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IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

IN RE: ZOLOFT LITIGATION **CIVIL ACTION NO. 14-C-7000**

THIS DOCUMENT APPLIES TO:

M.M., a minor by and through her mother and next friend J M v. Pfizer, Inc., et al. Civil Action No. 12-C-149 WNE

ORDER

On August 8, 2016, the Panel heard arguments on *Defendants' Motion for Summary Judgment.* Having reviewed and maturely considered the briefs and evidence submitted by the parties, and the arguments presented by counsel, and having conferred with one another to insure uniformity of their decision, as contemplated by Rule 26.07(a) of the West Virginia Trial Court Rules, the Presiding Judges unanimously **GRANT** Defendants' motion for summary judgment for the reasons set forth below.

FINDINGS OF FACT

1. On July 11, 2012, Plaintiff and M.M. (the "Minor Plaintiff") filed this civil action in the Circuit Court of Wayne County, West Virginia, arising out of injuries allegedly caused by the prescription medication sertraline hydrochloride, trade name Zoloft®.[1] Plaintiffs alleged that they are citizens of Michigan. (Compl. ¶ 10 (Transaction ID 54957463); Am. Compl. ¶ 9 (Trans. ID 57945570).)

2. Plaintiffs further alleged that the Minor Plaintiff sustained birth defects as a result of the Mother Plaintiff's ingestion of sertraline during pregnancy. (Compl. ¶¶ 64-65; Am. Compl. ¶ 9.)

3. Plaintiffs asserted a number of products liability and derivative claims arising out of this allegation. Plaintiffs do not allege that the Zoloft or sertraline the Mother Plaintiff ingested was adulterated or that the labeling with which it was sold was not in compliance with the FDA-approved labeling for the product. (Compl. ¶¶ 116-178.)

[1] As used herein, "Zoloft" includes its generic form, sertraline.

4. On September 20, 2013, the Plaintiffs provided interrogatory responses confirming they are residents of Michigan; the Mother Plaintiff was prescribed Zoloft or sertraline by a physician in Michigan and ingested Zoloft in Michigan; and the Minor Plaintiff was born in Michigan and received treatment for her alleged injuries in Michigan. The Plaintiffs' discovery responses do not identify any witnesses who are located in, or any events that took place in, any other state. (Def. Ex. 1.)

5. On July 9, 2014, Defendants moved to dismiss this action and twenty others brought by non-resident plaintiffs on the grounds of forum non conveniens. (Trans. ID 55708149.)

6. Defendants also moved to dismiss this action under Michigan law. (Trans. ID 55706714.)

7. On October 21, 2014, the Panel denied the motion to dismiss under Michigan law as premature (Transaction ID 56225190), and granted in part and denied in part Defendants' motion to dismiss on forum non conveniens grounds (Transaction ID 56224960).

8. Among other things, the Panel determined that it is required by W.Va. Code § 55-8-16(a)(2011) to apply the law of the place of injury to the Plaintiff Family's failure to warn claims. *See* (Transaction ID 56224960), paragraph 57 ("the Panel is required by statute to apply the law of the location of injury to each of the subject Plaintiff Families' failure to warn claims"); paragraph 60 (Plaintiff Family's public policy argument is rendered academic insofar as it applies to failure to warn claims by § 55-8-16(a)); and paragraph 62 (because Plaintiff Family filed complaint after effective date of § 55-8-16 the Panel is bound to apply the law of the state of injury to failure to warn claims).

9. Pursuant to the Court's Second Case Management Order (Transaction ID 57813632), Plaintiffs filed an Amended Complaint on September 30, 2015. The Amended Complaint contains the same core factual allegations as the original complaint, but omits certain causes of action, among other changes. Plaintiffs now plead three causes of action: (1) strict

liability; (2) failure to warn; and (3) negligence. They also seek punitive damages. (Am. Compl. ¶¶ 95-132.)

10. The following facts are undisputed: (1) Zoloft was approved for safety and efficacy by the United States Food and Drug Administration ("FDA"); (2) Plaintiffs do not allege that the Zoloft Mrs. took was adulterated or that its labeling was not in compliance with the FDA-approved labeling for the product; and (3) the FDA has not ordered Zoloft removed from the market and it has not withdrawn approval for Zoloft.

11. Plaintiffs have not alleged with specificity any misrepresentations made to the FDA. Nor do they plead that any such representations were intentionally false or concerned information that was required to be submitted to the FDA. Plaintiffs have also made no allegation that, if proven, would establish that any such alleged, but unidentified, misrepresentations to the FDA would have caused the FDA to not approve Zoloft or to withdraw its approval for Zoloft. Nor do Plaintiffs allege that the FDA has ever made a determination of fraud regarding Zoloft or sertraline.

