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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:  
*Allen, et. al. v. Takeda Pharmaceuticals  
North America, Inc., et al.*  
(Case No. 12-cv-00064)

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

**MEMORANDUM RULING: DIPAK PANIGRAHY, M.D.**

This multidistrict litigation arises from product liability claims against the manufacturer and marketer of Actos® and other drugs containing pioglitazone. Pending before this Court is the Defendants' Motion to Exclude Testimony of Plaintiffs' Expert, Dipak Panigrahy, M.D.<sup>1</sup> For the following reasons, the Defendants' Motion will be denied.

**EVIDENCE AT ISSUE**

Dr. Panigrahy, a physician and assistant professor of pathology at Harvard Medical School, also works as a researcher at the Center for Vascular Biology Research at the Beth Israel Deaconess Medical Center in Boston, Massachusetts. His report<sup>2</sup> includes the following opinions:

1. It is my opinion that pioglitazone is a dual PPAR ligand that has both alpha and gamma activity;

<sup>1</sup> Rec. Doc. 3467. This motion has been urged on behalf of all named defendants in this matter. The Memorandum in Support of Defendants' Motion to Exclude Testimony of Plaintiffs' Expert Dipak Panigrahy, M.D. is found at Rec. Doc. 3467-1 ["Memorandum"]; the Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Exclude Testimony of Plaintiffs' Expert Dipak Panigrahy, M.D. is found at Rec. Doc. 3621 ["Opposition"]; and the Defendants' Reply in Support of Defendants' Motion to Exclude Testimony of Plaintiffs' Expert Dipak Panigrahy, M.D. is found at Rec. Doc. 3661 ["Reply"]. For these purposes only, the Court will make no distinction between and among Defendants as, for these purposes, there is no legal distinction.

<sup>2</sup> "The Panigrahy Report" was submitted by the Plaintiffs as Exhibit 7, and by the Defendants as Omnibus Exhibit C10.

2. It is my opinion that dual PPAR alpha/gamma ligands, as well as selective gamma ligands, cause bladder tumors and other cancers in laboratory animals exposed to these agents;
3. It is my opinion that pioglitazone exerts carcinogenic effects on laboratory animals, including the rat urothelium, most likely through receptor-mediated effects;
4. It is my opinion that there are biologically-plausible Mechanisms of Action to explain carcinogenic changes in the urothelium of rats exposed to pioglitazone that are not dependent upon the formation of microcrystals in urine;
5. It is my opinion that pioglitazone *causes* bladder cancers in rats and in humans;
6. It is my opinion that pioglitazone functions as both a tumor initiator and a tumor promoter via its effects on the tumor microenvironment;
7. It is my opinion that humans exposed to pioglitazone have an increased risk for developing bladder cancer; and
8. It is my opinion that there is a biologically-plausible mechanism(s) to support bladder carcinogenesis with short-term use/exposure of pioglitazone.<sup>3</sup>

*During Dr. Panigrahy's deposition, the Plaintiffs stipulated that Dr. Panigrahy would not be offering opinions based on epidemiologic or randomized clinical trial evidence, and that he is not going to offer opinions that pioglitazone does cause bladder cancer in humans.*<sup>4</sup> This stipulation, it would seem, would have the effect of amending Opinion No. 5 above such that it would read: It is my opinion that pioglitazone causes bladder cancer in rats and can cause bladder cancer in humans.<sup>5</sup>

The Defendants do **not challenge** Dr. Panigrahy's **qualifications**, nor the **relevance** of his opinions, nor the **methodology** by which he concludes that pioglitazone causes cancer in

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<sup>3</sup> Panigrahy Report, at 6-7.

<sup>4</sup> Defendants' Omnibus Exhibit B8 (hereafter the "Panigrahy Deposition"), at 177.

