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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:	
J.C., a minor by and through his mother and next friend Michelle C	Civil Action No. 12-C-146-WNE
I.H., a minor by and through her mother and next friend Angela H	Civil Action No. 13-C-229-WNE

ORDER REGARDING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

The Presiding Judges have reviewed and maturely considered *Defendants' Motion for Summary Judgment* (Transaction ID 59877656) filed in the above-captioned cases, *Plaintiffs' Response and Memorandum of Law in Opposition to Defendants' Motion for Summary Judgment* (Transaction ID 59958774), and *Defendants' Reply Memorandum of Law in Support of Motion for Summary Judgment* (Transaction ID 59979426), as well as the evidence submitted by the parties. The Presiding Judges have also reviewed and considered *Defendants' Proposed Findings of Fact and Conclusions of Law Regarding Defendants' Motion for Summary* Judgment (Transaction ID 59986448) and *Plaintiffs' Objections to Defendants' Proposed Findings of Fact and Conclusions of Law Regarding Defendants' Motion for Summary Judgment* (Transaction ID 60159418).

The Presiding Judges previously found that the facts and legal arguments were adequately presented, and the decisional process would not be significantly aided by oral argument. December 23, 2016 *Order* (Transaction ID 59991202). 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 and make the following findings of fact and conclusions of law.

INTRODUCTION

1. Plaintiffs are children who, through their parents, allege they suffered heart defects caused by *in utero* exposure to Zoloft, an anti-depressant manufactured and marketed by

Defendants Pfizer, Roerig, and Greenstone. See Pls.' Pretrial Mem., Transaction ID 59581253 at p. 1. Plaintiffs allege that Pfizer negligently failed to adequately warn about the risks of birth defects stemming from the use of Zoloft while pregnant, and that an adequate warning would have prevented the Minor Plaintiffs' injuries. *Id.* p. 5.

2. Plaintiffs designated Dr. Adam C. Urato as their expert on the adequacy of the Zoloft label. When Dr. Urato became unavailable due to a medical condition, and would not provide the Panel with an affidavit from his treating physician regarding his medical condition, or appear for deposition as ordered, the Panel granted Defendants' motion to exclude him as an expert witness. *Order Excluding Plaintiffs' Expert, Adam C. Urato, MD* (Transaction ID 59537225). However, notwithstanding the fact that "Plaintiffs' counsel failed to ascertain Dr. Urato's medical condition, determine whether Dr. Urato was able to testify in these cases, and request a replacement expert in a timely manner" the Panel granted Plaintiffs' request for leave to designate a new expert. *Id.* p. 3.

3. Plaintiffs designated Dr. David Kessler as their new expert on the adequacy of the Zoloft label. *Plaintiffs' Supplemental Disclosure of Experts* (Transaction ID 59574134) Defendants noticed Dr. Kessler's deposition for November 17, 2016. However, instead of producing Dr. Kessler for deposition, as noticed by Defendants and subsequently ordered by the Panel, or filing a motion explaining why Plaintiffs could not produce Dr. Kessler on the date noticed, Plaintiffs withdrew Dr. Kessler. *Plaintiffs' Supplemental Disclosure of Experts* (Transaction ID 59836094) filed November 15, 2016.

4. Following Plaintiffs' withdrawal of Dr. Kessler, Defendants moved for summary judgment arguing that, on the facts of this case, Plaintiffs could not meet their burden of proof regarding the adequacy of the Zoloft label without an expert witness. Plaintiffs objected to the motion, arguing that a genuine factual dispute exists regarding the adequacy of Pfizer's efforts to warn about the risks of Zoloft because: a) Pfizer's intentional failure to follow its own safety policies and procedures is sufficient to create a jury issue concerning the adequacy of Pfizer's efforts to warn; b) evidence that Pfizer failed to comply with applicable regulations requiring

warnings of "positive evidence of human fetal risk" is sufficient to create a jury issue concerning the adequacy of Pfizer's efforts to warn; c) expert testimony is not necessary to create a genuine factual dispute regarding the adequacy of Pfizer's efforts to warn; and d) to the extent expert testimony is necessary to establish the applicable standards, it is supplied by Pfizer's own doctors and pharmacovigilance experts.

5. For the reasons set forth below, the Panel finds that the adequacy of the Zoloft label requires a determination of facts outside the ordinary knowledge and experience of the average juror and concludes that expert testimony is required in this case. Having withdrawn their only expert designated to testify about the adequacy of the Zoloft label, Plaintiffs cannot meet their burden of proof on an essential element of their claims and, therefore, summary judgment in favor of Defendants is proper.

6. As an alternative ground for summary judgment, Defendants renewed their prior motion for summary judgment as to punitive damages and argued that without an expert on labeling, it will be impossible for Plaintiffs to prove that Defendants' failure to provide a different warning regarding the use of Zoloft in pregnancy was wanton, reckless, or otherwise rose to a level of culpability that could support punitive damages. See Defs' Mot. (Transaction ID 59877656) at ¶ 15. Because the Panel's ruling granting summary judgment on the first ground asserted by Defendants disposes of the Plaintiffs' claims in their entirety, the Panel does not address the Defendants' alternative ground as to punitive damages.

FINDINGS OF FACT[1]

7. Zoloft (sertraline) is a selective serotonin reuptake inhibitor ("SSRI") medication that has been widely-prescribed in the United States and throughout the world for a quarter-century. The FDA has approved Zoloft's label over 13 times over a period of 24 years. In 1991, the FDA approved Zoloft as safe and effective for the treatment of major depressive disorder.

[1] To the extent any Conclusion of Law constitutes a Finding of Fact, the Panel also adopts it as such.

The FDA subsequently approved Zoloft as safe and effective for the treatment of obsessive-compulsive disorder, panic disorder, post-traumatic stress disorder, premenstrual dysphoric disorder, and social anxiety disorder.[2] Plaintiffs did not dispute that the FDA has evaluated the safety of Zoloft for decades and that Zoloft has never been recalled and remains approved by the FDA as safe and effective. See *In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig.*, 26 F. Supp. 3d 449, 452-53 (E.D. Pa. 2014); and this Court's August 30, 2016, order granting Defendants' motion for summary judgment in *M.M. v. Pfizer, Inc., et al.* Civil Action No. 12-C-149 WNE ("*M* ") (Transaction ID 59488864) at ¶¶ 10, 16.[3]

8. Plaintiffs presented no evidence that Pfizer withheld relevant information from the FDA. See August 30, 2016 *Order* entered in *M* (Transaction ID 59488864) at ¶¶ 13-16. Indeed, the record shows that the FDA is fully aware of the allegations being made in the Zoloft birth defect litigation, but has not required Pfizer to revise the Zoloft label in response. *Id.* ¶ 16.[4]

9. At all relevant times, the governing FDA regulations required that prescription medicine manufacturers include one of five categories as part of the pregnancy section of the label (A, B, C, D and X), indicating increasing levels of risk in pregnancy.[5] The FDA

[2] Plaintiffs did not dispute the regulatory history of Zoloft, which was set forth in Section II of *Defendants' Omnibus Memorandum in Opposition to Plaintiffs' Motions in Limine Nos. 4, 5, 6, 8, 11, 15, and 16* (Transaction ID 59471050), together with the exhibits cited therein, incorporated by reference in *Defendants' Motion for Summary Judgment*.