12. The FDA has promulgated regulations governing the content and form of information to be submitted to it, both pre- and post-marketing. *See, e.g.*, 21 C.F.R. 314.50 (governing the content and form of a new drug application); 21 C.F.R. 314.70 (governing supplements and changes to an application); 21 C.F.R. § 314.80 (governing postmarketing reporting of adverse drug experiences); 21 C.F.R. § 314.81 (governing other postmarketing reports). Plaintiffs have not shown that the data and information described in their exhibits were required to be submitted to the FDA or that required information (rather than specific documents) was withheld from the FDA.

13. Plaintiffs cite to various animal studies and toxicology reports prepared by Pfizer, providing their own interpretations of those complex, scientific documents, without expert testimony to support their interpretations. (*Plaintiffs' Amended Response to Defendants' Memorandum of Law in Support of Their Motion for Summary Judgment* ("Am. Resp.") (Trans. ID 58950879) at 2, 13.) This is mere speculation and allegation by the Plaintiffs. More

importantly, Plaintiffs have not shown that the results of animal studies conducted by Pfizer were not reported to the FDA in accordance with its regulations. The record shows that the FDA-approved Zoloft label summarizes the animal studies, describes the adverse effects seen in those studies, states that there was no evidence of teratogenicity, and ends with the statement: "The clinical significance of these effects is unknown. There are no adequate and well-controlled studies in pregnant women. ZOLOFT (sertraline hydrochloride) should be used during pregnancy only if the potential benefit justifies the risk to the fetus." (Pl. Ex. A at 25.)

14. Plaintiffs also refer to evaluations of adverse event reports, again offering their own speculative, non-expert interpretation of such documents. (Am. Resp. at 2-3.) However, the FDA has specific requirements and forms governing the reporting of such information to it. *See* 21 C.F.R. § 314.80. Plaintiffs have not shown that Pfizer failed to submit any required adverse event report to the FDA.

15. Plaintiffs further cite to a statement in Pfizer's Core Data Sheet and foreign labels that "[w]omen of childbearing potential should employ an adequate method of contraception if taking sertraline," again offering their own interpretation of the referenced documents. (Am. Resp. at 3-4, 8-9. 13-14.). However, Plaintiffs have not shown that any required information (rather than a specific document) was withheld from the FDA. To the contrary, Pfizer has submitted unrebutted evidence that the FDA requested copies of foreign labels during the approval process for Zoloft. In response, Pfizer provided the FDA with copies of foreign labels for the United Kingdom and Ireland, as well as the International Product Document ("IPD") which was used as the basis for labels in other countries. (Def. Ex. 15.) Each of these documents contained the contraception language cited by Plaintiffs. (*Id.*) Thus, it appears the FDA was aware of the contraception language when it approved Zoloft.

16. Litigation against Pfizer involving allegations that Zoloft causes birth defects has been pending in various jurisdictions since 2011, and there has been a fair amount of publicity about the litigation. There have been two trials (each resulting in a defense verdict). (Def. Exs. 5 & 6.) Shortly before trial in a third case began, a Pennsylvania state court excluded the

Plaintiffs' experts and entered summary judgment in favor of Pfizer. (Def. Exs. 7 & 8.) In the federal multidistrict litigation ("MDL"), there have been two *Daubert* hearings, each resulting in the exclusion of plaintiffs' proffered expert testimony on human causation.[2] As a result of those rulings, the MDL court granted Pfizer's motion for summary judgment as to all cases then pending in the MDL, dismissing the claims of more than 300 plaintiff-families.[3] Significantly, the plaintiffs in the federal MDL sent their most recent general causation expert report to the FDA. (Def. Ex. 9.) Yet, despite years of public airing of plaintiffs' allegations against Pfizer in the courts and media, Zoloft remains on the market and continues to be widely prescribed. The FDA has not withdrawn approval for Zoloft or removed Zoloft from the market.

17. In September 2014, the Organization of Teratology Information Specialists (OTIS), responding to the question "Can taking [Zoloft] during my pregnancy cause birth defects?" explained that "[Zoloft] is one of the better studied antidepressants during pregnancy. There are reports of over 2000 pregnancies exposed to [Zoloft] during the first trimester." The organization further explained to mothers wondering whether Zoloft is safe during pregnancy that, while "[s]ome studies have found associations between [Zoloft] use during pregnancy and particular birth defects[,] . . . *most studies have not found that women taking [Zoloft] during pregnancy are more likely to have a baby with a birth defect than women not taking [Zoloft]. Overall, the available information does not suggest that [Zoloft] increases the risk for birth defects above the 3-5% background risk that is seen in the general population.*" (Def. Ex. 3, emphasis added.)

18. More recently, the Centers for Disease Control ("CDC") summarized the findings of a study conducted by CDC investigators published in the British Medical Journal ("BMJ"):

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[2] *See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 449, 465 (E.D. Pa. 2014), *reconsid. denied*, 2015 WL 314149 (E.D. Pa. Jan. 23, 2015); *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466, 481 (E.D. Pa. 2014); *In re: Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 2015 WL 7776911, at *16 (E.D. Pa. Dec. 2, 2015).