<sup>5</sup> See *Id.* at 177, 298, where the stipulation is found.

animals. The Defendants' **sole challenge** is to **the methodology by which Dr. Panigrahy reached the conclusion that Actos® can cause cancer in humans.**<sup>6</sup>

## LAW AND ANALYSIS

### I. APPLICABLE LAW

While state law governs the Plaintiffs' claims in this matter, the Federal Rules of Evidence control the admission of expert testimony.<sup>7</sup> Under the Federal Rules of Evidence, "relevant" evidence is admissible, while irrelevant evidence not admissible.<sup>8</sup> Evidence is "relevant" if it has any tendency to make a fact more or less probable than it would be without the evidence, and the fact being proven or disproven is of consequence in determining the action.<sup>9</sup> The party seeking to have expert opinion testimony admitted into evidence bears the burden of demonstrating, by a preponderance of the evidence, that the expert's findings and conclusions are based on the scientific method and, therefore, are reliable.<sup>10</sup>

The Federal Rules of Evidence require that a judge, faced with a proffer of expert scientific testimony, must begin by determining, pursuant to Rule 104(a), whether the expert is proposing to (i) testify to scientific knowledge (ii) that will assist the trier of fact to understand or determine fact in issue.<sup>11</sup> This will require a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or

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<sup>6</sup> Memorandum, at 2.

<sup>7</sup> Huss v. Gayden, 571 F.3d 442, 452 (5<sup>th</sup> Cir. 2009), *citing* Mathis v. Exxon Corp., 302 F.3d 448, 459 (5<sup>th</sup> Cir. 2002).

<sup>8</sup> F.R.E. 402.

<sup>9</sup> F.R.E. 401.

<sup>10</sup> Moore v. Ashland Chemical, Inc., 151 F.3d 269, 276 (5<sup>th</sup> Cir. 1998) (*en banc*).

<sup>11</sup> Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 592, 113 S.Ct. 2786, 2796, 125 L.Ed.2d 469 (1993).

methodology properly can be applied to the facts in issue.<sup>12</sup> This requirement is found in Rule 702 of the Federal Rules of Evidence, which reads as follows in its entirety:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
- (b) the testimony is based on sufficient facts or data;
- (c) the testimony is the product of reliable principles and methods; and
- (d) the expert has reliably applied the principles and methods to the facts of the case.

In the United States Supreme Court's landmark decision in Daubert v. Merrell Dow Pharmaceuticals, Inc., the Court acknowledged the existence of a federal court's gatekeeping role with regard to expert scientific opinion testimony, characterizing that role as one ensuring that such evidence meet the requirements of both reliability and relevance.<sup>13</sup> "Reliability" as discussed in Daubert refers to *evidentiary* reliability, *i.e.*, trustworthiness, rather than *scientific* reliability, which asks whether application of the principle produces consistent results, a distinction often blurred by Defendants' arguments. In a case involving scientific evidence, evidentiary reliability is based upon scientific validity, which asks whether the principle supports what it purports to show.<sup>14</sup>

The objective of this requirement is to make sure that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same

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<sup>12</sup>Daubert, 509 U.S. at 592-93; Moore, 151 F.3d at 276.

<sup>13</sup> Moore, 151 F.3d at 275.

<sup>14</sup> Daubert, 509 U.S. at 590 n.9.

level of intellectual rigor that characterizes the practice of an expert in the relevant field.<sup>15</sup> The Supreme Court identified several non-exclusive factors a court should consider in determining whether proffered scientific opinion testimony is sufficiently reliable to permit admission into the record.<sup>16</sup> Those factors are:

- whether the expert's theory can be or has been tested;
- whether the theory has been subject to peer review and publication;
- the known or potential rate of error of a technique or theory when applied;
- the existence and maintenance of standards and controls; and
- the degree to which the technique or theory has been generally accepted in the scientific community.<sup>17</sup>

Several years later, the Supreme Court clarified when it held the gatekeeping role applied to all types of expert opinion testimony, not just scientific evidence, and revisited the reliability analysis.<sup>18</sup> Moreover, the Supreme Court reiterated that a court must have considerable leeway in deciding, in a particular case, how to go about determining whether particular expert testimony is reliable.<sup>19</sup> Therefore, the test of reliability is flexible and there is no necessary or exclusive list of factors that must exist in order for a particular opinion to be admissible.<sup>20</sup>

Daubert makes clear that the factors it mentions do not constitute a definitive checklist or test. Daubert adds that the gatekeeping inquiry must be tied to the facts of a particular case. We agree with the Solicitor General that the facts identified in Daubert may or may not be pertinent in assessing

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<sup>15</sup> Kumho Tire Company, Ltd. v. Carmichael, 526 U.S. 137, 152, 199 S.Ct. 1176, 143 L.Ed.2d 238 (1999). See also Brown v. Illinois Central Railroad Co., 705 F.3d 531, 535 (5<sup>th</sup> Cir. 2013).

