763 F.Supp.2d 1312
United States District Court,
S.D. Florida.

In re TRASYLOL PRODUCTS LIABILITY LITIGATION—MDL–1928.
This Document Relates To: All Cases.

Case No. 1:08–MD–01928.
|
May 10, 2010.

Synopsis

Background: Manufacturer of prescription drug moved in limine, in multidistrict products liability litigation, to exclude in all cases evidence, testimony, and argument alleging that it provided inadequate or incomplete data to Food and Drug Administration (FDA) in connection with marketing and sale of drug.

[Holding:] The District Court, Donald M. Middlebrooks, J., held that evidence or testimony that manufacturer failed to adequately or timely provide information to FDA, pursuant to FDA reporting obligations that ran to FDA, was inadmissible.

Motion granted.

West Codenotes

Recognized as Preempted
M.C.L.A. § 600.2946(5)

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ORDER ON BAYER'S MOTION IN LIMINE TO EXCLUDE EVIDENCE, TESTIMONY, AND ARGUMENT ALLEGING THAT BAYER PROVIDED INADEQUATE OR INCOMPLETE DATA TO THE FEDERAL FOOD AND DRUG ADMINISTRATION

DONALD M. MIDDLEBROOKS, District Judge.

THIS CAUSE comes before the Court upon Defendants' (hereinafter, collectively, "Bayer's") Motion *in limine* (DE 5603) to exclude evidence, testimony, and argument alleging that Bayer provided inadequate or incomplete data to the federal Food and Drug Administration ("FDA") in connection with the marketing and sale of its prescription drug Trasylol, filed on April 27, 2010, 709 F.Supp.2d 1323 (S.D.Fla.2010). Plaintiffs filed an Opposition to the Motion (DE 5732) on May 5, 2010. The Court has reviewed the record and is otherwise advised in the premises.

I. Background

A. Procedural Background

Initially, Bayer filed this Motion *in limine* (DE 3994) on January 29, 2010, in the *Anna Bryant v. Bayer Corp. et al.* (Case No. 9:08–cv–80868), *Naguib Bechara et al. v. Bayer Corp. et al.* (Case No. 9:08–cv–80776), and *Melissa Morrill v. Bayer Corp. et al.* (Case No. 9:08–cv–80424) cases. Plaintiffs filed a Response in opposition (DE 4240), to which Bayer replied (DE 4502).

Pursuant to the Court's request for supplemental briefing on the issue at a hearing held on February 26, 2010, Bayer and Plaintiffs submitted Supplemental Briefs in support of and in opposition to the Motion (DE 4680 and DE 4741 respectively). Bayer also filed a Response to Plaintiffs' Supplemental Brief (DE 4793). The Court held a hearing on the Motion on April 1, 2010.

***1316** The *Morrill* case, scheduled for trial on April 26, 2010, was filed under Florida law. In preparation for that trial, Plaintiffs filed a supplemental brief on the effect of Florida's product liability statute to Bayer's preemption argument (DE 5355). Bayer responded to that supplemental brief (DE 5605).

While the Motion *in limine* was initially filed only in the *Bryant, Bechara,* and *Morrill* cases, none of these cases went to trial.[1] Therefore, the Court denied Bayer's Motion as moot on April 22, 2010 (DE 5530). On April 27, 2010, Bayer filed the instant Motion (DE 5603) in all cases in the MDL, incorporating by reference the briefing and argument that have already occurred.[2] Therefore, the summaries below are taken from the parties' initial filings.

1 The *Bryant* and *Morrill* cases settled while the *Bechara* case was disposed of by summary judgment.

2 While Bayer incorporates by reference the briefing and argument that have occurred in this MDL, its argument is now broader. Initially Bayer argued that Plaintiffs should be precluded from offering evidence, testimony, or argument that Bayer allegedly failed to provide more timely or different information to the FDA in connection with the marketing and sale of Trasylol. Now, Bayer also argues that Plaintiffs should not be allowed to suggest that Bayer violated the FDCA, 21 U.S.C. § 301 et. seq., "which categorically forecloses private rights of action and makes the alleged violation of the FDCA enforceable only by the federal government." (DE 5603 at 1.) Plaintiffs respond that Bayer's Motion "should be denied because it improperly asserts that evidence of violations of the Federal Food, Drug, and Cosmetic Act ... must always be characterized as a claim for 'fraud on the FDA' and thus be preempted." (DE 5732 at 1.) Because Bayer incorporates by reference the briefing that has occurred in this MDL, and that briefing does not cover Bayer's current, broader position, the Court will consider only the argument that was presented in Bayer's initial Motion.

B. Bayer's Motion (DE 3994)

Bayer argues that pursuant to *Buckman Co. v. Plaintiffs' Legal Comm.,* 531 U.S. 341, 350–51, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001), and Rule 403, Plaintiffs should be precluded from arguing or proffering testimony or evidence that Bayer failed to adequately or timely provide information to the FDA, such as the Kress study, the St. George's Hospital study, or the i3 study.

In laying out the process by which the FDA regulates prescription drugs, Bayer states that the Federal Food, Drug & Cosmetics Act ("FDCA") authorizes the FDA, alone, to enforce compliance with its disclosure and other provisions. (DE 3994 at 3. (citing 21 U.S.C. § 337(a)[3])) In doing so, the FDA may investigate suspected fraud or misrepresentation by a manufacturer such as Bayer. (DE 3994 at 3. (citing 21 U.S.C. § 372)) While the FDA approved Bayer's application to market Trasylol in 1993, it has never determined that Bayer failed to comply with FDCA standards for disclosing information to the agency about Trasylol or that any such non disclosure affected the agency's decisions about whether Trasylol should continue to be marketed. (DE 3994 at 4–5.)

[3] Under § 337(a), "[A]ll such proceedings for the enforcement, or to restrain violations of this chapter shall be by and in the name of the United States."

In *Buckman,* the United States Supreme Court held that a state-law claim based on a theory that a plaintiff's injuries are the result of a medical device manufacturer's failure to provide sufficient information to the FDA are preempted by the FDCA. Accordingly, Bayer argues that

> *Buckman* makes clear that the adequacy of regulatory submissions to FDA is an issue that can be determined by FDA ***1317** alone, and may not be considered by juries applying the divergent law of 50 States. Therefore, plaintiffs cannot attempt to prove their state-law claims against Bayer by arguing that Bayer's submissions to FDA were insufficient—or speculating about what the agency might have done with different information.