[3] See *In re: Zoloft (Sertraline Hydrochloride) Products Liab. Litig.*, 2016 WL 1320799, at *11 (E.D. Pa. Apr. 5, 2016).

> In this CDC study published in The BMJ, researchers re-assessed several previously reported links between SSRI use and birth defects using more recent data. These results reflect not only the new data, but also incorporate results from previously published independent studies. . . .
>
> * * *
>
> Reassuringly, researchers did not confirm links between [Zoloft], the SSRI used most often, and any of the birth defects observed in previous studies.

(Def. Ex. 4; *See also* Def. Ex. 13.)

CONCLUSIONS OF LAW

I. Legal Standard

19. Summary judgment is appropriate if "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." W. Va. R. Civ. P. 56(c); *accord Fleet v. Webber Springs Owners Ass'n*, 235 W. Va. 184, 188, 772 S.E.2d 369, 373 (2015)("[a] motion for summary judgment should be granted only when it is clear that there is no genuine issue of fact to be tried and inquiry concerning the facts is not desirable to clarify application of the law")(internal citation omitted). "A material fact is one that has the capacity to sway the outcome of the litigation under the applicable law." Syl. Pt. 5, *Jividen v. Law*, 194 W. Va. 705, 461 S.E.2d 451 (1995).

20. "If the moving party makes a properly supported motion for summary judgment and can show by affirmative evidence that there is no genuine issue of material fact, the burden of production shifts to the nonmoving party who must either (1) rehabilitate the evidence attacked by the moving party, (2) produce additional evidence showing the existence of a genuine issue for trial, or (3) submit an affidavit explaining why further discovery is necessary as provided in Rule 56(f) of the West Virginia Rules of Civil Procedure." Syl. Pt. 3, *Williams v. Precision Coil, Inc.*, 194 W. Va. 52, 459 S.E.2d 329 (1995).

21. "[T]he party opposing summary judgment must satisfy the burden of proof by offering more than a mere 'scintilla of evidence,' and must produce evidence sufficient for a reasonable jury to find in a nonmoving party's favor." *Painter v. Peavy*, 192 W. Va. 189, 192-93, 451 S.E.2d 755, 758-759 (1994).

22. "Summary judgment is appropriate where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, such as where the nonmoving party has failed to make a sufficient showing on an essential element of the case that it has the burden to prove." *Id.* at 193, 759 (citations omitted). The nonmoving party may not rely on speculation and unsupported allegations to oppose summary judgment, but must offer "'significant probative evidence tending to support the complaint.'" *Id.* (citations omitted).

II. Choice of Law

23. Defendants argue that the Plaintiffs' claims are barred by Michigan law. As an initial matter, this Panel must determine whether Michigan law applies to the Plaintiffs' claims.

24. The version of West Virginia Code section 55-8-16(a) in effect when this lawsuit was filed provided that:

> It is public policy of this state that, in determining the law applicable to a product liability claim brought by a nonresident of this state against the manufacturer or distributor of a prescription drug for failure to warn, the duty to warn shall be governed solely by the product liability law of the place of injury ("lex loci delicti").

W. Va. Code § 55-8-16(a) (2011).[4]

25. Plaintiffs argue that the Panel should decline to apply Michigan law as a matter of public policy and, in doing so, misconstrue the Panel's prior ruling. Because the applicable version of W. Va. Code § 55-8-16(a) applied only to failure to warn claims, the Panel determined that it was not precluded from applying West Virginia public policy considerations to Plaintiffs' other claims when deciding Defendants' motion to dismiss on grounds of forum non conveniens.

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[4] The statute was revised in 2015 to state, "It is public policy of this state that, in determining the law applicable to a product liability claim brought by a nonresident of this state against the manufacturer or distributor of a prescription drug *or other product, all liability claims at issue* shall be governed solely by the product liability law of the place of injury ('lex loci delecti')." W. Va. Code § 55-8-16(a) (2015)(emphasis added). The amendments to the statute apply "prospectively to all civil actions commenced on or after July 1, 2015." *Id.* at § 55-8-16(b). Because the civil action was commenced in 2012, the 2011 version of the statute applies. *See* § 55-8-16(b) (2011).

(Court's *Order* entered October 21, 2014, Transaction ID 56224960 ¶ 63).[5] However, while the Panel left open the possibility of applying law other than Michigan to Plaintiffs' non-failure-warn claim, the Panel's decision was clear that Michigan law applied to Plaintiffs' failure to warn claims.

26. "Product liability actions may be premised on three independent theories – strict liability, negligence and warranty. Each theory contains different elements which plaintiffs must prove in order to recover." Syl. Pt. 6, *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603 (1983). Additionally, in strict liability actions, a defective product may fall into three categories: (1) design defect; (2) structural or manufacturing defect; and (3) use defect arising out of inadequate warnings. *Morningstar v. Black and Decker Mfg. Co.*, 162 W. Va. 857, 888-89, 253 S.E.2d 666, 682 (1979).

