

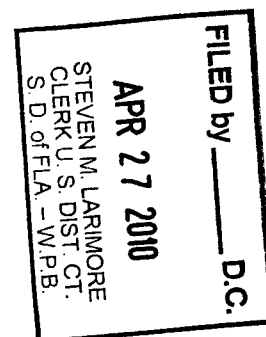
UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 08-MD-01928-MIDDLEBROOKS/JOHNSON

IN RE: TRASYLOL PRODUCTS  
LIABILITY LITIGATION - MDL-1928

This Document Relates To: All Actions

---



**ORDER ON BAYER'S MOTION TO EXCLUDE TESTIMONY OF PLAINTIFFS'**  
**EXPERT SUZANNE PARISIAN**

THIS CAUSE comes before the Court upon Defendants' (hereinafter, collectively, "Bayer's") Motion to Exclude Testimony of Plaintiffs' Expert Suzanne Parisian<sup>1</sup> ("Motion") (DE 3065), filed on December 17, 2009. Plaintiffs filed a Response (DE 3841), to which Bayer replied (DE 4098). I held a *Daubert* hearing on April 13, 2010, and have reviewed the pertinent parts of the record and am advised in the premises. For the reasons stated below, Bayer's Motion shall be granted; Dr. Parisian's testimony shall be excluded in its entirety.

---

<sup>1</sup> Dr. Suzanne Parisian is proffered as an expert on FDA regulations, procedures, and labeling requirements. She received a Masters in Biology and a medical degree from University of South Florida; she is board certified in Anatomic and Clinical Pathology. From 1991 to 1995, Dr. Parisian was an FDA Medical Officer for the FDA's Center for Devices and Radiological Health. After leaving the FDA, she founded MD Assist, Inc., a regulatory and medical consulting firm specializing in matters involving FDA-regulated products. (Parisian Report at 1-7.)

## I. Legal Standard

The admissibility of expert testimony is governed by the framework set out in Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). The party seeking to have the expert testimony admitted bears the burden of demonstrating its admissibility by a preponderance of proof. *Davidson v. U.S. Dep't of Health & Human Servs.*, 2007 WL 3251921, at \*2 (E.D. Ky. Nov. 2, 2007) (internal citations omitted). *See also United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004) (“The burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion.”).

According to Rule 702,

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

FED. R. EVID. 702. According to the Supreme Court, the inquiry envisioned by Rule 702 is a flexible one, in which federal judges perform a “gatekeeping role” to ensure that speculative and unreliable opinions do not reach the jury. *Daubert*, 509 U.S. at 594-95, 597 (“Its [Rule 702’s] overarching subject is the scientific validity and thus the evidentiary relevance and reliability—of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.”).

In *Daubert*, the Supreme Court listed several factors federal judges may consider in determining whether to admit expert scientific testimony under Rule 702: whether an expert’s theory or technique can be and has been tested; whether the theory or technique has been

subjected to peer review and publication; whether the known or potential rate of error is acceptable; and whether the expert's theory or technique is generally accepted in the scientific community.<sup>2</sup> 509 U.S. at 593-94 (declining to set forth a "definitive checklist or test").

The Supreme Court subsequently held that the *Daubert* factors "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony. . . . Too much depends upon the particular circumstances of the particular case at issue." *Kumho*, 526 U.S. at 150 (internal citations and quotations omitted). Accordingly, "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable. . . . [A] trial court should consider the specific factors identified in *Daubert* where they are reasonable measures of the reliability of expert testimony." *Id.* at 152. The trial court has the same kind of latitude in deciding how to test an expert's reliability as it enjoys when it decides whether or not that expert's relevant testimony is reliable. *Id.*

The Eleventh Circuit engages in a three part inquiry to determine the admissibility of expert testimony under Rule 702, considering whether:

- (1) [T]he expert is qualified to testify competently regarding the matters he intends to address;
- (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and
- (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue.

---

<sup>2</sup> In *Daubert*, the Supreme Court considered the federal judge's gatekeeping role in ensuring that all *scientific* expert testimony is not only relevant, but reliable. The Supreme Court later held that this basic gatekeeping obligation and *Daubert*'s general principles apply to *all* expert testimony, not just testimony that is classified as scientific. *Kumho Tire Co., Ltd., v. Carmichael*, 526 U.S. 137, 147 (1999).

*Quiet Tech. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1340-41 (11th Cir. 2003) (internal citations omitted). The Eleventh Circuit has noted that “the primary purpose of any *Daubert* inquiry is for the district court to determine whether that expert, ‘whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.’” *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1255 (11th Cir. 2005) (quoting *Kumho*, 526 U.S. at 152.).

## **II. Background**

### **A. Bayer’s Motion, Plaintiffs’ Response, and Bayer’s Reply**

According to Plaintiffs, Dr. Parisian’s proffered testimony provides the bases for twelve opinions falling into four general areas: (1) the general nature of the approval and regulatory process; (2) the duties and obligations of drug manufacturers in relation to FDA regulations and industry standards; (3) Bayer’s actions in relation to FDA regulations, industry standards and the FDA regulatory process generally; and (4) her opinion as to whether Bayer’s actions were reasonable and appropriate. (DE 3841 at 7.)

Bayer moves to exclude Dr. Parisian’s expert testimony for the following reasons: (1) she lacks the expertise to offer regulatory, medical, or scientific opinions about Trasylol; (2) her testimony consists of nothing more than factual narratives, legal conclusions, personal opinions, and unsupported speculation – all of which fall outside the purview of proper expert testimony; and (3) she has not applied a sound methodology to the facts of the case to reach reliable conclusions. (DE 3065 at 4.)

Bayer's arguments in support of exclusion and Plaintiffs' arguments against exclusion are organized into these three categories below.

**i. Dr. Parisian's Expertise**

As a threshold matter, Bayer argues that Dr. Parisian is not qualified to offer expert testimony on three matters that encompass the vast majority of her proposed testimony: (1) foreign regulatory issues; (2) causation opinions about Trasylol and the implications of studies; and (3) FDA's regulation of prescription pharmaceuticals such as Trasylol. (DE 3065 at 4.)

In regards to foreign regulatory issues, the following testimony is at issue: (1) the findings of two foreign Inspection Reports regarding deficiencies identified in Bayer's Pharmacovigilance and Quality Assurance Procedures; and (2) the May 2006 label change for Trasylol's EU label regarding the risks of renal dysfunction, which was not requested by Bayer to be made for the U.S. label. (Parisian Report at ¶¶ 207-214.)

Bayer contends that this testimony should be excluded because Dr. Parisian seeks to testify about foreign regulatory matters while conceding that she is unqualified to do so. (DE 3065 at 5. (citing Parisian Dep. at 78:19-25, 80:16-19.))

According to Plaintiffs, in coming to her opinion that Bayer had means of awareness of risks associated with Trasylol and problems with its safety signal program, Dr. Parisian reviewed all information available to her, including a foreign inspection report and foreign drug label. (DE 3841 at 18.) Dr. Parisian is not being offered to testify as a foreign regulatory expert; her opinions "touch briefly" on foreign regulatory issues "for the purpose of illuminating what Bayer

should have been aware of with regard to Trasylol or what it should have been disclosing to the FDA under FDA requirements and industry standards.” (DE 3841 at 17-18.)

Bayer replies that Plaintiffs should not be permitted to end run *Daubert*'s gatekeeping requirements by offering unqualified expert testimony framed as an opinion about what information Bayer should have known.<sup>3</sup> (DE 4098 at 2.)

In regards to Dr. Parisian's opinions on medical causation<sup>4</sup> and the implications of scientific studies related to Trasylol,<sup>5</sup> Bayer argues that this testimony should be excluded because Dr. Parisian is unqualified to render opinions regarding the alleged side effects of Trasylol or the implications of scientific studies related to Trasylol: she has testified that she is not Plaintiffs' causation expert. (DE 3065 at 6. (citing Parisian Dep. at 26:5-14.))

Plaintiffs respond that Dr. Parisian is not being offered as a causation expert: her opinions “touch briefly” on causation “for the purpose of illuminating what Bayer should have been aware of with regard to Trasylol or what it should have been disclosing to the FDA under FDA

---

<sup>3</sup> Bayer adds that to the extent Dr. Parisian is not rendering her own opinions, but is merely stating what the documents say about foreign regulatory matters, this is not expert testimony and should be excluded as unhelpful to the trier of fact. (DE 4098 at 4.)

<sup>4</sup> For example, Dr. Parisian opines that “[B]efore FDA's approval of the NDA for Trasylol, Bayer should have been aware of the increased dose dependent risks which had been associated with patients receiving full dose Trasylol. Bayer should also have been aware that Trasylol carried an increased risk at any dose of renal failure for certain populations of patients.” (Parisian Report at ¶ 24.)