(DE 3994 at 1–2.) According to Bayer, numerous courts have held that plaintiffs may not evade *Buckman* by claiming that a violation of the FDCA gives rise to their asserted state-law causes of action and introducing such evidence in support of their state-law claims. (DE 3994 at 7–8.) Bayer does not contend that all correspondence between it and the FDA is irrelevant. (DE 3994 at 9.) "Rather, Bayer submits that under *Buckman,* any argument that Bayer's communications or submissions were not timely, not complete, or could have included different or 'better' information ... is irrelevant and inadmissible because the sufficiency of submissions to FDA is to be judged solely by FDA." (DE 3994 at 9.)

In regards to exclusion under Rule 403, Bayer asserts that

> The only possible reason for plaintiffs to introduce such evidence would be to argue to the jury that FDA would have reached a different decision regarding warnings or labeling for Trasylol if Bayer had provided more timely or 'better' information. But what FDA *may* have done, if anything, with different data and how that information *may* have ultimately affected Trasylol's regulatory status, if at all, is precisely the type of speculation *Buckman* and Rule 403 prohibit.

(DE 3994 at 9.) Instead, Plaintiffs should be focusing on whether Trasylol is capable of causing and did cause the injuries at issue, and the adequacy of warnings given to each plaintiff's physician. (DE 3994 at 10.)

C. Plaintiffs' Opposition (DE 4240)

Plaintiffs respond that evidence "will not be offered to show that had the FDA been properly advised, it [ ] would have acted differently." (DE 4240 at 2.) Instead, "evidence will be offered to show that Bayer acted negligently in failing to properly disclose information to the FDA, the medical and scientific communities, and to the public." (DE 4240 at 2.) According to Plaintiffs, such evidence is relevant, not precluded by *Buckman'* s narrow holding, and not prejudicial or speculative under Rule 403.

In terms of relevance, Plaintiffs argue that the evidence is relevant to establishing Plaintiffs' state-law claims, demonstrating Bayer's negligence, and refuting Bayer's assertions that it complied with all regulatory requirements and that such compliance is an indication that Bayer exercised due care. (DE 4240 at 1, 8.) According to Plaintiffs, Bayer's failure to comply with federal reporting requirements is evidence of its failure to

act as a reasonable prudent company, something that bears on Bayer's negligence. Further, evidence of Bayer's misrepresentations to the FDA is relevant as it relates to "Bayer's knowledge about the adequacy of its warnings and the truth of information that it represented to or concealed from [Plaintiff] and [Plaintiff's] physicians." (DE 4240 at 11.)

Plaintiffs state that Bayer's reliance on *Buckman* is misplaced: Plaintiffs have not asserted an impermissible cause of action for fraud-on-the-FDA. (DE 4240 at 2.) "*Buckman* simply preempts the legal theory of fraud on the FDA. It does not preclude the admission of *evidence* or *testimony* regarding a defendant's misrepresentations to the FDA."[4] (DE 4240 at 3.)

[4] Plaintiffs also state that "Bayer's improper expansion of the *Buckman* case would unjustifiably preclude Plaintiff from providing essential and relevant evidence that demonstrates Bayer's knowledge regarding the harms of Trasylol. Essentially, Bayer is arguing that because its fraud was not limited to physicians, the scientific community and the public, but included the FDA, Plaintiff should be precluded from making any references to Bayer's fraud. Bayer's argument is not only absurd, but has been rejected by numerous courts." (DE 4240 at 6.)

***1318** In regards to Rule 403, Plaintiffs assert that they will not speculate about FDA actions but will instead "offer evidence as to what the agency did or did not do based on what the agency did or did not know." (DE 4240 at 9.)

D. Bayer's Reply (DE 4502)

In its Reply, Bayer asserts that Plaintiffs' argument misstates Bayer's position, misunderstands the law on preemption, and ignores the many cases that have applied *Buckman* to bar plaintiffs from offering evidence of fraud-on-the-FDA in support of state-law failure to warn tort claims. (DE 4502 at 2.)

Bayer clarifies that it does not argue that Plaintiffs' state-law tort claims are barred *via* implied preemption principles. (DE 4502 at 9.) Accordingly, Bayer does not argue that Plaintiffs should be barred from introducing evidence about the *conclusions* of studies such as the i3 study to support their state-law tort claims where such evidence would be relevant. (DE 4502 at 4.) Rather, Bayer argues that Plaintiffs are not permitted to make the *separate* point that any delay in disclosure to the FDA constituted a fraud on the agency and affected the agency's regulatory judgment. (DE 4502 at 4.) "[T]he proffered evidence that Bayer engaged in fraud on the FDA in support of those state-law claims [is] preempted under *Buckman*." (DE 4502 at 9.)

According to Bayer, Plaintiffs' argument is contradictory: while Plaintiffs argue that they may introduce evidence that Bayer misled the FDA, they concede that they cannot argue that the FDA would have acted differently had Bayer disclosed the information it allegedly withheld. (DE 4502 at 3.) "Speculation about what FDA may have done with different information is inadmissible under *Buckman* for the same reason that evidence that Bayer failed to provide information to FDA is inadmissible: it is solely the 'FDA's responsibility to police fraud consistently with the Administration's judgment and objectives.' " (DE 4502 at 3. (citing *Buckman,* 531 U.S. at 350–51, 121 S.Ct. 1012.))

Furthermore, Bayer asserts that its defense of regulatory compliance does not change the fraud-on-the-FDA analysis: FDA approval is evidence that the FDA determined the drug to be "safe and effective" under federal law. (DE 4502 at 5. (citing 21 U.S.C. § 393(b)(2)(B))) While the defense of FDA approval requires no speculation by the factfinder, "asking a jury to assess whether a regulated entity complied with its federal disclosure obligations to the agency or effected a fraud on the agency is a very different proposition." (DE 4502 at 6.) Because there has not been an FDA finding of noncompliance in this Case, the introduction of Plaintiffs' proffered evidence and testimony would require the jury to speculate about what the FDA may have done differently with different information. (DE 4502 at 6.)

E. The Parties' Supplemental Briefs (DEs 4680, 4741, and 4793)

Bayer's Supplemental Brief centers around the argument that it may present evidence of its regulatory submissions and FDA responses, including FDA's approval of Trasylol for marketing, while Plaintiffs should not be permitted to argue that Bayer did not timely submit certain information ***1319** to the FDA or violated the FDCA.[5] (DE 4680 at 1.) According to Bayer, numerous courts have applied this framework, recognizing the

difference between evidence of compliance and noncompliance with FDCA requirements in a tort action. (DE 4680 at 6.)

