference scheduled for May 22, 2014 is hereby CANCELLED.

The Monthly Status Conference scheduled for June 19, 2014 will be held as SCHEDULED.

The Special Masters will schedule working group meetings, as appropriate.

On June 19, 2014, after the Monthly Status Conference, a Federal Rule of Civil Procedure  
(FRCP) Rule 16 Pre-Trial Conference will be held to facilitate and adjust the Discovery Plan in the  
MDL.

Trial counsel who have not appeared, in an official capacity, before this Court are  
REQUIRED to attend.

The actual start time for the Pre-Trial Conference will be designated by the Special Masters  
in conjunction with the Court.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 30 day of April, 2014.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

APR 24 2014

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

This Document Applies To:  
*All Cases*

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**ORDER: MAY, 2014 STATUS CONFERENCE  
AND RULE 16 PRE-TRIAL CONFERENCE**

In its ongoing management of the Multidistrict Litigation, the Court issues the following  
ORDERS:

The Monthly Status Conference scheduled for May 22, 2014 will be held as SCHEDULED;  
additionally, all normal working group meetings, as designated by the Special Masters, will be held;

After the Monthly Status Conference, a Federal Rule of Civil Procedure (FRCP) Rule 16  
Pre-Trial Conference will be held to facilitate and adjust the Discovery Plan in the MDL;


Trial counsel who have not appeared, in an official capacity, before this Court are  
REQUIRED to attend.

The actual start time for the Pre-Trial Conference will be designated by the Special Masters  
in conjunction with the Court.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 24 day of April, 2014.

REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

APR 11 2014 

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

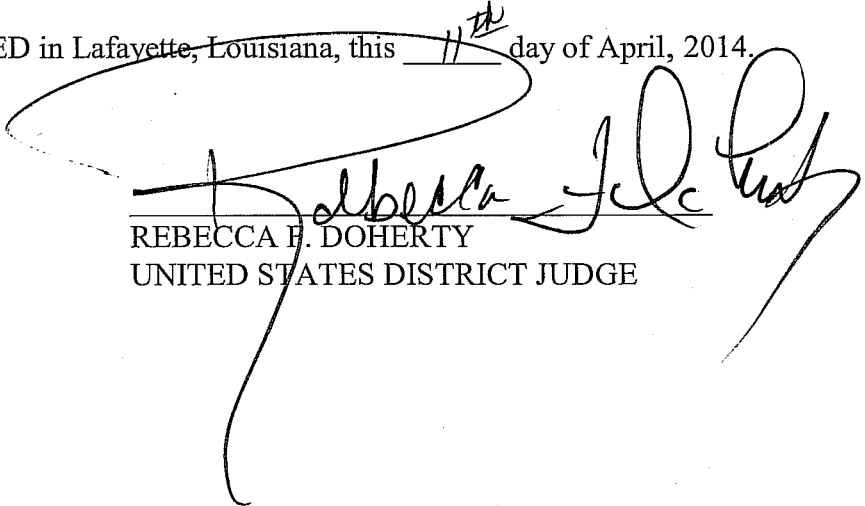
**ORDER:**  
**APRIL, 2014 STATUS CONFERENCE**

This Court, considering the duration of the First Bellwether Trial, *Allen et al. v. Takeda Pharmaceuticals North America Inc., et al.* (12-cv-00064), which recently concluded, and further considering the parties' focus on the post-trial motions, and after conferring with the Special Masters, hereby CANCELS April's Monthly Status Conference scheduled for April 25, 2014.

Considering the foregoing,

IT IS HEREBY ORDERED the Monthly Status Conference scheduled for April 25, 2014 is  
**CANCELLED.**

THUS DONE AND SIGNED in Lafayette, Louisiana, this 11<sup>th</sup> day of April, 2014.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE



U.S. DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
RECEIVED LAFAYETTE

MAR 14 2014

TONY F. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

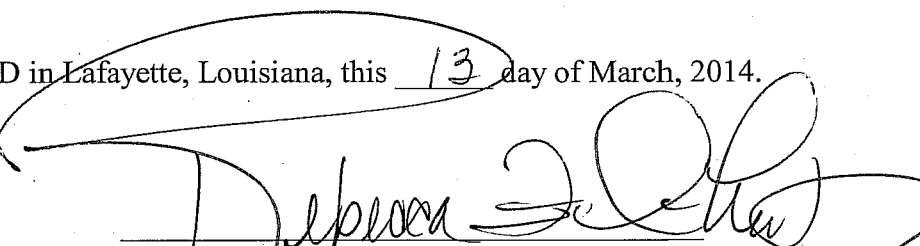
**ORDER:**  
**MARCH, 2014 STATUS CONFERENCE**

This Court, recognizing the parties are focused on the First Bellwether Trial, *Allen et. al. v. Takeda Pharmaceuticals North America Inc., et. al.* (12-cv-00064), which is currently under way, and after discussions with the Special Masters, hereby CANCELS March's Monthly Status Conference scheduled for March 20, 2014.

Considering the foregoing,

IT IS HEREBY ORDERED that the March Monthly Status Conference scheduled for March 20, 2014 is **CANCELLED**.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 13 day of March, 2014.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

COPY SENT  
DATE 3/14/14  
BY RFD  
TO RFD  
CB

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

This Document Applies To:  
*All Cases*

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**ORDER:**  
**FEBRUARY, 2014 STATUS CONFERENCE**

This Court, recognizing the parties are focused on the First Bellwether Trial, *Allen et. al.v. Takeda Pharmaceuticals North America Inc., et. al.* (12-cv-00064), which is currently under way, and after discussions with the Special Masters, hereby CANCELS February's Monthly Status Conference scheduled for February 20, 2014.

Considering the foregoing,

IT IS HEREBY ORDERED that the February Monthly Status Conference scheduled for February 20, 2014 is **CANCELLED**.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 14 day of February, 2014.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

JAN 17 2014

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE ACTOS® (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:

*John Chiody, et ux v.*

*Takeda Pharmaceuticals America, Inc., et al*

*Civil Action No. 12-2319*

MAGISTRATE JUDGE HANNA

ORDER

For the reasons more fully set forth by this Court on the record on January <sup>15</sup>~~16~~, 2014 in the matter entitled "Allen, *et ux v. Takeda Pharmaceuticals North America, Inc., et al*," Civil Action 12-cv-00064,

IT IS HEREBY ORDERED that the Second Pilot Bellwether Trial in which the trial of this matter currently is set to begin on April 14, 2014, shall be and is CONTINUED WITHOUT DATE.

IT IS HEREBY ORDERED that all deadlines currently set in this matter (found in the Scheduling Order: Rec. Doc. 2520 and the First Amended Scheduling Order: Rec. Doc. 3375) are SUSPENDED.

The Special Masters will schedule a telephone conference, within the next 2 weeks, to establish the new trial date and set new deadlines.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 17 day of January, 2014.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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JAN - 3 2014

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER:**  
**JANUARY, 2014 STATUS CONFERENCE**

This Court, recognizing the exigencies related to the upcoming Bellwether Trial, *Allen et. al v. Takeda Pharmaceuticals North America Inc., et. al.* (12-cv-00064), and after extensive discussions with the Special Masters, hereby makes the following changes to the schedule for January 2014:

**January 23, 2014 Status Conference Cancelled**

The next Monthly Status Conference in this matter was scheduled to be held on January 23, 2014 at 10:30 a.m. This Court hereby CANCELS January's Monthly Status Conference in preparation for upcoming Bellwether Trial.

**January 23, 2014**

Counsel, however, are instructed to maintain their availability to confer with the Court on January 23, 2014, if necessary. The Special Masters will notify those counsel that might be required to attend.

Considering the foregoing,

IT IS HEREBY ORDERED that the January Monthly Status Conference is **CANCELLED**.

IT IS FURTHER ORDERED that Counsel are to maintain their availability to confer with the Court in preparation for trial on **January 23, 2014**, if necessary.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 3 day of January, 2014.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

DEC 12 2013 *OS*

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

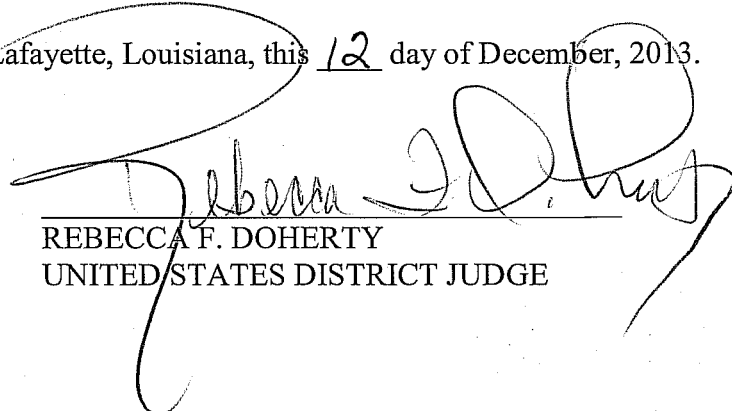
**THIRD AMENDED COURT ORDER:  
PLAINTIFFS' STEERING COMMITTEE**

The "Court Order: Plaintiffs' Steering Committee,"<sup>1</sup> as amended,<sup>2</sup> is hereby further amended as follows:

Dawn M. Chmielewski a current member of the Plaintiffs' Steering Committee ("PSC") has joined the firm of Neblett, Beard & Arsenault and is no longer affiliated with Climaco, Wilcox, Peca, Tarantino & Garofoli Co., L.P.A. This move results in two (2) members of the PSC from the same firm.

Consequently, pursuant to request without objection, Dawn M. Chmielewski is removed as a member of the PSC but will continue to work with the PSC under the auspices of Neblett, Beard & Arsenault.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 12 day of December, 2013.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

<sup>1</sup> Rec. Doc. 560.

<sup>2</sup> Rec. Docs. 2320 and 2856.

RECEIVED

DEC 11 2013 *MS*

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone) Products Liability Litigation  
MDL No. 11-md-2299, All Cases

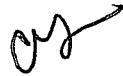
Date: December 11, 2013

**MINUTE ENTRY:**  
**AGENDA FOR DECEMBER 11, 2013 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Wednesday, December 11, 2013:

- I. Report on Developments in the MDL since the September 26, 2013 Status Conference
- II. Status of Federal and State Court Filings
- III. Status of Discovery
- IV. A Bellwether Trial Update
- V. Report on status of outstanding Motions
- VI. Report on status of outstanding Orders
- VII. Common Benefit Claims Process Update
- VIII. Report on *Pro Se* process
- IX. State Court Update
- X. PSC Liaison Update
- XI. Next Status Conference Date

RECEIVED

NOV 26 2013 

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
*All Cases*

MAGISTRATE JUDGE HANNA

**ORDER:**  
**DECEMBER, 2013 STATUS CONFERENCE**  
**AND DAUBERT HEARINGS**

This Court, recognizing the exigencies related to the upcoming Bellwether Trial, and after extensive discussions with the Special Masters, hereby makes the following changes to the schedule for December 2013:

**December 11, 2013**

The next Monthly Status Conference in this matter was scheduled to be held on December 19, 2013 at 10:30 a.m. This Court hereby reschedules December's Monthly Status Conference to December 11, 2013 at 10:30 a.m., in open court. Consequently, the regular Working Group Meeting, which is traditionally scheduled for the morning of the Monthly Status Conference, will be held on December 11, 2013 at 9:15 a.m., in chambers.

Additionally, in preparation for the first Bellwether Trial, *Allen et. al v. Takeda Pharmaceuticals North America Inc., et. al.* (12-cv-00064), after the Court concludes the Monthly Status Conference, this Court will hold an additional Special Working Group Meeting, in chambers, on December 11, 2013 at 2:00 p.m., which **must** include **all** Trial Counsel. Trial Counsel attendance is *mandatory*.



**December 12, 2013**

At 9:30 a.m. central time, on December 12, 2013, this Court will, again be in open court: at that time, should this Court choose to place any rulings as to the pending *Daubert* motions on the record, this Court will do so at that time. This Court, also, will hear any oral argument on any *Daubert* motions, **should this Court determine oral argument is needed.** The parties will be notified, by the Special Masters, prior to December 12, 2013, whether this Court anticipates it will rule on any motion, orally on the record, and/or whether this Court desires oral argument on any motion. Additionally, the parties were notified, through the Special Masters, this Court does not anticipate, after reviewing the *Daubert* motions and corresponding briefing, that presentation of any additional evidence or live witness testimony will be needed. However, should this change, the Court will notify the parties through the Special Masters and additional time will be scheduled. This Court grants this preliminary determination so that the parties can avoid unnecessary expert standby charges.

**December 13, 2013**

Should there be a need for additional time in open Court, the Court will, again, commence at 9:30 a.m. central time. Counsel should be prepared to participate, on December 13, 2013, if requested by the Court.

Considering the foregoing,

IT IS HEREBY ORDERED that the December Monthly Status Conference is rescheduled to **December 11, 2013 at 10:30 a.m.**, in open court, the normal Working Group Meeting will take place on **December 11, 2013 at 9:15 a.m.**, in chambers, prior to the Monthly Status Conference.

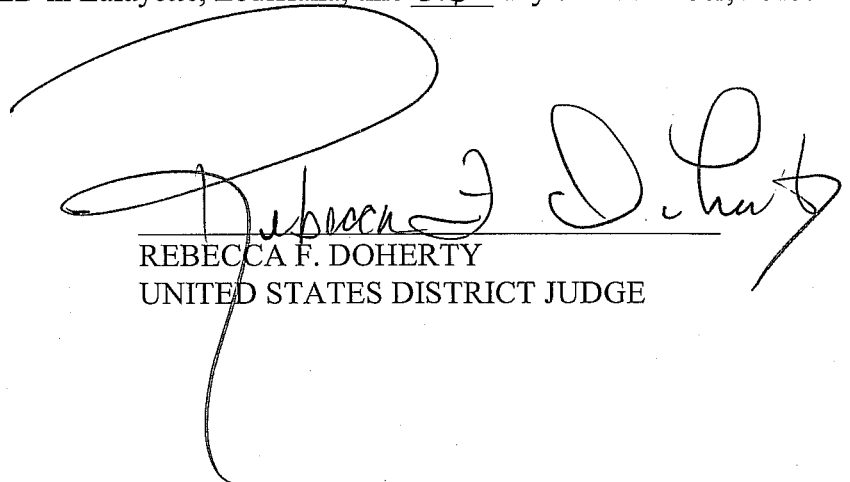
IT IS FURTHER ORDERED that a Special Working Group Meeting to include Trial

Counsel will be held on **December 11, 2013 at 2:00 p.m.**

IT IS FURTHER ORDERED that on **December 12, 2013 at 9:30 a.m.**, should this Court choose to make any oral rulings on the record and/or request oral argument, both will occur on December 12, 2013.

IT IS FURTHER ORDERED that, if necessary, on December 13, 2013 at 9:30 a.m. this Court will continue to hear oral argument on any remaining *Daubert* motions.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 26 day of November, 2013.

A large, stylized handwritten signature in black ink, appearing to read 'Rebecca F. Doherty', is written over a horizontal line. The signature is highly cursive and loops around the line.

REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA**

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
All Cases

MAGISTRATE JUDGE HANNA

**ORDER:**  
**SEPTEMBER, 2013 STATUS CONFERENCE**

The next monthly status conference in this matter is scheduled to be held September 26, 2013. This Court is aware that counsel have been tasked with complying with the deadlines and requirements established by this Court as well as those established by numerous state courts where Actos®-related cases are pending. Counsel have contacted this Court (through the Special Masters) requesting leave to participate by telephone or to inform the Court of other limitations on their attendance. However, this Court has been reluctant to consider making any scheduling change, for the following reasons.

For 18 months, the parties have been on notice that this Court expects trial counsel to participate in all significant interactions with this Court.<sup>1</sup> Once a trial schedule was set in this matter (in early 2013), this Court began reminding the parties, at each monthly status conference, of its expectation that trial counsel for both sides would attend all substantive pre-trial interactions with this Court, except if excused by this Court (directly or through the Special Masters). The PSC has complied with these instructions, identifying both Richard Arsenault and Mark Lanier as trial co-counsel and arranging for both to attend status conferences (and

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<sup>1</sup> See First General Order – All Actions (Doc. 4).

obtaining leave for Mr. Lanier to refrain from attending those from which he has been absent). By contrast, the Defendants did not notify this Court that anyone other than defense lead counsel would seek leave to serve as trial counsel. Nonetheless, Ms. Gourley recently informed this Court (initially through the Special Masters and on September 13, 2013 to this Court directly during a telephone status conference) that lead counsel intended to have Mr. Bruce Parker serve as co-trial counsel in the bellwether pilot trials. However, this Court has yet to meet Mr. Parker; Mr. Parker has not attended a single status conference (in person or by telephone); this Court is unaware that Mr. Parker has sought leave even once to miss a monthly status conference (or any other conference); and this Court is unaware of a single action taken by the Defendants to comply with this Court's clearly-stated expectation that trial counsel in this matter would participate prior to trial.

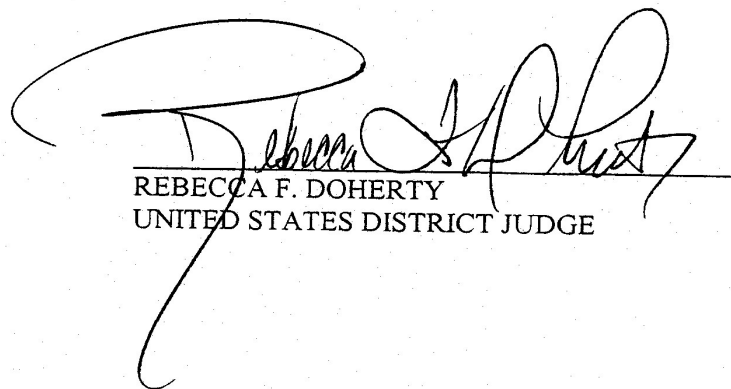
This development gives this Court grave concern. The small number of hearings currently scheduled to occur prior to the evidentiary hearing scheduled to begin on December 13, 2013, means that there is a strong likelihood that the Defendants will not be able to comply with this Court's instructions and are at significant risk of an order limiting them to only one trial counsel – specifically, Ms. Gourley – at both the evidentiary hearing and the bellwether pilot trials. This Court initially refused to change the schedule for the September status conference in any way, in an effort to preserve for the defense a full opportunity to comply with its instructions; but the Court has been assured that there is no reasonable expectation that Mr. Parker will have completed the An trial currently underway in Maryland by that date and, therefore, there is no reasonable expectation that Mr. Parker would be able to attend the September status conference under any circumstances. Therefore, this Court is convinced that it is not depriving Mr. Parker of a realistic opportunity to appear before this Court on September

26, 2013. Thus, no additional prejudice will accrue to the defense if the status conference does not proceed as scheduled.

In acknowledgment of the numerous scheduling conflicts associated with the September 26, 2013 status conference and in recognition of the fact that the defense will not suffer any further prejudice,

IT IS HEREBY ORDERED that COUNSEL WHO SEEK TO ATTEND the monthly status conference, as well as the working group meeting, ***SHALL ATTEND BY TELEPHONE RATHER THAN IN PERSON.*** *With regard to the status conference*, the Plaintiffs' Steering Committee is requested to arrange for the same conferencing service that has been in use every month, but is requested to provide dial-in information and instructions to the defense team, as well as plaintiffs' counsel. Counsel who have been appearing live in Court during the monthly status conferences will be given the ability to speak during the call; all other counsel, as has been the norm, will be limited to listening to the conference. *With regard to the working group meeting*, dial-in information will be provided to counsel by the Special Masters.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 18<sup>th</sup> day of September, 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

AUG 26 2013

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 11-md-2299

JUDGE DOHERTY

This Document Applies to:  
ALL CASES

MAGISTRATE JUDGE HANNA

**ORDER: MEET AND CONFER**

Pursuant to this Court's deadlines set in the Second Amended Scheduling Order: Pilot Bellwether Program (First Trial) (Rec. Doc. 2657), the Case Management Order: Motions (Rec. Doc. 2742) and any other applicable Orders, this Court recognizes a need for the parties to attempt to work through issues for which Motions in Limine would normally be filed, prior to the filing of such motion.

Considering the foregoing, IT IS HEREBY ORDERED that the parties are to meet and confer, in person, *prior* to the filing of any Motion in Limine.

SO ORDERED, this 26 day of August, 2013.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

AUG 26 2013

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 11-md-2299

This Document Applies to:

JUDGE DOHERTY

ALL CASES

MAGISTRATE JUDGE HANNA

**MONTHLY STATUS CONFERENCE DATES FOR 2014**

This Court will conduct Status Conferences on the following dates for the 2014 calendar year:

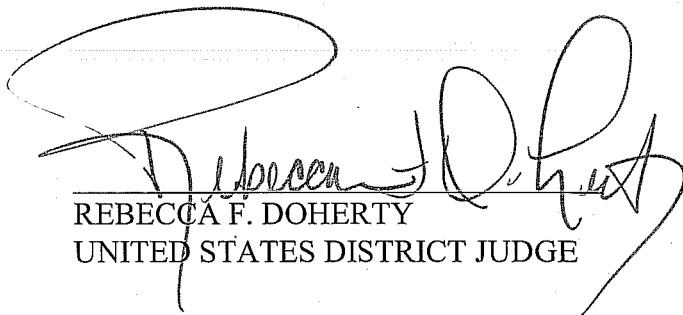
- January 23, 2014
- February 20, 2014
- March 20, 2014
- April 25, 2014
- May 22, 2014
- June 19, 2014
- July 24, 2014
- August 21, 2014
- September 25, 2014
- October 23, 2014
- November 20, 2014
- December 18, 2014

Status Conferences will be held in open court beginning at 10:30 a.m. On the date of each Status Conference, this Court will conduct a pre-conference Working Group meeting, the membership of which will be identified prior to each conference.

Defendants' and Plaintiffs' lead and co-lead counsel and the Plaintiffs' Steering Committee members are asked to anticipate their participation in each Status Conference, and might be requested by the Court to participate in a working meeting, to be held on the day prior to each Status Conference. Counsel will be informed in advance whether they will be requested to attend working

meetings and, if so, whether they will be required to participate in person or, alternatively, by telephone or video conference.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 26 day of August 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE



**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone) Products Liability Litigation  
MDL No. 11-md-2299, All Cases

Date: August 21, 2013

**MINUTE ENTRY:**  
**AGENDA FOR AUGUST 22, 2013 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, August 22, 2013:

- I. Report on Developments in the MDL since the July 25, 2013 Status Conference
- II. Status of Federal and State Court Filings
- III. Status of Discovery
- IV. Report on status of outstanding Orders, if any
- V. Common Benefit Claims Process Update
- VI. A Bellwether Trial Update
- VII. Report on status of outstanding Motions, if any
- VIII. *Pro Se* issues, if any
- IX. Next Status Conference: September 26, 2013

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone) Products Liability Litigation  
MDL No. 11-md-2299, All Cases

Date: July 24, 2013

**MINUTE ENTRY:**  
**AGENDA FOR JULY 25, 2013 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, July 25, 2013:

- I. Report on Developments in the MDL since the June 20, 2013 Status Conference
- II. Status of Federal and State Court Filings
- III. Status of Discovery
- IV. Report on status of outstanding Orders, if any
- V. Common Benefit Claims Process Update
- VI. A Bellwether Trial Update
- VII. Report on status of outstanding Motions, if any
- VIII. *Pro Se* issues, if any
- IX. Next Status Conference: August 22, 2013

**RECEIVED**

USDC, WESTERN DISTRICT OF LA  
TONY R. MOORE, CLERK

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF LOUISIANA

DATE 7/16/13



IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies To:  
All Cases

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**SUPPLEMENTAL ORDER ON EXPERT-RELATED ISSUES**  
**(FIRST PILOT BELLWETHER TRIAL)**

The instant Order is intended to provide additional guidance to parties in complying with previously-issued orders.<sup>1</sup> Should any party become aware of any expert-related issue that is not addressed or covered by this, or any previously-issued, Order(s), this Court requests the party make immediate contact with this Court, through the Special Masters, to discuss the issue(s).

**I. Expert Testimony and Availability**

A. All experts must be available to sit for a deposition during the original deposition period *and* during the supplemental deposition period, as necessary. With regard to each expert, the producing party shall identify, simultaneously with producing his or her report, the days during both deposition periods when the expert is available to sit for a deposition.

B. All experts must be available to present testimony at some time during the expert evidentiary hearing referenced below. With regard to each expert, the producing party shall identify, simultaneously with producing his or her report, the days during the evidentiary hearing when the expert can be available to provide testimony.

---

<sup>1</sup> In addition to the deadlines, information, and instructions found in the instant order, the parties are referred to the Second Amended Scheduling Order: Pilot Bellwether Program (First Trial) (Rec.Doc. 2657) and the Case Management Order: Motions (Rec. Doc. 2742), for those provisions already in place as to experts and/or expert-related issues.

C. Additionally, with regard to each expert, the producing party shall declare, simultaneously with producing his or her report, whether the expert's trial testimony will be presented live or by deposition.

## **II. Depositions**

The parties will be permitted to take supplemental expert depositions, when necessary. However, the scope of such supplemental depositions shall be limited to issues raised by the supplementation of expert reports and may not return to issues addressed in the original report or in an earlier deposition.

## **III. Motions**

It will be especially important, in this case, for paper copies of motions and attached exhibits (particularly where exhibits are voluminous) to be provided to this Court. With regard to exhibits submitted with briefs, the Court expects that:

- the exhibits will be accompanied by an index;
- the exhibits will be tabbed, with each exhibit page-numbered (either by Bates numbers or otherwise);
- citations to exhibits will be to both the exhibit number and the page number on which the referenced information is found;
- if a party opposing a motion relies on any of the same exhibits that were submitted in support of the motion itself, please do not re-attach the exhibit but simply refer, by identifying page(s), to the exhibit provided by the opposing party.

## **IV. Evidentiary Hearing**

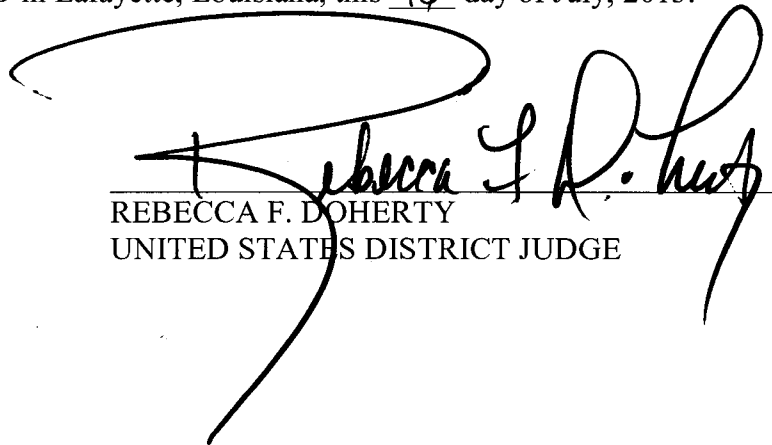
A. This Court has set aside a considerable amount of time on its calendar for evidentiary hearings and oral argument on Daubert motions and expert-related *limine* motions. *These dates are: December 11 through 13, 2013; December 16 through 20, 2013; December 30 through 31, 2013; and, if necessary, January 7 through 10, 2014.*

B. As early as possible, but after having received the motions filed, this Court will determine which of the experts this Court will require to present live testimony in order for a ruling to be issued on any pending motion, and will determine the sequence in which motions will be considered (and witnesses will be heard). These decisions will be conveyed to counsel as soon as they are made.

**V. Pre-Trial Conference**

It is this Court's intention that all expert-related disputes and issues will have been addressed prior to the pre-trial conference. Should any such issues remain unresolved at the conclusion of the evidentiary hearing – for instance, in the event that further briefing is requested, or changes are triggered by new developments, etc. – they will be addressed, before or during the pre-trial conference.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 16 day of July, 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: June 20, 2013

**MINUTE ENTRY:**  
**AGENDA FOR JUNE 20, 2013 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, June 20, 2013:

- I. Status of Federal and State Court Filings
- II. Report on Developments in the MDL since the May 23, 2013 Status Conference
- III. Status of Discovery
- IV. Report on status of outstanding Orders, if any
- V. Common Benefit Claims Process Update
- VI. A Bellwether Trial Update
- VII. Next Status Conference: July 25, 2013

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JUN 13 2013

*JS*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

This Document Applies to:  
All Cases

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**SECOND AMENDED COURT ORDER:  
PLAINTIFFS' STEERING COMMITTEE**

The "Court Order: Plaintiffs' Steering Committee,"<sup>1</sup> as amended,<sup>2</sup> is hereby further amended, as follows:

During the course of these proceedings, it has become clear to this Court that certain outside counsel have particular expertise, experience, qualities and/or attributes that enable them to perform considerable tasks, and fulfill certain roles, that benefit both the Plaintiffs' Steering Committee and the common interests of the plaintiffs in this matter. In acknowledgement of this fact, this Court hereby APPOINTS the following additional counsel to the Plaintiffs' Steering Committee:

- Donald C. Arbitblit  
Lieff Cabraser Heimann & Bernstein, LLP  
275 Battery Street, 29<sup>th</sup> Floor  
San Francisco, California 94111-3339  
Tel: (415) 956-1008  
Email: darbitblit@lchb.com
- Dawn M. Chmielewski  
Climaco, Wilcox, Peca, Tarantino & Garofoli Co., L.P.A.  
55 Public Square, Suite 1950  
Cleveland, Ohio 44113  
Tel: (216) 621-8484

<sup>1</sup> Rec. Doc. 560.

<sup>2</sup> Rec. Doc. 2320.

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THUS DONE AND SIGNED in Lafayette, Louisiana, this 13 day of

June, 2013.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE



RECEIVED

MAY 23 2013



UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: May 23, 2013

**MINUTE ENTRY:**  
**AGENDA FOR MAY 23, 2013 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, May 23, 2013:

- I. Status of Federal and State Court Filings
- II. Report on Developments in the MDL since the April 25, 2013 Status Conference
- III. Status of Discovery
- IV. Report on status of outstanding Orders, if any
- V. Common Benefit Claims Process Update
- VI. A Bellwether Trial Update
- VII. Next Status Conference: June 20, 2013

MAY 21 2013 

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Cases

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER: MOTIONS**

The submission to this Court of contested motions in the captioned proceedings shall be made in accordance with the following instructions.

**I. SCOPE OF ORDER**

This Order shall apply to all contested motions in the captioned proceedings. It shall not apply to unopposed motions, which the parties may continue to file as they have been doing. The stay on filing contested motions shall remain in place except for the categories of motions described herein.

**II. MOTIONS**

The parties will be permitted to file the following categories of contested motions within the following timeframes.

**A. DISCOVERY**

Discovery motions may be filed at any time prior to the discovery deadline in the action in which the motion is filed. *However, no discovery motion may be filed without prior consultation with the Special Masters; the Court strongly suggests genuine consideration of any guidance the Special Masters might offer be given by the parties before filing any such motion.* This Court has issued instructions to the Special Masters to assist the parties, to the

fullest extent possible, to resolve discovery disputes without the need for formal motions and briefing. Any motion filed without prior consultation with the Special Masters will be denied summarily.

**B. CLASS ACTION ISSUES**

**Deadline: May 31, 2013**

The parties may file motions by this deadline that are related to the class action allegations asserted in any case in these proceedings. However, should any party take the position that further discovery is required before a motion challenging class allegations or supporting class certification may be filed, the party shall provide notice of this fact to this Court, *via* the Special Masters. The Special Masters will assist the parties in addressing issues raised with the Court.

**C. CHOICE OF LAW ISSUES**

**Deadline: June 28, 2013**

The parties shall notify the Court, through the Special Masters, of their conclusion(s) as to the applicable law to each claim made against each defendant in each of the bellwether cases. In the event the parties disagree as to any conclusion as to a bellwether case(s), the Special Masters will consult with this Court and briefing deadlines will be set to allow an early determination to be made on any disputed choice of law question.

**D. DISPOSITIVE MOTIONS, MOTIONS IN *LIMINE*<sup>1</sup>**

**Deadline, 1<sup>st</sup> Pilot Bellwether Trial: October 14, 2013**

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<sup>1</sup> Please see this Court's Scheduling Order: Pilot Bellwether Program (First Trial) (Rec. Doc. 2359) and Scheduling Order: Pilot Bellwether Program (Second Trial) (Rec. Doc. 2520) for additional briefing deadlines associated with dispositive and *limine* motions.

All dispositive motions and *limine* motions associated with the *First Pilot Bellwether Trial* shall be filed no later than this deadline. Prior to this deadline, the Special Masters will solicit from counsel (confidentially, if preferred) lists of *limine* motions that the parties intend to file and will follow up with discussions with counsel as to the filing of those identified motions. The purpose of these consultations will be for the Special Masters to provide guidance to counsel with regard to the necessity of filing and response to *limine* motions.

**Deadline, 2<sup>nd</sup> Pilot Bellwether Trial: January 13, 2014**

All dispositive motions and *limine* motions associated with the *Second Pilot Bellwether Trial* shall be filed no later than this deadline. Prior to this deadline, the Special Masters will solicit from counsel (confidential, if preferred) lists of *limine* motions the parties intend to file and will follow up with discussions with counsel as to the filing of those identified motions. The purpose of these consultations will be for the Special Masters to provide guidance to counsel with regard to the necessity of filing and response to *limine* motions.

**F. DAUBERT<sup>2</sup>**

**Deadline, 1<sup>st</sup> Pilot Bellwether Trial: October 21, 2013**

All *Daubert* motions associated with the *First Pilot Bellwether Trial* shall be filed no later than this deadline.

**Deadline, 2<sup>nd</sup> Pilot Bellwether Trial: January 20, 2014**

All *Daubert* motions associated with the *Second Pilot Bellwether Trial* shall be filed no later than this deadline.

**III. GUIDELINES**

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<sup>2</sup> Please see this Court's Scheduling Order: Pilot Bellwether Program (First Trial) (Rec. Doc. 2359) and Scheduling Order: Pilot Bellwether Program (Second Trial) (Rec. Doc. 2520) for additional briefing deadlines, as well as an evidentiary hearing, associated with *Daubert* motions.

A. Should any party wish to file a contested motion that is not discussed or described in this Order, counsel are strongly encouraged to contact the Special Masters for guidance as to how and when to bring the issue to the attention of the Court.

B. All motions must comply with this Court's standard rules, except to the extent waived or modified by orders issued in these proceedings. Counsel are encouraged to consult the local rules before filing any motion; they may be found on this Court's website, at <http://www.lawd.uscourts.gov/local-rules>. To the extent that counsel have any questions, they are strongly encouraged to contact any of the Special Masters in this matter, all of whom have extensive experience of, and familiarity with, the local rules.

C. Counsel are cautioned that this Court does not automatically grant leave to file reply briefs. Any party wishing to file a reply brief must first consult with the Special Masters and if necessary, thereafter, seek leave to file, making sure to attach a copy of the proposed brief to the motion for leave.<sup>3</sup> Any motion for leave that has not been discussed with the Special Masters will be summarily denied for failure to comply with this Order. Any proposed motion for leave to file a reply brief and attached proposed reply brief that merely reiterate argument, instead of responding to unanticipated opposition argument, will not be permitted to be filed.

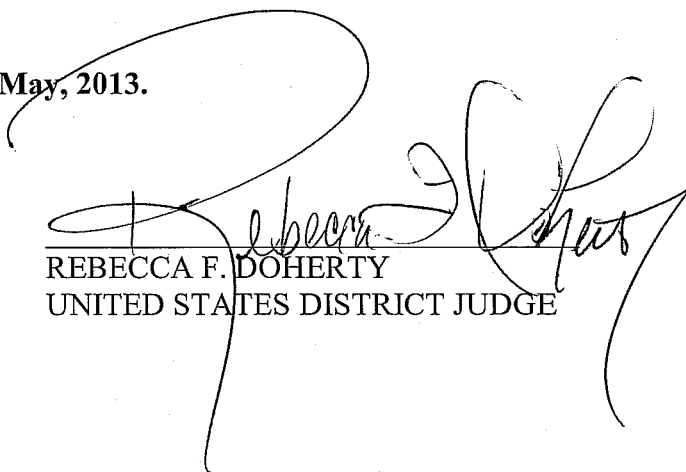
D. The Plaintiffs' Steering Committee will take the lead on facilitating briefing on behalf of all Plaintiffs, except where the PSC explicitly refuses to make arguments with regard to a motion or issue. Where non-PSC counsel intend to present separate argument on a given motion, Counsel are required to coordinate their efforts with the PSC to avoid unnecessary duplication.

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<sup>3</sup> See Local Rules for additional instructions concerning the filing of reply briefs.

E. All parties should be aware that, with regard to motions, this Court does not grant oral argument merely as a matter of course. Should oral argument be required on any given motion, counsel will be notified by the Court or the Special Masters, and oral argument will be scheduled by the Court.

**SO ORDERED**, this 21 day of May, 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Cases

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**SECOND AMENDED SCHEDULING ORDER:  
PILOT BELLWETHER PROGRAM (FIRST TRIAL)**<sup>1</sup>

This Court having considered the scope of these proceedings, the number of plaintiffs, the amount of discovery that will be required, and the time necessary to complete pre-trial preparations, hereby establishes a Pilot Bellwether Program [“PBP”]. The PBP establishes a stream-lined trial preparation schedule for a minimum of two Pilot Bellwether trials. This Court is aware that the schedule established herein will place extraordinary burdens on this Court, counsel, and the parties. Nonetheless, this abbreviated schedule is imposed so as to serve the very important goal of moving these proceedings toward completion of this Court’s responsibilities in a reasonable timeframe.

**PLEASE NOTE: THE DEADLINES ESTABLISHED HEREIN SHOULD BE CONSIDERED HARD AND FAST. THEY WILL NOT BE EXTENDED, CONTINUED, OR DELAYED BY THE COURT IN ANY WAY ABSENT EXTRAORDINARILY GOOD CAUSE SHOWN.**<sup>2</sup>

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<sup>1</sup> Based upon recent developments including, plaintiffs dismissing two (2) of five (5) cases nominated by Defendants in the *Pilot Bellwether Discovery Pool*, and one (1) case not providing a *Lexecon* or venue waiver, this Court has modified the *Pilot Bellwether Discovery Pool* process. This Court, also, has issued Case Management Order: Bellwether Nominations on May 3, 2013, containing the updated details.

<sup>2</sup> As to deadlines that impact this Court’s ability to complete its tasks – tasks such as briefing deadlines – the parties are expected to comply with all deadlines or obtain extensions from the Court. However, with regard to deadlines that do not have an immediate impact on the Court’s ability to perform its tasks, the parties are permitted to grant extensions to each other, but should be advised that such extensions will not be enforced by this Court.

**Trial Date (1<sup>st</sup> Pilot Bellwether Trial):** *January 27, 2014*  
**Pre-Trial Conference:** *January 13, 2014, 10:00 am*

**Trial Date (2<sup>nd</sup> Pilot Bellwether Trial):** *April 14, 2014*  
**Pre-Trial Conference:** *March 31, 2014, 10:00 am<sup>3</sup>*

#### **DEADLINES**

- 2/28/2013:** Plaintiffs shall provide a complete set of all *requests for production* of documents to Defendants.
- 3/25/2013:** The Court shall establish a *schedule for anticipated motions and briefing of legal issues*.
- 4/1/2013:** Each side shall nominate *Pilot Bellwether Discovery Pool* participants, as follows.
- Each side will nominate 5 plaintiffs to participate in discovery.
  - The only plaintiffs eligible to be included in the discovery pool will be plaintiffs who submitted Plaintiff Fact Sheets to the Defendants by December 31, 2012.
  - To the extent that a plaintiff wishes to participate in the discovery pool but has not complied with the December 31, 2012 deadline, he or she may participate if, and only if, a completed fact sheet and authorizations, together with a complete set of medical records, can be produced to the Defendants no later than *March 8, 2013*.

The following additional limitations shall apply to the Pilot Bellwether Discovery Pool nominees:

- (a) No plaintiff who has asserted a class action is eligible for participation as a member of the Pilot Bellwether Discovery Pool.
  - (b) No plaintiff may be a nominee unless he or she: (i) actually consumed Actos; (ii) has been diagnosed with diabetes; and (iii) has been diagnosed with bladder cancer (no fear of cancer case).
- Nominating counsel shall certify, with regard to every Pilot Bellwether Discovery Pool nominee, that: (i) counsel has reviewed all available information about the nominee; (ii) counsel believes that the nominee's case can be ready for trial by January 27, 2014 (or, in the case of Defendants' nominees, April 14, 2014); (iii) counsel intends to try the

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<sup>3</sup> A separate Scheduling Order providing deadlines for the second Pilot Bellwether trial has been issued.



nominee's case, if accepted by this Court; (iv) counsel does not intend to dismiss the nominee's case; and (v) counsel has no reason to believe that the nominee's case will be settled individually prior to trial.

- 4/8/2013:** With regard to the Pilot Bellwether Discovery Pool nominees, Defendants shall notify this Court and Co-Lead Counsel whether or not they waive their right, as applicable, to venue or to have non-Louisiana cases remanded to transferor courts for trial (*the Lexecon issue*).
- 4/8/2013:** Defendants shall notify the PSC, with regard to the Pilot Bellwether Discovery Pool nominees, of any gap in the *essential preliminary discovery* required by this Court's Case Management Order: Plaintiff Fact Sheets (Rec. Doc. 1355).
- 4/22/2013:** Plaintiffs shall *cure any deficiencies* in essential preliminary discovery on Pilot Bellwether Discovery Pool nominees.
- 4/23/2013:** Pilot Bellwether Discovery Pool Nominees may *move for leave to amend their complaints*.<sup>4</sup>
- 5/3/2013:** Parties to exchange first *witness and exhibit lists*.<sup>5</sup> "Witnesses" shall include factual witnesses as well as experts, identified by area of expertise (deadline for identifying experts by name is separate). *Updates due the first day of each month thereafter*. No witness or exhibit may be added without leave of Court once the discovery deadline has passed; however, witnesses and exhibits may be removed through January 2, 2014. Counsel are cautioned that, in creating witness and exhibit lists, good faith is expected at all times.
- 6/3/2013:** Defendants must *certify good-faith belief* that all documents requested by the Plaintiffs, agreed by the Defendants to be produced, and/or ordered by this Court, have been produced or will be produced within ten (10) days of this date.
- 7/15/2013:** Plaintiffs' shall *identify their nominee* for the first trial. Defendants shall *identify their nominee* for the second trial.
- 8/1/2013:** *Expert-Related Deadlines* Begin

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<sup>4</sup> In filing any motion for leave to amend, counsel are cautioned to comply with Local Rule 7.6.

<sup>5</sup> This requirement is imposed in lieu of the Fed. R. Civ. Pro. 26(f) reporting requirement.

Plaintiffs' Deadlines	Defendants' Deadlines
<b>8/1:</b> Plaintiffs to identify experts and produce background information ( <i>See Fed. R. Civ. Pro. 26(a)(1)(B)(iv-vi)</i> )	<b>8/26:</b> Defendants to identify experts and produce background information ( <i>See Fed. R. Civ. Pro. 26(a)(1)(B)(iv-vi)</i> )
<b>8/7:</b> Plaintiffs to produce expert reports	<b>9/3:</b> Defendants to produce expert reports
<b>9/5 through 10/4:</b> Plaintiffs' expert depositions <sup>6</sup>	<b>9/5 through 10/4:</b> Defendants' expert depositions

**10/11/2013:** Deadline for *supplementation, if any, of expert reports and completion of supplemental expert depositions*, if any. In light of the fact that expert reports must be produced prior to the completion of discovery, supplementation of reports and depositions will be permitted (pursuant to Fed. R. Civ. Pro. 26(a)(1)(D)) in order to respond to factual information discovered after an original report is issued.

**10/1/2013:** *Discovery* Deadline<sup>7</sup>

**10/14/2013:** Motions Deadline Begin (*limine, any remaining dispositive motions*)

Motions: 10/14

Oppositions: 11/1

Replies: 11/8<sup>8</sup>

**10/17/2013:** *Deposition Excerpt Designations* Deadlines Begin

Plaintiffs' Deadlines	Defendants' Deadlines
<b>10/17:</b> Plaintiffs to produce excerpt designations, if any	<b>10/28:</b> Defendants to produce excerpt designations, if any
<b>11/11:</b> Plaintiffs' objections to Defendants' designations and counter-designations	<b>10/31:</b> Defendants' objections to Plaintiffs' designations and counter-designations

<sup>6</sup> Depositions of Plaintiffs' experts shall occur before depositions of Defendants' experts within the same discipline.

<sup>7</sup> Counsel are expected to schedule and sequence discovery so as to permit all deadlines to be met. This Court's Special Masters, as well as Magistrate Judge Hanna, will be available to assist the parties in such scheduling should it prove necessary. Moreover, if a separate Order is necessary, counsel should notify this Court, through the Special Masters.

<sup>8</sup> The parties shall have 10 days following "service" of all reply briefs to resolve any matters concerning privilege or confidentiality pursuant to paragraph 10 of the Protective Order (*i.e.*, Case Management Order: Protecting the Confidentiality of Discovery Materials).

No replies will be permitted. This Court will determine whether and, if so, when argument will be heard on the admissibility of deposition excerpts.

**10/21/2013:** Motions Deadline Begin (*Daubert* motions)

Motions: **10/21**  
Oppositions: **11/18**  
Replies: **11/25<sup>9</sup>**

**12/11/2013:** *Expert evidentiary hearing* (to address *Daubert*, all other expert-related objections, and all expert-related pre-trial issues)

**1/2/2014:** Final *identification* of **will-call witnesses** (and the substance of their testimony) and *identification and exchange* of all **exhibits** (and the purpose for which they are offered).

**1/6/2014:** Deadline for completing *Trial Depositions*

In an effort to streamline trial preparation as much as possible, the *Court expects the parties to make significant efforts to produce witnesses for trial* rather than relying on deposition testimony. To the extent that trial depositions are necessary, they must be completed by this date.

**1/6/2014:** *Pre-trial order*

Attached to this Order is a modified version of this Court's standard pre-trial order form, together with instructions on completing the PreTrial Order. Counsel are strongly encouraged to consult with the Special Masters for guidance, instructions, and assistance in preparing the PreTrial Order.

**1/13/2014:** *Pre-trial conference*

**1/22/2014:** *Bench books*  
*Glossary*  
*Training for electronic courtroom*<sup>10</sup>

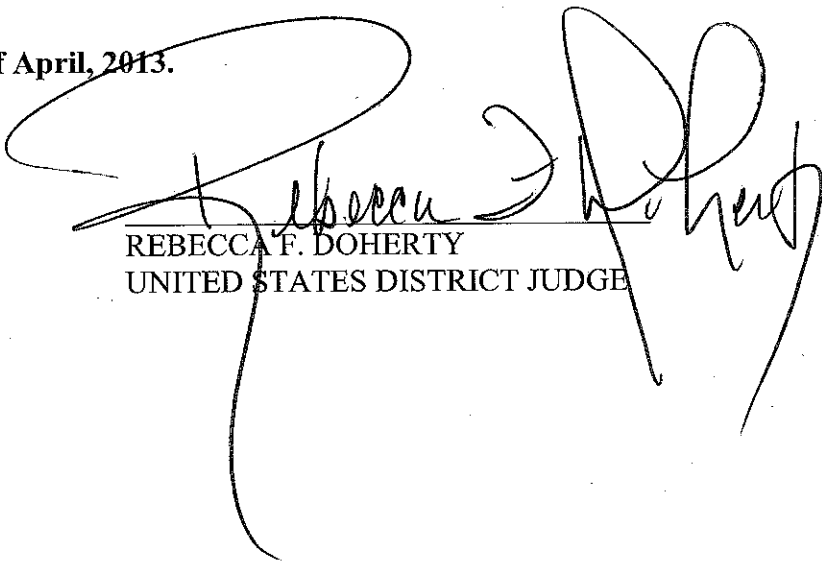
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<sup>9</sup> The parties shall have 10 days following "service" of all reply briefs to resolve any matters concerning privilege or confidentiality pursuant to paragraph 10 of the Protective Order (*i.e.*, Case Management Order: Protecting the Confidentiality of Discovery Materials).

<sup>10</sup> This is the deadline by which training must be completed, but counsel are encouraged to schedule such training earlier than January 22, 2014. Counsel must bring to the training the laptops that they intend to use for the presentation of exhibits.

1/27/2014: Trial of the first bellwether case.

SO ORDERED, this 3 day of April, 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

**IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Cases

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**FIRST AMENDED CASE MANAGEMENT ORDER:  
DISCOVERY PROTOCOL<sup>1</sup>**

This Court and counsel have been working on crafting the instant order for several months. The evolution of these proceedings, including changes due to the filing of a substantial number of state court actions, discovery proceedings in those matters, and the fact that a number of trials have been set around the nation, have made it advisable for this Court to delay completion, signing, and implementation of this order. However, as these proceedings have now arrived at an appropriate point for full discovery to proceed, this Court enters the current discovery protocol. Should further evolution in these proceedings require amendment of this order, this Court will entertain requests for such amendments, and issue the appropriate changes as deemed appropriate.

**I. SCOPE OF ORDER**

**A. Order Applicable to All Cases in MDL Proceedings.**

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<sup>1</sup> This amendment changes the heading and content of Section IV to reflect the change to an "Expert Evidentiary Hearing" on pages 7-8 of the instant Order, and addresses the number of examiners in Section V (J) on page 15 of the instant Order.

This Order shall apply to all cases currently pending in MDL No. 2299 and to all related actions that have been or will be originally filed in, transferred to, or removed to this Court and assigned hereto as “MDL” cases (collectively, “the MDL proceedings”). This Order is binding on all parties and their counsel in all cases currently pending or subsequently made part of these proceedings and shall govern each case in these MDL proceedings. This Order shall apply to all discovery conducted by the Plaintiffs’ Steering Committee (“PSC”) on behalf of all Plaintiffs (including any committees or sub-committees specifically authorized by the PSC to conduct such discovery), as well as all discovery conducted by Defendants.

**B. Parties.**

For the purpose of this Order, the term “Plaintiffs’ Counsel” or “the PSC” shall be used to refer to the Plaintiffs’ Co-Lead Counsel or their designee. The term “State Plaintiffs’ Counsel” shall refer to counsel representing plaintiffs in one or more state case actions involving Actos® related product liability claims. The term “Defendants’ Counsel” shall be used to refer to the Defendants’ Lead Counsel or her designee in the MDL. The term “Involved Counsel” shall refer to those attorneys participating in a particular discovery pursuit who may include Plaintiffs’ Counsel or their designee; State Plaintiffs’ Counsel or their designee; or Defendants’ Counsel or her designee.

**II. COORDINATION WITH OTHER LITIGATIONS**

**A. Coordination to Extent Practicable.**

Plaintiffs’ Counsel and Defendants’ Counsel in these MDL proceedings, and all other counsel designated by the Court in prior or subsequent Case Management Orders, shall work to coordinate to the extent practicable the conduct of this litigation with other product liability actions involving Actos pending in any State Court. Such coordination is intended to conserve scarce judicial resources, eliminate duplicative discovery, serve the convenience of the parties

and witnesses, and promote the just and efficient conduct of this litigation. To the extent that any discovery generated in the MDL proceedings were to be used in any state court proceedings by agreement, this Court's Case Management Order: Protecting the Confidentiality of Discovery Materials entered by this Court on July 30, 2012 (hereinafter "Protective Order") shall apply.

**B. Intent to Coordinate with State Courts.**

In order to achieve the full benefits of this MDL proceeding, this Court has and will continue to encourage coordination with State Courts presiding over related cases, to the extent such State Courts so desire, up to and including issuance of any joint orders that might allow full cooperation as between and among the courts and the parties. As the Court indicated at the initial case management conference, and has been reiterated thereafter, this Court intends to work actively to reach out to any State Court that is interested in coordinating discovery activities. The Court expects counsel for parties in the MDL proceeding to help ensure that such coordination is achieved wherever it is practicable and desired by a given state court or courts.

**III. WRITTEN FACT DISCOVERY**

**A. General Written Discovery**

**1. General Discovery Directed to Takeda Entities and Eli Lilly**

All generic (non-case-specific) discovery propounded to the Takeda Entities, Eli Lilly, and non-party witnesses by plaintiffs – including deposition notices, interrogatories, and production requests – in this MDL proceeding shall be undertaken by, or under the direction of, the PSC on behalf of all Plaintiffs with cases in these MDL proceedings. Any discovery not limited to a specific plaintiff shall be assigned by the PSC. The PSC shall, where practicable, and if desired by the state courts, coordinate its discovery requests with State Plaintiffs' Counsel to reduce or eliminate duplicative discovery requests.

**Specific deadlines and time lines for discovery are found within the Scheduling Order. Throughout the progression of the MDL litigation, the parties should refer to the most recent version of the Scheduling Order for specific deadlines.**

## **2. Document Production by Takeda Entities and Eli Lilly**

The Takeda Entities and Eli Lilly shall produce documents to the PSC for the use of Plaintiffs in these proceedings. The format for such production shall be governed by the Case Management Order: Protocol Relating to the Production of Electronically Stored Information as entered on July 30, 2012 (hereinafter "ESI Protocol Order") and all other Orders of this Court. By agreement of the parties and pursuant to this Court's order, the Takeda Entities began producing documents to the PSC on April 6, 2012. The sequence in which the documents are produced need not conform to the requirements of Federal Rule of Civil Procedure 34(b) but must be produced pursuant to the Court's ESI Protocol Order, any further Order by this Court or Special Master, or agreement by the parties. This document production to the PSC shall serve as the document production by defendants in this MDL proceeding.

## **3. Plaintiffs' Document Repository**

The PSC shall bear the cost of and administer its own document repository unless agreed otherwise by the parties and approved by this Court. All documents produced by Defendants in this proceeding shall be produced to the PSC's designee and in the manner agreed to by the parties and approved by this Court or upon Order of this Court.

All counsel shall be responsible for assuring and shall take all reasonable and necessary steps to assure the security of any confidential information produced pursuant to the Protective Order and shall act to assure the limitation of access to confidential information to only those persons covered by the Protective Order. In particular, if counsel for any party makes documents



available *via* the Internet, such counsel shall be held responsible for assuring that all reasonable and necessary steps have been taken to ensure the Internet site is secure and may not be accessed by individuals who are not authorized to review confidential information. Should any party supplying confidential information suspect that sufficient security is not in place, that party may request the assistance of the Court in obtaining certification that the Internet site is secure and may only be accessed pursuant to the Protective Order entered by this Court.

**4. Additional General Discovery by Plaintiffs of Takeda Entities and Eli Lilly**

The parties are encouraged to engage in informal discovery on generic issues where possible and appropriate. The PSC also may serve Master Set(s) of Requests for Production and Master Set(s) of Interrogatories (not to exceed fifty interrogatories each, including all discrete subparts, unless good cause is shown) on the Takeda Entities collectively (*i.e.*, the PSC may not serve master discovery on each Takeda entity individually) and on Eli Lilly (collective total of 100 interrogatories).

**B. Case-Specific Written Discovery**

**1. Plaintiffs and Defendants**

**a. Plaintiff Fact Sheet, Authorizations, and Defendant Fact Sheet in All Cases**

As set forth in greater detail and governed by the Court's orders on plaintiff and defendant fact sheets, every plaintiff (except those asserting only consortium claims) is required to serve defendants' counsel with a Plaintiff Fact Sheet (PFS) and executed Authorizations and the Takeda Entities and Eli Lilly are required to serve (collectively) a single Defendant Fact Sheet (DFS) on plaintiffs' counsel in each case.

b. Case-Specific Discovery in Designated Discovery Pool Cases

The Takeda Entities and Eli Lilly collectively may serve one Set of Requests for Production (not to exceed fifty requests total), a Master Set of Interrogatories (not to exceed twenty-five interrogatories, including all discrete subparts total), and Set(s) of Requests for Admission on each individual plaintiff included within the designated discovery pool. Plaintiffs shall serve written responses, objections, and/or documents within thirty (30) days after receipt of such discovery requests, as detailed by Federal Rules of Civil Procedure. The process for designated discovery pool selections shall be the subject of a further order of this Court.

2. Case-Specific Fact Depositions in Designated Discovery Pool Cases

Case-specific discovery in any case included in the designated discovery pool will commence immediately after the cases are selected. In connection with any individual plaintiff's designated discovery pool case, the parties may take "core discovery," as described in the Scheduling Order. In the event any party seeks discovery depositions in designated discovery pool cases beyond core discovery, they may do so only with the written agreement of opposing counsel or by application to the Court for good cause.<sup>2</sup>

**Specific deadlines and time lines for discovery are found within the Scheduling Order. The parties should refer to the most recent version of the Scheduling Order for specific deadlines.**

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<sup>2</sup> The limitation to core discovery in designated discovery pool cases absent agreement of counsel or leave of Court is not applicable to cases which might be selected as designated discovery cases. Additional case-specific fact depositions may be taken in cases selected for trial.

#### IV. EXPERT DISCOVERY<sup>3</sup>

In an effort to streamline the process by which counsel, the parties, and the Court familiarize themselves with the scientific backdrop of these proceedings, as well as to facilitate the Court's rulings on Daubert issues, an evidentiary hearing on the Daubert motions will occur at the Expert Evidentiary Hearing.

##### A. General Experts

With regard to general experts, the parties will, in sequence:

- Identify experts and produce reports in accordance with deadlines and instructions contained in the Scheduling Order and other orders of this Court.
- Conduct expert depositions in accordance with the deadlines and instructions contained in the Scheduling Order and other orders of this Court.
- File and brief expert-related motions in *limine* and Daubert motions in accordance with the deadline and instruction contained in the Scheduling Order and other orders of this Court.
- Participate in an evidentiary hearing to address issues raised in the motions in *limine* or Daubert motions, which will be conducted simultaneously with an Expert Evidentiary Hearing (described below).

Following the evidentiary hearing, this Court will rule on all outstanding *limine* and Daubert motions.

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<sup>3</sup> Though a brief description of generic expert related discovery, the Expert Evidentiary Hearing process is included here, this Court intends to issue a separate order to provide full detail on these processes.

**B. Expert Evidentiary Hearing**

The Expert Evidentiary Hearing is designed to permit the Court to address any and all issues dealing with experts and expert testimony. This Court will coordinate with Counsel to identify the issues that will be addressed at the Expert Evidentiary Hearing. It is anticipated that if oral argument is required, on any expert related issue, argument will be presented at the Expert Evidentiary Hearing.

**C. Case-Specific Experts in Designated Cases**

Specific deadlines and timelines for discovery related to case-specific experts in designated cases are found within the Scheduling Order, the parties should refer to the most recent order, which shall govern with regard to specific deadlines.

**V. DEPOSITION PROCEDURES**

**A. Scope of Section.**

This section shall apply to the notices of depositions of any witnesses currently or formerly affiliated with the Takeda and Eli Lilly Entities (Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals America, Inc., Takeda Global Research & Development Center, Inc., Takeda California, Inc., formerly known as Takeda San Diego, Inc., Takeda Pharmaceuticals International, Inc., Eli Lilly & Company, and any of their respective parent companies, subsidiaries, and affiliates). Notices of the depositions of expert witnesses or case-specific fact witnesses relating to individual Plaintiffs (*e.g.*, health care providers, individual Plaintiffs, Takeda and Eli Lilly sales representatives, or other case-specific witnesses) may be the subject of a further order of this Court.

**B. Coordination.**

The parties are reminded that deposition discovery in the context of MDL proceedings can be extraordinarily complex, demanding, and expensive. The process of scheduling and taking depositions, when such large numbers of cases and attorneys are involved, requires a large degree of coordination, cooperation, and effort. Counsel are expected, throughout this process, to meet and confer and to strive to reach agreement between and among all involved parties where possible. Where the conclusion is reached, mutually, that agreement is not possible despite good faith negotiations, the parties are encouraged to timely contact the Court, through the Special Masters, to seek informal guidance and assistance and a determination as to whether or not it will be necessary to conduct a formal process for resolution of the dispute.

This Court has established a weekly discovery telephone status conference to be held with the Special Masters in order to facilitate prompt, efficient, and effective discovery.

Except where otherwise specifically noted, this order applies to depositions noticed in these MDL proceedings (“MDL depositions”) and is not intended to limit, or apply to, depositions taken in Actos®-related state court actions (“State Court depositions”), except to the extent that the parties (or one or more State Court(s)) agree(s) that such State Court depositions will be bound by this Order or an agreement among all parties which has been approved by this Court.

**C. Avoidance of Duplicative Depositions.**

The parties shall avoid duplication of discovery effort where possible, and the PSC shall open a line of communication with State Plaintiffs’ Counsel for the purpose of reaching this goal. The parties are encouraged to coordinate deposition discovery with State Plaintiffs’ Counsel to

the maximum extent possible so as to minimize the risk that any witness is unnecessarily deposed on the same subject multiple times.

Defendants' Counsel shall advise the PSC of all depositions that previously have been taken in State Court Actos-related actions, as of the date of entry of this order, and shall provide the transcripts of such depositions to the PSC. To the extent permitted by, and consistent with, federal law and procedure, those deposition transcripts may be requested to be used as if taken in these proceedings subject to any party's right to object.

**D. Federal Rules of Civil Procedure.**

With the entry of this order lifting the discovery stay for all purposes, all discovery, including depositions of Non-Takeda Fact Witnesses and Experts, are now permitted. Any and all such depositions shall be taken in accordance with the rules set forth in the Federal Rules of Civil Procedure, except as delineated in this Order. In any circumstance where either the PSC or the Defense feels that good cause exists for creating additional exceptions to these rules, they should meet and confer in an attempt to reach an agreement on such an exception. Failing such an agreement, the PSC and the Defense may request such an exception by contacting the Special Masters, who will convey the request to this Court.

**E. Notices.**

Cross-Noticing of Future Depositions. In those instances where the depositions of fact witnesses are noticed in these proceedings and cross-noticed in any related State Court actions, or *vice versa*, it is this Court's intention that such cross-notices shall be encouraged, to the extent possible, in order to avoid such witnesses being deposed more than once. Any deposition taken in any State Court action of such witnesses may be cross-noticed in this MDL by agreement of Plaintiffs' Counsel and Defendants' Counsel and thereafter, may be used in these proceedings, as

permitted by federal law, or by agreement of Involved Counsel. Without such agreement, the notice is subject to motion to quash and subject to strike. Once a deposition has been noticed and taken in the MDL proceedings, then the Plaintiffs in the MDL proceedings may not take a subsequent deposition of that witness in the MDL proceeding, except for good cause shown as determined by this Court and contemplated by the Federal Rules of Civil Procedure or upon consent of Plaintiffs' Counsel and Defendants' Counsel. In such instances, the subsequent deposition shall be restricted to such additional inquiry permitted by the Court or agreed upon by the Plaintiffs' Counsel and Defendants' Counsel.

**F. Length and Scope**

This Court establishes the following criteria to govern the length and scope of deposition within the MDL proceeding which shall govern in lieu of the Federal Rules of Civil Procedure as to length and scope.