[3] On September 29, 2016, Plaintiffs/Petitioners filed a Notice of Appeal seeking reversal of the Court's August 30, 2016 order granting Defendants' motion for summary judgment in the *Maskill* case, "particularly ruling that Michigan law applies to the Maskills' claims, that Petitioners did not produce evidence sufficient to satisfy their burden on the applicability of the fraud-on-the-FDA exception to the Michigan statue, and that even if Plaintiffs had presented evidence on all three elements of the fraud-on-the-FDA exception to the Michigan statue sufficient to create a genuine issue of fact, it would still not save their claims because the exception is preempted by federal law." The findings of fact in *Maskill* that are cited in this order were not appealed.

[4] The Zoloft label is currently under review by the FDA for reasons unrelated to this litigation. Due to a change in the FDA's regulations governing pregnancy labeling, the FDA has proposed revised language for the pregnancy section. The FDA's proposed revision to the pregnancy section states, *inter alia*: "The weight of evidence from epidemiologic studies of pregnant women exposed to [Zoloft] in the first trimester suggest no difference in major birth defect risk compared to the background rate for major birth defects in pregnant women who were not exposed to [Zoloft]." (Defs' Mot., Ex. B. at p. 3)

[5] See *In re Zoloft*, 26 F. Supp. 3d at 452-53 & n.7.

determined that Zoloft should carry a Category C warning, which applies to medications for which animal studies show some risk in pregnancy,[6] but for which there are no adequate well-controlled studies in humans and the potential benefits of use during pregnancy may outweigh the potential risks.[7] Thus, regarding use in pregnancy, the Zoloft label in 2003 (when the Mother Plaintiffs in *C* and *H* used Zoloft) stated:

> **Pregnancy–Pregnancy Category C–**Reproduction studies have been performed in rats and rabbits at doses up to 80 mg/kg/day and 40 mg/kg/day, respectively. These doses correspond to approximately 4 times the maximum recommended human dose (MRHD) on a mg/m2 basis. There was no evidence of teratogenicity at any dose level. When pregnant rats and rabbits were given sertraline during the period of organogenesis, delayed ossification was observed in fetuses at doses of 10 mg/kg (0.5 times the MRHD on a mg/m2 basis) in rats and 40 mg/kg (4 times the MRHD on a mg/m2 basis) in rabbits. When female rats received sertraline during the last third of gestation and throughout lactation, there was an increase in the number of stillborn pups and in the number of pups dying during the first 4 days after birth. Pup body weights were also decreased during the first four days after birth. These effects occurred at a dose of 20 mg/kg (1 times the MRHD on a mg/m2 basis). The no effect dose for rat pup mortality was 10 mg/kg (0.5 times the MRHD on a mg/m2 basis). The decrease in pup survival was shown to be due to in utero exposure to sertraline. 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 potential risk to the fetus.

Defs' Mot., Ex. A at p. 19. The label also stated that "[p]atients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy." *Id.* at p. 15.

10. The safety of Zoloft in pregnancy has been assessed in dozens of published scientific studies and in numerous reviews and meta-analyses of these data. No regulatory body, health organization, or peer-reviewed publication has ever concluded that Zoloft causes cardiac malformations. Several organizations, after applying accepted criteria for determining causation,

[6] The risk observed in animal studies does not have to be a teratogenic risk and the FDA approved Zoloft's label stating that animal studies do not show teratogenicity. (Defs' Mot., Ex. A at p. 19.)

[7] See *In re Zoloft*, 26 F. Supp. 3d at 452-53 & n.7; See also Defs' Mot., Ex. A at p. 19.

have concluded that the evidence does not support a causal link between Zoloft and birth defects. For example:

- ***The American Psychiatric Association and American College of Obstetricians and Gynecologists*** has concluded that "the current data on SSRI exposure show ***no*** consistent information to support specific morphological teratogenic risks." [8]

- ***The Organization of Teratology Information Specialists*** – a professional organization that provides "evidence-based information to mothers, health care professionals, and the general public about medications [taken] during pregnancy," [9] concluded that "[o]verall, 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." [10]

- ***The American Heart Association*** evaluated the risk of cardiac birth defects in children treated with SSRIs and concluded that, with the exception of Paxil, studies "indicate that there is ***no*** increased risk of CHD associated with the use of most SSRIs."[11]

- In 2015, the ***Centers for Disease Control ("CDC")*** summarized the findings of a recent study conducted by its investigators, concluding: "Reassuringly, researchers did ***not*** confirm links between [Zoloft], the SSRI used most often, and any of the birth defects observed in previous studies."[12]

11. Thus, the undisputed evidence presented by the Defendants showed that the FDA and the scientific community have evaluated the safety of Zoloft for decades and that Zoloft has never been recalled, remains approved by the FDA as safe and effective, and thousands of physicians each year continue to prescribe it to bring needed relief to their patients who suffer from depression, anxiety disorders, and other conditions. See FOF ¶¶ 7-11; See also *In re Zoloft,*

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[8] Yonkers et al., *The management of depression during pregnancy: a report from the American Psychiatric Association and the American College of Obstetricians and Gynecologists*, 114(3) Obstet. Gynecol. 703 (§ 3.4.2) (2009) (Defs' Mot., Ex. C) (emphasis added).

[9] Welcome | MotherToBaby.Org, http://mothertobaby.org/home/welcome/ (last visited Nov. 28, 2016) (Defs'Mot., Ex. D).

[10] OTIS, Sertraline (Zoloft) and Pregnancy (Sept. 2014) at 1 (Defs' Mot., Ex. E) (emphasis added).

[11] Donofrio et al., *Diagnosis and Treatment of Fetal Cardiac Disease: A Scientific Statement From the American Heart Association*, 129 Circulation 2183, 2190 (2014) (Defs' Mot., Ex. F) (emphasis added).

[12] 7/8/15 CDC Press Release, http://www.cdc.gov/pregnancy/meds/treatingfortwo/features/ssrisandbirthdefects.html (last visited Nov. 28, 2016) Defs' Mot., Ex. G (emphasis added).

26 F. Supp. 3d at 452-53; and August 30, 2016 *Order* entered in *M* (Transaction ID 59488864) at ¶¶ 10, 16.

12. Defendants also presented undisputed evidence that independent organizations have warned that inclusion of warnings that are not supported by the science can lead to unintended and adverse consequences for the patient. Such organizations have noted that expectant mothers may be wary of taking any medication during pregnancy and an excessive warning may discourage necessary treatment of the mother's depression or other mood disorder. For example, OTIS cautions expectant mothers that "[i]t is important to discuss with your health care provider the risks associated with taking sertraline during pregnancy as compared to the risks of stopping sertraline. Studies have shown that when depression is left untreated during pregnancy, there may be increased risks for miscarriage, preeclampsia, preterm delivery, low birth weight, and a number of other harmful effects on the mother and the baby." Defs' Mot., Ex. E at pp.1-2. Similarly, the CDC states that "[d]epression and other mental health conditions can be serious. Many women need to take medication during pregnancy to appropriately manage their symptoms. . . . Abruptly stopping the use of medicines to treat these conditions can have serious consequences." Defs' Mot., Ex. G at p. 1.