27. As ordered by the Panel, Plaintiffs' filed an amended complaint on September 30, 2015. Their amended complaint alleges three causes of action: (1) strict liability; (2) failure to warn; and (3) negligence (Am. Compl. ¶¶ 95-132). However, no matter how Plaintiffs label their causes of action or characterize the evidence, the only claim they are asserting is strict liability based on failure to warn.

28. Plaintiffs' argument that their strict liability and negligence claims survive under West Virginia law makes it clear that their only claim is failure to warn. (Am. Resp. at 7-8) ("In a use defectiveness, or failure to warn, case, 'the focus is not so much on a flawed physical condition of the product, as on its unsafeness arising out of the failure to adequately label, instruct or warn.'")(internal citations omitted); *Id.* ("A strict liability claim brought on failure to warn theory 'covers situation when a product may be safe as designed and manufactured, but which becomes defective because of the failure to warn of dangers which may be present when the product is used in a particular manner.'")(internal citations omitted); *Id.* at 8 ("Here,

[5] Defendants argue that the only state other than Michigan whose law could constitutionally be applied to Plaintiffs' non-failure-to-warn claims is New York, citing *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 822 (1985)). Because Plaintiffs have made clear that they are not pursuing claims other than failure to warn, the Panel need not resolve this issue.

Plaintiffs base their strict liability and negligence claims on the theory that Defendants *failed to warn* the medical community and public about the risks of taking Zoloft during pregnancy despite knowing that such risks existed.")(emphasis added); *Id.* ("if the Panel determines that Plaintiffs must demonstrate that a feasible alternative design was available, notwithstanding that West Virginia (and New York) common law only require such a showing where the Plaintiff has claimed that a design defect existed in the product at issue, *Plaintiffs contend that the feasible alternative design was to provide adequate labeling information that warned of the risks of the use of Zoloft in pregnant women or women of childbearing age."*)(emphasis added)

29. During oral argument, Plaintiffs' counsel argued that Plaintiffs had made a case for defective design. However, his argument was premised entirely on failure to warn:

> And under West Virginia law - whether you call it a failure to warn case or a defective design case - it's really looking at the same thing: What -- what are we talking about, right? And on a defective design case, where you have a product with an inadequate label, then you have a -- you've made a case for defective design.
>
> If you have a pipe that is only rated for a certain pressure but that pipe doesn't have information about what it's rated for, the design is defective.
>
> I know, Judge Swope, you've handled, you know, auto product liability cases. If you have a tire, it doesn't tell you how much to inflate the tire, so that it's either underinflated or overinflated, that tire -- that tire is defective. Same here.
>
> The drug is not just the molecule. The drug is in the packaging that it goes in, including the warning label. And in this case, the warning is inadequate. The warning in this case - and as evidenced and you guys have seen it in the briefing - did not contain essential information about the use of the product for women of childbearing potential.

(August 8, 2016 Tr. at 37:1-38:1.)

30. Plaintiffs' counsel has also argued that W. Va. Code § 55-8-16(a) says only that in a failure to warn case, the duty will be governed by the place of injury. *Id.* at 35:22-36:2. However, the Michigan statute at issue does not merely provide an affirmative defense to manufacturers of prescription drugs. It states affirmatively that a drug approved by the FDA is

not defective, absent one of the exceptions. In other words, under Michigan law, a manufacturer meets its duty to provide an adequate warning when it sells a drug accompanied by a label that has been approved by the FDA. *See Taylor v. SmithKline Beecham Corp.*, 658 N.W.2d 127, 131 (Mich. 2003).

31. The Plaintiffs are nonresidents and the place of their alleged injury is Michigan, because that is where the Mother Plaintiff was prescribed Zoloft, ingested Zoloft, and resided during her pregnancy. It is also where the Minor Plaintiff was born and treated for her injuries. Because the gravamen of Plaintiffs' claims is for is failure to warn, as the Panel has previously determined, Michigan law applies pursuant to W. Va. Code § 55-8-16(a).

32. The Panel, therefore, finds that Michigan law governs Plaintiffs' claims in this action.

III. Summary Judgment

A. The Michigan Statute

33. The Michigan statute applicable to Plaintiffs' claims provides, in relevant part:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

Mich. Comp. Laws § 600.2946(5). Michigan's highest court has expressly confirmed that in adopting this statute, "the [Michigan] Legislature . . . determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that *no tort liability may lie*." *Taylor*, 658 N.W.2d at 131 (emphasis added).

34. This action is "a product liability action against a manufacturer or seller." Mich. Comp. Laws § 600.2946(5). The Michigan statute defines a "[p]roduct liability action" broadly to include "an action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product." *Id.* § 600.2945(h).

35. The elements of the Michigan statutory bar are satisfied because Zoloft was "approved for safety and efficacy by the [FDA]" and "its labeling [was] in compliance with the [FDA's] approval at the time the drug left the control of [Pfizer]." Mich. Comp. Laws § 600.2946(5).