<sup>16</sup> See discussion, 509 U.S. at 594-595.

<sup>17</sup> Moore, 151 F.3d at 275.

<sup>18</sup> Kumho Tire, 526 U.S. at 141-142.

<sup>19</sup> Id. at 152.

<sup>20</sup> Id., at 141-142, 149.

reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony. The conclusion, in our view, is that we can neither rule out, nor rule in, for all cases and for all time the applicability of the factors mentioned in Daubert, nor can we now do so for subsets of cases categorized by category of expert or by kind of evidence. Too much depends upon the particular circumstances of the particular case at issue.<sup>21</sup>

In the Fifth Circuit, “[t]o determine whether proffered testimony is reliable, the trial court must make ‘a preliminary assessment of whether the reasoning or methodology underlying the testimony is . . . valid and of whether that reasoning or methodology properly can be applied to the facts in issue.’”<sup>22</sup> Further, “[t]o establish reliability under Daubert, an expert bears the burden of furnishing ‘some objective, independent validation of [his] methodology.’”<sup>23</sup> In doing so, “[t]he expert’s assurances that he has utilized generally accepted [principles] is insufficient.”<sup>24</sup>

In Brown the Fifth Circuit held that the trial court did not abuse its discretion where an expert testified that offered opinions were reliable merely upon and because of “education and experience” and did not engage in or rely upon a credible methodology, particularly in the face of evidence in opposition to those opinions. Standing alone then, it is insufficient for an expert to base his or her opinion on education and experience alone, especially in the face of evidence to the contrary.

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<sup>21</sup> Kumho Tire, at 150 (citations and quotation marks omitted).

<sup>22</sup> Brown v. Illinois Central Railroad Co., 705 F.3d 531, 535 (5th Cir. 2013) (quoting Daubert, 509 U.S. at 592–93).

<sup>23</sup> Brown, 705 F.3d at 536 (quoting Moore, 151 F.3d at 276).

<sup>24</sup> Id. (quoting Moore, 151 F.3d at 276).

## II. ANALYSIS

Plaintiffs bear the ultimate burden on this issue, thus, this Court will first look to Plaintiffs' *prima facie* showing. The task for this Court within this Motion, as the gatekeeper, is to determine whether the Plaintiffs' experts will have the necessary qualifications, employed a required process, methodology, rely upon sufficiently sound scientific evidence and comport with the inquiry and factors identified in Daubert, within their respective areas of expertise so as to be allowed to pass the gatekeeper inquiry. The specific analysis of this issue will begin with consideration of the Plaintiffs' evidence in support of their *prima facie* case, and then proceed to consideration of the Defendants' specific challenges.

### A. Dr. Panigrahy's Report, Opinions, and Supporting Evidence

As noted above, Dr. Panigrahy has provided a report in this matter. The body of the Panigrahy Report is 46 pages in length, with an attached list of the 178 references upon which he relied in developing his opinions, and with an attached list of the case materials he reviewed in developing his opinions and producing his report. The Panigrahy Report contains:

- a description of his qualifications;<sup>25</sup>
- a list of the opinions he has reached in this matter;<sup>26</sup>
- a discussion of pioglitazone and its effect on PPAR activity;<sup>27</sup>
- a discussion of the processes involved in tumor formation;<sup>28</sup>
- a discussion of the role that PPARs play in the development of cancer;<sup>29</sup>

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<sup>25</sup> Panigrahy Report, at 2-5.

<sup>26</sup> Id. at 6-7. This Court notes, as discussed above, that one of Dr. Panigrahy's opinions (*i.e.*, that pioglitazone does cause cancer in humans) has been amended by stipulation of the parties and, therefore, will not be presented at trial.

<sup>27</sup> Id. at 8-16.

<sup>28</sup> Id. at 17-21.

- an extensive discussion of the plausible mechanisms by which pioglitazone causes bladder carcinogenicity in human beings;<sup>30</sup>
- a discussion of pioglitazone's ability to cause bladder tumors in humans with less than one year of exposure;<sup>31</sup>
- a discussion of Takeda's crystal hypothesis of bladder carcinogenesis;<sup>32</sup> and
- an explanation of his theory of human risk for bladder cancer after exposure to pioglitazone.<sup>33</sup>

The Panigrahy Report reveals that he has conducted a *study-based investigation* of the evidence concerning the intersection of pioglitazone, PPARs, cancer development, and bladder carcinogenicity in humans.