13. In deciding Defendants' motion, this Panel was not called upon to decide whether the conclusions of these organizations are correct. Instead, the fact that these organizations have reached such conclusions was offered as evidence that Plaintiffs' claims regarding the inadequacy of the Zoloft label are not so obvious that expert testimony in support of Plaintiffs' claims is not required.

14. To address their burden to show that the 2003 Zoloft label was inadequate, Plaintiffs designated Dr. Adam C. Urato as their labeling expert. *Plaintiffs' Supplemental Disclosure of Experts* (Transaction ID 58672066). Dr. Urato's deposition was eventually scheduled for June 13, 2016, but the deposition did not go forward due to Dr. Urato's health. Defendants moved to exclude Dr. Urato when Plaintiffs' failed to produce him for deposition. *Defendants' Motion to Exclude Plaintiffs' Expert Adam C. Urato, M.D.* (Transaction ID

59216981). During the August 8, 2016, hearing on Defendants' motion, Plaintiffs' counsel argued, "Doctor Urato is a key liability expert of ours. And I agree with something Mr. Farrell said about Pfizer wanting a trial. We also want a trial to go forward with our key liability expert. We shouldn't be hamstrung and not have our key liability expert." Transcript, August 8, 2016, Hearing at p. 7:1-7. When asked if another expert could be substituted for Dr. Urato and, if so, what kind of delay would occur if Plaintiffs had to get another expert, Plaintiffs' counsel replied, "there's a couple other experts that have testified in these cases *** We could get them up to speed pretty quick." Id. at p. 13:8-9 and 12-13.

15. Over Defendants' objections, the Court denied Defendants' motion to exclude Dr. Urato without prejudice to renew the motion, and ordered Dr. Urato's deposition to be taken no later than August 29, 2016. *Order Regarding Rulings on August 8, 2016* (Transaction ID 59400916). On August 22, 2016, Plaintiffs acknowledged they were still unable to produce Dr. Urato and sought leave to designate a new liability expert. *Plaintiffs' Expedited Motion to Modify the Court's Earlier Ruling Regarding Plaintiffs' Expert Adam C. Urato, M.D. and Motion for Protection and for Leave to Designate a Replacement Expert* (Transaction ID 59456773). Plaintiffs' counsel again stated that Dr. Urato was going to be Plaintiffs' "key liability expert" in these cases, but "based upon extremely private information provided to Plaintiffs' counsel, Dr. Urato will not be medically able to sit for an expert deposition by August 29th or anytime in the coming months." *Id.* at pp. 1-2

16. To properly consider the basis of Plaintiffs' motion, the Panel held the motion in abeyance on August 31, 2016, and ordered Plaintiffs' counsel to file under seal an affidavit from Dr. Urato's treating physician no later than September 7, 2016, containing, among other things, a detailed medical diagnosis for Dr. Urato, an affirmation that Dr. Urato was not medically able to sit for an expert deposition, and the date on which Dr. Urato's medical condition was first communicated to Plaintiffs' counsel. *Order Regarding Plaintiffs' Expert, Adam C. Urato* (Transaction ID 59497067) at p. 1.

17. On September 7, 2016, Plaintiffs' counsel served a letter on the Panel advising that, "Despite our efforts, we have had very limited contact with Dr. Urato and he has not supplied us with the affidavit from his treating doctor." See *Letter* (Transaction ID 59530040). Because Plaintiffs' counsel did not submit the affidavit, as ordered, and because Plaintiffs' counsel represented that Dr. Urato would not be available for deposition, the Panel denied Plaintiffs' motion for protection for Dr. Urato. September 9, 2016 *Order Excluding Plaintiffs' Expert, Adam C. Urato, MD* (Transaction ID 59537225) at p. 2.

18. Finding Plaintiffs' counsel was aware no later than June 9, 2016, that Dr. Urato would not be able to appear for deposition for health reasons; Plaintiffs' counsel failed to make Dr. Urato available for deposition on August 29, 2016, as ordered; and Plaintiffs' counsel failed to submit the affidavit of Dr. Urato's treating physician as ordered; the Panel granted Defendants' motion to exclude Dr. Urato for good cause shown, and precluded him from testifying as an expert in these cases. *Id.* at pp. 2-3.

19. The Panel further found that, "Plaintiffs' counsel failed to ascertain Dr. Urato's medical condition, determine whether Dr. Urato was able to testify in these cases, and request a replacement in a timely manner. However, it would be unfair to punish the litigants for their counsel's lack of diligence." *Id.* at p. 3. Accordingly, the Panel granted Plaintiffs' motion seeking leave to designate a replacement expert for Dr. Urato, and ordered the replacement expert designated by September 16, 2016. *Id.* The Panel also ordered that, "[b]ecause Defendants are the parties prejudiced by Plaintiffs' counsel's delay, they shall be allowed to propose a reasonable date for a deposition of Plaintiffs' replacement expert for Dr. Urato after they learn the identity of the new expert." *Id.*

20. On September 16, 2016, in accordance with the Court's order, Plaintiffs designated Dr. David Kessler to replace Dr. Urato as an expert witness in the *C* and *H* cases stating:

> Plaintiffs' designate Dr. Kessler as their expert on failure to warn issues for these two Plaintiffs. Defendants are well aware of his opinions. Dr. Kessler's opinions

> are contained in his report that was produced on July 10, 2015 in MDL 2342 (In re: Zoloft) and his deposition taken on September 17, 2015 in MDL 2342 (In re: Zoloft). He will not be providing opinions on causation.

Plaintiffs' Supplemental Disclosure of Experts (Transaction ID 59574134)

21. Defendants' counsel made several efforts to schedule Dr. Kessler's deposition. See Exhibits A and B to *Defendants' Response to Plaintiffs' Motion for Protection to Limit Length of Defendants' Deposition of Plaintiffs' Expert David A. Kessler, M.D.* (Transaction ID 59815525). When Plaintiffs' counsel failed to agree to any of Defendants' proposed dates or suggest alternatives, Defendants noticed Dr. Kessler's deposition for November 17, 2016. See *Notice of Deposition of David Kessler, M.D.* (Transaction ID 59717805).

22. On November 7, 2016, ten days before Dr. Kessler was scheduled to be deposed, Plaintiffs filed a motion requesting that the Panel enter an order limiting the length of Defendants' deposition of Dr. Kessler to no more than three hours, arguing that:

> Dr. Kessler has provided a thorough, 116-page report detailing his opinions in the Federal Zoloft MDL, and Pfizer has already deposed Dr. Kessler on those opinions for an entire day in the Federal Zoloft MDL. That earlier deposition was 416 pages and 34 exhibits. Dr. Kessler's opinions in this case are the same as those that were provided in the Federal Zoloft MDL. Thus there is no legitimate reason to depose him at all – let alone for any significant period of time.

