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 F. GARY TOBACK

THIS CAUSE comes before the Court upon Defendants' (hereinafter, collectively, "Bayer's") Motion to Exclude Testimony of Plaintiffs' Expert F. Gary Toback[1] ("Motion") (DE 3063), filed on December 17, 2009. Plaintiffs filed a Response (DE 3859), to which Bayer replied (DE 4105). I 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 in part and denied in part.

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

[1] Dr. F. Gary Toback received an M.D. degree from New York University in 1967 and a Ph.D. in Biochemistry from Boston University in 1974. He is certified by the American Board of Internal Medicine, Subspecialty in Nephrology, and the National Board of Medical Examiners. He is currently a practicing clinical nephrologist and Professor of Medicine and Cell Physiology at the University of Chicago. (Toback Report at 1).

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.*, No. 7:06-129-DCR, 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.[2] 509 U.S. at 593-94

[2] 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

(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.

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

---

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).

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 & Analysis

Dr. Toback's Report contains a summary of his opinions:

- Aprotinin[3] negatively impacts renal function both functionally and structurally.
- Numerous studies and analyses over the last two decades establish that Aprotinin increases the risk of renal impairment and acute renal failure.
- Dialysis may be needed when patients experience renal failure due to an accumulation of salt, water and potassium in the body which can result in severe health consequences for the patient.
- Renal impairment and acute renal failure can have long term effects on patients including increased mortality, infections, sepsis, permanent decreased kidney function and other long term problems.

(Toback Report at 2-3). Bayer moves to exclude Dr. Toback's expert testimony with regard to opinions proffered on the following subjects: (1) Trasylol could cause renal failure, and the physiological mechanism for this relationship;[4] (2) Bayer's failure to compare Trasylol to Amicar (aminocaproic acid) and tranexamic acid; (3) information that should have been included in Trasylol's labeling; (4) Bayer's and the FDA's knowledge, state of mind, and motive; (5) Bayer's withholding of adverse event reporting data from the FDA; and (6) a factual narrative regarding what happened at the FDA Advisory Committee meeting.

Bayer's arguments in support of exclusion and Plaintiffs' arguments against exclusion, as well

---

[3] Trasylol is also known as Aprotinin. The Court will use these terms interchangeably.

[4] Although Bayer states that it seeks to exclude Dr. Toback's testimony "about the mechanism through which Trasylol purportedly causes renal failure," Bayer also states that fundamental flaws require exclusion not only of Dr. Toback's "mechanism" testimony, but also his opinion on general causation. (DE 3063 at 2-3).

as the Court's decision, are organized into these six categories below.

A. Trasylol could cause renal failure, and the physiological mechanism for this relationship

Plaintiffs offer Dr. Toback to testify that "Aprotinin increases the risk of renal impairment and acute renal failure." (Toback Report at 2). Furthermore, he would opine that aprotinin could cause renal failure through "functional" and "structural" adverse effects on the kidneys. (Toback Report at 4). As to the functional effect,

> When Aprotinin inhibits production of vasodilators, the afferent arterioles become more responsive to 'vasoconstrictors' which narrow the vessels so less blood is delivered to the glomeruli. Reduced glomerular filtration . . . is the result. . . . In this way Aprotinin acts on kidney blood vessels to reduce glomerular filtration rate (GFR) and renal blood flow (RBF). Severe reductions of these hemodynamic functional parameters can result in renal ischemia (insufficient oxygen delivery to kidney cells) and the subsequent development of kidney injury/renal failure.

(Toback Report at 5).

As to the structural effect,

> [S]ufficient Aprotinin delivered to the kidneys by infusion during cardiac surgery could engorge the phagolysosomes and cause renal cellular injury. . . . The renal changes induced by Aprotinin observed in animals were interpreted as easily reversible, but this may be a consequence of the capacity of injured and necrotic tubular cells to be capable of rapid regeneration.

(Toback Report at 6-8).

Additionally, Dr. Toback states in his report that Trasylol has a prothrombotic effect that could adversely affect renal function. (Toback Report at ¶ 16).

Bayer argues that Dr. Toback's general causation and mechanism testimony must be excluded because: (1) the three proffered mechanism theories are admittedly speculative and not based on reliable data; and (2) Dr. Toback cannot identify a threshold level at which Trasylol is toxic. (DE

3063 at 2-3).

According to Bayer, Dr. Toback's first mechanism theory (the functional effect) is supported by only one rat study (Seto), which cannot prove causation in humans. (DE 3063 at 4). Dr. Toback's extrapolation from a single rat study is especially problematic because another study (Schweizer), not mentioned in Dr. Toback's Report or deposition, found that Trasylol had no effect on renal blood flow in humans. (DE 3063 at 4-5). Furthermore, Bayer argues that the rat study does not support Dr. Toback's theory because he conceded that the reduction in filtration did not trigger acute renal failure. (DE 3063 at 5).