Depositions scheduled after issuance of this Order shall be in accordance with the following protocol:

1. If there is no coordination with the state court litigants for a deposition originating from the state courts, any depositions noticed within the MDL by plaintiffs shall be governed by the Federal Rules of Civil Procedure and its length and scope requirements. (7 hours)
2. If there is coordination and agreement by the MDL plaintiffs with state court litigants within a deposition either noticed or originated in the state court, any depositions scheduled by the MDL plaintiffs in the MDL case thereafter shall be 12 hours and limited to new documents, obtained 30 days (or later), preceding the deposition date, new subjects, and follow up lines of inquiry. Counsel are

cautioned Federal Rule of Civil Procedure 30 remains applicable to viable objections.

Participation by MDL plaintiffs in a deposition originating in the state court does not preclude the scheduling of a supplemental deposition within the MDL, however, said depositions shall be conducted pursuant to the Order of this Court.

Additionally, participation in deposition discovery as delineated within this Order does not preclude the taking of a trial deposition for those cases which might be remanded to the transferor court.

Questioning by Takeda and Eli Lilly, and off the record time, shall not count against any applicable limits. Sufficient time shall be reserved for all counsel designated pursuant to Paragraph VI.B.4.a of this Order to conduct examinations; no designated counsel shall be denied arbitrarily the opportunity to examine. Counsel designated pursuant to Paragraph VI.B.4.a of this Order need not cross-notice any deposition to be entitled to examination time. Consequently, Involved Counsel shall coordinate when taking depositions in order to honor any applicable limitations.

**G. Scheduling.**

**1. Number of Depositions.**

No more than eight (8) depositions of common fact witnesses currently or formerly employed by any of the Takeda and Eli Lilly Entities shall be taken per month, absent agreement of the Parties or order of the Court. Such limitation shall include any depositions conducted pursuant to Federal Rule of Civil Procedure 30(b)(6). Depositions, commonly referred to as “30(b)(6) depositions,” which seek to obtain information regarding general matters such as corporate structure, personnel in relevant departments, discoverable data bases and/or



who might be discoverable witnesses and/or where and how discoverable information is located and maintained, may be noticed at any time following entry of this order.

**2. Parties to Meet and Confer on Scheduling.**

Absent extraordinary circumstances, Involved Counsel shall consult in advance with proposed deponents in an effort to schedule depositions at mutually convenient times and places. Notices of depositions to be conducted pursuant to Federal Rule of Civil Procedure 30(b)(6) may be served as of the entry of this Order. Involved Counsel shall work cooperatively to ensure a fair and orderly process for the scheduling of depositions.

**1. Deposition Notices Must Be Served At Least Twenty-One Days in Advance.**

Plaintiffs' Counsel shall notice depositions of witnesses currently or formerly affiliated with the Takeda and Eli Lilly Entities as soon as practicable after the Parties agree to dates and locations for the depositions, but in no event shall a notice be issued less than twenty-one days before the deposition is set to occur, except upon written agreement of all Involved Counsel or order of this Court. Plaintiffs' Counsel may notice and serve such depositions via e-mail.

**4. Postponements.**

Once a deposition has been mutually scheduled by the Parties, it shall not be taken off the calendar, rescheduled, or relocated less than three calendar days in advance of the date it is scheduled to occur, except upon agreement among the examiner designated by the party noticing the deposition and Lead Counsel for the opposing party and counsel for the witness, or by leave of Court for good cause shown.

**H. Attendance at Depositions.**

1. **Who May Attend.** Unless otherwise agreed to by the parties, depositions may be attended only by the parties, the parties' counsel, the deponent, the deponent's attorney, in-house counsel for the parties, court reporters, videographers, and essential members and/or employees from the law firms of counsel of record. Unnecessary attendance in person or by telephone by non-examining counsel is discouraged and the presumption will operate that such attendance may not be compensated in any common benefit fee application to the Court without good cause shown to the Court prior to such duplicative attendance. Any such request shall be submitted to the Court (through Deputy Special Master DeJean) in a manner and in sufficient time to allow the Court reasonable opportunity to respond, but in no case shall a request be made later than 15 days prior to the scheduled start of the deposition.

2. **Notice of Intent to Attend a Deposition.** In order for Defendants' Lead Counsel to make arrangements for adequate deposition space and to notify building security, all counsel who intend to attend the deposition of a witness currently or formerly affiliated with the Takeda and Eli Lilly Entities shall advise Plaintiffs' Co-Lead Counsel no fewer than three business days prior to the deposition. Counsel shall promptly pass this information along to Defendants' Lead Counsel.

I. **Treatment of Confidential Documents or Testimony.** While a deponent is being examined about any document that is confidential because (i) the parties have so agreed, (ii) a party has designated the document to be confidential pursuant to the Protective Order associated with this litigation, or (iii) the Court has so ordered, attendance at that portion of the deposition by persons to whom disclosure is not authorized by agreement of the parties or by order of the Court shall be prohibited. Any portion of the deposition transcript

containing confidential information shall be sealed pursuant to this Court's Protective Order. Sealed portions of deposition transcripts may be opened, read, and utilized for only those purposes permitted by the terms of this Court's Protective Order, or, if applicable and appropriate, also any protective order entered in a State Court action where the transcript is being used.

**J. Examiners.**

**1. Designation of Examiners for Plaintiffs.**

The deposing party may designate no more than two attorneys to examine a deponent. When two attorneys are designated to participate in a deposition, the subjects covered by each shall be allocated in a manner that ensures that there will be no overlap between the two assignments. Duplicative, overlapping, or redundant questioning will not be permitted. State Plaintiffs' Counsel, if participating in an MDL-noticed deposition, whether by agreement of all relevant parties or by Order of this Court, may designate only one examiner from each State in which any litigation might be pending, however, examination should not be duplicative. The PSC, shall meet and confer with the State Plaintiffs' Counsel, if participating, with respect to such designations and coordination as to the applicable limitations, where possible.

**2. Notice of Examiners.**

At least three business days prior to the deposition, Plaintiffs' Counsel shall notify Defendants' Counsel of the PSC plaintiffs' examiner(s) designated pursuant to ¶ VI.B.4.a. If unforeseen circumstances require a change of an examiner(s) after such notification, Plaintiffs' Counsel must notify Defendants' Counsel of the change immediately upon learning of the necessity for the change. Such a change alone shall not be cause for postponing the deposition.

### **3. Sharing of Time.**

The examining attorneys designated by the PSC and the State Plaintiffs' Counsel, if any, shall meet and confer for the purpose of determining how time shall be shared, the order of questioning, and responsibility for objections; it is anticipated multiple objections on a given point or question by multiple plaintiffs' attorneys will be discouraged. Such coordination is intended to ensure all designated counsel have an appropriate amount of time to protect their clients' interests. If agreement cannot be reached, counsel are to notify the Court, through the Special Masters, for assistance in setting the terms of any particular deposition no later than five (5) days before commencement of the deposition.

### **4. Coordination of Examination Issues**

The Plaintiffs' attorneys designated to conduct the examination by the PSC and the State Plaintiffs' Counsel, if any, shall coordinate, where practicable, with each other so as to conduct as thorough and non-duplicative an examination as is possible. Any Plaintiffs' Counsel in any related federal or state action who is not so designated may suggest matters for inquiry in any deposition noticed in these actions by providing to the PSC, or the State Plaintiffs' Counsel, if any, or their designee, a written list and brief explanation of such matters. The examiner designated by the State Plaintiffs' Counsel, if any, may cover the same *topics or issues* covered by the examiner designated by the PSC, and *vice versa*, but the later examining counsel may not ask duplicative questions unless agreed to by all Involved Counsel or by order of this Court.

### **5. Use of Depositions in MDL and State Court Proceedings.**

Any examination conducted by any examiner may be used in the MDL proceedings, consistent with the law, Federal Rules of Civil Procedure and Evidence, agreement of all Involved Counsel, and order or order(s) of this Court.

**K. Sequence of Examination.**

In the absence of any alternative agreement by Involved Counsel, questioning at the depositions will be conducted in the following sequence for depositions noticed by the PSC in the MDL: (i) the examiners designated by the PSC and by the State Plaintiffs' Counsel, if any, in the order to which they agree in advance of the deposition ; (ii) counsel for the Takeda and Eli Lilly Entities; (iii) individual counsel for the deponent, if any; and (iv) any re-cross and/or redirect by such counsel, in the same order.

Questioning at the depositions will be conducted in the following sequence for depositions noticed by Defendants' Counsel: (i) counsel for the Takeda and Eli Lilly Entities; (ii) the examiners designated by the PSC and by the State Plaintiffs' Counsel, if any, in the order to which they agree in advance of the deposition; (iii) individual counsel for the deponent, if any; and (iv) any re-cross and/or redirect by such counsel, in the same order.

**L. Objections.**

**1. How Objections Made.**

Objections shall be made only by counsel designated pursuant to Paragraph VI.B.4.a of this Order, plus individual counsel for the deponent (if any), and shall be made by stating, "Objection" and the legal basis for the objection (limited to the legal bases described below) in a concise manner. For the purposes of this Court, an objection by designated counsel shall be deemed to apply to all non-designated counsel for purposes of the deposition and future use of the deposition.

**2. Bases for Objections.**

No objection shall be made during the taking of a deposition except to assert the following grounds, as reflected in the Federal Rules of Evidence: (i) the form of a question

including leading; (ii) responsiveness of the answer, (iii) a privilege; (iv) a right to confidentiality; (v) a limitation imposed pursuant to a previously entered court order; or (vi) a question is argumentative, harassing or abusive including “asked and answered.” In connection with an objection to the form of the question, the examiner may inquire as to the grounds for the objection in order to allow the amendment of the question.

### **3. Objections Preserved.**

All objections, except as to (i) the form of the question including leading, (ii) the responsiveness of an answer, or (iii) the assertion of a privilege shall be preserved for later ruling by the applicable court(s) in which the deposition testimony is offered and may be asserted in connection with the proffer of the deposition testimony at trial. Objections as to the admissibility of documents introduced during a deposition are not waived by failure to raise the objection during the deposition, but rather are preserved for later ruling upon timely assertion of the objection by this Court, or by the applicable trial judge.

#### **M. Consultation with Witness.**

A witness may consult with his or her counsel or counsel for either party during a deposition. When a question is pending, the witness must first answer the question before consulting with any counsel, except that the witness and counsel may consult at any time for the purpose of determining whether a privilege exists or whether the information sought is subject to an applicable protective order.

#### **N. Videotaped Depositions.**

##### **1. Right to Videotape Depositions.**

Any party shall have the right to request that the deposition of any party or witness be recorded on videotape and such written request shall be provided with the deposition notice.

Where the party wishing to videotape did not notice the deposition, a request for video tape recording shall be submitted to the PSC, no later than ten (10) days before the date on which the deposition is scheduled to occur. All videotaped depositions shall be accompanied by a simultaneous audio tape and stenographic transcript.

**2. Videography Technicians.**

The party giving notice that the deposition will be videotaped shall assure that all video technicians who record the deposition possess the skills, experience, and equipment necessary to understand and comply with this Order and any further Order relating to the equipment and techniques to be used. Counsel for that party shall provide a copy of this Order and any other applicable orders to the video technicians no later than five (5) days prior to the deposition.

**3. Video Operator's Services Must Be Offered Equally.**

Services and products offered or provided by the video operator or the entity providing the services of the video operator to any party or to any party's attorney or non-party who is financing all or part of the deposition shall be offered or provided to all parties or their attorneys attending the deposition in the same manner as offered to the party financing all or part of the deposition. No service or product may be offered or provided by the video operator or by the entity providing the services of the video operator to any party or any party's attorney or nonparty who is financing all or part of the deposition unless the service or product is offered or provided to all parties or their attorneys attending the deposition in the same manner and fashion. All services and products offered or provided shall be made available at the same time and on the same terms to all parties or their attorneys.

**4. Video Operator.**

The operator(s) of the videotape recording equipment shall be subject to the provisions of Fed. R. Civ. P. 28(c). At the start of the deposition, the operator(s) shall swear or affirm to record the proceedings fairly and accurately.

**5. Video Operator Shall Not Comment on Demeanor.**

The video operator and the organization providing the video and audio services shall not provide to any party or any other person or entity any service or product consisting of their notations or comments regarding the demeanor of any witness, attorney, or party present at the deposition. The video operator and the organization providing the video and audio services shall not collect any personal identifying information about the witness as a service or product to be provided to any party or non-party in any way whatsoever.

**6. No Distortion.**

The camera operators shall not distort the appearance or the demeanor of participants in the deposition by the use of camera or sound recording techniques, or by zooming in or out, or manipulation of the sound or picture in any manner whatsoever.

**7. Confidentiality.**

Videographer and Court Reporter shall be bound by the Protective Order or any other order issued by this Court. Any party obtaining copies of exhibits or copies of the transcript or videotaped depositions must sign a written acknowledgement of the application of any Protective Order that might apply to material within that deposition. It is anticipated this acknowledgement will mirror the verbal affirmation given by all present at the deposition. No person shall sell or provide any copy of any discovery to anyone without receiving express written permission of Plaintiffs' Counsel and Defendants' Counsel.



**8. Attendance.**

Each witness, attorney, and other person attending the deposition shall be identified on camera at the commencement of the deposition. Thereafter, absent further order of the Court, only the deponent (and any demonstrative materials and exhibits used during the deposition, which may be taped via split screen) will be videotaped.

**9. Oath and Identification of Attendees.**

The oath shall be administered to the deponent on camera and on the audio recording and all individuals, including the videographer and Court Reporter, shall affirmatively acknowledge the application of any protective order that might apply.

**10. Standards.**

The deposition will be conducted in a manner to replicate, to the extent feasible, the presentation of evidence at a trial. Unless physically incapacitated, the deponent shall be seated at a table or in a witness box except when reviewing or presenting demonstrative materials for which a change in position is required. To the extent practicable, the deposition will be conducted in a neutral setting, against a solid background, with only such lighting as is required for accurate video recording. Lighting, camera angle, lens setting, and field of view will be changed only as might be necessary in order to record accurately the natural body movements of the deponent or to portray exhibits and materials used during the deposition. Sound levels will be altered only as necessary to record satisfactorily the voices of counsel and the deponent. Eating and smoking by deponents or attendees during the deposition will not be permitted.

**11. Interruptions.**

Videotape recording will be suspended during all “off the record” discussions and shall note such suspension.

## **12. Conclusion of Deposition.**

At the conclusion of a deposition, a statement shall be made on camera or on the audio recording that the deposition is ended where and when agreed to by the parties and shall set forth any stipulations made by counsel concerning the custody of the audio or video recording, the transcript, and the exhibits, as well as any other pertinent matters, in particular addressing any material subject to a protective order or privilege.

## **13. Preservation of Original Media.**

The video operator shall preserve custody of the original video medium in its original condition until further order of the Court. No part of the video or audio record of a video deposition shall be edited in any fashion, or released or made available to any member of the public unless authorized by the Court or pursuant to the terms of the Protective Order or other Order of this Court.

## **14. Index.**

The videotape operator shall use a counter on the recording equipment and after completion of the deposition shall prepare a log, cross-referenced to counter numbers, that identifies the positions on the tape at which examination by different counsel begins and ends, objections are made and examination resumes, and at which exhibits are identified, as well as any interruption of continuous tape recording, whether for recesses, "off the record" discussions, mechanical failure, or otherwise.

## **15. Use of Depositions at Trial.**

Prior to any trial, Plaintiffs' Counsel and Defendants' Counsel shall meet and confer with respect to the use of any videotaped deposition testimony or deposition exhibits (including exhibits displayed through trial software such as Trial Director, Summation, or Concordance).

The procedures for and manner of display of any such testimony or exhibits to the jury at trial shall be the subject of a further order by this Court or the applicable trial court.

**O. Use of Exhibits.**

**1. Paper Copies of Exhibits at Deposition.**

Extra paper copies of documents about which counsel plan to examine the deponent shall be provided to counsel for the deponent and counsel for the other party participants reasonably expected to attend, during the course of the deposition if not before. To the extent possible, all exhibits shall have printed bates numbers affixed, which shall remain constant throughout the litigation.

**2. Marking of Deposition Exhibits.**

All exhibits will be marked for identification by using the deponent's last name and a sequential number beginning with 1 (*e.g.*, Smith-1 and by reference to the Bates number of the first page of the exhibit being referenced). If a document is used in more than one deposition, it must be marked in each deposition in the manner noted with the original and consistent Bates stamp number; it is anticipated the Bates number shall remain constant throughout the litigation. All documents marked as exhibits will be attached to the original transcript and will be retained with the original transcript. Copies of exhibits may be attached to copies of the transcript where the party ordering the transcript pays for the costs of copying those exhibits.

**3. Exhibits without Bates Stamps.**

Deposition exhibits that have not been previously produced in the litigation or previously assigned a bates stamp number, shall be assigned a bates stamp number from a range of numbers reserved for this purpose. The first time such a document is referenced as an exhibit at a deposition, it shall be marked with the assigned bates stamp number and shall be placed in the

depository at the conclusion of the deposition and shall retain that bates stamp number throughout the litigation. Bates stamp numbers shall not be duplicated.

**P. Time to Review Transcript.**

Each deponent has the right to read and sign the deposition transcript within forty-five days after receipt of the transcript from the court reporter. This time period shall not be extended, absent good cause shown. Should the deponent fail to sign the transcript within forty-five days, all parties have the right to use a copy of the transcript in the manner provided by this Court as though the copy were the original transcript. Should the deponent fail to sign the errata sheet within forty-five days, the transcript will be deemed to have been read and approved by the deponent. In the event the original transcript is unsigned, lost, or inadvertently destroyed, a certified copy reflecting any changes made to the original transcript may be used in place of the original.

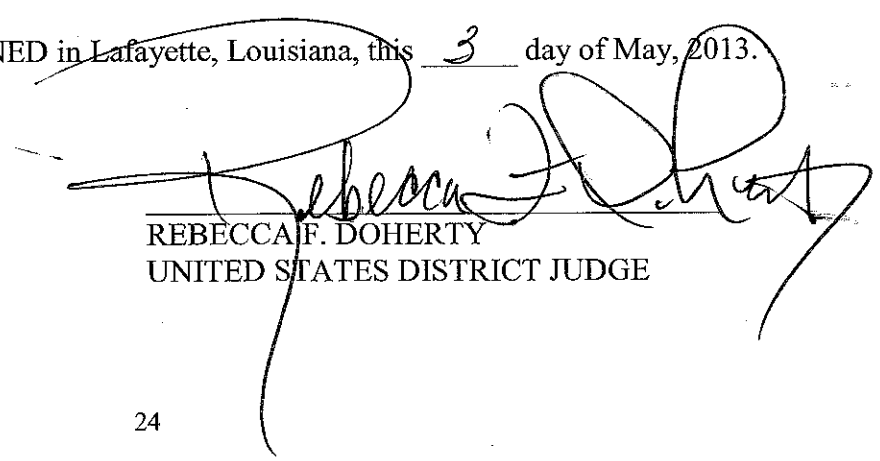
**VI. MODIFICATION**

This Order is subject to modification by agreement of the Plaintiffs' Counsel and Defendants' Counsel parties, subject to Court approval, or by further order of this Court.

**VII. DISCOVERY STAY**

Upon entry of this Order the Discovery Stay in these MDL proceedings is lifted for all purposes, allowing for discovery consistent with this and future orders.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 3 day of May, 2013.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

**IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Cases

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:  
BELLWETHER NOMINATIONS**

In light of recent developments, this Court hereby modifies the bellwether nomination process established in the “Scheduling Order: Pilot Bellwether Program (First Trial),”<sup>1</sup> as amended.<sup>2</sup>

**BELLWETHER IDENTIFICATION PROCESS**

The bellwether nominee pool is hereby reduced to eight: four nominations by the Plaintiffs and four nominations by the Defendants. The nominations, and follow-up procedures, are as follows:

**5/6/2013:** Each side shall finalize nominations, as follows:

- *The Plaintiffs’ current bellwether nominee pool shall be reduced from five (5) to four (4). The Plaintiffs shall identify the bellwether nominee whose case will be removed from the pool by 4:00 p.m. central on Monday, May 6, 2013.*
- *The Defendants have identified three additional bellwether nominees and will reduce that number to two, for a total of 4 nominees. The Defendants shall identify the bellwether nominee whose case will be removed from the pool by 4:00 p.m. central on Monday, May 6, 2013.*

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<sup>1</sup> Rec. Doc. 2359.

<sup>2</sup> Rec. Doc. 2602; “Second Amended Scheduling Order: Pilot Bellwether Program (First Trial),” issued May 3, 2013.

The two additional bellwether nominees shall hereafter in this order be referenced as the "new nominees."

- ***Simultaneous with identifying the new nominees***, the Defendants shall certify that: (i) counsel has reviewed all available information about the nominee; and (ii) counsel believes that the nominee's case can be ready for trial by April 14, 2014.
- In addition to the foregoing certifications by Defense counsel, each new nominee's lead counsel shall certify as follows: (i) counsel intends that the nominee's case be tried, if accepted by this Court; (ii) counsel does not intend to dismiss the nominee's case; (iii) counsel has no reason to believe that the nominee's case will be settled individually prior to trial; and (iv) counsel shall inform the Court, by way of certification, as to whether the nominee will waive their right, as applicable, to venue or to have non-Louisiana cases remanded to transferor courts for trial (*the Lexecon issue*). ***These certifications shall be filed into the record by May 10, 2013.***

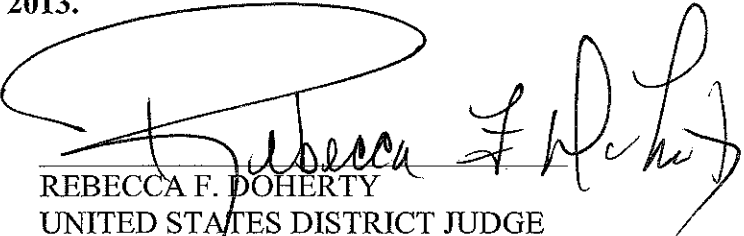
**5/10/2013:** Defendants shall notify the PSC, with regard to the Pilot Bellwether Discovery Pool nominees, of any gap in the ***essential preliminary discovery*** required by this Court's Case Management Order: Plaintiff Fact Sheets (Rec. Doc. 1355).

**5/28/2013:** Plaintiffs shall ***cure any deficiencies*** in essential preliminary discovery on Pilot Bellwether Discovery Pool nominees.

**5/31/2013:** Pilot Bellwether Discovery Pool Nominees may ***move for leave to amend their complaints***.<sup>3</sup>

***Except as expressly modified in this order, the bellwether-related provisions in the Scheduling Order: Pilot Bellwether Program (First Trial), as amended, shall remain in force and effect.***

SO ORDERED, this 3 day of May, 2013.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

<sup>3</sup> In filing any motion for leave to amend, counsel are cautioned to comply with Local Rule 7.6.

APR 23 2013

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Cases

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**FIRST AMENDED SCHEDULING ORDER:  
PILOT BELLWETHER PROGRAM (FIRST TRIAL)<sup>1</sup>**

This Court having considered the scope of these proceedings, the number of plaintiffs, the amount of discovery that will be required, and the time necessary to complete pre-trial preparations, hereby establishes a Pilot Bellwether Program [“PBP”]. The PBP establishes a stream-lined trial preparation schedule for a minimum of two Pilot Bellwether trials. This Court is aware that the schedule established herein will place extraordinary burdens on this Court, counsel, and the parties. Nonetheless, this abbreviated schedule is imposed so as to serve the very important goal of moving these proceedings toward completion of this Court’s responsibilities in a reasonable timeframe.

**PLEASE NOTE: THE DEADLINES ESTABLISHED HEREIN SHOULD BE CONSIDERED HARD AND FAST. THEY WILL NOT BE EXTENDED, CONTINUED, OR DELAYED BY THE COURT IN ANY WAY ABSENT EXTRAORDINARILY GOOD CAUSE SHOWN.<sup>2</sup>**

<sup>1</sup> This amendment affects only those deadlines associated with *Daubert* motions, the Expert Roundtable/*Daubert* evidentiary hearing, and the PreTrial Order, all of which are found on Pages 4-5 of the instant Order.

<sup>2</sup> As to deadlines that impact this Court’s ability to complete its tasks – tasks such as briefing deadlines – the parties are expected to comply with all deadlines or obtain extensions from the Court. However, with regard to deadlines that do not have an immediate impact on the Court’s ability to perform its tasks, the parties are permitted to grant extensions to each other, but should be advised that such extensions will not be enforced by this Court.

**Trial Date (1<sup>st</sup> Pilot Bellwether Trial):** *January 27, 2014*  
**Pre-Trial Conference:** *January 13, 2014, 10:00 am*

**Trial Date (2<sup>nd</sup> Pilot Bellwether Trial):** *April 14, 2014*  
**Pre-Trial Conference:** *March 31, 2014, 10:00 am*<sup>3</sup>

#### DEADLINES

- 2/28/2013:** Plaintiffs shall provide a complete set of all *requests for production* of documents to Defendants.
- 3/25/2013:** The Court shall establish a *schedule for anticipated motions and briefing of legal issues*.
- 4/1/2013:** Each side shall nominate *Pilot Bellwether Discovery Pool* participants, as follows.
- Each side will nominate 5 plaintiffs to participate in discovery.
  - The only plaintiffs eligible to be included in the discovery pool will be plaintiffs who submitted Plaintiff Fact Sheets to the Defendants by December 31, 2012.
  - To the extent that a plaintiff wishes to participate in the discovery pool but has not complied with the December 31, 2012 deadline, he or she may participate if, and only if, a completed fact sheet and authorizations, together with a complete set of medical records, can be produced to the Defendants no later than *March 8, 2013*.

The following additional limitations shall apply to the Pilot Bellwether Discovery Pool nominees:

- (a) No plaintiff who has asserted a class action is eligible for participation as a member of the Pilot Bellwether Discovery Pool.
  - (b) No plaintiff may be a nominee unless he or she: (i) actually consumed Actos; (ii) has been diagnosed with diabetes; and (iii) has been diagnosed with bladder cancer (no fear of cancer case).
- Nominating counsel shall certify, with regard to every Pilot Bellwether Discovery Pool nominee, that: (i) counsel has reviewed all available information about the nominee; (ii) counsel believes that the nominee's case can be ready for trial by January 27, 2014 (or, in the case of Defendants' nominees, April 14, 2014); (iii) counsel intends to try the

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<sup>3</sup> A separate Scheduling Order providing deadlines for the second Pilot Bellwether trial has been issued.



nominee's case, if accepted by this Court; (iv) counsel does not intend to dismiss the nominee's case; and (v) counsel has no reason to believe that the nominee's case will be settled individually prior to trial.

- 4/8/2013:** With regard to the Pilot Bellwether Discovery Pool nominees, Defendants shall notify this Court and Co-Lead Counsel whether or not they waive their right, as applicable, to venue or to have non-Louisiana cases remanded to transferor courts for trial (*the Lexecon issue*).
- 4/8/2013:** Defendants shall notify the PSC, with regard to the Pilot Bellwether Discovery Pool nominees, of any gap in the *essential preliminary discovery* required by this Court's Case Management Order: Plaintiff Fact Sheets (Rec. Doc. 1355).
- 4/22/2013:** Plaintiffs shall *cure any deficiencies* in essential preliminary discovery on Pilot Bellwether Discovery Pool nominees.
- 4/23/2013:** Pilot Bellwether Discovery Pool Nominees may *move for leave to amend their complaints*.<sup>4</sup>
- 5/3/2013:** Parties to exchange first *witness and exhibit lists*.<sup>5</sup> "Witnesses" shall include factual witnesses as well as experts, identified by area of expertise (deadline for identifying experts by name is separate). *Updates due the first day of each month thereafter*. No witness or exhibit may be added without leave of Court once the discovery deadline has passed; however, witnesses and exhibits may be removed through January 2, 2014. Counsel are cautioned that, in creating witness and exhibit lists, good faith is expected at all times.
- 6/3/2013:** Defendants must *certify good-faith belief* that all documents requested by the Plaintiffs, agreed by the Defendants to be produced, and/or ordered by this Court, have been produced or will be produced within ten (10) days of this date.
- 7/15/2013:** Plaintiffs' shall *identify their nominee* for the first trial. Defendants shall *identify their nominee* for the second trial.
- 8/1/2013:** *Expert-Related Deadlines* Begin

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<sup>4</sup> In filing any motion for leave to amend, counsel are cautioned to comply with Local Rule 7.6.

<sup>5</sup> This requirement is imposed in lieu of the Fed. R. Civ. Pro. 26(f) reporting requirement.

Plaintiffs' Deadlines	Defendants' Deadlines
<b>8/1:</b> Plaintiffs to identify experts and produce background information ( <i>See Fed. R. Civ. Pro. 26(a)(1)(B)(iv-vi)</i> )	<b>8/26:</b> Defendants to identify experts and produce background information ( <i>See Fed. R. Civ. Pro. 26(a)(1)(B)(iv-vi)</i> )
<b>8/7:</b> Plaintiffs to produce expert reports	<b>9/3:</b> Defendants to produce expert reports
<b>9/5 through 10/4:</b> Plaintiffs' expert depositions <sup>6</sup>	<b>9/5 through 10/4:</b> Defendants' expert depositions

**10/11/2013:** Deadline for *supplementation, if any, of expert reports and completion of supplemental expert depositions*, if any. In light of the fact that expert reports must be produced prior to the completion of discovery, supplementation of reports and depositions will be permitted (pursuant to Fed. R. Civ. Pro. 26(a)(1)(D)) in order to respond to factual information discovered after an original report is issued.

**10/1/2013:** *Discovery* Deadline<sup>7</sup>

**10/14/2013:** Motions Deadline Begin (*limine, any remaining dispositive motions*)

Motions: **10/14**

Oppositions: **11/1**

Replies: **11/8<sup>8</sup>**

**10/17/2013:** *Deposition Excerpt Designations* Deadlines Begin

Plaintiffs' Deadlines	Defendants' Deadlines
<b>10/17:</b> Plaintiffs to produce excerpt designations, if any	<b>10/28:</b> Defendants to produce excerpt designations, if any
<b>11/11:</b> Plaintiffs' objections to Defendants' designations and counter-designations	<b>10/31:</b> Defendants' objections to Plaintiffs' designations and counter-designations

<sup>6</sup> Depositions of Plaintiffs' experts shall occur before depositions of Defendants' experts within the same discipline.

<sup>7</sup> Counsel are expected to schedule and sequence discovery so as to permit all deadlines to be met. This Court's Special Masters, as well as Magistrate Judge Hanna, will be available to assist the parties in such scheduling should it prove necessary. Moreover, if a separate Order is necessary, counsel should notify this Court, through the Special Masters.

<sup>8</sup> The parties shall have 10 days following "service" of all reply briefs to resolve any matters concerning privilege or confidentiality pursuant to paragraph 10 of the Protective Order (*i.e.*, Case Management Order: Protecting the Confidentiality of Discovery Materials).

No replies will be permitted. This Court will determine whether and, if so, when argument will be heard on the admissibility of deposition excerpts.

**10/21/2013:** Motions Deadline Begin (*Daubert* motions)

Motions: 10/21  
Oppositions: 11/18  
Replies: 11/25<sup>9</sup>

**12/11/2013:** *Expert evidentiary hearing* (to address *Daubert*, all other expert-related objections, and all expert-related pre-trial issues)

**1/2/2014:** Final *identification* of **will-call witnesses** (and the substance of their testimony) and *identification and exchange* of all **exhibits** (and the purpose for which they are offered).

**1/6/2014:** Deadline for completing *Trial Depositions*

In an effort to streamline trial preparation as much as possible, the *Court expects the parties to make significant efforts to produce witnesses for trial* rather than relying on deposition testimony. To the extent that trial depositions are necessary, they must be completed by this date.

**1/6/2014:** *Pre-trial order*

Attached to this Order is a modified version of this Court's standard pre-trial order form, together with instructions on completing the PreTrial Order. Counsel are strongly encouraged to consult with the Special Masters for guidance, instructions, and assistance in preparing the PreTrial Order.

**1/13/2014:** *Pre-trial conference*

**1/22/2014:** *Bench books*  
*Glossary*  
*Training for electronic courtroom*<sup>10</sup>

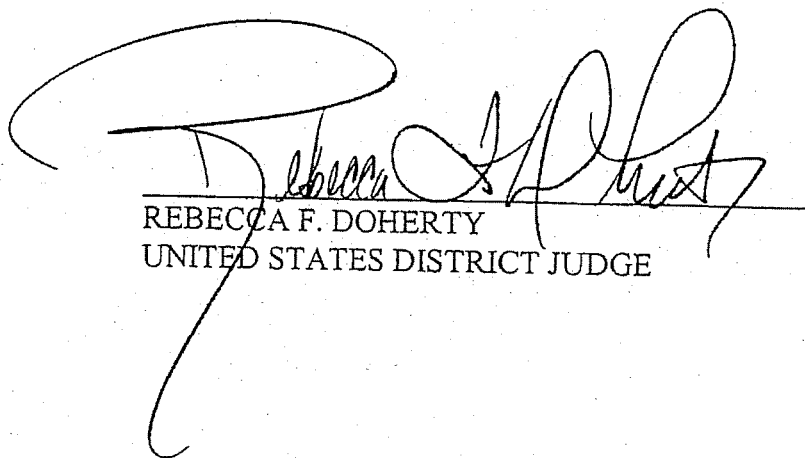
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<sup>9</sup> The parties shall have 10 days following "service" of all reply briefs to resolve any matters concerning privilege or confidentiality pursuant to paragraph 10 of the Protective Order (*i.e.*, Case Management Order: Protecting the Confidentiality of Discovery Materials).

<sup>10</sup> This is the deadline by which training must be completed, but counsel are encouraged to schedule such training earlier than January 22, 2014. Counsel must bring to the training the laptops that they intend to use for the presentation of exhibits.

1/27/2014: Trial of the first bellwether case.

SO ORDERED, this 23 day of April, 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

**PRETRIAL ORDER REQUIREMENTS**  
**U.S. District Judge Rebecca F. Doherty**

**1. Claims and Responses [In Outline Form]**

Plaintiff(s) shall identify each and every claim that he or she asserts as to each Defendant, with regard to each claim, shall identify: (a) the law that applies to such claim; (b) the remedy sought from that Defendant; and (c) the law supporting the availability of the requested remedy from that Defendant.

Defendant(s) shall provide a response to each claim that has been asserted, identifying the following information: (a) any challenge to the legal basis for each claim; (b) all affirmative defenses asserted in response to each claim and the legal bases therefor, (c) whether the dispute as to each claim is one of law or fact; and (d) the law supporting the responses.

When jurisprudence is cited in support of any claim, remedy, defense, or allegation discussed in this section, the citation shall include point cites.

**FAILURE TO INCLUDE A CLAIM OR DEFENSE IN THIS ORDER WILL BE DEEMED AN ABANDONMENT OF THE CLAIM OR DEFENSE.**

**2. Procedural History and Posture**

The parties shall set out the procedural history of the case, including (a) *disposition* of motions filed, and ruling (*i.e.*, granted or denied); (b) a list of any *pending* motions, and document number; and (c) the status of venue objections or waivers. To the extent that written venue waivers (including those addressed by Lexecon, Inc. v. Milberg, Weiss, Bershad, Hynes & Lerach, 523 U.S. 26, 118 S.Ct. 956, 140 L.Ed.2d 62 (1998)) have not previously been submitted into the record, such written waivers must be included in the PreTrial Order.

**3. Issues of Law, if any remain**

Identify any TRUE issues of LAW that remain unresolved as of the pretrial conference.

**4. Any Remaining Anticipated Evidentiary Issues**

Each party shall identify any remaining anticipated evidentiary issues which are unresolved as of the pretrial conference.

**5. Thumbnail Sketch of Facts**

Each party shall give a BRIEF (*i.e.*, two or three paragraphs only) thumbnail sketch of the **specific facts** that support its claim(s) as to each Defendant or defense(s) of each Defendant.

6. **Witnesses**

Each party shall set out a **will call**<sup>1</sup> witness list, which conforms to the privacy concerns addressed at FED. R. CIV. P. 5.2. Additionally, with regard to each witness, the list shall: (a) indicate whether the witnesses will be testifying live, by deposition transcript, or by deposition video; (b) include a brief description of the testimony of each witness, and (c) identify the purpose for which the testimony is being presented.

Counsel should be aware that the Court discourages the use of duplicative witnesses.

7. **Exhibits**

Each party shall provide a **will use**<sup>2</sup> exhibit list, which conforms with the privacy concerns addressed at FED. R. CIV. P. 5.2.

The Court will expect that the parties have complied with this Court's Scheduling Order: Pilot Bellwether Program (First Trial) (Rec. Doc. 2359) setting a deadline of January 2, 2014, for identifying and exchanging the documents intended to be used at trial.

8. **Objections to Witnesses and Exhibits**

List here any objections to the witnesses or exhibits of another party, including those objections contained in FED. R. CIV. P. 26(a)(3), *except objections as to relevance*. Exhibits will be *deemed authentic* unless an authenticity objection is explicitly made.

The Court will attempt to rule on as many objections as possible during the pretrial conference. With regard to exhibits, the Court will notify the parties of those exhibits that must be produced to the Court prior to the pretrial conference to facilitate the Court's consideration.

Any objections not specifically stated in the Pretrial Order, except as to relevance as noted above, are deemed waived unless excused by the court for good cause shown.

9. **Stipulations**

The Court encourages counsel to stipulate to all possible uncontested, legally relevant facts, as well as legal issues, in the interests of reducing costs and delays at trial. List here any matters to which the parties can stipulate and include those written stipulations, signed by each involved party's counsel. Counsel shall state whether the stipulations are to be read to the jury and when; therefore, the stipulations **MUST** be in writing.

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<sup>1</sup> The Court defines "will call" witnesses as those whom a party intends to call in its case-in-chief.

<sup>2</sup> The Court defines "will use" exhibits as those that a party intends to submit into evidence in its case-in-chief.

#### **10. Jury Instructions/Jury Interrogatories**

JOINT jury instructions and JOINT jury interrogatories shall be submitted as an attachment to the PreTrial Order. Additionally, the Court requires an electronic version of these documents. The parties must: (1) provide the Court with a CD-ROM, or submit an email attachment to the Actos law clerk, containing all jury instructions and jury interrogatories in WordPerfect format, and (2) provide a copy of same to the Special Masters in Word format. Jury instructions taken from the most recent edition of the Fifth Circuit Pattern Instructions need not be reproduced; rather, the parties may identify those instructions by number only.

If there is a dispute as to an instruction or interrogatory, the parties are to agree to the extent possible, and annotate the disagreement with proper page-specific citations to the jurisprudence being relied upon to support the party's position. If the dispute is one of fact to be proved at trial, the fact at issue shall be identified in an annotation and the language for an instruction supporting each factual scenario shall be attached, noting its application to that fact if found. **Parties are to be prepared to discuss disputes as to Jury Instructions and Interrogatories at the pretrial conference.**

#### **11. Voir Dire**

Proposed voir dire questions specific to a party or issue, if any, should accompany this order. Counsel shall not duplicate this Court's boilerplate voir dire, which already have been provided.

#### **12. Estimated Length of Trial**

The parties shall indicate the expected duration of trial, which includes jury deliberations and time for selecting a jury.

#### **13. Court and Court Reporter Materials**

**Counsel are directed to Scheduling Order: Pilot Bellwether Program (First Trial) (Rec. Doc. 2359) for applicable deadlines.**

**Bench Books.** The parties shall submit **two** bench books to Chambers, FOR THE EXCLUSIVE USE of the trial judge and her law clerk. *Please Note:* Exhibits contained in the *bench books will not be submitted into evidence.* Counsel must have **original exhibits (or agreed-to copies)** for submission into the record.

**Glossary.** The real time glossary shall be delivered **to the court reporter.** The glossary shall contain all key word indices from **all** depositions taken in the case, all witness lists, exhibit lists and copies of all expert reports. *See* example of a Real Time Glossary posted on our website at <http://www.lawd.uscourts.gov/>.

**Scanned Electronic Exhibits.** A CD-ROM containing all exhibits must be delivered to the Courtroom Deputy. Please refer to the "Guidelines for Submission of Exhibits on CD ROM"

posted on our website, at <http://www.lawd.uscourts.gov/>, or obtain a copy from the Clerk of Court's office.

If you have any further questions not answered in the sources cited above, please contact the Electronic Courtroom Coordinator for the Western District of Louisiana or the Judge's Courtroom Deputy, Christine Guidry, at (337) 593-5000.

#### **14. Counsel Affirmations**

The Pretrial Order shall contain the following affirmations:

- a. Trial counsel shall affirm, absent permission otherwise: (1) they will download their trial documents and exhibits to their personal equipment (or to an outside party's equipment hired for these purposes) and counsel will meet with the courtroom technology coordinator no later than seven days before trial, noting the scheduled date; or, (2) counsel will provide a CD-ROM containing the documents to the Courtroom Deputy and counsel will meet with the courtroom technology coordinator no later than seven days before trial, noting the scheduled date; or (3) counsel will affirm he or she is familiar with the Visual Presenter.
- b. The parties shall affirm they have complied with the supplementation requirements of FED. R. Civ. P. 26(e).
- c. Counsel shall affirm their understanding that failure to comply with any requirement of the Federal Rules of Civil Procedure, the Scheduling Order: Pilot Bellwether Program (First Trial) (Rec. Doc. 2359), or other orders of this court, will risk the imposition of the sanctions provided for by the Federal Rules of Civil Procedure.
- d. Counsel shall affirm their need, if any, for handicap provisions for themselves or any witness, which are provided by the court.
- e. Counsel shall affirm they, timely, will provide the real time glossary to the court reporter.



UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

PLAINTIFF

CIVIL ACTION NO.:

VERSUS

JUDGE DOHERTY

DEFENDANT

MAGISTRATE JUDGE HANNA

**PRETRIAL ORDER:**  
**FIRST PILOT BELLWETHER PROGRAM TRIAL<sup>1</sup>**

Trial Date: *January 27, 2014*

Pretrial Conference Date: *January 13, 2014 at 10:00 A.M. Central Time*

Type of Trial: JURY

Trial Attorney Attending:<sup>2</sup>

Party/Claim Represented:

_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

1. **Claims and Responses:**

2. **Procedural History and Posture:**

<sup>1</sup> A document containing definitions, explanations, and instructions concerning preparation of the PreTrial Order shall be provided herewith. Counsel are encouraged to consult with the Special Masters – all of whom have extensive experience preparing PreTrial Orders in Judge Doherty’s court – should they require any assistance.

<sup>2</sup>All trial counsel must attend the pretrial conference absent court order.

3. **Issues of Law, if any remain:**
4. **Any Remaining Anticipated Evidentiary Issues:**
5. **Thumbnail Sketch of Facts:**
6. **Witnesses:**
7. **Exhibits:**
8. **Objections to Witnesses and Exhibits:**
9. **Stipulations:**
10. **Jury Instructions/Jury Interrogatories:**
11. **Voir Dire:**
12. **Estimated Length of Trial:**
13. **Court and Court Reporter Materials:**
14. **Counsel Affirmations:**

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(Date)

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(Original or FAX Signatures of Trial Counsel)

APR 23 2013 *YJ*

**IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Actions

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**FIRST AMENDED CASE MANAGEMENT ORDER:  
Protecting the Confidentiality of Discovery Materials<sup>1</sup>**

For good cause shown, the Court issues the following Protective Order:

**1. Discovery Material.**

(a) This Order applies to all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise (collectively “discovery material”), by any party to this proceeding (the “Producing Party”) to any other party (the “Receiving Party”).

(b) At the time this Order is entered in the *In re Actos (Pioglitazone) Products Liability Litigation* (W.D. La., MDL No. 2299), it becomes binding upon all parties presently involved, or who are later named, in these proceedings including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, experts, consultants, representatives, directors, officers, employees, and others as set forth in this Order.

<sup>1</sup> This amendment effects only one change to the original order: it substitutes a new Exhibit A (“Endorsement”), one which eliminates the need for a notarial act in favor of allowing individuals to execute a declaration that comports with 28 U.S.C. § 1746.

(c) If additional parties are added other than parents, subsidiaries or affiliates of current parties to this litigation, their ability to receive Confidential Information as set forth in this Order will be subject to their being bound, by agreement or Court Order, to this Order.

(d). The entry of this Protective Order does not prevent any party from seeking a further order of this Court regarding Discovery Materials.

(e) Nothing herein shall be construed to affect in any manner the admissibility at trial or hearings before this Court of any document, testimony, or other evidence.

**2. Confidential Discovery Material.** “Confidential Discovery Material,” as used herein, means information of any type, kind or character that the Producing Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Rule 26(c)(1)(G), whether it is a document, information contained in a document, information revealed during a deposition or other testimony, information revealed in an interrogatory response, or information otherwise revealed. Discovery material containing trade secrets, or other confidential or proprietary research, development, manufacturing or commercial or business information may be designated by the Producing Party as “Confidential.” Without prejudice to the right of a Producing Party to object to the production of the following information or of a party to seek production and/or de-designation, examples of the information that may be alleged to be subject to such designation include but are not limited to the Producing Party’s:

a. Customer names and compilations of information related to opinion leaders and other consultants;

b. Proprietary licensing, distribution, marketing, design, development, research and manufacturing information regarding products and medicines, whether previously or currently marketed or under development (not to include disseminated marketing materials or materials that, on its face, was published to the general public);

c. Unpublished clinical studies, scientific literature, and related documents;

d. Information concerning competitors;

e. Production information;

f. Personnel records and information;

g. Financial information not publicly filed with any federal or state regulatory authorities or not contained within any publicly available quarterly or annual reports;

h. Private medical information that identifies a person unless such identifying information is redacted; and

i. Information submitted to any governmental or regulatory agency, which information is exempt from public disclosure.

**3. Discovery Material and Foreign Law.** Any entity organized under the laws of a country other than the United States, including but not limited to Japan, France, Germany, and the United Kingdom, that produces information in this litigation may designate as confidential those documents in any form (including electronic or paper

form) containing “Protected Data” within the meaning of the applicable data protection or privacy laws, if any.<sup>2</sup>

**4. Use of Confidential Discovery Material.**

(a) Any discovery material that is designated as “Confidential” in accordance with Paragraph 2 above, along with any copies, abstracts, summaries, excerpts, compilations thereof, or information derived from such discovery material, and any notes or other records regarding the contents of such discovery material (collectively “confidential discovery material”), shall not be used for any business or competitive purpose, except by the Producing Party, or for any other purposes whatsoever, other than the litigation of cases in this MDL, including post-MDL proceedings in transferor courts (hereinafter referred to collectively as “this litigation”), and for any other action brought by or on behalf of a former pioglitazone user alleging injuries or other damages therefrom (“Other Actos Lawsuits”), so long as all parties are bound by and subject to this Order or another judicially approved order that is identical to or the substantial equivalent to this Order. Confidential discovery material will not be disclosed except in accordance with paragraphs 4(b), 7, 10, and 11.

(b) Prior to being given access to confidential discovery material, any person falling within subparagraphs 7(a)(vi) or 7(a)(vii) shall be provided with a copy of

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<sup>2</sup> “Protected Data” shall refer to any information that a party believes in good faith to be subject to foreign data protection laws. Protected Data constitutes highly sensitive materials requiring special protection. Examples of such data protection laws include but are not limited to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L281/31) (European Union personal information); Data Protection Act 1998 (c. 29) (United Kingdom personal information); the German Federal Data Protection Act (Germany personal information); French Data Protection Act. Law No. 78-17 of January, 6, 1978, J.C.P. 1978, III, No. 44692; and The Personal Information Protection Act (Law No. 57 of 2003) (Japan personal information).

this Order and shall execute a copy of the Endorsement of Protective Order, attached as Exhibit A. Counsel providing such access to confidential discovery material shall retain copies of the Endorsement(s) of Protective Order and shall provide them to counsel producing confidential discovery materials as provided below. For testifying experts, a copy of the Endorsement of Protective Order executed by the testifying expert shall be furnished to counsel for the party who produced the confidential discovery material to which the expert has access.

**5. Designation of Confidential Discovery Material.**

(a) Confidential discovery material, if in writing, shall have the following language stamped on the face of the writing, or shall otherwise have such language clearly marked in the margins:

**“CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER”**

Such stamping or marking will take place prior to production by the Producing Party, or subsequent to selection by the Receiving Party for copying but prior to the actual copying if done expeditiously. The stamp shall be affixed in such manner in the margins as not to obliterate or obscure any written matter.

(b) To the extent that confidential discovery material is stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) (“Computerized Material”) is produced by any party in such form, the Producing Party may designate such matters as confidential by a designation of **“CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER”** on the media. Whenever any Receiving Party reduces such material to

hardcopy form, that party shall mark the hardcopy form with the corresponding “**CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER**” designation.

(c) In the case of deposition testimony relating to documents designated as confidential, the portion of the transcript in which confidential writings are offered, identified or discussed shall also be designated as confidential. Any additional confidentiality designations shall be made within thirty (30) calendar days after the transcript has been received by counsel making the designation, and shall specify the testimony being designated confidential by page and line number(s). Until the expiration of such thirty (30) day period, the entire text of the deposition, including exhibits, shall be treated as confidential under this Order.

(d) In the event that the Producing Party inadvertently fails to designate discovery material as confidential in this or any other litigation, it may make such a designation subsequently by notifying all parties to whom such discovery material was produced, in writing as soon as practicable. After receipt of such notification, the Receiving Party shall treat the designated discovery material as confidential, subject to that party’s right to dispute such designation in accordance with Paragraph 8.

**6. Consent to Jurisdiction.** All persons receiving or given access to confidential discovery material in accordance with the terms of this Order consent to the continuing jurisdiction of the Court for the purposes of enforcing this Order and remedying any violations thereof.

**7. Disclosure of Confidential Discovery Material.**

(a) Confidential discovery material shall not be disclosed to anyone other than the following categories of persons:



i. The Court (and any appellate court), including court personnel, Special Masters and members of their staffs, jurors, and alternate jurors only in the manner provided in paragraph 10 below.

ii. If produced by Plaintiffs, Defendants' in-house counsel, paralegals and clerical support staff, and outside counsel, including any attorneys employed by or retained by Defendants' outside counsel who are assisting in connection within this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel or retained by the attorneys employed by or retained by Defendants' outside counsel. To the extent a Defendant does not have in-house counsel, it may designate two individuals employed by each Defendant (in addition to outside counsel) to receive Confidential Discovery Materials produced by Plaintiffs.

iii. If produced by any Defendant, a Plaintiff in this litigation, Plaintiff's attorneys in this litigation, including the paralegal, clerical, secretarial and other staff employed or retained by such counsel. Additionally, confidential discovery material produced by any defendant in this MDL may be disclosed to the named plaintiff(s) in Other Actos Lawsuits, and their counsel, including paralegal, clerical, secretarial and other staff employed or retained by such other plaintiffs' counsel if: (a) the lawsuit alleges or involves injuries or damages resulting from the use of pioglitazone; and (b) an order identical to or the substantial equivalent to this Order has been entered in such lawsuit or all counsel for plaintiff who receive the documents agree to be governed by the terms of this Order and shall sign an Endorsement of Protective Order, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms. Further, confidential discovery material produced

by any defendant in this MDL may be disclosed to counsel representing an Actos claimant with an unfiled claim, if: (a) the claim alleges or involves injuries or damages resulting from the use of pioglitazone; and (b) all counsel for claimant who receive the documents agree to be governed by the terms of this Order and shall sign an Endorsement of Protective Order, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms.

iv. If produced by any Defendant, clients of Plaintiff's attorneys in this litigation, including those with unfiled claims, if those clients agree to be governed by the terms of this Order and shall sign a Confidentiality Agreement, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms.

v. If produced by any Defendant, outside counsel for any other Defendant, including any attorneys employed by or retained by any other Defendant's outside counsel who are assisting in connection with this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel.

vi. Any Defendant's insurer or counsel for its insurer provided that prior to receiving confidential discovery materials a person with sufficient authority to bind each insurer and its counsel executes the Endorsement of Protective Order and provides a copy to the Producing Party on behalf of the insurer or law firm. Any materials provided to an insurer or its counsel shall not be used for any purpose other than evaluation of the claims asserted in this litigation and shall not be used outside the claims asserted in this litigation.

vii. Court reporters (including persons operating video recording equipment at depositions) and persons preparing transcripts of testimony to the extent necessary to prepare such transcripts.

viii. Retained experts, advisors and consultants, including persons directly employed by such experts, advisors and consultants (collectively "Experts"), but only to the extent necessary to perform their work in connection with this litigation or Other Actos Lawsuits in which an order that is identical to or the substantial equivalent of this Order has been entered.

ix. The persons who authored the confidential discovery material, were a source of the confidential discovery material, are in good faith believed to be referenced in the confidential discovery material and already familiar with the subject-matter of the confidential discovery material or who received such confidential discovery material.

(b) All parties and their respective counsel, paralegals and the employees and assistants of all counsel receiving discovery material shall take all steps reasonably necessary to prevent the disclosure of confidential discovery material other than in accordance with the terms of this Order.

(c) A plaintiff's current or former healthcare provider who has agreed on the record at deposition to maintain the confidentiality of any document intended to be used at the deposition may be shown or questioned about Confidential Discovery Material at the deposition, provided that no copies of the Confidential Discovery Material shall be left in the possession of the healthcare provider witness and copies of that Confidential Discovery Material shall not be attached to or included with any original or

copy of the transcript of that deposition provided to the healthcare provider; however, copies of the Confidential Discovery Material shall be attached to the deposition transcript and made available for the use of the deponent in the event he or she testifies at trial. Counsel present at the deposition should make a good faith effort to obtain the healthcare provider's agreement on the record to maintaining confidentiality and no counsel shall make efforts to dissuade the healthcare provider from refusing to agree on the record to maintaining the confidentiality of any such documents. Regardless of whether any deponent signs the Endorsement of Protective Order attached as Exhibit A, this Order will apply to any deponent who is shown or examined about Confidential Discovery Material and the deponent cannot take any exhibits with them nor can he/she reveal any information learned from the confidential materials shown to them. This paragraph is not intended to prevent any deponent from seeking other relief from this Court.

(d) Except for plaintiff's current or former healthcare provider (who are subject to the foregoing sub-section) and current employees and consultants of the defendants or the producing party, each person who is permitted to see confidential documents shall first be shown a copy of this Order and shall further be advised of the obligation to honor the confidentiality designation.

(e) Disclosure of confidential discovery material other than in accordance with the terms of this Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate, including without limitation, contempt, injunctive relief and damages.

**8. Disputes concerning designation of Confidential Discovery Material.**

a) If at any time a Receiving Party wishes in good faith to dispute a designation of discovery material as confidential hereunder, such party shall notify the designating party of such dispute in writing (Dispute Notice), specifying by exact document numbers the discovery material in dispute and providing a brief explanation of the basis of the dispute with regard to each such document or other discovery material. No more than 50 documents shall be challenged in a single Dispute Notice, and only one Dispute Notice may be sent within a three-week period. If no change in designation is offered by the Producing Party, the Producing Party must provide within fourteen (14) calendar days a written explanation of the good faith basis for the designation(s) at issue.

If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, the Receiving Party shall, in writing (Challenge Notice), notify the Producing Party that a resolution cannot be reached regarding the confidentiality designation of a document or, the Receiving Party may elect to file and serve a motion that identifies the challenged material and sets forth the basis for the challenge to the confidentiality designation. Any such motion shall be accompanied by a Motion for Leave to File Under Seal (“Sealing Motion”), in accordance with this Court’s order concerning Sealing Motions. On such motion, the Producing Party shall have the burden of proving that the material is entitled to protection, as if this Order has not been entered, pursuant to Rule 26(c)(1)(G). On such a motion by the Receiving Party, the Producing Party shall have no less than fifteen (15) calendar days to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief.<sup>3</sup> The Opposition shall be accompanied by a Sealing Motion.

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<sup>3</sup> If the number of pending challenges becomes burdensome, the parties agree to alter the schedule to provide sufficient time for an Opposition.

If the Receiving Party elects to serve a Challenge Notice rather than move, the Producing Party shall, within twenty-one (21) calendar days of receiving such notice from the Receiving Party, file and serve a motion that identifies the challenged material and sets forth in detail the basis for the confidentiality designation. Any such motion shall be accompanied by Sealing Motion. The Producing Party shall have the burden of proof on such motion to establish the propriety of its confidentiality designation. The time allotted under this paragraph for a Producing Party to respond in writing to a Challenge Notice or to file and serve a motion setting forth the basis of a challenged confidentiality designation shall not be shortened except upon a showing of good cause.

(b) All discovery material designated as confidential under this Order, whether or not such designation is in dispute pursuant to subparagraph 8(a) above, shall retain that designation and be treated as confidential in accordance with the terms hereof unless and until:

- i. the Producing Party agrees in writing that the material is no longer confidential and subject to the terms of this Order; or
- ii. fourteen (14) calendar days after the expiration of the appeal period of an Order of this Court that the matter shall not be entitled to confidential status (or such longer time as ordered by this Court) if the Order on appeal is not subject to a stay; or
- iii. the Producing Party does not respond as set forth above within fourteen (14) calendar days of service of the Dispute Notice; or
- iv. the Producing Party does not serve a motion within twenty-one (21) days of receiving a Challenge Notice.

9. **Designation by Non-Parties.** Any non-party who is producing discovery materials in this litigation may subscribe to and obtain the benefits of the terms and protections of this Order by designating pursuant to the terms of this Order as “Confidential” the discovery materials that the non-party is producing. Such subscription shall be through a Notice filed with this Court and such Notice shall indicate that the Non Party agrees to this Order in its entirety.

10. **Filing with the Court.** The parties will use the following procedure for submitting to the Court papers consisting of, relating to, containing, incorporating, reflecting, describing, or attaching Confidential Information: Other than motion practice relating to disputes concerning designation of Confidential Discovery Material which shall be filed, together with a Sealing Motion, pursuant to paragraph 8 of this order. All papers consisting of, relating to, containing, incorporating, reflecting, describing, or attaching Confidential Information shall be timely served upon opposing counsel pursuant to Court Ordered deadlines or agreements by the parties. A courtesy copy of such papers shall simultaneously be provided to the Deputy Special Master. Following service of Reply papers upon opposing counsel, the parties shall meet and confer in good faith for up to twenty-one (21) days to resolve objections of the use of any confidential information or confidential documents in the briefs (Confidential Document Review Period or CDRP). During the CDRP, any party objecting to the use of any information or documents in the briefs must contact the filing party and both sides must attempt in good faith to resolve the objection(s). If no resolution is achieved within the CDRP and the objecting party is not waiving its objection, then the objecting party must file a Sealing Motion no later than the last day of the CDRP. The objecting party shall refrain from

filing any papers that are the subject of the objection until either Sealing Motion is resolved or, if no Sealing Motion has been filed with the Court, the expiration of the CDRP.

**11. Use of Confidential Discovery Material at Hearings or Trial.** This Order does not restrict or limit the use of confidential discovery material at any trial. However, prior to any hearing that is held other than a trial at which the use of confidential discovery material is anticipated, the parties shall meet and confer regarding the use of the confidential discovery material. If the parties cannot agree, the parties shall request the Court to rule on such procedures.

**12. Responses to Subpoenas or Other Process.** If a Receiving Party or its counsel or expert is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization which calls for production of any confidential discovery material produced by another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such document or information until fourteen (14) calendar days after notifying counsel for the producing party in writing of all of the following: (1) the information and documentation which is requested for production in the subpoena; (2) the date on which compliance with the subpoena is requested; (3) the location at which compliance with the subpoena is requested; (4) the identity of the party serving the subpoena; and (5) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena has been issued. The party, counsel or expert receiving the subpoena or other process shall cooperate, to



the extent reasonably possible, with the Producing Party in any proceeding relating thereto.

**13. Return or Destruction of Confidential Discovery Materials.** Within thirty (30) calendar days of the conclusion of any attorney's last case in this proceeding, including any appeals related thereto, at the written request and opinion of the Producing Party, such attorney and any persons to whom he or she disclosed confidential discovery material under this Order shall return and surrender or destroy any such material or copies thereof to the Producing Party at the Producing Party's expense. Such persons shall return or surrender any discovery materials produced by the Producing Party and any and all copies (electronic or otherwise), summaries, notes, compilations, and memoranda related thereto; provided, however, that counsel may retain their privileged communications, work product, Endorsements of Protective Order, materials required to be retained by applicable law, and all court-filed documents even though they contain discovery materials produced by the Producing Party, but such retained privileged communications and work product shall remain subject to the terms of this Order. At the written request of the Producing Party, any person or entity having custody or control of recordings, notes, memoranda, summaries or other written materials, and all copies thereof, relating to or containing discovery materials produced by the Producing Party shall deliver to the Producing Party an affidavit certifying that reasonable efforts have been made to assure that all such discovery materials produced by the Producing Party and any copies thereof, any and all records, notes, memoranda, summaries, or other written material regarding the discovery materials produced by the Producing Party (except for privileged communications, work product and court-filed documents as stated

above) have been delivered to the Producing Party in accordance with the terms of this Order or destroyed. In lieu of returning the materials, the Producing Party may direct that the materials be destroyed in a manner that will protect the confidential discovery materials and the destroying party shall certify that it has done so.

**14. Reservation of Rights.**

(a) Except as provided for herein, nothing in this Order shall prevent or restrict counsel for any party in any way from inspecting, reviewing, using or disclosing any discovery material produced or provided by that party, including discovery materials designated as confidential.

(b) Nothing shall prevent disclosure beyond that required under this Order if the producing party consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders such disclosure and that Order is not subject to an appellate stay within twenty-one (21) calendar days after it is issued.

(c) No disclosure pursuant to this Paragraph shall waive any rights or privileges of any party granted by this Order.

**15. No Effect on Other Obligations.** This Order shall not enlarge or affect the proper scope of discovery in this or any other litigation, nor shall this Order imply that confidential discovery material is properly discoverable, relevant, or admissible in this or any other litigation. Each party reserves the right to object to any disclosure of information or production of any documents that the Producing Party designates as confidential discovery material on any other ground it may deem appropriate. The actions of the parties and their counsel in designating (or de-designating) discovery

material as confidential pursuant to this Order shall not constitute evidence that is admissible to a jury at trial.

**16. Obligation of Good Faith.** All parties and counsel for such parties in this litigation shall make a good faith effort to ensure that their experts, employees, and agents comply with this Order. In the event of a change in counsel, retiring counsel shall fully instruct new counsel of their responsibilities under this Order.

**17. Modifications/Continuing Effect.** By written agreement of the parties, or upon motion and order of the Court, the terms of this Order may be amended or modified. This Order shall continue in force until amended or superseded by express order of the Court, and shall survive any final judgment or settlement in this litigation.