Motion for Protection to Limit Length of Defendant's Deposition of Plaintiffs' Expert David A. Kessler, M.D. (Transaction ID 59803229) at p. 1

23. In their motion, Plaintiffs discussed their designation of Dr. Kessler at length:

> Dr. Kessler has been designated to testify regarding whether Pfizer adequately warned about the risks associated with exposure to Zoloft, including the adequacy of its Zoloft labeling, and its post-marketing surveillance efforts relating to Zoloft. Dr. Kessler is also expected to provide testimony regarding the specific regulatory procedures and regulations with which pharmaceutical manufacturers must comply when developing and marketing drug products in the United States and communicating safety information. He is expected to explain a pharmaceutical manufacturer's responsibility to update its labeling when new information that (sic) causes the labeling to become inaccurate, false or misleading. Dr. Kessler is also expected to explain the different ways a pharmaceutical manufacturer can convey new safety information, including updated labeling, publications, verbal communications, advertisements, medical

> information letters, and the dissemination of Dear Health Care Professional letters.

Id. at p. 3.

24. Plaintiffs did not advise the Court of the approaching date for Dr. Kessler's deposition in their motion. However, in response to the motion, Defendants expressed concern that Plaintiffs' motion had been "made as a pretext for another unilateral cancellation of a noticed deposition." *Defendants' Response to Plaintiffs' Motion for Protection to Limit Length of Defendant's Deposition of Plaintiffs' Expert David A. Kessler, M.D.* (Transaction ID 59815525) at p. 4. A few hours after Defendants filed their response, counsel for Defendants received an email from counsel for Plaintiffs stating that they needed to reschedule Dr. Kessler's deposition. No explanation was offered. Defendants' counsel responded that they did not agree to rescheduling the deposition and indicated that Plaintiffs should bring a motion See *Supplement to Defendants' Response to Plaintiffs' Motion for Protection to Limit Length of Defendant's Deposition of Plaintiffs' Expert David A. Kessler, M.D.* (Transaction ID 59824734)

25. On November 14, 2016, the Panel entered an order denying Plaintiffs' motion to impose hourly limits on Dr. Kessler's deposition and ordered Plaintiffs to produce Dr. Kessler for deposition on November 17, 2016, as previously noticed. *Order* (Transaction ID 59831619) Rather than produce Dr. Kessler as scheduled and as ordered by the Panel, or file a motion explaining why they were unable to comply with the Panel's order, Plaintiffs withdrew Dr. Kessler as an expert on November 15, 2016. *Plaintiffs' Supplemental Disclosure of Experts* (Transaction ID 59836094)

26. Plaintiffs represented to this Panel that their labeling expert was a critical witness for them. For example, when responding to Defendants' motion to exclude Dr. Urato, Plaintiffs described him as their "key liability expert." See *Plaintiffs' Response to Defendants' Motion to Exclude Plaintiffs' Expert Adam C. Urato, M.D., Motion for Protection and Enlargement of Time, and, In the Alternative, Motion for Leave to Designate a New Expert* (Transaction ID 59275406) at p. 1. Plaintiffs further explained that:

> Dr. Urato is therefore an extremely well qualified and important liability witness for Plaintiffs. He has produced a 46 page expert report that explains his opinions, and the bases for his opinions, in great detail. He has done a great deal of work on this case in connection with his expert report and to form the opinions stated therein.
>
> Plaintiffs would be severely prejudiced if Dr. Urato's testimony is excluded from this case. If Dr. Urato's recent health issues ultimately prevent him from being able to testify, then Plaintiffs would seek to designate a new expert in his place, considering the importance of the liability topics on which he is designated to opine and the unexpected nature of Dr.Urato's health issues.

Id. at p. 5. In arguing for leave to designate a replacement expert, Plaintiffs also argued that Dr. Urato's medical circumstances "should not prejudice Plaintiffs' ability to try their case on the merits with a testifying expert on liability." *Id.* at p. 12. See also Transcript, August 8, 2016, Hearing at p. 7:1-7.

27. When Plaintiffs were unable to produce Dr. Urato for deposition, they again sought relief from this Panel, once again characterizing Dr. Urato as their "key liability expert" and seeking "leave to designate a new expert on liability issues." *Plaintiffs' Expedited Motion to Modify the Court's Earlier Ruling Regarding Plaintiffs' Expert Adam C. Urato, M.D. and Motion for Protection and for Leave to Designate a Replacement Expert* (Transaction ID 59456773) at p. 2. Plaintiffs further stated: "Plaintiffs thus respectfully request that the Panel permit Plaintiffs to designate a new expert on liability issues in the place of Dr. Urato. Dr. Urato's medical condition is unfortunate, particularly for Dr. Urato, but it should not prejudice Plaintiffs' ability to try their case on the merits with a testifying expert on liability." *Id.* at p. 4.

28. In their response to Defendants' motion for summary judgment, Plaintiffs cite to a number of company documents, arguing that such documents show that Defendants were aware of the risks of Zoloft during pregnancy and failed to provide an adequate warning of such risks. See Pls' Resp. (Transaction ID 59958774) at pp. 2-11. Defendants dispute the factual assertions made by Plaintiffs, but argue that the Panel need not resolve such disputed facts in order to decide the motion for summary judgment. See Defs' Reply (Transaction ID 59979426) at pp.

8-13. The Panel agrees and will not herein attempt to resolve such factual disputes. The Panel finds that the subject matter of the documents relied on by Plaintiffs (animal studies, epidemiology, adverse event reports, core data sheets, FDA regulations) are not within the common knowledge and experience of the average juror and, for the reasons set forth below, such evidence cannot substitute for expert testimony on the adequacy of the Zoloft label.

CONCLUSIONS OF LAW

I. Summary Judgment Standards

29. 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, 708, 461 S.E.2d 451, 454 (1995).

30. "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, 56 459 S.E.2d 329, 333 (1995).

31. "[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).

32. "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, 451 S.E.2d at 759. 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. Plaintiffs' Claims and Burden of Proof

33. Plaintiffs allege that the Zoloft label inadequately warned of the risks of birth defects and that an adequate warning would have prevented the Minor Plaintiffs' injuries. (*See* Pls.' Pretrial Mem. (Transaction ID 59581253) at p. 1. While West Virginia recognizes both negligent and strict liability failure to warn claims, the Plaintiffs' burden under either theory is similar.

34. "'Negligence' is either the failure to do what a reasonable and prudent person would ordinarily have done under the circumstances, or doing what such a person under the existing circumstances would not have done." *Honaker v. Mahon*, 210 W. Va. 53, 58, 552 S.E.2d 788, 793 (2001). "Negligence is the violation of the duty of taking care under the given circumstances. It is not absolute, but is always relative to some circumstance of time, place, manner, or person." Syl. Pt. 1, *Dicken v. Liverpool Salt & Coal Co.*, 41 W. Va. 511, 23 S.E. 582 (1895), quoted in Syl. Pt. 2, *Honaker*.

35. In strict liability, "product unsafeness arising from failure to warn 'is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to the economic costs, at the time the product was made.'" *Ilosky v. Michelin Tire Corp.*, 172 W. Va. 435, 443, 307 S.E.2d 603, 611 (1983) quoting *Morningstar v. Black & Decker Mfg. Co.*, 162 W. Va. 857, 889, 253 S.E.2d 666, 682-83 (1979).