<sup>5</sup> For example, Dr. Parisian opines that “These three studies [Treasure, Kincaid, and Kress and Stone] provide reasonable evidence of causal association of risk of Trasylol as well as association of increased risk with increasing dose. Yet Bayer failed to provide these studies to FDA and it failed to warn doctors of the risks associated with Trasylol. Bayer also failed to warn of the risks of administration of full dose of Trasylol by revising its label warning under 21 CFR §201.57 and 21 USC §352(a); (f)(1) & (2), and (n).” (Parisian Report at ¶ 31.)

requirements and industry standards.” (DE 3841 at 17.) According to Plaintiffs, the purpose of the statement that Bayer should have been aware that Trasylol carried an increased risk of renal failure “is to let the jury know that part of the FDA process includes identifying issues which merit further monitoring or investigation and that Bayer would have been aware of the need to monitor renal issues because they were expressed as a safety concern by the FDA’s medical officer at the time of NDA approval.” (DE 3841 at 17.)

As for the discussion of scientific studies related to Trasylol, Plaintiffs state that they are “discussed only as they relate to a manufacturer’s duty to test, study, monitor, and communicate with the FDA.” (DE 3841 at 18.) While Dr. Parisian acknowledges that an epidemiologist would be better qualified to discuss the statistical significance of the studies, Dr. Parisian is an expert “within the context of discussing the role of the studies in the FDA process and in a responsible manufacturer’s pharmacovigilance.” (DE 3841 at 18.)

Bayer replies that Plaintiffs should not be permitted to end run *Daubert*’s gatekeeping requirements by offering unqualified expert testimony framed as an opinion about what information Bayer should have known.<sup>6</sup> (DE 4098 at 2.) More specifically, the opinion identified by Plaintiffs requires Dr. Parisian to reach a causation opinion that Trasylol did carry an increased risk of renal failure; Plaintiffs have conceded that Dr. Parisian is not qualified to make the causation finding embedded in this opinion. (DE 4098 at 3.) According to Bayer, Dr. Parisian’s opinions regarding epidemiological studies suffer from the same flaws: Dr. Parisian makes

---

<sup>6</sup> Bayer adds that to the extent Dr. Parisian is not rendering her own opinions, but is merely stating what the documents say about causation, this is not expert testimony and should be excluded as unhelpful to the trier of fact. (DE 4098 at 4.)

improper opinions about the epidemiological significance of studies in discussing the import of these studies as they relate to Bayer's duties. (DE 4098 at 3.)

Finally, Bayer argues that Dr. Parisian is unqualified to render opinions on FDA's regulation of prescription drugs such as Trasyolol because she has "no real-world experience with FDA's regulation of prescription drugs or a company's compliance with FDA prescription drug requirements": her assignment at FDA was in the part of the FDA that regulates medical devices, not prescription drugs.<sup>7</sup> (DE 3065 at 8.)

Plaintiffs respond that Dr. Parisian is qualified to opine on the FDA's regulations and procedures with regard to pharmaceutical products: Dr. Parisian's experience with the FDA is not specific to any one drug or device and qualifies her to offer expert opinions on either drug or device matters. (DE 3841 at 17.) According to Plaintiffs, Bayer's argument ignores: (1) Dr. Parisian's experience and knowledge of FDA regulations as they apply to pharmaceuticals; and (2) the fact that no court has ever found Dr. Parisian unqualified to offer an opinion on FDA regulations in a pharmaceutical case. (DE 3841 at 14.) Plaintiffs enumerate Dr. Parisian's experiences with FDA regulations applicable to pharmaceuticals, such as her work on numerous projects involving devices and drugs and her responsibilities for FDA compliance as it pertains

---

<sup>7</sup> According to Bayer, "FDA's regulatory system pertaining to drugs is separate and distinct from the system that governs devices, such that experience in one division does not qualify an expert to testify regarding regulations that govern the other." (DE 3065 at 8 n.3.) Furthermore, "Dr. Parisian's limited involvement with so-called combination products that draw on aspects of prescription drugs and medical device regulation does not qualify her to opine on all aspects of FDA prescription drug regulation, as she purports to do here." (DE 3065 at 8 n.3. (internal citations omitted))

to both drugs and devices.<sup>8</sup> (DE 3841 at 15.)

**ii. Dr. Parisian's Opinions and the Proper Scope of Expert Testimony**

Bayer argues that even if the Court were to deem Dr. Parisian qualified, her testimony should be excluded because it consists of nothing more than factual narratives that do not assist the trier of fact, legal conclusions that invade both the province of the court and jury, and personal, speculative opinions that are irrelevant or otherwise improper subjects for expert testimony. (DE 3065 at 9.)

First, according to Bayer, nearly 150 pages of Dr. Parisian's Report are dedicated to summarizing Trasylol's regulatory history and selected Bayer documents.<sup>9</sup> Bayer argues that this testimony, consisting of matters of fact, should be excluded because it improperly invades the province of the jury and is "advocacy" that represents Dr. Parisian's personal belief as to the weight of the evidence. (DE 3065 at 10-11.) Bayer cites to other courts that "have excluded similar narratives by Dr. Parisian masquerading as expert testimony."<sup>10</sup> (DE 3065 at 10.)

Plaintiffs respond that the factual materials considered by Dr. Parisian are not intended

---

<sup>8</sup> Plaintiffs note that the regulations, procedures, and compliance issues for medical devices and drugs are very similar; the FDCA governs the approval of both drugs and devices. Furthermore, Bayer's regulatory expert, Dr. Waymack, "testified that there are 'great similarities' between the FDA's drug and device regulations and that he believes that experience in one area would afford a person the ability to provide 'valuable insights' in another area." (DE 3841 at 16.)

<sup>9</sup> Bayer cites to Dr. Parisian's Report, ¶¶ 81-342.

<sup>10</sup> Bayer cites to the following courts: *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 191-92 (S.D.N.Y. 2009); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 879-87 (E.D. Ark. 2008), *aff'd*, 586 F.3d 547, 571 (8th Cir. 2009).

to be the subject of Dr. Parisian's testimony in and of themselves: they are "relevant to explaining the regulatory context in which they were created, illustrating the considerations that are relevant at different stages of the regulatory process, and allowing Dr. Parisian to apply her expertise to draw inferences that would not otherwise be apparent." (DE 3841 at 19.)

Bayer replies that Plaintiffs' argument deliberately confuses the issue: there are many instances in which Dr. Parisian does not sufficiently connect the Report's factual assertions to expert analysis or opinion.<sup>11</sup> (DE 4098 at 7.) "There is no dispute that merely presenting this factual narrative to the jury would be improper." (DE 4098 at 7.)

Second, according to Bayer, nearly every opinion in Dr. Parisian's Report improperly seeks to opine that Bayer violated the FDCA and FDA regulations in its development and marketing of Trasylol, and thus was not a reasonable pharmaceutical manufacturer. (DE 3065 at 12-13.) Bayer argues that these opinions amount to improper legal conclusions that should be excluded for two reasons: (1) they go beyond the scope of proper expert testimony by usurping the role of the court in instructing the jury on the law and role of the jury in applying the law to the facts of the case; and (2) some of these opinions are preempted by federal law.<sup>12</sup> (DE 3065 at 12.)

Plaintiffs first respond that Dr. Parisian is not offering a legal conclusion (*e.g.*, that Bayer was negligent): she is "informing the jury of the FDA regulations that form the pharmaceutical

---

<sup>11</sup> Bayer cites to ¶¶ 81-131 of the Parisian Report as examples of statements that merely "regurgitate factual evidence and documentary records." (DE 4098 at 7.)

<sup>12</sup> Bayer cites to Dr. Parisian's testimony that Bayer delayed in providing studies to the FDA. According to Bayer, this testimony contravenes the Supreme Court's holding in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350-51 (2001).

industry's standard of care and applying her expertise to offer an opinion on where and whether Bayer complied with those standards." (DE 3841 at 20.) According to Plaintiffs, Dr. Parisian's opinions are admissible because: (1) they are based on her analysis of facts<sup>13</sup>; and (2) where specialized knowledge is necessary to understand the defendant's obligations, experts are permitted to opine as to whether the defendant's conduct violated the standard of care.<sup>14</sup> (DE 3841 at 20-24.) Plaintiffs note that Dr. Parisian's testimony does not usurp the role of the trial judge in instructing the jury as to the applicable law because the ultimate legal outcome in this Case is not governed by federal regulations, but rather by state law theories of negligence and strict liability. (DE 3841 at 24.)

Plaintiffs also assert that Dr. Parisian's testimony is not preempted by *Buckman*, which applies only to fraud-on-the-FDA claims and imposes no limitations on Plaintiffs' state-law-based personal injury claims. (DE 3841 at 24.) Plaintiffs cite to *Wyeth v. Levine*, 129 S. Ct. 1187

---

<sup>13</sup> According to Plaintiffs, "[T]he question with regard to admissibility under Rule 704 is whether the expert's opinions assist the jury in understanding the evidence or determining a *factual* issue. The answer here is that they do." While Bayer characterizes Dr. Parisian's opinions that Bayer failed to comply with FDA standards as "impermissible legal conclusions," they are actually "fact-based opinions comparing Bayer's conduct to a specialized standard of care." Plaintiffs asserted that such fact-based conclusions are not conclusory legal opinions and are proper under Rule 702 and 704. (DE 3841 at 21.)