SO ORDERED, this 23 day of April, 2013



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

**AGREED TO BY COUNSEL OF RECORD**

**IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Actions

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**ENDORSEMENT OF PROTECTIVE ORDER**

Pursuant to 28 U.S.C. § 1746, I do hereby declare as follows:

It is my understanding that information or documents designated Confidential are provided to me subject to the Protective Order regarding confidential information produced in discovery, entered July 30, 2012 (the "Protective Order"), in the above-captioned litigation; that I have been given a copy of and have read the Protective Order, and that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Protective Order, indicating my agreement to be bound by the Protective Order, is a prerequisite to my review of any information or documents designated as confidential pursuant to the Protective Order.

I further agree that I shall not disclose to others, except in accord with the Protective Order, any confidential discovery material, in any form whatsoever, and that such confidential discovery material and the information contained therein may be used only for the purposes authorized by the Protective Order.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such discovery material and further information will continue even after this litigation concludes.

I further agree and attest to my understanding that, if I fail to abide by the terms of the Protective Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court for the Western District of Louisiana, to the extent allowed by law and to the full extent determined by the United States Court(s), for the purposes of any proceedings relating to enforcement of the Protective Order.

I further agree to be bound by and to comply with the terms of the Protective order as soon as I sign this Agreement, whether or not the Protective Order has yet been entered as an Order of Court.

I declare, under penalty of perjury, that the foregoing is true and correct to the best of my knowledge, information, and belief.

Signed this \_\_\_\_\_ day of \_\_\_\_\_, 201\_\_\_\_\_.

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**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: April 23, 2013

**MINUTE ENTRY:**  
**AGENDA FOR APRIL 25, 2013 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, April 25, 2013:

- I. Status of Federal and State Court Filings
- II. Report on Developments in the MDL since the March 21, 2013 Status Conference
- III. PSC's Introduction of Matt Garretson
- IV. Status of Bellwether Nomination Process
- V. Status of Discovery
- VI. Report on status of outstanding Orders, if any
- VII. Clerk's Office Survey Announcement
- VIII. Next Status Conference: May 23, 2013

MAR 27 2013

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Cases

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**SCHEDULING ORDER:**  
**PILOT BELLWETHER PROGRAM (SECOND TRIAL)**

This Court having established a Pilot Bellwether Program ["PBP"], the following abbreviated schedule for proceeding toward the second Pilot Bellwether Trial serves the very important goal of moving these proceedings toward completion of this Court's responsibilities in a reasonable timeframe.

**PLEASE NOTE: THE DEADLINES ESTABLISHED HEREIN SHOULD BE CONSIDERED HARD AND FAST. THEY WILL NOT BE EXTENDED, CONTINUED, OR DELAYED BY THE COURT IN ANY WAY ABSENT EXTRAORDINARILY GOOD CAUSE SHOWN.<sup>1</sup>**

**Trial Date (2<sup>nd</sup> Pilot Bellwether Trial):** *April 14, 2014*  
**Pre-Trial Conference:** *March 31, 2014, 10:00 am*

**DEADLINES**

- 5/16/2013:** Plaintiffs shall provide a complete set of all *requests for production* of documents to Defendants.
- 6/10/2013:** The Court shall establish a *schedule for anticipated motions and briefing of legal issues*.

**No dates will be included in this Scheduling Order** to address any process for nominating plaintiffs for inclusion in the Pilot Bellwether Discovery Pool for the second Pilot Bellwether Trial, nor for identifying the plaintiffs whose cases will be tried in the Pilot program, because

<sup>1</sup> As to deadlines that do impact this Court's ability to complete its tasks – tasks such as briefing deadlines – the parties are expected to comply with all deadlines or obtain extensions from the Court. However, with regard to deadlines that do not have an immediate impact on the Court's ability to perform its tasks, the parties are permitted to grant extensions to each other, but should be advised that such extensions will not be enforced by this Court.

that process is included in the Scheduling Order: Pilot Bellwether Program (First Trial) (Rec. Doc. 2359).

**7/19/2013:** Parties to exchange first *witness and exhibit lists*.<sup>2</sup> “Witnesses” shall include factual witnesses as well as experts, identified by area of expertise (deadline for identifying experts by name is separate). *Updates due the first day of each month thereafter*. No witness or exhibit may be added without leave of Court once the discovery deadline has passed; however, witnesses and exhibits may be removed through **January 2, 2014**. Counsel are cautioned that, in creating witness and exhibit lists, good faith is expected at all times.

**8/19/2013:** Defendants must *certify good-faith belief* that all documents requested by the Plaintiffs, agreed by the Defendants to be produced, and/or ordered by this Court, have been produced or will be produced within ten (10) days of this date.

**10/17/2013:** *Expert-Related Deadlines* Begin

Plaintiffs' Deadlines	Defendants' Deadlines
<b>10/17:</b> Plaintiffs to identify experts and produce background information ( <i>See Fed. R. Civ. Proc. 26(a)(1)(B)(iv-vi)</i> )	<b>11/11:</b> Defendants to identify experts and produce background information ( <i>See Fed. R. Civ. Proc. 26(a)(1)(B)(iv-vi)</i> )
<b>10/23:</b> Plaintiffs to produce expert reports	<b>11/18:</b> Defendants to produce expert reports
<b>11/25 through 12/23:</b> Plaintiffs' expert depositions <sup>3</sup>	<b>11/25 through 12/23:</b> Defendants' expert depositions

**1/6/2014:** Deadline for supplementation, if any, of expert reports and completion of supplemental expert depositions, if any. In light of the fact that expert reports must be produced prior to the completion of discovery, supplementation of reports and depositions will be permitted (pursuant to Fed. R. Civ. Pro. 26(a)(1)(D)) in order to respond to factual information discovered after an original report is issued.

**12/30/2013:** *Discovery* Deadline<sup>4</sup>

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<sup>2</sup> This requirement is imposed in lieu of the Fed. R. Civ. Proc. 26(f) reporting requirement.

<sup>3</sup> Depositions of Plaintiffs' experts shall occur before depositions of Defendants' experts within the same discipline.

<sup>4</sup> Counsel are expected to schedule and sequence discovery so as to permit all deadlines to be met. This Court's Special Masters, as well as Magistrate Judge Hanna, will be available to assist the parties in such scheduling should it prove necessary. Moreover, if a separate Order is necessary, counsel should notify this Court, through the Special Masters.



**1/13/2014:** Motions Deadline Begin (*limine, any remaining dispositive motions*)

Motions: 1/13  
Oppositions: 1/27  
Replies: 2/3<sup>5</sup>

**1/16/2014:** *Deposition Excerpt Designations* Deadlines Begin

Plaintiffs' Deadlines	Defendants' Deadlines
1/16: Plaintiffs to produce excerpt designations, if any	1/27: Defendants to produce excerpt designations, if any
2/10: Plaintiffs' objections to Defendants' designations and counter-designations	1/30: Defendants' objections to Plaintiffs' designations and counter-designations

No replies will be permitted. This Court will determine whether and, if so, when argument will be heard on the admissibility of deposition excerpts.

**1/20/2014:** Motions Deadline Begin (*Daubert* motions)

Motions: 1/20  
Oppositions: 2/17<sup>6</sup>

Reply arguments on *Daubert* motions, if necessary, may be presented at the evidentiary hearing

**3/3/2014:** *Expert Roundtable/Daubert evidentiary hearing*<sup>7</sup>

**3/20/2014:** Final *identification* of **will-call witnesses** (and the substance of their testimony) and *identification and exchange of all exhibits* (and the purpose for which they are offered).

**3/24/2014:** Deadline for completing *Trial Depositions*

In an effort to streamline trial preparation as much as possible, the *Court expects the parties to make significant efforts to produce witnesses for trial* rather than

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<sup>5</sup> The parties shall have 10 days following "service" of all reply briefs to resolve any matters concerning privilege or confidentiality pursuant to paragraph 10 of the Protective Order (*i.e.*, Case Management Order: Protecting the Confidentiality of Discovery Materials).

<sup>6</sup> The parties shall have 10 days following "service" of all opposition briefs to resolve any matters concerning privilege or confidentiality pursuant to paragraph 10 of the Protective Order (*i.e.*, Case Management Order: Protecting the Confidentiality of Discovery Materials).

<sup>7</sup> This Court will make a determination as to whether a second expert roundtable will be necessary – and, if so, the rules and procedures that will apply to the second roundtable – *after* the first one is completed and its usefulness has been evaluated.

relying on deposition testimony. To the extent that trial depositions are necessary, they must be completed by this date.

3/24/2014: *Pre-trial order*

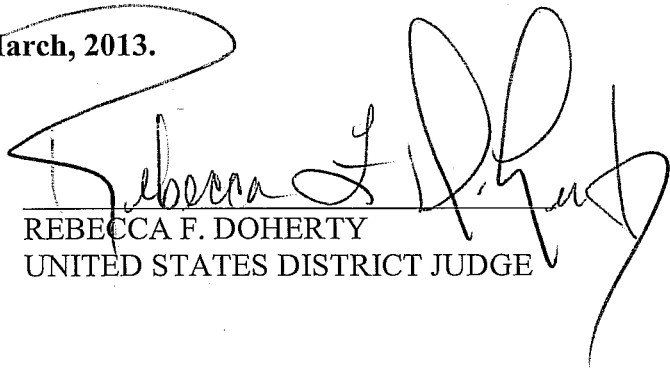
The Court will amend its standard pre-trial order form and will provide the new form to counsel no later than 4/1/2013.

3/31/2014: *Pre-trial conference*

4/7/2014: *Bench books*  
*Glossary*  
*Training for electronic courtroom.*<sup>8</sup>

4/14/2014: *Trial* of the second bellwether case.

SO ORDERED, this 27 day of March, 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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<sup>8</sup> This is the deadline by which training must be completed, but counsel who have not done so are encouraged to schedule such training earlier than April 7, 2014. Counsel must bring to the training the laptops that they intend to use for the presentation of exhibits.

RECEIVED

MAR 26 2013 

**IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

**IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION**

This Document Applies to All Cases

6-11-md-2299

JUDGE DOHERTY

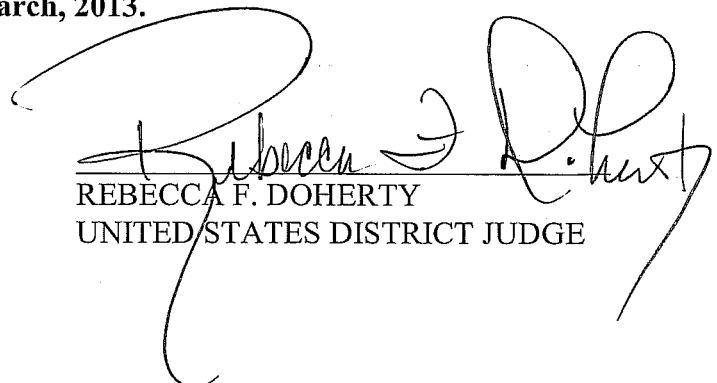
MAGISTRATE JUDGE HANNA

**COURT ORDER:  
CONTACT INFORMATION**

This Court having considered the importance of efficiency in the dissemination of information in the above captioned Multidistrict Litigation, and the importance of ensuring material communications are received by counsel, issues the instant Order. Pursuant to Local Civil Rule 11.1, “[e]ach attorney and pro se litigant has a continuing obligation to apprise the court of any address change.” Local Rule 11.1. Consistent with Local Rule 11.1:

IT IS HEREBY ORDERED that counsel meet this obligation, in particular, that the e-mail address provided by any counsel on file with the Plaintiffs’ Steering Committee (the “PSC”), and the Plaintiff’s Liaison Counsel, must be kept current. IT IS FURTHER ORDERED that a rebuttable presumption of notice and receipt is created where the PSC, and/or Plaintiff’s Liaison Counsel, disseminates, via email, correspondence to the email address of counsel on file. Said email communication is presumed received by counsel, and counsel is presumed to be on full notice for any issues where notice is relevant.

**SO ORDERED, this 26 day of March, 2013.**

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

MAR 27 2013

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

LAFAYETTE DIVISION

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: March 27, 2013

MINUTE ENTRY

As was discussed at the March 21, 2013 Status Conference in open court, this Court was to have issued a schedule for anticipated motions and briefing of legal issues on March 25, 2013 ("Motions Order"); as was explained in open court, because primary defense counsel are presently in trial and the PSC is engaged in intensive discovery, that deadline has been extended. The Special Masters are currently working with counsel to finalize the Motions Order as expeditiously as possible, and this Court will issue the Motions Order as soon as it is received.

Additionally, the Scheduling Orders for Pilot Bellwether Program (First Trial) [Doc. 2359] and Pilot Bellwether Program (Second Trial) indicate this Court is to amend its standard pre-trial order form and provide it to counsel no later than April 1, 2013. However, until this Court has received the information from the Motions Order, the standard pre-trial order cannot be amended and the new form finalized. Consequently, the deadline referenced in this Court's Scheduling Orders Pilot Bellwether Program (First Trial) [Doc. 2359] and Pilot Bellwether Program (Second Trial) is also UPSET by this Court. The new pre-trial order form will be submitted to counsel as expeditiously as possible after this Court has received the Motions Order from the parties.

RECEIVED

MAR 21 2013 *JR*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

This Document Applies to:  
All Cases

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**SELECT DISCOVERY ISSUES**

**I. Scope of Order**

This Order applies to claims currently pending in MDL No. 2299, currently pending in the Western District of Louisiana and related to MDL No. 2299, or subsequent to the date of this Order, filed in, removed to, or transferred to this Court (collectively, "MDL Proceedings"). This Order is binding on all parties and their counsel in all cases currently pending or subsequently made part of these proceedings and shall govern each case in the proceedings.

**II. Order Regarding the Production of Documents for Which Defendants Claim Attorney Client Privilege or Work-Product Protection**

A. The parties have agreed to the terms of this order which shall result in the production of certain documents in MDL 2299 that were produced in related litigation but not produced in MDL 2299 before the entry of this Order, as well as documents that will be produced after the date this Order is entered in other related litigations, that might otherwise be withheld by Defendants in this MDL 2299 but for the entry of this Order, (hereinafter referred to as the "subject documents.")

B. Pursuant to Rule 502(d) of the Federal Rules of Evidence, the Court hereby orders that as to the subject documents the attorney-client privilege, work-product protection, or other

applicable privileges are not waived by disclosure connected with the MDL Proceedings, specifically including disclosure or production of materials that are not privileged under the law applicable in the Illinois Actos® litigation that would otherwise be withheld by Defendants as privileged in the MDL Proceedings. The disclosure of the subject documents covered by the attorney-client privilege, work-product protection, or other applicable privileges in the MDL Proceedings will not constitute a waiver of privilege or work product protection in this or any other proceeding, state or federal.

C. Defendants shall identify any document produced pursuant to this order on a privilege log, as required by Case Management Order regarding Assertions of Attorney-Client Privilege and Work Product Doctrine, filed on July 10, 2012.

D. This Order does not affect or change any of the parties' rights or obligations under the previously entered Case Management Order regarding Assertions of Attorney-Client Privilege and Work Product Doctrine, filed on July 10, 2012 and all associated rights are specifically reserved. The agreement and this Order are neutral, such that neither party is waiving its position related to the applicability of privilege to the "subject documents", waiver of any such privilege, or challenges related to the Privilege Order (related to its interpretation, applicability, need for modification or scope).

### **III. Order Related to Defendants' Trade Secrets Concerning Non-Actos® Drug Information**

A. The parties have reached agreement related to Non-Actos related drug information, under which. non-Actos® drug information that is contained in Defendants' documents and is not publicly available constitutes confidential, commercially valuable information used in the operation of Defendants' businesses, that Defendants have maintained reasonably secret, and in which Defendants have invested resources. This non-Actos® drug

information affords Defendants an actual or potential advantage over others. Therefore, the Court finds that non-Actos® drug information that is contained in Defendants' documents and is not publicly available constitutes trade secrets. The parties do not waive their right to challenge whether any particular information is properly considered trade secret or not.

B. The Court further finds that Defendants' production of documents containing those trade secrets in connection with this litigation is made subject to this Order. Such production will not constitute public disclosure or dissemination of Defendants' trade secrets.

C. Plaintiffs and authorized recipients of Defendants' trade secrets referenced in Section III will maintain the confidentiality of that trade secret information pursuant to this Order and the Case Management Order Protecting the Confidentiality of Discovery Materials, filed on July 30, 2012. Plaintiffs and authorized recipients of Defendants' trade secret information will not use that trade secret information for any purpose other than the current litigation and any appeal thereof.

D. Any use of Defendants' trade secret information referenced in Section III, in a manner inconsistent with this Order, shall violate this Order.

E. This Court shall retain continuing jurisdiction after the conclusion of the MDL Proceedings for the enforcement of this order.

#### **IV. Order Related to Certain Redactions**

The Court hereby approves, with the consent of the parties, the following procedure regarding "Other Drug" redactions applied, and to be applied, by Defendants.

A. The parties agree that Defendants shall undertake a targeted retrospective analysis of already applied "Other Drug" redactions. This analysis will include textual comparison of documents in pre-redaction and post-redaction states, a search (using terms agreed to by the PSC and Defendants) that will be applied to the results of the textual comparison, reexamination of documents by Defendants, and revisions of redactions to conform with the new guidelines agreed to by the parties. Both the text search process and redaction revision process will be performed by Defendants, but in coordination with the PSC. Defendants shall provide a list of documents identified by the search that Defendants determine do not require redaction modification pursuant to the new guidelines. The PSC and Defendants agree that the PSC may request additional selected documents be reexamined for redaction issues and the parties agree to work cooperatively and efficiently in that regard, and seek Court intervention as necessary.

B. On a prospective basis, the parties agree that "Other Drug" redactions applied by Defendants as of and after the date of this Order shall be subject to the guidelines set forth below. Defendants may not redact Other Drug, Manufacturing information, or exclude Non-Responsive Family Member documents but for the following circumstances:

1. Redactions for Other Drugs shall be:
  - a. Limited in scope to redactions of discrete and separate sections of documents whereby only information related to such other drugs is contained in such sections, and where the nature of the information discussed in such discrete sections is not related in context in any manner to the remaining responsive sections of the document, *i.e.* involving analysis, comparison, or otherwise necessary for full understanding of the responsive sections of the document.



- b. Limited to restrictions imposed related to readability and contextual understanding, so that such redactions will not be made within paragraphs or sentences containing non-redactable information, and such that the readability and understanding of the context of the non-redacted material is not impaired. Defendants will not redact tables of contents, cover pages, titles, section headers, or PowerPoint slide titles.
2. Redactions for Other Drugs may not include compounds that
- a. contain pioglitazone;
  - b. are PPAR agonist (as defined by the list jointly developed by PSC and Defendants);
  - c. are alogliptin or a drug containing alogliptin;
  - d. are a TZD (as defined by the list jointly developed by PSC and Defendants); or
  - e. are related to a drug for which Takeda contemplated or made plans related to the marketing, by Takeda, or other manufacturer, of a fixed-dose combination with pioglitazone,
3. Redactions for Other Drugs shall not be applied where the text relates to:
- a. studies involving other drug(s) where patients have been given or will be given pioglitazone during the study;
  - b. bladder cancer, bladder tumors, urothelial cancer or tumors, bladder or urothelial neoplasms or hyperplasia, microcrystal or

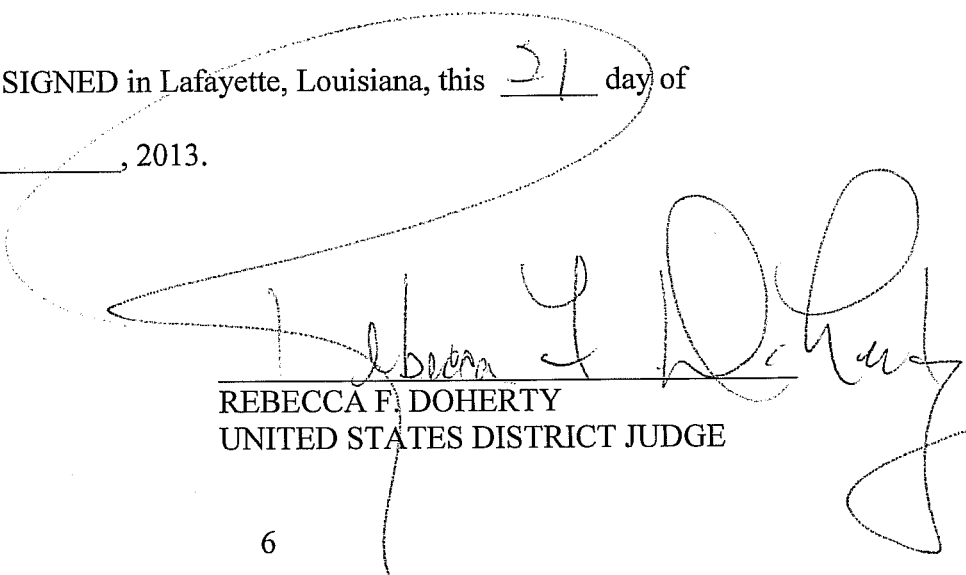
crystal formation in the bladder in laboratory, non-clinical, animal or human studies;

- c. the comparison of other drug(s) with pioglitazone, or devising strategy with respect to Actos® in any way;
- d. toxicological properties of any Defendant drugs involving bladder tumors (cancer, neoplasms, or hyperplasia or other terms indicative of bladder tumors); or
- e. where unbranded discussion of diabetes issues occurs in the context of otherwise responsive Takeda documents; however, discussion of diabetes issues related to Defendants' other diabetes products, outside the context of Actos®, shall be properly redactable subject to the other guidelines herein.

4. Where special situations may create the need for redactions not anticipated by this agreement, before applying any such redactions, or where the PSC shall wish to challenge specific relevance redactions, the parties shall meet and confer, and if needed, confer with the Special Masters, to determine how the situation shall be handled.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 21 day of

March, 2013.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

MAR 21 2013

*JD*

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: March 21, 2013

**MINUTE ENTRY:**  
**AGENDA FOR MARCH 21, 2013 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, March 21, 2013:

- I. Status of Federal and State Court Filings
- II. Report on Developments in the MDL since the January 24, 2013 Status Conference
- III. Status of Discovery
- IV. Report on status of outstanding Orders, if any
  - a. 2<sup>nd</sup> Pilot Bellwether
  - b. *Daubert* Hearings
  - c. Motions Schedule
- V. Common Benefit Claims Process Update
- VI. Pilot Bellwether Program
- VII. Next Status Conference: April 25, 2013



## DEADLINES

**2/28/2013:** Plaintiffs shall provide a complete set of all *requests for production* of documents to Defendants.

**3/25/2013:** The Court shall establish a *schedule for anticipated motions and briefing of legal issues*.

**4/1/2013:** Each side shall nominate *Pilot Bellwether Discovery Pool* participants, as follows.

- Each side will nominate 5 plaintiffs to participate in discovery.
- The only plaintiffs eligible to be included in the discovery pool will be plaintiffs who submitted Plaintiff Fact Sheets to the Defendants by December 31, 2012.
- To the extent that a plaintiff wishes to participate in the discovery pool but has not complied with the December 31, 2012 deadline, he or she may participate if, and only if, a completed fact sheet and authorizations, together with a complete set of medical records, can be produced to the Defendants no later than *March 8, 2013*.

The following additional limitations shall apply to the Pilot Bellwether Discovery Pool nominees:

- (a) No plaintiff who has asserted a class action is eligible for participation as a member of the Pilot Bellwether Discovery Pool.
  - (b) No plaintiff may be a nominee unless he or she: (i) actually consumed Actos; (ii) has been diagnosed with diabetes; and (iii) has been diagnosed with bladder cancer (no fear of cancer case).
  - Nominating counsel shall certify, with regard to every Pilot Bellwether Discovery Pool nominee, that: (i) counsel has reviewed all available information about the nominee; (ii) counsel believes that the nominee's case can be ready for trial by January 27, 2014 (or, in the case of Defendants' nominees, April 14, 2014); (iii) counsel intends to try the nominee's case, if accepted by this Court; (iv) counsel does not intend to dismiss the nominee's case; and (v) counsel has no reason to believe that the nominee's case will be settled individually prior to trial.
- 4/8/2013:** With regard to the Pilot Bellwether Discovery Pool nominees, Defendants shall notify this Court and Co-Lead Counsel whether or not they waive their right, as applicable, to venue or to have non-Louisiana cases remanded to transferor courts for trial (*the Lexecon issue*).

- 4/8/2013:** Defendants shall notify the PSC, with regard to the Pilot Bellwether Discovery Pool nominees, of any gap in the *essential preliminary discovery* required by this Court's Case Management Order: Plaintiff Fact Sheets (Rec. Doc. 1355).
- 4/22/2013:** Plaintiffs shall *cure any deficiencies* in essential preliminary discovery on Pilot Bellwether Discovery Pool nominees.
- 4/23/2013:** Pilot Bellwether Discovery Pool Nominees may *move for leave to amend their complaints*.<sup>3</sup>
- 5/3/2013:** Parties to exchange first *witness and exhibit lists*.<sup>4</sup> "Witnesses" shall include factual witnesses as well as experts, identified by area of expertise (deadline for identifying experts by name is separate). *Updates due the first day of each month thereafter*. No witness or exhibit may be added without leave of Court once the discovery deadline has passed; however, witnesses and exhibits may be removed through January 2, 2014. Counsel are cautioned that, in creating witness and exhibit lists, good faith is expected at all times.
- 6/3/2013:** Defendants must *certify good-faith belief* that all documents requested by the Plaintiffs, agreed by the Defendants to be produced, and/or ordered by this Court, have been produced or will be produced within ten (10) days of this date.
- 7/15/2013:** Plaintiffs' shall *identify their nominee* for the first trial. Defendants shall *identify their nominee* for the second trial.
- 8/1/2013:** *Expert-Related Deadlines* Begin

Plaintiffs' Deadlines	Defendants' Deadlines
<b>8/1:</b> Plaintiffs to identify experts and produce background information ( <i>See</i> Fed. R. Civ. Proc. 26(a)(1)(B)(iv-vi))	<b>8/26:</b> Defendants to identify experts and produce background information ( <i>See</i> Fed. R. Civ. Proc. 26(a)(1)(B)(iv-vi))
<b>8/7:</b> Plaintiffs to produce expert reports	<b>9/3:</b> Defendants to produce expert reports
<b>9/5 through 10/4:</b> Plaintiffs' expert depositions <sup>5</sup>	<b>9/5 through 10/4:</b> Defendants' expert depositions

<sup>3</sup> In filing any motion for leave to amend, counsel are cautioned to comply with Local Rule 7.6.

<sup>4</sup> This requirement is imposed in lieu of the Fed. R. Civ. Proc. 26(f) reporting requirement.

<sup>5</sup> Depositions of Plaintiffs' experts shall occur before depositions of Defendants' experts within the same discipline.

**10/11/2013:** Deadline for supplementation, if any, of expert reports and completion of supplemental expert depositions, if any. In light of the fact that expert reports must be produced prior to the completion of discovery, supplementation of reports and depositions will be permitted (pursuant to Fed. R. Civ. Pro. 26(a)(1)(D)) in order to respond to factual information discovered after an original report is issued.

**10/1/2013:** *Discovery* Deadline<sup>6</sup>

**10/14/2013:** Motions Deadline Begin (*limine, any remaining dispositive motions*)

Motions: **10/14**

Oppositions: **11/1**

Replies: **11/8**<sup>7</sup>

**10/17/2013:** *Deposition Excerpt Designations* Deadlines Begin

<b>Plaintiffs' Deadlines</b>	<b>Defendants' Deadlines</b>
<b>10/17:</b> Plaintiffs to produce excerpt designations, if any	<b>10/28:</b> Defendants to produce excerpt designations, if any
<b>11/11:</b> Plaintiffs' objections to Defendants' designations and counter-designations	<b>10/31:</b> Defendants' objections to Plaintiffs' designations and counter-designations

No replies will be permitted. This Court will determine whether and, if so, when argument will be heard on the admissibility of deposition excerpts.

**10/21/2013:** Motions Deadline Begin (*Daubert* motions)

Motions: **10/21**

Oppositions: **11/18**<sup>8</sup>

Reply arguments on Daubert motions, if necessary, may be presented at the evidentiary hearing

**12/2/2013:** *Expert Roundtable/Daubert evidentiary hearing*

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<sup>6</sup> Counsel are expected to schedule and sequence discovery so as to permit all deadlines to be met. This Court's Special Masters, as well as Magistrate Judge Hanna, will be available to assist the parties in such scheduling should it prove necessary. Moreover, if a separate Order is necessary, counsel should notify this Court, through the Special Masters.

<sup>7</sup> The parties shall have 10 days following "service" of all reply briefs to resolve any matters concerning privilege or confidentiality pursuant to paragraph 10 of the Protective Order (*i.e.*, Case Management Order: Protecting the Confidentiality of Discovery Materials).

<sup>8</sup> The parties shall have 10 days following "service" of all opposition briefs to resolve any matters concerning privilege or confidentiality pursuant to paragraph 10 of the Protective Order (*i.e.*, Case Management Order: Protecting the Confidentiality of Discovery Materials).

**1/2/2014:** Final *identification* of **will-call witnesses** (and the substance of their testimony) and *identification and exchange of all exhibits* (and the purpose for which they are offered).

**1/6/2014:** Deadline for completing *Trial Depositions*

In an effort to streamline trial preparation as much as possible, the *Court expects the parties to make significant efforts to produce witnesses for trial* rather than relying on deposition testimony. To the extent that trial depositions are necessary, they must be completed by this date.

**1/6/2014:** *Pre-trial order*

The Court will amend its standard pre-trial order form and will provide the new form to counsel no later than **4/1/2013**.

**1/13/2014:** *Pre-trial conference*

**1/22/2014:** *Bench books*  
*Glossary*  
*Training for electronic courtroom.*<sup>9</sup>

**1/27/2014:** *Trial* of the first bellwether case.

SO ORDERED, this 19 day of February, 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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<sup>9</sup> This is the deadline by which training must be completed, but counsel are encouraged to schedule such training earlier than January 22, 2014. Counsel must bring to the training the laptops that they intend to use for the presentation of exhibits.



FEB 13 2013

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

This Document Applies to:  
All Cases

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**CLAIMS FOR COMMON BENEFIT FEES AND EXPENSES**

This Court has established a Plaintiffs Steering Committee (“PSC”), the members of which have been given the duty to act in this matter on behalf of all of the plaintiffs in these proceedings (*i.e.*, to act for the common benefit of all plaintiffs), in addition to acting on behalf of their own clients. *See* Court Order: Plaintiffs Steering Committee (Rec. Doc. 560), as amended (Rec. Doc. 2320) (“PSC Order”). Pursuant to both the PSC Order and Case Management Order: PSC’s Management of Timekeeping, Cost Reimbursement and Related Common Benefit Issues (Rec. Doc. 1357) (“Timekeeping Order”), common benefit tasks may be assigned to plaintiffs’ attorneys who are willing and able to perform such tasks.<sup>1</sup>

In the event that the Plaintiffs recover any sum of money from the Defendants in these proceedings (whether by judgment or by settlement)—and this Court expresses no opinion or expectation as to the likelihood of such recovery—Participating Counsel may be entitled to compensation for authorized contributions to the common benefit effort and the associated time spent and expenses incurred. This Court is aware of the conflicts and disputes that can arise when such compensation requests are made. In an effort to minimize the scope of those potential difficulties, this Court has appointed Deputy Special Master Kenneth W. DeJean, whose duties are

<sup>1</sup> As in the Timekeeping Order, any attorney providing approved or authorized common benefit services is a “Participating Counsel” for purposes of the instant order.

directed at management and oversight of matters related to the PSC, including, but not limited to, the assignment of duties and tasks that inure to the common benefit of all Plaintiffs, together with monitoring requests for reimbursement of common benefit fees and expenses as they arise and recommending approval or denial of those requests. Deputy Special Master DeJean was chosen for this role by this Court because he has extensive experience as a member of the plaintiffs' bar; and has filled the roles of counsel, as well as special master, in various complex litigations (including both class actions and multi-district litigation). Thus, this Court considers Deputy Special Master DeJean an expert in the litigation of complex matters from the plaintiff's perspective and will take his recommendations very seriously.

Considering the foregoing,

IT IS HEREBY ORDERED that, in the event this Court establishes a Common Benefit Fund, (a) tasks performed for the common benefit of all plaintiffs ("Common Benefit Work") and (b) time expended, or expenses incurred, in performing Common Benefit Work ("Common Benefit Costs") shall be compensated from the Fund ONLY in accordance with the rules set forth below.

#### **I. COMMON BENEFIT WORK**

The common benefit tasks that are necessary or advisable in these proceedings shall be determined by the PSC and assigned pursuant to the PSC Order and the Timekeeping Order. The PSC has internally delegated responsibility over decisions made pursuant to the instant Case Management Order to the PSC Executive Committee ("PEC"), thus, hereafter reference will be to the PEC.

##### **A. Application for Common Benefit Work**

Every counsel of record who wishes to provide Common Benefit Work must seek approval from the PEC, by way of either request or suggestion (an "Application"), *prior* to performing such

tasks.<sup>2</sup> See PSC Order and Timekeeping Order. Approval must occur *prior* to the commencement of the task, except where exigent circumstances are shown. Where approval is obtained, Participating Counsel are expected to submit requests for reimbursement of Common Benefit Costs incurred as a result of the performance of such tasks, as described in Section II of this Order (a “Request”).

**B. Deputy Special Master DeJean**

In the event an Application for Common Benefit Work is denied by the PEC, an attorney of record may appeal the denial to Deputy Special Master DeJean. A copy of any such appeal (containing an explanation of the work requested, together with an explanation of the necessity or advisability of having the work performed and for having it performed by the Applicant) shall be provided to the PEC, through Co-Lead Counsel. The PEC shall be granted an opportunity to be heard on the appeal, by providing a written response to Deputy Special Master DeJean and a copy to the Applicant. If approval is granted by Deputy Special Master DeJean, Participating Counsel are expected to perform the task(s), then submit a Request(s) for reimbursement of Common Benefit Costs incurred during the performance of such tasks, as described in Section II of this Order. If Deputy Special Master DeJean denies an Application for approval of Common Benefit Work, then the Applicant may lodge his or her objections using the procedures described in Section III.

**C. Presumption of Approval of Application**

The approval of an Application for Common Benefit Work by either, Co-Lead Counsel, the PEC, or Deputy Special Master DeJean shall carry with it the presumption of approval by this Court.

**II. COMMON BENEFIT COSTS**

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<sup>2</sup> Counsel should use the processes established by the PEC for requesting such approval.

As noted above, "Common Benefit Costs" are those fees and expenses incurred by Participating Counsel in completing tasks assigned or approved by either Co-Lead Counsel, the PEC, or Deputy Special Master DeJean, as authorized by the PSC Order, the Timekeeping Order, or the instant Case Management Order. This Court will presume that any Request for reimbursement of Common Benefit Costs that has **not** been processed as described did not provide a common benefit to the Plaintiffs.

**A. Submission of Request for Reimbursement of Common Benefit Costs**

Any Participating Counsel who has incurred Common Benefit Costs is required to submit a Common Benefit Time Report in accordance with the instructions contained within the Timekeeping Order. (Rec. Doc. 1357)

**B. Deputy Special Master DeJean**

With regard to Requests for reimbursement of Common Benefit Costs, Deputy Special Master DeJean shall have two primary duties. First, he shall provide oversight for Common Benefit Time Reports generally. Second, he shall review contested Common Benefit Time Reports.

1. Oversight

Deputy Special Master DeJean shall conduct periodic reviews of the Common Benefit Time Reports submitted by Participating Counsel. He shall conduct these reviews at a time and frequency of his choosing so as to permit him to become reasonably current (*i.e.*, with a backlog of fewer than 60 days' worth of Time Reports) by the end of calendar year 2013. Should Deputy Special Master DeJean discover, during his oversight review of Time Reports, any matter requiring further attention, he shall have the authority to confer with Participating Counsel for the purpose of obtaining the necessary information, adjustments, or changes to the Time Reports. In the event that such consultation does not result in Time Reports that are satisfactory, he shall confer with Special Master Russo and this Court for the purpose of (i) determining whether the issue must be addressed

immediately (or, alternatively, can await this Court's attention at the time that Objections are addressed as described in Section III), and (ii) developing a plan for addressing such issues.

2. Review

On or before March 31, 2013, the PEC shall provide Deputy Special Master DeJean with a copy of any contested Common Benefit Time Report (*i.e.*, any Request not approved by Co-Lead Counsel or the PEC) for Common Benefit Costs incurred on or before the date of this order. Thereafter, on the last day of each month, Co-Lead Counsel or the PEC shall provide Deputy Special Master DeJean with a copy of contested Common Benefit Time Reports submitted to the PEC at the end of the previous month.

Deputy Special Master DeJean shall review each contested Common Benefit Time Report and shall recommend that each be affirmed or overruled (completely or in part). Unless Deputy Special Master DeJean recommends full approval of a particular contested Common Benefit Time Report, he shall issue written reasons for his recommendation. The written reasons shall be provided to the PEC, through Co-Lead Counsel, and the Requesting Counsel whose Request is overruled. Should a Requesting Counsel wish to object to the recommendation, he, she, or they may submit such objections by complying with the procedures established in Section III.

**C. Timeliness**

As previously ordered by this Court in the Timekeeping Order, all Applications for approval of Common Benefit Work must be filed *prior* to the commencement of the task, except where exigent circumstances can be shown. Additionally, Requests for reimbursement of Common Benefit Costs must be filed by the end of the month following the month during which the task was performed or costs incurred. Otherwise, the Application or Request shall be deemed untimely and shall be denied as untimely, unless good cause is shown. Mere negligence will not constitute good cause.

With regard to Common Benefit Work that was performed prior to the issuance of this Order, Participating Counsel are expected to be in compliance with the Timekeeping Order, which allowed for late submission of Requests for work completed before the Timekeeping Order was issued.

### **III. OBJECTIONS**

In any instance where Deputy Special Master DeJean recommends denial of a contested Application for Common Benefit Work or of a Request for reimbursement of Common Benefit Costs, or approves a contested Application or Request over the objection of Co-Lead Counsel or the PEC, the procedure described in this Section shall be available to the Applicant, Requesting Counsel, or PEC to lodge his, her, or their objections to the recommendation. This procedure is designed to permit as much immediate review as practicable while the case is proceeding, without creating unnecessary risk of *ex parte* communication with the Court.

#### **A. Objections to Deputy Special Master DeJean's Recommendations**

In the event that Deputy Special Master DeJean recommends denial of a contested Application or Request, or approval over the objection of the PEC, he shall issue written reasons for his recommendation. The written reasons shall be as complete as possible, without revealing unnecessary factual allegations or insight into the Plaintiffs' or Defendants' strategy, tactics, or theory of their case. Deputy Special Master DeJean shall maintain the original of his written reasons in his files and shall provide copies of his reasons to (a) the Applicant or Requesting Counsel; (b) the Plaintiffs' Executive Committee, through Co-Lead Counsel, and (c) Special Master Russo.

If Deputy Special Master DeJean recommends approval of a contested Application or Request, no further review will occur absent good cause shown. If the PEC elects to challenge Deputy Special Master DeJean's recommendation for cause, it must submit its objection in

accordance with the instructions found in this Section no later than 14 calendar days after the written reasons are served upon the PEC, through Co-Lead Counsel, *via* email.

If Deputy Special Master DeJean recommends denial of a Request or Application, then his written reasons shall include an instruction to the Applicant or Requesting Counsel that, if he, she, or they wish to lodge objections to the recommendation, those objections must be submitted, in accordance with the instructions contained in this Section, no later than 14 calendar days after the written reasons are served upon counsel *via* email.

**B. Special Master Russo's Recommendations**

In the event a Requesting Counsel, Applicant, or the PEC elects to lodge objections to a recommendation by Deputy Special Master DeJean, his, her, or their objections shall be submitted directly to Special Master Russo, with a copy to be provided to the two objecting sides (the PEC's objections must be copied to the Requesting Counsel or Applicant while objections by an Applicant or Requesting Counsel must be provided to the PEC, through Co-Lead Counsel). Once the PEC, Applicant, or Requesting Counsel has responded to the objections, Special Master Russo shall issue written reasons documenting (a) his *de novo* review of the Application or Request, together with Deputy Special Master DeJean's written reasons, (b) his adoption or rejection of Deputy Special Master DeJean's recommendation, and (c) his recommendation that the Application or Request be approved or denied. In doing so, Special Master Russo shall take care to avoid revealing unnecessary factual allegations or insight into the Plaintiffs' or Defendants' strategy, tactics, or theory of their case.

Special Master Russo shall maintain the original of his recommendation and written reasons, if any, in his files and shall provide copies of both to (a) the Applicant or Requesting Counsel; and (b) the PSC Executive Committee, through Co-Lead Counsel. When Special Master Russo's recommends that an Application or Request be denied, his written reasons shall include an

instruction to the Applicant or Requesting Counsel that: (a) he or she remains free to conduct the task(s) for which approval is sought, with the understanding that the Court will make its determination, at the end of these proceedings, whether any common benefit accrued to the plaintiffs; and/or (b) the Request for reimbursement of Common Benefit Costs will be addressed at the end of these proceedings, by this Court, with full opportunity to assert objections at that time.

### C. Hearing

In the event this Court establishes a Common Benefit Fund, this Court, or its designee, shall conduct a hearing – closer in time to the termination of these proceedings – for the purpose of ruling on any denied Applications or Requests, as well as unsatisfactory Time Reports identified by Deputy Special Master DeJean. At the appropriate time, prior to said hearing, this Court will issue an order instructing counsel who wish to challenge such denials to notify this Court in writing of their intention to do so. The failure to timely provide such written notice will result in **any denied Application(s), Request(s), or Time Reports being deemed WAIVED and thus DENIED.**

### D. Rulings

Given the number of contested Applications, Requests, and unsatisfactory Time Reports that normally are involved in MDL proceedings, the parties should be aware that, **once a ruling on an Application, Request, or Time Report is made by this Court, the ruling will be final, as to this Court, and not subject to reconsideration.** Similarly, **once payment of a Request has been authorized by this Court, or a Time Report has been approved by this Court, the determination is final and shall not be reconsidered, or open to further challenge.** However, a ruling on a Request pursuant to this Case Management Order is limited to the amount of time (*i.e.*, number of hours expended on Common Benefit Work) incurred and is not a final determination as to the value (*i.e.*, hourly rate or multiplier, if any) of the time expended. This Court will determine the dollar amount at an appropriate time during the latter stages of these proceedings.



#### IV. GENERAL INSTRUCTIONS

Counsel should be aware of this Court's expectation that Requests for Common Benefit Costs incurred, whether in this venue or another, will be submitted to this Court for approval throughout the course of these proceedings, **in accordance with the instructions contained herein and the Orders referenced herein.** Counsel should also be on full notice that they bear the full and announced risk for any tasks completed, or costs incurred, without obtaining approval pursuant to this Case Management Order and the Orders referenced herein.

Counsel should take specific notice that any Request for reimbursement of Common Benefit Costs that violates the terms of this Case Management Order **shall be presumed denied and not considered to have been performed for the common benefit of the Plaintiffs.** Such Requests will be entertained only upon a showing, by counsel, of good cause. Counsel should take further notice that negligence, whether on behalf of counsel or his or her staff, will not be considered good cause.

The subject of this Case Management Order amends and supplements, to some degree, this Court's Order Appointing Special Masters (Rec. Doc. 532). To the extent there might be a conflict or disparity between the Order Appointing Special Masters and the instant Order, the instructions contained in the instant Order shall control. Additionally, the subject of this Case Management Order addresses some of the same subject matter as the Timekeeping Order (Rec. Doc. 1357), and is intended to be read in tandem with that order.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 13 day of February, 2013.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

FEB 13 2013



TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: February 13, 2013

MINUTE ENTRY

Due to conflicts on multiple counsel's behalf who are pivotal to the issues presently before the Court, the Status Conference in *open court scheduled for February 21, 2013 is hereby CANCELLED.*

In lieu of the open court Status Conference, however, certain counsel should anticipate participation in multiple telephone conferences to address the issues presently pending before this Court. The Special Masters will notify those counsel who are to participate in the working group telephone conferences and apprise them as to the times and dates.

FEB - 4 2013 JS

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

**AMENDED COURT ORDER:**  
**PLAINTIFFS' STEERING COMMITTEE**

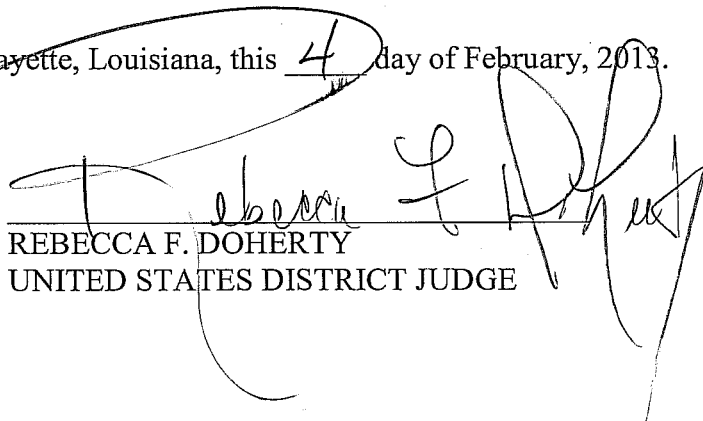
This Court issued a Court Order: Plaintiffs' Steering Committee on April 13, 2012. [Rec. Doc. 560] This Order incorporates that Order in its entirety and amends only as to the following addition:

**II. Executive Committee**

- **W. Mark Lanier**

Mr. Lanier is hereby appointed to the Executive Committee of the PSC, with primary responsibility of providing trial expertise, *inter alia*, as recommended by the PSC Executive Committee, and he shall be available to perform any other administrative or leadership tasks assigned by the PSC.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 4 day of February, 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

FEB - 4 2013 *JS*

**UNITED STATES DISTRICT COURT**

**WESTERN DISTRICT OF LOUISIANA**

**LAFAYETTE DIVISION**

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: February 4, 2013

**MINUTE ENTRY**

After conducting the January 2013 Periodic Review pursuant to the Case Management Order: Periodic Review Process issued by this Court and after discussion with the PSC Executive Committee this Court will add W. Mark Lanier, a current member of the PSC to the Executive Committee. This Court recognizes the important role in the MDL that Mr. Lanier will undertake going forward and understands the need for that role to be represented on the Executive Committee. This Court will issue an amended Order reflecting the aforementioned addition to the Executive Committee.

RECEIVED

JAN 29 2013



TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

This Document Applies to:  
All Cases

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**COURT ORDER:**  
**APPOINTMENT OF A *PRO SE* LIAISON**

In response to this Court's request that the Plaintiffs' Steering Committee ("PSC") designate one of its members to provide information and guidance to *pro se* plaintiffs in the *In Re: Actos (Pioglitazone) Products Liability Litigation*, the PSC has recommended W. James Singleton of The Singleton Law Firm, 4050 Linwood Ave., Shreveport, Louisiana. Considering this recommendation,

IT IS ORDERED BY THIS COURT, pursuant to Federal Rule of Civil Procedure 53, that W. James Singleton be appointed as *Pro Se* Liaison in this matter, and that Mr. Singleton be tasked with acting as liaison between the PSC and the *pro se* plaintiffs. The *Pro Se* Liaison shall proceed with all reasonable diligence and shall exercise his rights and responsibilities as follows, to-wit:

**I. Duties.**

The *Pro Se* Liaison shall be responsible for providing information, explanation, and assistance to *pro se* plaintiffs in order to facilitate their compliance with the orders of this Court, the deadlines established by this Court, and the Federal Rules of Civil Procedure.

A. The *Pro Se Liaison* shall assist *pro se* plaintiffs by explaining their options regarding the prosecution of their Actos lawsuits. The *Pro Se Liaison* shall make Orders, Forms, Fact Sheets, and any other relevant documentation of the MDL available to the *pro se* plaintiffs, and shall assist with any questions they have regarding these materials, including, in the case of wrongful death claims, guidance in obtaining and executing the necessary forms granting claimant access to the decedent's medical records.

B. The *Pro Se Liaison* shall provide to all *pro se* plaintiffs any and all pertinent information that should be disseminated upon initial contact by a *pro se* plaintiff, including all pertinent orders, docket sheet, any scheduling documentation, etc.

C. The *Pro Se Liaison* shall assist any incarcerated *pro se* prisoners with their application to proceed *IN FORMA PAUPERIS*.

D. The *Pro Se Liaison* shall maintain a current list of all *pro se* plaintiffs. The list shall include the name and contact information for each *pro se* plaintiff.

E. The *Pro Se Liaison* shall maintain a log of any and all communications with each and every *pro se* plaintiff, including the date of the communication, a description of the substance of the communication, and the proffered resolution of the problem (if any).

F. The *Pro Se Liaison* shall retain any and all written information obtained from the *pro se* plaintiffs, any and all written communications exchanged with the *pro se* plaintiffs, any and all written information provided to the *pro se* plaintiffs, and the log described in Paragraph I(E) above, until the resolution of this case (whether by adjudication, settlement or otherwise), further order of this Court, or until the *Pro Se Liaison's* services are no longer required.

E. The *Pro Se Liaison* shall provide semi-annual reports describing his compliance with the responsibilities imposed herein, submitting copies to the PSC, the Special Master, and all *pro se* plaintiffs. To the extent that the *Pro Se Liaison*, the PSC, and/or the Special Master

deem it advisable to obtain from the Court either input or any other response to the *Pro Se* Liaison's semi-annual reports, the Special Master shall inform the Court and request such assistance.

## **II. Authority.**

A. Should the number of *pro se* plaintiffs increase substantially, the *Pro Se* Liaison shall have the authority, subject to the approval of the PSC and the Special Master, to engage additional support personnel to assist in the discharge of responsibilities set forth herein.

B. The *Pro Se* Liaison may initiate contact and communicate with the Special Master, any *pro se* plaintiff, or counsel for any plaintiff, as the *Pro Se* Liaison deems appropriate, with respect to the efficient administration and management of this MDL. To the extent possible, such communication shall not involve the substance or merits of any given lawsuit.

C. The *Pro Se* Liaison shall not have authority to:

- (a) Issue binding decisions; or
- (b) Issue extensions of time with respect to any court-imposed (or Special Master-imposed) deadline.

## **III. Miscellaneous.**

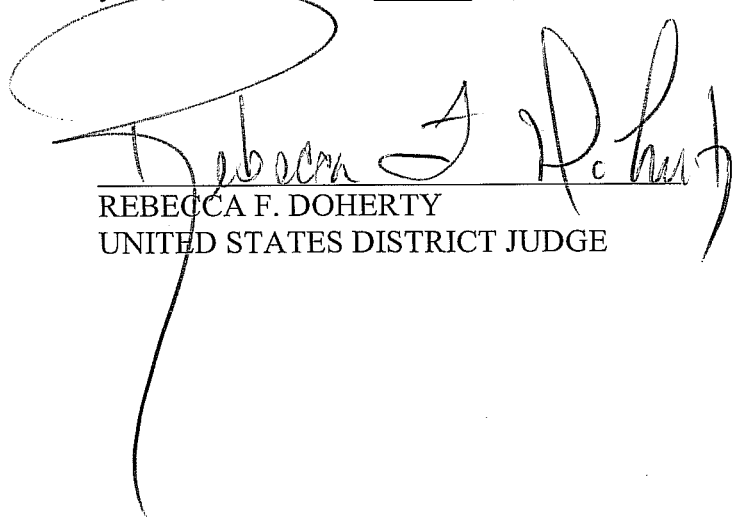
A. **Length of Appointment.** The *Pro Se* Liaison shall serve until such time as he resigns or the PSC, subject to approval by the Special Master, and if necessary this Court, determines that the services of the *Pro Se* Liaison are no longer needed for the efficient management of *pro se* litigants.

B. **Privilege.** The *Pro Se* Liaison does not represent the *pro se* plaintiffs but shall act only as liaison with the Court. Information received by the *Pro Se* Liaison from *pro se* plaintiffs shall be deemed confidential.

**C. Contact.** Should the *Pro Se* Liaison have questions regarding the administration or management of this case, or should questions arise concerning his assistance to the *pro se* plaintiffs, the *Pro Se* Liaison shall contact the Plaintiffs' Co-Lead Counsel in the first instance. If further input is required, the *Pro Se* Liaison (and/or PSC), shall contact the Special Master.

**D. Compensation.** As the *Pro Se* Liaison will be providing services to this Court by assisting in the management of these proceedings, the *Pro Se* Liaison and his associates shall be compensated from the Common Benefit Fund as part and parcel of compensation to be provided to Participating Counsel at the conclusion of this case.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 29 day of January, 2013.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE



**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: January 23, 2013

**MINUTE ENTRY:**  
**AGENDA FOR JANUARY 24, 2013 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, January 24, 2013:

- I. Status of Federal and State Court Filings
- II. Report on Developments in the MDL since the December 13, 2012 Status Conference
- III. Status of Discovery
- IV. Report on status of outstanding Orders, if any
- V. Docketing Issues
- VI. Website Update
- VII. Periodic Review
- VIII. Next Status Conference: February 21, 2013

The court reserves the right to add any agenda items as needed. Should any agenda items be added, the final agenda will be posted prior to the meeting. Consequently, one should check for additional postings.

RECEIVED

JAN 16 2013

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: January 16, 2013

**MINUTE ENTRY - AGENDA FOR JANUARY 24, 2013 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, January 24, 2013:

- I. Status of Federal and State Court Filings
- II. Report on Developments in the MDL since the December 13, 2012 Status Conference
- III. Status of Discovery
- IV. Update on "Work In Progress" elements from December 13, 2012 Status Conference
- V. Defendant Fact Sheet status; Plaintiff Fact Sheet status
- VI. Report on status of outstanding Orders, if any
- VII. Update on ESI/Predictive Coding Progress
- VIII. Docketing Issues
- IX. Website Update
- X. Periodic Review
- XI. Next Status Conference: February 21, 2013

The court reserves the right to add any agenda items as needed. Should any agenda items be added, the final agenda will be posted prior to the meeting. Consequently, one should check for additional postings.

RECEIVED

JAN - 8 2013

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

**IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**PROTOCOL FOR *IN EXTREMIS* DEPOSITIONS**

Many plaintiffs in these proceedings have alleged that they suffer from serious health conditions. Should any counsel (for a plaintiff or for the defendants) become aware that a party's or witness' health has deteriorated to the point that his or her competency or survival is at risk, counsel is under a good faith obligation to comply with the terms of this Order. As set out more fully below, this obligation specifically extends to cooperating in scheduling and preparing for a deposition, in the event that such a deposition is sought by either party.

**I. SCOPE OF ORDER**

This Order shall apply to all cases currently pending in MDL No. 2299 and to all related actions that have been or will be originally filed in, transferred to, or removed to this Court and assigned hereto as "MDL" cases (collectively, "the MDL proceedings"). This Order is binding on all parties and their counsel in all cases currently pending or subsequently made part of these proceedings and shall govern each case in these MDL proceedings. This Order is not intended to interfere with, undermine, or contradict the procedures established in Rule 27(a) of the Federal Rules of Civil Procedure.

## II. IN EXTREMIS

This Court intends to ensure that all parties are given a fair opportunity to take perpetuation or preservation deposition testimony where it is reasonably practicable to do so. For purposes of this Order, a person will be considered “*in extremis*” when he or she:

- has reached, or is expected to reach within the next six months, the state or condition of being no longer capable of testifying competently in a deposition; or
- is not expected to survive beyond the next six months.

## III. NOTICE

A. Counsel shall give notice to opposing lead counsel as soon as possible upon learning of a plaintiff’s or witness’ *in extremis* condition. The notice must be made in writing, with a certification by noticing counsel as to the nature of the person’s *in extremis* condition and his or her competency to testify. If the person in question is a plaintiff, the notice shall be accompanied by a letter from the treating physician briefly describing the plaintiff’s condition and providing a prognosis. The notice also shall contain a suggested date, time, and location for the person’s *in extremis* deposition, which will serve as the starting point for negotiations between counsel for the parties.

B. Within five (5) calendar days of receiving such notice, counsel receiving notice shall inform noticing counsel as to whether or not there is agreement on the need to take the deposition. If there is no agreement, counsel shall jointly contact this Court, through the Special Masters, to bring the dispute to the attention of this Court as soon as reasonably possible.

**PLEASE NOTE:** This order is not intended to create additional obligations on the part of any counsel to these proceedings – beyond those imposed by the ethical and professional obligations assumed by any counsel anytime they agree to participate in litigation – to monitor

the health and well-being of the plaintiffs or witnesses in these proceedings. Nor is this Order intended to create any obligation linked to constructive notice, but is triggered only when actual notice occurs. This Court intends, instead, to establish rules for what will happen when counsel become aware that a person's condition has become *in extremis*, or is approaching that status.

#### **IV. PREPARATION FOR *IN EXTREMIS* DEPOSITION**

**A. *In Extremis* Plaintiffs.** As soon as practicable after providing the notice, Plaintiff's counsel shall provide to Defendants' Lead Counsel any and all medical and pharmacy records in their possession, as well as current signed medical authorizations and a Plaintiff Fact Sheet, to the extent that those documents and records have not previously been produced in this litigation. In those cases where a Plaintiff Fact Sheet and medical records and documents have been produced, Plaintiff's counsel shall provide any new medical or pharmacy records in his or her possession, as well as an updated Plaintiff Fact Sheet, if the information in that Plaintiff Fact Sheet has changed since its initial production.

**B. *In Extremis* Witnesses.** As soon as practicable after providing notice, noticing counsel shall provide to receiving counsel all medical information in his or her possession about the witness' condition (except if protected by privacy laws) and shall cooperate with receiving counsel to obtain as much current, accurate information as possible about the witness' physical and mental condition.

**C. **Timing.**** Except for good cause shown, counsel shall comply with this Section at least seven (7) days before the date on which the *in extremis* deposition is noticed to proceed. In the event that good cause exists and the requisite 7-day notice cannot be provided, counsel shall meet and confer about the person's competency to testify. If the person in question is a plaintiff, the Plaintiff's counsel certifies that Plaintiff is competent and is agreeable to testify during this

meet-and-confer, Plaintiff's counsel shall provide any and all medical records in their possession, including medical records or other proof to indicate that the Plaintiff used Actos and experienced the alleged injury set forth in the Complaint or Plaintiff Fact Sheet, at least two (2) days before the date on which the deposition is noticed to proceed.

**D. Cooperation to Obtain Records.** Should Defendants' counsel encounter difficulty in timely securing medical and pharmacy records before a Plaintiff's deposition, Plaintiff's counsel will, upon request, provide reasonable assistance to Defendants' Lead Counsel in securing such records.

## **V. SCHEDULING**

Upon receiving notice of a plaintiff's or a witness' *in extremis* condition and competency to testify, and once agreement is reached that a deposition will be taken, the parties shall meet and confer in good faith to confirm the date, time, and location of the deposition. Counsel who elects to take the deposition shall be responsible for securing and providing a court reporter and, if desired, a videographer for the deposition.

## **VI. OBJECTIONS**

A. If Plaintiff's counsel follows the procedures set forth in the Case Management Order, Plaintiff's counsel need not notice an emergency hearing in order to proceed with a Plaintiff's *in extremis* deposition. Should the non-noticing party have a good faith objection to the deposition, however, counsel shall notify opposing counsel and the Court (through the Special Masters), in writing, of their objection and request immediate assistance in either resolving the dispute or presenting the matter to Magistrate Judge Hanna as quickly as possible.


B. Any objections shall be brought to the Court's attention as soon as practicable, but, in any event, no less than two (2) business days before the Plaintiff's deposition is noticed to

proceed. If the objection(s) are overruled, the deposition shall proceed at the date, time, and location at which it was initially noticed.

**VII. ASSISTANCE**

This Court is aware of, and sensitive to, the emotional difficulties that attend circumstances such as those discussed in this Order and does not intend to force counsel to exacerbate those difficulties. In the event that counsel finds that the terms of this order create insurmountable barriers to proceeding as this Court expects, counsel are encouraged to contact this Court, through the Special Masters, for assistance in achieving the goals described herein.

THUS DONE AND SIGNED this 8<sup>th</sup> day of January, 2013.



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HONORABLE PATRICK J. HANNA  
UNITED STATES MAGISTRATE JUDGE

RECEIVED

JAN - 2 2013 *MS*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

This Document Applies to:  
All Cases

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**PERIODIC REVIEW PROCESS**

Pursuant to the Case Management Order: Plaintiffs' Steering Committee [Rec. Doc. 560] issued by this Court on April 13, 2012, wherein this Court reserved the right to "determine whether the membership of the Plaintiffs' Steering Committee ("PSC") should remain in place or should be adjusted to allow better, or more efficient, performance of the duties assigned herein..." this Court now issues the particular procedure for this Review Process.<sup>1</sup>

**I. Scope**

This Order will govern the procedures affording MDL attorneys a mechanism to bring forward any concerns, comments, or suggestions about the administration of this MDL, the PSC, or the Special Masters.

**II. Date of Reviews**

This Court will issue a Minute Entry setting all relevant dates including, the date of the in-person sessions, and any applicable deadlines (*i.e.*, for written comment by MDL attorneys).

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<sup>1</sup> The Review Process will be conducted annually to ensure that the mechanisms put into place by this Court are still the most efficient, and the best way to administer this MDL.



### **III. Comment by MDL Attorneys**

#### **A. Procedure**

Any MDL attorney who wishes to communicate any comments, concerns, or suggestions concerning the PSC, the administrative of this MDL, or any aspect of the Special Masters' appointment and functioning in these proceedings must do so *in writing*. All writings shall be submitted in the manner established by minute entry, no later than ten (10) days prior to the scheduled in-person review session, unless specified otherwise in a corresponding minute entry. Where the subject matter of concern is the PSC, an attorney comment must be submitted to Deputy Special Master DeJean; where the subject matter of concern is the administration of these MDL proceedings, an attorney comment must be submitted to Special Master Russo; and where the subject matter of concern is the Special Masters, an attorney comment must be submitted directly to this Court.

Special Master Russo and Deputy Special Master DeJean will remove from any comments submitted to them anything that can adversely affect the impartiality of the Court. Once this process has been completed, both Deputy Special Master DeJean and Special Master Russo will present all comments to the Court for review. At that time, this Court will review the written comments and thereafter, address any issues or concerns that need be addressed.

### **IV. PSC Executive Committee Report**

#### **A. Procedure**

The Executive Committee of the PSC will prepare a PSC Executive Committee Report ("Report") that will be submitted to this Court through Special Master Russo addressing the following particulars: (a) outlining workflow (*i.e.*, how much work is allocated to the PSC, how much work is being completed by attorneys outside the PSC, etc.); (b) discussing the

cohesiveness of the PSC membership; (c) addressing the PSC's efficiency in steering the MDL; and (d) any concerns that the Executive Committee has regarding any issue related to the administration of these proceedings. All information in this Report is to be prepared generally so as to **not** convey substantive or strategic information about the case.

This Report shall be submitted to Special Master Russo no later than ten (10) days prior to the scheduled in-person review session, unless specified otherwise in a corresponding minute entry.