According to Bayer, Dr. Toback's second mechanism theory (the structural effect) is also speculative because it is supported by one human study. The cited animal studies cannot show causation in humans. (DE 3063 at 6).

Similarly, the third mechanism theory (the prothrombotic effect) is only supported by one study (Sundt), the results of which are questionable. (DE 3063 at 7).

Plaintiffs respond that neither *Daubert* nor the Eleventh Circuit require that a mechanism of action be known to a certainty in order for general causation testimony to be reliable.[5] (DE 3859 at 6, 10-15). Furthermore, Dr. Toback's testimony on Trasylol's biologically plausible mechanisms of action is based upon sufficient data and *not* unreliable simply because: (1) it is partially supported by

[5] According to Plaintiffs, Bayer's argument to the contrary is both factually and legally flawed. "Dr. Toback is basing his causation opinion upon multiple, consistent, peer-reviewed epidemiological studies producing scientific evidence of an association between Trasylol and renal injury. . . . In this case, a biologically plausible mechanism of action is merely one (of several) factors supporting Dr. Toback's view that the scientific data finding an association supports a conclusion of causation–it is not the sole basis for causation as was the case in *McClain*." (DE 3859 at 13-14).

animal studies, the importance of which has been recognized by courts;[6] (2) Bayer contests the quality of one supporting study (Sundt); and (3) Dr. Toback cannot establish a threshold dose at which Trasylol causes renal failure.[7] (DE 3859 at 15-22).

Bayer replies that flawed studies bear on the admissibility of Dr. Toback's mechanism of action testimony because they reflect an improper methodology.

Bayer also replies that Dr. Toback's general causation opinion is inadmissible because he does not provide a biologically proven mechanism connecting Trasylol to renal failure; Plaintiffs' argument that biological plausibility is sufficient to prove causation has been rejected by the Eleventh Circuit. (DE 4105 at 2-3). Furthermore, Dr. Toback does not compensate for a lack of proven mechanism: he has not applied the Bradford Hill criteria or considered the totality of the scientific literature before forming his general causation opinion. (DE 4105 at 5).

I find that Plaintiffs have established, by a preponderance of proof, that Dr. Toback's opinion that "Aprotinin increases the risk of renal impairment and acute renal failure" should be admitted pursuant to Rule 702 and *Daubert*. Dr. Toback supports his opinion with research tested in the scientific community, including in multiple peer-reviewed publications and epidemiological studies

---

[6] Plaintiffs note that "Bayer muddles the argument regarding animal studies in the same way that it confuses the entirety of its challenge to Dr. Toback's testimony: by equating biological plausibility with causation itself. . . . The animal studies are merely evidence of the mechanistic effect of Trasylol on biological systems–which supports (without having to single-handedly prove) his opinion that Trasylol causes kidney injuries." (DE 3859 at 17).

[7] Plaintiffs state that the establishment of a threshold dose is not an absolute requirement for a reliable causation opinion. Because the dosage is known for Trasylol, "the pertinent question is not where is the minimum dose threshold for injury, but has the specified dose been shown to cause injury. Here, there is substantial evidence to show that it has." (DE 3859 at 21-22).

involving humans and animals, which contain known rates of error.[8]

Furthermore, this is not a case where "there is simply too great an analytical gap between the data and the opinion proffered." *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Dr. Toback possesses relevant expertise,[9] a point that Bayer does not dispute, and applies it to draw the tailored conclusion that "Aprotinin *increases the risk* of renal impairment and acute renal failure."[10] (Toback Report at 2 (emphasis added)).

Additionally, I agree with Plaintiffs that biological plausibility is a factor to be considered in making this determination, and that a causal relationship can be established even when the mechanism of action is unknown. *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 3806435, at *8-9 (M.D. Fla. June 23, 2009); *In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1295-96 (M.D. Fla. 2007).