<sup>14</sup> Plaintiffs argue that "Understanding the FDA regulations that set the standards for the pharmaceutical industry, and determining the facts which are significant in identifying whether that standard was met, requires specialized knowledge and expertise. . . . Without Dr. Parisian's testimony, the jury would be left to determine whether Bayer acted as a reasonable pharmaceutical company without any guidance to the governing regulations and industry standards or any assistance in determining which medical events or information was pertinent to that determination. For this reason, Dr. Parisian has routinely been permitted to offer opinions on whether a defendant's conduct violated the FDA. . . . The fact that FDA regulations and procedures are not a matter of common knowledge sets this case apart from the cases Bayer cites as precedent for excluding Dr. Parisian's testimony as a legal conclusion." (DE 3841 at 22-23.)

(2009), as confirming that state law claims against a drug manufacturer based on failure to warn remain viable in the post-*Buckman* era; plaintiffs may use evidence of the regulatory process so long as they do not bring an independent claim for relief based on fraud-on-the-FDA. (DE 3841 at 25.)

In addition to arguing that Dr. Parisian is not qualified to offer testimony on foreign regulatory actions, Bayer claims that such testimony should be excluded as irrelevant and unnecessarily confusing in this Case, where U.S. domestic law provides the only applicable standards for pharmaceutical companies. (DE 3065 at 15.) Bayer argues that the probative value of such testimony would be substantially outweighed by the danger of unfair prejudice and jury confusion, such that it should be excluded under Rule 403. (DE 3065 at 16.)

Plaintiffs respond that Dr. Parisian's references to foreign regulatory actions will not confuse the jury. (DE 3841 at 26.) According to Plaintiffs, Dr. Parisian is not designated as an expert on foreign regulatory standards: "The limited references in Dr. Parisian's report to foreign occurrences are made in the context of setting forth the facts that were considered in arriving at her opinions." (DE 3841 at 26.) For example, one of Dr. Parisian's opinions<sup>15</sup> is that Bayer deviated from its standard operating procedure (SOP) for Global Drug Safety by ignoring certain safety signals: the citation to two foreign pharmacovigilance inspection reports sets forth Bayer's SOP for detecting drug safety risks and shows Bayer's awareness of pharmacovigilance deficiencies. (DE 3841 at 26.) Also, in coming to an opinion on whether Bayer provided full and timely disclosures to the FDA in 2006, Dr. Parisian considered Bayer's acceptance, during that

---

<sup>15</sup> Plaintiffs cites to page 12 of Dr. Parisian's Report.

year, of a change to its European label adding warnings about renal dysfunction. (DE 3841 at 26.) Plaintiffs assert that neither of these references have potential for confusing the jury because they do not turn upon the application of foreign law or the correctness of the foreign action. (DE 3841 at 26.)

Finally, Bayer makes three arguments for excluding Dr. Parisian's opinions about Bayer's and the FDA's conduct and knowledge. First, Bayer argues that many of Dr. Parisian's opinions are grounded in conclusory assertions that Bayer knew or should have known about alleged safety information at various points in time and conjecture as to why Bayer took or failed to take certain actions.<sup>16</sup> (DE 3065 at 17.) Bayer argues that speculation about FDA's knowledge and why the agency took certain actions related to Trasylol is similarly inadmissible.<sup>17</sup> (DE 3065 at 17.) According to Bayer, the fact that Dr. Parisian purports to base her conclusions on documentary evidence does not render her opinions admissible: the jury is capable of drawing inferences directly from the evidence presented at trial. (DE 3065 at 18.)

Second, Bayer argues that Dr. Parisian's personal opinions that Bayer failed to act as a responsible pharmaceutical manufacturer must be excluded because they are based on Dr. Parisian's personal ethical standards rather than specialized knowledge or expertise and are unsupported by any expert analysis based on FDA regulations or other potentially applicable

---

<sup>16</sup> Bayer cites to Opinions # 4, 9, and 10 in Dr. Parisian's Report as examples of the opinions it contests.

<sup>17</sup> Bayer cites to ¶ 150 of Dr. Parisian's Report.

industry standards.<sup>18</sup> (DE 3065 at 19.)

Third, Bayer argues that Dr. Parisian improperly injects personal and unsupported “bad company” opinions about pharmaceutical companies generally and Bayer specifically.<sup>19</sup> (DE 3065 at 20.) According to Bayer, this kind of advocacy is inappropriate and does not assist the trier of fact in understanding a complex or technical aspect of the litigation. (DE 3065 at 20.)

Plaintiffs respond that: (1) Dr. Parisian’s opinions regarding Bayer’s conduct are not speculative; (2) Dr. Parisian does not offer testimony regarding Bayer’s knowledge or state of mind; and (3) Dr. Parisian does not offer personal opinions regarding pharmaceutical companies. (DE 3841 at 27-30.) Instead, Dr. Parisian will offer testimony regarding “(1) the standard of care of a pharmaceutical company in the position of Bayer with respect to the study, approval and post-market surveillance of Trasylol, and (2) Bayer’s breach of that standard of care as reflected in the many documents upon which she bases her opinions.” (DE 3841 at 27.)

According to Plaintiffs, while Dr. Parisian will not be testifying as to Bayer’s intent, she may draw “reasonable inferences from the documentary evidence as to what information was available to [] Bayer at a given time, and what [] action (if any) the available information would provoke from a reasonable and prudent pharmaceutical company.” (DE 3841 at 27.)

Further, Plaintiffs state that expert opinions are excluded as impermissibly personal where they are devoid of expertise or analysis: the opinions that Bayer characterized as personal

---

<sup>18</sup> Bayer cites to ¶ 233 of Dr. Parisian’s Report as an example of the kind of opinions it contests.

<sup>19</sup> Bayer cites to ¶ 53 and ¶ 250 of Dr. Parisian’s Report as examples of the kind of opinions it contests.

opinions are actually adequately tied to Dr. Parisian's regulatory expertise. (DE 3841 at 28.) For example, Dr. Parisian's statement, at ¶ 233 of the Report, that underreporting of renal failure events by physicians heightened Bayer's responsibility to test and monitor Trasyolol's safety was made in the context of a discussion of what factors a pharmaceutical company would be considering when looking at adverse event reports and how they would be interpreting the information contained therein. (DE 3841 at 28-29.)

Finally, Plaintiffs argue that the opinions that Bayer characterizes as "bad company" opinions are not personal opinions but instead ones involving specialized analysis and expertise. For example, Dr. Parisian's reference, in ¶ 250 of the Report, to an e-mail in which Bayer executives looked to refute the Mangano study, serves as one of the many bases for her opinion that Bayer failed to comply with the disclosure and label requirements of 314.70 and 314.80.<sup>20</sup> (DE 3841 at 29.)

In its Reply, Bayer asserts that despite Plaintiffs' assurances that Dr. Parisian can not say what Bayer knew, she repeatedly pontificates about what Bayer knew and why Bayer took certain actions with respect to Trasyolol.<sup>21</sup> (DE 4098 at 13.) Bayer also argues that Dr. Parisian's Report makes clear that she intends to offer impermissible personal opinion testimony in the guise of

---

<sup>20</sup> Plaintiffs note that the opinion contained in ¶ 53 of Dr. Parisian's Report does not implicate Bayer. "In the context of explaining how the streamlined drug approval process and limited scope of pre-approval testing increases reliance on post-marketing surveillance, Dr. Parisian merely notes that drug side effects have been hidden from the FDA by burying data in large submissions, threatening authors into not reporting adverse events or employing ghost-writers to publish 'independent' studies. . . . Plaintiff is not offering testimony from Dr. Parisian that Bayer violated the FDA by employing a ghostwriter." (DE 3841 at 30 n.12.)

<sup>21</sup> Bayer cites to ¶ 34 of Dr. Parisian's Report, where she opines about the goals of Bayer's marketing plan.

expert testimony.<sup>22</sup> (DE 4098 at 14.)

**iii. The Reliability of Dr. Parisian's Methodology and Opinions**

Bayer asserts that Dr. Parisian's conclusions are not based on the sound application of valid scientific methodology to the facts of the case and therefore fail to meet *Daubert's* reliability requirement. (DE 3065 at 20.) While Dr. Parisian claims to have used the same methodology in forming her opinions in this Case as she used while working as a medical reviewer for the FDA, Bayer stated that she "conducted only a cursory and conclusory look at Trasylol from the perspective of the plaintiffs in this case." (DE 3065 at 21.) Bayer also asserts that many of Dr. Parisian's conclusions are based on speculation and have no reliable basis in expertise.<sup>23</sup> (DE 3065 at 22.)

Plaintiffs claim that Dr. Parisian's testimony is founded on data and is methodologically reliable. (DE 3841 at 30.) According to Plaintiffs, Dr. Parisian considered numerous materials that are the types of materials relied upon by experts in the field, including: the Federal Food, Drug and Cosmetic Act, applicable sections of the Code of Federal Regulations, FDA Guidances, pertinent scientific literature, deposition testimony from Bayer employees and other experts, publicly available documents such as Bayer's New Drug Application, patent office records, and

---

<sup>22</sup> In addition to the examples cited in its Motion, Bayer points to ¶ 392 of the Report, in which Dr. Parisian opines that "A reasonable pharmaceutical manufacturer with a concern for patient safety would have pursued studies regarding the renal effects long before March 2006. Bayer's safety study was undertaken to help refute or discredit Dr. Mangano's renal failure and risk findings."