## **V. In-Person Review Sessions**

This Court and Magistrate Judge Hanna, on the date designated in a corresponding Minute Entry, shall hold closed discussion sessions individually, with the Defendants' Lead Counsel, and thereafter, the PSC's Executive Committee. ("Review Session")

### **A. Structure**

The Court will meet with counsel from each side individually and hold frank, closed-door conversations to evaluate the administrative elements of this MDL. The Court will begin the breakout sessions with the Defendants' Lead Counsel, and finish with the PSC's Executive Committee.

### **B. Time**

The Review Session will last as long as necessary to allow counsel to discuss freely any concerns, comments, or suggestions they may have regarding the level of this Court's involvement in day-to-day management of these proceedings, the Special Masters functioning, the PSC's structure and membership, the Defendants' Lead Counsel, and interaction with the Court.

**C. Tone**

The Review Session is intended to be an open session where counsel can freely and candidly discuss with the Court and Magistrate Judge Hanna any concerns, suggestions, or comments they may have regarding the MDL and its administration.

**D. Substance**


Any administrative concerns counsel wish to discuss with the Court shall be discussed in the Review Session. However, counsel are cautioned and warned that only discussions on **administrative matters** will be allowed. Any reference to, or substantive discussion of, anything relating to the case will not be allowed, and any breach of this rule, no matter how slight, will NOT be tolerated. The process will be conducted with the utmost fairness to both the Defendants and the Plaintiffs.

**VI. Amendment**

Once the review process has been completed in January 2013, this Court may amend this Order and the Review Process described herein, if it appears that such an amendment is necessary to better serve the interests of all involved. Future reviews will be conducted pursuant to this Order and future corresponding minute entries.

**CONFIDENTIALITY:** All materials submitted in accordance with this Order are for the **exclusive use** of this Court and shall not be seen by any other party. Once the Review Process is complete, all information will be shredded and disposed of.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 2 day of January, 2013.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

JAN - 2 2013

UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

LAFAYETTE DIVISION

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: January 2, 2013

**MINUTE ENTRY:**  
**JANUARY 2013 PERIODIC REVIEW DATES & DEADLINES**

Pursuant to the Case Management Order: Periodic Review Process issued by this Court the following dates, deadlines, times, and information are for the January 2013 Periodic Review:

**Dates & Times:**

The date of the in-person Review Session with Defendants' Lead Counsel and PSC's Executive Committee will be **January 24, 2013 at 12:00 p.m.** (The session will take place after the monthly status conference is adjourned.)

All Comments by MDL attorneys are due no later than **January 11, 2013 at 12:00 p.m.**

The PSC's Executive Committee Report is due no later than **January 11, 2013 at 12:00 p.m.**

**Procedural Information:**

Comments or the PSC Executive Committee Report addressed to Special Master Russo shall be sent via email with a request for delivery confirmation to: **grusso@joneswalker.com**

Comments addressed to Deputy Special Master DeJean shall be sent via email with a request for delivery confirmation to: **kwdejean@kwdejean.com**

Comments addressed to this Court shall be sent via email with a request for delivery confirmation to: **Hanna\_MDL\_orders@lawd.uscourts.gov**

Next Periodic Review: **January 2014**

RECEIVED

DEC 21 2012

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**DISCOVERY PROTOCOL**

This Court and counsel have been working on crafting the instant order for several months. The evolution of these proceedings, including changes due to the filing of a substantial number of state court actions, discovery proceedings in those matters, and the fact that a number of trials have been set around the nation, have made it advisable for this Court to delay completion, signing, and implementation of this order. However, as these proceedings have now arrived at an appropriate point for full discovery to proceed, this Court enters the current discovery protocol. Should further evolution in these proceedings require amendment of this order, this Court will entertain requests for such amendments, and issue the appropriate changes as deemed appropriate.

**I. SCOPE OF ORDER**

**A. Order Applicable to All Cases in MDL Proceedings.**

This Order shall apply to all cases currently pending in MDL No. 2299 and to all related actions that have been or will be originally filed in, transferred to, or removed to this Court and assigned hereto as “MDL” cases (collectively, “the MDL proceedings”). This Order is binding on all parties and their counsel in all cases currently pending or subsequently made part of these

proceedings and shall govern each case in these MDL proceedings. This Order shall apply to all discovery conducted by the Plaintiffs' Steering Committee ("PSC") on behalf of all Plaintiffs (including any committees or sub-committees specifically authorized by the PSC to conduct such discovery), as well as all discovery conducted by Defendants.

**B. Parties.**

For the purpose of this Order, the term "Plaintiffs' Counsel" or "the PSC" shall be used to refer to the Plaintiffs' Co-Lead Counsel or their designee. The term "State Plaintiffs' Counsel" shall refer to counsel representing plaintiffs in one or more state case actions involving Actos® related product liability claims. The term "Defendants' Counsel" shall be used to refer to the Defendants' Lead Counsel or her designee in the MDL. The term "Involved Counsel" shall refer to those attorneys participating in a particular discovery pursuit who may include Plaintiffs' Counsel or their designee; State Plaintiffs' Counsel or their designee; or Defendants' Counsel or her designee.

**II. COORDINATION WITH OTHER LITIGATIONS**

**A. Coordination to Extent Practicable.**

Plaintiffs' Counsel and Defendants' Counsel in these MDL proceedings, and all other counsel designated by the Court in prior or subsequent Case Management Orders, shall work to coordinate to the extent practicable the conduct of this litigation with other product liability actions involving Actos pending in any State Court. Such coordination is intended to conserve scarce judicial resources, eliminate duplicative discovery, serve the convenience of the parties and witnesses, and promote the just and efficient conduct of this litigation. To the extent that any discovery generated in the MDL proceedings were to be used in any state court proceedings by agreement, this Court's Case Management Order: Protecting the Confidentiality of Discovery Materials entered by this Court on July 30, 2012 (hereinafter "Protective Order") shall apply.

**B. Intent to Coordinate with State Courts.**

In order to achieve the full benefits of this MDL proceeding, this Court has and will continue to encourage coordination with State Courts presiding over related cases, to the extent such State Courts so desire, up to and including issuance of any joint orders that might allow full cooperation as between and among the courts and the parties. As the Court indicated at the initial case management conference, and has been reiterated thereafter, this Court intends to work actively to reach out to any State Court that is interested in coordinating discovery activities. The Court expects counsel for parties in the MDL proceeding to help ensure that such coordination is achieved wherever it is practicable and desired by a given state court or courts.

**III. WRITTEN FACT DISCOVERY**

**A. General Written Discovery**

**1. General Discovery Directed to Takeda Entities and Eli Lilly**

All generic (non-case-specific) discovery propounded to the Takeda Entities, Eli Lilly, and non-party witnesses by plaintiffs – including deposition notices, interrogatories, and production requests – in this MDL proceeding shall be undertaken by, or under the direction of, the PSC on behalf of all Plaintiffs with cases in these MDL proceedings. Any discovery not limited to a specific plaintiff shall be assigned by the PSC. The PSC shall, where practicable, and if desired by the state courts, coordinate its discovery requests with State Plaintiffs’ Counsel to reduce or eliminate duplicative discovery requests.

**Specific deadlines and time lines for discovery are found within the Scheduling Order. Throughout the progression of the MDL litigation, the parties should refer to the most recent version of the Scheduling Order for specific deadlines.**

## **2. Document Production by Takeda Entities and Eli Lilly**

The Takeda Entities and Eli Lilly shall produce documents to the PSC for the use of Plaintiffs in these proceedings. The format for such production shall be governed by the Case Management Order: Protocol Relating to the Production of Electronically Stored Information as entered on July 30, 2012 (hereinafter “ESI Protocol Order”) and all other Orders of this Court. By agreement of the parties and pursuant to this Court’s order, the Takeda Entities began producing documents to the PSC on April 6, 2012. The sequence in which the documents are produced need not conform to the requirements of Federal Rule of Civil Procedure 34(b) but must be produced pursuant to the Court’s ESI Protocol Order, any further Order by this Court or Special Master, or agreement by the parties. This document production to the PSC shall serve as the document production by defendants in this MDL proceeding.

## **3. Plaintiffs’ Document Repository**

The PSC shall bear the cost of and administer its own document repository unless agreed otherwise by the parties and approved by this Court. All documents produced by Defendants in this proceeding shall be produced to the PSC’s designee and in the manner agreed to by the parties and approved by this Court or upon Order of this Court.

All counsel shall be responsible for assuring and shall take all reasonable and necessary steps to assure the security of any confidential information produced pursuant to the Protective Order and shall act to assure the limitation of access to confidential information to only those persons covered by the Protective Order. In particular, if counsel for any party makes documents available *via* the Internet, such counsel shall be held responsible for assuring that all reasonable and necessary steps have been taken to ensure the Internet site is secure and may not be accessed by individuals who are not authorized to review confidential information. Should any party



supplying confidential information suspect that sufficient security is not in place, that party may request the assistance of the Court in obtaining certification that the Internet site is secure and may only be accessed pursuant to the Protective Order entered by this Court.

**4. Additional General Discovery by Plaintiffs of Takeda Entities and Eli Lilly**

The parties are encouraged to engage in informal discovery on generic issues where possible and appropriate. The PSC also may serve Master Set(s) of Requests for Production and Master Set(s) of Interrogatories (not to exceed fifty interrogatories each, including all discrete subparts, unless good cause is shown) on the Takeda Entities collectively (*i.e.*, the PSC may not serve master discovery on each Takeda entity individually) and on Eli Lilly (collective total of 100 interrogatories).

**B. Case-Specific Written Discovery**

**1. Plaintiffs and Defendants**

a. Plaintiff Fact Sheet, Authorizations, and Defendant Fact Sheet in All Cases

As set forth in greater detail and governed by the Court's orders on plaintiff and defendant fact sheets, every plaintiff (except those asserting only consortium claims) is required to serve defendants' counsel with a Plaintiff Fact Sheet (PFS) and executed Authorizations and the Takeda Entities and Eli Lilly are required to serve (collectively) a single Defendant Fact Sheet (DFS) on plaintiffs' counsel in each case.

b. Case-Specific Discovery in Designated Discovery Pool Cases

The Takeda Entities and Eli Lilly collectively may serve one Set of Requests for Production (not to exceed fifty requests total), a Master Set of Interrogatories (not to exceed twenty-five interrogatories, including all discrete subparts total), and Set(s) of Requests for

Admission on each individual plaintiff included within the designated discovery pool. Plaintiffs shall serve written responses, objections, and/or documents within thirty (30) days after receipt of such discovery requests, as detailed by Federal Rules of Civil Procedure. The process for designated discovery pool selections shall be the subject of a further order of this Court.

## 2. Case-Specific Fact Depositions in Designated Discovery Pool Cases

Case-specific discovery in any case included in the designated discovery pool will commence immediately after the cases are selected. In connection with any individual plaintiff's designated discovery pool case, the parties may take "core discovery," as described in the Scheduling Order. In the event any party seeks discovery depositions in designated discovery pool cases beyond core discovery, they may do so only with the written agreement of opposing counsel or by application to the Court for good cause.<sup>1</sup>

**Specific deadlines and time lines for discovery are found within the Scheduling Order. The parties should refer to the most recent version of the Scheduling Order for specific deadlines.**

## IV. EXPERT DISCOVERY<sup>2</sup>

In an effort to streamline the process by which counsel, the parties, and the Court familiarize themselves with the scientific backdrop of these proceedings, as well as to facilitate the Court's rulings on Daubert issues, an evidentiary hearing on the Daubert motions will be combined with an Experts' Roundtable.

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<sup>1</sup> The limitation to core discovery in designated discovery pool cases absent agreement of counsel or leave of Court is not applicable to cases which might be selected as designated discovery cases. Additional case-specific fact depositions may be taken in cases selected for trial.

<sup>2</sup> Though a brief description of generic expert related discovery, the Experts' Roundtable process is included here, this Court intends to issue a separate order to provide full detail on these processes.

**A. General Experts**

With regard to general experts, the parties will, in sequence:

- Identify experts and produce reports in accordance with deadlines and instructions contained in the Scheduling Order and other orders of this Court.
- Conduct expert depositions in accordance with the deadlines and instructions contained in the Scheduling Order and other orders of this Court.
- File and brief expert-related motions in *limine* and Daubert motions in accordance with the deadline and instruction contained in the Scheduling Order and other orders of this Court.
- Participate in an evidentiary hearing to address issues raised in the motions in *limine* or Daubert motions, which will be conducted simultaneously with an Experts' Roundtable (described below).

Following the evidentiary hearing, this Court will rule on all outstanding *limine* and Daubert motions.

**B. Experts' Roundtable/Evidentiary Hearing**

As the evidentiary hearing is designed to permit the parties to present evidence with regard to Daubert motions (in other words, experts' qualifications and methodology), any required evidentiary hearing will be consolidated with an Experts' Roundtable which may consist of a hearing in which both parties may present their experts' direct testimony, or a summary thereof, and qualifications to the Court or jury and the experts may be traversed as to qualifications, and cross-examined by the parties and/or the Court. Once all experts on a given subject have presented their qualifications and testimony, or summary of their testimony, both direct and cross, the experts will retire to the jury box and might be examined by the Court. The purpose of

the Court's examination will be to invite each expert to evaluate and respond, in real time, to his or her counterpart's testimony and opinions. It is expected and intended that this process will create an opportunity for all counsel to evaluate their own and their opponents' experts and testimony and to allow for Court guided interaction between and among the experts. However, all parties should be prepared for and aware that the Court might question a given expert while on the witness stand as to questions or issues upon which the Court must make an evidentiary or legal determination.

Upon request of the parties, the Court will consider permitting the Experts' Roundtable to be filmed, and will consider permitting the attendance of one or two shadow juries (and questioning of the jurors by the Court or participating counsel at the conclusion of the roundtable discussion). With regard to the Experts' Roundtable, the parties are encouraged to consider whether there might be other procedural mechanisms available to the Court that might assist the parties' efforts in evaluating their cases, grant additional information or insight, and move this matter toward resolution. The parties are welcome to submit any such suggestions to this Court through the Special Masters.

**C. Case-Specific Experts in Designated Cases**

Specific deadlines and timelines for discovery related to case-specific experts in designated cases are found within the Scheduling Order, the parties should refer to the most recent order, which shall govern with regard to specific deadlines.

**V. DEPOSITION PROCEDURES**

**A. Scope of Section.**

This section shall apply to the notices of depositions of any witnesses currently or formerly affiliated with the Takeda and Eli Lilly Entities (Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., formerly known as Takeda Pharmaceuticals

North America, Inc., Takeda Pharmaceuticals America, Inc., Takeda Global Research & Development Center, Inc., Takeda California, Inc., formerly known as Takeda San Diego, Inc., Takeda Pharmaceuticals International, Inc., Eli Lilly & Company, and any of their respective parent companies, subsidiaries, and affiliates). Notices of the depositions of expert witnesses or case-specific fact witnesses relating to individual Plaintiffs (e.g., health care providers, individual Plaintiffs, Takeda and Eli Lilly sales representatives, or other case-specific witnesses) may be the subject of a further order of this Court.

**B. Coordination.**

The parties are reminded that deposition discovery in the context of MDL proceedings can be extraordinarily complex, demanding, and expensive. The process of scheduling and taking depositions, when such large numbers of cases and attorneys are involved, requires a large degree of coordination, cooperation, and effort. Counsel are expected, throughout this process, to meet and confer and to strive to reach agreement between and among all involved parties where possible. Where the conclusion is reached, mutually, that agreement is not possible despite good faith negotiations, the parties are encouraged to timely contact the Court, through the Special Masters, to seek informal guidance and assistance and a determination as to whether or not it will be necessary to conduct a formal process for resolution of the dispute.

This Court has established a weekly discovery telephone status conference to be held with the Special Masters in order to facilitate prompt, efficient, and effective discovery.

Except where otherwise specifically noted, this order applies to depositions noticed in these MDL proceedings (“MDL depositions”) and is not intended to limit, or apply to, depositions taken in Actos®-related state court actions (“State Court depositions”), except to the extent that the parties (or one or more State Court(s)) agree(s) that such State Court depositions

will be bound by this Order or an agreement among all parties which has been approved by this Court.

**C. Avoidance of Duplicative Depositions.**

The parties shall avoid duplication of discovery effort where possible, and the PSC shall open a line of communication with State Plaintiffs' Counsel for the purpose of reaching this goal. The parties are encouraged to coordinate deposition discovery with State Plaintiffs' Counsel to the maximum extent possible so as to minimize the risk that any witness is unnecessarily deposed on the same subject multiple times.

Defendants' Counsel shall advise the PSC of all depositions that previously have been taken in State Court Actos-related actions, as of the date of entry of this order, and shall provide the transcripts of such depositions to the PSC. To the extent permitted by, and consistent with, federal law and procedure, those deposition transcripts may be requested to be used as if taken in these proceedings subject to any party's right to object.

**D. Federal Rules of Civil Procedure.**

With the entry of this order lifting the discovery stay for all purposes, all discovery, including depositions of Non-Takeda Fact Witnesses and Experts, are now permitted. Any and all such depositions shall be taken in accordance with the rules set forth in the Federal Rules of Civil Procedure, except as delineated in this Order. In any circumstance where either the PSC or the Defense feels that good cause exists for creating additional exceptions to these rules, they should meet and confer in an attempt to reach an agreement on such an exception. Failing such an agreement, the PSC and the Defense may request such an exception by contacting the Special Masters, who will convey the request to this Court.

**E. Notices.**

Coordination

Cross-Noticing of Future Depositions. In those instances where the depositions of fact witnesses are noticed in these proceedings and cross-noticed in any related State Court actions, or *vice versa*, it is this Court's intention that such cross-notices shall be encouraged, to the extent possible, in order to avoid such witnesses being deposed more than once. Any deposition taken in any State Court action of such witnesses may be cross-noticed in this MDL by agreement of Plaintiffs' Counsel and Defendants' Counsel and thereafter, may be used in these proceedings, as permitted by federal law, or by agreement of Involved Counsel. Without such agreement, the notice is subject to motion to quash and subject to strike. Once a deposition has been noticed and taken in the MDL proceedings, then the Plaintiffs in the MDL proceedings may not take a subsequent deposition of that witness in the MDL proceeding, except for good cause shown as determined by this Court and contemplated by the Federal Rules of Civil Procedure or upon consent of Plaintiffs' Counsel and Defendants' Counsel. In such instances, the subsequent deposition shall be restricted to such additional inquiry permitted by the Court or agreed upon by the Plaintiffs' Counsel and Defendants' Counsel.

**F. Length and Scope**

This Court establishes the following criteria to govern the length and scope of deposition within the MDL proceeding which shall govern in lieu of the Federal Rules of Civil Procedure as to length and scope.

Depositions scheduled after issuance of this Order shall be in accordance with the following protocol:

1. If there is no coordination with the state court litigants for a deposition originating from the state courts, any depositions noticed within the MDL by plaintiffs shall be governed by the Federal Rules of Civil Procedure and its length and scope requirements. (7 hours)
  
2. If there is coordination and agreement by the MDL plaintiffs with state court litigants within a deposition either noticed or originated in the state court, any depositions scheduled by the MDL plaintiffs in the MDL case thereafter shall be 12 hours and limited to new documents, obtained 30 days (or later), preceding the deposition date, new subjects, and follow up lines of inquiry. Counsel are cautioned Federal Rule of Civil Procedure 30 remains applicable to viable objections.

Participation by MDL plaintiffs in a deposition originating in the state court does not preclude the scheduling of a supplemental deposition within the MDL, however, said depositions shall be conducted pursuant to the Order of this Court.

Additionally, participation in deposition discovery as delineated within this Order does not preclude the taking of a trial deposition for those cases which might be remanded to the transferor court.

Questioning by Takeda and Eli Lilly, and off the record time, shall not count against any applicable limits. Sufficient time shall be reserved for all counsel designated pursuant to Paragraph VI.B.4.a of this Order to conduct examinations; no designated counsel shall be denied arbitrarily the opportunity to examine. Counsel designated pursuant to Paragraph VI.B.4.a of this Order need not cross-notice any deposition to be entitled to examination time.



Consequently, Involved Counsel shall coordinate when taking depositions in order to honor any applicable limitations.

**G. Scheduling.**

**1. Number of Depositions.**

No more than eight (8) depositions of common fact witnesses currently or formerly employed by any of the Takeda and Eli Lilly Entities shall be taken per month, absent agreement of the Parties or order of the Court. Such limitation shall include any depositions conducted pursuant to Federal Rule of Civil Procedure 30(b)(6). Depositions, commonly referred to as “30(b)(6) depositions,” which seek to obtain information regarding general matters such as corporate structure, personnel in relevant departments, discoverable data bases and/or who might be discoverable witnesses and/or where and how discoverable information is located and maintained, may be noticed at any time following entry of this order.

**2. Parties to Meet and Confer on Scheduling.**

Absent extraordinary circumstances, Involved Counsel shall consult in advance with proposed deponents in an effort to schedule depositions at mutually convenient times and places. Notices of depositions to be conducted pursuant to Federal Rule of Civil Procedure 30(b)(6) may be served as of the entry of this Order. Involved Counsel shall work cooperatively to ensure a fair and orderly process for the scheduling of depositions.

**3. Deposition Notices Must Be Served At Least Twenty-One Days in Advance.**

Plaintiffs’ Counsel shall notice depositions of witnesses currently or formerly affiliated with the Takeda and Eli Lilly Entities as soon as practicable after the Parties agree to dates and locations for the depositions, but in no event shall a notice be issued less than twenty-one days before the deposition is set to occur, except upon written agreement of all Involved

Counsel or order of this Court. Plaintiffs' Counsel may notice and serve such depositions via e-mail.

**4. Postponements.**

Once a deposition has been mutually scheduled by the Parties, it shall not be taken off the calendar, rescheduled, or relocated less than three calendar days in advance of the date it is scheduled to occur, except upon agreement among the examiner designated by the party noticing the deposition and Lead Counsel for the opposing party and counsel for the witness, or by leave of Court for good cause shown.

**H. Attendance at Depositions.**

**1. Who May Attend.** Unless otherwise agreed to by the parties, depositions may be attended only by the parties, the parties' counsel, the deponent, the deponent's attorney, in-house counsel for the parties, court reporters, videographers, and essential members and/or employees from the law firms of counsel of record. Unnecessary attendance in person or by telephone by non-examining counsel is discouraged and the presumption will operate that such attendance may not be compensated in any common benefit fee application to the Court without good cause shown to the Court prior to such duplicative attendance. Any such request shall be submitted to the Court (through Deputy Special Master DeJean) in a manner and in sufficient time to allow the Court reasonable opportunity to respond, but in no case shall a request be made later than 15 days prior to the scheduled start of the deposition.

**2. Notice of Intent to Attend a Deposition.** In order for Defendants' Lead Counsel to make arrangements for adequate deposition space and to notify building security, all counsel who intend to attend the deposition of a witness currently or formerly affiliated with the Takeda and Eli Lilly Entities shall advise Plaintiffs' Co-Lead Counsel no fewer than three

business days prior to the deposition. Counsel shall promptly pass this information along to Defendants' Lead Counsel.

**I. Treatment of Confidential Documents or Testimony.** While a deponent is being examined about any document that is confidential because (i) the parties have so agreed, (ii) a party has designated the document to be confidential pursuant to the

Protective Order associated with this litigation, or (iii) the Court has so ordered, attendance at that portion of the deposition by persons to whom disclosure is not authorized by agreement of the parties or by order of the Court shall be prohibited. Any portion of the deposition transcript containing confidential information shall be sealed pursuant to this Court's Protective Order. Sealed portions of deposition transcripts may be opened, read, and utilized for only those purposes permitted by the terms of this Court's Protective Order, or, if applicable and appropriate, also any protective order entered in a State Court action where the transcript is being used.

**J. Examiners.**

**1. Designation of Examiners for Plaintiffs.**

The PSC may designate no more than one attorney to examine a deponent. State Plaintiffs' Counsel, if participating in an MDL-noticed deposition, whether by agreement of all relevant parties or by Order of this Court, may designate only one examiner from each State in which any litigation might be pending, however, examination should not be duplicative. The PSC, shall meet and confer with the State Plaintiffs' Counsel, if participating, with respect to such designations and coordination as to the applicable limitations, where possible.

## **2. Notice of Examiners.**

At least three business days prior to the deposition, Plaintiffs' Counsel shall notify Defendants' Counsel of the PSC plaintiffs' examiner(s) designated pursuant to ¶ VI.B.4.a. If unforeseen circumstances require a change of an examiner(s) after such notification, Plaintiffs' Counsel must notify Defendants' Counsel of the change immediately upon learning of the necessity for the change. Such a change alone shall not be cause for postponing the deposition.

## **3. Sharing of Time.**

The examining attorneys designated by the PSC and the State Plaintiffs' Counsel, if any, shall meet and confer for the purpose of determining how time shall be shared, the order of questioning, and responsibility for objections; it is anticipated multiple objections on a given point or question by multiple plaintiffs' attorneys will be discouraged. Such coordination is intended to ensure all designated counsel have an appropriate amount of time to protect their clients' interests. If agreement cannot be reached, counsel are to notify the Court, through the Special Masters, for assistance in setting the terms of any particular deposition no later than five (5) days before commencement of the deposition.

## **4. Coordination of Examination Issues**

The Plaintiffs' attorney designated to conduct the examination by the PSC and the State Plaintiffs' Counsel, if any, shall coordinate, where practicable, with each other so as to conduct as thorough and non-duplicative an examination as is possible. Any Plaintiffs' Counsel in any related federal or state action who is not so designated may suggest matters for inquiry in any deposition noticed in these actions by providing to the PSC, or the State Plaintiffs' Counsel, if any, or their designee, a written list and brief explanation of such matters. The examiner designated by the State Plaintiffs' Counsel, if any, may cover the same *topics or issues* covered

by the examiner designated by the PSC, and *vice versa*, but the later examining counsel may not ask duplicative questions unless agreed to by all Involved Counsel or by order of this Court.

**5. Use of Depositions in MDL and State Court Proceedings.**

Any examination conducted by any examiner may be used in the MDL proceedings, consistent with the law, Federal Rules of Civil Procedure and Evidence, agreement of all Involved Counsel, and order or order(s) of this Court.

**K. Sequence of Examination.**

In the absence of any alternative agreement by Involved Counsel, questioning at the depositions will be conducted in the following sequence for depositions noticed by the PSC in the MDL: (i) the examiners designated by the PSC and by the State Plaintiffs' Counsel, if any, in the order to which they agree in advance of the deposition ; (ii) counsel for the Takeda and Eli Lilly Entities; (iii) individual counsel for the deponent, if any; and (iv) any re-cross and/or redirect by such counsel, in the same order.

Questioning at the depositions will be conducted in the following sequence for depositions noticed by Defendants' Counsel: (i) counsel for the Takeda and Eli Lilly Entities; (ii) the examiners designated by the PSC and by the State Plaintiffs' Counsel, if any, in the order to which they agree in advance of the deposition; (iii) individual counsel for the deponent, if any; and (iv) any re-cross and/or redirect by such counsel, in the same order.

**L. Objections.**

**1. How Objections Made.**

Objections shall be made only by counsel designated pursuant to Paragraph VI.B.4.a of this Order, plus individual counsel for the deponent (if any), and shall be made by stating, "Objection" and the legal basis for the objection (limited to the legal bases described below) in a

concise manner. For the purposes of this Court, an objection by designated counsel shall be deemed to apply to all non-designated counsel for purposes of the deposition and future use of the deposition.

## **2. Bases for Objections.**

No objection shall be made during the taking of a deposition except to assert the following grounds, as reflected in the Federal Rules of Evidence: (i) the form of a question including leading; (ii) responsiveness of the answer, (iii) a privilege; (iv) a right to confidentiality; (v) a limitation imposed pursuant to a previously entered court order; or (vi) a question is argumentative, harassing or abusive including “asked and answered.” In connection with an objection to the form of the question, the examiner may inquire as to the grounds for the objection in order to allow the amendment of the question.

## **3. Objections Preserved.**

All objections, except as to (i) the form of the question including leading, (ii) the responsiveness of an answer, or (iii) the assertion of a privilege shall be preserved for later ruling by the applicable court(s) in which the deposition testimony is offered and may be asserted in connection with the proffer of the deposition testimony at trial. Objections as to the admissibility of documents introduced during a deposition are not waived by failure to raise the objection during the deposition, but rather are preserved for later ruling upon timely assertion of the objection by this Court, or by the applicable trial judge.

### **M. Consultation with Witness.**

A witness may consult with his or her counsel or counsel for either party during a deposition. When a question is pending, the witness must first answer the question before consulting with any counsel, except that the witness and counsel may consult at any time for the

purpose of determining whether a privilege exists or whether the information sought is subject to an applicable protective order.

**N. Videotaped Depositions.**

**1. Right to Videotape Depositions.**

Any party shall have the right to request that the deposition of any party or witness be recorded on videotape and such written request shall be provided with the deposition notice. Where the party wishing to videotape did not notice the deposition, a request for video tape recording shall be submitted to the PSC, no later than ten (10) days before the date on which the deposition is scheduled to occur. All videotaped depositions shall be accompanied by a simultaneous audio tape and stenographic transcript.

**2. Videography Technicians.**

The party giving notice that the deposition will be videotaped shall assure that all video technicians who record the deposition possess the skills, experience, and equipment necessary to understand and comply with this Order and any further Order relating to the equipment and techniques to be used. Counsel for that party shall provide a copy of this Order and any other applicable orders to the video technicians no later than five (5) days prior to the deposition.

**3. Video Operator's Services Must Be Offered Equally.**

Services and products offered or provided by the video operator or the entity providing the services of the video operator to any party or to any party's attorney or non-party who is financing all or part of the deposition shall be offered or provided to all parties or their attorneys attending the deposition in the same manner as offered to the party financing all or part of the deposition. No service or product may be offered or provided by the video operator or by the entity providing the services of the video operator to any party or any party's attorney or

nonparty who is financing all or part of the deposition unless the service or product is offered or provided to all parties or their attorneys attending the deposition in the same manner and fashion. All services and products offered or provided shall be made available at the same time and on the same terms to all parties or their attorneys.

**4. Video Operator.**

The operator(s) of the videotape recording equipment shall be subject to the provisions of Fed. R. Civ. P. 28(c). At the start of the deposition, the operator(s) shall swear or affirm to record the proceedings fairly and accurately.

**5. Video Operator Shall Not Comment on Demeanor.**

The video operator and the organization providing the video and audio services shall not provide to any party or any other person or entity any service or product consisting of their notations or comments regarding the demeanor of any witness, attorney, or party present at the deposition. The video operator and the organization providing the video and audio services shall not collect any personal identifying information about the witness as a service or product to be provided to any party or non-party in any way whatsoever.

**6. No Distortion.**

The camera operators shall not distort the appearance or the demeanor of participants in the deposition by the use of camera or sound recording techniques, or by zooming in or out, or manipulation of the sound or picture in any manner whatsoever.

**7. Confidentiality.**

Videographer and Court Reporter shall be bound by the Protective Order or any other order issued by this Court. Any party obtaining copies of exhibits or copies of the transcript or videotaped depositions must sign a written acknowledgement of the application of any Protective



Order that might apply to material within that deposition. It is anticipated this acknowledgement will mirror the verbal affirmation given by all present at the deposition. No person shall sell or provide any copy of any discovery to anyone without receiving express written permission of Plaintiffs' Counsel and Defendants' Counsel.

**8. Attendance.**

Each witness, attorney, and other person attending the deposition shall be identified on camera at the commencement of the deposition. Thereafter, absent further order of the Court, only the deponent (and any demonstrative materials and exhibits used during the deposition, which may be taped via split screen) will be videotaped.

**9. Oath and Identification of Attendees.**

The oath shall be administered to the deponent on camera and on the audio recording and all individuals, including the videographer and Court Reporter, shall affirmatively acknowledge the application of any protective order that might apply.

**10. Standards.**

The deposition will be conducted in a manner to replicate, to the extent feasible, the presentation of evidence at a trial. Unless physically incapacitated, the deponent shall be seated at a table or in a witness box except when reviewing or presenting demonstrative materials for which a change in position is required. To the extent practicable, the deposition will be conducted in a neutral setting, against a solid background, with only such lighting as is required for accurate video recording. Lighting, camera angle, lens setting, and field of view will be changed only as might be necessary in order to record accurately the natural body movements of the deponent or to portray exhibits and materials used during the deposition. Sound levels will

be altered only as necessary to record satisfactorily the voices of counsel and the deponent. Eating and smoking by deponents or attendees during the deposition will not be permitted.

**11. Interruptions.**

Videotape recording will be suspended during all “off the record” discussions and shall note such suspension.

**12. Conclusion of Deposition.**

At the conclusion of a deposition, a statement shall be made on camera or on the audio recording that the deposition is ended where and when agreed to by the parties and shall set forth any stipulations made by counsel concerning the custody of the audio or video recording, the transcript, and the exhibits, as well as any other pertinent matters, in particular addressing any material subject to a protective order or privilege.

**13. Preservation of Original Media.**

The video operator shall preserve custody of the original video medium in its original condition until further order of the Court. No part of the video or audio record of a video deposition shall be edited in any fashion, or released or made available to any member of the public unless authorized by the Court or pursuant to the terms of the Protective Order or other Order of this Court.

**14. Index.**

The videotape operator shall use a counter on the recording equipment and after completion of the deposition shall prepare a log, cross-referenced to counter numbers, that identifies the positions on the tape at which examination by different counsel begins and ends, objections are made and examination resumes, and at which exhibits are identified, as well as

any interruption of continuous tape recording, whether for recesses, “off the record” discussions, mechanical failure, or otherwise.

**15. Use of Depositions at Trial.**

Prior to any trial, Plaintiffs’ Counsel and Defendants’ Counsel shall meet and confer with respect to the use of any videotaped deposition testimony or deposition exhibits (including exhibits displayed through trial software such as Trial Director, Summation, or Concordance). The procedures for and manner of display of any such testimony or exhibits to the jury at trial shall be the subject of a further order by this Court or the applicable trial court.

**O. Use of Exhibits.**

**1. Paper Copies of Exhibits at Deposition.**

Extra paper copies of documents about which counsel plan to examine the deponent shall be provided to counsel for the deponent and counsel for the other party participants reasonably expected to attend, during the course of the deposition if not before. To the extent possible, all exhibits shall have printed bates numbers affixed, which shall remain constant throughout the litigation.

**2. Marking of Deposition Exhibits.**

All exhibits will be marked for identification by using the deponent’s last name and a sequential number beginning with 1 (*e.g.*, Smith-1 and by reference to the Bates number of the first page of the exhibit being referenced). If a document is used in more than one deposition, it must be marked in each deposition in the manner noted with the original and consistent Bates stamp number; it is anticipated the Bates number shall remain constant throughout the litigation. All documents marked as exhibits will be attached to the original transcript and will be retained

with the original transcript. Copies of exhibits may be attached to copies of the transcript where the party ordering the transcript pays for the costs of copying those exhibits.

### **3. Exhibits without Bates Stamps.**

Deposition exhibits that have not been previously produced in the litigation or previously assigned a bates stamp number, shall be assigned a bates stamp number from a range of numbers reserved for this purpose. The first time such a document is referenced as an exhibit at a deposition, it shall be marked with the assigned bates stamp number and shall be placed in the depository at the conclusion of the deposition and shall retain that bates stamp number throughout the litigation. Bates stamp numbers shall not be duplicated.

#### **P. Time to Review Transcript.**

Each deponent has the right to read and sign the deposition transcript within forty-five days after receipt of the transcript from the court reporter. This time period shall not be extended, absent good cause shown. Should the deponent fail to sign the transcript within forty-five days, all parties have the right to use a copy of the transcript in the manner provided by this Court as though the copy were the original transcript. Should the deponent fail to sign the errata sheet within forty-five days, the transcript will be deemed to have been read and approved by the deponent. In the event the original transcript is unsigned, lost, or inadvertently destroyed, a certified copy reflecting any changes made to the original transcript may be used in place of the original.

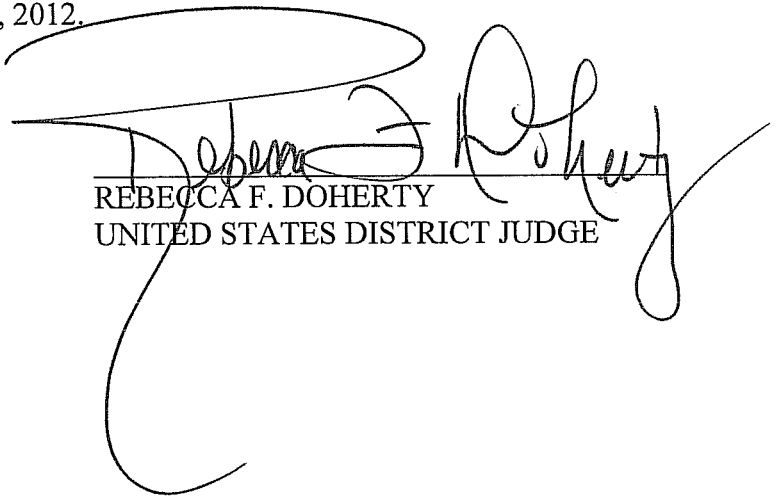
## **VI. MODIFICATION**

This Order is subject to modification by agreement of the Plaintiffs' Counsel and Defendants' Counsel parties, subject to Court approval, or by further order of this Court.

**VII. DISCOVERY STAY**

Upon entry of this Order the Discovery Stay in these MDL proceedings is lifted for all purposes, allowing for discovery consistent with this and future orders.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 21<sup>st</sup> day of December, 2012.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: December 12, 2012

**MINUTE ENTRY:**  
**AGENDA FOR DECEMBER 13, 2012 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, December 13, 2012:

- I. Status of Federal and State Court Filings
- II. Developments in the MDL since the October 25, 2012 Status Conference
  - a. Hard Copy Document Inspection Report
  - b. Privilege Log Challenge Status
  - c. Pro Se Representation
  - d. Webmaster Issues
  - e. ESI Update (Predictive Coding/Training)
- III. Work In Progress
  - a. Clinical Trial Identification and Production of Ancillary Documentation
  - b. 3<sup>rd</sup> Party Discovery including Upjohn Discovery/Production
  - c. Sales Representative Discovery/Deposition
  - d. Eli Lilly Production

- e. Foreign Document Production
- IV. Report on Relevant Case-Specific Issues
- V. Forthcoming “Review” and “Review Sessions”
- VI. Next Conference: **January 24, 2013**

RECEIVED

NOV 16 2012 *JS*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

This Document Applies to:  
All Cases

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**DEPUTY SPECIAL MASTER DEJEAN'S FEES AND COSTS**

Pursuant to this Court's Order Appointing Special Masters, Deputy Special Master DeJean, was appointed to manage and oversee matters related to the Plaintiffs' Steering Committee. This Order will establish the rules under which Deputy Special Master DeJean is to submit his fees and costs for payment. By agreement of the parties, Deputy Special Master DeJean's fees and costs for payment shall be borne, until further notice, by the Plaintiffs.

IT IS HEREBY ORDERED that, beginning with the 4<sup>th</sup> quarter of 2012, Deputy Special Master DeJean shall:

- create quarterly statements, dated no later than 30 days after the quarter has ended, reflecting the time he has expended fulfilling his duties (in one-tenth hour increments), together with out-of-pocket expenses he has incurred, and such statements shall be maintained in his files until further order of this Court;
- simultaneously, Deputy Special Master DeJean shall submit to this Court (directing the submission to Magistrate Judge Hanna with a copy to Judge Doherty), a summary statement(s) from which any and all confidential information (as well as information referring to or identifying any confidential information) has been omitted. Only upon timely and proper request by an



appropriate party made in writing, and submitted to this Court through co-lead counsel for Plaintiffs, or their designee, and only if granted by this Court after allowing objection by an appropriate opposing party submitted through co-lead counsel for Plaintiffs, or their designee, shall the quarterly statements be made available to any appropriate party. Additionally, neither Magistrate Judge Hanna nor Judge Doherty will receive or review the quarterly statements without prior, full notice being given to co-lead counsel for the Plaintiffs.

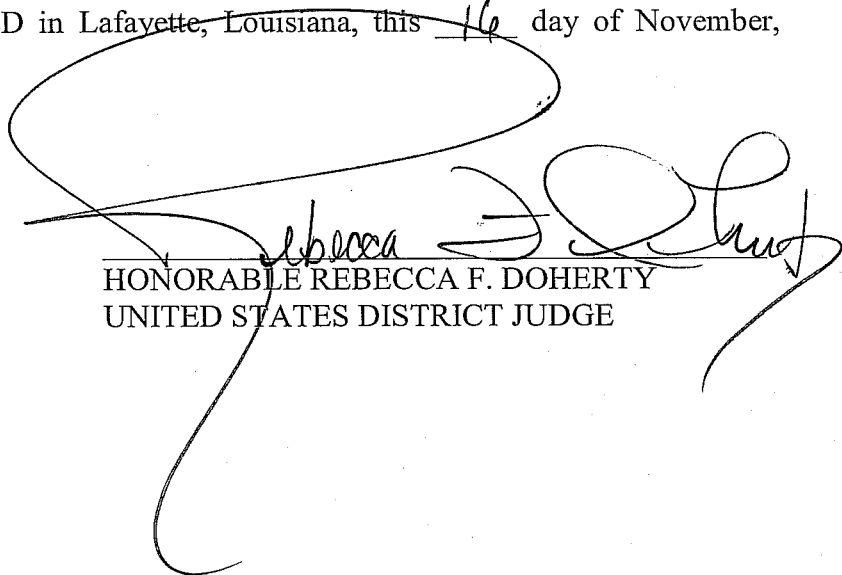
- with regard to fees and expenses incurred prior to the entry of this Order, Deputy Special Master DeJean shall submit statements (complying with the same procedure described above) in accordance with the following schedule:
  - for fees incurred in March, 2012, statements shall be submitted by November 26, 2012
  - for fees incurred in April, 2012, statements shall be submitted by December 3, 2012
  - for fees incurred in May, 2012, statements shall be submitted by December 10, 2012
  - for fees incurred in June, 2012, statements shall be submitted by December 17, 2012
  - for fees incurred in the 3<sup>rd</sup> quarter of 2012, statements shall be submitted by December 28, 2012.

All fees and expenses incurred on and after October 1, 2012 shall be submitted in accordance with the quarterly billing procedure described above.

IT IS HEREBY FURTHER ORDERED that the Deputy Special Master DeJean is excused from the obligation to provide detailed descriptions of his activities in his statements and Requests for Distribution of Funds. This Court finds that this unusual order is necessary because: (a) Deputy Special Master DeJean has expressly been granted the authority to

participate in *ex parte* contact with counsel for the Plaintiffs in these proceedings; (b) this Court is aware that, in the months since Deputy Special Master DeJean was appointed, counsel have freely exercised their right to engage in *ex parte* contact with him; (c) these *ex parte* exchanges have been extremely helpful to Deputy Special Master DeJean's ability to assist this Court in managing these proceedings much more efficiently than would have been the case without it; (d) this Court might not be able to protect Deputy Special Master DeJean's records from being subject to subpoena issued by other courts, either while these proceedings are ongoing or after they have been terminated; and (e) this Court wishes to ensure that Deputy Special Master DeJean's records are not used by any party or counsel to render non-confidential that which was discussed with a well-founded expectation of confidentiality.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 16 day of November, 2012.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

NOV 13 2012

*OM*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

This Document Applies to:  
All Cases

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**DEFENDANT FACT SHEETS**

**I. Scope of Order**

This Agreed Order applies to claims based on alleged ingestion of Actos®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, or pioglitazone (“Actos”) that (i) currently are pending in MDL No. 2299, (ii) currently are pending in the Western District of Louisiana and are related to MDL No. 2299, or (iii) subsequent to the date of this Order are filed in, removed to, or transferred to this Court (collectively, “MDL Proceedings”). This Order is binding on all parties and their counsel in all cases currently pending or subsequently made part of these proceedings and shall govern each case in the proceedings.

**II. Defendant Fact Sheets**

The Court hereby approves, with the consent of the parties, the use of the Defendant Fact Sheet (“DFS”) attached as **Exhibit A**.

A. The parties have agreed upon a DFS. *See* Exhibit A. Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals U.S.A., Inc., and Takeda Global Research & Development Center, Inc. (collectively, “Takeda”) shall collectively serve upon Plaintiffs’ Liaison Counsel and each Plaintiff’s counsel of record (as identified in the PFS) an electronic copy of a complete DFS negotiated by the parties. Eli Lilly & Company (“Eli Lilly”) shall provide a DFS only if the

Plaintiff alleges use of Actos® beginning on or before December 31, 2007. For cases in which Plaintiff alleges use of Actos® solely between January 1, 2008 and December 31, 2008, Eli Lilly shall provide the names of Eli Lilly sales representatives who called on Plaintiff's prescribing physician(s) and the dates of those calls.

B. In connection with negotiations regarding the DFS, which Defendants Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., Takeda Global Research & Development Center, Inc., and, if applicable, Eli Lilly, shall serve on plaintiffs pursuant to the terms of the applicable case management order, Counsel for the Takeda and Eli Lilly Defendants ("Counsel") have conducted an investigation to determine sources of information sought in the requests set forth in the DFS. As a result of this investigation, Counsel represent to Plaintiffs and this Court that only the aforementioned Defendants, Takeda Pharmaceuticals USA, Inc., Takeda Pharmaceuticals America, Inc., Takeda Global Research and Development Center, Inc., and Eli Lilly, systematically collect and record information sought in the DFS. Though Takeda Pharmaceutical Company Limited is involved in the maintenance of a database containing adverse event reporting information, such information is duplicative of information accessible by Takeda Global Research & Development Center, Inc. Other Takeda Defendants, such as Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals International, Inc., and Takeda California, Inc., have no involvement in the sale or marketing of Actos®, or in the tracking and reporting of adverse event reports, and do not systematically collect and record information sought in the DFS. Plaintiffs shall be granted the opportunity to refute Defendants' representations if Plaintiffs believe that discovery shows the involvement of Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals International, Inc., Takeda Pharmaceutical Company Limited, and/or Takeda California, Inc. in a way that will require Defendants to produce a DFS for one or more of these

entities. To refute Defendants' representations and initiate Defendants' obligations to produce a DFS for any additional entities, Plaintiffs shall first meet and confer with Defendants regarding whether a DFS is required from these entities. If no agreement is reached through the meet-and-confer process, the parties shall seek the Court's guidance before Plaintiffs commence any such discovery.

### **III. Production of Defendant Fact Sheets and Challenges to Completeness**

A. For cases in which a PFS is served after the date of this Order, Takeda and, if applicable, Eli Lilly shall provide a complete DFS within 90 days after receipt of a PFS that meets the triggering requirements established in Section B. below. The DFS will include all available documents responsive to the requests within the DFS, including Actos®-related records for Plaintiffs' Treating Health Care Providers, as defined in the DFS.

B. For a PFS to trigger Defendants' DFS obligations, Plaintiff must:

1. Answer all applicable questions **in Sections I (A), II (A-F), III, IV, and V (A and B) of the PFS<sup>1</sup>**;
2. Include a signed Declaration and Certification (found at Sections X and XII of the PFS);
3. Provide duly executed record release Authorization(s); **and**
4. Designate treating health care provider(s) by completing a "Plaintiff's Designation of Treating Physicians for Defendant Fact Sheets" form.

C. If Defendants contend that any PFS is not substantially complete in that the requisite triggering information set forth in Section B. above is incomplete, they shall notify

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<sup>1</sup> Non-substantive omissions, such as the inadvertent failure to provide a zip code, phone number, or other non-substantive information, shall not form the basis of a claim that a Plaintiff's PFS is not substantially complete so that a DFS is not required.

Plaintiff's individual counsel by E-Mail within thirty (30) days of any alleged deficiencies. Failure to notify Plaintiff's counsel within the thirty (30) days shall mean Defendants will provide a complete DFS within 90 days after receipt of the PFS. Upon receipt of an E-Mail alleging deficiencies, Plaintiff shall have twenty-one (21) days to respond or otherwise contest the deficiencies alleged in the E-Mail. If Defendants allege a PFS deficiency that pertains to the triggering requirements established in Section III.B.1. or 2. above, if Plaintiff has not contested the deficiency, Plaintiff shall respond by producing a supplemental PFS. If Defendants allege a PFS deficiency that pertains to the documentation triggering requirements established in Section III.B.3. or 4. above, if Plaintiff has not contested the deficiency, Plaintiff shall respond by producing the documentation necessary to meet the triggering requirements. If the parties cannot reach agreement through this meet-and-confer process, the matter may be presented to the Court for resolution.

D. For cases in which a PFS was served on or prior to the date of this Order, defendants shall have 45 days from the date of this Order to notify Plaintiff's counsel of any deficiencies pursuant to Section III.C. and shall have 90 days from the date of this Order to serve a DFS in those cases in which a PFS that meets the triggering requirements of Section III.B. has been served.

E. If Takeda and, if applicable, Eli Lilly, have not produced a complete DFS to Plaintiff's counsel of record by the deadlines set forth in Sections III. A, C, and D of this Order, Plaintiff's counsel shall send a Notice of Overdue or Deficient Discovery to Defendants' Counsel at [ActosMDL.DFS@nelsonmullins.com](mailto:ActosMDL.DFS@nelsonmullins.com). To the extent service via email is not possible, the Notice of Overdue or Deficient Discovery may be served on Defendants' Counsel by sending via first class or overnight mail addressed to Dell P. Chappell, 1320 Main Street, 17<sup>th</sup> Floor,

Columbia, South Carolina 29201. The Notice shall identify the alleged deficiency and state that Takeda and, if applicable, Eli Lilly have twenty-one (21) days to cure the deficiency or otherwise respond to Plaintiff's Notice. If Plaintiff's counsel has not received a complete DFS by the end of the twenty (21)-day notice period, Plaintiff's counsel may, after meeting and conferring with Defendants' Counsel in good faith, seek relief from the Court.

F. Service of the DFS shall be made as follows:

(a) Upon the individual Plaintiff's counsel of record, electronically *via* email. Electronic service shall be supplemented with service of a CD *via* first class or overnight mail, if requested by counsel.

(b) Upon the Plaintiffs Steering Committee, electronically *via* email to Plaintiffs' Counsel at ActosDFS@weitzlux.com. To the extent service via email is not possible, the DFS may be served on Plaintiffs' Counsel by sending them in electronic format on CD via first class or overnight mail addressed to Jonathan Sedgh, 700 Broadway, New York, NY 10003.

#### **IV. Plaintiff's Designation of Treating Health Care Providers**

A. The DFS defines a Treating Health Care Provider as any physician, medical provider, practice, clinic, person, or entity identified with particularity in the PFS who prescribed and/or dispensed Actos® and up to two (2) additional health care providers who have treated the Plaintiff for their alleged Actos®-related injuries and have been designated by the Plaintiff pursuant to the provisions of Case Management Order: Defendant Fact Sheets. The parties have agreed that these two (2) additional health care providers who have treated the Plaintiff for their alleged Actos®-related injuries shall be designated by using the Plaintiff's Treating Health Care Provider Designation form attached as **Exhibit B**.

B. Plaintiffs shall designate their two (2) additional health care providers who have treated the Plaintiff for their alleged Actos®-related injuries at the time of submitting a PFS. For those cases in which a PFS has already been submitted, Plaintiffs shall make such designations within thirty (30) days from the entry of this order.<sup>2</sup>

**V. Additional Agreements and Obligations of the Parties**

A. DFS responses and documents produced therein shall be considered interrogatory answers and responses to requests for production under the Federal Rules of Civil Procedure, and shall be governed in the same manner and standards applicable to written discovery under the Federal Rules of Civil Procedure. The DFS questions and document requests have been negotiated and agreed to by the parties. All objections to the admissibility of information contained in the DFS are reserved and therefore no objections shall be lodged in the responses to the questions and requests contained in the DFS absent special circumstances. The admissibility of information in responses to the DFS shall be governed by the Federal Rules of Evidence and no objections are waived by virtue of any DFS response.

B. Plaintiffs' use of the DFS is in lieu of interrogatories and other discovery devices that they would otherwise have propounded, without prejudice to the Plaintiffs' right to propound additional discovery as part of any bellwether program, in cases selected for trial, or upon remand of a case to its transferor court. Nothing in the DFS shall be deemed to limit the scope of inquiry at depositions, nor shall anything in the DFS or this Order be construed to limit the ability of Plaintiffs to engage in discovery to the fullest extent allowable by the Federal Rules of Civil Procedure and this Court's Orders once case-specific discovery is initiated. The

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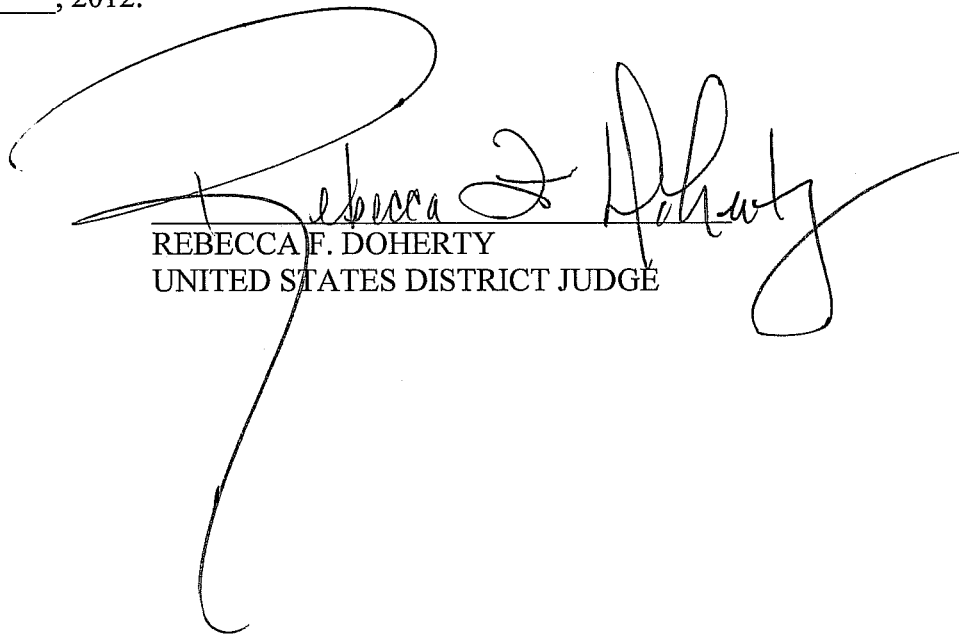
<sup>2</sup> If a Plaintiff does not intend to designate additional health care providers pursuant to the terms of this Order, the Plaintiff must serve the designation and indicate "none requested" in order to trigger Defendants' DFS obligations.



admissibility of information in the DFS shall be governed by the Federal Rules of Evidence, and no objections are waived by virtue of any DFS response.

C. The parties may agree to an extension of the above time limits for service of a DFS and the Plaintiffs are encouraged to respond reasonably to such requests. If the parties cannot agree on reasonable extensions of time, such party may apply to the Court for such relief.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 13<sup>th</sup> day of November, 2012.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

<b>In Re: Actos (Pioglitazone) Products Liability Litigation</b>	* * * * * *	<b>6:11-md-2299</b>
<b>This Document Applies to:</b>	* * * *	<b>JUDGE DOHERTY</b>  <b>MAGISTRATE JUDGE HANNA</b>

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**DEFENDANT FACT SHEET**

For each Plaintiff from whom a substantially complete and verified Plaintiff Fact Sheet (“PFS”) has been received, Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals U.S.A. Inc. f/k/a Takeda Pharmaceuticals North America, Inc. and Takeda Global Research & Development Center, Inc. (collectively “TAKEDA”); and Eli Lilly and Company (“LILLY” or collectively with TAKEDA as “DEFENDANTS”) must complete this Defendant Fact Sheet (“DFS”) and identify or provide documents and/or data responsive to the questions set forth below to the best of their knowledge. If a named party to the lawsuit, Defendant LILLY must complete a DFS only if the Plaintiff alleges use of Actos<sup>1</sup> beginning on or before December 31, 2007. For cases in which Plaintiff alleges use of Actos® solely between January 1, 2008 and December 31, 2008, Defendant LILLY shall provide the names of the LILLY sales representatives who called on Plaintiff’s prescribing physician(s) and the dates of those calls.

In completing this DFS, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can. You must supplement your responses if you learn that they are incomplete or incorrect in any material respect. You must also supplement your responses in the event that additional information is provided from the Plaintiff that relates to the questions raised in the DFS. The DFS shall be completed in accordance with the requirements and guidelines set forth in the applicable Case Management Order.

In the event the DFS does not provide you with enough space for you to complete your responses or answers, please attach additional sheets if necessary. Please identify any documents that you are producing as responsive to a question or request by bates number.

This DFS must be completed and served on each Plaintiff’s counsel identified in the PFS 90 days after the date that a substantially complete and verified Plaintiff Fact Sheet (PFS) has been served on Defendants.

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<sup>1</sup> As used herein, the term “Actos” includes pioglitazone hydrochloride, Actos®, ACTOplus Met®, ACTOplus Met XR®, and Duetact®.

## DEFINITIONS

As used herein, the terms “YOU,” “YOUR,” or “YOURS” means the responding Defendants.

“DEFENDANTS” shall mean and refer to those companies involved in the development, manufacture and distribution of the drugs known as ACTOS, including Takeda Pharmaceuticals America, Inc.; Takeda Pharmaceuticals U.S.A. Inc. f/k/a Takeda Pharmaceuticals North America, Inc.; Takeda Global Research & Development Center, Inc.; Takeda Pharmaceutical Company Limited; Takeda Pharmaceuticals LLC; Takeda Pharmaceuticals International Inc.; and Takeda California, Inc. f/k/a Takeda San Diego Inc. (collectively “TAKEDA”); and Eli Lilly and Company (“LILLY” or collectively with TAKEDA as “DEFENDANTS”).

TAKEDA and LILLY, unless specifically defined to include a third-party, shall each answer each document request and question that not only calls for your knowledge, but also for all knowledge that is available to you by reasonable inquiry, including inquiry of your "officers," "directors," "agents," "employees," and attorneys.

As used herein, the term “DOCUMENTS” and/or “DOCUMENTATION” are coextensive with the meaning of the terms “DOCUMENTS,” “writings,” and “tangible things,” and shall have the broadest possible meaning and interpretation and shall, without limitation, mean and refer to any written, printed, typed, photostatic, photographed, recorded, computer generated, computer-stored, or otherwise maintained record or COMMUNICATION or representation, including (i) any data compilation in any form, whether comprised of letters, words, numbers, pictures, sounds, bytes, emails, electronic signals or impulses, electronic data, active files, deleted files, file fragments, or any combination thereof; (ii) all memoranda, notes, records, letters, envelopes, telegrams, messages, studies, analyses, contracts, agreements, projections, estimates, working papers, accounts, analytical records, reports and/or summaries of investigations, opinions or reports of consultants, opinions or reports of experts, opinions or reports of accountants, other reports, trade letters, press releases, comparisons, books, diaries, articles, magazines, newspapers, booklets, brochures, pamphlets, circulars, bulletins, notices, forecasts, drawings, diagrams, instructions, minutes of meetings or COMMUNICATIONS of any type; (iii) video files, audio files, inter- and intra-office COMMUNICATIONS, questionnaires, surveys, charts, graphs, photographs, phonographs, films, tapes, discs, data cells, drums, printouts and all other compiled data (translated, if necessary, through intermediary or other devices into usable forms); (iv) any records or information maintained on, stored in or generated on any electronic transfer or storage system, any preliminary versions, drafts or revisions of any of the foregoing; (v) and other writings or DOCUMENTS of whatever description or kind, whether prepared by DEFENDANTS or authorized by or on behalf of DEFENDANTS, all non-identical copies and drafts of any of the above-described DOCUMENTS currently or formerly in the possession, custody or control of DEFENDANTS, or the former or present directors, officers, counsel, agents, employees, partners, consultants, principals, and/or persons acting on DEFENDANTS’ behalf.

As used herein, the word “COMMUNICATION” and/or “CORRESPONDENCE” shall mean and refer to any oral, written, spoken, or electronic transmission of information, including, but not limited to, meetings, discussions, conversations, telephone calls, memoranda, letters, emails,

text messages, postings, instructions, conferences, seminars, or any other exchange of information between DEFENDANTS and any other person or entity.

As used herein, the term “RELATING TO,” “RELATE TO,” “REFERRING TO,” “REFER TO,” “REFLECTING,” “REFLECT,” “CONCERNING,” or “CONCERN” shall mean and refer to any DOCUMENT or COMMUNICATION evidencing, regarding, concerning, discussing, embodying, describing, summarizing, containing, constituting, showing, mentioning, reflecting, pertaining to, dealing with, relating to, referring to in any way or manner, or in any way logically or factually, connecting with the matter described in that paragraph of these demands, including DOCUMENTS or COMMUNICATIONS attached to or used in the preparation of or concerning the preparation of the DOCUMENTS or COMMUNICATIONS.

As used herein, “ELECTRONIC DATA” or “DATA” shall mean and refer to the original (native electronic format), and any non-identical copies (whether non-identical because of notes made on copies or attached comments, annotations, marks, transmission notations, or highlighting of any kind) of writings of every kind and description whether inscribed by mechanical, facsimile, electronic, magnetic, digital, or other means. Electronic data includes, by way of example only, computer programs (whether private, commercial, or works-in-progress), programming notes or instructions, activity listings of electronic mail receipts and/or transmittals, output resulting from the use of any software program, including word processing DOCUMENTS, spreadsheets, database files, charts, graphs and outlines, electronic mail, operating systems, source code of all types, peripheral drivers, PIF files, batch files, ASCII files, and any and all miscellaneous files and/or file fragments, regardless of the media on which they reside and regardless of whether said electronic data consists of an active file, deleted file or file fragment. Electronic data includes any and all items stored on computer memories, hard disks, floppy disks, CD-ROMs, removable media such as zip drives, USB drives, storage cartridges, Bernoulli Boxes and their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape, computer chips, including, but not limited to, EPROM, PROM, RAM and ROM, on or in any other vehicle for digital data storage and/or transmittal. The term electronic data also includes the file, folder tabs and/or containers and labels appended to, or associated with, any physical storage device associated with each original and/or copy.

As used herein, “ELECTRONIC MEDIA” shall mean and refer to any magnetic or other storage media device used to record electronic data. Electronic media devices may include computer memories, hard disks, floppy disks, CDROM, removable media such as Bernoulli Boxes and their equivalent, magnetic tapes of all types, microfiche, punched cards, punched tape, computer chips, including, but not limited to, EPROM, PROM, RAM and ROM, or on or in any other vehicle for digital data storage and/or transmittal.

As used herein, “KEY OPINION LEADER” or “THOUGHT LEADER” shall mean and refer to physicians, often academic researchers, who are believed by DEFENDANTS to be effective at transmitting messages to their peers and others in the medical community. This term shall mean and refer to any doctors or medical professionals hired by, consulted with, or retained by DEFENDANTS to, amongst other things, consult, give lectures, respond to media inquires, conduct clinical trials, write articles or abstracts, sign their names as authors to articles or

abstracts written by others, and occasionally make presentations on their behalf at regulatory meetings or hearings.