[5] More specifically, where the FDA "considered some piece of information prior to approving the Trasylol labeling, Bayer should be able to present that fact as relevant to (if not dispositive of) its response to plaintiffs' argument that the labeling was inadequate as a matter of state law. To the extent Bayer did not disclose something to the agency, Bayer would not be able to make such an argument. In all events, plaintiffs remain free to argue that notwithstanding the agency's labeling determinations, state law required a stronger warning, including that any piece of information about which plaintiffs are aware should have been included in the labeling as a matter of state law." (DE 4680 at 2–3.)

In support of this argument, Bayer states that FDA's actual regulatory determinations are relevant, require no speculation, and present no affront to *Buckman.* According to Bayer, the evidence is relevant because: 1) prescription drugs such as Trasylol may not be marketed in the United States without initial and ongoing FDA approval; and 2) compliance with regulatory requirements provides some evidence that the defendant acted with due care or lacked the malice necessary for awarding punitive damages. (DE 4680 at 2, 4.) The evidence requires no speculation and is unlikely to cause jury confusion or to prejudice any party because it is based on what the FDA actually did or determined. (DE 4680 at 2.) Furthermore, the evidence presents no tension with *Buckman* because the jury is not asked to second-guess the FDA's actual decisions, speculate about its actions, or interfere with its judgment. (DE 4680 at 4.)

On the other hand, evidence of alleged misrepresentations to the FDA or noncompliance with the FDCA (as evidence of negligence under state law) is barred under *Buckman,* irrelevant, and unduly prejudicial and speculative, especially considering that the FDA has never taken action against Bayer with respect to its Trasylol-related disclosures. According to Bayer, such evidence risks the jury imposing liability because it believes that Bayer violated FDA disclosure requirements for which no private right of action exists, not because Plaintiffs have established the elements of their state-law claims. (DE 4680 at 2.)

> Unlike the clear and objective manner in which FDA approval can be shown, determining alleged noncompliance with the FDCA standards requires the jury to assume the role of the FDA.... Even if not asked to speculate about agency action, the jury nonetheless may improperly use state law to enforce requirements Congress intended to be administered by federal officials in accordance with federal standards.... [E]ven if showings of non-compliance had some relevance, they would improperly invite the jury to speculate, and therefore are forbidden. Because that speculation invites the imposition of liability based on a perceived FDCA violation alone, not because plaintiffs have satisfied the elements of their state law claims, it is even more inappropriate.

(DE 4680 at 8.)

While Bayer argues that Plaintiffs may not rely on Bayer's knowledge of particular information to argue that it breached certain obligations to the FDA and that such breach establishes the requisite elements of Plaintiffs' claims or is a ground for assessing punitive damages under state law, Bayer does not claim that Plaintiffs should be precluded from arguing that Bayer knew certain information, which triggered a state-law duty to warn Plaintiffs' prescribing physicians. (DE 4680 at 10–11.) Accordingly, Plaintiffs may argue ***1320** that Bayer's warnings were inadequate as a matter of state law based on information known to the company and that, had Bayer disclosed certain information to a Plaintiff's prescribing doctor (as opposed to the FDA), that doctor would not have prescribed Trasylol to that Plaintiff or would have used it differently such that the Plaintiff would not have been injured. (DE 4680 at 10–11.) These failure to warn showings are appropriate because they do not turn on whether and when Bayer had a federal duty to disclose information to the FDA or whether those federal reporting duties were violated. (DE 4680 at 11.)

In their Supplemental Brief, Plaintiffs argue that regulatory evidence is integral to this Case and admissible for various purposes. Accordingly, it is relevant to

establish a violation of the minimum standard of care, to determine punitive damages, to impeach testimony that Bayer complied with FDA requirements, and to prevent jury confusion regarding the FDA and the regulatory process. (DE 4741 at 10–12.)

Bayer responds that "[W]hether a claim is labeled 'fraud-on-the-FDA' or whether a plaintiff tries to show that a company[ ] violated FDCA disclosure requirements, the jury must engage in the same impermissible speculative inquiry, and the defendant is at equal risk of being held liable under state law for allegedly violating an obligation arising under federal law." (DE 4793 at 5.)

II. Analysis

A. Reconciling *Buckman Co. v. Plaintiffs' Legal Comm.* and *Wyeth v. Levine*

While Bayer claims that *Buckman v. Plaintiffs' Legal Comm.* bars the introduction of the evidence and testimony at issue, Plaintiffs assert that Bayer's reliance on *Buckman* is misplaced and that the narrowness of its holding was reaffirmed by the Supreme Court in *Wyeth v. Levine.*

In *Buckman,* the plaintiffs claimed injuries resulting from the use of orthopedic bone screws in the pedicles of their spines, and accused the defendant[6] of making fraudulent representations to the FDA in the course of obtaining approval to market the screws. 531 U.S. 341, 344, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001). Plaintiffs claimed that such representations were at least a but-for cause of their injuries: "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." *Id.* The plaintiffs sought damages under state tort law.

6 The defendant (petitioner) was a consulting company that assisted the screws' manufacturer in navigating the federal regulatory process for these devices.

The Supreme Court granted certiorari to resolve a split among the Courts of Appeals and decide whether these fraud-on-the-FDA claims were expressly or impliedly preempted.

The Supreme Court began its analysis by stating that there is no presumption against federal preemption in this case because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied." *Id.* at 347, 121 S.Ct. 1012 (internal citations and quotations omitted). "To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.*

The Court held that the state-law fraud-on-the-FDA claims conflicted with, and were therefore impliedly preempted by, the FDCA, as amended by the Medical Device Amendments of 1976.[7] ***1321** *Id.* at 348, 121 S.Ct. 1012.

7 In light of the Court's holding on implied preemption, it expressed no view on whether these claims were subject to express preemption under 21 U.S.C. § 360k. *Buckman,* 531 U.S. at 348 n. 2, 121 S.Ct. 1012.

> The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.... [W]ere plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.[8]

8 The Court noted that while certain state-law causes of action that parallel federal safety requirements may be allowed, it does not hold that *any* violation of the FDCA will support a state-law claim. Here, the fraud claims existed solely by virtue of the FDCA disclosure requirements. *Buckman,* 531 U.S. at 353, 121 S.Ct. 1012.

Id. at 348, 353, 121 S.Ct. 1012.

The Court cited to the various disclosure requirements and provisions that are aimed at detecting, deterring, and

punishing false statements made during the FDA approval process, the FDA's power to investigate suspected fraud, the citizens' ability to report wrongdoing and petition the FDA to take action, and the FDA's power to pursue criminal prosecutions. *Id.* at 349, 121 S.Ct. 1012. "The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud upon the Administration." *Id.* According to the court, state-law fraud-on-the-FDA claims conflict with the FDA's responsibility to police fraud consistently with its judgment and objectives. *Id.* at 350, 121 S.Ct. 1012.