36. In *Morningstar*, the Supreme Court of Appeals of West Virginia explained the difference between strict liability and negligence as follows: "The cause of action covered by the term 'strict liability in tort' is designed to relieve the plaintiff from proving that the manufacturer was negligent in some particular fashion during the manufacturing process and to permit proof of the defective condition of the product as the principal basis of liability." Syl. Pt. 3, 162 W. Va. at 857, 253 S.E.2d at 667. Whether based in strict liability or negligence, the question is whether the defendant acted reasonably under the circumstances. See *Muzichuck v. Forest Labs., Inc.*, 2015 WL 235226, at *8-9 (N.D.W. Va. Jan. 16, 2015) (applying West Virginia law), *appeal dism'd* (Dec. 1, 2015). Any distinction between strict liability and negligent failure to warn under West Virginia law is not material to Defendants' motion.

III. Expert Testimony Is Required on Matters Outside the Common Knowledge and Experience of the Average Juror

37. "Although the question of adequacy of a warning is one of fact to be determined by the jury, experts may testify on such matters in their fields of expertise." *Ilosky*, 172 W. Va. at 449, 307 S.E.2d at 617. For example, in *Ilosky*, the Supreme Court held that plaintiff's expert could testify as to the adequacy of warnings as they related to informing ultimate tire consumers of the potential dangers of using radial and conventional tires together. *Id.*

38. The Supreme Court explained the important role that an expert witness plays in failure to warn cases in *Morningstar*:

> We believe that a risk/utility analysis does have a place in a tort product liability case by setting the general contours of relevant expert testimony concerning the defectiveness of the product. *In [a] product liability case, the expert witness is ordinarily the critical witness. He serves to set the applicable manufacturing, design, labeling and warning standards based on his experience and expertise in a given product field.*
>
> Through his testimony the jury is able to evaluate the complex technical problems relating to product failure, safety devices, design alternatives, *the adequacy of warnings and labels*, as they relate to economic costs. In effect, the expert explains to the jury the risk/utility standards and gives the jury reasons why the product does or does not meet such standards, which are essentially standards of product safeness.

162 W. Va. at 887, 253 S.E.2d at 682 (emphasis added); *accord Ilosky*, 172 W. Va. at 448-49, 307 S.E.2d at 617.

39. The Supreme Court has repeatedly held that expert testimony is required on complex technical, scientific, and medical issues beyond the common knowledge and experience of the average person. For example, in *Addair v. Litwar Processing Co.*, No. 11-0397, 2012 WL 2914980 (W. Va. Feb. 9, 2012), the Supreme Court affirmed summary judgment after the trial court precluded plaintiffs from calling expert witnesses as a sanction for plaintiffs' failure to comply with the expert witness disclosure deadline. 2012 WL 2914980, at *2-3. The Supreme Court explained that without expert witnesses, the plaintiffs would be unable to meet their burden of proof on an essential element of their case – the existence of an occupational disease. *Id.* at *2. As the Court explained:

> [T]he plaintiff petitioners have alleged that they sustained occupational diseases: a variety of complex health consequences resulting from their exposure to chemicals in the course of their employment. These are not simple ailments that have resulted from common causes familiar to the average layperson. Instead, these are complex illnesses that allegedly have arisen from exposure to chemicals of which the average person has no knowledge or experience. Under these circumstances, we find expert testimony to be necessary to establish the existence of an occupational disease.

Id.

40. Similarly, in *Moats v. Preston County Commission*, 206 W. Va. 8, 521 S.E.2d 180 (1999), the Supreme Court responded to a certified question regarding whether expert testimony was required and explained the difference between matters that may be obvious to a layman and matters of scientific complexity that require expert testimony. *Id.* at 15-16, 521 S.E.2d at 187-88. The decedent in *Moats* had been placed in the custody of a community health facility following an involuntary commitment. In the process of transporting the decedent, a representative of the facility left the decedent unsupervised at the sheriff's office, and the decedent committed suicide by consuming bathroom cleaner. *Id.* at 11, 521 S.E.2d at 183. The Supreme Court found that, based on the facts in the record before them, the plaintiff would

probably need expert testimony to show a deviation from the standard of care. *Id.* at 16, 521 S.E.2d at 188. The Court explained that, "[t]his case involves complicated medical issues, specifically, the manner and method of protecting someone who is suicidal. While there may be some circumstances where an expert is not needed, such as where a loaded gun is left in the presence of a mentally-ill person, that is not the case here." *Id.* As a result, notwithstanding "the plaintiff's attempt to characterize this case as simply a failure to report [the decedent's] suicidal tendencies," the Court held that determining whether the defendant "deviated from the standard of care involves more complex issues that are not within the common knowledge of lay jurors." *Id.* Applying the principles in *Addair* and *Moats* to the facts of this case, whether Pfizer acted as a reasonable manufacturer in providing information regarding the use of Zoloft during pregnancy involves questions of science and medicine outside the common knowledge and experience of lay jurors.

41. In informed consent cases, the Supreme Court has also held that "expert medical testimony would ordinarily be required to establish certain matters including: (1) the risks involved concerning a particular method of treatment, (2) alternative methods of treatment, (3) the risks relating to such alternative methods of treatment and (4) the results likely to occur if the patient remains untreated." Syl. Pt. 5, *Cross v. Trapp*, 170 W. Va. 459, 461, 294 S.E.2d 446, 448 (1982). Although the Court held in the same syllabus point that expert testimony was not required on "the scope of a physician's duty to disclose medical information to his or her patient," Plaintiffs are not challenging the scope of Pfizer's duty here. Rather, they are challenging the specific risks associated with use of Zoloft during pregnancy and whether those were adequately explained in the label. Under the principles set forth in *Cross*, expert testimony is required.

42. The Supreme Court has also repeatedly held that, in malpractice cases, the failure to adhere to the relevant standard of care requires expert testimony. *See* Syl. Pt. 2, *Roberts v. Gale*, 149 W. Va. 166, 139 S.E.2d 272 (1964) ("It is the general rule that in medical malpractice cases negligence or want of professional skill can be proved only by expert witnesses."). As a

result, the Supreme Court affirmed summary judgment in *Farley v. Meadows*, 185 W. Va. 48, 404 S.E.2d 537 (1991), where the plaintiff "had ample time to retain an expert, and failed to do so." *Id.* at 50-51, 404 S.E.2d at 539-40.

IV. On the Facts of this Case, Plaintiffs Were Required to Present Expert Testimony Regarding the Adequacy of the Zoloft Label to Meet Their Burden of Proof

43. While the Supreme Court did not establish an absolute requirement for expert testimony regarding the adequacy of a product label in *Morningstar*, its observations regarding the importance of expert testimony suggest that such testimony will often be required. Determining whether this is such a case requires application of the well-established test set forth above: Is the question of whether a reasonably prudent pharmaceutical manufacturer would have included different warnings on the Zoloft label an issue within the common knowledge and experience of an average juror? *Cf. Watson v. Inco Alloys Internationals, Inc.*, 209 W. Va. 234, 243, 545 S.E.2d 294, 303 (2001) (observing that "questions involving the design of and appropriate warnings for lift trucks are not within the common knowledge and experience of a lay juror".)[13] Indeed, the scientific and medical issues inherent in preparing an adequate warning for a prescription medication are likely more complicated than the warnings for lift trucks at issue in *Watson*. And, as noted above, in several contexts, the Supreme Court has held that comparable medical issues require expert testimony.