As used herein, the phrase “PROVIDED” means sold, given, distributed, shipped, delivered or otherwise placed into the stream of commerce.

As used herein, the phrase “TREATING HEALTH CARE PROVIDER” means any physician, medical provider, practice, clinic, person, or entity identified with particularity in the PFS who prescribed and/or dispensed Actos® to the Plaintiff and up to two (2) additional health care providers who have treated the Plaintiff for their alleged Actos®-related injuries and have been designated by the Plaintiff pursuant to the provisions of Case Management Order: Defendant Fact Sheets. Treating Health Care Provider” shall refer not only to the medical professional who prescribed Actos® to the Plaintiff or up to two additional health care providers who have treated the Plaintiff for injuries claimed to be related to Actos®, but also anyone working within his or her office, including, but not limited to, employees, nurses, nurse practitioners, and office or clerical staff of the clinic, practice, or medical group.

As used herein, the phrase “PROMOTIONAL ITEMS” means any and all promotion items, marketing devices, freebies, merchandise, handouts, meals, or any other items related to Actos®, including, but not limited to, physical items marked with the Actos® trademark such as anatomical models, notepads, post-it-notes, pens, flashlights, office supplies, models for patient demonstration, diagnostic tools and aids, medical assessment and dosage calculators, pharmacy and pharmacist tools, patient compliance tools, custom medical calculators and software, branded apparel, leather portfolios, prescription pads, picture frames, letter openers, clipboards, water bottles, coffee mugs/cups, pocket/pen lights, key chains, badge-holders, bags, travel accessories, and other “freebies” provided to Prescribing Health Care Providers.

**I. Case Information**

This DFS pertains to the following case:

Case caption: \_\_\_\_\_

Civil Action No. \_\_\_\_\_

Court in which action was originally filed: \_\_\_\_\_

Date that this DFS was completed: \_\_\_\_\_

Name and Address of all persons who provided information responsive to the questions posed in this DFS:

A: \_\_\_\_\_  
(Name)

\_\_\_\_\_  
(Job Title)

\_\_\_\_\_  
(Address)

\_\_\_\_\_  
(Phone Number)

B: ✓

\_\_\_\_\_  
(Name)

\_\_\_\_\_  
(Job Title)

\_\_\_\_\_  
(Address)

\_\_\_\_\_  
(Phone Number)

## II. Contacts With Treating Health Care Providers

For each Treating Health Care Provider identified in the PFS, please state the following:

### A. Dear Doctor Letters:

1. Please identify and any "Dear Doctor," "Dear Health Care Provider," "Dear Colleague," or any other similar type of document or letter sent to the Plaintiff's Treating Health Care Provider concerning Actos®. Please identify each such document or letter by stating the name and address of the person(s) who sent the document or letter; the date that each document or letter was sent; the name and address of the person(s) to whom each document or letter was sent; and identify by Bates number any and all documentation, including lists or database records, which demonstrates that these documents or letters were sent.

Sender (Name and Address)	Letter or Document Date	Recipient (Name and Address)	Bates Number of Supporting Documentation

2. Please identify the person(s) and/or data sources in which the information

provided in Section II. A. was retrieved.

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B. Physician's Information Request Letters ("PIR"):

1. Please indicate if any of the Treating Health Care Provider(s) identified in the PFS has ever initiated a PIR by identifying the name and address of the sender of the PIR; the date it was sent; the name and address of the recipient; and whether or not a response to the PIR or similar document was sent.

Sender (Name and Address)	PIR Date	Recipient (Name and Address)	Response Sent? (Yes or No)

2. For each PIR in which a response was sent as indicated by a "Yes" above, please identify the format of the response; the date the response was sent; the name and address of the sender of the response; the name and address of the recipient of the response; and provide or identify by Bates number any and all documentation, including lists or database records, which demonstrates that these responsive documents were sent.

Original PIR or Request Document Date	Format of Response (Letter or Otherwise)	Date Response Sent	Response Sender (Name and Address)	Response Recipient (Name and Address)	Bates Number of Supporting Documentation

3. Please identify the person(s) and/or data sources in which the information provided in Section II. B. was retrieved.

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C. Other Contacts

- For each Treating Health Care Provider identified in the PFS, please identify by name any of the Defendants' Sales Representatives and/or any other detail person ("Representative") who came in contact with the Treating Health Care Provider and provide dates of each contact that relate to Actos®. Please indicate the Representative's dates of employment with the Defendant, and, if that Representative is no longer employed by the Defendant, provide the last known address and phone number of that Representative.

Treating Health Care Provider	Name of Representative (Provide Last Known Address and Telephone Number if No Longer Employed)	Dates of Employment	Date(s) of Contact

- For each Representative identified in Section II.C.1., please indicate the designated Territory in which the Representative was assigned and the Representative's applicable Supervising District Manager(s) and Regional Sales Director(s).

Representative	Territory	Supervising District Manager(s)	Regional Sales Director(s)

- Have Defendants or their representatives ever provided any of Plaintiff's Treating



Health Care Providers with Actos® samples?

Yes \_\_\_\_\_ No \_\_\_\_\_

A. If the answer is “yes,” please state the Treating Health Care Provider that received the samples; the dates in which such samples were provided; the amount, dosage, and lot numbers of such samples; and the name of the Representative who provided the samples.

HealthCare Provider	Date Shipped to and/or Provided	Amount, Dosage, and Lot Numbers	Representative who Provided

4. For each Treating Health Care Provider, please state whether Defendants or their representatives ever provided him/her with “Promotional Items.”

Yes \_\_\_\_\_ No \_\_\_\_\_

A. If the answer is “yes,” please state the Treating Health Care Provider that received the Promotional Items; the name of the Representative who provided the items; the dates in which such items were provided; a description and quantity of the items.

Healthcare Provider	Representative who Provided	Date(s) Provided	Description and Quantity

*To the extent available, a physical sample of the promotional item shall be provided to plaintiff's counsel.*

5. For each Representative identified in Section II.C.1., please identify or produce all call notes for calls with Plaintiff's Treating Health Care Provider(s).

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7. For each Representative identified in Section II.C.1., please identify or produce all informational or promotional information that the Representative distributed to any of Plaintiff's Prescribing Health Care Providers.

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8. Please identify the person(s) and/or data sources in which the information provided in Section II. C. was retrieved.

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**III. Consulting With Plaintiff's Treating Health Care Provider**

**A. Consulting and Professional Relationships**

1. If any of Plaintiff's Treating Health Care Providers identified in the PFS have been retained or compensated as a "key opinion leader," "thought leader," member of a "speaker's bureau," "clinical investigator," "consultant," or in any other capacity relating to the subject of diabetes medications (including Actos®) and/or the treatment of diabetes, bladder cancer, congestive heart failure, or myocardial infarction please identify date(s) that the Treating Health Care Provider was consulted, retained or compensated; the nature of the affiliation; and the amount of remuneration for expenses and/or fees.

Treating Health Care Provider	Date(s) that Treating Health Care Provider was Consulted, Retained or Compensated	Nature of Affiliation	Remuneration


2. For any Treating Health Care Provider identified in response to III.A.1., please identify or produce all documents or correspondence provided to the Treating Health Care Provider by Takeda or Eli Lilly concerning the potential benefits and/or risks of diabetes medications (including Actos®) and/or the treatment of diabetes, bladder cancer, congestive heart failure, or myocardial infarction.

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3. For each Treating Health Care Provider identified in Section III.A.1., please identify or produce any documentation relating to monetary compensation paid to that Treating Health Care Provider, including, but not limited to, completed 1099 forms or other IRS documentation.

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4. For each Treating Health Care Provider identified in Section III.A.1., please identify or produce all documents relating to all consulting agreements contracts, and retainer agreements entered into with the Treating Health Care Provider.

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5. For each Treating Health Care Providers identified in Section III.A.1., please indicate whether they were ever attended any Defendant- sponsored conferences or events (“Programs”) relevant to the treatment of diabetes, bladder cancer, congestive heart failure, or myocardial infarction, and provide the title, location,

date(s) and topic(s) of the program.

Treating Health Care Provider	Title, Location, and Date(s) of Program	Topic(s) of Program

6. For any Program identified in response to III.A.5., please identify all speakers at the Program.

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**IV. Plaintiff's Treating Health Care Provider's Practices**

For each Treating Health Care Provider identified in the PFS, please state and produce the following:

- A. Do you have or have you had access to any database or other information that tracks the prescribing or treating practices of Plaintiff's Treating Health Care Provider(s) with respect to Actos® or any other diabetes drug (including, but not limited to, the product(s) prescribed, the number of prescriptions, the number of refills, and the time when these products were prescribed or refilled).

Yes \_\_\_\_\_ No \_\_\_\_\_

If your answer is "yes", please identify the database or document which captures that information, to the extent available:

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- B.. Please identify the person(s) and/or data sources in which the information provided in Section IV. was retrieved.

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V. **Plaintiff's Medical Condition**

- A. Have you been contacted by Plaintiff, any of his/her Treating Health Care Providers, or anyone acting on behalf of Plaintiff (other than Plaintiff's counsel) concerning Plaintiff?

Yes \_\_\_\_\_ No \_\_\_\_\_

- B. If you have been contacted by any person or entity concerning the Plaintiff, please state the name of the person(s) who contacted you and the name and address of the person(s) who contacted in response.

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- C. Please identify or produce all documents which reflect any communication between any person and you concerning Plaintiff.

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- D. Please identify or produce any and all documents, data, information, notes and/or materials produced in the course of your response, evaluation, investigation, and/or follow up after the submission of any MedWatch form and/or Adverse Event Report on behalf of or in reference to the Plaintiff, including back-up documentation and any evaluation or investigation you conducted. With respect to adverse event reports generated by the receipt of a legal claim or complaint, Defendants shall produce the adverse event data, but not the underlying legal claim or complaint, or any other related document(s) generated or obtained through the legal process (e.g. medical records, discovery responses, legal correspondence, etc.)

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- E. Please identify the person(s) and/or data sources in which the information provided in Section V. was retrieved.

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**VI. Advertising**

- A. Aside from national advertising (i.e. advertising that was not directed to any specific geographic region), did you advertise Actos® in the Media Market in which Plaintiff lived at the time that he or she used Actos® as disclosed in the PFS?

Yes \_\_\_\_\_ No \_\_\_\_\_

1. If your answer to VI.A. is “yes,” please provide, to the extent available, the name, identity, and/or title of the advertisement; the nature of the media (i.e., print or television); the media location(s), outlet(s), publication(s) and/or channel(s); and the date(s) the advertisement ran.

Name/Identity/Description of the Advertisement	Nature of Media (print or television)	Media Location(s), Outlet(s), Publication(s) and/or Channels	Dates that Advertisements Ran

- B. Aside from national advertising (i.e. advertising that was not directed to any specific geographic region), did you advertise Actos® in the Media Market in which Plaintiff’s Treating Health Care Provider’s office was located, as listed in the PFS, at the time that Plaintiff used Actos® as disclosed in the PFS?

Yes \_\_\_\_\_ No \_\_\_\_\_

1. If your answer to VI.B. is “yes,” please provide, to the extent available, the name, identity, and/or title of the advertisement; the nature of the media (i.e., print or television); the media location(s), outlet(s), publication(s) and/or channel(s); and the date(s) the advertisement ran.

Name/Identity/Description of the Advertisement	Nature of Media (print or television)	Media Location(s), Outlet(s), Publication(s) and/or Channels	Dates that Advertisements Ran

**VII. Documents**

- A. To the extent you have not already done so, please produce a copy of all documents and things that fall into the categories listed below. These include documents in the possession of any of your present and former employees, including information provided to your attorneys:
1. Any document which relates to or refers to Plaintiff.
  2. Any document sent to or received from any of Plaintiff’s Treating Health Care Providers.
  3. “Dear Doctor,” “Dear Health Care Provider,” “Dear Colleague” letters, or PIR’s sent to or received from Treating Health Care Providers and any and all other related documentation.
  4. Any and all documentation sent to or received during the course of communications with Plaintiff’s Treating Health Care Providers and Defendants’ Sales Representatives, and/or any other detail representatives.
  5. Promotional items and/or any other tangible items exchanged between Plaintiff’s Treating Health Care Providers and Defendants’ Sales Representatives, Marketing Organization Representatives, Employees, and/or any other detail representatives.
  6. The call notes for calls with Plaintiff’s Treating Health Care Provider(s), for each Sales Representatives, and/or any other detail representatives identified in Sections I-VI above.
  7. Any and all documentation relating to your retention and/or compensation of any of Plaintiff’s Treating Health Care Providers as a “key opinion leader,” “thought leader,” member of a “speaker’s bureau,” “clinical investigator,” “consultant,” or in any other capacity relating to the subject of diabetes medications (including Actos®).

8. Any and all documents including tax returns for any amounts of money paid to Plaintiff's Treating Health Care Providers.
9. Any and all documents relating to Plaintiff's Treating Health Care Provider(s)' attendance at Defendant sponsored conferences or events relevant to the treatment of diabetes, bladder cancer, congestive heart failure, or myocardial infarction, including, but not limited to, programs, brochures, agendas, attendee lists, speaker lists, and/or promotional materials.
10. Any and all documents reflecting any actual communication between you and Plaintiff's Treating Health Care Providers concerning the risks of the injuries of Actos®.
11. Any and all documents reflecting any contracts or actual communications between you and any of Plaintiff's Treating Health Care Providers regarding Actos®.
12. Any market surveys or other surveys to or received from any of Plaintiff's Treating Health Care Providers.
13. Any and all documentation which purports to describe, analyze, investigate, track, and/or report the prescribing practices of any of Plaintiff's Treating Health Care Providers relating to Actos®, subject to the approval and/or agreement of the owner (IMS Health) of the prescribing data to release the data, which approval and/or agreement Defendant will request.
14. Any and all documentation relating to contact between you and the Plaintiff (other than with Plaintiff's counsel).
15. Any and all documents, data, information, notes and/or materials produced in the course of your response, evaluation, investigation, and/or follow up after the submission of any MedWatch form and/or Adverse Event Report on behalf of or in reference to the Plaintiff, including back-up documentation and any evaluation or investigation you conducted. With respect to adverse event reports generated by the receipt of a legal claim or complaint, Defendants shall produce the adverse event data, but not the underlying legal claim or complaint, or any other related document(s) generated or obtained through the legal process (e.g. medical records, discovery responses, legal correspondence, etc.)
16. Aside from national advertising, copies of any and all advertisements directed toward the media markets in which the Plaintiff resided and/or Plaintiff's Treating Health Care Provider's office is located.



17. Any other document, printout, communication or tangible item identified in, referred to, and/or pertaining to any of the requests or responses in Sections I-VII above.

**Certification of Counsel**

Undersigned counsel for Defendants Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals America, Inc., and Takeda Global Research & Development Center, Inc. (Counsel) certifies that Counsel and/or members or associates in Counsel's firm instructed Counsel's Firm, Defendants, Defendants' other current or former attorneys (Other Attorneys) and/or agents for any of the foregoing, to engage in best efforts to identify, locate and supply all responsive documents demanded in the Request to Produce to Defendants approved by Case Management Order \_\_ that were in the possession, custody or control of Counsel, Defendants, Other Attorneys and/or agents, and Counsel further certifies that Counsel has a good faith belief that these instructions were followed by all of the aforementioned persons.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name

\_\_\_\_\_  
Date

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

This Document Applies to:  
All Cases

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**PLAINTIFF'S TREATING HEALTH CARE PROVIDER DESIGNATION  
FOR DEFENDANT FACT SHEETS**

Pursuant to the provisions of Case Management Order: Defendant Fact Sheet, the definition of "TREATING HEALTH CARE PROVIDER" includes up to two (2) additional health care providers who have treated the Plaintiff(s) for injuries claimed to be related to Actos® and have been designated by the Plaintiff(s). Plaintiff(s) hereby submits the following designation of up to two (2) additional health care providers who have treated the Plaintiff(s) for their Actos®-related injuries:

**I. Case Information**

A. Plaintiff(s)' Name(s): \_\_\_\_\_

Case No. (W.D.L.A. or Other): \_\_\_\_\_

Date PFS Submitted: \_\_\_\_\_

Attorney Who Submitted PFS: \_\_\_\_\_

Firm: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-Mail Address: \_\_\_\_\_

**II. Designation(s):**

<b>Name &amp; Specialty</b>	<b>Address &amp; Phone Number</b>	<b>Dates of Treatment</b> <b>(Provide approx date(s) if precise date(s) are unknown)</b>	<b>Reason for Treatment</b>

Undersigned Counsel for Plaintiff(s) hereby submits.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: November 7, 2012

**MINUTE ENTRY**

Due to the delays and complexities created by Hurricane Sandy's assault on the East Coast last week, as well as the further delays being created today and tomorrow by the most recent storm that currently is working its way toward the very same part of the country, *the monthly status conference scheduled for November 15, 2012 is hereby CANCELLED.*

Lead counsel should expect to hear from the Special Masters about scheduling one or more telephone conferences on November 15, in order to take advantage of time that has been set aside and to use that time to make as much forward progress as circumstances will permit.

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: October 24, 2012

**MINUTE ENTRY:  
AGENDA FOR OCTOBER 25, 2012 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, October 25, 2012:

- I. Status of Federal and State Court Filings
- II. Report on Developments in the MDL since the September 20 Status Conference
- III. Status of proceeding with 30(b)6 Depositions, including:
  - Pharmacovigilance
  - Hard Copy Materials
  - Corporate Organizational Structure
  - Third Party Vendors
  - Regulatory
  - Sales and Marketing
  - Medical Affairs
  - ESI/ Databases
  - Sales Representatives
- IV. Defendant Fact Sheet status
- V. Discovery Protocol status
- VI. Amended Scheduling Order status
- VII. PSC Assessment/Hold Back Motion

- VIII. Update on ESI/Predictive Coding Progress
- IX. Inspection of Document Facility
- X. Privilege Log Issues
- XI. Chicago State Court Depositions
- XII. Report from liaison counsel regarding compliance with communications to state court litigants
- XIII. Next Status Conference: November 15, 2012

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OCT - 9 2012 *ms*

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**JOINT EXPENSES**

This Court having previously found it necessary to appoint Special Masters to provide the Court with support in management of these proceedings, having allowed input by the Defendants and the Plaintiffs (by way of the Plaintiffs' Steering Committee), and being aware of the potential that additional expenses might be incurred during the course of these proceedings,

IT IS HEREBY ORDERED that:

1. The parties shall be cast with certain costs of these proceedings, in the manner described below.
2. The designated costs shall be cast 50% to the Plaintiffs collectively, and 50% to the Defendants collectively.
3. Special Master Russo shall open a checking account (to be named "In re Actos (Pioglitazone) Products Liability Litigation Joint Expenses Account") in Mid-South Bank, NA, whose home office is in Lafayette, Louisiana (the "Joint Expense Account"), for the purpose of serving as holder of funds collected from the parties until such time as funds are disbursed.

4. Special Master Russo shall engage the accounting firm of Arsement, Redd, and Morella, LLC for the purpose of auditing and administering the Joint Expense Account pursuant to the terms of this order.
5. The Plaintiffs and Defendants shall provide funds in the following amounts, on the following schedule, to cover those costs, fees, and joint expenses that have been incurred since December 29, 2011, as well as those costs, fees and joint expenses that might be incurred in future:
  - \$100,000 each, to be paid no later than October 29, 2012;
  - \$100,000 each, to be paid no later than November 26, 2012;
  - thereafter, \$100,000 each, per quarter, to be paid no later than 15 days after each quarter has ended, *e.g.*, for 4<sup>th</sup> quarter of 2012, payment is due by January 15, 2013; for 1<sup>st</sup> quarter of 2013, payment is due by April 15, 2013, etc. This schedule shall remain in place until further notice. These amounts will be adjusted (either increased or decreased) as necessary.
6. Funds in the Joint Expense Account will be used to pay Special Masters' fees and costs, banking fees, accounting fees, travel costs for the Court (or for state court judges), as well as any other unusual out of pocket expenses related to these proceedings that might be incurred by this Court or the Special Masters, with full and transparent notice given by the Court and/or the Special Masters. In the event that the Court anticipates charging the Joint Expense Account for its own expenditures, notice will be given to co-lead counsel or their designee, in advance of the expenditure, where possible, and counsel will be given an opportunity to



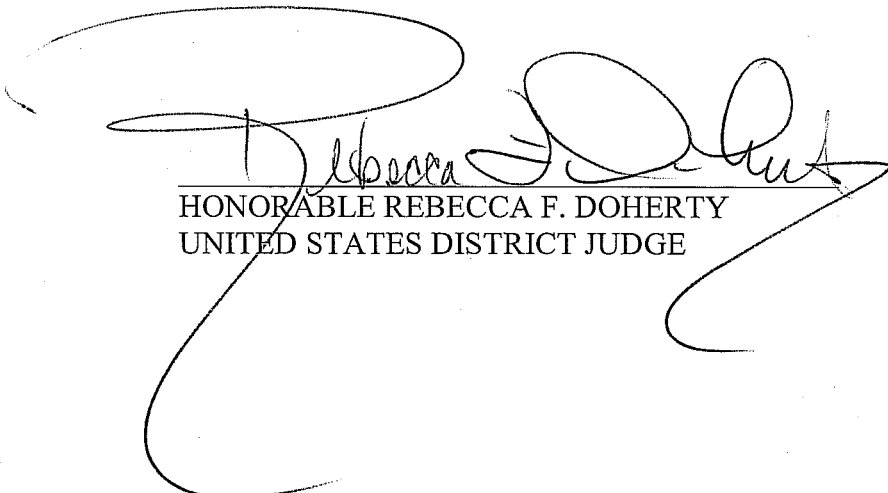
submit objections by way of the co-lead counsel for Plaintiffs and Defendants, or their designee.

7. Should the Defendants and Plaintiffs, by way of co-lead counsel or their designee, wish to use the Joint Expense Account to fund joint expenses such as a court reporting firm hired on behalf of all parties in the case, or for any other expenses incurred jointly, they should jointly draft an agreed amendment to this Order for signature by the Court, prior to submission of the expenses.
8. At the end of these proceedings, any funds remaining in the Joint Expense Account shall be returned, 50% to the Plaintiffs and 50% to the Defendants.
9. Funds in the Joint Expense Account shall be distributed in accordance with the following procedures:
  - A Request for Distribution of Funds shall be submitted to this Court, and filed into the record, with a copy provided to Magistrate Judge Hanna.
  - The parties shall have seven (7) days to file objections with Magistrate Judge Hanna to any Request for Distribution of Funds.
  - Magistrate Judge Hanna shall review each such Request, together with any objection filed, and issue a recommendation for payment in full, partial payment, or denial of the request in its entirety. The parties shall have seven (7) days to file objections with the Court, to Magistrate Judge Hanna's recommendation. This Court shall consider Magistrate Judge Hanna's recommendation, together with all objections made to such recommendation, and thereafter order payment, modified payment, or denial of payment.

- Only upon order issued by this Court shall the accounting firm issue payment and only in the amount ordered by the Court.
- No funds shall be distributed, except upon order of this Court for any purpose, whatsoever.

10. The accounting firm shall issue to this Court, directed to Magistrate Judge Hanna with a copy to this Court, a quarterly report of the activity in the account since the last report, including the current balance and all distributions made and to whom.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 9 day of October, 2012.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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OCT - 9 2012

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE: ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**SPECIAL MASTER FEES AND COSTS**

This Court has cast costs in this matter against the Plaintiffs and Defendants jointly, and has established a Joint Expense Account for the purpose of reimbursing such costs as they are incurred. This Order is entered for the purpose of establishing the rules under which the Special Masters are to submit their fees and costs for payment.

IT IS HEREBY ORDERED that, beginning with the 3<sup>rd</sup> quarter of 2012, Special Master Russo and Deputy Special Master Rodriguez shall:

- create quarterly statements, dated no later than 30 days after the quarter has ended, reflecting the time they have expended fulfilling their duties (in one-tenth hour increments), together with out-of-pocket expenses they have incurred, and such statements shall be maintained in their files until further order of this Court;
- simultaneously, the Special Masters shall submit to this Court (directing the submission to Magistrate Judge Hanna with a copy to Judge Doherty), and send to co-lead counsel for the Plaintiffs and Defendants for distribution to all MDL counsel within five (5) days thereafter, summary statement(s) from which any and all confidential information (as well as information referring to or identifying any confidential information) has been omitted;

- only upon timely and proper request by an appropriate party made in writing, and submitted to the Court through the co-lead counsel(s) for Plaintiffs or Defendants, or their designee, and only if granted by this Court after allowing objection by an appropriate opposing party submitted through the co-lead counsel(s) for Plaintiffs or Defendants, or their designee, shall the quarterly statements be made available to any party. Additionally, neither Magistrate Judge Hanna nor Judge Doherty will receive or review the quarterly statements without prior, full notice being given to co-lead counsel for the Plaintiffs and the Defendants.

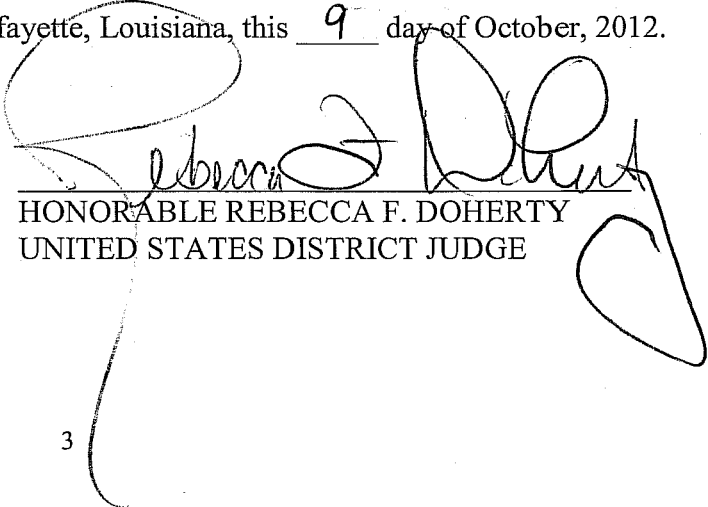
IT IS HEREBY FURTHER ORDERED that, with regard to fees and expenses incurred prior to the entry of this Order, Special Master Russo and Deputy Special Master Rodriguez shall submit statements (complying with the same procedure described above) in accordance with the following schedule:

- for fees incurred in March, 2012, statements shall be submitted by October 19, 2012
- for fees incurred in April, 2012, statements shall be submitted by October 26, 2012
- for fees incurred in May, 2012, statements shall be submitted by November 2, 2012
- for fees incurred in June, 2012, statements shall be submitted by November 9, 2012
- for fees incurred in the 3<sup>rd</sup> quarter of 2012, statements shall be submitted by November 16, 2012.

All fees and expenses incurred on and after October 1, 2012 shall be submitted in accordance with the quarterly billing procedure described above.

IT IS HEREBY FURTHER ORDERED that the Special Masters in this case are excused from the obligation of providing detailed descriptions of their activities in their statements and Requests for Distribution of Funds. This Court finds that this unusual provision is necessary and appropriate as: (a) the Special Masters have expressly been granted by all involved the authority to participate in *ex parte* contact with counsel for all parties in these proceedings; (b) this Court and all parties are aware that, in the months since the Special Masters have been appointed, counsel have freely exercised their right to engage in *ex parte* contact with the Special Masters; (c) the parties and the Special Masters agree these *ex parte* exchanges have been extremely helpful to the Special Masters' ability to assist the parties and this Court in managing these proceedings much more efficiently than would have been the case without them; (d) thus, this Court must be able to protect the Special Masters' records from being subject to subpoena issued by other courts, either while these proceedings are ongoing or after they have been terminated; and (e) this Court wishes to ensure that the Special Masters' records are not used by any party or counsel to render non-confidential that which was discussed with a well-founded expectation of confidentiality.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 9 day of October, 2012.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: September 18, 2012

**MINUTE ENTRY:**  
**AGENDA FOR SEPTEMBER 20, 2012 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, September 20, 2012:

- I. Information from Clerk of Court's Office**
- II. Status of New Filings and Transfers**
- III. Status of State Court Filings**
- IV. Report on Developments in the MDL since August 23 Status Conference**
- V. Orders expected to be issued before next conference**
  - Defendants Fact Sheets
  - Expense-related orders
  - Discovery Protocol
  - Amendment to Scheduling Order
- VI. Next Status Conference: October 25, 2012**

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IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Actions

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:  
Protecting the Confidentiality of Discovery Materials**

For good cause shown, the Court issues the following Protective Order:

**1. Discovery Material.**

(a) This Order applies to all hard copy and electronic materials, the information contained therein, and all other information produced or disclosed during this proceeding, including all copies, excerpts, summaries, or compilations thereof, whether revealed in a document, deposition, other testimony, discovery response or otherwise (collectively "discovery material"), by any party to this proceeding (the "Producing Party") to any other party (the "Receiving Party").

(b) At the time this Order is entered in the *In re Actos (Pioglitazone) Products Liability Litigation* (W.D. La., MDL No. 2299), it becomes binding upon all parties presently involved, or who are later named, in these proceedings including their respective corporate parents, subsidiaries and affiliates and their respective attorneys, principals, experts, consultants, representatives, directors, officers, employees, and others as set forth in this Order.

(c) If additional parties are added other than parents, subsidiaries or affiliates of current parties to this litigation, their ability to receive Confidential

Information as set forth in this Order will be subject to their being bound, by agreement or Court Order, to this Order.

(d) The entry of this Protective Order does not prevent any party from seeking a further order of this Court regarding Discovery Materials.

(e) Nothing herein shall be construed to affect in any manner the admissibility at trial or hearings before this Court of any document, testimony, or other evidence.

**2. Confidential Discovery Material.** “Confidential Discovery Material,” as used herein, means information of any type, kind or character that the Producing Party believes in good faith constitutes, reflects, discloses, or contains information subject to protection under Rule 26(c)(1)(G), whether it is a document, information contained in a document, information revealed during a deposition or other testimony, information revealed in an interrogatory response, or information otherwise revealed. Discovery material containing trade secrets, or other confidential or proprietary research, development, manufacturing or commercial or business information may be designated by the Producing Party as “Confidential.” Without prejudice to the right of a Producing Party to object to the production of the following information or of a party to seek production and/or de-designation, examples of the information that may be alleged to be subject to such designation include but are not limited to the Producing Party’s:

a. Customer names and compilations of information related to opinion leaders and other consultants;

b. Proprietary licensing, distribution, marketing, design, development, research and manufacturing information regarding products and



medicines, whether previously or currently marketed or under development (not to include disseminated marketing materials or materials that, on its face, was published to the general public);

- c. Unpublished clinical studies, scientific literature, and related documents;
- d. Information concerning competitors;
- e. Production information;
- f. Personnel records and information;
- g. Financial information not publicly filed with any federal or state regulatory authorities or not contained within any publicly available quarterly or annual reports;
- h. Private medical information that identifies a person unless such identifying information is redacted; and
- i. Information submitted to any governmental or regulatory agency, which information is exempt from public disclosure.

**3. Discovery Material and Foreign Law.** Any entity organized under the laws of a country other than the United States, including but not limited to Japan, France, Germany, and the United Kingdom, that produces information in this litigation may designate as confidential those documents in any form (including electronic or paper form) containing “Protected Data” within the meaning of the applicable data protection or privacy laws, if any.<sup>1</sup>

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<sup>1</sup> “Protected Data” shall refer to any information that a party believes in good faith to be subject to foreign data protection laws. Protected Data constitutes highly sensitive materials requiring special protection. Examples of such data protection laws include but are not limited to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the Protection of Individuals with Regard to the

#### 4. Use of Confidential Discovery Material.

(a) Any discovery material that is designated as “Confidential” in accordance with Paragraph 2 above, along with any copies, abstracts, summaries, excerpts, compilations thereof, or information derived from such discovery material, and any notes or other records regarding the contents of such discovery material (collectively “confidential discovery material”), shall not be used for any business or competitive purpose, except by the Producing Party, or for any other purposes whatsoever, other than the litigation of cases in this MDL, including post-MDL proceedings in transferor courts (hereinafter referred to collectively as “this litigation”), and for any other action brought by or on behalf of a former pioglitazone user alleging injuries or other damages therefrom (“Other Actos Lawsuits”), so long as all parties are bound by and subject to this Order or another judicially approved order that is identical to or the substantial equivalent to this Order. Confidential discovery material will not be disclosed except in accordance with paragraphs 4(b), 7, 10, and 11.

(b) Prior to being given access to confidential discovery material, any person falling within subparagraphs 7(a)(vi) or 7(a)(vii) shall be provided with a copy of this Order and shall execute a copy of the Endorsement of Protective Order, attached as Exhibit A. Counsel providing such access to confidential discovery material shall retain copies of the Endorsement(s) of Protective Order and shall provide them to counsel producing confidential discovery materials as provided below. For testifying experts, a

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Processing of Personal Data and on the Free Movement of Such Data, 1995 O.J. (L281/31) (European Union personal information); Data Protection Act 1998 (c. 29) (United Kingdom personal information); the German Federal Data Protection Act (Germany personal information); French Data Protection Act. Law No. 78-17 of January, 6, 1978, J.C.P. 1978, III, No. 44692; and The Personal Information Protection Act (Law No. 57 of 2003) (Japan personal information).

copy of the Endorsement of Protective Order executed by the testifying expert shall be furnished to counsel for the party who produced the confidential discovery material to which the expert has access.

**5. Designation of Confidential Discovery Material.**

(a) Confidential discovery material, if in writing, shall have the following language stamped on the face of the writing, or shall otherwise have such language clearly marked in the margins:

**“CONFIDENTIAL - SUBJECT TO PROTECTIVE ORDER”**

Such stamping or marking will take place prior to production by the Producing Party, or subsequent to selection by the Receiving Party for copying but prior to the actual copying if done expeditiously. The stamp shall be affixed in such manner in the margins as not to obliterate or obscure any written matter.

(b) To the extent that confidential discovery material is stored or recorded in the form of electronic or magnetic media (including information, files, databases, or programs stored on any digital or analog machine-readable device, computers, Internet sites, discs, networks, or tapes) (“Computerized Material”) is produced by any party in such form, the Producing Party may designate such matters as confidential by a designation of **“CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER”** on the media. Whenever any Receiving Party reduces such material to hardcopy form, that party shall mark the hardcopy form with the corresponding **“CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER”** designation.

(c) In the case of deposition testimony relating to documents designated as confidential, the portion of the transcript in which confidential writings are

offered, identified or discussed shall also be designated as confidential. Any additional confidentiality designations shall be made within thirty (30) calendar days after the transcript has been received by counsel making the designation, and shall specify the testimony being designated confidential by page and line number(s). Until the expiration of such thirty (30) day period, the entire text of the deposition, including exhibits, shall be treated as confidential under this Order.

(d) In the event that the Producing Party inadvertently fails to designate discovery material as confidential in this or any other litigation, it may make such a designation subsequently by notifying all parties to whom such discovery material was produced, in writing as soon as practicable. After receipt of such notification, the Receiving Party shall treat the designated discovery material as confidential, subject to that party's right to dispute such designation in accordance with Paragraph 8.

**6. Consent to Jurisdiction.** All persons receiving or given access to confidential discovery material in accordance with the terms of this Order consent to the continuing jurisdiction of the Court for the purposes of enforcing this Order and remedying any violations thereof.

**7. Disclosure of Confidential Discovery Material.**

(a) Confidential discovery material shall not be disclosed to anyone other than the following categories of persons:

i. The Court (and any appellate court), including court personnel, Special Masters and members of their staffs, jurors, and alternate jurors only in the manner provided in paragraph 10 below.

ii. If produced by Plaintiffs, Defendants' in-house counsel, paralegals and clerical support staff, and outside counsel, including any attorneys employed by or retained by Defendants' outside counsel who are assisting in connection within this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel or retained by the attorneys employed by or retained by Defendants' outside counsel. To the extent a Defendant does not have in-house counsel, it may designate two individuals employed by each Defendant (in addition to outside counsel) to receive Confidential Discovery Materials produced by Plaintiffs.

iii. If produced by any Defendant, a Plaintiff in this litigation, Plaintiff's attorneys in this litigation, including the paralegal, clerical, secretarial and other staff employed or retained by such counsel. Additionally, confidential discovery material produced by any defendant in this MDL may be disclosed to the named plaintiff(s) in Other Actos Lawsuits, and their counsel, including paralegal, clerical, secretarial and other staff employed or retained by such other plaintiffs' counsel if: (a) the lawsuit alleges or involves injuries or damages resulting from the use of pioglitazone; and (b) an order identical to or the substantial equivalent to this Order has been entered in such lawsuit or all counsel for plaintiff who receive the documents agree to be governed by the terms of this Order and shall sign an Endorsement of Protective Order, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms. Further, confidential discovery material produced by any defendant in this MDL may be disclosed to counsel representing an Actos claimant with an unfiled claim, if: (a) the claim alleges or involves injuries or damages resulting from the use of pioglitazone; and (b) all counsel for claimant who receive the

documents agree to be governed by the terms of this Order and shall sign an Endorsement of Protective Order, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms.

iv. If produced by any Defendant, clients of Plaintiff's attorneys in this litigation, including those with unfiled claims, if those clients agree to be governed by the terms of this Order and shall sign a Confidentiality Agreement, in the form annexed hereto as Exhibit A, acknowledging that he or she has read this Order and shall abide by its terms.

v. If produced by any Defendant, outside counsel for any other Defendant, including any attorneys employed by or retained by any other Defendant's outside counsel who are assisting in connection with this litigation, and the paralegal, clerical, secretarial and other staff employed or retained by such outside counsel.

vi. Any Defendant's insurer or counsel for its insurer provided that prior to receiving confidential discovery materials a person with sufficient authority to bind each insurer and its counsel executes the Endorsement of Protective Order and provides a copy to the Producing Party on behalf of the insurer or law firm. Any materials provided to an insurer or its counsel shall not be used for any purpose other than evaluation of the claims asserted in this litigation and shall not be used outside the claims asserted in this litigation.

vii. Court reporters (including persons operating video recording equipment at depositions) and persons preparing transcripts of testimony to the extent necessary to prepare such transcripts.

viii. Retained experts, advisors and consultants, including persons directly employed by such experts, advisors and consultants (collectively “Experts”), but only to the extent necessary to perform their work in connection with this litigation or Other Actos Lawsuits in which an order that is identical to or the substantial equivalent of this Order has been entered.

ix. The persons who authored the confidential discovery material, were a source of the confidential discovery material, are in good faith believed to be referenced in the confidential discovery material and already familiar with the subject-matter of the confidential discovery material or who received such confidential discovery material.

(b) All parties and their respective counsel, paralegals and the employees and assistants of all counsel receiving discovery material shall take all steps reasonably necessary to prevent the disclosure of confidential discovery material other than in accordance with the terms of this Order.

(c) A plaintiff’s current or former healthcare provider who has agreed on the record at deposition to maintain the confidentiality of any document intended to be used at the deposition may be shown or questioned about Confidential Discovery Material at the deposition, provided that no copies of the Confidential Discovery Material shall be left in the possession of the healthcare provider witness and copies of that Confidential Discovery Material shall not be attached to or included with any original or copy of the transcript of that deposition provided to the healthcare provider; however, copies of the Confidential Discovery Material shall be attached to the deposition transcript and made available for the use of the deponent in the event he or she testifies at

trial. Counsel present at the deposition should make a good faith effort to obtain the healthcare provider's agreement on the record to maintaining confidentiality and no counsel shall make efforts to dissuade the healthcare provider from refusing to agree on the record to maintaining the confidentiality of any such documents. Regardless of whether any deponent signs the Endorsement of Protective Order attached as Exhibit A, this Order will apply to any deponent who is shown or examined about Confidential Discovery Material and the deponent cannot take any exhibits with them nor can he/she reveal any information learned from the confidential materials shown to them. This paragraph is not intended to prevent any deponent from seeking other relief from this Court.

(d) Except for plaintiff's current or former healthcare provider (who are subject to the foregoing sub-section) and current employees and consultants of the defendants or the producing party, each person who is permitted to see confidential documents shall first be shown a copy of this Order and shall further be advised of the obligation to honor the confidentiality designation.

(e) Disclosure of confidential discovery material other than in accordance with the terms of this Order may subject the disclosing person to such sanctions and remedies as the Court may deem appropriate, including without limitation, contempt, injunctive relief and damages.

8. **Disputes concerning designation of Confidential Discovery Material.**

a) If at any time a Receiving Party wishes in good faith to dispute a designation of discovery material as confidential hereunder, such party shall notify the designating party of such dispute in writing (Dispute Notice), specifying by exact



document numbers the discovery material in dispute and providing a brief explanation of the basis of the dispute with regard to each such document or other discovery material. No more than 50 documents shall be challenged in a single Dispute Notice, and only one Dispute Notice may be sent within a three-week period. If no change in designation is offered by the Producing Party, the Producing Party must provide within fourteen (14) calendar days a written explanation of the good faith basis for the designation(s) at issue.

If a Receiving Party elects to press a challenge to a confidentiality designation after considering the justification offered by the Producing Party, the Receiving Party shall, in writing (Challenge Notice), notify the Producing Party that a resolution cannot be reached regarding the confidentiality designation of a document or, the Receiving Party may elect to file and serve a motion that identifies the challenged material and sets forth the basis for the challenge to the confidentiality designation. Any such motion shall be accompanied by a Motion for Leave to File Under Seal (“Sealing Motion”), in accordance with this Court’s order concerning Sealing Motions. On such motion, the Producing Party shall have the burden of proving that the material is entitled to protection, as if this Order has not been entered, pursuant to Rule 26(c)(1)(G). On such a motion by the Receiving Party, the Producing Party shall have no less than fifteen (15) calendar days to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief.<sup>2</sup> The Opposition shall be accompanied by a Sealing Motion.

If the Receiving Party elects to serve a Challenge Notice rather than move, the Producing Party shall, within twenty-one (21) calendar days of receiving such notice from the Receiving Party, file and serve a motion that identifies the challenged material

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<sup>2</sup> If the number of pending challenges becomes burdensome, the parties agree to alter the schedule to provide sufficient time for an Opposition.

and sets forth in detail the basis for the confidentiality designation. Any such motion shall be accompanied by Sealing Motion. The Producing Party shall have the burden of proof on such motion to establish the propriety of its confidentiality designation. The time allotted under this paragraph for a Producing Party to respond in writing to a Challenge Notice or to file and serve a motion setting forth the basis of a challenged confidentiality designation shall not be shortened except upon a showing of good cause.

(b) All discovery material designated as confidential under this Order, whether or not such designation is in dispute pursuant to subparagraph 8(a) above, shall retain that designation and be treated as confidential in accordance with the terms hereof unless and until:

- i. the Producing Party agrees in writing that the material is no longer confidential and subject to the terms of this Order; or
- ii. fourteen (14) calendar days after the expiration of the appeal period of an Order of this Court that the matter shall not be entitled to confidential status (or such longer time as ordered by this Court) if the Order on appeal is not subject to a stay; or
- iii. the Producing Party does not respond as set forth above within fourteen (14) calendar days of service of the Dispute Notice; or
- iv. the Producing Party does not serve a motion within twenty-one (21) days of receiving a Challenge Notice.

9. **Designation by Non-Parties.** Any non-party who is producing discovery materials in this litigation may subscribe to and obtain the benefits of the terms and protections of this Order by designating pursuant to the terms of this Order as

“Confidential” the discovery materials that the non-party is producing. Such subscription shall be through a Notice filed with this Court and such Notice shall indicate that the Non Party agrees to this Order in its entirety.

10. **Filing with the Court.** The parties will use the following procedure for submitting to the Court papers consisting of, relating to, containing, incorporating, reflecting, describing, or attaching Confidential Information: Other than motion practice relating to disputes concerning designation of Confidential Discovery Material which shall be filed, together with a Sealing Motion, pursuant to paragraph 8 of this order. All papers consisting of, relating to, containing, incorporating, reflecting, describing, or attaching Confidential Information shall be timely served upon opposing counsel pursuant to Court Ordered deadlines or agreements by the parties. A courtesy copy of such papers shall simultaneously be provided to the Deputy Special Master. Following service of Reply papers upon opposing counsel, the parties shall meet and confer in good faith for up to twenty-one (21) days to resolve objections of the use of any confidential information or confidential documents in the briefs (Confidential Document Review Period or CDRP). During the CDRP, any party objecting to the use of any information or documents in the briefs must contact the filing party and both sides must attempt in good faith to resolve the objection(s). If no resolution is achieved within the CDRP and the objecting party is not waiving its objection, then the objecting party must file a Sealing Motion no later than the last day of the CDRP. The objecting party shall refrain from filing any papers that are the subject of the objection until either Sealing Motion is resolved or, if no Sealing Motion has been filed with the Court, the expiration of the CDRP.

**11. Use of Confidential Discovery Material at Hearings or Trial.** This Order does not restrict or limit the use of confidential discovery material at any trial. However, prior to any hearing that is held other than a trial at which the use of confidential discovery material is anticipated, the parties shall meet and confer regarding the use of the confidential discovery material. If the parties cannot agree, the parties shall request the Court to rule on such procedures.

**12. Responses to Subpoenas or Other Process.** If a Receiving Party or its counsel or expert is served with a subpoena or other process by any court, administrative or legislative body, or any other person or organization which calls for production of any confidential discovery material produced by another party, the party to whom the subpoena or other process is directed shall not, to the extent permitted by applicable law, provide or otherwise disclose such document or information until fourteen (14) calendar days after notifying counsel for the producing party in writing of all of the following: (1) the information and documentation which is requested for production in the subpoena; (2) the date on which compliance with the subpoena is requested; (3) the location at which compliance with the subpoena is requested; (4) the identity of the party serving the subpoena; and (5) the case name, jurisdiction and index, docket, complaint, charge, civil action or other identification number or other designation identifying the litigation, administrative proceeding or other proceeding in which the subpoena has been issued. The party, counsel or expert receiving the subpoena or other process shall cooperate, to the extent reasonably possible, with the Producing Party in any proceeding relating thereto.

**13. Return or Destruction of Confidential Discovery Materials.** Within thirty (30) calendar days of the conclusion of any attorney's last case in this proceeding, including any appeals related thereto, at the written request and opinion of the Producing Party, such attorney and any persons to whom he or she disclosed confidential discovery material under this Order shall return and surrender or destroy any such material or copies thereof to the Producing Party at the Producing Party's expense. Such persons shall return or surrender any discovery materials produced by the Producing Party and any and all copies (electronic or otherwise), summaries, notes, compilations, and memoranda related thereto; provided, however, that counsel may retain their privileged communications, work product, Endorsements of Protective Order, materials required to be retained by applicable law, and all court-filed documents even though they contain discovery materials produced by the Producing Party, but such retained privileged communications and work product shall remain subject to the terms of this Order. At the written request of the Producing Party, any person or entity having custody or control of recordings, notes, memoranda, summaries or other written materials, and all copies thereof, relating to or containing discovery materials produced by the Producing Party shall deliver to the Producing Party an affidavit certifying that reasonable efforts have been made to assure that all such discovery materials produced by the Producing Party and any copies thereof, any and all records, notes, memoranda, summaries, or other written material regarding the discovery materials produced by the Producing Party (except for privileged communications, work product and court-filed documents as stated above) have been delivered to the Producing Party in accordance with the terms of this Order or destroyed. In lieu of returning the materials, the Producing Party may direct that

the materials be destroyed in a manner that will protect the confidential discovery materials and the destroying party shall certify that it has done so.

**14. Reservation of Rights.**

(a) Except as provided for herein, nothing in this Order shall prevent or restrict counsel for any party in any way from inspecting, reviewing, using or disclosing any discovery material produced or provided by that party, including discovery materials designated as confidential.

(b) Nothing shall prevent disclosure beyond that required under this Order if the producing party consents in writing to such disclosure, or if the Court, after notice to all affected parties, orders such disclosure and that Order is not subject to an appellate stay within twenty-one (21) calendar days after it is issued.

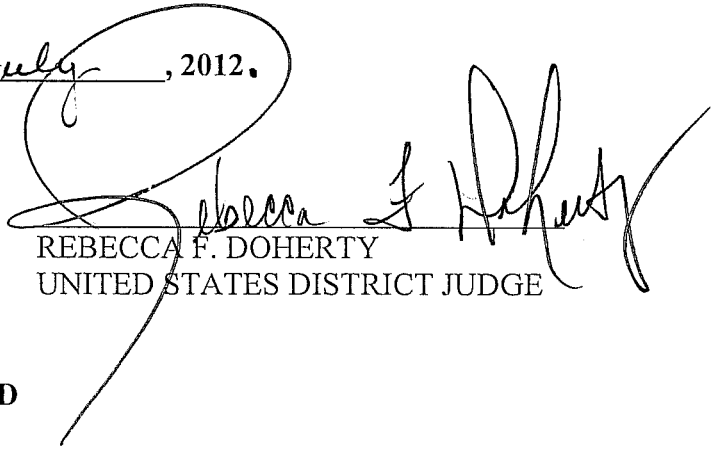
(c) No disclosure pursuant to this Paragraph shall waive any rights or privileges of any party granted by this Order.

**15. No Effect on Other Obligations.** This Order shall not enlarge or affect the proper scope of discovery in this or any other litigation, nor shall this Order imply that confidential discovery material is properly discoverable, relevant, or admissible in this or any other litigation. Each party reserves the right to object to any disclosure of information or production of any documents that the Producing Party designates as confidential discovery material on any other ground it may deem appropriate. The actions of the parties and their counsel in designating (or de-designating) discovery material as confidential pursuant to this Order shall not constitute evidence that is admissible to a jury at trial.

16. **Obligation of Good Faith.** All parties and counsel for such parties in this litigation shall make a good faith effort to ensure that their experts, employees, and agents comply with this Order. In the event of a change in counsel, retiring counsel shall fully instruct new counsel of their responsibilities under this Order.

17. **Modifications/Continuing Effect.** By written agreement of the parties, or upon motion and order of the Court, the terms of this Order may be amended or modified. This Order shall continue in force until amended or superseded by express order of the Court, and shall survive any final judgment or settlement in this litigation, to the full extent allowed by law.

SO ORDERED, this 30 day of July, 2012.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

AGREED TO BY COUNSEL OF RECORD

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Actions

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**ENDORSEMENT OF PROTECTIVE ORDER**

I hereby attest to my understanding that information or documents designated Confidential are provided to me subject to the Protective Order regarding confidential information produced in discovery, entered \_\_\_\_\_, \_\_\_\_\_ (the "Protective Order"), in the above-captioned litigation; that I have been given a copy of and have read the Protective Order, and that I agree to be bound by its terms. I also understand that my execution of this Endorsement of Protective Order, indicating my agreement to be bound by the Protective Order, is a prerequisite to my review of any information or documents designated as confidential pursuant to the Protective Order.

I further agree that I shall not disclose to others, except in accord with the Protective Order, any confidential discovery material, in any form whatsoever, and that such confidential discovery material and the information contained therein may be used only for the purposes authorized by the Protective Order.

I further agree and attest to my understanding that my obligation to honor the confidentiality of such discovery material and further information will continue even after this litigation concludes.



I further agree and attest to my understanding that, if I fail to abide by the terms of the Protective Order, I may be subject to sanctions, including contempt of court, for such failure. I agree to be subject to the jurisdiction of the United States District Court for the Western District of Louisiana, to the full extent allowed by law and to the full extent determined by the United States Court(s), for the purposes of any proceedings relating to enforcement of the Protective Order.

I further agree to be bound by and to comply with the terms of the Protective order as soon as I sign this Agreement, whether or not the Protective Order has yet been entered as an Order of Court.

Date:

By: \_\_\_\_\_

Subscribed and sworn to before me this

\_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_\_

\_\_\_\_\_  
NOTARY PUBLIC

RECEIVED

JUL 27 2012 *JO*

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

This Document Applies to:  
All Cases

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**SECOND AMENDED CASE MANAGEMENT ORDER:  
Direct Filing and Service of Process<sup>1</sup>**

**I. Scope of Order**

This Agreed Order applies to claims brought by any U.S. citizen or resident based on alleged ingestion of Actos®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, or pioglitazone (“Actos”) that (i) currently are pending in MDL No. 2299, (ii) currently are pending and related to MDL No. 2299, or (iii) will be filed in, removed to, or transferred to this Court (collectively, “the MDL Proceedings”).

**II. Direct Filing of Cases in MDL 2299**

A. In order to eliminate delays associated with transfer to this Court of cases filed in or removed to other federal district courts, and to promote judicial efficiency, any plaintiff whose case would be subject to transfer to MDL 2299 may file his or her case directly in the MDL Proceedings in the Western District of Louisiana (such cases are sometimes referenced as “Direct-Filed Cases”).

B. Each case filed directly in the MDL Proceedings by a plaintiff who resides in a federal district other than the Western District of Louisiana will be filed in the MDL

<sup>1</sup> This Second Amended Case Management Order: Direct Filing and Service of Process SUPERCEDES the original and First Amended Case Management Order, which were entered as Doc. 520 and Doc. 559, respectively. This Second Amended Case Management Order contains a new Paragraph III, providing additional information in regards to the filing of Bundled Complaints, and addresses service issues in Paragraph IV; no other aspect of the original or First Amended Case Management Order was altered.

Proceedings for purposes of pretrial proceedings, consistent with the Judicial Panel on Multidistrict Litigation’s December 29, 2011 Transfer Order (“Transfer Order”).

C. Defendants will not challenge the venue of any Direct-Filed Case. Upon the completion of pretrial proceedings consistent with the Transfer Order, this Court, pursuant to 28 U.S.C. §1404(a), will transfer Direct-Filed Cases to the federal district court in the district where the plaintiff allegedly was injured by use of Actos, or where the plaintiff resides at the time of such transfer, subject to severance of multi-plaintiff actions if necessary. The parties will jointly advise the Court of the district to which each Direct-Filed Case should be transferred.

D. Parts II.B and II.C do not preclude the parties from agreeing, at a future date, to try certain Direct-Filed Cases in this District.

E. The inclusion of any action in *In Re: Actos Products Liability Litigation*, MDL 2299, whether such action was or will be filed originally or directly in the Western District of Louisiana, shall not constitute a determination by this Court that jurisdiction or venue is proper in this district.

F. Complaints in Direct-Filed Cases shall bear the following caption:

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

	)	
<b>IN RE: ACTOS PRODUCTS LIABILITY</b>	)	<b>MDL No. 6:11-md-2299</b>
<b>LITIGATION</b>	)	
	)	<b>JUDGE DOHERTY</b>
<b>JOHN DOE</b>	)	
	)	<b>MAGISTRATE JUDGE HANNA</b>
<b>vs.</b>	)	
	)	<b>Civil Action No.:</b> _____
<b>XYZ CORPORATION and ABC</b>	)	
<b>COMPANY</b>	)	
	)	

Pleadings filed thereafter in any Direct-Filed Case shall comply with the First General Order with regard to caption format and contents.

G. Any attorney admitted to practice and in good standing in any United States District Court is admitted *pro hac vice* in this litigation and association of local co-counsel for purposes of litigation, including direct filing, is not required. However, as noted in the Court's First General Order, counsel must file a certificate of good standing with their initial filing.

H. Prior to any lawyer filing a Direct-Filed Case, that attorney must register for and have a Louisiana CM/ECF log in name and password. Other than this modification, the normal local filing requirements will apply. See Local Rules of the United States District Court for the Western District of Louisiana, available at [http://www.lawd.uscourts.gov/Court\\_Rules/Docs/localrules.pdf](http://www.lawd.uscourts.gov/Court_Rules/Docs/localrules.pdf). These rules include, *but are not limited to*, the following specifics:

- Civil Cover Sheet. A civil cover sheet, indicating that the new matter is related to the MDL Proceedings (*i.e.*, MDL No. 11-md-2299), must be filed with the complaint.
- Attorneys. Each attorney shall provide the following identifying information on the signature block:

/s/ Jane Doe  
Jane Doe  
NAME OF LAW FIRM  
ADDRESS  
TELEPHONE  
FAX  
EMAIL@EMAIL.com  
Attorney for Plaintiff

- Filing Fees: Internet credit card payments are required for all complaints and are made online through Pay.gov. Plaintiff's counsel will be prompted to pay the required filing fee at the time the complaint is filed.
- Summonses. After the complaint is filed, plaintiff's counsel is free to create the necessary summonses and proceed with service as required by law or as permitted herein.

### **III. Bundled Complaints**

A. In an effort to minimize the expenses of all parties, and to promote judicial efficiency, this Court has developed a system that enables claims of more than one plaintiff to be filed in a single Complaint, also referred to as the "Lead Complaint." This process shall henceforth be referred to as "bundling" or the filing of "Bundled Complaints."

B. In the section of the Lead Complaint entitled "Plaintiff Specific Allegations," each individual plaintiff shall be listed in consecutively numbered paragraphs, and each paragraph shall include subsections containing case-specific allegations for each plaintiff.

C. Once a Bundled Complaint is filed, this Court will, *sua sponte*, issue an order severing the individual plaintiffs listed in the Plaintiff Specific Allegations (the "Severance Order"). Individual Civil Action Numbers and case captions will then be assigned for each individual plaintiff, and the new civil action numbers and short title of each case caption will be attached as "Attachment 1," to the Severance Order.

### **IV. Service of Process – Takeda Entities**

A. Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. (formerly known as Takeda Pharmaceuticals North America, Inc.), Takeda Pharmaceuticals America, Inc., Takeda Global Research & Development Center, Inc., Takeda California, Inc. (formerly known as Takeda San Diego, Inc.), and Takeda Pharmaceuticals International, Inc. agree, without waiver of any defenses, to accept service of process as set forth in this Order.

B. For purposes of this Order, the “U.S. Takeda entities” are: Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals America, Inc., Takeda Global Research & Development Center, Inc., Takeda California, Inc., and Takeda Pharmaceuticals International, Inc.

C. Service on U.S. Takeda Entities. With regard to complaints that have already been filed, plaintiffs who have not already served the U.S. Takeda entities through original service may effectuate service, as described in this Paragraph IV.C, within 30 days of receiving notice of this Order. With regard to complaints filed on or after the date of this order, plaintiffs may effectuate service on U.S. Takeda entities, as described in this Paragraph IV.C, within 30 days of the filing of the complaint.

Service on any named U.S. Takeda entity may be made by serving a copy of the complaint and one summons directed to Takeda Pharmaceuticals USA, Inc. on Takeda’s registered agent for service of process at:

CT Corporation  
208 South LaSalle Street, Suite 814  
Chicago, IL 60604

For service pursuant to this paragraph, a separate summons need not be issued to each U.S. Takeda entity for service to be effective. Further, for a Bundled Complaint, service

of the Lead Complaint, together with a copy of the applicable Severance Order listing the individual cases and their civil action numbers shall be sufficient to effectuate service of process for each of the individual cases associated with the Lead Complaint. Service on Takeda Pharmaceuticals USA, Inc. shall be sufficient to effectuate service on all U.S. Takeda entities.

Service pursuant to this paragraph may be made by either certified United States Mail or through service of process in accordance with Rule 4 of the Federal Rules of Civil Procedure.

*Note:* Service pursuant to this Paragraph IV.C *shall not be made and shall not be attempted*, on any entity other than the U.S. Takeda entities identified in Section IV.C of this Order.

D. The Return of Service filed with the Court shall include an Affidavit, which shall confirm the name of all defendants served and, for a Bundled Complaint, shall include the applicable Severance Order, confirming service of the individual cases.

E. Service on Takeda Pharmaceutical Company Limited. With regard to complaints that have already been filed, plaintiffs who have not already served Takeda Pharmaceutical Company Limited (“TPC”) through original service may effectuate service, as described in this Paragraph IV.E, within 60 days of receiving notice of this Order. With regard to complaints filed on or after the date this Order is issued, plaintiffs may effectuate service, as described in this Paragraph IV.E, within 60 days of filing a complaint.

Service on TPC may be made by delivering a cover letter, a copy of the complaint, and a summons directed to TPC *via* registered mail, return receipt requested, or *via* commercial courier service that provides equally reliable evidence of delivery, to:

Takeda Pharmaceutical Company Limited  
Attn: Legal Department  
1-1 Doshomachi 4-chome  
Chuo-Ku, Osaka,  
540-8645, Japan

For service to be effective, plaintiffs also must send a copy of the cover letter that was mailed to TPC to:

Stacey Dixon Calahan  
Assistant General Counsel, Litigation  
Takeda Pharmaceuticals U.S.A., Inc.  
One Takeda Parkway  
Deerfield, Illinois 60015.

F. If plaintiffs abide by the terms of this Order, service on the U.S. Takeda entities will be considered effective on the date that CT Corporation is served with the documents discussed in Sections IV.C of this Order, and service on TPC will be considered effective on the date that TPC receives the summons and complaint in Osaka, Japan.

**V. Responses to Complaints and Discovery by Other Takeda Entities**

A. It is defendants' position that Takeda America Holdings, Inc., Takeda Ventures, Inc., and/or Takeda Pharmaceuticals LLC are not proper parties to the Actos litigation, because it is defendants' position that none had any involvement with Actos, including in the design, development, manufacturing, advertising, marketing, labeling, sale or distribution of the medication.



B. If plaintiffs name as defendants Takeda America Holdings, Inc. (“TAH”), Takeda Ventures, Inc. (“TVI”), and/or Takeda Pharmaceuticals LLC (“TPLLC”) in any complaint filed in, removed to, or transferred to the MDL proceedings, TAH, TVI, and/or TPLLC shall be relieved of any obligation to move, answer, or otherwise plead in response to each such complaint until further order of this Court. TAH, TVI, and TPLLC also are relieved of any obligation to respond to discovery requests until further order of this Court.

C. If plaintiffs believe that discovery shows the involvement of TAH, TVI, and/or TPLLC in a way that will require plaintiffs to pursue one or more of these entities as a defendant, plaintiffs shall meet and confer with defendants regarding whether discovery is required from these entities. If no agreement is reached through the meet-and-confer process, the parties shall seek the Court’s guidance before plaintiffs commence any such discovery.

**V. Service of Process – Eli Lilly & Company**

A. With regard to complaints that have already been filed, plaintiffs who have not already served Eli Lilly & Company through original service may effectuate service, as described in this Paragraph V.A, within 30 days of receiving notice of this Order. With regard to complaints filed on or after the date of this Order, plaintiffs may effectuate service on Eli Lilly & Company, as described in this Paragraph V.A, within 30 days of filing a complaint.

Service on Eli Lilly & Company may be made by serving a copy of the complaint and summons on Eli Lilly & Company’s registered agent for service of process at:

National Registered Agents Inc.  
200 West Adams Street

Chicago, IL 60606

B. With regard to service of Bundled Complaints on Eli Lilly & Company, service of the Lead Complaint, together with a copy of the applicable Severance Order listing the individual cases and their civil action numbers shall be sufficient to effectuate service of process for each of the individual cases associated with the Lead Complaint. Return of Service filed with the Court shall include an Affidavit, which shall confirm the name of all defendants served, and, for a Bundled Complaint, shall include the applicable Severance Order, confirming service of the individual cases.