The Court cautioned that allowing state-law fraud-on-the-FDA claims would cause applicants to fear that their FDA disclosures would be deemed appropriate by the FDA but later judged insufficient in state court. Such a scenario would cause applicants to submit unnecessary information to the FDA, resulting in additional burdens on the FDA's evaluation of an application. *Id.* at 351, 121 S.Ct. 1012.

Writing for the concurrence, Justice Stevens stated that

> This would be a different case if, prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the [regulatory] process and had then taken the necessary steps to remove the harm-causing product from the market. Under those circumstances, respondent's state-law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation but would be grounded in the agency's explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decisionmaking or overburdening its personnel, thereby alleviating the Government's central concerns regarding fraud-on-the-agency claims.

Id. at 354, 121 S.Ct. 1012. In such a case, state damages remedies would supplement and facilitate, rather than encroach upon, the federal enforcement scheme. *Id.*

While the *Buckman* Court considered preemption of fraud-on-the-FDA claims, the question presented by the petitioner in ***1322** *Wyeth* was whether the FDA's drug labeling judgments preempted state-law products liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use. 555 U.S. 555, 129 S.Ct. 1187, 1193, 173 L.Ed.2d 51 (2009). According to the Supreme Court, "The narrower question presented is whether federal law pre-empts Levine's [plaintiff's] claim that Phenergan's label did not contain an adequate warning about using the IV-push method of administration."[9] *Id.* at 1194.

[9] The injectable form of Phenergan, a drug used to treat nausea, can be administered intramuscularly or intravenously; it can be administered intravenously through either the "IV-push" method, whereby the drug is injected directly into a patient's vein, or the "IV-drip" method, whereby the drug is introduced into a saline solution and slowly descends through a catheter inserted in a patient's vein. The drug causes gangrene if it enters a patient's artery. The plaintiff's injury resulted from an IV-push injection: Phenergan entered the plaintiff's artery and caused gangrene, resulting in the amputation of her forearm. The plaintiff brought action against Wyeth, Phenergan's manufacturer, relying on common-law negligence and strict liability theories. Although Phenergan's labeling warned of the danger of gangrene and amputation following inadvertent intra-arterial injection, Levine alleged that the labeling was defective because it failed to instruct clinicians to use the IV-drip method of intravenous administration instead of the higher risk IV-push method. *Wyeth,* 129 S.Ct. at 1191–92.

The FDA had approved Wyeth's label for Phenergan when it approved its new drug application in 1955 and when it later approved changes in the drug's labeling. *Id.* at 1191. The Court had to decide whether those approvals provided Wyeth with a complete defense to the plaintiff's tort claims. *Id.* Wyeth argued that the plaintiff's state law claims were preempted because: 1) it would have been impossible for it to comply with the state-law duty to modify Phenergan's labeling without violating federal law; and 2) recognition of the plaintiff's state-law tort action created an unacceptable obstacle to the accomplishment and execution of Congressional objectives because it substituted a lay jury's decision about drug labeling for the expert judgment of the FDA.[10] *Id.* at 1193–94.

[10] Wyeth contended that the FDCA established both a floor and a ceiling for drug regulation and that once the FDA approved a drug's label, a state-law verdict may not deem it to be inadequate. 129 S.Ct. at 1199.

The Court emphasized that its answer to the question presented was guided by two cornerstones of its preemption jurisprudence: 1) "the purpose of Congress is the ultimate touchstone in every pre-emption case"; and 2) when Congress legislates in a field traditionally occupied by the states, there is an assumption against preemption, unless that is the clear and manifest purpose of Congress. *Id.* at 1194–95 (internal citations omitted).

The Court rejected Wyeth's first argument. Accordingly,

> Impossibility pre-emption is a demanding defense. On the record before us, Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements. The CBE [changes being effected] regulation permitted Wyeth to unilaterally strengthen its warning, and the mere fact that the FDA approved Phenergan's label does not establish that it would have prohibited such a change.

Id. at 1199. The Court also rejected Wyeth's second argument, finding it to be contrary to all evidence of Congress' purposes.

> If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70–year history. But ***1323** despite its 1976 enactment of an expression pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs. Its silence on the issue coupled with certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.

Id. at 1200 (internal citations and quotations omitted). The Court concluded that although some state-law claims may frustrate the achievement of congressional objectives, this is not such a case. *Id.* at 1204. The FDA's approvals of Phenergan's label did not provide Wyeth with a complete defense to the plaintiff's state-law tort claims. *Id.* at 1191.

[1] *Buckman* and *Wyeth* can be reconciled: while traditional state-law claims for failure to warn are not impliedly preempted by the FDCA, fraud-on-the-FDA claims are impliedly preempted by the FDCA.

B. *Desiano v. Warner–Lambert & Co. & Garcia v. Wyeth–Ayerst Labs.*

While *Buckman* held that state fraud-on-the-FDA claims were impliedly preempted by federal law, the Second and Sixth Court of Appeals considered whether, under the rationale of *Buckman,* federal law also preempts a state's use of a fraud exception to a state statute which narrowed common law liability when the FDA had approved the marketing of a drug. *See Desiano v. Warner–Lambert & Co.,* 467 F.3d 85 (2d Cir.2007); *Garcia v. Wyeth–Ayerst Labs.,* 385 F.3d 961 (6th Cir.2004). Both courts considered this question as it applied to a Michigan statute immunizing drug manufacturers from products liability claims if the drug in question was approved for safety and efficacy by the FDA, and the drug and its labeling were in compliance with the FDA approval at the time it left the control of the manufacturer.[11] *See* MICH. COMP. LAWS § 600.2946(5). Under the statute, the manufacturer is not immune, *inter alia,* if it "Intentionally withholds from or misrepresents to the [FDA] information concerning the drug that is required to be submitted under the [FDCA] ..., and the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." MICH. COMP. LAWS § 600.2946(5).

[11] Prior to its amendment in 1995, Michigan's products liability statute provided that evidence of compliance with FDA standards was admissible in a products liability action in determining if the standard of care had been met.

[2] While the Sixth Circuit held that, pursuant to *Buckman,* federal law preempts the state claims at issue in some settings,[12] the Second Circuit held that it does not. The Second Circuit's judgment was affirmed by an equally divided Supreme Court.[13] *Warner–Lambert Co. v.* ***1324** *Kent,* 552 U.S. 440, 128 S.Ct. 1168, 170 L.Ed.2d 51 (2008).