I find that Dr. Toback's opinion as to Trasylol's physiological effects on the kidney

---

[8] For example, Dr. Toback states that the Mangano, Karkouti, and i3 studies, which focused on human patients, found that "the incidence of adverse effects on the renal function was due to the use of Aprotinin." All three studies applied statistical analysis. In particular, Dr. Toback's report states that the i-3 study "compare[d] three Aprotinin doses with low-dose aminocaproic acid," examined a large number of patients, and applied controls for the purpose of excluding unrelated factors. Although "[t]he strength of association of Aprotinin with renal failure compared with aminocaproic acid [in the i3 study] was less than that reported by Mangano *et al.* vs. aminocaproic acid, and Karkouti *et al.* vs. tranexamic acid," the i3 results "showed that patients receiving Aprotinin were more likely to develop ARF and/or die tha[n] those treated with EACA [aminocaproic acid]," and "the Mangano study revealed evidence of an Aprotinin-associated increased incidence of renal failure and death." (Toback Report at 11, 13, 15-16).

[9] Dr. Toback has spent his professional life studying the kidney (Toback Report at 1-2) and has authored numerous publications in the scientific community in the field of nephrology, including with respect to kidney function and structure. (DE 3063-2 at 8-17).

[10] Although Dr. Toback's Report contains a section titled "Aprotinin causes renal failure," he states in his summary a more limited opinion that "Aprotinin increases the risk of renal impairment and acute renal failure." (Toback Report at 2, 8).

(mechanisms of action) provide additional support for his opinion that "Aprotinin increases the risk of renal impairment and acute renal failure." Bayer's criticisms are more directed to the weight of Dr. Toback's testimony rather than its admissibility.[11]

For example, Bayer criticizes Dr. Toback for relying on animal studies. While it may be problematic to infer causation in humans from animal studies, "[a]nimal studies often provide useful information about pathological mechanisms." *In re Accutane*, 511 F. Supp. 2d at 1291. Dr. Toback also supplements these animal studies with human studies by Bayer and in peer-reviewed publications. (Toback Report at 5-11). I find that Dr. Toback's reliance on animal studies as support for his mechanism opinion constitutes a reliable methodology.

Bayer also criticizes Dr. Toback for failing to address the dose-response relationship.[12] Bayer is misguided. That Dr. Toback does not know the level of aprotinin that could engorge the phagolysosomes and cause renal failure in every individual does not render his opinion speculative.

---

[11] Dr. Toback acknowledged weaknesses in his underlying data. For example, he conceded that the Seto study supporting his opinion on aprotinin's functional effect did not conclude that the reduction in filtration triggered ARF. (Toback Dep. at 184-85). As to aprotinin's structural effect on the kidneys, Dr. Toback opined that "[t]he renal changes induced by Aprotinin observed in animals were interpreted as easily reversible." (Toback Report at 8).

[12] Bayer cites to the following exchange at Dr. Toback's deposition:

Q: The last sentence of [a paragraph in the Toback Report dealing with the structural effect] says, "However, sufficient aprotinin delivered to the kidneys by infusion during cardiac surgery could engorge the phagolysosomes and cause renal cellular injury." That's your view?

A: Yes.

Q: When you say sufficient aprotinin, what are you referring to there?

A: I'm trying to get around the problem that in certain patients the amount of aprotinin *that may be required to do that* will be different from other patients. And I don't know how much that would be, and I don't have access to kidney tissue to measure it. And so it's a virtual amount.

(Toback Dep. at 274:19-275:9 (emphasis added).

Dr. Toback cites to multiple studies, including of humans, addressing the link between specified doses of aprotinin and an increased risk of renal impairment.[13]

Furthermore, Bayer's questioning of certain studies on which Dr. Toback relies (e.g., Seto and Sundt) for his mechanism opinion does not render it speculative. Dr. Toback possesses relevant expertise, and provides a thorough explanation of Trasylol's adverse functional and structural effects on the kidney.[14] *See In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d 1071, 1077-78 (D. Minn. 2008) ("The general rule that the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility applies equally to *Daubert* motions in MDL matters involving allegations that a drug has caused harm to plaintiffs. . . . Only if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded.") (internal citations and quotations omitted). *But see Joiner*, 522 U.S. at 146 ("A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.") (internal citations omitted).

Bayer's arguments in favor of exclusion are either misdirected or directed at the weight of Dr.

---

[13] In addition to the Mangano, Karkouti, and i3 studies, (see *supra* note 8), Dr. Toback cites other studies of the adverse effects on renal impairment that aprotinin doses could cause in humans. For example, Dr. Toback states that some studies found that higher doses of Aprotinin were associated with higher risks. (Toback Report at 10-13).

[14] Dr. Toback states in his summary of opinions, "Aprotinin negatively impacts renal function both functionally and structurally." Under the "Aprotinin Mechanism of Action" section, Dr. Toback discusses the functional and structural effects under two subsections and explicitly states that "Two adverse effects of Aprotinin on the kidneys have been described that could cause acute renal failure/acute kidney injury. These can be considered as functional and structural adverse effects." (Toback Report at 4). Although Bayer challenges Dr. Toback's opinion as to Trasylol's prothombotic effect as a third, distinct, mechanism opinion, Dr. Toback states that "Aprotinin-induced adverse effects on renal function" could be "a consequence of the prothrombotic/antifibrinolytic effect" of aprotinin. (Toback Report at ¶ 16).