Service pursuant to Section V. may be made by either certified United States Mail or through service of process in accordance with Rule 4 of the Federal Rules of Civil Procedure.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 27 day of

July, 2012.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

JUL 27 2012

*JD*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

**In Re: Actos (Pioglitazone) Products  
Liability Litigation**

) MDL NO. 6:11-md-2299

) JUDGE DOHERTY

**This Document Applies to:**

) MAGISTRATE JUDGE HANNA

All Cases

**CASE MANAGEMENT ORDER:**  
**PROTOCOL RELATING TO THE PRODUCTION OF**  
**ELECTRONICALLY STORED INFORMATION (“ESI”)**

Pursuant to the agreement reached between the Plaintiffs and Defendants herein, this Court enters the following Order concerning the production of electronically stored information in these proceedings:

**A. Scope**

1. General. The procedures and protocols outlined herein govern the production of electronically stored information (“ESI”) by the Parties. Section E titled “Search Methodology Proof of Concept” applies only to the predictive coding and advanced analytics sampling procedure as outlined in that Section. Sections A through D and Sections F through J apply throughout the pendency of this litigation. This Order governs all parties to these proceedings, whether they currently are involved or become so in the future. The Parties to this protocol (“Protocol”) will take reasonable steps to comply with this agreed-upon Protocol for the production of documents and information existing in electronic format. All disclosures and

productions made pursuant to this Protocol are subject to the Privilege Protocol and Protective Order entered in this matter.

2. Limitations and No-Waiver. The Parties and their attorneys do not intend by this Protocol to waive their rights to the attorney work-product privilege, except as specifically required herein, and any such waiver shall be strictly and narrowly construed and shall not extend to other matters or information not specifically described herein. All Parties preserve their attorney client privileges and other privileges and there is no intent by the protocol, or the production of documents pursuant to the protocol, to in any way waive or weaken these privileges. All documents produced hereunder are fully protected and covered by the Parties' confidentiality agreements, and order(s) of the United States District Court, as well as any clawback agreements, and protective order(s) of the United States District Court effectuating same.

**B. ESI Preservation**

1. The Parties have issued litigation notices to those identified as most likely to have discoverable information.

**C. Sources**

1. While Defendants' fact gathering is ongoing, the following are data sources identified to date that are most likely to contain discoverable information. Defendants agree to provide additional discovered data sources likely to contain relevant information. Defendants agree to provide information about the data sources to the extent applicable and known in addition to that found in the subparagraphs below, including the date range of information contained in the data source, the department(s) utilizing the data source, whether the data source is hosted internally or externally, and the database type.

a	ARISg	Adverse Event Database
b	BLUE	Labeling and promotional materials management system
c	Galaxy	Regulatory document management system
d	MEDIsorce	Product information request database
e	T-Rx	Field sales call database
f	TSARS (or "S Drive")	Takeda Statistical Analysis and Repository System
g	T-Track	Clinical Science Liaison database
h	IRIS	Research grant management system
i	LARC	Clinical Science Liaison education resources database
j	Sample Guardian	Product sample management database
k	TEG	Takeda Educational Grant management system
l	PubBase	Publications management system
m	Records Management System	Records Operation Center ("ROC") information system

a. ARISg: ARISg is an adverse event database. It contains information that the Pharmacovigilance department at TRGD U.S. receives regarding adverse events related to Takeda drugs, including adverse event reports ("AERs") received from, without limitation, physicians, patients, clinical trials, medical literature, and foreign entities. ARISg is the software used for this database, which is sometimes called T-Gaea within Takeda. It has been in effect since 1999.

b. BLUE: This database is used by the Marketing department in the approval process for promotional materials. It contains a labeling module and a module for promotional pieces and marketing campaigns. BLUE has been active from April 2008 to present. The vendor is Schawk Blue.

c. Galaxy: Galaxy is a document repository system used by the Regulatory department containing components of regulatory submissions to the Food and Drug Administration. It went into production in 2009.

d. MEDIsource: This data system is used by the Medical Information and Quality Assurance departments to capture and respond to product information requests and non-medical product complaints. It has a Siebel component that documents the intake of requests for information from physicians and provides a response; a Documentum system with standard response and customer response letters; and Info Maestro which pulls information from the standard response letter and from the Sieble system to create the response letter to an individual physician.

e. T-Rx: This database contains information regarding U.S. commercial field sales calls.

f. TSARS (or “S Drive”): This is Takeda’s Statistical Analysis and Repository System and is a Unix centralized repository used to manage Clinical and research data. It is used by the Analytical Science department. It contains clinical SAS data sets and programs used to analyze those data sets for purposes of final submission reports – tables, listings, and graphs.

g. T-Track: This database is a customized application of Seibel’s Customer Relationship Management system for use by Takeda’s field based Clinical Science Liaisons.

h. IRIS: This system is used by Takeda for the intake and processing of external research grant requests. It is a vendor hosted system (SteepRock is the vendor). It was implemented within the last five years.

i. LARC: This database includes articles, presentations, and publications related to Takeda products and the therapeutic areas they address. Quosa is the vender for this database. It is accessible by Clinical Science Liaisons in their respective therapeutic areas.

j. Sample Guardian: This database contains product sample management data regarding sample transactions and inventory reconciliations.

k. TEG: Takeda Educational Grant database is used for education grant request management.

l. PubBase: PubBase is a Documentum-based system used for the management and storage of publication documents.

m. Records Management System: This data source is used by the Records Operations Center (“ROC”), where physical records are maintained.

**D. Custodians**

1. The following are custodians who have been identified as most likely to have information relevant to this litigation. For these custodians, data is being pulled from e-mail, computer hard drives, and physical files that are in the possession, custody, and control of Takeda. Investigation is ongoing by both Parties as to potential additional custodians at Takeda (including potential Japanese custodians) and Eli Lilly and Company. Current key custodians include:

1.	Baron, David	Vice President, NonClinical Safety/Efficacy
2.	Spanheimer, Robert	Vice President, Medical and Scientific Affairs
3.	Greeby, Jennifer	Director, Marketing (Diabetes)
4.	Recker, David	Senior Vice President, Clinical Science
5.	Paris, Maria	Former Vice President, Pharmacovigilance
6.	Gerrits, Charles	Former Senior Director, Pharmacoeconomics
7.	Johnston, Janet	Associate Director, Safety Surveillance
8.	Thom, Claire	Former Vice President, Research and Development
9.	Daly, Rich	Former Vice President, Marketing
10.	Perez, Alfonso	Vice President, Clinical Science Strategy

11.	Ortell, Una	Director, Promotion and Advertising
12.	Orlando, Dan	Former Vice President, Sales
13.	Lee, Jessie	Manager, Regulatory Affairs Strategy
14.	Cuomo, Maryann	Associate Director, Regulatory Labeling
15.	Weisbrich, Shay	Vice President, Franchise Leader (Former Director, Marketing)
16.	Kupfer, Stuart	Vice President, Clinical Science
17.	Ramstack, Mary	Sr. Director, Strategic Project Planning and Management
18.	Roebel, Mick	Sr. Director, Regulatory Affairs
19.	Lorenz, Janet	Associate Director, Regulatory Affairs, Promotion and Advertising
20.	Pritza, Mary Jo	Former Associate Director, Regulatory Affairs
21.	Caracci, Mike	Former Director, Marketing
22.	Tynan, Julie	Assistant Project Director, Strategic Project and Planning Management
23.	Hull, Andy	Vice President, Alliance Management (former Vice President, Marketing)
24.	Fusco, Gregory	Sr. Medical Director, Pharmacoepidemiology and Analysis
25.	Caggiano, Christopher	Sr. Product Manager, Diabetes Marketing
26.	Ryan, D'Arcy	Former Director, Marketing
27.	Khan, Mehmood	Former Sr. Vice President, Medical and Scientific Affairs
28.	Harris, Thomas	Vice President, Regulatory Affairs
29.	Trochanov, Anton	Associate Medical Director, Pharmacovigilance

#### **E. Search Methodology Proof of Concept**

1. General. The Parties have discussed the methodologies or protocols for the search and review of ESI collected from Takeda sources, including but not limited to e-mail, and the following is a summary of the Parties' agreement on the use of a search methodology proof of concept to evaluate the potential utility of advanced analytics as a document identification mechanism for the review and production of this data. The Parties agree to meet and confer regarding the use of advanced analytics for other data sources. While the Parties agree to explore the use of advanced analytics as a technique to ensure appropriate responses to discovery



requests, the Parties agree that Defendants retain the right to review documents after predictive coding but prior to production for relevance, confidentiality, and privilege. A sampling of documents withheld after such review will take place pursuant to Section E.10.

2. General Overview of Advanced Analytics/Predictive Coding Process. Takeda utilizes software provided by Epiq Systems (“Epiq”) to search and review ESI for production in this case. Epiq uses Equivio’s Relevance software for advanced analytics and predictive coding.

Epiq will collect e-mail documents from four key Takeda custodians, which will be combined to create the “sample collection population.” The Parties will meet and confer to determine the names of the four custodians. Additionally, Takeda will add a set of regulatory documents which have already been collected to the “sample collection population.” Takeda and Plaintiffs will each nominate three individuals (“the experts”) to work collaboratively at the offices of Nelson Mullins, 1320 Main Street, Columbia, SC 29201 to train the Equivio Relevance system. Plaintiffs’ experts will execute a Nondisclosure and Confidentiality Agreement in the form attached as Exhibit A hereto. To the extent that Plaintiffs’ experts are exposed to information that would be subject to withholding or redaction under the Protective Order in this matter, Plaintiffs’ experts agree not to disclose such information to co-counsel, client, any Party, or any third party without obtaining prior written consent of the other Party regarding the particular piece of information sought to be disclosed. Before the meeting, the Parties shall be provided a copy of the applicable Equivio training documents, handbook, or manual. The Parties’ experts will receive technical training on the Equivio Relevance software and coding process and will work together to make one relevance decision for documents in the Control and Training sets, as described in more detail below.

The Parties will review a number of documents required by the Equivio Relevance system for the data to reach Stability as described below. Once Stability is reached, the Control and Training sets are then used to begin the predictive coding process. Using the Control and Training documents, the system calculates relevance scores for the entire sample collection population, with each document in the sample collection population receiving a relevance score of 0 through 100.

Attorneys representing Takeda will have access to the entire sample collection population to be searched and will lead the computer training, but they will work collaboratively with Plaintiffs' counsel during the Assessment and Training phases. Takeda's experts will conduct an initial review of documents presented by the Equivio Relevance system for privilege. The privileged documents will be either entirely withheld from viewing by Plaintiffs' experts or printed and redacted. A privilege log for such documents will be provided. The Parties, after review of the privilege log, reserve the right to require that such documents be deemed as "skip" (same as designation used for technical problem documents). Otherwise, these documents may still be used to train the system. Both Parties will then review all of the non-privileged documents during the training process (i.e., both documents coded as relevant and irrelevant). The Parties' experts will review the documents in collaboration and determine the coding to be applied to the documents. To the extent the Parties disagree regarding the coding of a particular document or designation of privilege, they will meet and confer in an effort to resolve the dispute prior to contacting the Court for resolution.

At the conclusion of the training process and upon calculation of relevance scores, the Parties will meet and confer regarding which relevance score will provide a cutoff for documents

to be manually reviewed by defense counsel for production. However, the Parties reserve the right to seek relief from the Court prior to the commencement of the final manual review.

At the recommendation of Epiq, no seeding will take place at this time. The Parties may meet and confer if it is determined that seeding may be applicable at a later date.

Plaintiffs' experts and counsel shall not remove any of the Control or Training documents from the offices of Nelson Mullins, nor shall they be allowed to copy such documents. The Parties agree that Defendants do not waive protection of trade secret or confidential information in allowing Plaintiffs to review documents under this sampling mechanism. All documents reviewed pursuant to this sampling protocol shall be done under the Protective Order in this matter as well as any Privilege Protocol or clawback agreement that shall be reduced to an order acceptable to the Court.

3. Relevance Tags. The Parties agree that as part of the Assessment and Training phases, all of the non-privileged and privilege-redacted documents reviewed by both parties' experts will be categorized as relevant, not relevant, or skip (to be used for documents with technical problems). The privileged-withheld documents will be categorized by Defendants' experts as relevant, not relevant, or skip, subject to the Parties' right to have any privileged-withheld documents categorized as a "skip." The Parties shall immediately discuss any disagreements on coding in good faith, so that the training may be improved accordingly, and may seek guidance from the Court or the Court appointed special masters if necessary.

4. Collection & Data Preparation. The Parties will meet and confer to agree upon the four custodians that will be selected for the sampling. E-mail and attachment documents will be collected from the four custodians and added to the collected regulatory documents, together

comprising the sample collection population. Documents may be removed from the sample collection population if they are:

- a. Spam,
- b. Commercial e-mail,
- c. Files without text,
- d. Exact duplicates within the custodians (see Section G.6 regarding production of information for duplicate documents), and
- e. System files, etc. (*i.e.*, the documents that the samples will be selected from will be de-NISTED)

Epiq will extract the sample collection population documents' text and build an index.

5. Assessment Phase. The Equivio Relevance software generates an initial simple random sample of 500 documents from the sample collection population. Takeda's experts will initially review the documents for privilege. Any documents deemed privileged by Takeda's experts will be either entirely withheld from viewing by Plaintiffs' experts or printed and redacted prior to viewing by Plaintiffs' experts, and logged on a privilege log consistent with the Privilege Protocol in this matter. These documents may still be used to train the system. To the extent the Parties disagree regarding the privilege decision for a particular document, they will meet and confer in an effort to resolve the dispute prior to contacting the Court for resolution. The Parties' experts will then work collaboratively to determine the relevance of the non-privileged and privilege-redacted documents. The relevance of the privileged-withheld documents will be determined by Defendants' experts. The documents reviewed in the Assessment Phase make up the Control Set. The Control Set is used for estimating richness

(percentage of relevant documents in a population), and also serves as a reference point for calculating recall and precision.

a. The application's estimates of richness use a confidence level of 95%. The initial Control Set of 500 documents yields a confidence estimation of richness with an error margin of plus or minus 4.3%. This is a worst-case error margin assuming richness of 50%. For lower levels of richness, the error margin will also be lower. For example, for richness of 10%, the error margin would be plus or minus 2.6%, while for 5%, the error margin would be plus or minus 1.9%.

b. The Control Set also creates a basis for calculating recall and precision, which are then used for monitoring training progress and calculating results.

c. Equivio Relevance tracks the progress of the Assessment Phase to achieve the appropriate level of statistical validation. These levels of validation are referred to in the Equivio system as "Baseline," at the lowest level, through "Statistical," at the highest level. The terms "Baseline" and "Statistical" are used by Equivio Relevance as indicators to the user as to the progress of the Assessment Phase. The validation level achieved depends on the number of relevant documents found by the user in the Control Set. At the "Baseline" level, the number of relevant documents in the control set is too low to allow statistically valid estimates of recall and precision. The Parties will ensure that the number of Control Set documents reviewed will reach the "Statistical" level.

d. For informational purposes, the "Statistical" level of validation in Equivio requires the presence of at least 70 relevant documents in the Control Set. For document collections with richness of 14% and above, a Control Set of 500 documents is sufficient to reach

the “Statistical” level of validation. For lower levels of richness, additional documents will need to be reviewed in the Assessment Phase in order to reach the “Statistical” level.

e. Based on a confidence level of 95%, the Statistical level of validation yields an error margin on recall estimates of plus or minus 11.7%. This is a worst-case error margin assuming recall of 50%. The Parties will continue the Assessment Phase, beyond the “Statistical” level, until the Control Set contains at least 385 relevant documents. This sample will yield an error margin on recall estimates of plus or minus 5%.

6. Iterative Training Phase. Following the creation of the Control Set at the Statistical validation level, the Equivio Relevance system selects a random sample of forty documents. Takeda’s experts will initially review the forty documents for privilege. Any documents deemed privileged by Takeda’s experts will be either entirely withheld from viewing by Plaintiffs’ experts or printed and redacted prior to viewing by Plaintiffs’ experts, and logged on a privilege log consistent with the Privilege Protocol in this matter. These documents may still be used to train the system. The Parties’ experts will then work collaboratively to determine the relevance of the non-privileged and privilege-redacted documents. The relevance of the privileged-withheld documents will be determined by Defendants’ experts, subject to the Parties’ right to have any privileged-withheld documents categorized as a “skip” and not included in the training. To the extent the Parties disagree regarding the relevance or privilege decision for a particular document, they will meet and confer in an effort to resolve the dispute prior to contacting the Court for resolution.

a. Once the experts have completed the first Training Set, the Equivio Relevance system calculates the Training Status. The three possible states are “Not Stable,” “Nearly Stable,” or “Stable.”

b. The experts continue to review samples of forty documents each, using the process outlined in paragraph 6 above, until the Stable Training Status is reached.

c. The subsequent samples of forty documents are selected using an Active Learning approach. Active Learning means that each training sample is selected based on what has been learned from previous samples. The object is to maximize the sample's contribution to the training process. Therefore, the system chooses samples that provide comprehensive coverage of the population (reducing under-inclusiveness), while fine-tuning the concept of relevance that the Classifier is developing (reducing over-inclusiveness). The system reaches Stability when the marginal contribution of additional samples to the enhancement of the Classifier approaches zero, as determined by the Equivio software and which determination (Stability) is not configurable.

7. Calculation of Relevance Scores. Upon completion of the Training Phase once Stability is reached, and any related meet and confer sessions and agreed upon coding corrections, the Equivio Relevance system will run over the sample collection population and calculate relevance scores for each document in the sample collection population. Each document in the sample collection population receives a relevance score of 0 through 100, with 0 being least likely to be relevant and 100 being most likely.

8. Final Search, Review, and Production of Sample Collection Population Documents. The Parties will meet and confer regarding which relevance score will provide a cutoff that will yield a proportionate set of documents that will be manually reviewed by Takeda for production. All of the documents above the agreed upon relevance score in the sample collection population will be reviewed by Takeda. Documents found by Takeda's review to be relevant and non-privileged documents will be produced to Plaintiffs.

9. Quality Control by Random Sample of Irrelevant Documents. In addition, at the conclusion of the process described above, and prior to generating the review set, the Parties will collaboratively review at the offices of Nelson Mullins in Columbia, SC a random sample of documents in the sample collection population with relevance scores below the cut-off score set for establishing the review set (aka the “Rest”). These documents are flagged for culling, and will not be included in the review set. In Equivio Relevance, this test is referred to as “Test the Rest.” The purpose for this phase is to verify that the Rest contains a low prevalence of relevant documents and that the proportionality assumptions underlying the cut-off decision are valid.

a. The Test the Rest sample is designed to provide a confidence level of 95%. The default sample size is 500 documents. The margin of error depends on the percentage of relevant documents in the Rest. For example, if 5% of the Rest documents are found to be relevant, the margin of error is 1.9%. If 1% are relevant, the margin of error is 0.8%.

b. Takeda’s experts will initially review the Rest sample documents for privilege. Any documents deemed privileged by Takeda’s experts will be either entirely withheld from viewing by Plaintiffs’ experts or printed and redacted prior to viewing by Plaintiffs’ experts, and logged on a privilege log consistent with the Privilege Protocol in this matter. The Parties’ experts will then work collaboratively to determine the relevance of the non-privileged and privilege-redacted documents. The relevance of the privileged-withheld documents will be determined by Defendants’ experts, subject to the Parties’ rights to have any privilege-withheld document categorized as a “skip” for purposes of the Test the Rest sample. To the extent the Parties disagree regarding the relevance or privilege decision for a particular document, they will meet and confer in an effort to resolve the dispute prior to contacting the Court for resolution.



10. Sampling of Documents Not Produced After Predictive Coding. After the predictive coding process completes, and Takeda's counsel reviews and produces documents from the sample collection population consistent with paragraph 8, the Parties will collaboratively review at the offices of Nelson Mullins in Columbia, SC a random sample of documents above the agreed-upon cutoff relevance score that were withheld from production on relevance grounds. The Parties agree to meet and confer regarding an appropriate sample size.

a. Takeda's experts will initially review the sample documents for privilege. Any documents deemed privileged by Takeda's experts will be either entirely withheld from viewing by Plaintiffs' experts or printed and redacted prior to viewing by Plaintiffs' experts, and logged on a privilege log consistent with the Privilege Protocol in this matter. The Parties' experts will then work collaboratively to determine the relevance of the non-privileged and privilege-redacted documents. The relevance of the privileged-withheld documents will be determined by Defendants' experts, subject to the Parties' rights to have any privilege-withheld document categorized as a "skip" for this purpose. To the extent the Parties disagree regarding the relevance or privilege decision for a particular document, they will meet and confer in an effort to resolve the dispute prior to contacting the Court for resolution.

11. Post-Predictive Coding Sampling Meet and Confer. The Parties shall meet and confer in good faith to resolve any difficulties and finalize the method for searching documents on a going forward basis. To the extent that the Parties cannot agree, they shall apply to the Court for relief. Defendant shall not be required to proceed with the final search and review unless and until objections raised by either Party have been adjudicated by the Court or resolved by written agreement of the Parties. The Parties reserve the right to request a meet and confer

regarding the designation of any document as a “skip” for purposes of the control sample, training, or Test the Rest, if agreement cannot be reached.

**F. Costs**

1. Takeda reserves its right to seek relief from the Court (e.g., a cost shifting award and pursuant to the principles of proportionality). *See* Fed. R. Civ. P. 1, 26(b)(2)(C), 26(b)(2)(B), & 26(g); *Electronic Discovery*, 11 Sedona Conf. J. 289 (2010); *see also* Fed. R. Evid. 403 (inadmissibility of cumulative evidence).

2. Plaintiffs agree to bear all of the costs associated with their compliance with the terms of this protocol. Plaintiffs agree to bear all of the costs associated with the receipt and review of ESI produced hereunder including the costs associated with its ESI experts who will be involved with Plaintiffs in all aspects of this ESI protocol.

**G. Format of Production For Documents Produced by Defendants**

1. TIFF/Native File Format Production. Documents will be produced as single-page TIFF images with corresponding multi-page text, native file format document if applicable under paragraph G.2, and necessary load files. Native files, along with all corresponding metadata, will be preserved. TIFF images will be of 300 dpi quality or better. The load files will include an image load file as well as a metadata (.DAT) file with the metadata fields identified below on the document level to the extent available.

	<u>Field</u>	<u>Summation Field</u> <u>(Florida)</u>	<u>Definition</u>	<u>Doc Type</u>
1	SOURCE	SOURCE	Name of party producing the document	All
2	CUSTODIAN	CUSTODIAN	Name of person or non-human data source from where documents/files are produced. <i>**Where redundant names occur, individuals should be distinguished by an initial which is kept constant throughout productions (e.g., Smith, John A. and Smith, John B. Where data is collected from an archive, the archive will be listed as custodian.</i>	All
3	CUSTODIANAPPENDMULTI	CUSTODIANAPPENDMULTI	Name of Takeda person or non-human data source from where duplicate documents/files were suppressed. <i>**Where redundant names occur, individuals should be distinguished by an initial which is kept constant throughout productions (e.g., Smith, John A. and Smith, John B. Where data is collected from an archive, the archive will be listed as custodian.</i>	All
4	CUSTODIAN ID	CUSTODIAN ID	Each CUSTODIAN from #2 or 3 above will be assigned a unique numeric identifier that will be maintained throughout productions. Where data is collected from an archive, the archive will be listed as custodian.	All

	Field	Summation Field (Florida)	Definition	Doc Type
5	BEGBATES	BEGDOC#	Beginning Bates Number (production number)	All
6	ENDBATES	ENDDOC#	End Bates Number (production number)	All
7	PGCOUNT	PGCOUNT	Number of pages in the document	All
8	FILESIZE	FILESIZE	File Size	All
9	APPLICAT	APPLICAT	Commonly associated application for the specified file type.	All
10	FILEPATH	FILEPATH (for Edocs)	File source path for electronically collected documents other than emails, which includes location, file name, and file source extension.	Edocs
11	RELATIVE PATH APPEND	RELATIVE PATH APPEND (for Edocs)	File source path for duplicate electronically collected documents other than emails, which includes location, file name, and file source extension.	Edocs
12	NATIVEFILELINK	DOCLINK	For documents provided in native format only	All
13	TEXTPATH	LOGFILE or FULLTEXT	File path for OCR or Extracted Text files	All
14	MSGID	MSGID	Value extracted from parent message during processing	Email
15	FROM	FROM	Sender	Email
16	TO	TO	Recipient	Email
17	cc	cc	Additional Recipients	Email
18	BCC	BCC	Blind Additional Recipients	Email
19	SUBJECT	SUBJECT	Subject line of email	Email
20	PARENTBATES	PARENTID	BeginBates number for the parent email of a family (will not be populated for documents that are not part of a family)	Email

	Field	Summation Field (Florida)	Definition	Doc Type
21	ATTACHBATES	ATTACHID	Bates number from the first page of each attachment	Email
22	BEGATTACH	(will be provided from ATTRANGE)	First Bates number of family range (i.e. Bates number of the first page of the parent email)	Email
23	ENDATTACH	(will be provided from ATTRANGE)	Last Bates number of family range (i.e. Bates number of the last page of the last attachment)	Email
24	ATTACHCOUNT	ATTACHMENT COUNT	Number of attachments to an email	Email
25	ATTACHNAME	ATTACHMENT LIST	Name of each individual attachment	Email
26	DATESENT (mm/dd/yyyy hh:mm:ss AM)	DATESENT	Date Sent	Email
27	DATERCVD (mm/dd/yyyy hh:mm:ss AM)	DATERCVD	Date Received	Email
28	EMAILDATSORT (mm/dd/yyyy hh:mm:ss AM)	DATESENT	Sent Date of the parent email (physically top email in a chain, i.e. immediate/direct parent email)	Email
29	Email Outlook Type	Email Outlook Type	Type of Outlook item, e.g. email, calendar item, contact, note, task	Email
30	HASHVALUE	MD5HASH	MD5 Hash Value	All
31	TITLE	DOCTITLE	Title provided by user within the document	Edocs
32	AUTHOR	AUTHOR	Creator of a document	Edocs
33	DATECRTD	DATECRTD	Creation Date	Edocs
34	MODIFIED BY	LAST EDITED BY	Person who has modified a document	Edocs
35	LASTMODD (mm/dd/yyyy)	LASTMODD (mm/dd/yyyy hh:mm:ss)	Last Modified Date	Edocs

	<u>Field</u>	<u>Summation Field</u> <u>(Florida)</u>	<u>Definition</u>	<u>Doc Type</u>
36	DocumentType	DocumentType	Descriptor for the type of document: <b>"E-document"</b> for electronic documents not attached to emails; <b>"Emails"</b> for all emails; <b>"E-attachments"</b> for files that were attachments to emails; and <b>"Physicals"</b> for hard copy physical documents that have been scanned and converted to an electronic image.	All
37	Importance	Importance	High Importance - indicates Priority Email message.	Email
38	Redacted	Redacted	Descriptor for documents that have been redacted. <b>"Yes"</b> for redacted documents; <b>"No"</b> for unredacted documents.	All
39	ProdVol	ProdVol	Name of media that data was produced on.  Wave 00 I - Hard Drive	All
40	Confidentiality	Confidentiality	Indicates if the document has been designated as <b>"Confidential"</b> pursuant to any applicable Protective Order. <b>"Yes"</b> for Confidential documents; <b>"No"</b> for documents that are not so designated.	All
41	Email folder	Email folder	Folder in which non-archive collected email is stored within the custodians mailbox, such as <b>"inbox"</b> , <b>"sent"</b> , <b>"deleted"</b> , <b>"draft"</b> , or any custom folder.	Email

	<u>Field</u>	<u>Summation Field</u> <u>(Florida)</u>	<u>Definition</u>	<u>Doc Type</u>
42	Relevance score	Relevance score	Relevance score assigned by Equivio for documents that have been through the predictive coding process	All

a. This list of fields does not create any obligation to create or manually code fields that are not automatically generated by the processing of the ESI; that do not exist as part of the original Metadata of the document; or that would be burdensome or costly to obtain.

2. Defendants will produce spreadsheets (.xls/.xlsx files) and PowerPoint presentations (.ppt/.pptx files) in native form as well as audio and video files (e.g., mp3s, wavs, mpegs, etc.), except that spreadsheets and PowerPoint documents will be produced in TIFF format if redactions are applied. Audio and video files shall be edited if redactions are required, subject to appropriate identification of any such audio or video files having been edited. In addition, for any redacted documents that are produced, the documents' metadata fields will be redacted where required. The Parties will meet and confer regarding a request for the production of any other materials including documents in native file format.

3. The Parties agree to meet and confer regarding the format of production for structured databases.

4. Appearance. Subject to appropriate redaction, each document's electronic image will convey the same information and image as the original document, including formatting, such as bolding, highlighting, font size, italics. Documents will be produced in black and

white. After production, a Party may request that a document be produced in color at which time the Parties may meet and confer about such production. Documents that present imaging or formatting problems will be identified and the Parties will meet and confer in an attempt to resolve the problems.

5. Document Numbering. Each page of a produced document will have a legible, unique page identifier “Bates Number” electronically “burned” onto the image at a location that does not obliterate, conceal or interfere with any information from the source document. The Bates Number for each page of each document will be created so as to identify the producing Party and the document number. In the case of materials redacted in accordance with applicable law or confidential materials contemplated in any Protective Order or Confidentiality Stipulation entered into by the Parties, a designation may be “burned” onto the document’s image at a location that does not obliterate or obscure any information from the source document.

6. De-NISTing and Deduplication. Electronic file collections will be De-NISTed, removing commercially available operating system and application file contained on the current NIST file list. Defendants will globally deduplicate identical ESI as follows:

a. Electronic Files: Duplicated electronic files will be identified based upon calculated MD5 Hash values for binary file content. File contents only will be used for MD5 Hash value calculation and will not include operating system metadata (filename, file dates) values. All files bearing an identical MD5 hash value are a duplicate group. The document reviewed by Defendants for privilege, relevance, or confidentiality shall be deemed the primary duplicate document within the group. Generally, the Defendants shall not remove any of the objective coding fields listed in paragraph G.1 above, in either primary or duplicate documents. If redactions are applied to the subject and/or text fields, however, Defendants may apply the



same redactions to all other documents within the duplicate group. Defendants shall only produce one document image or native file for duplicate ESI documents within the group. For Takeda sources, the following metadata fields as described in Section G.1 associated with the produced document will provide information for duplicate documents not produced: CustodianAppendMulti and RelativePathAppend.

b. Messaging Files: Duplicate messaging files will be identified based upon MD5 Hash values for the message family, including parent object and attachments. The following fields will be used to create the unique value for each message: To; From; CC; BCC; Date Sent; Subject; Body; and, MD5 Hash values for all attachments, in attachment order. Duplicate messaging materials will be identified at a family level, including message and attachment(s). All files bearing an identical MD5 Hash value are a duplicate group. The documents reviewed by Defendants for privilege, relevance, or confidentiality shall be deemed the primary duplicate document within the group. For identified duplicate ESI, the Defendants shall not remove any of the objective coding fields listed in paragraph G.1 above. If redactions have been applied to such fields, Defendants may substitute and replace the subject and text fields with those reviewed by Defendants' counsel for the primary duplicate ESI document for the other documents within the duplicate group. Defendants shall only produce one document image or native file for duplicate ESI documents within the group. For Takeda sources, the following metadata field as described in Section G.1 associated with the produced document will provide information for duplicate documents not produced: CustodianAppendMulti.

c. E-mail Threading: The producing Party may identify e-mail threads where all previous emails which make up the thread are present in the body of the final e-mail in the thread. Any party electing to use this procedure must notify all receiving parties that e-mail

thread suppression has been proposed to be performed on a specified production and the Parties agree to meet and confer regarding the format of this production, and reserve the right to seek Court guidance on the issue should agreement not be reached.

7. Production Media. The producing Party may produce documents via a secure file transfer mechanism and/or on readily accessible, computer or electronic media as the Parties may hereafter agree upon, including CD-ROM, DVD, external hard drive (with standard PC compatible interface), (the “Production Media”). Each piece of Production Media will be assigned a production number or other unique identifying label corresponding to the date of the production of documents on the Production Media (e.g., “Defendant Takeda Production April 1, 2012”) as well as the sequence of the material in that production (e.g. “-001”, “-002”). For example, if the production comprises document images on three DVDs, the producing Party may label each DVD in the following manner “Defendant Takeda Production April 1, 2012”, “Defendant MSL Production April 1, 2012-002”, “Defendant Takeda Production April 1, 2012-003.” Additional information that will be identified on the physical Production Media includes: (1) text referencing that it was produced in *In re: Actos (Pioglitazone) Products Liability Litigation*; and (2) the Bates Number range of the materials contained on the Production Media. Further, any replacement Production Media will cross-reference the original Production Media and clearly identify that it is a replacement and cross-reference the Bates Number range that is being replaced.

8. Write Protection and Preservation. All computer media that is capable of write protection should be write-protected before production.

9. Inadvertent Disclosures. The terms of the Case Management Order: Assertions of Attorney-Client Privilege and Work Product Doctrine shall apply to this protocol.

10. Duplicate Production Not Required. The Parties shall meet and confer regarding any Party's request to produce identical paper copies of data already produced in electronic form.

**H. Timing.**

1. The Parties will use their reasonable efforts to produce ESI in a timely manner consistent with the Court's discovery schedule.

2. The Parties will produce ESI on a rolling basis.

**I. General Provisions.**

1. Any practice or procedure set forth herein may be varied by agreement of the Parties, and first will be confirmed in writing, where such variance is deemed appropriate to facilitate the timely and economical exchange of electronic data.

2. Should any Party subsequently determine it cannot in good faith proceed as required by this protocol; the Parties will meet and confer to resolve any dispute before seeking Court intervention.

3. The Parties agree that e-discovery will be conducted in phases and the Parties will meet and confer regarding discovery of data sources not listed herein.

4. Regardless of the foregoing, the Parties are under a continuing obligation to produce identified responsive, non-privileged documents and to identify sources of potentially discoverable materials consistent with their obligations under Federal Rules of Civil Procedure.

**J. Items Requiring Meet and Confer.**

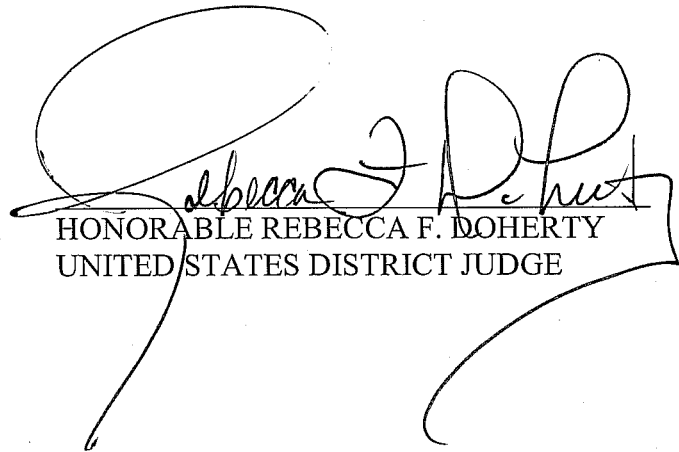
1. The Parties agree to meet and confer regarding the following items in advance of impacted productions:

- a. Whether the E-mail Property metadata field is able to be produced
- b. Certain technical specifications for productions:

- (1) Hard copy document unitization
- (2) Microsoft "Auto" features or macros
- (3) Embedded objects
- (4) Compressed Files
- (5) Load file organization

**IT IS SO ORDERED.**

THUS DONE AND SIGNED in Lafayette, Louisiana, this 27 day of July, 2012.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

EXHIBIT A

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

<u>In Re: Actos (Pioglitazone) Products</u>	)	MDL NO. 6:11-md-2299
Liability Litigation	)	
	)	JUDGE DOHERTY
	)	
This Document Applies to:	)	MAGISTRATE JUDGE HANNA
	)	
All Cases	)	
	)	
	)	
	)	
	)	
	)	

NONDISCLOSURE AND CONFIDENTIALITY AGREEMENT

I, \_\_\_\_\_, state the following:

1. I have read and I understand the Protocol Relating to the Production of Electronically Stored Information and Order in the above-captioned action (a copy of which is attached and whose definitions are incorporated herein) and I attest to my understanding that access to information of the Parties may be provided to me and that such access shall be governed by the terms and conditions and restrictions of the Order. I agree to be bound by the terms of the Order and hereby subject myself to the jurisdiction of the Court for all purposes related to the Order.

2. I shall not use or disclose any information to others, except in accordance with Order. I also understand that, in the event that I fail to abide by the terms of this Nondisclosure and Confidentiality Agreement and/or Order, I may be subject to sanctions by way of contempt of court and to separate legal and equitable recourse by the Parties.

3. I will comply with all of the provisions of the Order. I will hold in confidence, will not disclose to anyone not qualified under the Order, and will use only for the purposes authorized under the Order for the above-captioned litigation any information that is disclosed to me.

4. I understand that my agreement survives the termination of the above-captioned litigation, whether by settlement or other termination. I therefore understand such termination shall not relieve me from any of the continuing obligations of confidentiality imposed by the Order.

5. I hereby submit to the jurisdiction of the United States District Court to the extent allowed by law and to the full extent determined by the United States District Court for the purpose of enforcement of this Nondisclosure and Confidentiality Agreement and the Order.

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Signature

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Printed Name and Address

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Date

RECEIVED

JUL 13 2012



IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

This Document Applies to All Cases

6-11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**SCHEDULING ORDER**

This Court, having considered the scope of these proceedings, the number of plaintiffs (both current and anticipated), the amount of discovery that will be required, and the time necessary to complete pre-trial preparations and commence bellwether trials, hereby establishes the following deadline targets.

**NOTICE:** All parties should be aware that, should any of this Court's assumptions be proven substantially in error, *this Order is subject to amendment, with deadlines possibly being moved either earlier or later.*

1. In light of the discovery plans approved to date, and in anticipation of the entry of a discovery protocol, the parties in all cases in this proceeding are relieved from complying with the requirements of Federal Rule of Civil Procedure 26(a) and (f) at this time. However, once the discovery pool has been selected by the parties, Rule 26(f) Reports will be required for those cases selected for inclusion in the Discovery Pool.
2. **July 16, 2012** – Defendants shall provide to the Special Masters and PSC an *estimate as to the number of documents they can produce by June 3, 2013* assuming a diligent document review process.
3. **August 13, 2012** – The parties shall submit to the Court, through the Special Master(s), a joint draft *Discovery Protocol*.
4. **October 31, 2012** – The Court shall issue an order describing the *Bellwether Trial Protocol*.

5. **June 3, 2013** - Defendants' counsel shall *certify* that they have engaged in best efforts to identify, locate and supply all responsive Electronically Stored Information and document production discovery requested by the Plaintiffs' Steering Committee.<sup>1</sup>
6. **June 3, 2013** - The parties shall each select 20 cases ("*Discovery Pool*") from the eligible pool of cases.<sup>2</sup>
7. **June 10, 2013** – Defendants shall notify the PSC of any selected Discovery Pool case in which Defendants assert there is *missing essential preliminary discovery* in the PFS form and authorizations, that impairs the parties' ability to proceed with case-specific discovery in the particular case. *The parties shall make a good faith effort to resolve any such issue or present any outstanding disputes to the Court within 14 days thereafter.*
8. **July 1, 2013** – The parties shall produce to the Court a *Rule 26(f) Report* on each Discovery Pool case, using the form that will be adapted for these proceedings.
9. **1<sup>st</sup> day of each month thereafter, until the Pre-Trial Order is filed** – The parties shall exchange updated *witness and exhibit lists*. No witness or exhibit may be added without leave of Court once the fact discovery deadline has passed (except for experts identified, and reports produced, in accordance with this order); however, witnesses and exhibits may be removed up through submission of the Pre-Trial Order.
10. **September 30, 2013** - The parties shall complete *core discovery*<sup>3</sup> in Discovery Pool cases.

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<sup>1</sup> All subsequent target pretrial deadlines in this Order presume that the Defendants can comply with this June 3, 2013 deadline. Defendants' ability to comply with this deadline will be reassessed by the Court, through the Special Master(s), periodically, including in approximately two months, following receipt of Defendants' estimate as to the number of documents they can produce by June 3, 2013, commencement of the "Search Methodology Proof of Concept" set forth in Section E of the Protocol Relating to the Production of Electronically Stored Information, and after resolution of any scope of discovery issues that remain outstanding.

<sup>2</sup> Cases shall be considered eligible for selection to the Discovery Pool if filed, served, and a Plaintiff's Fact Sheet and properly executed authorizations have been served upon Defendants by December 30, 2012. In determining the size of the Discovery Pool, the parties have agreed that any cases dismissed after selection to the Discovery Pool will not be replaced.

<sup>3</sup> Core Discovery by the parties shall include depositions of the plaintiff(s), the prescribing doctor(s) and treating doctor(s), and two additional depositions per side. In the event any party seeks depositions beyond these case-specific fact witnesses in an individual plaintiff's case, agreement (in writing) must be obtained or, if no agreement can be obtained after a good faith attempt, leave of Court may be sought.



11. **October 1, 2013** – The Court shall establish a *schedule of deadlines* for *dispositive motions* presenting legal challenges only, emanating from those cases selected for inclusion in the Discovery Pool.
12. **October 16, 2013** – The *selection of bellwether trial cases* and *sequence of trials* shall be *set*.<sup>4</sup>
13. **October 30, 2013** – Deadline for filing *amendments* to pleadings in selected bellwether cases. This deadline is designed to permit the parties to clarify the pleadings; any attempt to add new parties to this action, or to introduce new issues, at this stage of the proceedings will bear the presumption of denial.
14. **December 2, 2013** – Plaintiffs shall complete *Defendant depositions* and Non-Case-Specific *Third Party discovery* and depositions in the first bellwether case in a manner consistent with the Discovery Protocol.
15. **December 18, 2013** – The parties shall complete *case-specific fact discovery* in the first bellwether trial case.
16. **January 31, 2014** - *Plaintiffs* shall designate and serve reports for *generic experts* and *case-specific* experts in the first bellwether trial case. Depositions of Plaintiffs’ generic experts shall occur before depositions of Defendants’ disclosed experts within the same discipline.<sup>5</sup>
17. **March 4, 2014** - *Defendants* shall designate and serve reports for *generic experts* and *case-specific* experts in the first bellwether trial case.<sup>6</sup>
18. **March 11, 2014** - Commencement of *expert depositions in the first bellwether case*.
19. **April 1, 2014** - The parties shall exchange *deposition excerpt designations*, to be used in lieu of live testimony, in the first bellwether trial case.<sup>7</sup>

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<sup>4</sup> The parties shall submit a proposed order setting forth their agreed-upon process for handling bellwether trial pool cases or, if they cannot agree, shall provide their competing submissions to the Court and Special Masters by a date to be subsequently determined.

<sup>5</sup> The parties in good faith will schedule depositions of their experts within a reasonable amount of time after serving the experts’ reports.

<sup>6</sup> The Court will determine what, if any, process (in addition to motion practice) might be employed to evaluate the parties’ experts and the opinions offered.

<sup>7</sup> New excerpt designations are allowed for any deposition that has not occurred as of this date. Supplementation of excerpt designations is allowed in response to information developed in connection with taking,

20. **May 15, 2014** – The parties shall exchange *objections to deposition excerpt designations* and exchange *counter-deposition designations* in the first bellwether trial case.
21. **May 22, 2014** - Completion of *expert depositions in the first bellwether case*.
22. **June 5, 2014** – The parties shall exchange *objections to counter-deposition designations* in the first bellwether trial case.
23. **June 13, 2014** – The parties shall *brief their objections to deposition excerpt designations*. Copies of all relevant excerpts – tabbed for the Court’s ease of reference – shall be attached. The parties are expected to engage in good faith negotiations to resolve as many objections as possible prior to this filing.
24. **June 19, 2014** - The parties shall serve on opposing counsel, the Court, and the Special Master(s) *Daubert motions* and *summary judgment* motions in the first bellwether trial case.<sup>8</sup> The parties are advised to review, and comply with, the Local Rules of the Western District of Louisiana as they apply to summary judgment motions and supporting documents.
25. **July 10, 2014** - The parties shall serve on opposing counsel, the Court, and the Special Master(s) *motions in limine* in the first bellwether trial case.<sup>9</sup>
26. **July 14 - 18, 2014** – *Oral argument* on deposition excerpt designations, if required by the Court.
27. **July 24, 2014** – The parties shall serve on opposing counsel, the Court, and the Special Master(s) *oppositions* to *Daubert* and *summary judgment* motions, if any, in the first bellwether trial case.

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or preparing for, expert depositions. However, this excerpt designation process must be completed in a manner to allow the parties to reasonably comply with the June 13, 2014 deadline. noted in Paragraph 23.

<sup>8</sup> All motions containing confidential or privileged information shall **not** be filed with the Clerk of the Court until any confidentiality issues are resolved. However, opposing counsel, the Court, and the designated Deputy Special Master shall be provided courtesy copies of any such filings no later than the deadlines established herein.

<sup>9</sup> Should oral argument be requested as to any given motion, and should that request be granted as to any given motion, oral argument will take place in September 2014 at a time designated by the Court..

28. **August 5, 2014** – The parties shall serve on opposing counsel, the Court, and the Special Master(s) *replies* to *Daubert* and *summary judgment* motions, if any, in the first bellwether trial case.<sup>10</sup>
29. **August 11, 2014** - The parties shall serve on opposing counsel, the Court, and the Special Master(s) *oppositions* to *motions in limine* in the first bellwether trial case.
30. **August 18, 2014** - The parties shall serve on opposing counsel, the Court, and the Special Master(s) *replies* to *motions in limine* in the first bellwether trial case.
31. **September 24, 2014** – *Plaintiffs* shall submit to Defendants *inserts* for pre-trial order, voir dire, jury interrogatories, and jury instructions.
32. **October 1, 2014** – *Defendants* shall submit to Plaintiffs *inserts* for pre-trial order, voir dire, jury interrogatories, and jury instructions.
33. **October 2 – 7, 2014** – Counsel for the parties shall *confer* to create the Pre-Trial Order, joint jury instructions, joint jury instructions, and proposed voir dire requests.
34. **October 8, 2014** – The parties shall file the *Pre-trial Order*, together with proposed *voir dire* requests, *joint jury interrogatories*, and *joint jury instructions*.
35. **October 22, 2014, 10:00 a.m.** – *Pre-Trial Conference* for the first bellwether case.<sup>11</sup>
36. **October 24, 2014** – *Glossary* of Real Time terms.
37. **October 24, 2014** – Final *exchange of exhibits*.
38. **October 27, 2014** – Parties to produce *bench books* to the Court.
39. **November 3, 2014** - *Trial* of the first bellwether case.

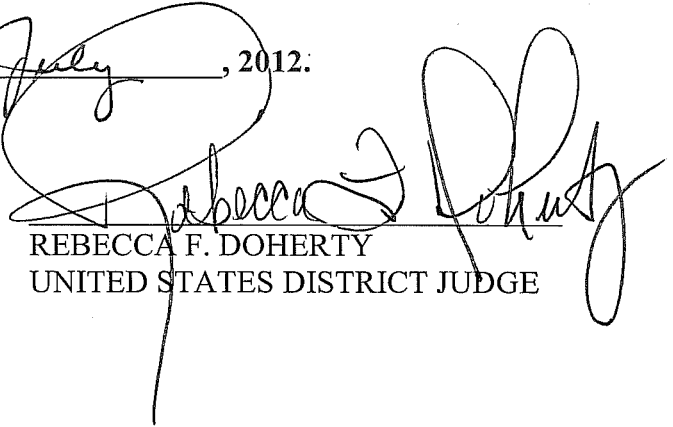
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<sup>10</sup> The parties shall have 21 days following service of all reply briefs, referenced herein, to resolve any matters concerning privilege or confidentiality pursuant to paragraph 10 of the Protective Order (*i.e.*, Case Management Order: Protecting the Confidentiality of Discovery Materials).

<sup>11</sup> This Court's pre-trial conferences are extensive and address both substantive and procedural issues at length. Counsel should expect that the pre-trial conference will be lengthy, and make their plans accordingly.

40. January 12, 2015 – *Trial* of the second bellwether case.

SO ORDERED, this 13 day of July, 2012:



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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JUL 13 2012

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**DISCOVERY STAY IS LIFTED**

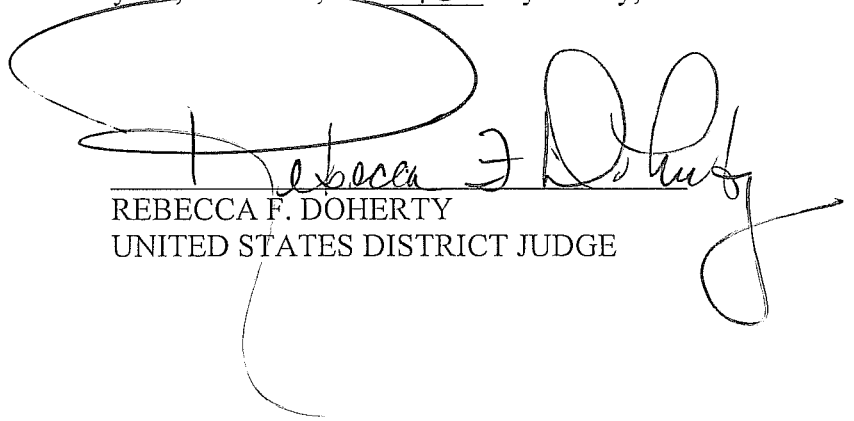
Considering the current status of these proceedings, including the impressive levels of cooperation, coordination, and negotiation that have taken place among counsel for the plaintiffs and the defense, as well as the orders that have been issued and the ones that are shortly to be issued,

IT IS HEREBY ORDERED that the stay of discovery put in place by this Court on January 23, 2012 is hereby LIFTED, as follows:

- Discovery shall proceed, with all due diligence, in accordance with the Discovery Protocol to be issued, orders that have been issued by this Court (including the order addressing plaintiff fact sheets and the privilege protocol), as well as those orders shortly to be issued (including the order addressing the production of ESI, the protective order, and the order addressing the defendants' fact sheets), as well as any other orders of the Court issued hereafter.
- Until the Discovery Protocol is issued (which is expected to be issued in August, 2012), all counsel must obtain leave of Court to propound any discovery.

- Once the Discovery Protocol is issued, discovery will proceed in accordance with that Order.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 13 day of July, 2012.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

JUL 10 2012

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE)  
PRODUCTS LIABILITY  
LITIGATION

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This Document Relates to All Cases  
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MDL Docket No.  
  
6:11-MD-2299

**CASE MANAGEMENT ORDER:**

**Assertions of Attorney-Client Privilege and Work Product Doctrine**

**I. Scope of Order**

This Order is entered to provide general principles and specific guidelines that shall apply to assertions of attorney-client and/or work-product privilege, the protocols that shall be followed with regard to privilege logs, and the method of determining any disputes relating to the assertion of the attorney-client privilege or work product doctrine by any party. This Order applies to claims brought by any U.S. citizen or resident based on alleged ingestion of Actos®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, or pioglitazone (“Actos”) that (i) currently are pending in MDL No. 2299, (ii) currently are pending in the Western District of Louisiana and are related to MDL No. 2299, or (iii) will be filed in, removed to, or transferred to this Court within the noted proceeding(s) (collectively, “the MDL Proceedings”).

**II. Grounds for Asserting Privilege**

In order to avoid any future dispute about what substantive law might apply to a claim of attorney-client privilege, the parties have agreed that federal common law governing privilege applies, including the general and specific principles set forth in *In re Vioxx Prod. Liab. Litig.*, 501 F. Supp. 2d 789 (E.D. La. 2007), as summarized in part below. The parties have also agreed

the work product doctrine shall be governed by the law of the U.S. Court of Appeals, Fifth Court, as described in part below.

**A. General Principles**

1. The attorney-client privilege applies only if:
  - (a) the asserted holder of the privilege is or sought to become a client;
  - (b) the person to whom the communication was made;
    - (i.) is a member of the bar of a court, or his or her subordinate;  
and
    - (ii.) in connection with this communication is acting as a lawyer;
  - (c) the communication relates to a fact of which the attorney was informed;
    - (i.) by his or her client;
    - (ii.) without the presence of strangers;
    - (iii.) for the purpose of securing primarily either;
      - (a) an opinion on law or;
      - (b) legal services or;
      - (c) assistance in some legal proceeding;
    - (iv.) and not for the purpose of committing a crime or tort; and
  - (d) the privilege has been claimed and not waived by the client.<sup>1</sup>
2. The attorney-client privilege applies where counsel was participating in the

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<sup>1</sup> *In re Vioxx Products Liab. Litig.*, 501 F. Supp. 2d 789, 795 (E.D. La. 2007). This definition was adopted by the Fifth Circuit Court of Appeals in 1975 in *In re Grand Jury Proceedings*, 517 F.2d 666, 670 (5th Cir.1975).



communications primarily for the purpose of rendering legal advice or assistance.<sup>2</sup> Therefore, merely because a legal issue can be identified that relates to on-going communications does not justify shielding those communications from discovery. The lawyer's role as a lawyer must be primary to his or her participation in the communications.<sup>3</sup> The burden of persuasion on all elements of claimed privileges is exclusively the proponent's.<sup>4</sup>

3. The work product doctrine only applies to documents or data compilations that are created in anticipation of litigation. Fed. R. Civ. P. 26(b)(3). Thus, to assert work product privilege, the document or data compilation must be prepared by or for the party or its representative (including the party's attorney, consultant, surety, indemnitor, insurer, or agent) for prospective litigation, meaning that the primary motivating purpose behind the creation of the document was to aid in pending or threatened litigation.

## **B. Specific Guidelines**

1. The attorney-client privilege protects documents and communications addressed solely to an attorney with apparently limited circulation with an identifiable legal question raised by the author (whether or not it was answered by the attorney). The attorney's response (if any) is also privileged if its primary purpose is to provide legal advice.<sup>5</sup>

2. When an e-mail message is addressed to both lawyers and non-lawyers for review, comment, and approval ("mixed-purpose" communication), the message is protected by

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<sup>2</sup> *Vioxx*, 501 F. Supp. 2d at 798.

<sup>3</sup> *See id.* at 798.

<sup>4</sup> *See id.* at 798-99.

<sup>5</sup> *See id.* at 795-796. The Court in *Vioxx* discussed two exceptions to this general rule: (1) when the attorney had conveyed information to the client that the attorney had acquired from third parties (e.g., previously published articles and discussions with third parties like a U.S. attorney), and (2) when in-house lawyers were electronically rendering their advice (in the form of line edits) on a non-privileged attachment to non-privileged client communications and the non-privileged attachment was claimed as privileged because of the advice its lawyers chose to place on it. As to the latter situation, the lawyer's comments and changes may be redacted.

the attorney-client privilege if the proponent can satisfy the burden of proving that the non-lawyers are included on the communication to apprise them of the legal services sought. Absent this exception, neither the message nor attachments to it are protected by the attorney-client privilege.<sup>6</sup>

3. For a mixed-purpose communication, any portion of such a communication that specifically requests legal advice may be redacted. The attorney's response to such a communication is similarly privileged to the extent it provides legal advice. If the attorney provides comments or changes on an attachment to the communication (in the form of line edits or other comments embedded in the document), those comments and changes may be redacted subject to the provisions below:

- (a) If the document on which attorney comments and changes were being proposed was not a typical legal instrument and the response had changes and commentary that were extensive or related purely to technical, scientific, promotional, management, or marketing matters that do not appear to be related to legal assistance, then the proponent may not redact the comments and changes of the attorney unless the proponent can satisfy the burden of proving that the primary purpose of the responses was providing legal advice;
- (b) If the document on which attorney comments and changes were being proposed related to identifiable legal instruments like a proposed contract, the comments and changes are privileged, even with extensive editorial and grammatical revisions, because they

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<sup>6</sup> *See id.* at 809 (“A corporation’s choices of means and format in the communications between their lawyers and employees cannot limit their adversaries’ right to discovery of what otherwise is non-privileged and discoverable.”).

are the type of instruments that one reasonably expects more extensive input and guidance from reviewing attorneys.<sup>7</sup>

4. The attorney-client privilege protects what independently is not privileged only if it is attached to, or incorporated in, a communication that is protected by the privilege.<sup>8</sup> For instance, if a memorandum was written only to an attorney within the corporation's legal department, with an attachment for examination, review, comment, and approval, the e-mail and attachment are sent primarily for the purpose of obtaining legal advice and, therefore, are protected by the attorney-client privilege. The attorney-client privilege does not, however, protect a document sent from one corporate officer to another simply because a copy is sent to counsel. The document is protected if the proponent can satisfy the burden of proving that the primary purpose of the document was a request for or the provision of legal advice.

5. The attorney-client privilege protects the additional dissemination of a privileged e-mail when the conveyance was by a non-lawyer recipient only if it is clear that legal advice previously obtained was being circulated to those within the corporate structure who needed the advice in order to fulfill their corporate responsibilities.<sup>9</sup> The attorney-client privilege does *not* protect e-mails that were either to or from an attorney but did not reveal the substance of what either the client was communicating (for example attaching a study, report, article, etc.) or the attorney was advising (because the comments appeared on the attachment), regardless of whether the attachments are privileged.<sup>10</sup>

6. The attorney-client privilege protects communications among non-attorneys if the purpose of the communication is to gather information necessary for the obtaining of legal

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<sup>7</sup> *Id.* at 811.

<sup>8</sup> *Id.*

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 812.

advice or to convey such legal advice. Absent extraordinary circumstances, the burden to demonstrate a privileged purpose of the communication will not be met when an attorney is not the sender or a recipient of a communication.<sup>11</sup>

7. Where an attorney was involved in the process of drafting an otherwise non-privileged document, drafts of the document are privileged to the extent they reveal the attorney's legal advice and are not otherwise privileged.<sup>12</sup>

8. The attorney work-product doctrine, in part, shelters the mental processes of an attorney. The work-product doctrine also protects materials assembled and brought into being by the party or its representative at the direction of counsel in anticipation of litigation. Excluded from the scope of work-product are materials assembled in the ordinary course of business or pursuant to public requirements unrelated to litigation.<sup>13</sup>

9. Materials are not protected as attorney work-product merely because they were prepared by the party or its representative at the direction of counsel at a time when litigation was ongoing or imminent. The test is whether the primary motivating purpose behind the creation of the document was to aid in existing or possible future litigation.<sup>14</sup>

### **III. Privilege Log Protocol**

#### **A. General Principles**

The party asserting a privilege shall provide sufficient information in its privilege logs to enable the opposing party to assess the applicability of the privilege.<sup>15</sup> Additionally, the burden

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<sup>11</sup> See *Smithkline Beecham Corp. v. Apotex Corp.*, 232 F.R.D. 467, 477 (E.D. Pa. 2005)

<sup>12</sup> See *Vioxx*, 501 F. Supp. 2d at 802-804. See also *Smithkline Beecham Corp.*, 232 F.R.D. at 477-78 (“In general, attorney-client privilege does not shield documents merely because they were transferred to or routed through an attorney.”) (internal citations omitted).

<sup>13</sup> See *U.S. v. El Paso Co.*, 682 F.2d 530 (5th Cir.1982).

<sup>14</sup> See *U.S. v. El Paso Co.*, 682 F.2d 530 (5th Cir.1982).

<sup>15</sup> Fed. R. Civ. P. 26(b)(5).

of demonstrating the applicability of a privilege rests on the party asserting same.<sup>16</sup> A party asserting privilege is required to provide specific, rather than generic, information about the withheld information.<sup>17</sup>

**B. Specific Privilege Log Protocols**

1. Privilege logs provided in lieu of producing documents requested shall comply with Rule 26(b)(5), which requires a party to:

- (a) Expressly identify the privilege asserted; and
- (b) Describe the nature of the documents, communications, or tangible things not produced or disclosed—and do so *in a manner that, without revealing information itself privileged or protected, will enable other parties to assess the claim.*<sup>18</sup>

2. Privilege logs provided in lieu of producing documents requested shall substantially follow the form set forth in Exhibit 1.

3. Such privilege logs, if any – specifically identifying every withheld or redacted document by Bates number – shall be produced no more than 30 days after the date upon which the documents *are required to be produced or were partially produced.*

4. A separate entry in the privilege log – specifically identifying every withheld or redacted document by Bates number – shall be made for each document as to which any party asserts a privilege, with each entry identifying all parties asserting the privilege. E-mail threads may be treated as a single document with a single entry in the privilege log where the same claim of privilege or attorney work product extends to the entire thread. Large e-mail threads that are

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<sup>16</sup> *Hodges, Grant & Kaufmann v. United States*, 768 F.2d 719, 720 (5th Cir. 1985).

<sup>17</sup> *In re Pabst Licensing, GmbH Patent Litig.*, No. CIV. A. MDL 1298, 2001 WL 1135268, \*2-3 (E.D. La. Sept. 19, 2001).

<sup>18</sup> Fed. R. Civ. P. 26(b)(5).

not included in the same privilege claim shall be assigned separate Bates numbers and identified by separate entries in the privilege log if they are being withheld for a variety of privilege claims to allow separate descriptions of each privilege portion. Large e-mail threads that precede direct or limited exchanges with attorneys shall be assigned separate Bates numbers and identified by separate entries in the privilege log if they are being withheld pursuant to these guidelines.<sup>19</sup>

5. No entry on the privilege log asserting attorney-client privilege will be sufficient unless it provides a clear description showing that the attorney was acting in his or her professional legal capacity.<sup>20</sup>

6. Unacceptable descriptions are those that include only vague characterizations such as “documents regarding requests for legal advice,” “regulatory issues,” “study issues,” or “public relations documents” absent additional explanation clarifying the basis for the claim of privilege or work product protection.

7. No entry on the privilege log asserting work product privilege will be sufficient unless it provides a clear description that the subject document or communication directly relates to pending or threatened litigation.

8. It shall be insufficient to give only generic descriptions that simply incant the code words of the privilege, for example, “regarding litigation issues” or “preparatory measures taken in anticipation of litigation.”

9. It shall be inadequate to provide entries that do not identify authors or recipients contending instead that such information is “N/A” or “Distribution.”<sup>21</sup> In this circumstance,

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<sup>19</sup> *In re Vioxx Products Liab. Litig.*, 501 F. Supp. 2d 789, 812 (E.D. La. 2007). Simply because technology has made it possible to physically link these separate communications (which in the past would have been separate memoranda) does not justify treating them as one communication and denying the demanding party a fair opportunity to evaluate privilege claims raised by the producing party.

<sup>20</sup> *Id.* at 797.

<sup>21</sup> See *Freeport-McMoran Sulphur L.L.C. v. Mullen Energy Equipment Resources*, No. Civ.A. 03-1496, {L0210064.3}

identify is “to disclose the title and employer.” For each specific author or recipient listed, it shall be inadequate to provide entries that do not disclose the title and employer of those individuals who sent, who received, or who were copied on, allegedly privileged communications.