12 According to the Sixth Circuit, "It is one thing, however, to say that *Buckman* applies to the exemptions contained in [the Michigan statute]; it is quite another to say that *Buckman* preempts these exemptions in all of their applications. Doubtless, *Buckman* prohibits a plaintiff from invoking the exceptions on the basis of *state court* findings of fraud on the FDA. Such a state court proceeding would raise the same inter-branch-meddling concerns that animated *Buckman.* But the same concerns do not arise when the FDA *itself* determines that a fraud has been committed on the agency during the regulatory-approval process.... Thus, in this setting, it makes abundant sense to allow a State that chooses to incorporate a federal standard into its law of torts to allow that standard to apply when the federal agency itself determines that fraud marred the regulatory-approval process. In the final analysis, the exemptions are invalid as applied in some settings ... but not in others. *Garcia,* 385 F.3d at 966.

13 "Judgment entered by an equally divided Court is not entitled to precedential weight." *Trans World Airlines, Inc. v. Hardison,* 432 U.S. 63, 73 n. 8, 97 S.Ct. 2264, 53 L.Ed.2d 113 (1977) (internal citations and quotations omitted).

[3] According to the Sixth Circuit, although this case presented a somewhat different "legal regime" from the one invalidated in *Buckman,*[14] the difference between the circumstances presented in *Buckman* and those at issue was immaterial: "*Buckman* teaches that state tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Garcia,* 385 F.3d at 966 (internal citations and quotations omitted). Having decided that the Michigan statute's exemptions are preempted in some settings, the court went on to consider whether § 600.2946(5) should be invalidated in its entirety. *Id.* After considering Michigan's general severability clause, the Sixth Circuit held that the fact that the fraud-on-the-FDA exception is preempted does not require invalidation of other applications or provisions of the statute. *Id.* at 966–67.[15]

14 The Michigan legislature provided general immunity for drug manufacturers with a specific exception for circumstances involving, *inter alia,* fraud on the FDA. In contrast, *Buckman* involved a *specific* cause of action for fraud-on-the-FDA. *Garcia,* 385 F.3d at 965–66.

15 "As a result of the Michigan statute and Sixth Circuit application of the preemption doctrine, most suits of the instant nature in Michigan against drug manufacturers are functionally foreclosed. In order to maintain a product liability suit against a drug manufacturer under Michigan law, a plaintiff need allege more than the elements of the common law tort. A plaintiff must also allege the federal government has established that the drug manufacturer either committed fraud against the FDA or bribed an FDA official." *White v. SmithKline Beecham Corp.,* 538 F.Supp.2d 1023, 1029 (W.D.Mich.2008).

While the Second Circuit was guided by the Sixth Circuit's holding that the Michigan statute did not create a new cause of action for misleading the FDA but instead restricted when victims could recover under preexisting state products liability law, it decided that it did not have to adopt the Sixth Circuit's reading of *Buckman. Desiano,* 467 F.3d at 92, 94. Accordingly, "[W]e must decide for ourselves whether Michigan's surviving common law cause of action is implicitly preempted by federal law under the rationale of *Buckman.*" *Id.* at 92. The court disagreed with the Sixth Circuit's conclusion that there is no meaningful difference between the fraud-on-the-FDA claims struck down in *Buckman* and the claims under Michigan tort law. *Id.* at 93. According, to the Second Circuit, there are three crucial differences between the nature of the claim which the Michigan statute exempts from abolition and the claim in *Buckman. Id.*

First, while the presumption against preemption did not apply in *Buckman* because "[p]olicing fraud against federal agencies is hardly a field which the States have traditionally occupied," the cause of action at issue could not be characterized as a state's attempt to police fraud against the FDA. *Id.* at 93–94 (quoting *Buckman,* 531 U.S. at 347, 121 S.Ct. 1012.). "The Michigan legislature's desire to rein in state-based tort liability falls squarely within its prerogative to regulat[e] matters of health and safety, which is a sphere in which the presumption against

preemption applies.... [T]he existence of the presumption in the instant case requires an altogether different analysis from that made in *Buckman.*" *Id.* at 94 (internal citations and quotations omitted).

Second, the plaintiffs here were asserting traditional state tort claims rather than a fraud-on-the-FDA claim that was asserted ***1325** in *Buckman. Id.* The claims at issue were premised on traditional duties between a product manufacturer and consumers rather than a newly-created duty between a manufacturer and the FDA. *Id.* at 94–95. As such, the Second Circuit concluded that if it were to hold that the claims were preempted, it would be holding that Congress, "without any explicit expression of intent, should nonetheless be taken to have modified ... traditional state law duties between pharmaceutical companies and their consumers." *Id.* at 95. Furthermore, in cases where fraud-on-the-FDA is a specific cause of action and there are no freestanding allegations of wrongdoing apart from that fraud, proof of fraud against the FDA is sufficient to impose liability. *Id.* On the contrary, the complaints at issue alleged various violations of common law duties; the common law claims survive because there is *also* evidence of fraud in FDA disclosures. *Id.* "*Buckman* cannot be read as precluding such preexisting common law liability based on other wrongs, even when such liability survives only because there was also evidence of fraud against the FDA." *Id.*

Third, in the case at issue, proof of fraud against the FDA is not an element of a products liability claim. *Id.* at 96. Rather, Michigan law creates an affirmative defense that the pharmaceutical company may invoke; the existence of properly-obtained FDA approval becomes germane *only* if a defendant company chooses to invoke it. *Id.*

> Finding preemption of traditional common law claims were fraud is not even a required element—but may be submitted to neutralize a drugmaker's use of an affirmative defense available under state law—would result in preemption of a scope that would go far beyond anything that has been applied in the past. Until and unless Congress states explicitly that it intends invalidation of state common law claims merely because issues of fraud may arise in the trial of such claims, we decline to read general statutes like the FDCA and the MDA as having that effect.

Id. Finding that Michigan law does not implicate the concerns present in *Buckman,* the Second Circuit concluded that the Michigan immunity exception is not prohibited through preemption; common law liability is not foreclosed by federal law. *Id.* at 98.

I find the rationale of the Sixth Circuit's decision in *Garcia* to be more persuasive. The concerns expressed by the Supreme Court in *Buckman* hold true not only where there is a separate fraud-on-the-FDA claim but also where a plaintiff seeks to prove fraud on the FDA in order to bring a traditional state-law torts suit. If the Court were to find fraud-on-the-FDA when the FDA itself has not made such a finding, the Court would be intruding upon the FDA's right to police itself and second-guessing what the FDA would have done had it received the information that was allegedly withheld from it by the defendant-company.