44. Where expert testimony is required on an essential element of a plaintiff's claim, the absence of such testimony means that a plaintiff cannot meet his or her burden of proof and summary judgment is proper. For example, in *Muzichuck v. Forest Laboratories, Inc.*, 2015 WL 235226 (N.D.W. Va. Jan. 16, 2015), *appeal dism'd* (Dec. 1, 2015), the federal court, applying

[13] *See also Crawford v. Gen. Motors Corp.*, 2007 WL 1960611, at *3 (N.D.W. Va. July 2, 2007) (applying West Virginia law and holding that "expert testimony is required in this case because the issue of whether an airbag was defectively designed or manufactured is well beyond the understanding of the average layman."); *SBA Network Servs., LLC v. Tectonic Eng'g & Surveying Consultants, P.C.*, 2014 WL 3797426, at *2 n.3 (N.D.W. Va. Aug. 1, 2014) (applying West Virginia law and concluding that want of professional skill in the construction of a telecommunications tower required expert testimony).

West Virginia law, granted the defendant's motion for summary judgment due, in part, to the plaintiffs' failure to support their failure to warn claims with expert testimony. After the plaintiffs' expert conceded that an appropriate warning was contained in the medicine's label at the relevant time, *id.* at *10, the plaintiff tried to make a case based on the manner in which the warnings were communicated. *Id.* at *10-11. The plaintiff argued, without expert support, that the defendant should have sent out Dear Doctor letters or sent a standard response letter to consumers. *Id.* at *11. Rejecting these arguments, the court noted that "[c]ritically, none of these alternatives is based on expert testimony." *Id.* Granting summary judgment, the court explained that plaintiff "has submitted no expert testimony supporting her proposed alternative means of warning; nor is there any evidence that her proposed alternative means of warning were viable. Thus, there is no material question of fact in dispute about whether [Defendant]'s efforts to warn by way of its package insert were adequate." *Id.*

45. Here, whether Pfizer behaved as a reasonably prudent manufacturer would when warning about use of Zoloft during pregnancy involves complex issues of science and medicine. As in the cases discussed above, expert testimony on this issue is required and, absent such evidence, summary judgment should be entered in favor of Defendants.

46. The only circumstance where the Supreme Court has held that expert testimony may not be required on matters of science and medicine is where the injury, defect, or want of care is so ***obvious*** that it falls within the common knowledge of the average person. *See, e.g.*, *Ilosky*, 172 W. Va. at 445-46, 307 S.E.2d at 614 (injury); *Roberts*, 149 W. Va. at 172-73, 139 S.E.2d at 276 (want of professional skill); *cf. SBA Network Servs., LLC v. Tectonic Eng'g & Surveying Consultants, P.C.*, 2014 WL 3797426, at *2 n.3 (N.D.W. Va. Aug. 1, 2014) ("Although West Virginia also recognizes the 'common knowledge' exception to the expert testimony requirement, that exception is inapplicable to this case, which involves construction and engineering related matters that are beyond the common knowledge of a lay juror.") (citation omitted). In this case, Plaintiffs cannot rely on the "obvious" exception to dispense with the requirement for expert testimony regarding the adequacy of the Zoloft label for several reasons.

47. *First*, this is not a case where the label is silent regarding the alleged risk. The label in effect at the relevant time contained a "Category C" pregnancy warning, described adverse pregnancy outcomes observed in animal studies, noted that there were "no adequate and well-controlled studies in pregnant women," and stated that Zoloft "should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus." Defs' Mot., Ex. A at p. 19. The label also stated that "[p]atients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy." *Id.* at p. 15. Evaluating whether this language was adequate based on the available information at the time is not within the common experience of most people. For example, the average juror does not possess the knowledge and experience necessary to determine whether Zoloft should have been a "Category C" or "Category D" warning.

48. *Second*, the FDA has repeatedly approved Zoloft's label. *See* FOF ¶ 7. The FDA is statutorily charged with protecting public health by ensuring that prescription drugs are safe and effective, and that they are accompanied by adequate warnings and instructions for use. *See* 21 U.S.C. § 393(b)(2)(B); 21 C.F.R. § 201.56(a)(1); 21 C.F.R. § 314.125. While FDA approval of the Zoloft label is not conclusive on the issue of the label's adequacy, as this Panel previously held, "[C]ompliance with the appropriate regulations is competent evidence of due care, but does not constitute due care *per se* or create a presumption of due care." Syllabus Point 1, *Miller v. Warren*, 182 W.Va. 560, 390 S.E.2d 207 (1990). See *Order Regarding Motions in Limine* (Transaction ID 59714082) at p. 3. Thus, while FDA approval is not conclusive on the issue of liability, the fact that the FDA, based on its expertise and judgment, has repeatedly determined that the Zoloft label provided appropriate information regarding the safe and effective use of Zoloft during pregnancy is another factor indicating that any alleged inadequacy of the Zoloft label is not so ***obvious*** that Plaintiffs can dispense with expert testimony.

49. *Third*, after over a decade of study, numerous independent organizations have concluded that the evidence does not support a causal link between Zoloft and birth defects. *See* FOF ¶ 10. As with FDA approval, such evidence may not be conclusive regarding Plaintiffs'

claims of causation and liability – an issue the Court need not decide. However, such evidence does mean that Plaintiffs cannot show that it was ***obvious*** in 2003 (when the Mother Plaintiffs in *C* and *H* used Zoloft) that a stronger warning against use in pregnancy was required.

50. *Fourth*, inclusion of warnings that are not supported by the science can lead to unintended and adverse consequences for the patient. "While it is important for a manufacturer to warn of potential side effects, it is equally important that it not overwarn because overwarning can deter potentially beneficial uses of the drug by making it seem riskier than warranted and can dilute the effectiveness of valid warnings." *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010); *see also Muzichuck*, 2015 WL 235226, at *8 n.2 ("Public policy recognizes a danger in 'overwarning' consumers of potential drug-related risks."). Independent organizations have noted that decisions regarding use of antidepressants during pregnancy must also consider the risks from relapsing depression and other conditions that could have a detrimental effect on the health of the mother and lead to adverse pregnancy outcomes. *See* FOF ¶ 13. Evaluating the science regarding the risks of untreated depression during pregnancy and factoring such evidence into a consideration of the adequacy of the Zoloft label is clearly beyond the common knowledge and experience of the average person.

51. *Finally*, Plaintiffs previously represented to this Panel that their labeling expert is a critical witness for them. *See* FOF ¶¶ 27-28. The test in West Virginia for whether expert testimony is *permitted* is the same as whether expert testimony is *required*. *See Watson*, 209 W. Va. at 243, 545 S.E.2d at 303 (2001) (observing that "the helpfulness requirement [for admissibility of expert testimony] simply means that the testimony does not concern something that is within the common knowledge and experience of a lay juror"); Syl. Pt. 3, *McCroskey v. Proctor*, 175 W. Va. 345, 346, 332 S.E.2d 646, 648 (1985) ("Expert opinion evidence concerning a matter as to which the jury are as competent to form an accurate opinion as the

witness, is inadmissible.") (citation and internal quotation marks omitted).[14] Accordingly, Plaintiffs' prior statements regarding the importance of their labeling expert and the prejudice to their case without such an expert are inconsistent with any assertion that they do not need such an expert because the alleged inadequacy of the Zoloft label is "obvious."[15]

52. In support of their assertion that they can meet their burden of proof as to the adequacy of the Zoloft label without expert testimony, Plaintiffs advance a rule for admission of expert testimony that is not supported by Supreme Court precedent. According to Plaintiffs, expert testimony regarding the adequacy of a warning should be required only as to matters of technological feasibility, not content. Pls' Resp. (Transaction ID 59958774) at p. 15. Plaintiffs misread West Virginia case law and confuse three different issues: (1) Whether a defendant was on notice of a risk, (2) whether the content of a label was adequate to communicate the risk, and (3) whether the method of communicating the risk was adequate. Whether expert testimony is required does not depend on an arbitrary distinction between these categories. Rather, West Virginia courts have consistently applied the same standard in all cases: Is the element of the plaintiffs' claim (standard of care, causation or injury) within the common understanding of average lay people? As discussed above, applying this test, West Virginia courts have repeatedly held that matters of a complex scientific, medical, or technical nature require expert testimony.