36. Accordingly, in the absence of an exception to manufacturer's immunity (discussed below), the Michigan statute requires dismissal of the Plaintiffs' claims. *See White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1031 (W.D. Mich. 2008) (granting judgment on the pleadings where "Plaintiffs have not alleged any fact which would invoke either of the two exceptions contained within the statute"); *Henderson v. Merck & Co., Inc.*, 2005 WL 2600220, at *11-12 (E.D. Pa. Oct. 11, 2005) (granting judgment on the pleadings under the Michigan statute, and noting "because plaintiff's complaint is devoid of allegations to trigger these exceptions, discovery on this issue would be futile"), *reconsid. denied*, 2005 WL 2864752 (E.D. Pa. Oct. 31, 2005); *See also Thurston v. Merck & Co.*, 415 F. App'x 585, 586 (5th Cir. 2011) (dismissal as a matter of law was warranted where plaintiff failed to "plead facts sufficient to meet any of the exceptions" to the Texas statute).

B. Plaintiffs Have Failed to Meet Their Burden to Create a Triable Issue of Material Fact as to the Fraud-on-the-FDA Exception to the Michigan Statute

37. The Michigan statute allows a product liability action against a manufacturer of an FDA-approved medicine to proceed if the manufacturer:

> intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act . . . and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.

Mich. Comp. Laws § 600.2946(5)(a).[6] Plaintiffs assert that this exception, also known as the "fraud-on-the-FDA exception," applies to their case.

[6] The Michigan statute contains other exceptions, but Plaintiffs have not argued that they apply in this case.

38. To successfully plead the fraud-on-the-FDA exception to the Michigan statute, the Plaintiffs must establish that: (1) the manufacturer intentionally withheld from or misrepresented to the FDA information concerning the drug; (2) the information was required to be submitted under the federal Food, Drug and Cosmetic Act ("FDCA"); and (3) 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 § 600.2646(5)(a).

39. Once Defendants met their burden to show that the Michigan statute applied and barred Plaintiffs' claims, the burden shifted to Plaintiffs to show that one of the exceptions applied. *Cf. Powderidge Unit Owners,* 196 W. Va. 692, 699, 474 S.E.2d 872, 879 (1996) (once defendant showed statute of limitations applied, plaintiff had burden of proving it was within the discovery exception).

40. The nonmoving party cannot satisfy his or her burden with evidence that is "conjectural or problematic. It must have substance in the sense that it limns differing versions of the truth which a factfinder must resolve. The evidence must contradict the showing of the moving party by pointing to specific facts demonstrating that, indeed, there is a 'trialworthy' issue." *Williams,* 194 W. Va. at 60, 459 S.E.2d at 337. "A 'trialworthy' issue requires not only a 'genuine' issue but also an issue that involves a 'material' fact." *Id.* (citations and footnotes omitted); *See also Powderidge Unit Owners,* 196 W. Va. at 698, 474 S.E.2d at 878 ("Genuineness and materiality are not infinitely elastic euphemisms that may be stretched to fit whatever preferrations catch a litigant's fancy."); *Celotex Corp. v. Catrett,* 477 U.S. 317, 317 (1986) ("[A] complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial.").

41. Here, Plaintiffs cite to vague allegations that Defendants represented to the FDA that Zoloft was safe and effective and concealed knowledge that Zoloft can cause birth defects to persons exposed *in utero* to support their argument that the fraud-on-the-FDA exception applies. (Am. Resp. at 14-15.) However, the nonmoving party cannot satisfy his burden with vague allegations, but most offer "concrete evidence" that would support a verdict in his favor.

Painter, 192 W. Va. at 193, 451 S.E.2d at 759. Mere allegations are insufficient to sustain the non-moving party's burden. *Sergent v. City of Charleston*, 209 W. Va. 437, 445, 549 S.E.2d 311, 319 (2001).

42. Plaintiffs also cannot meet their burden with evidence that, while disputed, is immaterial to the issue at hand. For example, in *Williams*, the plaintiff argued that an employee handbook constituted a contract of employment. Whether it did or not, the plaintiff failed to show that he knew about the handbook and relied upon it. As a result, "the plaintiff failed to put into dispute an essential element of his cause of action." 194 W. Va. at 65-66, 459 S.E.2d at 342-43. Likewise, in *Gibson v. Little Gen. Stores, Inc.*, 221 W. Va. 360, 655 S.E.2d 106 (2007), the West Virginia Supreme Court affirmed summary judgment where the plaintiff failed to produce competent evidence of product malfunction. *Id.* at 364, 655 S.E.2d at 110.