<sup>23</sup> Bayer cites to Opinion # 9 and ¶ 294 of Dr. Parisian's Report as examples of the kind of opinions it contests.

records of FDA communications.<sup>24</sup> (DE 3841 at 30.) According to Plaintiffs, “If Bayer believes that the basis of her opinion is inadequate in any particular, its’ [sic] counsel are free to cross-examine Dr. Parisian a[t] trial. But the argument that Dr. Parisian’s testimony as a whole lacks a valid methodology is simply without merit.” (DE 3841 at 31.)

### **B. Bayer’s Motion Raises Initial Concerns**

Bayer’s Motion to Exclude raised several valid concerns with Dr. Parisian’s Report and proposed trial testimony that I felt would be best addressed at a *Daubert* hearing.

More specifically, upon review, I found many of Bayer’s arguments relating to Dr. Parisian’s expertise and the proper scope of expert testimony to be meritorious. For example, I concluded that Dr. Parisian should not be allowed to opine on foreign regulatory matters because: (1) Dr. Parisian conceded that she is not an expert in this area; (2) her Report merely summarizes and restates the findings of the foreign Inspection Reports and the proposed change for Trasylol’s EU label, and thus her testimony can not be considered expert testimony that would be helpful to the trier of fact; and (3) such testimony should be excluded under Rule 403. *See, e.g., In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009) (finding that “Plaintiffs may not present evidence of foreign regulatory actions and foreign label changes during their main case” because the probative value of such evidence is “greatly overmatched by the jury confusion, waste of time, and unfair prejudice that would result if the Court were to allow Plaintiffs to introduce this evidence during their main case.”).

---

<sup>24</sup> Plaintiffs note that Bayer’s regulatory expert, Dr. Waymack, bases his opinions on the same materials. (DE 3841 at 30.)

Also, Dr. Parisian is neither a causation expert nor an epidemiologist. *See, e.g., In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d at 884 (finding that Dr. Parisian was unqualified to interpret a scientific study by Dr. Kerlikowske on breast cancer because it was epidemiologically based and related to causation, and thus outside her scope of expertise) (“As a regulatory expert, Dr. Parisian could not ‘explain and assist in the application’ of the Kerlikowske article to this case. Additionally, Dr. Parisian gave no indication that she relied on the article in forming her regulatory opinions. . . . [H]er testimony regarding the Kerlikowske article should have been excluded.”). While Dr. Parisian’s Report contains many opinions on the findings of scientific studies related to Trasylol and the association of Trasylol with various health risks, the Report alone did not allow me to conclude with certainty whether Dr. Parisian’s experience at the FDA qualifies her to make such opinions, even if they are relevant to Bayer’s obligations under the FDCA and FDA regulations.

Further, it was apparent that the majority of Dr. Parisian’s opinions fall outside the proper scope of expert testimony because they consist of a narrative of selected regulatory events and a summary of Bayer’s internal documents. For example, the statements made in ¶¶ 81-131 regarding FDA’s approval of Trasylol are used to support Opinions #3 and #4, which relate to Bayer’s failure to adequately perform clinical testing. (Parisian Report at 55.) However, in discussing Aprotinin’s Investigational New Drug (“IND”) application, Bayer’s pre-phase III meeting with the FDA, and Bayer’s submission of the NDA, Dr. Parisian cites to only three FDA regulations, none of which relates to her opinions on Bayer’s clinical testing deficiencies.<sup>25</sup>

---

<sup>25</sup> The one regulation invoked to show that Bayer was deficient was 21 C.F.R. § 312.42(b). However, this regulation related to Bayer’s *preclinical* testing deficiencies, not the

(Parisian Report at ¶¶ 86-119.) The remaining paragraphs relate to the FDA’s clinical review of aprotinin, the clinical trials conducted, and the FDA’s clinical assessment of Bayer’s NDA. (Parisian Report at ¶¶ 120-131.) In these paragraphs, Dr. Parisian merely recites the FDA Medical Officer Reviewer’s understanding of Bayer’s animal toxicology and scientific rationale along with that Reviewer’s conclusions regarding the clinical studies that had been conducted. Dr. Parisian makes no references to FDA regulations in her recitation of the foregoing facts and does not tie them to the opinions that they are intended to support.

Other courts have expressed concerns about the use of narrative testimony by Dr. Parisian. *See, e.g., In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d at 192 (finding that to the extent such evidence is admissible, it should be presented to the jury directly) (“Dr. Parisian’s commentary on any documents and exhibits in evidence will be limited to explaining the regulatory context in which they were created, defining any complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience or specialized knowledge. She will not be permitted to merely read, selectively quote from, or ‘regurgitate’ the evidence.”); *In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d at 879-87 (finding that the court should have struck much of Dr. Parisian’s testimony because it consisted of a regurgitation of the evidence devoid of expert analysis or opinion and unconnected to FDA regulations) (“Dr. Parisian, generally, did not ‘give the jury the tools they need to look at those documents, [to] understand them in the context of a regulatory background’ – she simply read the documents to the jury.”).

---

clinical testing deficiencies discussed by Dr. Parisian in Opinions #3 and #4. (Parisian Report at ¶ 94.)

I found that many of the opinions challenged by Bayer fall outside the proper scope of expert testimony because they contain improper references to Bayer's and the FDA's knowledge and intent or are personal "bad company" opinions not based on any FDA regulation or other applicable standard.<sup>26</sup>

The following are some examples of improper references to knowledge and intent. Opinion #4 discusses Bayer's motives in the promotion of Trasylol: "Bayer slipped information into its product insert's mechanism of action section to help allow it to promote a benefit for full dose Trasylol to physicians that did not have FDA's approval." (Parisian Report at 55.) Similarly, Opinion #9 states that Bayer was aware that the FDA changed its risk-benefit profile for Trasylol but "continued to expand the Trasylol sales force and provided training and sales aids designed to help minimize the risks of Trasylol for physicians." (Parisian Report at 100.) Opinion #10, which relates to Bayer's communication of Trasylol's risk to healthcare providers, contains no reference to any FDA regulation and instead regurgitates Dr. S. Horton's statements and opines on Bayer's intent in using key opinion leaders. (Parisian Report at 207.) The Report also refers to the FDA's "concerns" regarding renal dysfunction and "indications" that certain warnings would be insufficient. (Parisian Report at ¶ 150.) Not only does this paragraph regurgitate Trasylol's regulatory history and omit regulatory expert analysis, it improperly touches upon the FDA's knowledge and intent.

---

<sup>26</sup> The *Fosamax* court also excluded some of Dr. Parisian's opinions because they were too conclusory, insufficiently based on expertise or analysis, or merely "bad company" testimony with marginal relevance to the issues in controversy. 645 F. Supp. 2d at 191-92 (noting that Dr. Parisian could not name any standard that she was relying on to conclude that Merck had failed to adequately disclose something to physicians).

These opinions are inadmissible: courts have held that the question of (corporate) intent or motive is a classic jury question and not one for experts. *See, e.g., In re Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 546 (S.D.N.Y. 2004) (holding that expert testimony on motive or intent of corporations and regulatory agencies is inadmissible because it has no basis in any relevant body of knowledge or expertise and describes lay matters which the jury is capable of understanding without the expert's help); *In re: Diet Drugs*, 2000 WL 876900, at \*9 (E.D. Pa. 2000) ("If the witnesses' bases for the opinions concerning improper intent come from other evidence such as letters, admissions of AHP officers or employees, or other admissible evidence, *that* is what the jury should hear and the question of AHP's intent would flow from such evidence to be determined by the jury.").

The following are some examples of improper references to personal "bad company" opinions not based on any FDA regulation or other applicable standard. Dr. Parisian opines that "SAE reports of renal failure associated with aprotinin in this patient population will be under-reported by physicians. This increases the responsibility for Bayer to test and monitor the safety of Trasyolol and adequately update physicians about the potential risk." (Parisian Report at ¶ 233.) This opinion must be excluded because it is not based on any standard and amounts to no more than Dr. Parisian's personal opinion. In ¶ 250, Dr. Parisian merely restates an e-mail from Bayer's internal documents to support her opinion that Bayer had an "internal plan to obtain a negative statement against Mangano's findings from FDA." Not only does this statement lack any expert analysis, it improperly touches upon Bayer's motive and must be excluded. Finally, in ¶ 53, Dr. Parisian states "If adverse event reports did start to accumulate, recent public disclosures demonstrate that companies employed ghost-writers to publish contrary published

literature so that the company could point to ‘independent’ journal articles when questioned by FDA.” In their Response, Plaintiffs assert that this opinion “does not implicate Bayer at all.” (DE 3841 at 30 n.12.) Therefore, in addition to being a “bad company” opinion not grounded in expert analysis, this opinion has marginal relevance to the Case and should be excluded.

While finding that many of Bayer’s arguments were meritorious, based on the Motion alone, I was of the view that an FDA expert could be helpful to the jury. However, it was difficult to parse Dr. Parisian’s 250 page Report on a line by line basis, aided only by the written filings. The Report is broad and unwieldy: while each major opinion is followed by statements that are intended to provide the bases for that opinion, there is generally a striking disconnect between these statements and the major opinions. I felt that a *Daubert* hearing would best allow the Plaintiffs to establish the admissibility of Dr. Parisian’s testimony, opinion by opinion.