[14] As to some matters, such as an obvious injury, both expert and lay testimony may be permissible in some circumstances. *See Jordan v. Bero*, 158 W. Va. 28, 39, 210 S.E.2d 618, 628 (1974) ("While opinion evidence is not generally admissible on matters of common knowledge, such evidence may be admissible where the jury cannot be fully informed regarding the facts on which it is based."). For example, in *Ilosky*, the permanence of the plaintiffs' injury was obvious, but its likely future progression and economic consequences were addressed by expert testimony. *See infra* ¶35. However, the Supreme Court has never held that lay testimony may take the place of expert testimony as to complex medical and scientific issues.

[15] The Panel need not decide whether the inconsistency between Plaintiffs' prior and current positions regarding the importance of expert testimony warrants a finding of judicial estoppel. Nonetheless, the Panel notes that West Virginia courts have looked with disfavor on parties who "assume[] a certain position in a legal proceeding," and after they succeed in maintaining that position, "assume a contrary position" "simply because [their] interests have changed." *W. Va. Dep't of Transp., Div. of Highways v. Robertson*, 217 W. Va. 497, 504, 618 S.E.2d 506, 513 (2005) (citation and internal quotation marks omitted). Every court has "a duty to protect its integrity and prohibit dealing lightly with its proceedings." *Id.* at 504, 618 S.E.2d at 513.

53. Plaintiffs cited only two cases in support of their novel test – *Muzichuck v. Forest Labs., Inc* and *Ilosky v. Michelin Tire Corp.*– and failed to discuss in their response the numerous other relevant West Virginia authorities, including *Roberts v. Gayle* (*supra* ¶¶ 42 and 46); *Farley v. Meadows* (*supra* ¶ 42); *Watson v. Inco Alloys Internationa, Inc.* (*supra* ¶ 43), and federal decisions applying West Virginia law, such as *Crawford v. Gen. Motors Corp* (*supra* n.13) and *SBA Network Services Network Servs., LLC v. Tectonic Eng'g & Surveying Consultants, P.C.* (*supra* ¶ 46 and n. 13).

54. Neither *Muzichuck* nor *Ilosky* draw the distinction between the content of the warnings and the method of warnings that Plaintiffs put forward as the relevant test for when expert testimony is required. Instead, it was simply the nature of the claims brought by the plaintiffs in those cases that made the method of warning the focus of the litigation.

55. For example, in *Muzichuck*, the federal court did not hold that expert testimony on the content of the warning was not required. The plaintiffs' concession that an appropriate warning was contained in the medicine's label at the relevant time made such testimony irrelevant. See 2015 WL 235226 at *10. As a result, the *only* viable challenge made by the plaintiffs to the adequacy of the warning was the manner in which the warning was communicated. *Id.* at *10-11. On that issue Plaintiffs did not offer expert evidence, resulting in summary judgment. *Id.* at *11.

56. Similarly, in *Ilosky*, the plaintiff alleged that she lost control of her vehicle as a result of mixing radial and conventional tires on her vehicle. While there was a dispute as to what caused the plaintiff's accident, there was no dispute that mixing radial and conventional tires was dangerous. See 172 W. Va. at 442, 307 S.E.2d at 610. It was also undisputed that the manufacturer took steps to warn direct purchasers. As a result, the adequacy determination depended on what efforts the manufacturer should have taken to warn purchasers of used cars. *Id.* On that point, the plaintiff presented expert testimony. Overruling the defendant's challenge to the expert testimony, the Supreme Court quoted its prior decision in *Morningstar*, stating: "[i]n a products liability case, the expert witness is ordinarily the critical witness. He serves to

set the applicable manufacturing, design, labeling and warning standards *based on his experience and expertise in a given product field.*" *Id.* at 448, 307 S.E.2d at 617 (quoting *Morningstar*, 162 W. Va. at 887, 253 S.E.2d at 682, emphasis in *Ilosky*).

57. In that same decision, the Supreme Court again set forth the test for when expert testimony was required. The plaintiff, whose leg had been amputated, alleged that her injury was permanent and would limit her ability to do manual labor, thereby reducing her ability to find gainful employment. Because the nature and severity of her injury was obvious, it was appropriate for lay testimony. *See Ilosky*, 172 W. Va. at 446, 307 S.E.2d at 614. However, other aspects of the plaintiff's injury – such as the progression of her traumatic arthritis, addiction to pain medications and economic consequences – were appropriately supported by expert testimony. *Id.* And, while lay testimony as to injury was appropriate in *Ilosky*, the Supreme Court has time and again used the same test to determine whether expert testimony is required: Is the injury obvious and within the common knowledge and understanding of lay jurors, or does it involve matters of complex science or medicine? *See supra* ¶¶ 39-43.

V. Plaintiffs Cannot Meet Their Burden with Lay Interpretation of Company Documents That Discuss Complex Matters of Science, Government Regulations and Industry Standards

58. In the place of testimony from a qualified expert on the adequacy of the Zoloft label, Plaintiffs seek to substitute their attorneys' interpretation of internal company documents on complex scientific subjects. However, Plaintiffs' description of disputed facts makes clear that their challenge to the adequacy of the Zoloft label involves issues beyond the common understanding of lay jurors.

59. For example, Plaintiffs cite to various animal studies and toxicology reports prepared by Pfizer. See Pls' Resp. (Transaction ID 59958774) at pp. 2-3. Plaintiffs' interpretations of those complex, scientific documents are not supported by any expert testimony and, thus, constitute no more than speculation and allegation on the part of Plaintiffs. More importantly, the FDA-approved Zoloft label summarizes the animal studies and describes the

adverse outcomes seen in those studies. See FOF ¶ 9. Neither the interpretation of such studies nor the appropriate method for distilling such lengthy and complex information into a prescription drug label is within the ordinary knowledge and experience of the average juror.