Toback's opinion rather than its admissibility: vigorous cross-examination and the presentation of contrary evidence will be the appropriate means of attacking it. *Quiet Tech. v. Hurel-Dubois UK Ltd.*, 326 F.3d 1333, 1340-41 (11th Cir. 2003) ("[I]t is not the role of the district court to make ultimate conclusions as to the persuasiveness of the proffered evidence. . . . By attempting to evaluate the credibility of opposing experts and the persuasiveness of competing scientific studies, the district court conflated the questions of admissibility of expert testimony and the weight appropriately to be accorded such testimony by a fact finder.") (internal citations and quotations omitted).

In summary, I find that Plaintiffs have established, by a preponderance of proof, that Dr. Toback's opinion that "Aprotinin increases the risk of renal impairment and acute renal failure" should be admitted pursuant to Rule 702 and *Daubert*. Dr. Toback also may testify as to Trasylol's mechanisms of action. In particular, Dr. Toback may properly opine that Trasylol could cause ARF/AKI by impairing renal function either through inhibiting renal vasodilators and reducing blood flow and filtration or by causing blood clots to form in the kidneys (functional/prothrombotic effects). Dr. Toback also may opine that Trasylol could cause ARF/AKI by accumulating in the kidney cells (the structural effect).

B. The Adequacy of Bayer's Studies

Bayer argues that Dr. Toback's opinion that Bayer did not adequately test Trasylol because it did not conduct clinical trials comparing Trasylol with Amicar and tranexamic acid is inadmissible

for three independent reasons.[15] (DE 3063 at 9-10). First, Dr. Toback is not an expert on FDA regulations and has no expertise in how drugs are tested. (DE 3063 at 9). Second, to the extent this opinion seeks to establish Bayer's legal duty, it is inadmissible because experts may not testify to the legal implications of conduct. (DE 3063 at 10). Third, to the extent this opinion relates to Bayer's ethical or moral obligation, it constitutes an inadmissible personal opinion. (DE 3063 at 10).

Plaintiffs respond that Bayer overstates the scope of Dr. Toback's testimony: he will not opine on Bayer's legal or ethical duties but will "explain why he gave greater or lesser weight to particular studies when conducting his causation analysis based on whether they used placebo or one of the lysine analogues as a comparator." (DE 3859 at 23).

Bayer replies that, contrary to Plaintiffs' representations, this testimony should be excluded as impermissible legal or ethical testimony: Dr. Toback characterizes Bayer's placebo comparative trials as defective. (DE 4105 at 10 (citing Toback Dep. at 173:17-174:20)).

Regardless of Plaintiffs' characterization of the purpose of this testimony, I find that it is inadmissible under Rule 702 and *Daubert*. The testimony falls outside the scope of Dr. Toback's expertise and constitutes an inadmissible personal opinion. It must be excluded.

---

[15] Bayer cites to the following exchange at Dr. Toback's deposition:

Q: So is it your view that Bayer should have done a large randomized controlled clinical trial comparing aprotinin to Amicar and tranexamic acid in the early 1990s?

A: Yes. Now, using a placebo is a real problem for me as a control. I talked before that I would rather see the Amicar and tranexamic acids. But the downside of placebo in that it's not the comparator, as you called it, is that . . . . I'm not aware that Bayer actually did a comparative study where they looked at aprotinin versus Amicar versus tranexamic acid. And I would have thought they would do that.

Q: And that's what you're talking about on the last page of your report?

A: Yes, I am. I'm really – I'm just surprised. I just don't understand why they wouldn't have done that. Don't you think? Okay.

(Toback Dep. at 173:17-174:20).

C. Trasylol's Labeling

Dr. Toback opines that Bayer should have included information regarding the Sundt study in its package insert. (DE 3063 at 11 (citing Toback Dep. at 174:16-175:16, 176:5-177:5)). Bayer argues that this opinion should be excluded because Dr. Toback concedes that he is not an expert on FDA regulations and has no expertise in crafting or evaluating drug labels. (DE 3063 at 12).

Plaintiffs state that they do not intend to offer Dr. Toback as an expert on FDA labeling issues and do not attempt to establish the admissibility of Dr. Toback's labeling opinion. (DE 3859 at 23). The testimony at issue is therefore excluded.