Additionally, I thought that a *Daubert* hearing would best allow me to strictly limit the permissible scope of Dr. Parisian’s testimony *pretrial* and avoid the problems faced by the Judge Wilson in *In re Prempro Prods. Liab. Litig.* There, the judge outlined the permissible testimony *pretrial* but came across substantial problems with Dr. Parisian’s testimony during trial. 554 F. Supp. 2d at 878-79. More specifically, the plaintiff asserted, as Plaintiffs here assert, that Dr. Parisian would opine about the information that the FDA requires and whether or not the defendant-company’s response was appropriate under FDA guidelines. *Id.* at 880-87. However, Dr. Parisian simply summarized documents without referencing FDA requirements or providing any expert analysis; on a motion for JNOV, the court determined that it should not have admitted or should have struck much of Dr. Parisian’s testimony. *Id.* (“Parisian often did nothing, or little, more than read exhibits. . . . [M]ost of Dr. Parisian’s punitive damages testimony should have

been excluded.”). Despite repeated sidebar conferences, Dr. Parisian continued to read lengthy passages from exhibits, offered testimony beyond her expert report, and failed to limit her testimony to any FDA regulations. *Id.*

I approached the *Daubert* hearing with these concerns in mind but was also open to the possibility that Plaintiffs could establish the admissibility of some of Dr. Parisian’s testimony.

### C. The *Daubert* Hearing

Dr. Parisian’s testimony at the six-hour *Daubert* hearing was problematic in various regards and intensified, rather than alleviated, my concerns. More specifically, when efforts were made to establish the foundation of her opinions, Dr. Parisian retreated into obfuscation and referenced irrelevant FDA regulations while refusing to answer questions. It was also apparent that her opinions were often inconsistent. Moreover, she considered evidence and formed new opinions the night before the *Daubert* hearing. Much of her testimony was based on her review of internal Bayer documents and lacked any valuable FDA expertise.

The following exchange between Mr. Beck<sup>27</sup> and Dr. Parisian exemplifies her unwillingness to answer questions directly.

- Q. I guess what you’re doing is you’re looking at studies and things like that, and you’re concluding whether there is reasonable evidence of a causal association of Trasyolol with renal failure, right?
- A. No, sir. I’m looking at the toxicology data and saying there were animal studies and there was information in the medical literature. I’m not an attorney.
- Q. Didn’t I just say the study? How is that different from my question?
- A. I don’t know. I’m not sure what your question is.

---

<sup>27</sup> At the *Daubert* hearing, Mr. Beck conducted the cross-examination on behalf of Bayer and Mr. Love conducted the direct examination on behalf of Plaintiffs.

- Q. You're looking at medical literature?
- A. Yes, sir.
- Q. And drawing a conclusion that the medical literature provides a reasonable evidence of potential causal association of Trasyolol with renal failure, correct?
- A. I am saying what I say there, that there is information –
- Q. Can you answer my question? Aren't you looking at medical literature and drawing the conclusion that it provides reasonable evidence of potential association, of potential causal association of Trasyolol with renal failure?
- A. Based on the information reviewed, that statement is there.
- Q. Can you answer my question?
- A. I am trying. . . . In that statement, yes, sir, because we're talking about reasonable evidence that extended from 1988 to around 2006 when it had become aware even to Bayer that there was potential renal failure. . . .
- Q. So again—I mean, what you've got in here, isn't it a back door causation opinion in the guise of talking about information available and regulatory affairs? You're drawing a causation conclusion that the medical studies showed reasonable evidence of causal association, right?
- A. I'm drawing a regulatory conclusion as to the type of information that should have been in the—information provided to physicians by 2006, 2007 in that paragraph.

(Hearing Tr. at 76:8-78:11.)

Instead of answering questions directly, Dr. Parisian often retreated to citing regulations that had marginal relevance to the issues being discussed.

An example of this occurred when Mr. Beck was cross-examining Dr. Parisian about her conclusion that Bayer should have taken actions based upon certain adverse event reports. Mr. Beck attempted to ask her about caveats published by the FDA stating that: (1) for any given report, there is uncertainty that the suspected drug caused the reaction because it could have been caused by the underlying disease, by concurrent drugs being taken, or by chance; (2) accumulated case reports can not be used to calculate incidence or estimates of drug use; and (3) true incidence rates can not be calculated from the Adverse Event Reporting Database. In response to the repeated question of whether it was her expert opinion that “once an adverse event report comes

to a drug company and they do whatever review they're supposed to do, that then there is certainty that the suspected drug caused the reaction?" Dr. Parisian simply cited to 314.80(b), which requires the manufacturer to review adverse drug experiences. (Hearing Tr. at 95:1-5.) She cited to that same regulation in response to the question of "Is there any FDA regulation or publication or anything in the world that you can cite to support this opinion that you've been expressing today that somehow the adverse event reports when they're sitting in the database maintained by a manufacturer are a completely different animal from when they're maintained by the FDA?" (Hearing Tr. at 96:22-97:97:2.) The following exchange ensued between Mr. Beck and Dr. Parisian.

- Q. Are you claiming that the true incidence rates can be calculated using the adverse event report database maintained by manufacturers?
- A. By a manufacturer, yes. By FDA, no.
- Q. Where in the world, anywhere, regulation, article, letter to the editor, where in the world does anybody else agree with you on that point?
- A. It's 314.80. That's why manufacturers update their labeling with safety signals that they identify as pharmacovigilance.
- Q. That language we just looked at, right?
- A. 314.80, yes.
- Q. (b)?
- A. (b). The whole thing. And then you also have 314.82, which is the annual report. . . .
- Q. Okay. Would you just sort of read it along and tell me where you get to the point where it says that the adverse report information can be used to calculate true incidence rates if it happens to be maintained by the manufacturer?
- A. All right. It would be in the annual report, 314.80, I guess that's 2i. 2i? Manufacturers' required to provide a brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug.
- Q. And you pretend that that is a statement in the regulations that true incidence rates can be derived from adverse event reports that are maintained in the manufacturers' database even though they can't if they're maintained in the FDA's database? That's what you claim, as an expert, in support for that.
- A. Yes, sir. I still do. They're totally different databases.

(Hearing Tr. at 100:11-102:17.)

In addition to evading questions about her opinions, Dr. Parisian offered opinions at the *Daubert* hearing that differed from the opinions she offered at her deposition and from those contained in her Report.

For example, when Mr. Love asked Dr. Parisian whether Bayer should have initiated a “changes being effected” (“CBE”) label under regulation 314.70 in response to the findings of the Kress study, she responded, “Yes, because this is a new issue about renal safety.” (Hearing Tr. at 40:7-14.) When I asked Dr. Parisian where such an opinion is located in the Report, she cited to page 165, under the heading “Bayer delays in providing FDA with safety studies about Trasyolol showing increased risk of mortality.” (Hearing Tr. at 41:18-20.) When I pointed out that this was a different opinion, Dr. Parisian finally admitted that her Report only contained the opinion that “they delayed and that they didn’t provide it [Kress study] to the FDA,” and not that Bayer should have submitted a CBE.<sup>28</sup> (Hearing Tr. at 42:5-6.)

Furthermore, Dr. Parisian offered opinions based on audio from a cardiac team meeting that Dr. Kelly, Mr. Morrill’s surgeon, attended, which she first listened to just a day before the *Daubert* hearing. (Hearing Tr. at 69:1-2.) While Mr. Beck stated that Dr. Parisian had not disclosed any opinions about the cardiac team meeting before the *Daubert* hearing, Mr. Love claimed that “with the right foundation this is the type of testimony that she could opine on about the messages Bayer was disseminating to physicians.” (Hearing Tr. at 64:10-13.) After playing

---

<sup>28</sup> When asked at her deposition whether Bayer should have submitted a CBE under 314.70 to put Kress in its label, Dr. Parisian responded, “No. What I’m saying is that they should have in some capacity informed the FDA. And they should have updated their warnings. They could use a CBE. They could use just a regular NDA supplement.” (Parisian Dep. at 284:4-13.)

the audio, Mr. Love asked Dr. Parisian “what was the take-home message that Dr. Kelly received just two weeks before Mr. Morrill’s surgery?” (Hearing Tr. at 64:21-23.) Dr. Parisian responded that “The presentation was stating that it was safe to use aprotinin, that it always gets better if you see some renal function change.” (Hearing Tr. at 65:2-4.) The following exchange ensued between Mr. Love and Dr. Parisian.

- Q. Based on the evidence you’ve seen in this case, is the message that Dr. Kelly heard two weeks before Mr. Morrill’s surgery consistent with what Bayer knew about the safety problems of Trasylol in 2003?
- A. Not from the documents reviewed. No, sir.
- Q. Is the message that Dr. Kelly received false?
- A. yes, sir.
- Q. Is that message accurate?
- A. No, sir.
- Q. Is that message misleading?
- A. Yes.