60. Plaintiffs also refer to evaluations of adverse event reports, again offering their own speculative, non-expert interpretation of such documents. Pls' Resp. (Transaction ID 59958774) at pp. 2-4. Defendants contest Plaintiffs' characterizations of the documents and cite testimony in support of their contention that descriptions of adverse events as possibly related to Zoloft use do not represent opinions of causation, but are a step in the process used to review adverse events.[16]

61. Defendants note that while Plaintiffs cite to interim steps in this process, they ignore the conclusions of these reports. For example, a 1994 report cited by Plaintiffs concluded that "[t]here appears to be no consistent clinical pattern among the findings of the five cases that would lead to the conclusion that sertraline has an adverse effect on pregnancy." Pls' Resp., Ex. F at p. 2011.[17] Similarly, a 1998 report cited by Plaintiffs stated: "The conclusions from this review therefore support the findings from the prior reviews that there was no consistent clinical profile to the adverse events examined indicating that fetal or neonatal exposure to sertraline had an adverse effect on pregnancy." Pls' Resp., Ex. J at p. 3020.

62. Defendants also cite to testimony from Pfizer witnesses that Pfizer's review of its safety database and other evidence did not support a causal association between Zoloft and birth defects or a signal for such an association.[18] The significance of adverse event reports, the process for evaluating them, the determination of when they rise to a signal and when they

[16] *See* Defs' Reply (Transaction ID 59979426) at p. 9, citing Defs' Mot., Ex. H (Dieck Dep. at 484:21-485:12; 712:11-713:22) and Defs' Mot., Ex. I (Gribko Dep. at 82:11-83:10; 85:12-22).

[17] Page references to bates-numbered exhibits are to the last four digits in the bottom right-hand corner.

[18] *See* Defs' Reply (Transaction ID 59979426) at p. 9 (citing Defs' Mot., Ex. H (Dieck Dep. at 479:8-24, 485:16-487:3, 737:22-738:3) and Defs' Mot., Ex. J (Raillard Dep. at 886:14-887:2).

should be incorporated into a prescription medicine's label are all matters outside the ordinary knowledge and experience of the average juror.

63. Citing an FDA guidance document on good pharmacovigilance practices, Plaintiffs also argue that an increase in spontaneous adverse event reporting in pregnant women described in a 1996 document "constituted a safety signal that merited further investigation and dissemination to prescribing physicians." Pls' Resp. (Transaction ID 59958774) at p. 3. However, neither the interpretation of such statistical data nor the FDA's guidance document is within the common knowledge and experience of the ordinary juror. Nor would the average juror be familiar with how a responsible drug manufacturer would incorporate such information, if at all, into the product's label.

64. Plaintiffs also cite to a statement in Pfizer's Core Data Sheet and International Product Documents that "[w]omen of childbearing potential should employ an adequate method of contraception if taking sertraline." Pls' Resp. (Transaction ID 59958774) at pp. 3-10. Again, Plaintiffs offer only the opinion of their attorneys regarding the proper interpretation of this language, an interpretation challenged by Defendants.

65. Defendants note that Plaintiffs' interpretation of the contraception language to mean that Zoloft should not be used during pregnancy is contradicted by other parts of the same document, which also states that Zoloft is not a teratogen and can be prescribed in pregnancy if the benefits outweigh the risk. Pls' Resp., Ex. Z at p. 2120. According to Defendants, a more reasonable interpretation is that women on Zoloft should plan their pregnancies so that they can discuss with their doctors the risks and benefits of taking Zoloft before getting pregnant. See Defs' Reply (Transaction ID 59979426) at pp. 10-11.

66. Defendants also point to testimony from Pfizer witnesses that labels in different countries were not required to include language from the Core Data Sheet verbatim so long as

the essential safety information was conveyed;[19] that the Core Data Sheet and the U.S. label were and are consistent with each other in conveying the essential message that Zoloft should be used during pregnancy only if the benefits outweigh the risk; and that women should discuss use of Zoloft with their physicians before becoming pregnant.[20]

67. Plaintiffs argument that they can make Pfizer company witnesses their "experts" on the Core Data Sheet and Pfizer's internal procedures for their implementation also fails. Pls' Resp. (Transaction ID 59958774) at pp. 17-20. Pfizer witnesses have testified that determining whether the Core Data Sheet and the U.S. label are consistent does not involve a comparison of the words used. Instead, it is a medical judgment as to whether the essential message regarding risk is conveyed appropriately in light of the regulations and physician practices in a particular country. See ¶¶ 60-61.) Medical consistency, to be measured in part on how language may be interpreted by physicians practicing in a particular country, is well beyond the knowledge and experience of the average juror. Further, Plaintiffs' attempt to make Pfizer witnesses their experts cannot satisfy their burden of proof as to inadequacy of the Zoloft label, because those witnesses have testified that the U.S. label was both adequate and consistent with the Core Data Sheet. *Id.*

68. Plaintiffs also cite to informal comments made by a Pfizer epidemiologist over a decade after the use of Zoloft by the Mother Plaintiffs. Pls' Resp. (Transaction ID 59958774) at pp. 4-5. First, it is impossible for Plaintiffs to establish with such evidence that the Pfizer label ***in 2003*** was inadequate. Second, Plaintiffs again ignore other documents that demonstrate, upon completion of the review, Pfizer determined that a causal relationship had not been established by epidemiologic studies. See Defs' Mot., Ex. M, at. pp. PFI00020903264-66. Finally, the

[19] *See* Defs' Reply (Transaction ID 59979426) at p. 11 (citing Defs' Ex. K, Brumfield Dep. at 718:16-724:3).

[20] *See id.* (citing Defs' Ex. K, Brumfield Dep. at 715:7-726:8; Defs' Ex. H, Dieck Dep. at 72:9-74:13, 75:7-77:4; Defs' Ex. J, Raillard Dep. at 181:10-185:1, 934:1-936:17; Defs' Ex. L, Sadrarhami Dep. at 860:19-868:13).

interpretation of epidemiologic studies and how to properly reflect them in the label of a prescription drug is not within the ordinary knowledge and experience of the average juror.

69. Plaintiffs also cite FDA regulations, but are not prepared to offer expert testimony interpreting those regulations or supporting their contention that the 2003 Zoloft label was in violation of them. Pls' Resp., (Transaction ID 59958774) at p. 14. Defendants point to the FDA's repeated approvals of the FDA label in response to Plaintiffs' allegations. Defs' Reply, (Transaction ID 59979426) at p. 12. As previously discussed, although FDA approval is not conclusive evidence that the Zoloft label was adequate, the FDA's repeated approvals point to the need for expert testimony on the label's compliance with FDA regulations.

70. This Panel does not need to resolve the disputed facts raised by Plaintiffs' Response to decide Defendants' Motion for Summary Judgment. The issue before the Panel is not whether such facts are disputed or whether they are relevant, but whether they can satisfy the Plaintiffs' burden to prove that the Zoloft label was inadequate without expert testimony.

The various documents cited by Plaintiffs to support their claims clearly illustrates the complexity of the issues presented by Plaintiffs' failure to warn claims. These issues are beyond the knowledge and experience of the average juror such that expert testimony is required. Because Plaintiffs cannot substitute documents for appropriate expert testimony regarding the adequacy of the Zoloft label to meet their burden of proof, their claims fail as a matter of law.

CONCLUSION

For the reasons set forth herein, the Panel unanimously GRANTS Defendants' Motion for Summary Judgment. Judgment is entered in favor of Defendants, and the claims of the above-captioned Plaintiffs are hereby DISMISSED WITH PREJUDICE. Any exceptions or objections are noted and preserved for the record.

The Court FINDS upon EXPRESS DETERMINATION that this is 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.

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: February 15, 2017.

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