Buckman is also implicated where a plaintiff seeks to use a violation of an FDA reporting requirement as proof of negligence. Even prior to *Buckman,* the Sixth Circuit questioned whether a state could use such a violation as an ingredient for tort liability. In *In re Bendectin Litig.,* 857 F.2d 290, 314 (6th Cir.1988),[16] the Sixth ***1326** Circuit pointed out that preemption could be an obstacle to a negligence per se theory based upon an alleged FDCA violation:

> [T]he determination that a violation of a federal statute such as the FDCA will create state tort liability is not a matter solely of state law. A state's ability to use a federal statute violation as a basis for state tort liability

16 The *In re Bendectin Litig.* case consisted of actions that were brought on behalf of children with birth defects against Merrell Dow Pharmaceuticals. 857 F.2d at 293. The plaintiffs alleged that their birth defects were caused by their pregnant mothers' ingestion of defendant's anti-nausea drug Bendectin. *Id.* In addition to requesting relief on the grounds of negligence, breach of warranty, strict liability, fraud, and gross negligence, the plaintiffs also claimed that proof of a violation of the FDCA would give rise to negligence per se and shift the burden to defendant to prove that Bendectin did not cause their injuries. *Id.* at 293, 312.

> and negligence per se depends on the intent of Congress, and not merely on the intent of the state. Thus, the congressional decision not to provide a private cause of action under the FDCA becomes quite important in considering the propriety of a state negligence per se action for violation of the FDCA. 'It may well be that a decision of Congress not to create a private remedy is intended to preclude all private enforcement. If that is so, then a state cause of action that makes relief available to private individuals for violations of the FDCA is preempted.' ... We recognize that a mere congressional intent to preclude a private right of action at the federal level for violations of the FDCA would not necessarily indicate that Congress intended to preclude a state remedy under a theory of negligence per se.
>
> *Id.* at 313–14 (finding negligence per se to be inapplicable to the facts of this case because the plaintiffs could not present sufficient evidence to indicate substantial probability of a causal link between ingestion of the mislabelled drug and plaintiffs' injuries, and thus could not shift the burden to defendant to prove that Bendectin did not cause plaintiffs' injuries) (declining to address whether Congress intended the FDCA to be used as a behavioral standard in such cases) (quoting *Merrell Dow v. Thompson,* 478 U.S. 804, 106 S.Ct. 3229, 3245, 92 L.Ed.2d 650 (1986) (Brennan, J., dissenting)).

Applying the laws of various states, district courts have also considered whether the argument that the FDA was defrauded, when not argued as a separate cause of action, was also preempted. For example, in *In re Aredia & Zometa Prods. Liab. Litig.,* 2009 WL 2497229 (M.D.Tenn. Aug. 13, 2009), the court considered whether the plaintiff could rebut Florida's statutory presumption[17] that the pharmaceutical drugs at issue were not defective because ***1327** they met FDA standards by alleging that the FDA approvals were improperly obtained. The court held that the issue of improperly obtained FDA approvals is preempted as a fraud-on-the-FDA claim pursuant to *Buckman. Aredia,* 2009 WL 2497229, at *2. Similarly, in *Lofton v. McNeil Consumer & Specialty Pharms.,* 682 F.Supp.2d 662 (N.D.Tex.2010), the court considered whether the fraud-on-the-FDA exception applies under a Texas statute providing a rebuttable presumption of immunity in failure to warn claims dealing with pharmaceutical products. The *Lofton* court considered the holdings of both *Garcia* and *Desiano* and found *Garcia'* s rationale to be more persuasive; it concluded that the defendants were entitled to the statutory presumption of immunity and that the fraud-on-the-FDA exception was preempted where the FDA did not find that it was defrauded. *Lofton,* 682 F.Supp.2d at 675–76. *See also Covert v. Stryker Corp.,* 2009 WL 2424559, at *1, *8 (M.D.N.C. Aug. 5, 2009) (finding that "any claims which are based upon an alleged breach of an FDA disclosure requirement" are impliedly preempted by federal law); *Grange v. Mylan Labs., Inc.,* 2008 WL 4813311, at *6–7 (D.Utah Oct. 31, 2008) (finding the Sixth Circuit's decision in *Garcia* to be more persuasive and holding that a section of the Utah Code regarding the unavailability of punitive damages for harms caused by FDA-approved drugs is preempted to the extent that it allows for an exception in cases where a plaintiff puts on independent evidence of information being withheld from the FDA); *Webster v. Pacesetter, Inc.,* 259 F.Supp.2d 27, 36–37 (D.D.C.2003) (finding that "plaintiffs cannot bootstrap their arguments regarding defendant's alleged failure to report and to investigate adverse incidents to the FDA into a defective warning case" since such claims are preempted by the FDCA under the Supreme Court's holding in *Buckman* and noting that what was told to the FDA cannot support a tort claim because it would invite the jury to speculate about what the FDA might do if the facts were different). *But see Globetti v. Sandoz Pharmaceuticals Corp.,* 2001 WL 419160 (N.D.Ala.2001) (finding that, in a product liability action, a plaintiff may not offer evidence simply to show concealment from the FDA, but such evidence "may be relevant to showing the defendant's knowledge relating to the adequacy of the warning or the truth of information represented to or concealed from plaintiff or her physician."); *Brown v. DePuy Spine, Inc.,* 2007 WL 1089337, at *13 (Mass.Super.Ct.2007) ("A state claim alleging negligence based on failure to disclose known risks to the FDA and, thereafter, to patients is not impliedly preempted because liability does not exist solely by proof of a violation of FDA disclosure requirements.").

17 Under FLA. STAT. § 768.1256,

> (1) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the product is not defective or unreasonably dangerous and the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm:
>
> (a) Complied with federal or state codes, statutes, rules, regulations, or standards relevant to the event causing the death or injury;

> (b) The codes, statutes, rules, regulations, or standards are designed to prevent the type of harm that allegedly occurred; and
> (c) Compliance with the codes, statutes, rules, regulations, or standards is required as a condition for selling or distributing the product.
> (2) In a product liability action as described in subsection (1), there is a rebuttable presumption that the product is defective or unreasonably dangerous and the manufacturer or seller is liable if the manufacturer or seller did not comply with the federal or state codes, statutes, rules, regulations, or standards which:
> (a) Were relevant to the event causing the death or injury;
> (b) Are designed to prevent the type of harm that allegedly occurred; and
> (c) Require compliance as a condition for selling or distributing the product.
> (3) This section does not apply to an action brought for harm allegedly caused by a drug that is ordered off the market or seized by the Federal Food and Drug Administration.