This Court has conducted an exhaustive review of the briefs, the exhibits submitted in support of both parties' arguments, and all studies and reports, including those of Dr. Panigrahy that are under challenge through the current motion. This Court finds, as a threshold matter, that Dr. Panigrahy is qualified to develop the opinions he has reached in this case, that as a threshold matter, he relied on standard and accepted scientific methods in formulating those opinions and again, as a threshold matter, the studies, publications and data which he relied upon were sufficiently reliable as to overcome the Defendants' threshold challenge. This Court has considered the five illustrative factors noted below and identified in Daubert and concluded that they either weigh in favor of the admissibility of Dr. Panigrahy's opinions and foundational

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<sup>29</sup> Id. at 21-25.

<sup>30</sup> Id. at 26-33.

<sup>31</sup> Id. at 33-34.

<sup>32</sup> Id. at 35-36.

<sup>33</sup> Id. at 36-37.

underpinnings, or, alternatively, do not weigh in favor of the exclusion of the challenged opinions and foundational underpinnings.

**B. Rule 702/Daubert Factors**

After full review of all argument, evidence and supporting documentation, this Court finds the five factors identified in Daubert, either weigh in favor of admissibility of Dr. Panigrahy's causation opinions or do not weigh in favor of exclusion of the challenged evidence.

- **Testability.** Dr. Panigrahy relies heavily on studies that have been published in peer-reviewed literature, including his own publications. As a threshold matter, the testability of the foundational underpinnings of Dr. Panigrahy's theory support a finding of admissibility. The fact that Dr. Panigrahy has not engaged in independent testing of pioglitazone in humans, but relies on published studies, is not fatal under the circumstances of this case because he has used an acceptable methodology and underlying foundational underpinnings have been tested.
- **Peer Review.** Dr. Panigrahy has cited a great many peer-reviewed publications that provide scientific support for his opinions. While it does not appear that Dr. Panigrahy's specific opinions in this case have been subjected to peer review, this Court finds the *underlying studies* relied upon, incorporated, and used as foundational support for his conclusions, are and have been sufficiently subject to peer review and are accepted within the relevant scientific community. The absence of peer review for Dr. Panigrahy's opinions, in and of itself, does not invalidate Dr. Panigrahy's opinion when otherwise accepted methodology has been employed to extrapolate information and analysis from peer-review publications. Dr. Panigrahy's heavy reliance on identified peer-reviewed publications, studies, and information lend strong support for the argument in favor of admissibility of his opinion and foundational support for his conclusions, as a threshold matter.
- **Rate of Error.** The published studies relied upon by Dr. Panigrahy have error rates attached to them and are readily available for review and cross examination. The absence of a rate of error as to his specific opinions should not be fatal in light of the availability of such error rates for the underlying studies on which he relies.
- **Standards and Controls.** Dr. Panigrahy is a highly-qualified pathologist who has conducted his investigation and developed his opinions, in this matter, in compliance with the standards and controls under which he normally operates in his professional life. This Court finds that those standards and controls lend strong support for the argument of/for reliability of Dr. Panigrahy's opinions, as a threshold matter.
- **General Acceptance.** The Panigrahy Report provides ample evidence that his methodology is generally-accepted in the scientific community and that his investigation (while it hasn't been conducted or replicated by any third party) is fully

consistent with those generally-accepted principles. Dr. Panigrahy's process employed, conclusions reached, and opinions posited have been guided by scientifically-accepted processes found within the accepted scientific method, and stand upon a foundation of independent peer-reviewed studies and articles. Consequently, this factor argues for allowing presentation of Dr. Panigrahy's opinions to the trier of fact.

This Court notes, that the Defendants have raised an *ipse dixit* challenge similar to the one discussed in Brown. This challenge will be discussed *supra*. For present purposes, this Court would simply note that the Panigrahy Report reveals that Dr. Panigrahy relies on many studies and publications, as well as extensive data, in reaching each of his opinions. This Court finds that the Plaintiffs have met their *prima facie* burden of demonstrating, as a threshold matter, that Dr. Panigrahy's opinions are admissible.