10. It shall be inadequate to provide entries containing only cryptic descriptions such as “list,” “presentation,” and “correspondence,” “attorney report,” “client inquiry,” “payment” and “attorney communication.”

11. It shall be inadequate to provide entries describing documents only as “labeling” or “regulatory” stemming from FDA regulation or perhaps in anticipation of FDA communications or inquiry.

12. It shall be inadequate to provide entries that do not identify the Bates numbers found on each and every withheld or redacted page.

#### **IV. Redaction of Confidential, Irrelevant, and Privileged Information.**

1. To protect against inappropriate disclosure of information subject to the attorney-client or other privilege and confidential information as defined in this Order, and to comply with all applicable state and federal laws and regulations, the Defendants or Plaintiffs may redact from produced documents, materials or other things, or portions thereof, the following items, or any other item(s) agreed upon by the parties or ordered by the Court:

- (a) The names, addresses, Social Security numbers, tax identification numbers, e-mail addresses, telephone numbers, and other personal identifying information of patients (including plaintiffs), health

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2004 WL 1299042, \* 11 (E.D. La. 2004), reconsideration denied, 2004 WL 1488665 (June 30, 2004) (“there is no way for the Court to know who prepared the draft insert, for whom it was prepared, and whether it was prepared for the purpose of seeking or rendering legal advice. Freeport has failed to establish that a privilege applies here . . .”).

care providers, and individuals enrolled as subjects in clinical studies or adverse event reports. Other general identifying information, however, such as patient or health care provider numbers, shall not be redacted unless required by state or federal law;

- (b) Materials that contain information protected from disclosure by the attorney-client privilege, the work product doctrine or any other recognized privilege;
- (c) Those portions of documents that contain information relating to Defendants' non-pioglitazone-containing medicines;
- (d) The street addresses, Social Security numbers, tax identification numbers, dates of birth, home telephone numbers, and cellular telephone numbers of employees in any records; and
- (e) The names, addresses, Social Security numbers, tax identification numbers, e-mail addresses, telephone numbers, and other personal identifying information of any clinical investigator in any records.

2. Defendants shall redact only those portions of a document that are within the scope of the permitted subject-matter set forth above, and not the entire document or page unless the entire document or page is within such scope.

3. Defendants shall indicate on each redaction a brief, but specific, identifier stating the basis for the redaction, *e.g.* "other product," "employee privacy," "attorney-client privilege." When a redacted document is produced, this identifier will be listed in a "reason for redaction" field included with the objective coding which accompanies the load file for the document production. Where a redaction is subsequently lifted by order of the Court or by agreement of



the parties (*e.g.*, subject to a privilege challenge), Defendants shall produce replacement media for that document, including the unredacted TIFF, text or OCR files, and objective coding, with appropriate load files.

4. Documents withheld from production based on a claim of privilege of any kind shall be identified, by Bates number and proper description, on a privilege log created in accordance with the stipulated protocol for discovery of electronically stored information.

5. Privilege logs shall promptly be supplemented under Fed. R. Civ. P. 26 (e)(1) as to any document which becomes producible thereafter.

6. Any failure to redact information described above does not waive any right to claims of privilege or privacy, or any objection, including relevancy, as to the specific document or any other document that is or will be produced.

#### **V. Inadvertent Production of Documents.**

Inadvertent production of documents (hereinafter “Inadvertently Produced Documents”) subject to work-product immunity, the attorney-client privilege, or other legal privilege protecting information from discovery shall not constitute a waiver of the immunity or privilege, provided that the Producing Party shall notify the Receiving Party in writing within 10 days from the discovery of the inadvertent production.

Upon receiving such a notification, the Inadvertently Produced Documents and all copies thereof shall, upon request, be returned to the Producing Party, all notes or other work product of the receiving party reflecting the contents of such materials shall be destroyed, and such returned or destroyed material shall be deleted from any litigation-support or other database.<sup>22</sup> Alternatively, the Receiving Party may elect to file a motion as described below. In the event that such a motion is filed, the Receiving Party, subject to the requirements below, may retain

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<sup>22</sup> Fed. R. Civ. P. 26(b)(5)(B).

possession of the Inadvertently Produced Documents as well as any notes or other work product of the receiving party reflecting the contents of such materials pending the resolution by the Court of the motion described below, but must not use or disclose the information until the motion is resolved.<sup>23</sup> Specifically, no use shall be made of such Inadvertently Produced Documents during depositions or at trial, nor shall they be disclosed to anyone who was not given access to them prior to the request to return or destroy them. If the Receiving Party's motion is denied and the time to appeal has expired without an appeal being filed, the Receiving Party shall promptly comply with the provisions of this paragraph concerning the return of Inadvertently Produced Documents to the Producing Party.

A party receiving Inadvertently Produced Documents may, after receipt of a Producing Party's notice of inadvertent production, file a motion with the Court to dispute the claim of privilege or immunity. Any such motion shall be accompanied by a Motion for Leave to File Under Seal ("Sealing Motion") in accordance with this Court's order concerning Sealing Motions. On such a motion, the Producing Party shall have no less than fifteen (15) calendar days to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief. The Opposition shall be accompanied by a Sealing Motion.

## **VI. Privilege Dispute Procedure**

1. If at any time a Receiving Party wishes in good faith to dispute a privilege designation, such party shall notify the Producing Party of such dispute in writing (Dispute Notice), specifying by exact document numbers the discovery material in dispute and providing a brief explanation of the basis of the dispute with regard to each such document or other discovery material.

2. No more than 50 documents shall be challenged in a single Dispute Notice, and only one Dispute Notice may be sent within a three-week period.

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<sup>23</sup> *Id.*

3. If no change in designation is offered by the Producing Party, the Producing Party must provide within fourteen (14) calendar days a written explanation of the good faith basis for the privilege designation(s) at issue.

4. If a Receiving Party elects to press a challenge to a privilege designation after considering the justification offered by the Producing Party, the Receiving Party shall, in writing, (Challenge Notice) notify the Producing Party that a resolution cannot be reached regarding the privilege designation of a document or, the Receiving Party may elect to file and serve a motion that identifies the challenged material and sets forth the basis for the challenge to the privilege designation. Any such motion shall be accompanied by a Sealing Motion. On such motion, the Producing Party shall have the burden of proving that the materials is entitled to protection, as if this Order has not been entered, pursuant to Rule 26(c)(1)(G). On such a motion by the Receiving Party, the Producing Party shall have no less than fifteen (15) calendar days, nor more than twenty-one (21) calendar days, to file and serve an Opposition, and the Receiving Party shall waive its right to file a reply brief.<sup>24</sup> The Opposition shall be accompanied by a Sealing Motion. If the Receiving Party elects to serve a Challenge Notice rather than move, the Producing Party shall, within twenty-one (21) calendar days of receiving such notice from the Receiving Party, file and serve a motion that identifies the challenged material and sets forth in detail the basis for the confidentiality designation. The Motion shall be accompanied by a Sealing Motion.

5. The Producing Party shall have the burden of proof on such motion to establish the propriety of its privilege or work product designation. The time allotted under this paragraph for a Producing Party to respond in writing to a Challenge Notice or to file and serve a motion setting forth the basis of a challenged designation shall not be shortened except upon a

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<sup>24</sup> If the number of pending challenges becomes burdensome, the parties agree to alter the schedule to provide sufficient time for an Opposition.

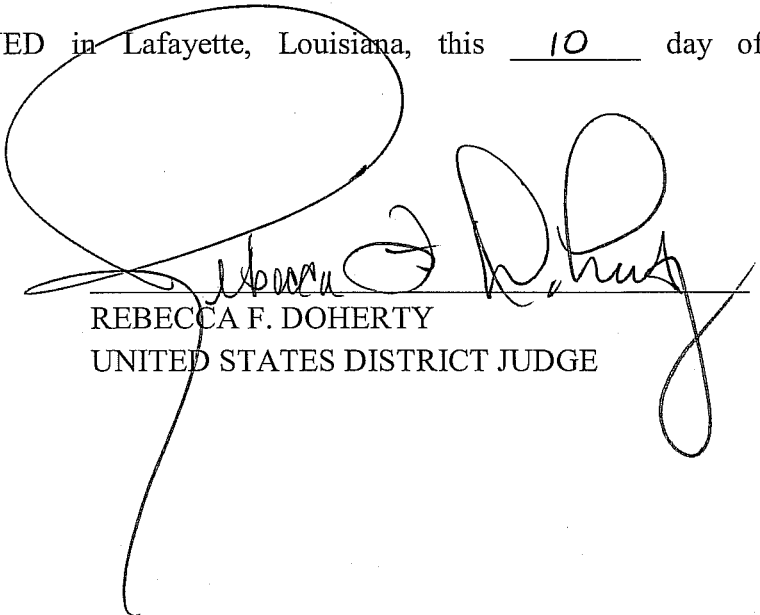
showing of good cause.

6. All discovery material designated as privileged under this Order, whether or not such designation is in dispute, shall retain that designation and be treated as privileged in accordance with the terms hereof unless and until:

- (a) the Producing Party agrees in writing that the material is no longer privileged and subject to the terms of this Order; or
- (b) fourteen (14) calendar days after the expiration of all appeal(s) period(s) of an Order(s) of this Court that the matter shall not be entitled to confidential status (or such longer time as ordered by this Court) if the Order on appeal is not subject to a stay; or
- (c) the Producing Party does not respond as set forth above within fourteen (14) calendar days of service of the Dispute Notice; or
- (d) the Producing Party does not serve a motion within twenty-one (21) days of receiving a Challenge Notice.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 10 day of

July, 2012.


  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

In re: *Actos (Pioglitazone) Products Liability Litigation*, MDL No. 6:11-md-2299 (W.D. La.)  
 Takeda Pharmaceuticals Privilege Log (Produced \_\_\_\_\_)

Bates Number	Date	Author	Recipient(s)	Copied Recipients	Description of Communication	Privilege Asserted
1	04/05/2012	Attorney, Esq.	B & C	D, E, F	E-mail concerning legal advice about marketing material.	Attorney-Client Privilege
2	04/06/2012	B	Attorney, Esq.		Document concerning legal advice about litigation.	Attorney-Client Privilege; Work Product
3	04/06/12	Attorney, Esq.	C	F	E-mail created because of litigation.	Work Product



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JUL - 9 2012 

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE) PRODUCTS  
LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

**CASE MANAGEMENT ORDER:**  
**PLAINTIFF FACT SHEETS**

**I. Scope of Order**

This Agreed Order applies to claims brought by any U.S. citizen or resident based on alleged ingestion of Actos®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, or pioglitazone (“Actos”) that, (i) currently are pending in MDL No. 2299, (ii) currently are pending in the Western District of Louisiana and are related to MDL No. 2299, or (iii) subsequent to the date of this Order are filed in, removed to, or transferred to this Court (collectively, “MDL Proceedings”). This Order is binding on all parties and their counsel in all cases currently pending or subsequently made part of these proceedings and shall govern each case in the proceedings.

**II. Plaintiff Fact Sheets**

A. The parties have agreed upon a Plaintiff Fact Sheet (“PFS”) that includes document requests in Section XI and an authorization for release of records. *See* Exhibits A and B. Each Plaintiff shall produce to Defendants a completed PFS, executed Authorizations and documents responsive to Section XI of the PFS (“Responsive Documents”) pursuant to the terms of this Order. The approved form Authorization is attached as Exhibit B, hereto.

B. A completed PFS, which requires that each Plaintiff sign the Declaration in Section X, shall be considered interrogatory answers and responses to requests for production under the Federal Rules of Civil Procedure, and will be governed by the standards applicable to written discovery

under the Federal Rules of Civil Procedure. As set forth in Section III.E, each PFS that is completed must be substantially-complete. Accordingly, Defendants' use of the PFS is in lieu of interrogatories and other discovery devices that they would otherwise have propounded, without prejudice to Defendants' right to propound additional discovery as part of a bellwether program, in cases selected for trial, or upon remand of a case to its transferor court.

C. The PFS questions and requests for production have been negotiated and agreed to by the parties. All objections to the admissibility of information contained in the PFS are reserved and therefore no objections shall be lodged in the responses to the questions and requests contained in the PFS absent special circumstances. The admissibility of information in responses to the PFS shall be governed by the Federal Rules of Civil Procedure and no objections are waived by virtue of any PFS response.

### **III. Schedule for Production of Plaintiff Fact Sheets**

A. Plaintiffs with cases must complete and serve a PFS, executed Authorizations and Responsive Documents on the following schedule:

1. In cases that are directly filed in the MDL, each Plaintiff must complete and serve a PFS, executed authorizations, and Responsive Documents within 45 days of the last Takeda or Eli Lilly Defendant's answer to the Plaintiff's complaint.
2. In cases that were filed and served before entry of this Order, each Plaintiff shall have seventy-five (75) days from the date of this Order to complete and serve a PFS, executed authorizations, and Responsive Documents.
3. For cases transferred to this MDL via Conditional Transfer Order by the JPML, each Plaintiff shall have sixty (60) days from the date of transfer of the case to this MDL to complete and serve a PFS, executed authorizations, and Responsive



Documents. A case shall be deemed transferred to the MDL either: (a) on the date that the certified copy of the Conditional Transfer Order issued by the Judicial Panel on Multidistrict Litigation (“JPML”) is entered in the docket of this Court, or (b) where transfer is contested, the date of transfer in any subsequent order from the JPML.

B. Defendants’ Counsel identified below will notify each plaintiff’s counsel of his/her obligation under Section III.A.3. The Court will notify plaintiff’s counsel of their obligations by dissemination of a form communication when a case is filed.

C. The parties may agree to an extension of the above time limits for service of a PFS and the Defendants are encouraged to respond reasonably to such requests. If the parties cannot agree on reasonable extensions of time, such party may apply to the Court for such relief.

D. Service of the PFS, authorization, and Responsive Documents shall be electronically via e-mail to Defendants’ Counsel at *AUS\_Actos\_PFS@gordonrees.com* and to Plaintiffs’ Co-Lead Counsel’s designee, Jonathan Sedgh, Esq., at *ActosPFS@weitzlux.com*. To the extent service via e-mail is not possible, the PFS, authorization, and Responsive Documents may be served on Defendants’ Counsel by sending them in electronic format on CD via first class or overnight mail addressed to:

ACTOS MDL Plaintiff Fact Sheet  
c/o Jeffrey A. Lilly  
Gordon & Rees LLP  
816 Congress Avenue, Suite 1510  
Austin, TX 78701

E. Each Plaintiff is required to provide Defendants’ Counsel (as set forth above) with a PFS that is substantially-complete in all respects. For a PFS to meet this requirement, Plaintiff must:

1. Answer all applicable questions in the PFS (Plaintiff may answer questions in good faith by indicating “not applicable” or “I don’t know” or “Unknown”)<sup>1</sup>;
2. Include a signed Declaration and Certification (found at Sections X and XII of the PFS);
3. Provide duly executed record release Authorization(s); and
4. Produce the documents requested in the PFS, to the extent such documents are in Plaintiff’s possession.

#### **IV. Authorizations for the Release of Records**

A. As set forth above, Authorization(s) for the Release of Records, together with copies of such records (to the extent that those records or copies are in the Plaintiff’s possession), shall be provided along with the PFS at the time the Plaintiff is required to serve a PFS pursuant to this Order. Each Authorization produced under this order shall be completed at the time of its production to Defendants’ Counsel (*i.e.*, each authorization must be signed, and information identifying the healthcare provider/records custodian, patient name, date of birth, and social security number must be filled in).

B. Authorizations need not be dated, but undated Authorizations constitute permission for Defendants’ Counsel to date (and where applicable, re-date) Authorizations before sending to records custodians. Should Plaintiffs provide Authorizations that are dated, or undated, neither shall constitute a deficiency or be deemed a substantially non-complete PFS.

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<sup>1</sup> Non-substantive omissions, such as the inadvertent failure to provide a zip code, phone number, or other non-substantive information, shall not form the basis of a claim that a Plaintiff’s PFS is not substantially-complete. Plaintiffs are reminded, however, that the PFS agreed to by the parties and entered pursuant to an Order of this Court, requires Plaintiffs to answer all applicable questions in good faith. A continued pattern of such omissions may be considered by the Court to be evidence of an absence of good faith.

C. If the Plaintiff is suing in a representative or derivative capacity, the authorizations must be signed and produced along with documentation, if it exists, establishing that the signatory is a duly appointed representative or is otherwise permitted to execute authorizations on behalf of the person who allegedly took Actos. Such documentation need only be provided one time.

D. Each Plaintiff shall serve upon Defendants' Counsel designated above, along with his or her PFS and Responsive Documents, an original signed "Authorization for Release of Records" for each health care provider, pharmacy, or other custodian of records identified in Plaintiff's PFS. The presumption is that plaintiff will provide authorizations for the release of records for all healthcare providers identified in their PFS. If a plaintiff elects to withhold an authorization for the release of a healthcare provider's records (as identified in Section IV of the PFS) on the basis of relevance, then Plaintiff's counsel shall set forth in detail a good faith basis for the objection to providing same.

E. Each Plaintiff asserting a wage loss claim shall also serve upon Defendants' Counsel designated above, along with his or her PFS and Responsive Documents, an original signed "Authorization for Release of Records" for each employer identified in Plaintiff's PFS.

F. In addition to the addressed Authorizations described above, Plaintiff's counsel shall also maintain in their file unaddressed, executed Authorizations. Plaintiff's counsel shall provide executed Authorizations to Defendants' Counsel or communicate an objection to said request for authorizations within 14 days of a request for Authorizations.

G. If a health care provider, employer, or other custodian of records for whom an Authorization has already been provided: (1) has a specific authorization form that it requires its patients to use; (2) requires a more recent authorization than the authorization initially provided by the Plaintiff; (3) requires a notarized authorization; or (4) requires an original signature, Defendants'

Counsel shall so notify Plaintiff's counsel and provide such specific authorization(s) and/or new blank authorization(s) to Plaintiff's counsel. Plaintiff shall execute such specific, updated, and/or original authorization(s) and provide them to Defendants' Counsel within thirty (30) days of the request.

**V. Non-Compliance with PFS Requirements**

A. Any Plaintiff who fails to comply with his or her PFS obligations under this Order may be subject to having his or her claims, as well as any derivative claim(s), dismissed. If Defendants have not received a substantially-complete PFS from Plaintiff by the deadline set forth in Section III.A of this Order, after twenty-one (21) days Defendants may send a Notice of Overdue Discovery to Plaintiff's counsel identifying that a substantially-complete PFS has not been provided and stating that the case may be subject to administrative closure if the requested information is not provided within twenty-one (21) days, and ultimately a dismissal with prejudice at a later date if Plaintiff does not provide a substantially-complete PFS pursuant to the terms of this Order. If, however, counsel for plaintiff contacts counsel for defendants to meet-and-confer prior to expiration of the twenty-one (21) day notice period, Defendants shall attempt to meet-and-confer with plaintiffs' counsel for at least seven (7) days beyond the twenty-one (21) day notice period before moving to administratively close Plaintiff's action. If Defendants have not received a substantially-complete PFS by the end of the twenty-one (21) day notice period and a request for a meet-and-confer has not been requested by plaintiff's counsel (or if a meet-and-confer has been requested by plaintiff's counsel and the seven (7) day period for such a meet-and-confer has expired without resolution), then Defendants may move the Court for an Order administratively closing Plaintiff's action (and Defendants shall set forth their compliance with the above requirements, including that no meet-and-confer was requested by plaintiff or that the parties met-and-conferred, but that no resolution was reached).

Plaintiff shall have 21 days from the date of Defendants' motion to file a response either certifying that the Plaintiff has served and Defendants have received a completed PFS or opposing Defendants' motion.<sup>2</sup>

1. The presumption is that a motion to administratively close an action under Section V.A of this Order is proper only where Plaintiff has failed to make a good faith effort to supply Defendants with a substantially-complete PFS as set forth in Section III.E and where defendants have a good faith basis for the motion.

2. Given the assumptions underlying administrative closures set forth above, the use of such a motion where a substantially-complete PFS has been served may be considered by the Court to be evidence of an absence of good faith.<sup>3</sup>

B. If Plaintiff has not served Defendants with a substantially-complete PFS within 60 days after entry of any such Order of Administrative Closure, Defendants may move the Court to reopen the action and thereafter move for a dismissal with prejudice. Plaintiff shall have 21 days from the date of Defendants' motion for a dismissal with prejudice to file a response either certifying that the

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<sup>2</sup> Consistent with the remainder of Section V, an order administratively closing an action pursuant to this Case Management Order shall include language substantially similar to the following:

This court having concluded that the plaintiff has failed to comply with his obligations pursuant to Case Management Order (Plaintiff Fact Sheets), IT IS HEREBY ORDERED that the Clerk of Court administratively terminate this action in his records, without prejudice to the right of the parties to reopen the proceedings. The instant order shall not be considered a dismissal or disposition of this matter. If plaintiff does not effect compliance with the Case Management Order (Plaintiff Fact Sheets) within the next 60 days, defendants may file a motion to reopen this matter and thereafter move for dismissal with prejudice pursuant to Case Management Order (Plaintiff Fact Sheets) § V.B. Should the plaintiff effect compliance with the Case Management Order (Plaintiff Fact Sheets) after the date of this Order, he may file a motion to reopen at any time before Defendants do so and prosecute his claims as though this order had not been entered.

<sup>3</sup> A motion to compel is the preferred procedural mechanism in those instances where substantial compliance has been achieved, but additional information or documents are sought.

Plaintiff has served and Defendants have received a substantially-complete PFS or opposing Defendants' motion for a dismissal with prejudice.

In the alternative, Plaintiff may move to reopen the case following entry of an Order of Administrative Closure that has been entered pursuant to this Order at any time before Defendants do so if Plaintiff effects compliance with this Order and the Order of Administrative Closure.

**VI. Copies of Records**

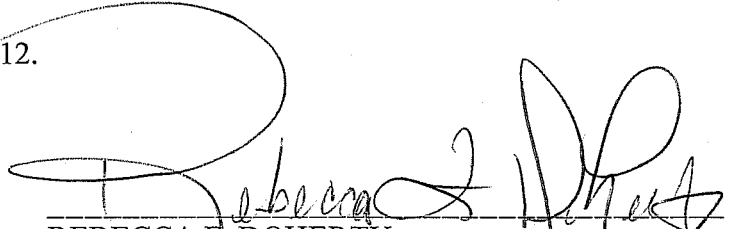
Defendants or their designee shall make available all records obtained by use of Authorizations to the attorney of record for each individual Plaintiff within thirty (30) days of receiving the records. The parties shall meet and confer regarding the mechanism for providing copies of medical records and the payment for such copies.

**VII. Defendant Fact Sheet**

A separate Case Management Order to govern a Defendant Fact Sheet ("DFS") shall be submitted to the Court shortly.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 9 day of

July, 2012.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

In Re: Actos (Pioglitazone) Products \*  
Liability Litigation \* 6:11-md-2299  
\*  
This Document Applies to: \* JUDGE DOHERTY  
\*  
\* MAGISTRATE JUDGE HANNA  
\*  
\_\_\_\_\_

ACTOS® PLAINTIFF FACT SHEET

Each plaintiff who alleges personal injury as a result of taking ACTOS®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, and/or any other medication containing pioglitazone hydrochloride approved for sale and marketing in the United States (collectively referred to as “Actos®”) must complete a Fact Sheet. If you are completing this Fact Sheet in a representative capacity on behalf of someone who has died or who otherwise cannot complete the Fact Sheet, please answer as completely as you can for that person.

In completing this Fact Sheet, please use the following definitions: (1) “you” refers to the person who used Actos®, unless otherwise specified; (2) “healthcare provider” means any hospital, clinic, medical center, physician's office, urgent care center, infirmary, laboratory, or other facility that provides medical care or advice, and any pharmacy, physical therapist, rehabilitation specialist, physician, osteopath, homeopath, chiropractor, nurse, herbalist, nutritionist, dietician, or any other persons or entities involved in the evaluation, diagnosis, care and/or treatment of you; and (3) “document” means any writing or record of any type in your possession or the possession of your attorney, including, but not limited to, written documents, e-mails, cassettes, videotapes, DVDs, photographs, medical records, charts, computer discs, tapes, or CDs, x-rays, drawings, graphs, non-identical copies, and other data from which information can be obtained and translated, if necessary, through electronic devices into a reasonably usable form. **You may attach as many sheets of paper as necessary to fully answer these questions.**

If you have any documents (as defined above), including, but not limited to, packaging, labeling, or instructions for Actos®, materials or items that you are requested to produce as part of answering this Fact Sheet or that relate to Actos®, or that relate to the injuries, claims, and/or damages that are the subject of your complaint, you must NOT dispose of, alter, or modify these documents or materials in any way. You are required to give all of these documents and materials to your attorney as soon as possible. If you are unclear about these obligations, please contact your attorney.

In completing the Fact Sheet, you are under oath and must provide information that is true and correct to the best of your knowledge. If you cannot recall all of the details requested, please provide as much information as you can. You must supplement your responses if you learn that they are incomplete or incorrect.

**I. Case Information**

A. Your Attorney's Name: \_\_\_\_\_

Firm: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone Number: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-Mail Address: \_\_\_\_\_

B. If you are completing this Fact Sheet in a representative capacity (on behalf of the estate of a deceased person or a minor), please complete the following:

1. Your name: \_\_\_\_\_

2. Your address: \_\_\_\_\_

\_\_\_\_\_

3. The individual/estate you are representing: \_\_\_\_\_

4. Your relationship to that individual/estate: \_\_\_\_\_

5. If you were appointed as a representative by a court, please state the:

Court that appointed you: \_\_\_\_\_

Date of appointment: \_\_\_\_\_

The names of any other representatives appointed by the Court: \_\_\_\_\_

\_\_\_\_\_

6. If you represent a decedent's estate, please state the:

Date of the decedent's death: \_\_\_\_\_

Place of the decedent's death: \_\_\_\_\_



THE REMAINDER OF THIS FACT SHEET REQUESTS INFORMATION ABOUT THE PERSON WHO USED ACTOS®. IF YOU ARE COMPLETING THIS FACT SHEET FOR SOMEONE ELSE, PLEASE ASSUME THAT "YOU" MEANS THE ACTOS® USER.

**II. Personal Information for the Actos® User**

A. Name: \_\_\_\_\_

B. Have you ever used any other names and, if so, when: \_\_\_\_\_  
\_\_\_\_\_

C. Address: \_\_\_\_\_

How long have you lived at this address? \_\_\_\_\_

D. Social Security Number: \_\_\_\_\_

E. Date and place of birth: \_\_\_\_\_

F. Sex: Male: \_\_\_\_\_ Female: \_\_\_\_\_

G. Ethnicity: African-American \_\_\_\_\_ Caucasian \_\_\_\_\_ Hispanic \_\_\_\_\_ Native American \_\_\_\_\_

Other (please specify) \_\_\_\_\_

H. Marital Status: \_\_\_\_\_

I. Spouse's name and date of marriage: \_\_\_\_\_

Has your spouse filed a loss of consortium or other claim in connection with this lawsuit?

Yes \_\_\_\_\_ No \_\_\_\_\_ N/A \_\_\_\_\_

J. If you have children, please state each child's name and date of birth: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

K. Have you ever served in any branch of the military? Yes \_\_\_\_\_ No \_\_\_\_\_

1. If yes, branch and dates of service: \_\_\_\_\_

2. Were you ever rejected or discharged from military service for any reason related to your medical, physical, or psychiatric condition? Yes \_\_\_\_\_ No \_\_\_\_\_

3. If yes, state the reason and date: \_\_\_\_\_  
\_\_\_\_\_

L. Education:

1. Provide the following information regarding your education, beginning with high school and continuing through your highest level of education:

Name of School	City/State	Degree awarded and/or area of study/major	Dates of Attendance

M. Are you currently employed? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please identify your current employer with name, address, and telephone number, and your occupation: \_\_\_\_\_

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

If not, did you leave your last job for a medical reason? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, describe why you left: \_\_\_\_\_

\_\_\_\_\_

Are you making a claim for lost wages or lost earning capacity? Yes \_\_\_\_\_ No \_\_\_\_\_

N. Please complete the following information regarding any employers (other than your current employer) that you have had in the last ten (10) years, or at any time since your first ingestion of Actos®, whichever is longer:

Name of Employer	Address & Phone No.	Job Title/Duties	Dates Employed

O. During the previous ten (10) years, or at any time since your first ingestion of Actos®, whichever is longer, have you been out of work for more than thirty (30) days during any calendar year for reasons related to your health (medical, physical, psychiatric or emotional condition)?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please state the dates, employer, and health condition: \_\_\_\_\_  
 \_\_\_\_\_

P. Identify each insurance carrier with whom you have had health insurance coverage at any time during the past ten (10) years:

Insurance Company	Policy Number	Policy Holder	Dates of Coverage

Q. Have you ever received Medicare, Medicaid or other government medical benefits within the past ten (10) years? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please describe the benefits received: \_\_\_\_\_  
 \_\_\_\_\_

R. Have you applied for workers' compensation, social security, and/or state or federal disability benefits within the past ten (10) years? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, then as to each application, separately state:

1. Date (or year) of application: \_\_\_\_\_

2. Nature of the claimed injury/disability: \_\_\_\_\_

3. The agencies to which you submitted your application: \_\_\_\_\_  
 \_\_\_\_\_

S. At any point during the previous ten (10) years, have you ever been convicted of, or pled guilty to, a felony? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please describe the charge to which you pled guilty or were convicted of, the court, and the outcome: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

T. Have you ever filed a lawsuit or made a claim, other than in the present suit, relating to any bodily injury? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please state the following:

1. Party you sued or made a claim against: \_\_\_\_\_
2. Court in which suit was filed: \_\_\_\_\_
3. Case/claim number: \_\_\_\_\_
4. Attorney who represented you: \_\_\_\_\_
5. Nature of injury/claim: \_\_\_\_\_

**III. Use of Actos®**

Date(s) of Use	Medication Prescribed	Dose	Name and Address of Prescribing Physician	Name and Address of Dispensing Pharmacy or where Actos was obtained

A. Do you currently use Actos®? Yes \_\_\_\_\_ No \_\_\_\_\_

B. Has any healthcare provider recommended that you not use Actos® or that you discontinue your use of Actos®? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, state the name and address of the healthcare provider and the date the recommendation was made: \_\_\_\_\_

\*If any such advice or recommendation was given in writing, please attach a copy.

C. Did you ever receive any samples of Actos®? Yes \_\_\_\_\_ No \_\_\_\_\_

If you answered yes, please state the following:

1. Who provided the samples? \_\_\_\_\_
2. When were the samples provided? \_\_\_\_\_
3. Did you request to any healthcare provider that he or she prescribe you Actos®?  
Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, which healthcare provider(s)? \_\_\_\_\_

- D. Have you had any direct communication, written or oral, with Takeda Pharmaceutical Company, Takeda Pharmaceuticals U.S.A., Inc. (formerly known as Takeda Pharmaceuticals North America, Inc.), Takeda Pharmaceuticals America, Inc., and/or Eli Lilly and Company or any of their representatives?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please describe the communication and the approximate date(s) on which it occurred:

\_\_\_\_\_  
\_\_\_\_\_

- E. Did you ever receive any written and/or oral information about Actos®? Yes \_\_\_ No \_\_\_

If yes, please specify the information you received: \_\_\_\_\_

\_\_\_\_\_

If yes, who provided this information? \_\_\_\_\_

\_\_\_\_\_

- F. Have you ever received assistance through a Patient Assistance Program for Actos®?

Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please identify the approximate dates during which you received assistance through the \_\_\_\_\_ program:

\_\_\_\_\_

- G. Have you ever visited a website, chatroom, message board, or other electronic forum containing information or discussion about Actos®? Yes \_\_\_\_\_ No \_\_\_\_\_ Unsure \_\_\_\_\_

If yes, please provide the name of the website(s): \_\_\_\_\_

\_\_\_\_\_

If yes, please identify the approximate date(s) on which you visited the website(s): \_\_\_\_\_

\_\_\_\_\_

**IV. Healthcare Providers and Pharmacies**

A. Identify the following for each healthcare provider with whom you have consulted during the previous ten (10) years, or five (5) years prior to your first ingestion of Actos®, whichever is longer, to the present (or, if you are a minor, please list all healthcare providers):

Name & Specialty	Address & Phone Number	Dates of Treatment (Provide approx date(s) if precise date(s) are unknown)	Reason for Treatment

B. Identify the following for each time you were hospitalized and/or received treatment in an emergency room or an out-patient setting during the previous ten (10) years, or five (5) years prior to your first ingestion of Actos®, whichever is longer, to the present (or, if you are a minor, please list all hospitalizations):

Name of Facility	Address & Phone Number	Dates of Treatment (Provide approx date(s) if precise date(s) are unknown)	Reason for Treatment

C. Identify the following for each pharmacy, drug store and/or other supplier (including mail order and internet pharmacies) where you have filled prescriptions during the previous ten (10) years, or five (5) years prior to your first ingestion of Actos®, whichever is longer, to the present (or, if you are a minor, please list all pharmacies or other medication suppliers):

Name	Address & Phone Number

V. **Injuries and Damages Alleged**

A. Are you claiming that you suffered bodily injury as a result of taking Actos®?

Yes \_\_\_\_\_ No \_\_\_\_\_

If you answered yes, please identify and describe your alleged injury(ies) and dates of diagnosis:

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B. To the extent not set forth in Section IV.A and IV.B above, please identify the following information for the healthcare providers who rendered care and treatment to you for the injury(ies) you allege above:

Name & address of Healthcare Provider(s) who rendered care and treatment to you for alleged Injury(ies)	Reason for Treatment

C. Has any healthcare provider told you that any of your alleged injury(ies) are the result of your use of Actos®? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, provide the healthcare provider's name and address and the approximate date of this conversation: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

D. Did you ever experience the type of injury or injury(ies) you allege were caused by Actos® prior to the date(s) set forth above? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please identify which injury(ies) and when you experienced them: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

If yes, please identify any healthcare provider(s) with whom you have treated for this alleged injury, including their name and address: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

E. Are you claiming that you have paid, or will have to pay, any monetary expenses or fees for medical treatment as a result of having taken Actos®? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please describe: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_



F. Are you claiming in this case that you suffered psychiatric or psychological injury as a result of your use of Actos®? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please describe: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

If yes, please identify any healthcare provider(s) with whom you have treated for this alleged injury, including their name and address: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**VI. Medical Background of the Actos® User**

A. Current Height \_\_\_\_\_ Current Weight \_\_\_\_\_

B. Smoking History:

1. Have you ever smoked cigarettes? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, when did you smoke? \_\_\_\_\_

If yes, how many cigarettes/packs per day/week? \_\_\_\_\_

Have your smoking habits changed over time? \_\_\_\_\_

2. Do you currently smoke cigarettes? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, how much do you currently smoke? \_\_\_\_\_

C. Alcohol History:

1. Do you currently drink alcohol (beer, wine, liquor, etc.)? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, how many drinks per week/month/year? \_\_\_\_\_

2. During the previous ten (10) years, have you consumed alcohol? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, during what period of time did you consume alcohol?  
\_\_\_\_\_

How many drinks per week/month/year did you consume?  
\_\_\_\_\_

D. Use of Illicit Drugs:

1. During the previous ten (10) years, have you used any illicit drugs of any kind (such as cocaine, crack, heroin, or LSD) without a prescription? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, which drug(s)? \_\_\_\_\_

If yes, when? \_\_\_\_\_

E. Medical History: Have you ever been diagnosed with any of the following?

Condition	Yes	No	Unknown	Date of Diagnosis (Provide approx date(s) if precise date(s) are unknown)
Type II diabetes mellitus				
Type I diabetes mellitus				
Gestational diabetes				
Diabetic coma				
Diabetic ketoacidosis (DKA)				
Diabetic ketosis				
Hyperglycemia (high blood sugar)				
Glycosuria/glucosuria (sugar in your urine)				
Impaired fasting glucose, pre-diabetes				
Insulin resistance				
Metabolic syndrome				
Other problems related to blood sugar, glucose, ketones, or insulin				
High cholesterol				
High blood pressure				
Bladder cancer				
Other cancer (please specify below)				
Type(s) of cancer				
Bladder infection				
Urinary tract infection or blockage				
Enlarged prostate				
Hyperplasia				
Kidney disease				
Kidney stones				
Myocardial infarction				
Cerebrovascular disease, including stroke				
Coronary artery disease				
Congestive heart failure				

F. *Other than* those injuries that you believe were caused by your use of Actos®, do you currently suffer from any physical injuries or disabilities? Yes \_\_\_\_\_ No \_\_\_\_\_

If yes, please identify:

The injury, illness, or disability: \_\_\_\_\_

Date(s) of onset: \_\_\_\_\_

Date(s) of diagnosis: \_\_\_\_\_

Name and address of treating physician: \_\_\_\_\_  
 \_\_\_\_\_

**VII. Medications**

Do you currently take, or have you ever taken, any of the following medications:

Medication	Yes	No	Unknown	If yes, dose and dates of usage (Provide approx date(s) if precise date(s) are unknown)
Metformin				
Avandia				
Rezulin				
Glucophage				
Fortamet				
Glyset				
Precose				
Prandin (Repaglinide)				
Starlix (Nateglinide)				
Lispro (Humalog)				
DiaBeta (Glyburide)				
Glargine/Lantus				
Glulinine				
Levemir (Detemir)				
Glucotrol (Glipizide)				
Amaryl (Glimepiride)				
Dymelor				
Glynase/PresTab				
Micronase				
Orinase				
Tolinase				
Symlin (Pramlintide)				
Januvia (Sitagliptin)				
Byetta (Exenatide)				
Other medications used to treat diabetes (specify )				
Cyclophosphamide (Cytosan)				
Empirin compound				
Ifosfamide (Ifex)				
Phenacetin				
Aristolochia fangchi				

**VIII. Family Medical History**

To the best of your knowledge, please indicate whether your *parents, siblings, children or grandparents* have ever suffered from or been treated for any of the following:

Condition	Yes	No	Unknown	If yes, identify the family relationship(s)
Diabetes mellitus				
Hyperglycemia				
Glucose intolerance				
Cancer (If yes, please specify _____ )				
Kidney disease				
Kidney stones				
Hyperplasia				
Enlarged prostate				

**IX. Fact Witnesses**

A. Other than your healthcare providers, please identify all persons whom you believe possess information concerning your alleged injury and/or other facts related to your claim:

Name	Address	Relationship to you

**X. Declaration**

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that all of the information provided in this Plaintiff Fact Sheet is true and correct to the best of my knowledge, information and belief formed after due diligence and reasonable inquiry.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

**XI. Documents: These Document Demands are made pursuant to Fed.R.Civ.P. 34.**

- A. Please sign and attach to this Fact Sheet authorizations allowing for release of all relevant records. (Please be sure that either you or your attorney complete the top portion of each authorization form for each provider for whom an authorization is being provided).
- B. If completing this Fact Sheet on behalf of a deceased person, please attach the legal documentation establishing that you are the legal representative of the estate and the Decedent's death certificate and autopsy report (if applicable).
- C. Please indicate whether you or your counsel have any of the following materials in your possession by placing a checkmark next to the word "yes" or "no." **If yes, attach a copy of any such documents. In responding, note that Actos® is pioglitazone hydrochloride.**
1. Medical records from any physician, hospital or healthcare provider for the previous ten (10) years or five (5) years prior to your first ingestion of Actos®, whichever is longer, to the present. Yes\_\_\_ No \_\_\_
  2. Pharmacy records for the previous ten (10) years or five (5) years prior to your first ingestion of Actos®, whichever is longer, to the present, including receipts, prescriptions or records of purchase. Yes\_\_\_ No\_\_\_
  3. Advertisements for Actos® or articles discussing Actos® which you reviewed before and during the time you took Actos®. Yes\_\_\_ No\_\_\_
  4. The packaging, including the box and label, for Actos® and any remaining medication (plaintiffs must retain the originals of the items requested). Yes\_\_\_ No\_\_\_
  5. Product use instructions, product warnings, package inserts, pharmacy handouts or other materials distributed with or provided to you in connection with your use of Actos®. Yes\_\_\_ No\_\_\_
  6. Any other documents or materials that mention Actos®, or any alleged health risks or hazards related to Actos® in your possession at or before the time of the injury alleged in your complaint.  
Yes\_\_\_ No\_\_\_
  7. Statements obtained from or given by any person, other than your attorney(s) or retained expert(s), having knowledge of facts relevant to the subject of this litigation.  
Yes\_\_\_ No\_\_\_
  8. Documents that were provided to you by any of the defendants. Yes\_\_\_ No\_\_\_

9. Documents constituting any communications or correspondence between you and any representative of the defendants. Yes \_\_\_ No \_\_\_
10. Photographs, drawings, journals, slides, videos, DVDs or any other media relating to your alleged injury or the quality of your life after developing the injury that you allege is the result of Actos®. Yes \_\_\_ No \_\_\_
11. If you claim you have suffered a loss of earnings or earnings capacity, your W-2s and/or any other tax records reflecting your income for each of the last five (5) years. Yes \_\_\_ No \_\_\_
12. If you claim you have suffered a loss of earnings or earnings capacity, all employment records in your possession, including employment applications, performance evaluations, paychecks and pay stubs for the five (5) years prior to the injury that you associate with Actos®, whichever is longer, to the present. Yes \_\_\_ No \_\_\_
13. If you claim any loss from medical expenses, copies of all bills from any physician, hospital, pharmacy or other healthcare provider documenting those medical expenses. Yes \_\_\_ No \_\_\_
14. If you have been the claimant or subject of any worker's compensation, Social Security or other disability proceeding, all documents relating to such proceeding that are in your possession. Yes \_\_\_ No \_\_\_
15. Journals, diaries, notes, letters, e-mails, tweets, Facebook posts, internet postings, and any other documents written or received by you (excluding communications to or from your attorney) within the previous ten (10) years which relate to Actos or the injuries you allege in this case. Yes \_\_\_ No \_\_\_
16. Print-outs of all websites or blogs which are maintained or created by you. Yes \_\_\_ No \_\_\_

**XII. Certification of Counsel**

Undersigned counsel for plaintiff(s) (Counsel) certifies that Counsel and/or members or associates in Counsel's firm instructed Plaintiff(s), Plaintiffs' other current or former attorneys and/or agents for any of the foregoing, to engage in best efforts to identify, locate and supply all responsive documents demanded in the Request to Produce to Plaintiff(s) approved by Case Management Order: Plaintiff Fact Sheets (dated July 9, 2012) that were in the custody or control of Counsel, Plaintiff, Plaintiffs' other current or former attorneys and/or agents for any of the foregoing, and Counsel further certifies that Counsel has a good faith belief that these instructions were followed by all of the aforementioned persons.

Date: \_\_\_\_\_

Signature: \_\_\_\_\_

**LIMITED AUTHORIZATION TO DISCLOSE AND HEALTH INFORMATION**  
**(Pursuant to the Health Insurance Portability and Accountability Act "HIPAA" of 4/14/03)**

TO:  
Patient Name:  
DOB:  
SSN:

I, \_\_\_\_\_, hereby authorize you to release and furnish to:  
**The Marker Group at 13105 Northwest Freeway, Suite 300, Houston, Texas 77040**, copies of the following information:

- \* All medical records, including inpatient, outpatient, and emergency room treatment, all clinical charts, reports, documents, correspondence, test results, statements, questionnaires/histories, office and doctor's handwritten notes, and records received by other physicians. Said medical records shall include all information regarding AIDS and HIV status.
- \* This authorization does allow the release of mental health or other psychiatric records, unless this box is checked
- \* All autopsy, laboratory, histology, cytology, pathology, radiology, CT Scan, MRI, echocardiogram and cardiac catheterization reports.
- \* All radiology films, mammograms, myelograms, CT scans, photographs, bone scans, pathology/cytology/histology/autopsy/immunohistochemistry specimens, cardiac catheterization videos/CDs/films/reels, and echocardiogram videos.
- \* All pharmacy/prescription records including NDC numbers and drug information handouts/monographs.
- \* All Worker's Compensation records, Social Security and disability records.
- \* All billing records including all statements, itemized bills, and insurance records.
- \* All employment records, including attendance reports, performance reports, W-4 forms, W-2 forms, medical reports and/or any and all other records relating to my employment, past and present.

1. To my medical provider: **this authorization is being forwarded by, or on behalf of, attorneys for the defendants for purposes of litigation. You are not authorized to discuss any aspect of the above-named person's medical history, care, treatment, diagnosis, prognosis, information revealed by or in the medical records, or any other matter bearing on his or her medical or physical condition, unless you receive an additional authorization permitting such discussion. Subject to all applicable legal objections, this restriction does not apply to discussing my medical history, care, treatment, diagnosis, prognosis, information revealed by or in the medical records, or any other matter bearing on my medical or physical condition at a deposition or trial.**
2. I understand that the information in my health record may include information relating to sexually transmitted disease, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV). It may also include information about behavioral or mental health services, and treatment for alcohol and drug abuse.
3. I understand that I have the right to revoke this authorization at any time. I understand that if I revoke this authorization I must do so in writing and present my written revocation to the health information management department. I understand the revocation will not apply to information that has already been released in response to this authorization. I understand the revocation will not apply to my insurance company when the law provides my insurer with the right to contest a claim under my policy. Unless otherwise revoked, this authorization will remain in effect until 4 years from the date of this authorization.

4. I understand that authorizing the disclosure of this health information is voluntary. I can refuse to sign this authorization. I need not sign this form in order to assure treatment. I understand I may inspect or copy the information to be used or disclosed as provided in CFR 164.524. I understand that any disclosure of information carries with it the potential for an unauthorized re-disclosure and the information may not be protected by federal confidentiality rules. If I have questions about disclosure of my health information, I can contact the releaser indicated above.
5. A notarized signature is not required. CFR 164.508. A copy of this authorization may be used in place of an original.

I have carefully read and understand the above, and do herein expressly and voluntarily authorize the disclosure of the above information about, or medical records of, my condition to those persons or agencies listed above.

Date: \_\_\_\_\_

\_\_\_\_\_  
(Signature) Patient or Patient Representative

\_\_\_\_\_  
Printed Name of Patient's Representative

\_\_\_\_\_  
Description of Representative's authority to act for patient /relationship to patient (if applicable)

Patient's Name and Address:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**This authorization is designed to be in compliance with the Health Insurance Portability and Accountability Act ("HIPAA") 45 CFR Parts 160 and 164.**



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IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

**AMENDED MONTHLY STATUS CONFERENCE DATES**

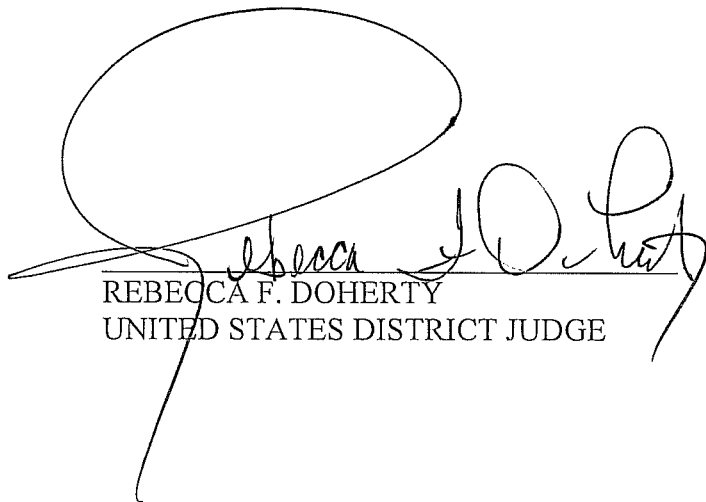
This Court will conduct Status Conferences upon the following dates in the remainder of 2012 and through 2013:

- August 23, 2012
- September 20, 2012
- October 25, 2012
- November 15, 2012
- December 13, 2012
- January 24, 2013
- February 21, 2013
- March 21, 2013
- April 25, 2013
- May 23, 2013
- June 20, 2013
- July 25, 2013
- August 22, 2013
- September 26, 2013
- October 24, 2013
- November 21, 2013
- December 19, 2013

Status Conferences will be held in open court beginning at 10:30 a.m. On the date of each Status Conference, this Court will conduct a pre-conference meeting of a working group, the membership of which will be identified prior to each conference.

Defendants' and plaintiffs' lead and co-lead counsel and Plaintiffs' Steering Committee members are asked to anticipate their participation might be requested, also, on the day prior to each Status Conference for the purpose of a working meeting, if requested by the Court. Counsel will be informed in advance whether or not they will be requested to attend working meetings and, if so, whether they may participate in person or, alternatively, by telephone or video conference.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 2 day of July, 2012.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

COPY SENT

DATE 7-3-12

BY CB

TO CB/IM/gm

RECEIVED

JUN 20 2012



UNITED STATES DISTRICT COURT

WESTERN DISTRICT OF LOUISIANA

LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: June 20, 2012

**MINUTE ENTRY:**  
**AGENDA FOR JUNE 21, 2012 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, June 21, 2012:

- I. Status of New Filings and Transfers
- II. Status of State Court Filings
- III. Compliance with Certificates of Good Standing
- IV. Service Issues with CT Corporation (Bundling/Amended CMO for Service/Filing)
- V. Liaison Counsel report regarding service of filings to all plaintiff counsel
- VI. Report on Developments in the MDL since May 24, 2012
- VII. July 27, 2012 Conference agenda
  - *Pro se* issues
  - Motion to Amend (*Steven Tate v. Takeda Industries, Inc.*, 6:12-cv-0171)  
(*Hensgens* hearing)
- VIII. Federal Bar Association

Lead counsel for plaintiffs and defendants are asked to inform the Court, through the special masters, as to who will be addressing the Court on each listed issue. Please provide this notice by **4:00 p.m. on Wednesday, June 20, 2012**. Whomever addresses the Court (together with lead counsel) will be considered part of the working group for the June 21, 2012 status conference, meaning that they will attend the status conference in person and will also participate in the working group meeting in Chambers, beginning at 9:15 a.m. on the morning of the status conference.

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MAY 22 2012

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

LAFAYETTE DIVISION

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: May 22, 2012

**MINUTE ENTRY:**  
**DEADLINE TO FILE ANSWERS**

In any given case filed in these proceedings, including related cases filed directly in this district, the defendants' deadline to file an answer or otherwise respond to the complaint in that given case, or any subsequent complaint filed in that case, shall be *30 days after the last defendant is served within that given case.*

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MAY 22 2012

*JD*

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: May 22, 2012

**MINUTE ENTRY:**  
**AGENDA FOR MAY 24, 2012 STATUS CONFERENCE**

The following matters will be addressed in the status conference scheduled to begin at 10:30 a.m. in Open Court on Thursday, May 24, 2012:

- I. *Changes to Docketing*
    - Magistrate Judge Hanna
  - II. *Status of New Filings and Transfers*
    - Ms. Gourley or representative
  - III. *Certificates of Good Standing*
    - Mr. Arsenault or representative
  - IV. *Bundling*
    - Mr. Arsenault or representative
  - V. *Report on Developments in the MDL since April 26, 2012*
    - Mr. Arsenault
    - Ms. Gourley
- (a) PSC Time & Expense Protocol Status
  - (b) PSC Litigation Fund Established
  - (c) Service Issues with CT
  - (d) Communications to all Plaintiff Counsel and Updates to New Counsel following initial appearance. State assignments added to website.

- (e) Plaintiff Fact Sheet
- (f) Protective Order

*VI. Report on Activities in state courts*

- Ms. Barrios
- Ms. Knutson

*VII. Review future conference dates; consider adjusting for scheduling conflicts*

- July 27, 2012 Status Conference Devoted to Pro Se issues

*VIII. Conclusion and Next Status Conference*

- June 22, 2012 (Friday) Next Status Conference

Lead counsel for plaintiffs and defendants are asked to identify, by notifying the special masters, the individuals who will be addressing the Court on each listed issue. Please provide this notice by *12:00 p.m. on Wednesday, May 23, 2012.*

Whomever addresses the Court (together with lead counsel) will be considered part of the *working group for the May 24, 2012 status conference*, meaning that they will attend the status conference in person and will also participate in the working group meeting *in Chambers, beginning at 9:15 a.m. on the morning of the status conference.*

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UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

In re: Actos (Pioglitazone)  
Products Liability Litigation

Applies to:  
All Actions

\* 6:11-md-02299-RFD-PJH  
\*  
\* JUDGE DOHERTY  
\*  
\* MAGISTRATE JUDGE HANNA

**COURT ORDER:**  
**PLAINTIFFS' STEERING COMMITTEE**

The parties having had notice the Court was considering the appointment of a plaintiffs' steering committee ("PSC") in this matter, counsel were permitted an opportunity to submit applications for membership on the PSC. This Court has considered the numerous applications that were submitted by counsel. The Court was impressed by the overwhelming quality of applicants and nominations for these positions, and thanks the applicants and nominees for participating in this process. After a great deal of consideration of the particular qualities of each of the applicants, as well as the need for management and coordination in these proceedings, the Court hereby APPOINTS the following individuals to the Plaintiffs' Steering Committee.

**I. Plaintiffs' Steering Committee**

**A. Committee Membership**

The following counsel shall be members of the committee:

- Vance R. Andrus  
Andrus, Hood & Wagstaff, PC  
1999 Broadway, Suite 4150  
Denver, Co 80202  
303-376-6360  
Fax: 303-376-6361  
Email: vance.andrus@ahw-law.com
- Richard Arsenault  
Neblett Beard & Arsenault

P O Box 1190  
Alexandria, LA 71309-1190  
318-487-9874  
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- Dawn Barrios  
Barrios Kingsdorf & Casteix  
701 Poydras Street, Suite 3650  
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Drakulich Firm  
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Fax: 504-584-5249  
Email: smurray@murray-lawfirm.com
  
- Dianne M. Nast  
Rodanast PC  
801 Estelle Drive  
Lancaster, PA 17601  
717-892-3000  
Fax: 717-892-1200  
Email: dnast@rodanast.com
  
- Stephanie O'Connor  
Douglas & London P.C.  
111 John Street, Suite 1400  
New York, NY 10038  
212-566-7500  
Fax: 212-566-7501  
Email: SOConnor@DouglasAndLondon.com
  
- Neil D. Overholtz  
Aylstock, Witkin, Kreios, Overholtz, PLLC  
17 East Main Street, Suite 200  
Pensacola, FL 32502  
Telephone: (877) 810-4808  
Email: NOverholtz@awkolaw.com
  
- Jerrold S. Parker  
Parker Waichman (FL)  
3301 Bonita Beach Road, Suite 101  
Bonita Springs, FL 34134  
239-390-8610  
Fax: 239-390-0055  
Email: actosmdl@yourlawyer.com

- Paul J. Pennock  
Weitz & Luxenberg (NY)  
700 Broadway 5th Fl  
New York, NY 10003  
212-558-5972  
Fax: 212-344-5461  
Email: ppennock@weitzlux.com
- Troy A. Rafferty  
Levin Papantonio et al  
P O Box 12308  
Pensacola, FL 32581  
850-435-7000  
Fax: 850-435-7020  
Email: trafferty@levinlaw.com
- Mark P. Robinson, Jr  
Robinson Calcagnie et al  
19 Corporate Center Dr  
Newport Beach, CA 92660  
949-720-1288  
Fax: 949-720-1292  
Email: mrobinson@rcrlaw.net
- Christopher A. Seeger  
Seeger Weiss  
77 Water Street, 26<sup>th</sup> Floor  
New York, NY 10005  
212-584-0700  
Email: cseeger@seegerweiss.com
- W. James Singleton  
Singleton Law Firm  
4050 Linwood Ave  
Shreveport, LA 71108  
318-631-5200  
Fax: 318-636-7759  
Email: wjsingleton@singletonlaw.com

## **B. Committee Duties**

The PSC shall take the lead in litigating these matters on behalf of all plaintiffs, meaning that they shall play the lead role in making strategic, tactical, and procedural decisions on behalf of the plaintiffs' counsel and *pro se* plaintiffs. Of course, the Court recognizes that all plaintiffs'

counsel and all plaintiffs retain the right to choose to act in their own best interest in these proceedings, but the large number of attorneys and plaintiffs requires a substantial amount of coordination of litigation efforts. To that end, the PSC shall be responsible for coordinating the plaintiffs' responses to the orders of the Court, for coordinating the presentation of issues to the Court for its consideration, and for overseeing the progress of these proceedings toward final resolution.

The PSC shall have the responsibility for assigning litigation-related tasks to counsel who provide indication of their willingness to work for the common benefit of all plaintiffs and the case. The committee are encouraged to distribute assignments among counsel who wish to work for the common benefit, taking into consideration the particular strengths and weaknesses of counsel requesting such assignments.

The PSC shall act as the first resource for counsel or parties with questions, comments, concerns, recommendations, or requests, and for transmitting to plaintiffs' liaison counsel or co-lead counsel any such questions, comments, concerns, recommendations, or requests that should come to the attention of the Court.

The PSC shall have responsibility for recommending the approval or denial of any claim made by an attorney for common benefit credit. Specifically, with regard to any claim that an attorney is entitled to be compensated or reimbursed for fees or costs incurred for the common benefit of the plaintiffs, the PSC shall review such claims and shall provide guidance to Special Master DeJean with regard to the propriety, fairness and reasonableness of such claims. The PSC is encouraged to create a formal process by which claims for compensation or reimbursement may be presented either before or shortly after being incurred. In doing so, they are to coordinate their efforts with Special Master DeJean, whose responsibilities, in part, encompass formal oversight of the approval process, imposing reasonable limits on such fees and

costs, and making recommendations to the Court for approval or denial of any such request. The Court shall rule on any such requests periodically throughout the litigation.

In the event of a global settlement, the PSC shall have the primary responsibility, with guidance and oversight by the Court through the Special Masters, for management and oversight of the process of distributing funds, reimbursing fees and expenses incurred for the common benefit, and for distributing the remaining fees to all plaintiffs' counsel.

## **II. Executive Committee**

This Court hereby appoints an executive committee of the PSC. The executive committee shall be composed of six members. The members of the executive committee shall have the following additional duties beyond those assigned to PSC members.

- **Richard Arsenault**

Mr. Arsenault is hereby appointed CO-LEAD COUNSEL, together with Paul Pennock, with primary responsibility for leading the PSC and for communicating with the Court on behalf of plaintiffs' counsel.

- **Paul Pennock**

Mr. Pennock is hereby appointed CO-LEAD COUNSEL, together with Richard Arsenault, with primary responsibility for leading the PSC and for communicating with the Court on behalf of plaintiffs' counsel.

- **Patrick Morrow**

Mr. Morrow is hereby appointed CO-LIAISON COUNSEL, with primary responsibility for communicating with plaintiffs' counsel on behalf of the PSC, as requested by lead counsel, and he shall be available to perform any other administrative tasks assigned by the PSC.

- **Dawn Barrios**

Ms. Barrios is hereby appointed STATE COURT LIAISON, with primary responsibility

for communication with counsel in the various Actos®-related state court actions currently pending, or which might be filed.

- **Stephanie O'Connor**

Ms. O'Connor is hereby appointed SCIENCE COORDINATOR, with primary responsibility for coordination, oversight and management of experts on behalf of the plaintiffs.

- **Mark Robinson**

Mr. Robinson is hereby appointed to provide the PSC and the Court with the assistance of his general expertise in multi-district litigation.

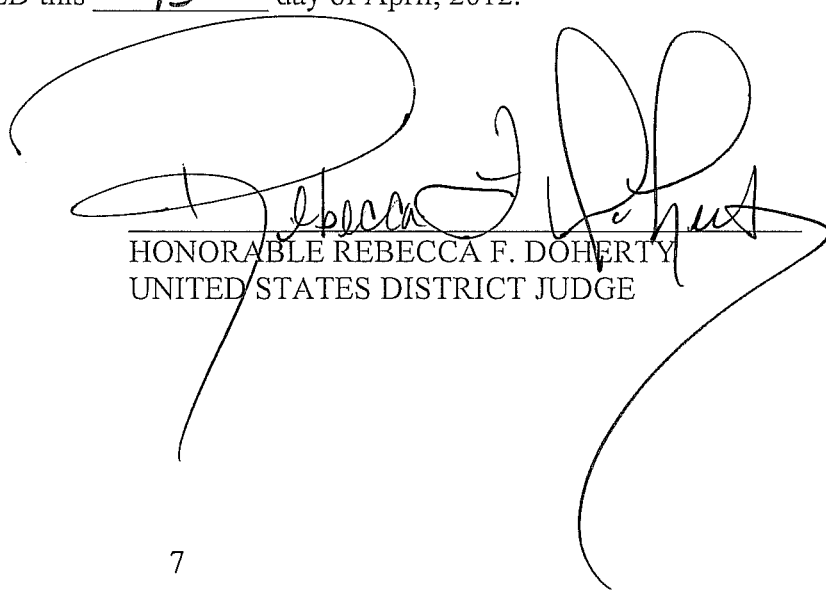
### **III. Oversight**

Periodically, the Court will determine whether the membership of the PSC should remain in place or should be adjusted to allow better, or more efficient, performance of the duties assigned herein.

### **IV. Effective Date**

The Court notified the members of the PSC of their appointment, and requested that they commence work in that capacity, on Monday, March 12, 2012, which shall be the effective date of the appointment and of this order.

THUS DONE AND SIGNED this 13 day of April, 2012.



HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

RECEIVED

APR 13 2012

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

To: All Counsel of Record  
Issued By: Judge Rebecca F. Doherty  
Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases  
Date: April 13, 2012

**MINUTE ENTRY:**  
**STATUS CONFERENCES**

The Court has scheduled monthly status conferences in this matter. The dates have been posted on the Actos® MDL website, <http://www.lawd.uscourts.gov/MDL2299/index.html>. In an abundance of caution, the Court has set aside two days for most of the monthly status conferences, where time was available. Counsel should be aware, however, that the Court does not expect status conferences, as a general matter, to last longer than one day. The Court anticipates that, for the most part, the second day will be used by working groups who are asked to accomplish specific tasks assigned by either the Court, the Special Masters, or lead counsel. The term “status conference,” is intended to refer to the time in Open Court used to accomplish the tasks, or address issues, identified on an agenda issued by this Court.

*All counsel are advised to review the following carefully, as it contains deadlines and other important information concerning monthly status conferences.*

**I. Status Conference Agendas**

Any counsel or party wishing to place a matter or an issue onto the agenda for the Court’s consideration is permitted to do so. In order to place a matter onto the agenda of a status conference, counsel or a party should contact the Plaintiffs’ Steering Committee (through the specific member to whom the oversight of your case has been assigned, or through liaison counsel, Mr. Morrow), identify the issue, and request that it be added to the agenda. This request should be made *no less than ten (10) calendar days prior to the status conference*. Lead counsel are responsible for coordinating all such requests and for presenting them to the Court. Counsel whose agenda item will be heard in Open Court must attend in person at the status conference during which their agenda item will be heard.