43. Plaintiffs' approach to summary judgment is comparable to the approach rejected by the West Virginia Supreme Court in *Miller v. City Hosp., Inc.*, 197 W. Va. 403, 475 S.E.2d 495 (1996) (per curiam). In *Miller*, the Supreme Court affirmed summary judgment in favor of an employer, when the plaintiff failed to produce sufficient evidence to create a material issue of fact on the "deliberate intention" exception to employer immunity under West Virginia's worker compensation laws. *See Id.* at 405, 475 S.E.2d at 497. The Court noted that while an issue of fact existed for *some* of the elements of the exception, the plaintiff failed to show that the defendant violated a safety statute or standard. *See Id.* at 409, 475 S.E.2d at 501. The plaintiff argued "that she ha[d] shown a violation of a safety statute or standard based on the general knowledge of the 'cause and effect between high stress and clinical depression and other disorders.'" *Id.* Rejecting her argument, the Supreme Court explained that "a general allegation is not a 'specific unsafe working condition [which] was a violation of a state or federal safety statute. . . .' and neither does such an allegation automatically show a violation 'of a commonly accepted and well-known safety standard within the industry.'" *Id.* The Court further stated that the plaintiff's "statement about general knowledge of stress does not meet her burden of

production to fulfill W. Va. R. Civ. P. 56(e)'s explicit mandate for 'specific facts.'" *Id.* at 410, 475 S.E.2d at 502.

44. Similar to *Miller*, Plaintiffs argue that Pfizer was aware of various risks associated with the use of Zoloft during pregnancy and, therefore, the Zoloft label was inadequate. These allegations are disputed by Pfizer; however, this dispute does not create an issue of material fact precluding summary judgment. Plaintiffs have not met their burden because they have not shown how any of the documents they rely on are relevant to the elements of the fraud-on-the-FDA exception to the Michigan statute: (1) did Pfizer intentionally withhold from or misrepresent to the FDA information concerning Zoloft; (2) was such information required to be submitted under the FDCA; and (3) would such information have caused the FDA to refuse to approve Zoloft or withdraw approval for Zoloft if it were accurately submitted?

45. As discussed in the Findings of Fact, Plaintiffs have not shown that any relevant and material information (as opposed to specific documents) required to be submitted to the FDA was withheld from the FDA. For example, Plaintiffs place great reliance on language regarding use of contraception found in Pfizer's Core Data Sheet for Zoloft.[7] However, Plaintiffs have not cited any regulation that requires a prescription drug manufacturer to provide a copy of a Core Data Sheet to the FDA. At oral argument, Plaintiffs' asserted that the Core Data Sheet should have been provided to the FDA pursuant to the Code of Federal Regulations 314.50. (August 8, 2016 Tr. at 40:12-16.) However, 21 C.F.R. § 314.50 governs the content and format of a new drug application and says nothing about Core Data Sheets. Moreover, the uncontroverted evidence shows that foreign labels and the International Product Document for Zoloft, all of which contained the contraception language, were provided to the FDA before Zoloft was approved. (Def. Ex. 15.)

46. Finally, Plaintiffs have not introduced any evidence that any of the information cited by Plaintiffs would have caused the FDA to refuse to approve Zoloft or to withdraw

[7] Defendants contend that Plaintiffs have misinterpreted this statement in the Core Data Sheet. However, the Panel need not resolve this dispute to decide this motion for summary judgment.

approval for Zoloft. As noted in the Findings of Fact, the FDA was aware of the results of animal tests, adverse event reports and language regarding contraception use in Pfizer's foreign labels and International Product Document. Further, the allegations made by Plaintiffs in this litigation have been made in other cases and have been the subject of significant publicity. The record shows that plaintiffs in the federal multidistrict litigation sent a copy of their expert report to the FDA. (Def. Ex. 9.) Thus, even though the FDA is aware of claims being made in litigation similar to this action, and of the opinions of plaintiffs' expert in the Zoloft federal MDL, Zoloft continues to be marketed with FDA approval.

47. At oral argument, Plaintiffs' counsel was asked whether the FDA had done anything with this information, and he could not identify any action the FDA had taken in response. (August 8, 2016 Tr. at 41:12-42:21.) He noted that the Zoloft label was undergoing revision but conceded that process reflected a new FDA approach to pregnancy labeling. (*Id.* at 42:1-12.) Regardless, the Michigan statute requires more than a label change; it requires evidence that the FDA would not have approved Zoloft or would have withdrawn approval for Zoloft. Plaintiffs have not produced even a scintilla of evidence to support such a claim.

48. Whether there is a genuine issue of fact to prevent summary judgment is not determined by the volume of submissions, but their relevance and materiality. Plaintiffs have failed to produce any relevant and material evidence sufficient to satisfy their burden on the applicability of the fraud-on-the-FDA exception to the Michigan statute.