D. Bayer's and the FDA's Knowledge, State of Mind, and Motive

Bayer argues that Dr. Toback's opinions on Bayer's and the FDA's motive, knowledge, intent, and state of mind are inadmissible because they fall outside the scope of his knowledge and expertise and are classic jury questions. (DE 3063 at 12-13 (citing Toback Report at ¶¶ 14-17, ¶ 21, ¶ 23, ¶ 25[16])).

Plaintiffs state that they do not intend to offer Dr. Toback as an expert on Bayer's or the

---

[16] The paragraphs cited by Bayer contain the following language: "It was well known to Bayer even in 1993"; "It is clear that Bayer scientists were aware of these findings and Aprotinin's [e]ffect on the kidneys"; "Bayer also knew there was a greater incidence of subsequent serum creatinine increases in patients with certain conditions"; "Bayer was able to argue successfully to the FDA that this incidence was acceptable"; "Bayer was clearly aware of adverse events with Trasylol"; "Bayer was aware of the renal connection with Aprotinin"; "[I]t is clear from the evidence that's not when the study was started or even when the results were first known by Bayer"; "Bayer knew patients who received Aprotinin had elevated serum creatinine concentrations"; "FDA was not aware of these new data when it held the September 21, [2]006 Advisory Committee meeting on Trasylol safety."

FDA's state of mind and do not attempt to establish the admissibility of Dr. Toback's state of mind opinions. (DE 3859 at 23). The testimony at issue is therefore excluded.

E. The Withholding of Adverse Event Reporting Data from the FDA

Dr. Toback opines that

> Bayer was clearly aware of adverse events with Trasylol. Document BAY00745435 which lists adverse experiences that were not reported to the FDA. This document dated March 10, 1993 indicates that 12 of 87 adverse events not reported to the FDA were patients who developed renal failure requiring dialysis associated with Aprotinin.

(Toback Report at ¶ 17). Bayer argues that this opinion should be excluded because it lacks a factual basis and would only be relevant to a fraud-on-the-FDA theory, which Plaintiffs cannot pursue. (DE 3063 at 14)..

Plaintiffs state that they do not intend to offer Dr. Toback as an expert on material provided or withheld from the FDA and do not attempt to establish the admissibility of Dr. Toback's opinion on this issue. (DE 3859 at 23). The testimony at issue is therefore excluded.

F. The FDA Advisory Committee Meeting

Bayer argues that Dr. Toback's factual narrative of what he believes happened at the FDA Advisory Committee meeting should be excluded because it does not constitute expert testimony. (DE 3063 at 14 (citing Toback Report at ¶ 25[17])).

---

[17] According to ¶ 25 of Dr. Toback's Report,

> On September 21, 2006 the FDA held a public meeting to discuss the safety and overall risk-benefit profile for Trasylol. At that meeting the committee discussed the findings from two published observational studies (Mangano et al., 2006; Karkouti et al., 2006), the Bayer worldwide safety review, and the FDA review of its own post-marketing database.

Plaintiffs state that they do not intend to offer Dr. Toback as an expert on the events occurring at the FDA Advisory Committee meeting and do not attempt to establish the admissibility of Dr. Toback's testimony on this issue. (DE 3859 at 23). The testimony at issue is therefore excluded.

III. Conclusion

Accordingly, it is hereby

ORDERED AND ADJUDGED that Bayer's Motion to Exclude Testimony of Plaintiffs' Expert F. Gary Toback (DE 3063) is **GRANTED IN PART and DENIED IN PART.** More specifically,

- The Motion is **DENIED** as to Dr. Toback's opinion that Trasylol that "Aprotinin increases the risk of renal impairment and acute renal failure."
- The Motion is **DENIED** as to Dr. Toback's opinion regarding Trasylol's physiological mechanism.
- The Motion is **GRANTED** as to Dr. Toback's opinion that Bayer should have compared Trasylol to Amicar (aminocaproic acid) and tranexamic acid.
- The Motion is **GRANTED** as to Dr. Toback's opinion on information that should have been included in Trasylol's labeling.
- The Motion is **GRANTED** as to Dr. Toback's opinion on Bayer's and the FDA's knowledge, state of mind, and motive.
- The Motion is **GRANTED** as to Dr. Toback's opinion that Bayer withheld adverse event reporting data from the FDA.

- The Motion is **GRANTED** as to Dr. Toback's factual narrative regarding what happened at the FDA Advisory Committee meeting.

DONE AND ORDERED in Chambers at West Palm Beach, Florida, this 10 day of September, 2010.

DONALD M. MIDDLEBROOKS
UNITED STATES DISTRICT JUDGE

Copies to: Counsel of Record