(Hearing Tr. at 65:6-16.) Aside from the major problem that Dr. Parisian only listened to the audio the night before the *Daubert* hearing and formed new opinions not otherwise disclosed in her Report or deposition, this opinion lacked regulatory analysis and did not require any regulatory expertise.

In fact, much of Dr. Parisian’s testimony at the *Daubert* hearing did not involve any regulatory analysis and instead consisted of conclusions made from a review of the regulatory history and Bayer’s internal documents. For example, when asked by Mr. Love “What is your understanding of why it [Kress] was disclosed” for the first time in November of 2006, Dr. Parisian responded

After the FDA became aware—well, from the documentation reviewed, after the FDA became aware of the i3 study, there was a conference call of a discussion between the FDA and the company. The FDA, Dr. Mills, particularly, asked if there were any other studies that Bayer needed to provide to the FDA. And so it was included in the formal

submission to the FDA in November, the listing of the Kress study, the St. George study was actually provided.

(Hearing Tr. at 55:9-17.) Dr. Parisian proceeded to provide the regulatory history based on her reading of the documents without any significant regulatory analysis, referencing an FDA safety alert as well as the contents of Trasylol's 2006 label.

An instance I found particularly egregious was Dr. Parisian's apparent effort to construct a factual scenario, entirely divorced from any regulatory expertise, to support the Plaintiffs' theory as to Bayer's knowledge. The trial for the *Morrill* case was set to begin two weeks after this *Daubert* hearing. Mr. Morrill's surgery had taken place on October 3, 2003, so it was desirable for the Plaintiffs to show that Bayer had knowledge of the results of the Kress study prior to that time.

On direct examination, Mr. Love asked Dr. Parisian when the Kress study was completed, and she responded that "according to the document provided to the FDA from Bayer, it was completed in 2002." (Hearing Tr. at 30:2-3.) She then mentioned that she "saw a seventh draft of the report in 2003." (Hearing Tr. at 30:5.)

On cross-examination, Dr. Parisian repeated her claim that the evidence indicated that the Kress study had been completed in 2002, prior to Mr. Morrill's surgery. (Hearing Tr. at 110:20-23.) When asked whether this contention had been disclosed in her Report, she responded: "I don't know if it is or not. It was disclosed to the FDA as 2002." (Hearing Tr. at 110:25-111:1.) On further cross-examination, she admitted that the only basis she had for concluding that the Kress study had been completed in 2002 was a listing on an attachment to a letter dated November 10, 2006 titled "Investigator Initiated Studies 2001 to 2006," which contained a "Study

Number 2002-024” corresponding to the Kress and Stone study. From that sole reference, Dr. Parisian concluded that although the draft report was dated November, 2003, after Mr. Morrill’s surgery, the study was completed in 2002, before the surgery. (Hearing Tr. at 112:15-22.)

None of this was disclosed in Dr. Parisian’s Report, and her conclusion surely does not involve any regulatory expertise. But even more troubling is her willingness, indeed eagerness, to advance the conclusion at all. The number, standing alone, tells us little, if anything, about when the study was completed. It is a basis for beginning an inquiry, not ending one. The most likely explanation for the number, particularly in view of the 2003 draft, is that the number reflects the date the study was initiated. Dr. Parisian’s willingness to offer “expert” opinion on such flimsy evidence and withhold any disclosures in advance is simply astonishing.

Instead of providing regulatory analysis, Dr. Parisian repeatedly arrived at conclusions based on her interpretation of Bayer’s internal documents. For example, during re-direct examination, Mr. Love showed Dr. Parisian a Bayer e-mail, asked her to read a portion he had highlighted, and then asked:

- Q. With respect to the date of this document, which is April 2003, what is your take-away with respect to how Dr. Kress feels about the conclusions in his study?
- A. He’s not happy with his conclusions.
- Q. Okay. And does he—well, read that sentence I’ve underlined again.
- A. ‘And feels the answer to the proposal question has already been shown in the preliminary analysis of their database.’ So he feels that his data is done.
- Q. Would that suggest to you that Bayer was in possession of his analysis?
- A. Yes.

(Hearing Tr. at 156:25-157:11.) Based on an e-mail between two Bayer employees, Dr. Parisian offered her “takeaway” about another person’s state of mind, whether he had reached a final conclusion, and whether Bayer was in possession of his analysis, all in the guise of regulatory

expertise.

When Mr. Beck pointed out sections of Dr. Parisian's Report that merely summarized Bayer's documents and testimony, Dr. Parisian refused to admit that these sections did not require regulatory expertise and lacked any regulatory analysis. The following exchange was typical:

- Q. And there is no regulatory expertise that's either required or utilized in your summary of Dr. Rozycki's testimony [Parisian Report at ¶ 30], is there?
- A. Yes, there is. Those three studies should have been provided to the FDA.
- Q. No, no, no. This sentence just says, 'According to Dr. Rozycki, the following three studies were not provided.' Now that statement where you're summarizing his testimony, that doesn't call for anything other than somebody who can read his testimony, right?
- A. Well, no. It does take someone who can read his testimony and knows what the issue is about; the issue is about information being provided to the FDA.
- Q. Your factual narrative here where you're describing his testimony, all-anybody can describe his testimony, they don't have to be a former FDA person, right?
- A. Not in the context in which it's being given. This is FDA based on my training and experience and looking at Bayer documents.

(Hearing Tr. at 82:23-83:16.) Similarly:

- Q. And let's look at Page 146 of your report. Down here at the bottom of the page with the heading in bold "h," it says: 'Bayer's internal plan to obtain a negative statement against Mangano's findings from FDA.' Now—and then you, underneath that heading about Bayer's internal plan, you quote from a single e-mail, right?
- A. Yes, sir.
- Q. And all this is, is your or the lawyer's who hired you, your factual conclusion about what the evidence shows about what Bayer's plan was, right?
- A. It was a statement from the e-mail internally and it's within a section with a heading.
- Q. There's no regulatory expertise required to make this argument about what the evidence shows, is there?
- A. Yes, sir. In terms of the context in which this is in a list of documents that have been reviewed.

(Hearing Tr. at 103:10-25.) Dr. Parisian refused to acknowledge that her testimony was not related to any regulatory expertise and that it merely restated and drew conclusions from

documentary evidence; she made no efforts to confine her testimony to the area in which she allegedly does have expertise: the FDA regulatory scheme.

Problematic testimony such as that outlined above caused me to have the following impressions at the *Daubert* hearing:

[T]here are a number of aspects about this that bother me. . . . The approach of laying out all these facts but never really discussing in any specifics an opinion is problematic. At least from the snippets I saw, it sounds like she elaborated a fair amount in her deposition from what she said in her report, and then today came with some new things that weren't in either one. And so I do think there's a problem with figuring out exactly what she plans to say to a jury, which causes me real concern. . . . I also found, particularly in cross-examination, she wouldn't answer a question. She just wouldn't answer Mr. Beck's questions . . . [S]he just refused to answer and repeated the same thing. . . . [I]t just didn't seem like there is ever then an opinion. And the other part of it is, all this, there is a lot of editorializing about motive, intent, whether somebody is behaving properly or not behaving properly without—you can't figure out quite where she is coming in arriving at these conclusions. . . . And aren't we entitled to know what the conclusion is or how she gets from the Kress study to an overall failure? I just don't see that logical progression in this. . . . There are a lot of facts and then there are these conclusions at the end, and I don't see the logical progression that's helpful to the jury. . . . I mean, one possibility would be for me to go through the opinions and just say yes or no. But I'm not sure that gets us—you know, he cross-examined on 10 for example, which is on Page 207. And I just don't see how you can give that opinion. I don't understand where that opinion comes from or how she's qualified to make it. Same thing with 11, and same thing about 12. . . . I guess I don't see where an FDA expert talking about FDA regs can come to that conclusion [discussing Opinion 12]. Opinion 11 . . . There she is testifying about what Bayer is aware of, and despite interaction—that opinion doesn't, to me, proceed from any expertise that she brings to bear. . . . [T]he question is whether the label should have been changed. And the ingredients in that, I can see how somebody could make, could come to a conclusion, but I don't understand from what I've seen, her thought process. I mean, that expert has to have a basis for opinions. It has to be helpful to the jury. You can't just say here are a lot of facts and I conclude that Bayer violated the standard of care. I mean, there's got to be—there's got to be a Step A, B, C. And I haven't seen it so far in this report. . . . You can't just regurgitate all the facts you know and then come to a conclusion. Because then there's no way to examine how she arrived at it. She doesn't explain it. She didn't today. . . . [S]ome of these studies might mean something, others might not. They might mean this, they might not—I mean, a jury doesn't understand that. I don't understand it. I don't know how to tell one study from another. And I am not convinced she does based on what I heard today. I know she knows about all these studies. She knows that they

were—they came out and that there were studies. But is her opinion that everything should have been included in the label? . . . [A]t least if you're an expert and you're going to say why the label is inadequate—say a little bit more than—you know, how would you have dealt with it.

(Hearing Tr. at 167:21-211:23.)