C. The Eleventh Circuit: *Lewis v. Brunswick*

While its precedential value has been eroded, I also find Judge Carnes's reasoning concerning regulatory fraud expressed in *Lewis v. Brunswick Corp.,* 107 F.3d 1494 (11th Cir.1997), *cert. granted, Lewis v. Brunswick Corp.,* 522 U.S. 978, 118 S.Ct. 439, 139 L.Ed.2d 337 (1997), *and cert. dismissed, Lewis v. Brunswick Corp.,* 523 U.S. 1113, 118 S.Ct. 1793, 140 L.Ed.2d 933 (1998), to be persuasive. In that case, the Eleventh Circuit found tort claims based on the absence of a propeller guard on a boat engine to be impliedly preempted by a Coast Guard regulatory decision not to require the guards. *Brunswick,* 107 F.3d at 1505 ("[C]laims based on the failure to install a product that the Coast Guard has decided should not be required would conflict with the regulatory uniformity purpose of the FBSA [Federal Boat Safety Act]. Without doubt the Lewises' product liability claims seek to impose a propeller guard requirement. That requirement ***1328** conflicts with the FBSA's grant of exclusive regulatory authority to the Coast Guard, and for that reason those claims are in conflict with and are therefore preempted by the Act.") (internal citation omitted).

Subsequently, in *Sprietsma v. Mercury Marine,* 537 U.S. 51, 123 S.Ct. 518, 154 L.Ed.2d 466 (2002), the Supreme Court held that state products liability claims were neither expressly nor impliedly preempted by the FBSA.[18] The issue before the Supreme Court in *Sprietsma,* however, did not include one of the arguments that the Eleventh Circuit considered in *Brunswick.* There, the Lewises argued that Brunswick had misled the Coast Guard and that their fraud claim should be viewed differently from their products liability claims in terms of preemption because it would not impose a propeller guard requirement.[19] *Brunswick,* 107 F.3d at 1505.

18 In regards to implied preemption, the Court rejected respondent's reliance on the Coast Guard's decision not to adopt a regulation requiring propeller guards on motorboats; it did not view that decision as the equivalent of a regulation prohibiting all States from adopting such a regulation. *Sprietsma,* 537 U.S. at 65, 123 S.Ct. 518. "Of course, if a state common-law claim directly conflicted with a federal regulation promulgated under the Act, or if it were impossible to comply with any such regulation without incurring liability under state law, preemption would occur. This, however, is not such a case." *Id.* The Court noted that although one of the FBSA's main goals was to foster uniformity in manufacturing regulations, "the concern with uniformity does not justify the displacement of state common-law remedies that compensate accident victims and their families and that serve the Act's more prominent objective, emphasized by its title, of promoting boating safety." *Id.* at 70, 123 S.Ct. 518.

19 As part of their fraudulent misrepresentation claim, the Lewises argued that Brunswick attempted to suppress the production of propeller guards by third persons and exaggerated the performance differences between guarded engines and unguarded engines to discourage government agencies from adopting a safety standard requiring propeller guards. *Brunswick,* 107 F.3d at 1497.

The Eleventh Circuit disagreed, in part because of the preemptive effect of the Coast Guard's position concerning propeller guards. *Id.* ("If the Lewises succeeded with their fraud claim, a jury could impose liability upon Brunswick for attempting to persuade the Coast Guard and others that propeller guards are unsafe. The necessary element of causation in any such claim would be that but for the wrongful conduct of Brunswick, propeller guards would have been required by the Coast Guard. Such a judgment would conflict with the Coast

Guard's position that propeller guards should not be required."). That portion of its rationale is vitiated by *Sprietsma.*

But Judge Carnes also wrote:

> Regulatory fraud claims of this nature are impliedly preempted for fundamental, systemic reasons. Permitting such claims would allow juries to second-guess federal agency regulators through the guise of punishing those whose actions are deemed to have interfered with the proper functioning of the regulatory process. If that were permitted, federal regulatory decisions that Congress intended to be dispositive would merely be the first round of decision making, with later more important rounds to be played out in the various state courts. Virtually any federal agency decision that stood in the way of a lawsuit could be challenged indirectly by a claim that the industry involved had misrepresented the relevant data or otherwise managed to skew the regulatory result.

Id. (internal citation omitted). This aspect of Judge Carnes's reasoning parallels the ***1329** concerns subsequently identified by the Supreme Court in *Buckman.*

D. The Court's Decision & Deferral of State–Specific Relevance Determinations

Buckman and its progeny deal with the preemption of claims, not evidence. Therefore, the Court must decide whether testimony or evidence that Bayer failed to adequately or timely provide information to the FDA is relevant to Plaintiffs' state-law claims rather than to a fraud-on-the-FDA claim that would be preempted by *Buckman.* In other words, *Buckman* informs the relevance analysis.

At the hearing on this Motion, Bayer emphasized the narrowness of its Motion: Bayer argues that *Buckman* applies to Plaintiffs' introduction of evidence relating to Bayer's violation of FDA reporting requirements (specifically, 21 C.F.R. § 314.80[20]) because this evidence would only be relevant to the argument that the FDA would have acted differently had it obtained the information at issue. In making this argument, Bayer noted that the reporting obligation runs to the FDA, not to the Plaintiffs or their prescribing physicians. Bayer does not argue that Plaintiffs' state-law claims are otherwise preempted.

20 This FDA regulation is titled "Postmarketing reporting of adverse drug experiences." It obligates an applicant of an FDA-approved drug to review all adverse drug experience information obtained from any source and report such information to the FDA as described in this section. Under § 314.80(j), "If an applicant fails to establish and maintain records and make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application."

Bayer stated that, at trial, it will argue that Trasylol is FDA-approved and that the jury is entitled to give weight to FDA approval. While Bayer argued that Plaintiffs may not present evidence of what was not submitted to the FDA, Bayer will present evidence of what was submitted to the FDA as part of the New Drug Application ("NDA") because FDA approval was based on that body of data. According to Bayer, the presentation of this evidence, as opposed to evidence of what was not submitted to the FDA, does not require speculation and will be relevant to the issues presented at trial.