C. Federal Law Preempts Reliance on the Fraud-on-the-FDA Exception

49. Even if Plaintiffs had presented evidence on all three elements of the fraud-on-the-FDA exception to the Michigan statute sufficient to create a genuine issue of fact, it would still not save their claims because the exception is preempted by federal law. Under the U.S. Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), a claim that a manufacturer committed fraud on the FDA is impliedly preempted by the federal Food, Drug, and Cosmetic Act. *Id.* at 348-53. The U.S. Supreme Court held that state law causes of action that require evidence that a manufacturer submitted false or misleading

information to the FDA are impliedly preempted because "the federal statutory scheme empowers the FDA," not individual citizens, "to punish and deter fraud against the Administration . . . to achieve a somewhat delicate balance of statutory objectives." *Id.* at 348. This balance "can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Id.*

50. In *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961 (6th Cir. 2004), the United States Court of Appeals for the Sixth Circuit held that, under *Buckman*, the fraud-on-the-FDA exception in the Michigan statute is preempted and, therefore, unavailable unless "the FDA *itself* determines that a fraud has been committed on the agency during the regulatory-approval process." *Id.* at 966; *accord Marsh v. Genentech, Inc.*, 693 F.3d 546, 551 (6th Cir. 2012); *In re Aredia & Zometa Prods. Liab. Litig.*, 352 F. App'x 994, 995 (6th Cir. 2009).[8] Thus, a plaintiff must plead and prove that the FDA *itself* determined that it was defrauded for immunity not to apply to a manufacturer of an FDA-approved medicine. *See Garcia*, 385 F.3d at 966. The United States Court of Appeals for the Fifth Circuit has likewise held that the fraud-on-the-FDA exception to Texas's analogous drug product liability statute is preempted unless "the FDA *itself* finds fraud." *Lofton v. McNeil Consumer & Specialty Pharms.*, 672 F.3d 372, 381 (5th Cir. 2012) (emphasis added).[9]

51. Plaintiffs do not allege that the FDA has ever made a determination of fraud regarding Zoloft or sertraline, much less that Defendants fraudulently obtained FDA approval for Zoloft.[10]

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[8] *See also Blair v. Genentech, Inc.*, 2011 WL 5088969, at *6 (W.D. Mich. Oct. 26, 2011) (holding that under *Garcia*, the fraud-on-the-FDA exception to the Michigan Act was preempted because plaintiff failed to allege a "federal finding of such fraud"); *Duronio v. Merck & Co., Inc.*, 2006 WL 1628516, at *5 (Mich. Ct. App. June 13, 2006) (adopting holding in *Garcia*); *In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312, 1325-27, 1329-30 (S.D. Fla. 2010) (excluding evidence that a manufacturer provided inadequate information to the FDA because the FDA itself had not reached that finding).

[9] *See also Solomon v. Bristol-Myers Squibb Co.*, 916 F. Supp. 2d 556, 571 (D.N.J. 2013); *Eckhardt v. Qualitest Pharms. Inc.*, 858 F. Supp. 2d 792, 799 (S.D. Tex. 2012), *aff'd*, 751 F.3d 674 (5th Cir. 2014); *Murthy v. Abbott Labs.*, 847 F. Supp. 2d 958, 976 (S.D. Tex. 2012).

[10] A determination that the second exception is preempted, absent a finding of fraud by the FDA, does not bar enforcement of the act. Under Michigan law, "[i]f any portion of an act or the application thereof to any person or circumstances shall be found to be invalid by a court, such invalidity shall not affect the remaining portions or applications of the act which can be given effect without the invalid portion or

52. In arguing against preemption, Plaintiffs confuse the critical distinction between their failure-to-warn claims and the statutory exception they invoke. For example, Plaintiffs state that "the United States Supreme Court has clearly recognized that plaintiffs' claims are not preempted by federal law" (Am. Resp. at 19), and Plaintiffs heavily rely upon *Wyeth v. Levine*, 555 U.S. 555 (2009), and *Altria Group, Inc. v. Good*, 555 U.S. 70 (2008) (*Id.* at 18-19). These decisions are inapplicable here. As the Sixth Circuit recognized in *Marsh*, Plaintiffs' view "confuses the validity of [a] substantive claim with the validity of [an] argument that immunity does not apply." *Marsh*, 693 F.3d at 554. The Fifth Circuit has also rejected the arguments Plaintiffs advance here with respect to an equivalent Texas statute, holding that to follow the view advanced by Plaintiffs would be to deny that the "statute is what it is—a requirement to prove fraud on the FDA." *Lofton*, 672 F.3d at 377.

53. Indeed, the allegations that Plaintiffs advance here to support their reliance on the fraud-on-the-FDA exception implicate precisely the concerns expressed by the Supreme Court in *Buckman*. In *Buckman*, the Supreme Court explained that "fraud-on-the-FDA claims would also cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court. Applicants would then have an incentive to submit a deluge of information that the Administration neither wants nor needs, resulting in additional burdens on the FDA's evaluation of an application." 531 U.S. at 351.

54. As discussed above, Plaintiffs do not identify any information required to be submitted to the FDA that was withheld. Instead they cite to various internal Pfizer documents they contend should have been provided to the FDA, even though the FDA has specified the information it needs and the format that it should be provided in. Allowing fraud-on-the-FDA

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application, provided such remaining portions are not determined by the court to be inoperable, and to this end acts are declared to be severable." Mich. Comp. Laws § 8.5. Here the immunity provision can be given effect because the fraud exception remains valid where the FDA itself has found fraud. Accordingly, preserving, rather than voiding, the immunity statute is more faithful to the Michigan Legislature's concern that "unlimited liability for drug manufacturers would threaten the financial viability of many enterprises and could add substantially to the cost and unavailability of many drugs." *Garcia*, 385 F.3d at 967.

claims to proceed, whether as a stand-alone claim or to support an exception to a statute such as Michigan's, risks causing the deluge of information to the FDA that the Supreme Court feared.