### III. Analysis

Based on a thorough review of Dr. Parisian's Report, deposition, and her testimony at the *Daubert* hearing, I find that Dr. Parisian's expert testimony must be excluded in its entirety pursuant to Rule 702 and the analysis under *Daubert*. Even assuming that Dr. Parisian is qualified to testify as to the FDCA and the FDA regulatory scheme as it applies to pharmaceuticals, I find that her testimony is due to be excluded for two major, independent reasons.<sup>29</sup> First, most of her testimony will not assist the trier of fact to understand the evidence or to determine a fact in issue. FED. R. EVID. 702. Second, I find that Dr. Parisian's opinions are unreliable. *Id.* Plaintiffs, although given plenty of chances, have failed to establish, by a preponderance of proof, the reliability and admissibility of any of Dr. Parisian's opinions in their submissions to the Court or in their direct examination of Dr. Parisian at the *Daubert* hearing. While there is a proper place for expert testimony with respect to FDA regulations in this Case, Dr. Parisian is not an appropriate witness for this testimony.

---

<sup>29</sup> While I could have allowed Dr. Parisian to testify as to the FDA regulatory scheme generally and a pharmaceutical manufacturer's obligations under that scheme, admitting this testimony would provide a relatively low value to the trier of fact but would present a great risk. In the past, courts have had trouble limiting Dr. Parisian's testimony, despite her and the plaintiffs assurance, that she would not exceed its proper scope. *See In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871 at 879-87. Dr. Parisian also demonstrated at the *Daubert* hearing that she was unable or unwilling to connect her opinions to any valuable regulatory expert analysis and opined on matters that were far beyond her expertise. *See* Section II.C. of this Order for some highlights.

**A. Lack of Assistance to the Trier of Fact**

Most of Dr. Parisian's testimony will not assist the trier of fact because she makes no effort to confine it to her area of expertise: the FDA regulatory scheme. As stated in Section II.B. of this Order, while the Report cites to some FDA regulations, it mostly consists of a factual narrative of Trasyolol's regulatory history and summaries of Bayer's internal documents. Dr. Parisian does not analyze the facts; she, in the words of the *Prempro* court, regurgitates them and reaches conclusory opinions that are purportedly based on these facts. These facts should be presented to the jury directly; Dr. Parisian assumes the role of Plaintiffs' advocate in her presentation of the facts and invades the province of the jury. In addition to restating the facts, Dr. Parisian makes conclusory opinions regarding Bayer's and the FDA's state of mind and knowledge based on her reading of internal Bayer documents and FDA correspondence. The jury can infer intent from this evidence directly: Dr. Parisian, as an FDA expert, is neither able nor allowed to assist the jury in this regard.

For example, according to Opinion #4,

Bayer failed to perform clinical testing necessary to support a new indication for benefits of full dose Trasyolol versus half dose Trasyolol in terms of effects on kallikrein and Systemic Inflammatory Response Syndrome (SIRs). As stated by Bayer's Dr. Horton, Bayer never conducted clinical studies to obtain FDA's approval for that new indication. Rather Bayer slipped information into its product insert's mechanism of action section to help allow it to promote a benefit for full dose Trasyolol to physicians that did not have FDA's approval.

(Parisian Report at 55.) This opinion does nothing more than rely on Bayer's internal documents to improperly opine on Bayer's motive.<sup>30</sup> While Dr. Parisian concludes that Bayer failed to

---

<sup>30</sup> Opinions #9, #10, #11, and #12 suffer from the same flaws. Opinion #9 states, in part, that "Despite FDA's safety concerns for the public, Bayer continued to expand the Trasyolol sales force and provided training and sales aids designed to help minimize the risks of Trasyolol for

perform clinical testing, she does not refer to any regulation and does not explain how she reached this conclusion. The section supporting this opinion does not do so either. Instead, it contains pure factual narrative regarding Trasylol's regulatory history and improper references to the FDA's knowledge and intent.<sup>31</sup> No connection is made between that history, which contains no regulatory analysis and can be presented to the jury directly, and the conclusions reached in Opinion #4. Therefore, I can not see how this testimony would assist the trier of fact. (Parisian

---

physicians." (Parisian Report at 100.) Opinion #11 states, in part, that "Bayer was aware that despite its promotion of the full dose regimen, it had not tested, labeled or adequately warned physicians of the increased dose-dependent risks of the full dose when compared to the half dose." Opinion #12 states "Despite FDA's concerns about public safety, Bayer continued to train its sales representatives and Medical Science Liaisons (MSL) in methods to minimize the life-threatening risks of aprotinin to health care providers." As support for these opinions Dr. Parisian employs the same tactic: relying on Bayer's internal documents to infer Bayer's motives or knowledge. For example, under the sub-section "Bayer's internal plan to obtain a negative statement against Mangano's findings from FDA," Dr. Parisian simply summarizes an e-mail between Bayer insiders and fails to include any regulatory analysis whatsoever. (Parisian Report at ¶ 250.) See also Parisian Report at ¶ 280, ¶ 275, ¶ 328 (cleverly attempting to invoke Bayer's intent without seeming to do so by stating "If Bayer's Global Drug Safety has a strategy to reduce reports of renal failure . . . that is the effect of not investigating cases or looking for larger safety trends.") (emphasis added), 230 ("Bayer had a business plan to 'exploit' Trasylol for new indications"), 235 ("Bayer's sales force attend workshop sessions designed to handle common physician safety objections to Trasylol"), 241 ("Despite FDA's concerns about public safety Bayer sought to minimize risk"), 243 ("Bayer internally was aware compa[r]ison claims could not be made without supporting clinical data").

<sup>31</sup> For example, under the sub-section "FDA places a hold on Trasylol launch materials," Dr. Parisian states "In the PITCH LETTER, FDA indicated that a 'fair balance statement must be added to this letter. The letter extols the virtues of Trasylol without revealing any [of] the risks.' FDA suggested adding anaphylaxis and renal dysfunction statements. Miles suggested that the statement 'please see full prescribing information' provided fair balance. FDA indicated that this was not enough. Miles agreed to add in a fair balance statement." (Parisian Report at ¶ 150.) Under the sub-section "FDA's DDMAC letter to Bayer for false & misleading promotion," Dr. Parisian summarizes the contents of DDMAC's letter to Bayer, commenting on DDMAC's considerations and concerns. (Parisian Report at ¶ 153.) Dr. Parisian was not a percipient witness to these events; her summary, devoid of expert analysis relevant to the Opinion that this sub-section is intended to support, will not assist the trier of fact.

Report at 55-99.)

Dr. Parisian's Report is replete with such improper references to Trasylol's regulatory history and Bayer's internal documents and FDA correspondence. While Plaintiffs argued that the presentation of such facts is necessary, as they are connected to Dr. Parisian's opinions, Dr. Parisian's major role in this litigation appears to be that of Plaintiffs' advocate rather than expert. Her expertise is not required to present the factual narrative to the jury, and she has no expertise that allows her to infer Bayer's and the FDA's knowledge and intent and present those inferences to the jury. Therefore, Dr. Parisian generally does not offer testimony involving "scientific, technical, or other specialized knowledge" that would assist the trier of fact to understand the evidence or to determine a fact in issue. FED. R. EVID. 702.

#### **B. Unreliability**

Based on a thorough review of Dr. Parisian's Report and her *Daubert* hearing testimony, I find that she generally takes a collection of facts, imputes motive and knowledge, and draws unsupported conclusions unrelated to any regulatory expertise.<sup>32</sup> Dr. Parisian could not adequately explain her analysis or methodology, neither in her Report, nor at the *Daubert* hearing. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected

---

<sup>32</sup> At the *Daubert* hearing, Mr. Love argued that Dr. Parisian's Report "lays out a chronology, and there are key opinions that she has that are based upon those facts in the chronology. That's what an expert does." (Hearing Tr. at 9:12-14.) While it may be that the key opinions are based upon those facts, Dr. Parisian's Report and testimony lack a very important link: the connection between the facts and the key opinions, or in other words, the expert analysis.

to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.”) (internal citations omitted). All of Dr. Parisian’s opinions suffer from this fatal flaw: she recounts Trasylol’s regulatory history, the contents of Bayer’s internal documents and e-mails, and the findings of scientific studies; she then offers a broad opinion, often outside her scope of expertise, that is not connected to the underlying facts in any apparent way and that lacks regulatory expert analysis.

Opinion #10 is a prime example.

As testified to by Dr. S. Horton in April 2009, Bayer utilized well-planned and coordinated communication schemes and sales representatives and key opinion leader training to ‘exploit’ Trasylol as Bayer’s ‘wonder drug.’ As part of Bayer’s Business Plan, it viewed use of publications, supplements, abstracts, health care provider continuing medical education, and Key Opinion Leader presentations at professional meetings as Promotional Programs intended to reinforce Bayer’s message to use Trasylol at full dose (Hammersmith Regimen). The full Hammersmith dose was promoted as safe and with additional benefits. The use of the full dose, however, was an ‘organizational driver’ for Bayer and potentially less safe than the half dose Trasylol regimen.<sup>33</sup>

(Parisian Report at 207.) At the *Daubert* hearing, Mr. Beck cross-examined Dr. Parisian on this Opinion.