At the hearing, Plaintiffs argued that *Buckman* does not apply to this MDL because *Buckman* dealt with the preclusion of a claim, not evidence. According to Plaintiffs, evidence of Bayer's violations of the FDA reporting requirements is relevant because it is evidence of concealment and the violation of the standard of care in a negligence claim. Plaintiffs stated that drug companies communicate with doctors in two ways: directly and indirectly via the FDA. If a drug company violates the reporting requirements of § 314.80, the indirect line of communication to doctors via the FDA is shut down. Plaintiffs maintained that they will not speculate as to what the FDA would have done with the information regarding adverse experiences with Trasylol, had it been submitted to the FDA pursuant to § 314.80.

Accordingly, the Court must determine whether evidence of Bayer's violation of FDA reporting requirements pursuant to § 314.80 would be relevant to Plaintiffs' state-law claims or whether the introduction of such evidence would amount to a claim that is substantively a fraud-on-the-FDA claim that would be preempted under the Supreme Court's ruling in *Buckman.*

[4] I conclude that evidence or testimony that Bayer failed to adequately or timely provide information to the FDA pursuant to FDA reporting obligations ***1330** that run to the FDA, such as § 314.80, is generally irrelevant to Plaintiffs' state-law claims and thus inadmissible. Such evidence or testimony would instead be relevant to a fraud-on-the-FDA claim that is preempted by *Buckman.* Bayer argued that the duty to disclose information under § 314.80 runs to the FDA, not to Plaintiffs or their prescribing physicians. Plaintiffs did not argue otherwise and stated that information disclosed under § 314.80 would only reach doctors indirectly, via the FDA. The duty at issue in this regulation is a duty to disclose to the FDA, not a duty that is owed to the Plaintiffs or their prescribing physicians. Therefore, evidence of a violation of this regulation does not constitute evidence of a breach of the standard of care at issue in Plaintiffs' state-law tort claims.

Plaintiffs argued that they will not speculate as to what the FDA would have done with the adverse event information, had it been submitted under § 314.80. Instead, they would argue that because Bayer violated § 314.80, one line of communication of safety information to doctors was shut down. However, invocation of § 314.80 necessarily requires the jury to speculate as to what the FDA would have done with the safety information at issue. This is because compliance with the FDA reporting requirements may have reduced the risk that a Plaintiff would have been harmed only if one speculates as to what the FDA would have done with the information Bayer withheld from it. In other words, this evidence would be relevant to Plaintiffs' state-law claims only if the jury speculates that the FDA would have somehow passed the safety information on to Plaintiffs or their prescribing physicians or would have required Bayer to change its label. *See Axen v. American Home Prods. Corp.,* 158 Or.App. 292, 974 P.2d 224, 236 (Or.Ct.App.1999) (in evaluating whether the trial court erred when it allowed plaintiffs to amend their complaint to allege that the defendant, AHP, was negligent in failing to abide by federal regulations § 314.80 and § 314.81 that required it to report certain scientific literature to the FDA, the Oregon Court of Appeals concluded that "[a] reasonable jury could have concluded that, had the FDA been notified of the Mayo Clinic and Mansour studies and had it required AHP to change its labeling, then Douglas Axen might have discontinued his use of amiodarone before its toxic effect robbed him of his vision.") This kind of speculation and second-guessing would intrude upon the FDA's right to police a violation of the reporting requirement itself and would violate the principles laid out in *Buckman.*[21]

21 This is also what makes the reporting regulation at issue different from the regulation mandating the content and format of a prescription drug's label, 21 C.F.R. § 201.57, which regulates the information that will be seen by prescribing doctors and patients directly. *But see Toole v. Richardson–Merrell Inc.,* 251 Cal.App.2d 689, 60 Cal.Rptr. 398 (Cal.Ct.App.1967) (finding that there is "no logical distinction between the labeling provisions on the one hand and the reporting provisions on the other, with respect to the class of persons to be protected or the harm to be prevented.").

I realize that, in the most general sense, the FDCA is designed to protect the public as a whole. However, the FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with its provisions. *See Buckman,* 531 U.S. at 349 n. 4, 121 S.Ct. 1012 (quoting 21 U.S.C. § 337(a)). While some FDA regulations may be relevant to establishing the standard of care in a state-law tort suit, reporting regulations that establish a reporting duty to the FDA, such as § 314.80, are not generally relevant to the standard of care applicable to the state-law claims in this Case.

***1331** Further, while exclusion of the evidence and testimony at issue will prevent jury speculation as to what the FDA would have done with the information at issue, Plaintiffs are free to argue whether and what information, if relevant, was withheld from them or their prescribing physicians or untimely disclosed to them or their prescribing physicians. Plaintiffs are simply incorrect in arguing that "Bayer's improper expansion of the *Buckman* case would unjustifiably preclude Plaintiff from providing essential and relevant evidence that demonstrates Bayer's knowledge regarding the harms of Trasylol." This Order in no way limits evidence or testimony demonstrating Bayer's knowledge regarding the harms of Trasylol.

Rather, it limits evidence or testimony demonstrating Bayer's failure to report such knowledge *to the FDA*.

While I find that evidence or testimony that Bayer failed to adequately or timely provide information to the FDA pursuant to FDA reporting obligations that run to the FDA, such as § 314.80, is generally irrelevant to Plaintiffs' state-law claims and thus inadmissible, this relevance determination may be altered depending on what unfolds at trial[22] and the state-specific issues presented in each Case.[23] At this moment, I am unable to entirely foreclose the possibility that the evidence and testimony at issue may become relevant at some point during any of the trials in this MDL.

22 For instance, at the hearing on this Motion, Bayer indicated that it is planning on presenting evidence of what information was submitted to the FDA in order to obtain approval for Trasylol. According to Bayer, this evidence does not require jury speculation as to what the FDA considered when it approved the Trasylol label. I do not fully agree with that assessment. While it may be a fact that the FDA had certain information when it considered approval, the introduction of such evidence may ultimately lead to speculation as to how the FDA weighed each piece of information in its risk-benefit analysis. This amounts to an improper intrusion into the FDA's deliberative process. Further, this kind of speculation is akin to the speculation involved in determining what the FDA would have done had it acquired additional information allegedly withheld from it by Bayer.

23 In its Motion, Bayer requested that this Court defer ruling on any state-law-specific issues related to FDA submissions that may arise in a particular case and give Bayer the opportunity to file additional briefing on such case-specific issues should they arise in the future. (DE 5603 at 2.)

III. Conclusion

Accordingly, it is hereby

ORDERED AND ADJUDGED that Bayer's Motion *in limine* to exclude evidence, testimony, and argument alleging that Bayer provided inadequate or incomplete data to the FDA (DE 5603) is **GRANTED.** The Court will reserve ruling on state-specific issues and may alter its relevance determination depending on what unfolds at trial.

All Citations

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