### **C. The Defendants' Challenges**

As a preliminary matter, this Court notes that Dr. Panigrahy's opinions and analysis support the Plaintiffs' theory of general causation, specifically, that there is a potential for pioglitazone to either cause or promote the development of bladder cancer and that it can do so within the first year of exposure. The gravamen of the dispute between the Plaintiffs and the Defendants as to Dr. Panigrahy's analysis, opinions, and conclusions – together with the role that those opinions and conclusions play in the Plaintiffs' overall theory of general causation – has been addressed to some degree in this Court's Memorandum Ruling: Development of Bladder Cancer Within One Year of Exposure (Rec. Doc. 3771), which is incorporated and adopted herein.

The Defendants do not here challenge Dr. Panigrahy's qualifications, nor the relevance of his opinions, nor the methodology by which he concluded that pioglitazone exposure causes cancer in animals. Their sole Daubert challenge is to the admissibility of Dr. Panigrahy's opinion concerning pioglitazone's potential to cause bladder cancer in humans; specifically, the

Defendants allege that Dr. Panigrahy relied solely on animal studies in his search for relevant information and that animal studies cannot provide the sole support for the conclusion that pioglitazone can cause bladder cancer in humans. This alleged gap in Dr. Panigrahy's foundational information is alleged to render his opinions unreliable and inadmissible.<sup>34</sup>

This Court has closely reviewed the Panigrahy Report, the Panigrahy Deposition, and the briefs and evidence submitted by both parties. Having reviewed this material, this Court notes that Dr. Panigrahy relied on no fewer than seven (7) published articles describing laboratory studies performed on human tissues;<sup>35</sup> the Panigrahy Report specifically discusses conclusions drawn from such data,<sup>36</sup> and the Panigrahy Deposition informed the Defendants that Dr. Panigrahy bases his opinions on *both* animal studies and human studies.<sup>37</sup> In other words, the record contains ample evidence that, *contrary to the Defendants' assertions*, Dr. Panigrahy *did* consider human data. Nonetheless, once again, the Defendants put forth an argument in blind reliance upon an absence of facts which without dispute exist. The Court, again, cautions Defendants, and, again, notes disagreeing with an experts' reliance upon or use of data *is not the same* as arguing such data does not exist. Such argument serves neither Defendants nor their cause and Defendants are, again, cautioned as to such false argument. The Defendants' challenge is overruled.

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<sup>34</sup> Memorandum, at 3.

<sup>35</sup> *See* Plaintiffs' Exhibits 10 through 16. This Court notes that Exhibit 10 is a published article by Dr. Sakamoto, who was a Takeda employee at the time the article was published. The Defendants have not acknowledged the heavy reliance and emphasis placed by Dr. Panigrahy on the Sakamoto study, which was performed on human tissue.

<sup>36</sup> *See, e.g.*, Panigrahy Report, at 16, 28.

<sup>37</sup> Panigrahy Deposition, at 144.

In addition to the Defendants' main argument, they have included several lesser statements or arguments that bear brief discussion:

- ***Iipse Dixit.*** The Defendants argue that Dr. Panigrahy's opinion should be excluded, pursuant to General Electric Company v. Joiner,<sup>38</sup> and Brown v. Illinois Central Railroad Company,<sup>39</sup> as unreliable *ipse dixit*. However, the Defendants' argument is founded solely on the suggestion – disproven above – that Dr. Panigrahy used no human-derived data to support his opinion that Actos® is a human carcinogen. The Defendants' argument is as follows: Dr. Panigrahy relied on animal studies and not human data; thus, he has no basis for concluding that Actos® is a potential human carcinogen; therefore, he must be relying solely on his own expertise to reach this conclusions, which is an *ipse dixit* argument. As discussed above, the fundamental assumption underlying this argument is incorrect (*i.e.*, the evidence demonstrates that Dr. Panigrahy *did* rely on human data and studies). Again, Defendants might disagree with Dr. Panigrahy's reliance upon, or interpretation of the significance of, or opinion garnered from, those studies; however, that does not equate to an absence of such studies. This fact alone would justify the rejection of the Defendants' argument. However, this Court has closely reviewed the Panigrahy Report and finds no express declaration, nor implicit assumption, that Dr. Panigrahy is attempting to rely solely upon his own expertise in forming his opinions, nor has he developed any opinion unsupported by *any* data or other evidence, nor does he invoke his own description of generally-accepted principles as sufficient support for any of his opinions. Quite to the contrary, this Court finds the Panigrahy Report is supported by reference to a great many peer-reviewed articles and other sources and authorities. The Defendants' objection to Dr. Panigrahy's opinions as unsupported are overruled and the dispute as to the opinion, itself, is one given over to the trier of fact.
- ***“So-called human evidence.”*** This phrase was used during the Panigrahy Deposition.<sup>40</sup> As it was used by Plaintiffs' counsel at that time, “so-called human evidence” seems intended to refer to epidemiological studies and clinical trials. The Defendants', it seem now, seek to question the stipulation reached by the parties as to this point as they repeatedly argue Dr. Panigrahy considered *no human evidence at all* in developing his opinions.<sup>41</sup> This Court has reviewed the