- Q. Now, this is 100 percent your spin or the lawyers who hired you spin on Bayer’s marketing approach and business plan, right?
- A. This is my opinion based on my review of documents.
- Q. Well, it’s certainly not based on FDA regulations, is it?
- A. It’s based on Dr. Horton’s testimony—if you’re talking about those quoted words, those are—
- Q. It’s not based on FDA regulations is it?
- A. It’s based on communications because—in terms of misbranding this information feeds into that type of information.
- Q. It’s not based on FDA regulations, is it?
- A. Yes, sir.

---

<sup>33</sup> Despite opinions such as this one, Dr. Parisian testified that she did not make any statements about Bayer’s state of mind or intent. (Hearing Tr. at 163:20-25.)

- Q. What FDA regulation is this opinion of yours based on?
- A. It would be based on 21 CFR 202.1.
- Q. How is that relevant—
- A. In terms of—
- Q. — to this opinion?
- A. To this opinion, this is discussing advertising, promotion materials to physicians. So it would be directly related to 201–202.1.
- Q. Well, 202.1, again, that sets forth some kind of standard, right?
- A. It is what the FDA—yes, I guess you would call it a standard. Yes, sir.
- Q. And this paragraph doesn't set forth the standard; this paragraph sets forth the closing argument about what the lawyers think the evidence shows, right?
- A. No, sir.
- Q. Well, where does it say anything about a standard in there under whatever it was, 202.1?
- A. In the intro I discuss—
- Q. In this Opinion No. 10.
- A. Oh. Well, the section following it discusses all the information that fed into that opinion, to support that opinion.
- Q. Oh, more factual discussions. Where—I'm saying—you claim this opinion has something to do with Section 202.1. Show me.
- A. Well, in terms of bases for Opinions 10 through 12, this is supporting that opinion. And the discussion in the very beginning was about 202.1, the requirements for advertising to—
- Q. We're back into the boilerplate cut and paste stuff now?
- A. It's not—yes, sir. We are.
- Q. Okay. Well, let's stick with Page . . . 207 rather than the cut and paste summary of the regulations. As I said, I understand that as somebody who worked at the FDA, you can help someone find the standards that apply, but that's not what you're doing in Opinion No. 10. What you're doing in Opinion No. 10 is drawing factual conclusions from testimony and documents and business plans where you're purporting to conclude that they violated the standard, right?
- A. No. I'm reviewing documents about marketing, and I've already set the standard in the cut and paste section as to what a manufacturer's required to do.
- Q. And now you're saying they didn't do it?
- A. And I'm giving examples to support the opinion.

(Hearing Tr. at 85:14-87:22.) While Dr. Parisian referenced a regulation that was allegedly included in the general, introductory section of her Report, this regulation is not discussed in the section “Bases for Opinions #10 - #12”; Dr. Parisian does not analyze the facts under this regulation to arrive at Opinion #10.

The same can be said of Dr. Parisian's remaining opinions. For example, Opinion #1 deals with Bayer's failure to "test, monitor, update and warn FDA about the post-operative risks of aprotinin (Trasylol) which included renal failure, thrombosis, and death," while Opinion #2 deals with Bayer's failure to update its product insert and promotions, warn physicians, and provide adequate large clinical trials. (Parisian Report at 24.) While Dr. Parisian references 21 U.S.C. § 352 and 21 CFR § 201.5 in Opinion #2, the section "Bases of Opinions #1 & #2" does not analyze Bayer's actions under the cited statute and regulation but rather provides a general background on the FDA process and the role of the FDA. Despite the heading, the section in no way provides an adequate basis for the opinions it is intended to support: the section does not even discuss Bayer's actions with respect to Trasylol, and certainly does not discuss how and why Bayer violated its duties under the relevant statute and regulation.<sup>34</sup> (Parisian Report at 24-55.)

On the rare occasion where Dr. Parisian states that Bayer violated a specific regulation with some specific action, she fails to explain why that regulation was violated. For example, Dr. Parisian opines "There were medical literature reports that Bayer should have been aware of for nephrotoxicity with APROTININ before its 1993 NDA approval. Bayer was required by 21 CFR 314.50 to have provided those reports to FDA in its marketing application. . . . However, instead of providing the information to FDA and physicians, Bayer sought to remove the information

---

<sup>34</sup> The same can be said of Opinion #3, which refers to Bayer's failure to "adequately perform clinical testing and monitoring of the safety and efficacy of Trasylol administration in complex CABG patient populations despite its awareness of potential negative post-operative renal effects, thrombosis and death." (Parisian Report at 55.) The section that supposedly supports this opinion is replete with narrative history; Dr. Parisian does not discuss any specific regulations and does not explain in any way how or why Bayer failed to adequately test and monitor the safety of Trasylol administration in complex CABG patient populations. (Parisian Report at 55-99.) Regulatory analysis—the critical link between the facts and the broad conclusions they are intended to support—is missing.

from Micromedex and pharmacists.” (Parisian Report at ¶¶ 283-284.) While quick to infer Bayer’s knowledge and bad motives from internal e-mails, Dr. Parisian fails to explain why Bayer violated 21 C.F.R. § 314.50: the critical link between the existence of the studies and the conclusion that a regulation was violated is missing from Dr. Parisian’s Report and testimony. At other times, Dr. Parisian opines that Bayer behaved inappropriately but fails to cite to any FDA standard that is violated. For example,

Bayer’s undisclosed involvement in the Dr. Royston letter to the editor was false and misleading as well as inappropriate. The information Bayer provided was not fair and balanced when Bayer’s role in the crafting and sign-off of the letter was not fully and accurately disclosed to physicians by Bayer’s primary Trasylol KOL. Furthermore, the Kincaid article raised serious safety issue for Bayer regarding combination use of ACE inhibitors and aprotinin. The responsibility of Bayer to follow-up on the Kincaid work was even more important to public safety due to the common prescription of ACEI drugs to cardiac patients undergoing CABG.

(Parisian Report at ¶ 294.) It is difficult to locate the regulatory analysis that Dr. Parisian purports to offer in these statements. *See also* Parisian Report at ¶ 348 (“Bayer had become aware of the contents of the Mangano manuscript in October 2004. Therefore, it was false and misleading in January 2006, to tell Bayer’s sales representatives to convey to physicians that Bayer had ‘just become aware of this manuscript.’ Bayer had first learned about the information . . . from Dr. Rosyton.”), ¶ 352 (“The letter also has misleading information about the anti-inflammatory benefits of full dose Trasylol to help justify the beneficial use of full dose when compared to a half-dose.”), ¶ 392 (“A reasonable pharmaceutical manufacturer with a concern for patient safety would have pursued studies regarding the renal effects long before March 2006. Bayer’s safety study was undertaken to help refute or discredit Dr. Mangano’s renal failure and risk findings.”).

Furthermore, some of Dr. Parisian’s opinions are unreliable because they are purely

speculative. According to Opinion #6,

Bayer failed to fully disclose to FDA prior to September 2006 that it had sponsored a pharmacoepidemiological safety study conducted by i3 to address risks of renal failure, thrombosis and death. Bayer delayed in providing FDA with i3 initial results until after FDA's September 2006 Advisory Panel meeting had been held about the safety of Trasylol. Bayer's actions denied FDA an opportunity to reschedule its Advisory Panel meeting until after it had received and reviewed the i3 data. The outcome of the meeting would have been different, and in fact label changes did later result as a consequence of the i3 data.<sup>35</sup>

(Parisian Report at 99.) Dr. Parisian was not a percipient witness to these events and is engaging in pure speculation as to the alternative outcome of a certain FDA meeting without providing any regulatory expertise or analysis.

While I have not discussed my concerns with the reliability of each of Dr. Parisian's opinions, the major problem identified—the lack of analysis or connection between the facts and the opinions—persists throughout Dr. Parisian's Report and *Daubert* testimony. I therefore find that Dr. Parisian's testimony must be excluded in its entirety. Plaintiffs have failed to meet their burden of establishing the reliability of Dr. Parisian's testimony by a preponderance of proof.

#### IV. Conclusion

Plainly stated, Dr. Parisian is an advocate, presented with the trappings of an expert but with no expectation or intention of abiding by the opinion constraints of Rule 702. She comes armed with a Report designed to be broad enough to allow her to gather and stack inference upon

---


<sup>35</sup> See also Parisian Report at ¶ 311 (“Upon learning of the availability of a future Bayer epidemiological safety information, FDA would have at least had an option to reschedule the Advisory Panel meeting for aprotinin until after the Agency had time to review the i3 Drug Safety study information in terms of its relationship to the findings of Mangano and Karkouti. By Bayer failing to even inform the FDA of the i3 study, Bayer took away FDA's options about when to have the meeting.”).

inference in order to offer her “takeaway” or “take home message” with respect to intent, knowledge, or causation in a manner unrelated to any regulatory expertise. Her testimony is unreliable and would not be of assistance to the jury.

Accordingly, it is hereby

**ORDERED AND ADJUDGED** that Bayer’s Motion to Exclude Testimony of Plaintiffs’ Expert Suzanne Parisian (DE 3065) is **GRANTED**. Dr. Parisian’s testimony shall be excluded in its entirety.

**DONE AND ORDERED** in Chambers at West Palm Beach, Florida, this 27 day of April, 2010.



DONALD M. MIDDLEBROOKS  
UNITED STATES DISTRICT JUDGE

Copies to: Counsel of Record