With regard to the April 19, 2012 status conference, lead counsel are requested to submit a list of issues to be added to the agenda by *1:00 p.m. on Monday, April 16, 2012*. Submissions

should be made to the Special Masters. Counsel should get any requests or suggestions to lead counsel as to the agenda, such that lead counsel can comply with the deadline noted.

With regard to the May 24, 2012 status conference and every conference thereafter, lead counsel are requested to submit a list of issues to be added to the agenda by the end of business *seven (7) calendar days prior to the first day of the status conference*. Submissions should be made to the Special Masters. Again, counsel must get their request or suggestions to lead counsel such that lead counsel can comply with the deadline noted.

Once the Court has considered all requests, together with the recommendations of the Special Masters, an agenda will be issued, will be noticed to all counsel, and will be posted on the website. Along with the agenda, the Court will issue a minute entry requesting lead counsel to identify the individuals who will be responsible for addressing the agenda items at the status conference. Those individuals, together with plaintiffs' and defendants' lead counsel(s) and plaintiffs' liaison counsel, will constitute the working group for a particular status conference. Because the agenda will vary from month to month, the Court anticipates the membership of the working group will vary accordingly, although it will always include lead counsel for plaintiffs, defendants, and plaintiffs' liaison counsel.

## **II. Status Conference Schedule**

The schedule for the status conferences will be as follows:

- 9:00 – the Court will meet with the Special Masters in Chambers
- 9:15 – the Court will meet in Chambers with the Special Masters and the working group
- 10:30 – the status conference will begin in Open Court, Courtroom 2

The Court usually breaks for lunch from 12:30 to 1:45. Afternoon sessions are expected to end by 6:00 p.m. unless additional time is essential. The status conference will continue on the second day *only if necessary to complete the agenda*. No counsel are required to remain after the status conference has adjourned (whether adjournment occurs on the first day of the status conference, or on the following day) unless notified otherwise by the Court, the Special Masters, or lead counsel.

## **III. Length of Conferences**

With regard to the monthly status conferences, the Court generally has set aside two days (although there are a few exceptions to this rule, as reflected on the website). It is the Court's intention and expectation that, where two days have been allocated, the status conference will begin in the morning of the first day and finish on the same day. When that happens, counsel who have not been asked to remain will be free to leave. However, counsel should be aware that, when a full agenda has been set for the status conference and the agenda cannot be completed in one day, the status conference will continue to the second scheduled day.

#### **IV. In Person or by Telephone**

With regard to participation in status conferences, counsel should be aware of the following. Lead counsel(s) for plaintiffs and defendants, and plaintiffs' liaison counsel, are expected to attend the monthly status conferences in person. Furthermore, counsel who are expected to address an issue on the agenda (whether by choice or because they have been appointed by lead counsel to do so) must appear in person at the status conference during which the agenda item has been scheduled for hearing. All other counsel may attend any monthly status conference by telephone (instructions for how to participate by telephone may be found on the website, News and Notes page), except to the extent the Court orders otherwise, or to the extent the Special Masters or lead counsel request that one or more individuals attend and participate in person. Members of the PSC are expected to attend the monthly status conference, either in person or by telephone, in accordance with the foregoing instructions.

#### **V. Excused Absences**

Anyone expected, ordered, or otherwise required to attend a monthly status conference who wishes to be excused from that expectation, requirement, or order (this applies whether counsel is expected to attend in person or by telephone) must contact Special Master Russo and seek leave not to attend and must identify the person or persons who will attend in his or her stead. Substitution cannot be made without prior approval of the Court having been obtained via Special Master Russo.



RECEIVED

APR 13 2012

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

LAFAYETTE DIVISION

To: All Counsel of Record

Issued By: Judge Rebecca F. Doherty

Re: In re: ACTOS® (Pioglitazone Products Liability Litigation)  
MDL No. 11-md-2299, All Cases

Date: April 13, 2012

**MINUTE ENTRY:**  
**COMMUNICATING WITH THE COURT**

This Court has now appointed special masters, the members of the Plaintiffs' Steering Committee ("PSC"), and notes defendants' selected lead counsel. In light of these appointments, the Court issues the following *guidance* for communications with the Court. The communications sequence described below is designed to streamline and coordinate communications for a more efficient and rapid response.

*All plaintiffs' counsel* who are not on the PSC are requested, first, to contact their appointed member of the PSC to discuss any question, comment, concern, recommendation, or request they might have for the Court. Members of the PSC will be able to answer many questions, as well as to coordinate comments or concerns with those that might be received from other counsel in the same time frame and/or on the same issue.

*PSC members* who receive any question, comment, concern, recommendation, or request that cannot be resolved without further input are requested to discuss same with the plaintiffs' co-lead counsel, Mr. Arsenault or Mr. Pennock.

Should *plaintiffs' lead counsel* require further input in order to resolve or address any issue brought to their attention, they should contact Deputy Special Master DeJean if the matter involves a question of PSC billing, approval of common-benefit fees or expenditures, or the assignment of duties by the PSC. For other issues (or in the event Mr. DeJean is unavailable), lead counsel should contact either Special Master Russo or Deputy Special Master Rodriguez, who will work with counsel to resolve the issue or to help facilitate contact with the Court as quickly as circumstances require.

*The defendants* are requested to communicate either through their lead counsel, Ms. Gourley, or through whomever Ms. Gourley appoints to communicate with the Court on a given issue, by first contacting either Special Master Russo or Deputy Special Master Rodriguez, who will work with counsel to resolve the issue or to help facilitate contact with the Court as quickly as circumstances require.

*The special masters* will have open and direct access to Magistrate Judge Hanna and Judge Doherty, as may be appropriate, for any issue that should be brought to the attention of the Court.

In the event of any emergency, or any breakdown in the communications sequence described above, counsel should, of course, feel free to contact the special masters directly or, failing any ability to obtain a prompt response, to contact the Court directly through Christine Guidry (337.593.5008), the case manager assigned to these proceedings.

Counsel previously were advised to use the email address [hanna\\_mdj\\_orders@lawd.uscourts.gov](mailto:hanna_mdj_orders@lawd.uscourts.gov) as a first option for communicating with the Court. This minute entry is designed to vacate and supersede those earlier instructions. However, the noted email address should still be used for emergency filings where CTOs have not yet been fully processed by the Clerk of Court.

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APR 13 2012

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

In re: Actos (Pioglitazone)  
Products Liability Litigation

Applies to:  
All Actions

\*  
\*  
\*  
\*  
\*

6:11-md-02299-RFD-PJH  
JUDGE DOHERTY  
MAGISTRATE JUDGE HANNA

**COURT ORDER:**  
**DEFENDANTS' LEAD COUNSEL**

In response to an inquiry by this Court to defense counsel in these proceedings, the Court has been informed that the defendants have identified lead counsel, who is authorized to act on behalf of all defendants. In consideration of this fact,

IT IS ORDERED that Sara Gourley shall be and is APPOINTED lead counsel on behalf of the defendants in this matter. Ms. Gourley's contact information is as follows:


Sara J. Gourley  
Sidley Austin (Chicago)  
1 S Dearborn St. 48th Floor  
Chicago, IL 60603  
Telephone: (312)853-7000  
Fax: (312) 853-7036  
Email: sgourley@sidley.com

Ms. Gourley shall be responsible for coordinating the defense on behalf of all named defendants and is empowered to appoint counsel of her choosing to take the lead on any given issue before the Court.

THUS DONE AND SIGNED this 12 day of April, 2012.

HONORABLE REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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APR 12 2012 

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

This Document Applies to:  
All Cases

MAGISTRATE JUDGE HANNA

**FIRST AMENDED CASE MANAGEMENT ORDER:  
Direct Filing and Service of Process<sup>1</sup>**

**I. Scope of Order**

This Agreed Order applies to claims brought by any U.S. citizen or resident based on alleged ingestion of Actos®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, or pioglitazone (“Actos”) that (i) currently are pending in MDL No. 2299, (ii) currently are pending in the Western District of Louisiana and are related to MDL No. 2299, or (iii) will be filed in, removed to, or transferred to this Court (collectively, “the MDL Proceedings”).

**II. Direct Filing of Cases in MDL 2299**

A. In order to eliminate delays associated with transfer to this Court of cases filed in or removed to other federal district courts, and to promote judicial efficiency, any plaintiff whose case would be subject to transfer to MDL 2299 may file his or her case directly in the MDL Proceedings in the Western District of Louisiana (such cases are sometimes referenced as “Direct-Filed Cases”).

B. Each case filed directly in the MDL Proceedings by a plaintiff who resides in a federal district other than the Western District of Louisiana will be filed in the MDL Proceedings

<sup>1</sup> This Amended Case Management Order: Direct Filing and Service of Process **SUPERSEDES** the original order, which was entered as Doc. 520 in the record of this matter. The only change is found in Paragraph III(D), at 5, *infra*. It corrects the service address for Takeda Pharmaceutical Company Limited in Osaka, Japan. All other aspects of the original Case Management Order remain the same.

for purposes of pretrial proceedings, consistent with the Judicial Panel on Multidistrict Litigation’s December 29, 2011 Transfer Order (“Transfer Order”).

C. Defendants will not challenge the venue of any Direct-Filed Case. Upon the completion of pretrial proceedings consistent with the Transfer Order, this Court, pursuant to 28 U.S.C. §1404(a), will transfer Direct-Filed Cases to the federal district court in the district where the plaintiff allegedly was injured by use of Actos, or where the plaintiff resides at the time of such transfer, subject to severance of multi-plaintiff actions if necessary. The parties will jointly advise the Court of the district to which each Direct-Filed Case should be transferred.

D. Parts II.B and II.C do not preclude the parties from agreeing, at a future date, to try certain Direct-Filed Cases in this District.

E. The inclusion of any action in *In Re: Actos Products Liability Litigation*, MDL 2299, whether such action was or will be filed originally or directly in the Western District of Louisiana, shall not constitute a determination by this Court that jurisdiction or venue is proper in this district.

F. Complaints in Direct-Filed Cases shall bear the following caption:

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

<b>IN RE: ACTOS PRODUCTS LIABILITY LITIGATION</b>	)	<b>MDL No. 6:11-md-2299</b>
<b>JOHN DOE</b>	)	<b>JUDGE DOHERTY</b>
vs.	)	<b>MAGISTRATE JUDGE HANNA</b>
<b>XYZ CORPORATION and ABC COMPANY</b>	)	<b>Civil Action No.: _____</b>

Pleadings filed thereafter in any Direct-Filed Case shall comply with the First General Order with regard to caption format and contents.

G. Any attorney admitted to practice and in good standing in any United States District Court is admitted *pro hac vice* in this litigation and association of local co-counsel for purposes of litigation, including direct filing, is not required. However, as noted in the Court's First General Order, counsel must file a certificate of good standing with their initial filing.

H. Prior to any lawyer filing a Direct-Filed Case, that attorney must register for and have a Louisiana CM/ECF log in name and password. Other than this modification, the normal local filing requirements will apply. *See* Local Rules of the United States District Court for the Western District of Louisiana, available at [http://www.lawd.uscourts.gov/Court\\_Rules/Docs/localrules.pdf](http://www.lawd.uscourts.gov/Court_Rules/Docs/localrules.pdf). These rules include, *but are not limited to*, the following specifics:

- Civil Cover Sheet. A civil cover sheet, indicating that the new matter is related to the MDL Proceedings (*i.e.*, MDL No. 11-md-2299), must be filed with the complaint.
- Attorneys. Each attorney shall provide the following identifying information on the signature block:

/s/ Jane Doe  
Jane Doe  
NAME OF LAW FIRM  
ADDRESS  
TELEPHONE  
FAX  
EMAIL@EMAIL.com  
Attorney for Plaintiff

- Filing Fees: Internet credit card payments are required for all complaints and are made online through Pay.gov. Plaintiff's counsel will be prompted to pay the required filing fee at the time the complaint is filed.
- Summonses. After the complaint is filed, plaintiff's counsel is free to create the necessary summonses and proceed with service as required by law or as permitted herein.

### **III. Service of Process – Takeda Entities**

A. Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. (formerly known as Takeda Pharmaceuticals North America, Inc.), Takeda Pharmaceuticals America, Inc., Takeda Global Research & Development Center, Inc., Takeda California, Inc. (formerly known as Takeda San Diego, Inc.), and Takeda Pharmaceuticals International, Inc. agree, without waiver of any defenses, to accept service of process as set forth in this Order.

B. For purposes of this Order, the "U.S. Takeda entities" are: Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals America, Inc., Takeda Global Research & Development Center, Inc., Takeda California, Inc., and Takeda Pharmaceuticals International, Inc.

C. Service on U.S. Takeda Entities. With regard to complaints that have already been filed, plaintiffs who have not already served the U.S. Takeda entities through original service may effectuate service, as described in this Paragraph III.C, within 30 days of receiving notice of this Order. With regard to complaints filed on or after the date of this order, plaintiffs may effectuate service on U.S. Takeda entities, as described in this Paragraph III.C, within 30 days of the filing of the complaint.

Service on any named U.S. Takeda entity made be made by serving a copy of the complaint and one summons directed to all named U.S. Takeda entities on Takeda’s registered agent for service of process at:

CT Corporation  
208 South LaSalle Street, Suite 814  
Chicago, IL 60604

For service pursuant to this paragraph, a separate summons need not be issued to each U.S. Takeda entity for service to be effective.

*Note:* Service pursuant to this Paragraph III.C *shall not be made and shall not be attempted*, on any entity other than the U.S. Takeda entities identified herein.

D. Service on Takeda Pharmaceutical Company Limited. With regard to complaints that have already been filed, plaintiffs who have not already served Takeda Pharmaceutical Company Limited (“TPC”) through original service may effectuate service, as described in this Paragraph III.D, within 60 days of receiving notice of this Order. With regard to complaints filed on or after the date this Order is issued, plaintiffs may effectuate service, as described in this Paragraph III.D, within 60 days of filing a complaint.

Service on TPC may be made by delivering a cover letter, a copy of the complaint, and a summons directed to TPC *via* registered mail, return receipt requested, or *via* commercial courier service that provides equally reliable evidence of delivery, to:

Takeda Pharmaceutical Company Limited  
Chuo-Ku, Osaka  
540-8645, Japan

For service to be effective, plaintiffs also must send a copy of the cover letter that was mailed to TPC to:



Stacey Dixon Calahan  
Assistant General Counsel, Litigation  
Takeda Pharmaceuticals U.S.A., Inc.  
One Takeda Parkway  
Deerfield, Illinois 60015.

E. If plaintiffs abide by the terms of this Order, service on the U.S. Takeda entities will be considered effective on the date that CT Corporation is served with the documents discussed in Sections III.C of this Order, and service on TPC will be considered effective on the date that TPC receives the summons and complaint in Osaka, Japan.

**IV. Responses to Complaints and Discovery by Other Takeda Entities**

A. It is defendants' position that Takeda America Holdings, Inc., Takeda Ventures, Inc., and/or Takeda Pharmaceuticals LLC are not proper parties to the Actos litigation, because it is defendants' position that none had any involvement with Actos, including in the design, development, manufacturing, advertising, marketing, labeling, sale or distribution of the medication.

B. If plaintiffs name as defendants Takeda America Holdings, Inc. ("TAH"), Takeda Ventures, Inc. ("TVI"), and/or Takeda Pharmaceuticals LLC ("TPLLC") in any complaint filed in, removed to, or transferred to the MDL proceedings, TAH, TVI, and/or TPLLC shall be relieved of any obligation to move, answer, or otherwise plead in response to each such complaint until further order of this Court. TAH, TVI, and TPLLC also are relieved of any obligation to respond to discovery requests until further order of this Court.

C. If plaintiffs believe that discovery shows the involvement of TAH, TVI, and/or TPLLC in a way that will require plaintiffs to pursue one or more of these entities as a defendant, plaintiffs shall meet and confer with defendants regarding whether discovery is required from

these entities. If no agreement is reached through the meet-and-confer process, the parties shall seek the Court's guidance before plaintiffs commence any such discovery.

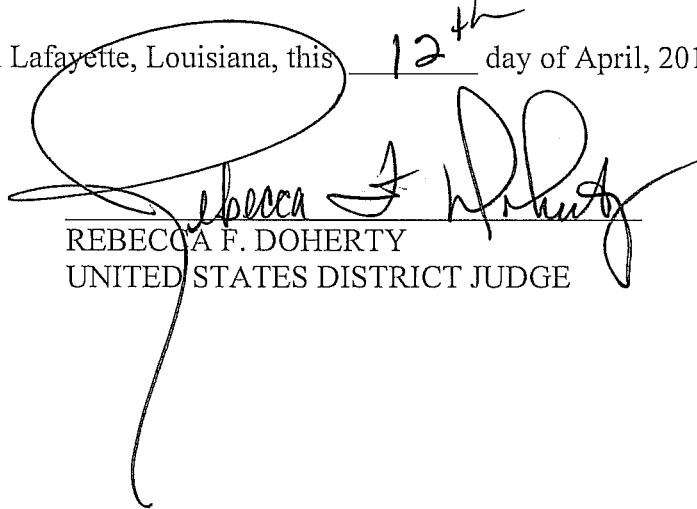
**V. Service of Process – Eli Lilly & Company**

A. With regard to complaints that have already been filed, plaintiffs who have not already served Eli Lilly & Company through original service may effectuate service, as described in this Paragraph IV.A, within 30 days of receiving notice of this Order. With regard to complaints filed on or after the date of this Order, plaintiffs may effectuate service on Eli Lilly & Company, as described in this Paragraph IV.A, within 30 days of filing a complaint.

Service on Eli Lilly & Company may be made by serving a copy of the complaint and summons on Eli Lilly & Company's registered agent for service of process at:

National Registered Agents Inc.  
200 West Adams Street  
Chicago, IL 60606

THUS DONE AND SIGNED in Lafayette, Louisiana, this 12<sup>th</sup> day of April, 2012.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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APR 11 2012



UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

In re: Actos (Pioglitazone)  
Products Liability Litigation

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6:11-md-02299-RFD-PJH  
JUDGE DOHERTY  
MAGISTRATE JUDGE HANNA

Applies to:  
All Actions

**ORDER APPOINTING SPECIAL MASTERS**

The parties having had notice that the Court was considering the appointment of special masters in this matter, and having had an opportunity to be heard and make suggestions and objections concerning the naming of the special masters; with the advice and consent of the parties, the Court now APPOINTS:

- Gary J. Russo as Special Master, with overall responsibility for the case management duties described below;
- Kenneth W. DeJean as Deputy Special Master, with responsibility solely for management and oversight of matters related to the Plaintiffs' Steering Committee, especially the assignment of duties and tasks that inure to the common benefit of all plaintiffs, making adjudicative reports and recommendations to Special Master Russo for approval of claims for those attorneys seeking credit for costs incurred and work performed for the common benefit of all plaintiffs, submitting periodic motions to the Court seeking review and approval or denial of summary descriptions of allocations of work, distribution of fees and reimbursement of costs incurred since the previous motion, and performing such other duties as might be requested of him by the Court or by the Special Master; and
- Carmen M. Rodriguez as Deputy Special Master, with primary responsibility for matters related to the law and legal analysis, especially considering contested motions and issuing reports and recommendations on same, as well as drafting orders and minute entries as might be requested by the Court, together with responsibility for any and all matters delegated by Special Master Russo.

These appointments are made pursuant to Fed. R. Civ. P. 53 and the inherent authority of the Court. The duties and terms of service the Special Masters and reasons for their appointment are set forth below.

## BACKGROUND

This Court was appointed as the transferee court in these proceedings on December 29, 2011. Since that time, this Court has initially received over 200 transferred cases. Moreover, a number of cases, also, have been filed directly in Western District of Louisiana and are being consolidated with these proceedings. This Court has been informed by counsel that the number of claims which will be included could reach into the thousands. In addition to its size, now and in the future, this MDL presents many difficult issues, including international involvement, and will require an inordinate amount of attention and oversight from the Court.

Other MDL courts, facing similar challenges, have easily concluded that appointment of Special Masters was appropriate to help the Court with various pretrial, trial, and post-trial tasks. Indeed, the appointment of a Special Master or Masters in cases such as this is common. As this Court will continue to carry a full docket of civil cases, this Court has concluded that it is necessary to appoint three individuals, each to assist the Court with certain aspects of case management, collectively which will include all aspects of case management, including the claims process, discovery, experts, legal issues, contested motions, bellwether trials, settlement efforts, etc. The 2003 amendments to Rule 53 specifically recognize the pretrial, trial, and post-trial functions of masters in contemporary litigation. Thus, the Court has concluded it is essential to appoint Special Masters to assist the Court in both effectively and expeditiously moving these disputes toward their final resolution.

### **I. Masters' Duties.**

The Special Masters will generally be assigned to (1) assist the Court with managing the litigation, including the claims process, discovery, experts, legal analysis, settlement efforts, communication with counsel, and any and all pretrial and post-trial matters that cannot be

addressed effectively and timely by an available district judge or magistrate judge of the district, as well as (2) perform any and all other duties assigned to them by the Court (as well as any ancillary acts required to fully carry out those duties) as permitted by both the Federal Rules of Civil Procedure and Article III of the Constitution. However, the Court retains sole authority to issue final rulings on all decisions made by the Special Masters, specifically including all matters formally submitted for adjudication.

This Court has reviewed recent legal authority addressing the duties of a Special Master that are permitted under the “Federal Rules of Civil Procedure and Article III of the Constitution.” Consonant with the foregoing findings and these general parameters, the currently-anticipated needs of the court, and the parties’ broad consent, the Court states that the Special Masters in these proceedings shall have the authority to:

- A. assist with preparation for attorney conferences (including formulating agendas), court scheduling, and negotiating changes to orders of this Court, including case management orders;
- B. establish discovery and other schedules, review and attempt to resolve informally any discovery conflicts (including, but not limited to, issues related to privilege, confidentiality, redactions, and access to medical and other records), and supervise discovery;
- C. oversee management of docketing, including the identification and processing of matters requiring court rulings;
- D. compile data and assist with, or make findings and recommendations with regard to, interpretation of scientific and technical evidence;
- E. assist with legal analysis of the parties’ motions or other submissions, whether made before, during, after, or in place of, trials, hearings, or oral argument, and make recommended findings of fact and conclusions of law;
- F. assist with responses to media inquiries;
- G. help to coordinate federal, state and international aspects of this litigation;

- H. direct, supervise, monitor, and report upon implementation and compliance with this Court's orders, and make findings and recommendations on remedial action if required;
- I. interpret any agreements reached by the parties;
- J. propose structures and strategies for settlement negotiations on the merits, and on any subsidiary issues, and evaluate parties' class and individual claims, as may become necessary;
- K. propose structures and strategies for attorneys fee issues and fee settlement negotiations, review fee and cost applications, and evaluate parties' individual claims for fees, as may become necessary;
- L. administer, allocate, and distribute funds and other relief, as may become necessary;
- M. adjudicate eligibility and entitlement to funds and other relief, as may become necessary;
- N. monitor compliance with structural injunctions, as may become necessary;
- O. make formal or informal recommendations and reports to the parties, and make recommendations and reports to the Court, regarding any matter pertinent to these proceedings; and
- P. communicate with parties and attorneys as needs may arise in order to permit the full and efficient performance of these duties.

The Court shall retain sole authority to issue final rulings on matters formally submitted for adjudication, unless otherwise agreed by the parties, and subject to waiver of objection to written orders or recommendations.

## **II. Communications with the Parties and the Court**

The Special Masters may communicate *ex parte* with the Court at their discretion, without providing notice to the parties, as necessary in order to fulfill their duties pursuant to this order. Moreover, the Special Masters may communicate *ex parte* with any party or attorney, as the Special Masters deem appropriate, for the purpose of ensuring the efficient administration and management of these proceedings. However, the Special Masters may not engage in *ex*

*parte* communications with any party or attorney concerning any substantive legal issue filed and pending before the Court.

### **III. Masters' Record**

The Special Masters shall maintain normal billing records of their time spent on this matter, with reasonably detailed descriptions of their activities and matters worked upon. With regard to any contested motion, or upon any other special request by the Court, the Special Masters shall (i) submit such report or recommendation to the Court in writing, as well as (ii) filing such report and recommendation into the record electronically. The Special Masters shall preserve for the record any document received from counsel or parties to this case that are not docketed in this or another court, but need not preserve for the record any document (whether created by a Special Master or anyone else) that is docketed in this or any other court.

### **IV. Review of the Special Masters' Orders**

The Special Masters shall either: (1) reduce any formal order, finding, report, or recommendation to writing and file it electronically on the case docket via Electronic Case Filing ("ECF"); or (2) issue any formal order, finding, report, or recommendation on the record, before a court reporter. The Special Master shall submit to the Court a proposed order adopting the report and recommendation. Any party may file an objection to an order, finding, report, or recommendation by a Special Master within *14 calendar days* of the date it was electronically filed, or within the time frame authorized by Fed. R. Civ. P. 6(d). **The failure to meet this deadline or to timely request an extension of the deadline shall result in permanent waiver of any objection to a Special Master's orders, findings, reports, or recommendations.**

**A. Recommended conclusions of law.**

The Court shall decide *de novo* all objections to conclusions of law made or recommended by a Special Master.

**B. Procedural rulings.**

The Court shall set aside a ruling by a Special Master on a procedural matter only for an abuse of discretion.

**C. Recommended factual findings.**

To the extent a Special Master enters an order, finding, report, or recommendation regarding an issue of fact, the Court shall review such issue *de novo*.

**V. Compensation**

The Special Masters shall be compensated at the following rates:

- \$375 per hour for the Special Masters' services;
- \$275 per hour for service provided by firm partners;
- \$200 per hour for service provided by firm associates;
- \$95.00 per hour for paralegal services.

With regard to the services provided by, and on behalf of, Deputy Special Master DeJean, the plaintiffs shall bear the cost of his fees and expenses, unless agreed or ordered otherwise. With regard to all other fees and expenses incurred by the Special Masters, the parties shall bear this cost equally (50% by the plaintiffs and 50% by the defendants). The Special Masters shall incur only such fees and expenses as may be reasonably necessary to fulfill their duties under this order, or such other orders as the Court may issue.

From time to time, on approximately a monthly basis, the Special Masters shall submit to the Court itemized statements of fees and expenses, which the Court will inspect carefully for



regularity and reasonableness. As the duties of the Special Masters include assisting the Court with management of the litigation as well as certain threshold legal analyses of the parties' submissions, the Court expects these itemized statements might reflect confidential communications between the Special Masters and the Court or between the Special Masters and counsel or parties. Accordingly, the Special Masters are ordered to submit, together with their itemized statements, summary statements which shall not reflect any confidential information and shall contain two signature lines for the Court (one for Magistrate Judge Hanna and one for Judge Doherty), accompanied by the statement "Approved for Disbursement." Additionally, the Special Masters are ordered not to include within their itemized statement any authorized *ex parte* information unless notified to the contrary by the Court to address specific issues.

The Court shall review the itemized statements *in camera* for the purpose of determining the reasonableness of the Special Masters' fees and costs. The itemized statements shall not be made available to the public or counsel. If the Court determines the Itemized Statement is regular and reasonable, the Court will sign the corresponding Summary Statement and transmit it to the plaintiffs' co-lead counsels, and defendants' lead counsel, who shall have five (5) calendar days to submit objections, if any, to the Court. The Court will review any objections and will make its final authorization and submission for payment thereafter. Once payment of a statement has been authorized, the Court will return the original itemized statements to the Special Masters, who shall preserve those originals until this matter has been fully and finally resolved for all purposes.

## **VI. Other Matters**

### **A. Affidavits**

Attached to this order are affidavits earlier submitted to the Court by the Special Masters.

**B. Cooperation**

The Special Masters shall have the full cooperation of the parties and their counsel. As agents and officers of the Court, the Special Masters shall enjoy the same protections from being compelled to give testimony and from liability for damages as those enjoyed by other federal judicial adjuncts performing similar functions. The parties will make readily available to the Special Masters any and all facilities, files, databases, and documents necessary to fulfill the duties and functions described in this order.

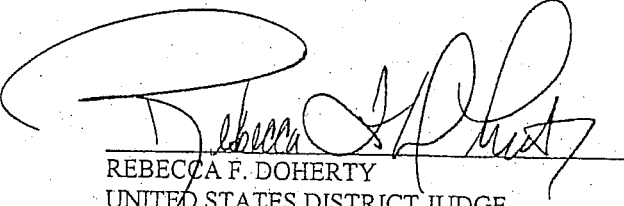
**C. Effective Date**

The Court notified the Special Masters they would be appointed, and requested they commence work on this matter, on Friday, March 16, 2012, which shall be the effective date of their appointment.

**D. Reasonable Diligence**

The Special Masters appointed herein are ordered to proceed with all reasonable diligence in fulfilling their duties.

THUS DONE AND SIGNED this 11 day of April, 2012.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION

In re: Actos (Pioglitazone)  
Products Liability Litigation

\*  
\*  
\*  
\*  
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6:11-md-02299-RFD-PJH

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**AFFIDAVIT OF GARY RUSSO**  
**TENDERED PURSUANT TO FED. R. CIV. P. 53**

STATE OF LOUISIANA

PARISH OF LAFAYETTE

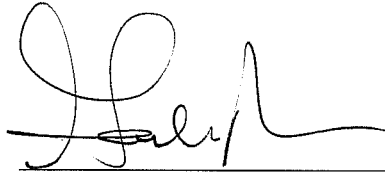
Gary J. Russo, being first duly sworn according to law, states the following:

I am an attorney at law, duly licensed to practice law in the States of Louisiana and Texas. My bar admissions are as follows:

- Louisiana State Bar Association –1979
- Texas State Bar Association – 1992
- Western District of Louisiana
- Eastern District of Louisiana
- Middle District Of Louisiana
- 5th Cir. of Appeals
- 11th Cir. of Appeals

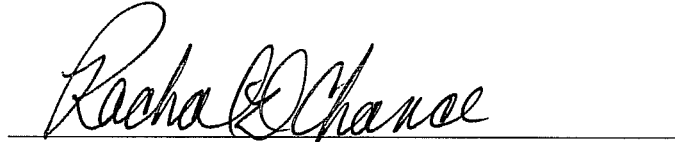
I have thoroughly familiarized myself with the issues involved in the Multi-District Litigation captioned In Re: Actos (Pioglitazone) Products Liability Litigation 6:11-md-02299-RFD-PJH. As a result of my knowledge of that case, I can attest and affirm that there are no non-

disclosed grounds for disqualification under 28 U.S.C. §455 that would prevent me from serving as the Special Master in the captioned matter.



GARY J. RUSSO

SWORN TO AND SUBSCRIBED before me, Notary Public, this 16<sup>th</sup> day of March, 2012.



NOTARY PUBLIC

Name: Rachel D. Chance

Notary Number: 31358

My Appointment Expires: death

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

In re: Actos (Pioglitazone)  
Products Liability Litigation

\* 6:11-md-02299-RFD-PJH  
\*  
\* JUDGE DOHERTY  
\*  
\* MAGISTRATE JUDGE HANNA

**AFFIDAVIT OF CARMEN RODRIGUEZ**  
**TENDERED PURSUANT TO FED. R. CIV. P. 53**

STATE OF LOUISIANA

PARISH OF LAFAYETTE

Carmen M. Rodriguez, being first duly sworn according to law, states the following:

I am an attorney at law, duly licensed to practice law in the State of Louisiana. My bar admissions are as follows:

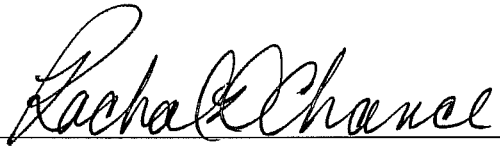
- Louisiana State Bar Association: Oct 08, 1993
- Western District of Louisiana: Dec 09, 1993
- Eastern District of Louisiana: July 29, 1998
- Middle District Of Louisiana: Jan 20, 1994
- 5th Cir. of Appeals: Jun 03, 2010
- U.S. Supreme Court: Dec 05, 2011

I have thoroughly familiarized myself with the issues involved in the Multi-District Litigation captioned In Re: Actos (Pioglitazone) Products Liability Litigation 6:11-md-02299-RFD-PJH. As a result of my knowledge of that case, I can attest and affirm that there are no non-

disclosed grounds for disqualification under 28 U.S.C. §455 that would prevent me from serving as the Special Master in the captioned matter.

  
CARMEN M. RODRIGUEZ

SWORN TO AND SUBSCRIBED before me, Notary Public, this 16<sup>th</sup> day of March,  
2012.

  
\_\_\_\_\_

NOTARY PUBLIC

Name: Rachel D. Chance

Notary Number: 31358

My Appointment Expires: death

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE DIVISION**

In re: Actos (Pioglitazone)  
Products Liability Litigation

\* 6:11-md-02299-RFD-PJH  
\*  
\* JUDGE DOHERTY  
\*  
\* MAGISTRATE JUDGE HANNA

**AFFIDAVIT OF KENNETH W. DEJEAN**  
**TENDERED PURSUANT TO FED. R. CIV. P. 53**

STATE OF LOUISIANA

PARISH OF LAFAYETTE

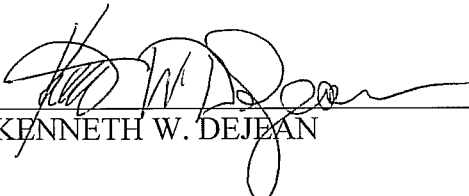
Kenneth W. DeJean, being first duly sworn according to law, states the following:

I am an attorney at law, duly licensed to practice law in the States of Louisiana and Colorado. My bar admissions are as follows:

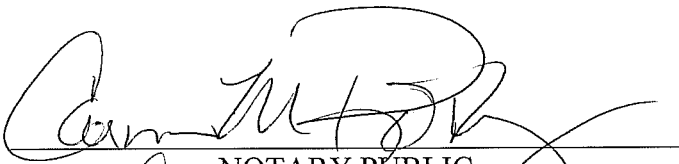
- Louisiana State Bar Association –1976
- Colorado State Bar Association – 1989
- U.S. District Court Eastern District of Louisiana, 1976
- U.S. District Court Western District of Louisiana, 1976
- U.S. Court of Appeals 5th Circuit, 1982
- U.S. Court of Appeals 11th Circuit, 1983
- U.S. Supreme Court, 1987

I have thoroughly familiarized myself with the issues involved in the Multi-District Litigation captioned In Re: Actos (Pioglitazone) Products Liability Litigation 6:11-md-02299-RFD-PJH. As a result of my knowledge of that case, I can attest and affirm that there are no non-

disclosed grounds for disqualification under 28 U.S.C. §455 that would prevent me from serving as the Special Master in the captioned matter.

  
KENNETH W. DEJEAN

SWORN TO AND SUBSCRIBED before me, Notary Public, this 16<sup>th</sup> day of March, 2012.

  
NOTARY PUBLIC  
Name: Carmen M. Rodriguez  
Notary Number: 22573  
My Appointment Expires: at death



RECEIVED

APR - 9 2012 *JS*

IN THE UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

TONY R. MOORE, CLERK  
WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

IN RE: ACTOS (PIOGLITAZONE-  
PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

This Document Applies to:  
All Cases

**CASE MANAGEMENT ORDER:  
Direct Filing and Service of Process**

**I. Scope of Order**

This Agreed Order applies to claims brought by any U.S. citizen or resident based on alleged ingestion of Actos®, ACTOplus Met®, ACTOplus Met XR®, Duetact®, or pioglitazone (“Actos”) that (i) currently are pending in MDL No. 2299, (ii) currently are pending in the Western District of Louisiana and are related to MDL No. 2299, or (iii) will be filed in, removed to, or transferred to this Court (collectively, “the MDL Proceedings”).

**II. Direct Filing of Cases in MDL 2299**

A. In order to eliminate delays associated with transfer to this Court of cases filed in or removed to other federal district courts, and to promote judicial efficiency, any plaintiff whose case would be subject to transfer to MDL 2299 may file his or her case directly in the MDL Proceedings in the Western District of Louisiana (such cases are sometimes referenced as “Direct-Filed Cases”).

B. Each case filed directly in the MDL Proceedings by a plaintiff who resides in a federal district other than the Western District of Louisiana will be filed in the MDL Proceedings for purposes of pretrial proceedings, consistent with the Judicial Panel on Multidistrict Litigation’s December 29, 2011 Transfer Order (“Transfer Order”).



G. Any attorney admitted to practice and in good standing in any United States District Court is admitted *pro hac vice* in this litigation and association of local counsel for purposes of litigation, including direct filing, is not required. However, as noted in the Court's First General Order, counsel must file a certificate of good standing with their initial filing.

H. Prior to any lawyer filing a Direct-Filed Case, that attorney must register for and have a Louisiana CM/ECF log in name and password. Other than this modification, the normal local filing requirements will apply. See Local Rules of the United States District Court for the Western District of Louisiana, available at [http://www.lawd.uscourts.gov/Court\\_Rules/Docs/localrules.pdf](http://www.lawd.uscourts.gov/Court_Rules/Docs/localrules.pdf). These rules include, *but are not limited to*, the following specifics:

- Civil Cover Sheet. A civil cover sheet, indicating that the new matter is related to the MDL Proceedings (*i.e.*, MDL No. 11-md-2299), must be filed with the complaint.
- Attorneys. Each attorney shall provide the following identifying information on the signature block:

/s/ Jane Doe \_\_\_\_\_  
Jane Doe  
NAME OF LAW FIRM  
ADDRESS  
TELEPHONE  
FAX  
EMAIL@EMAIL.com  
Attorney for Plaintiff

- Filing Fees: Internet credit card payments are required for all complaints and are made online through Pay.gov. Plaintiff's counsel will be prompted to pay the required filing fee at the time the complaint is filed.

- Summonses. After the complaint is filed, plaintiff's counsel is free to create the necessary summonses and proceed with service as required by law or as permitted herein.

### **III. Service of Process – Takeda Entities**

A. Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc. (formerly known as Takeda Pharmaceuticals North America, Inc.), Takeda Pharmaceuticals America, Inc., Takeda Global Research & Development Center, Inc., Takeda California, Inc. (formerly known as Takeda San Diego, Inc.), and Takeda Pharmaceuticals International, Inc. agree, without waiver of any defenses, to accept service of process as set forth in this Order.

B. For purposes of this Order, the “U.S. Takeda entities” are: Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals America, Inc., Takeda Global Research & Development Center, Inc., Takeda California, Inc., and Takeda Pharmaceuticals International, Inc.

C. Service on U.S. Takeda Entities. With regard to complaints that have already been filed, plaintiffs who have not already served the U.S. Takeda entities through original service may effectuate service, as described in this Paragraph III.C, within 30 days of receiving notice of this Order. With regard to complaints filed on or after the date of this order, plaintiffs may effectuate service on U.S. Takeda entities, as described in this Paragraph III.C, within 30 days of the filing of the complaint.

Service on any named U.S. Takeda entity made be made by serving a copy of the complaint and one summons directed to all named U.S. Takeda entities on Takeda's registered agent for service of process at:

CT Corporation  
208 South LaSalle Street, Suite 814  
Chicago, IL 60604

For service pursuant to this paragraph, a separate summons need not be issued to each U.S. Takeda entity for service to be effective.

*Note: Service pursuant to this Paragraph III.C shall not be made and shall not be attempted, on any entity other than the U.S. Takeda entities identified herein.*

D. Service on Takeda Pharmaceutical Company Limited. With regard to complaints that have already been filed, plaintiffs who have not already served Takeda Pharmaceutical Company Limited (“TPC”) through original service may effectuate service, as described in this Paragraph III.D, within 60 days of receiving notice of this Order. With regard to complaints filed on or after the date this Order is issued, plaintiffs may effectuate service, as described in this Paragraph III.D, within 60 days of filing a complaint.

Service on TPC may be made by delivering a cover letter, a copy of the complaint, and a summons directed to TPC *via* registered mail, return receipt requested, or *via* commercial courier service that provides equally reliable evidence of delivery, to:

Takeda Pharmaceutical Company Limited  
Attn: Legal Department  
1-1 Doshomachi 4-chome  
Chuo-Ku Osaka, 540-0865  
Japan

For service to be effective, plaintiffs also must send a copy of the cover letter that was mailed to TPC to:

Stacey Dixon Calahan  
Assistant General Counsel, Litigation  
Takeda Pharmaceuticals U.S.A., Inc.  
One Takeda Parkway

Deerfield, Illinois 60015.

E. If plaintiffs abide by the terms of this Order, service on the U.S. Takeda entities will be considered effective on the date that CT Corporation is served with the documents discussed in Sections III.C of this Order, and service on TPC will be considered effective on the date that TPC receives the summons and complaint in Osaka, Japan.

#### **IV. Responses to Complaints and Discovery by Other Takeda Entities**

A. It is defendants' position that Takeda America Holdings, Inc., Takeda Ventures, Inc., and/or Takeda Pharmaceuticals LLC are not proper parties to the Actos litigation, because it is defendants' position that none had any involvement with Actos, including in the design, development, manufacturing, advertising, marketing, labeling, sale or distribution of the medication.

B. If plaintiffs name as defendants Takeda America Holdings, Inc. ("TAH"), Takeda Ventures, Inc. ("TVI"), and/or Takeda Pharmaceuticals LLC ("TPLLC") in any complaint filed in, removed to, or transferred to the MDL proceedings, TAH, TVI, and/or TPLLC shall be relieved of any obligation to move, answer, or otherwise plead in response to each such complaint until further order of this Court. TAH, TVI, and TPLLC also are relieved of any obligation to respond to discovery requests until further order of this Court.

C. If plaintiffs believe that discovery shows the involvement of TAH, TVI, and/or TPLLC in a way that will require plaintiffs to pursue one or more of these entities as a defendant, plaintiffs shall meet and confer with defendants regarding whether discovery is required from these entities. If no agreement is reached through the meet-

and-confer process, the parties shall seek the Court's guidance before plaintiffs commence any such discovery.

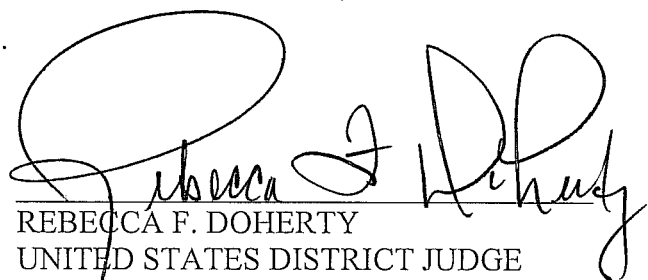
**V. Service of Process – Eli Lilly & Company**

A. With regard to complaints that have already been filed, plaintiffs who have not already served Eli Lilly & Company through original service may effectuate service, as described in this Paragraph IV.A, within 30 days of receiving notice of this Order. With regard to complaints filed on or after the date of this Order, plaintiffs may effectuate service on Eli Lilly & Company, as described in this Paragraph IV.A, within 30 days of filing a complaint.

Service on Eli Lilly & Company made be made by serving a copy of the complaint and summons on Eli Lilly & Company's registered agent for service of process at:

National Registered Agents Inc.  
200 West Adams Street  
Chicago, IL 60606

THUS DONE AND SIGNED in Lafayette, Louisiana, this 9<sup>th</sup> day of April, 2012.

  
REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

In Re: Actos (Pioglitazone) Products	*	
Liability Litigation	*	MDL No. 6:11-md-2299
	*	
	*	JUDGE DOHERTY
	*	
This Document Applies to:	*	MAGISTRATE JUDGE HANNA
All Cases	*	
	*	

**ORDER**

The **initial status conference** in the above-referenced matter will be conducted on **March 22, 2012 at 9:45 a.m.** CST in open court in Judge Doherty's courtroom, 4<sup>th</sup> Floor John M. Shaw Courthouse, Lafayette, Louisiana. All counsel designated or intending to be designated as Trial Counsel<sup>1</sup> in the MDL, whether within a direct filing or Conditional Transfer Order, must attend along with local counsel, if any. At least one attorney for each party must be present, unless the Court orders otherwise upon written request. An attorney may represent more than one party. All other counsel may attend. Parties not represented by counsel may appear in proper person.

In advance of the conference, this Court issues the following ORDERS and notes all required submissions and suggestions are to be emailed to [hanna\\_mdj\\_orders@lawd.uscourts.gov](mailto:hanna_mdj_orders@lawd.uscourts.gov) no later than March 1, 2012, 4:30 p.m. CST:

**Declaration of Body of Governing Law and Medical Status of Party**

Each counsel representing a party or parties shall file a one-sentence declaration as to what

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<sup>1</sup> Local Rule 11.2 requires designation as Trial Counsel.



*body of law* applies to the claims of each party they represent (e.g., California products liability law, New Hampshire products liability law). The foregoing declaration(s) shall be prepared jointly, that is, plaintiff's counsel and defense counsel shall confer to produce the one-sentence declaration. If there is dispute as to what *body of law* governs a claim, the **one-sentence declaration** shall note that dispute (e.g., plaintiff asserts Connecticut products liability law governs lawsuits ABC; defendant asserts New Hampshire products liability law governs lawsuits ABC; plaintiff and defendant agree Connecticut law applies to lawsuits XYZ).

Additionally, each enrolled plaintiff's counsel shall submit a one-sentence declaration describing the medical status of each client represented who is before this Court (e.g., is deceased; has been diagnosed with cancer; has fear of developing cancer, etc.).

#### **Steering Committee, Lead Counsel, Liaison Counsel**

Any counsel who is interested in serving on a committee or serving as a lead counsel or liaison counsel shall submit the following (2 page limit for entire submission):

- resumé
- the number of clients the attorney or his or her firm represents in the Actos litigation in federal court and the number of clients the attorney or his or her firm represents in the Actos litigation(s) in state court(s) and what body of law applies to each lawsuit
- experience handling mass tort cases or other MDLs
- experience as a committee member in mass tort cases or other MDLs
- any other quality(ies) the Court should consider
- fee proposals and/or rates of pay to be sought for work subject to the Common Benefit Fund (this does not request fee schedules entered into with individual clients)

Appointment of committees and lead and liaison counsel will be determined by the Court after full consideration of all information received and after the initial status conference.

### **Special Masters**

Notice is hereby given this Court anticipates using one or more Special Master(s). Any party, through counsel, wishing to make a suggestion for a candidate may make that suggestion no later than March 1, 2012, 4:30 p.m. CST, by emailing the suggestion to hanna\_mdl\_orders@lawd.uscourts.gov. The attorney or party making a suggestion should provide this Court with sufficient information for the Court to make a meaningful review and decision, however, the submission can be no more than 2 pages in length.

### **Suggestions for Agenda**

Any party or attorney wishing to make a suggestion for inclusion on the Agenda for the initial status conference may submit suggestions (no more than one page) for the Agenda by emailing those suggestions to hanna\_mdl\_orders@lawd.uscourts.gov.

### **Discovery**

Counsel shall come to the conference prepared to discuss discovery as it relates to the progression of the case.

### **Matters of Recusal**

Each counsel enrolled is reminded of Rule 7.1 of the Federal Rules of Civil Procedure. Parties are reminded and it is ORDERED that counsel shall immediately comply and keep such lists current for the duration of this litigation.

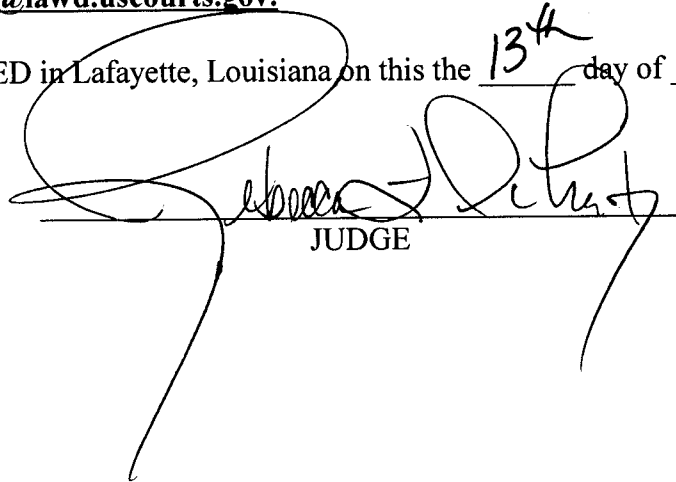
### **Contact Information**

Counsel are also reminded Local Rule 11.1 of the Western District requires “[e]ach attorney and pro se litigant has a continuing obligation to apprise the court of any address change.” Thus, all enrolled counsel are ORDERED to verify their contact information with the Clerk of Court and

reminded they must keep the Clerk of Court appropriately apprised of any changes in contact information. **Failure to do so places counsel at risk of having waived his or her right to participate in any interaction with the Court when they cannot be reached.**

**Reminder: Any submission or suggestion referenced in this Order is to be submitted no later than March 1, 2012, 4:30 p.m. CST, by emailing the submission or suggestion to hanna\_mdj\_orders@lawd.uscourts.gov.**

SO ORDERED in Lafayette, Louisiana on this the 13<sup>th</sup> day of February, 2012.



A large, stylized handwritten signature in black ink is written over a horizontal line. The signature is highly cursive and difficult to decipher, but it appears to be the name of the judge.

JUDGE

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WESTERN DISTRICT OF LOUISIANA  
LAFAYETTE, LOUISIANA

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

In Re: Actos (Pioglitazone) Products Liability Litigation	*	
	*	MDL No. 6:11-md-2299
	*	
	*	JUDGE DOHERTY
	*	
This Document Applies to: All Cases	*	MAGISTRATE JUDGE HANNA
	*	
	*	

FIRST GENERAL ORDER - ALL ACTIONS

It appearing that the matter transferred to this Court by order of the Judicial Panel on Multi-District Litigation pursuant to its order of December 29, 2011, hereinafter referred to as MDL 6:11-md-2299 ACTOS (Pioglitazone) Products Liability Litigation as well as any cases deemed by this Court or the Multidistrict Litigation Panel as "Related cases", merit special attention as complex litigation, it is therefore, ORDERED that:

**1. APPLICABILITY OF ORDER** - This First General Order shall govern prior to the entry of the Comprehensive Management Order (CMO), and supplement the CMO thereafter. The provision of this Order shall govern the practice and procedure in all actions originating within or deemed by this Court or the MDL Panel to be Related to the MDL 6:11-md-2299 ACTOS (Pioglitazone) Products Liability Litigation. This Order shall issue in all cases once deemed by the MDL Panel or this Court to be Related.

**2. RELATED CASES** - Any matters deemed Related by the MDL Panel or this Court to the MDL 6:11-md-2299 ACTOS (Pioglitazone) Products Liability Litigation shall be governed by this Order and the CMO, as well as all future orders of the court issued in the MDL 6:11-md-2299 ACTOS (Pioglitazone) Products Liability Litigation, unless otherwise specified by the Court.

3. **STAY** - Pending issuance of the CMO and further orders of this Court, all outstanding discovery proceedings and requests are stayed, and no further discovery shall be initiated except pursuant to the CMO.

4. **ORDERS** - Any threshold protective orders entered by any transferor District Court, shall remain in full force and effect unless or until modified by this Court or addressed in the CMO.

5. **MOTIONS** - All motions filed and pending before the transferor Court are deemed premature, and must be re-filed, if appropriate, pursuant to the provisions of the CMO once issued, and with proper heading and caption as discussed in paragraph 6. Motions, properly re-filed, will be determined upon the briefs filed; oral argument will not be held except by order of the Court and upon such notice as the Court may direct.

Any time sensitive threshold filings or motions, may be re-filed, if appropriate, with the proper caption and designation, with a specific affirmation as to why the filing is time sensitive and threshold in nature and, need not await issuance of the CMO; ONLY time sensitive threshold issues may be so filed before the CMO is in place.

Filings must be electronic, as discussed in paragraph 7, with a courtesy copy being provided to Magistrate Judge Hanna at [hanna\\_md\\_orders@lawd.uscourts.gov](mailto:hanna_md_orders@lawd.uscourts.gov).

6. **MASTER DOCKET FILE** - The Clerk of Court will maintain a Master Docket case file under the style "In Re: Actos (Pioglitazone) Products Liability Litigation" and the identification "MDL No. 6:11-md-2299". When a pleading is intended to be applicable to all actions, whether within the initial MDL assigned, transferred, tag-along, or direct filed cases deemed Related to the MDL, the filing shall note: "This Document Relates to All Cases." When a pleading is intended to apply to less than all MDL and Related cases, this Court's docket number for each individual case

to which the document number relates shall appear immediately after the words: “This Document Relates to”. The following is a sample of the pleading style:

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA

In Re: Actos (Pioglitazone) Products	*	
Liability Litigation	*	6: 11-md- 2299
	*	
	*	JUDGE DOHERTY
	*	
This Document Applies to:	*	MAGISTRATE JUDGE HANNA
(“All Actions” or specify by title and case	*	
number the individual applicable cases if the	*	
documents relates to less than all of the	*	
consolidated cases.)	*	

**7. FILING** - All cases are subject to electronic filing. A courtesy copy of any filing shall be submitted to Magistrate Judge Hanna at [hanna\\_md1\\_orders@lawd.uscourts.gov](mailto:hanna_md1_orders@lawd.uscourts.gov). Information on electronic filing procedures is available on the court’s website: [www.lawd.uscourts.gov](http://www.lawd.uscourts.gov). All motions, pleadings, stipulations, and all other formal documents shall filed in the Master Docket, as well as the individual cases as referenced in paragraph 6.

**8. COUNSEL** - Counsel properly admitted and shown to be in good standing in the transferor districts need not file a motion for admission *pro hac vice* in these proceedings, however, **they must file a certificate of good standing with the initial filing.**

Counsel who file directly within the Western District of Louisiana in a case anticipated to be deemed Related to MDL 6:11-md-2299 ACTOS (Pioglitazone) Products Liability Litigation need not file a motion for admission *pro hac vice*; however, **they must file a certificate of good standing with the initial filing.**

The *pro hac vice* **fee is waived** for filings within or Related to MDL 6:11-md-2299 ACTOS (Pioglitazone) Products Liability Litigation.

**Association of local counsel** is not required; however counsel are strongly advised to consider associating counsel **who have actually practiced within the Western District of Louisiana, Lafayette Division.**

Counsel, in each case, must designate the **Trial/Lead** counsel for that case. Trial/lead counsel SHALL appear at all interaction with the Court, unless or until otherwise ordered by the Court or modified by the CMO.

Counsel are advised to regularly review the docket sheet to ensure their appearance is properly entered, trial/lead counsel designated, and all contact information remains current and accurate.

All counsel appearing before this Court must **register for use within the electronic filing system** and be issued, by the court, an electronic login and password. Attorneys may register by visiting our website at: [www.lawd.uscourts.gov](http://www.lawd.uscourts.gov). Only attorneys shown on the docket **and** registered with our electronic filing system will receive notice from the Clerk's Office.

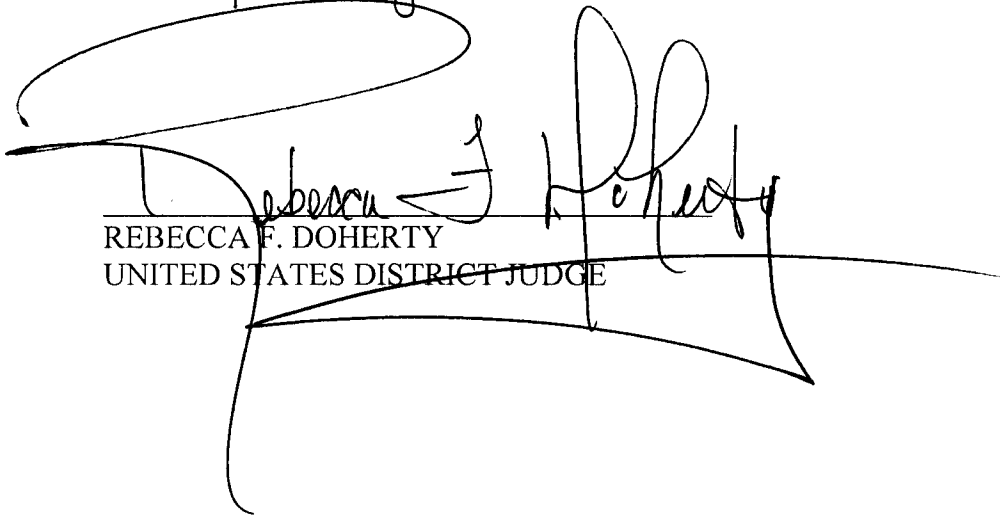
**It is ORDERED**, the login and password issued by the Western District of Louisiana upon registration, of attorneys not otherwise admitted to practice before this Court, will allow filing of documents only in the MDL 6:11-md-2299 ACTOS (Pioglitazone) Products Liability Litigation and Related cases. Said login and password are not to be used to file documents in any other case in the Western District of Louisiana, unless the attorney is otherwise formally admitted, or becomes otherwise formally admitted to practice in this district.

**9. CORPORATE DISCLOSURE** - To assist the Court in identifying any issues or matters of recusal or disqualification, counsel shall electronically file, no later than ten (10) days of receipt of this Order, and review and update on a regular basis, a list of all companies affiliated with the parties, and all counsel associated in the litigation.

**10. CONTACT PERSONS** - Filers with questions regarding procedures for electronic filing in the Western District of Louisiana are directed to the ECF Help Desk at (866) 323-1101. The courtroom deputy to whom all initial inquiries should be directed is Christine Guidry (337-593-5008). The docket clerk to whom all inquiries may be directed is Evelyn Alexander (337-593-5016).

The CMO, once issued by this Court, along with this Order and all subsequent Orders of this Court, unless otherwise designated by this Court, shall apply to and govern all cases filed within or deemed Related to MDL 6:11-md-2299 ACTOS (Pioglitazone) Products Liability Litigation.

SO ORDERED, this 23rd day of January, 2012.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE



UNITED STATES DISTRICT COURT

## Western District of Louisiana

The Honorable S. Maurice Hicks, Jr., Chief Judge ♦ Tony R. Moore, Clerk

[Home](#) » [Jurors](#) »

### Court Locations

[View](#)

[Edit](#)

Alexandria

Lafayette

Lake Charles

Monroe

Shreveport

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United States Post Office & Court House

Parishes: Avoyelles, Catahoula, Concordia, Grant, LaSalle, Natchitoches, Rapides, & Winn

### Hours & Contact information

All offices are closed on [Federal Holidays](#)

Phone: (318) 473-7415

Fax: (318) 473-7345

Hours: 8:00 am until noon, and 1:00 pm until 4:30 pm (Phones answered until 5:00 pm)

Drop Box Hours - 24/7

### Directions

[MAP](#) »

The Alexandria Courthouse is located in the block between 5th and 6th, and Murray and Johnston, in Alexandria, Louisiana.

For after hours filing, a drop box is located inside the Post Office, through the back doors, near the Pay Phones. The main entrance to the courthouse is facing Murray Street. There is a patron parking facility in the rear, and public parking on the surrounding streets. The courthouse is located in the central business district and is easily accessible from several highway exits. I-49 from the North, take exit 85A (Elliot St.-Downtown) and follow exit lane to Murray Street and turn left. I-49 from the South, take exit 85A (M.L King Dr.-Downtown) and follow exit lane to Murry Street and turn right.

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## Parking

There is a patron parking facility in the rear, and public parking on the surrounding streets.

### **Street Address:**

515 Murray Street, Suite 105  
Alexandria, Louisiana 71301  
(318) 473-7415

### **Mailing Address:**

United States Post Office & Court House  
515 Murray Street, Suite 105  
Alexandria, Louisiana 71301

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[Juror FAQs](#)

[Court Locations](#)

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[Home](#) | [Contact Us](#) | [Employment](#) | [Glossary of Legal Terms](#) | [FAQs](#)

[Privacy Policy](#) | [BrowseAloud](#)

---



UNITED STATES DISTRICT COURT

## Western District of Louisiana

The Honorable S. Maurice Hicks, Jr., Chief Judge ♦ Tony R. Moore, Clerk

[Home](#) » [Clerk's Office](#) »

### Employment

[View](#)

[Edit](#)


[Outline](#)

[Revisions](#)

[Track](#)

- [Clone content](#)

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[Click here for opportunities in other courts](#)

---

Fees and Online Payments

---

Court History

---

Article III Judges

Magistrate Judges

---

Court Holidays

---

Court Locations

---

Court Rules

---

Local Rules

Federal Rules

Standing Orders

Guide to Practice

ECF Procedures

Filing Without a Lawyer Handbook

Deficiency Checklist

---

Employment

---

Employment - Clerks Office

Employment - Chambers

Employment - Other Courts

---

Important E-Mail Addresses

---

Possession and Use of Electronic Devices in the Courthouse

---

Solicitations

---

Documentation

---



## Frequently Asked Questions

- **How do I request expungement of my case?**

[Edit](#)

- **How do I request clemency?**

[Edit](#)

- **How do I obtain a pardon from my conviction?**

[Edit](#)

- **When making a payment, if I do not have the exact amount required, is your office able to make change?**

[Edit](#)

- **How much are copies printed from your public terminal?**

[Edit](#)

- **Can I access your records online?**

[Edit](#)

- **Do you take credit card payments over the phone?**

[Edit](#)

- **What payment methods will your office accept?**

[Edit](#)

- **Can I get a copy of my birth/death certificate from your office?**

[Edit](#)

- **Does the court issue passports?**

[Edit](#)

- **Can the court replace my certificate of naturalization?**

[Edit](#)

- **How will I know when my naturalization ceremony is to occur?**

[Edit](#)

- **Where are naturalization records kept?**

[Edit](#)

- **Where can I get forms and information about becoming a United States citizen?**

[Edit](#)

- **What is the current post judgment interest rate?**

[Edit](#)

- **To whom do we make checks payable?**

[Edit](#)

- **Do I have to pay a fee every time I file a pleading?**

[Edit](#)

- **How do I get a transcript of court proceedings?**

[Edit](#)

- **What discovery material should be filed with the Clerk's Office?**

[Edit](#)

- **How are judges assigned to cases?**

[Edit](#)

- **Where are case and party indices located?**

[Edit](#)

- **May I file after-hours?**

[Edit](#)



## Do I have to file my pleadings in the division to which the case is assigned?

[Edit](#)

- **How do I contact the court?**

[Edit](#)

### FAQs

Fees and Online Payments

---

Court History

---

Article III Judges

Magistrate Judges

---

Court Holidays

---

Court Locations

---

Court Rules

---

Local Rules

Federal Rules

Standing Orders

Guide to Practice

ECF Procedures

Filing Without a Lawyer Handbook

Deficiency Checklist

---

Employment

---

Employment - Clerks Office

Employment - Chambers

Employment - Other Courts

---

Important E-Mail Addresses

---

Possession and Use of Electronic Devices in the Courthouse

---

Solicitations

---

Documentation

---

---

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[Privacy Policy](#) | [BrowseAloud](#)

---

UNITED STATES DISTRICT COURT

## Western District of Louisiana

The Honorable S. Maurice Hicks, Jr., Chief Judge ♦ Tony R. Moore, Clerk

[Home »](#)

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[View](#)

[Edit](#)

[Outline](#)

[Revisions](#)

[Track](#)

- [Clone content](#)

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- The date and time you access our site.
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