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<sup>38</sup> 522 U.S. 136, 146 (1997).

<sup>39</sup> 705 F.3d 531, 536 (5<sup>th</sup> Cir. 2013).

<sup>40</sup> Panigrahy Deposition, at 177 (“First of all, Dr. Panigrahy will not be offering any opinions that are based on the epidemiologic or randomized clinical trial evidence, the so-called human evidence.”)

<sup>41</sup> The following quotes are found in the Memorandum, at 3:

- “Dr. Panigrahy did not rely on any ‘so-called human evidence’ to prepare his opinions for this litigation.”

stipulation and finds that neither the Plaintiffs nor Dr. Panigrahy have asserted that Dr. Panigrahy relied solely on animal data in reaching his conclusion and even a cursory review of Dr. Panigrahy's report will establish that point. Defendants misread, change the intent and meaning of the "stipulation." Dr. Panigrahy's report is clear that human studies were reviewed by Dr. Panigrahy; thus, Defendants' challenge in this basis is overruled.

- **Definitive Causation.** The Defendants suggest that Dr. Panigrahy has opined as to definitive causation of bladder cancer in humans. "But even Dr. Panigrahy acknowledges that animal studies predict only *potential* human carcinogenicity, not that they definitively establish a cause and effect relationship between an exposure and human cancer."<sup>42</sup> However, this Court has located no evidence that Dr. Panigrahy, either in the Panigrahy Report or in the Panigrahy Deposition suggested that a *definitive causal association* between pioglitazone exposure and human bladder cancer had been, or could be, established through animal studies alone. To the contrary, all of the Panigrahy deposition testimony cited by the Defendants in support of this statement present Dr. Panigrahy's position that *potential carcinogenesis* has been demonstrated; none of the discussions involve statements by Dr. Panigrahy that "definitive" causation has been proven. The Defendant's objection is overruled.
- **Conflation.** In their Reply, the Defendants attempt to sidestep the evidence that Dr. Panigrahy did consider human-derived data by arguing that the particular "human data" relied upon by Dr. Panigrahy is *not the right type* of human data, as the "so-called 'human data' that Plaintiffs cite is from *in vitro* studies where human cells were studied in the laboratory, not studies that were performed on human beings."<sup>43</sup> While the Defendants seem to suggest that there is a proper type of "human studies" which exclude *in vitro* studies, this Court finds no support for that argument in Defendants' motion or, likely, within the scientific community. Defendants seem to argue – *after having argued no human studies were relied upon* – the *human studies* used to support Dr. Panigrahy's conclusions are **human epidemiological** studies and not *laboratory* studies conducted on human tissue. It is not clear to this Court why a *pathologist* should be limited, in his scientific endeavors, to relying only upon human epidemiological studies and not human tissue studies. Furthermore, the Defendants have not explained how

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- "[E]xplaining that Dr. Panigrahy is not relying on human studies to support his opinions."
  - "Despite the stipulation, Dr. Panigrahy intends to testify that, based only on the results of animal studies, Actos® 'can cause bladder cancer in humans.'"
  - "Because Dr. Panigrahy did not rely on anything other than animal studies to support his opinion that Actos® is a human carcinogen, there is an analytical gap in his reasoning."

<sup>42</sup> Memorandum, at 3 (emphasis in original).