55. Plaintiffs ask this Panel to disregard *Garcia*, *Marsh*, *Lofton*, and their numerous circuit and district court progeny and to instead follow the opinion in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), *aff'd by an equally divided court sub nom., Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008). However, *Desiano* is inconsistent with more persuasive and more recent decisions of the Fifth and Sixth Circuits and other courts interpreting the Michigan Act and the similar Texas statute, which have held that, under *Buckman*, a plaintiff must plead and prove that the FDA itself determined that it was defrauded. *See Lofton*, 672 F.3d at 380; *Marsh*, 693 F.3d at 554; *In re Aredia*, 352 F. App'x at 995.

56. In addition, *Desiano* cannot be reconciled with *Buckman.* Under *Desiano,* for a plaintiff to establish the fraud-on-the-FDA exception to the Michigan Act, a fact-finder would have to make precisely the determination the Supreme Court held in *Buckman* was preempted – that the FDA was defrauded by the defendant. *See Buckman,* 531 U.S. at 348-49; *Garcia,* 385 F.3d at 966 ("[S]tate tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims") (citation omitted); *In re Aredia & Zometa Prods. Liab. Litig.,* 2009 WL 2497229, at *2 (M.D. Tenn. Aug. 13, 2009) (under *Buckman,* plaintiff could not present evidence that a manufacturer improperly obtained FDA-approval of a drug to rebut a statutory presumption that the drug was not defective); *In re Aredia & Zometa Prods. Liab. Litig.*, 2008 WL 2944910, at *4 (M.D. Tenn. Jul. 25, 2008) (under a similar Texas statute, "in order to establish that the FDA would have acted differently if Defendant had submitted accurate information, Plaintiffs would have to 'go behind' the FDA processes, raising the concerns sought to be avoided in *Buckman*").

57. Neither *Desiano* nor its progeny are persuasive. Though West Virginia courts have not addressed this issue, multiple courts analyzing *Garcia* and *Desiano*, including the Fifth Circuit in *Lofton*, have held the Sixth Circuit's reasoning in *Garcia* is more consistent with *Buckman*. *Desiano* relies on a strained attempt to distinguish a stand-alone claim for fraud on

the FDA from proof that there has been fraud on the FDA. As the Fifth Circuit explained, that "strain[ed]" and inconsequential distinction is not "faithful to *Buckman*" and "overlooks the reality of trial practice and the precise statutory language." *Lofton*, 672 F.3d at 380. "Either way . . . a plaintiff must 'establish' a violation of FDA's required disclosures. In so doing, the plaintiff necessarily re-treads the FDA's administrative ground both to conduct discovery and to persuade a jury." *Id.* at 380; *See also In re Trasylol Prods. Liab. Litig.*, 763 F. Supp. 2d 1312, 1323-27 (S.D. Fla. 2010) (adopting *Garcia* over *Desiano* because "[t]he concerns expressed . . . 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"); *Grange v. Mylan Labs., Inc.*, 2008 WL 4813311, at *7 (D. Utah Oct. 31, 2008) (finding *Garcia* "more persuasive" than *Desiano*).[11]

CONCLUSION

In light of the foregoing, the Panel unanimously **GRANTS** Defendants' Motion for Summary Judgment. Judgment is entered in favor of Defendants and the claims of the above-captioned Plaintiff Family are hereby **DISMISSED WITH PREJUDICE**. Any exceptions or objections are noted and preserved for the record.

The Court **FINDS** upon **EXPRESS DETERMINATION** that this a final order available for the proper application of the appellate process pursuant to Rule 54(b) of the Rules of Civil Procedure and the Rules of Appellate Procedure. Accordingly, this order is subject to immediate appellate review. The parties are hereby advised: (1) that this is a final order; (2) that any party aggrieved by this order may file an appeal directly to the Supreme Court of Appeals of West Virginia; and (3) that a notice of appeal and the attachments required in the notice of appeal must be filed within thirty (30) days after the entry of this Order, as required by Rule 5(b) of the West Virginia Rules of Appellate Procedure.

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[11] *Hall v. Wyeth, Inc.*, 2010 WL 3860467 (E.D. Pa. Sept. 30, 2010), also cited by Plaintiffs (Am. Resp. at 20) is not a persuasive decision for the same reasons as *Desiano*.

The Clerk is directed to close this case and place it among the cases ended. A copy of this order is this day served on the parties of record via File & Serve*Xpress*.

It is so ORDERED.

ENTER: August 30, 2016.

/s/ James P. Mazzone
Lead Presiding Judge
Zoloft Litigation