<sup>43</sup> Reply, at 1 n.1.

“human data” from one type of human is reliable and yet, “human data” from another type of human isn’t. Moreover, the Defendants have in no way explained how it is that information derived from studies conducted on *human tissue* is not “human data” upon which a pathologist, such as Dr. Panigrahy, is entitled to rely in forming his opinions. The Defendants’ objection is overruled.

- ***Panigrahy’s Alleged Admission.*** Finally, the Defendants, as they have done in other contexts, intimate that Dr. Panigrahy has admitted the truth of their argument. “Regardless of Dr. Panigrahy’s qualifications, his publications, or the work he does outside of the courtroom (which Defendants did not contest), the methodology that he used to reach this opinion admittedly does not support his conclusion.”<sup>44</sup> The Defendants cite, as support for this statement, their own Memorandum, at page 3. This Court has searched page 3 of the Memorandum and found no evidence of an admission by Dr. Panigrahy that he used a methodology that does not support the conclusions he has reached in this case. In the absence of any evidence that Dr. Panigrahy actually made such an admission, this Court can neither credit the Defendants’ assertion, nor consider it as evidence of the unreliability of Dr. Panigrahy’s report and, *again, cautions Defendants* as to unsupported factual assertions.

### III. EVIDENTIARY HEARING

The Defendants requested this Court agree to hear live testimony from the experts prior to ruling on the instant motion; this Court carefully considered the Defendants’ request. The decision of how to go about ruling on the instant motion is squarely within this Court’s discretion.

The trial court must have the same kind of latitude in deciding *how* to test an expert’s reliability, and to decide whether and when special briefing or other proceedings are needed to investigate reliability, as it enjoys when it decides whether or not that expert’s relevant testimony is reliable. Our opinion in Joiner makes clear that a court of appeals is to apply an abuse-of-discretion standard when it reviews a trial court’s decision to admit or exclude expert testimony. That standard applies as much to the trial court’s decisions about how to determine reliability as to its ultimate conclusion. Otherwise, the trial judge would lack the discretionary authority needed both to avoid unnecessary “reliability” proceedings in ordinary cases where the liability of an expert’s methods is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert’s reliability

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<sup>44</sup> Reply, at 1.

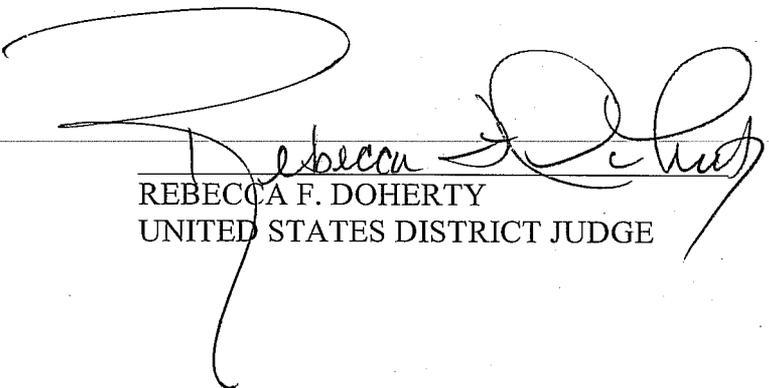
arises. Indeed, the Rules seek to avoid unjustifiable expense and delay as part of their search for truth and the just determination of proceedings.<sup>45</sup>

This Court reviewed the extensive briefing provided by both parties, as well as the large number of exhibits, including expert reports, depositions, and other documents, and concluded the nature of the challenges presented and the arguments made did not illustrate a need for live testimony. Live testimony would not be likely to contribute to any greater understanding of the nature of the dispute than can be and has been found in a careful reading and analysis of the briefs and accompanying evidence and documentation. The request for an opportunity to present live testimony in an evidentiary hearing is DENIED.

### CONCLUSION

For the foregoing reasons, the Defendants' Motion to Exclude Testimony of Plaintiffs' Expert, Dipak Panigrahy, M.D., shall be DENIED.

THUS DONE AND SIGNED this 6 day of January, 2014.



REBECCA F. DOHERTY  
UNITED STATES DISTRICT JUDGE

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<sup>45</sup> Kumho Tire, 526 U.S. at 152-53 (emphasis in original) (citations and quotations omitted).