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Transaction ID 59714082

IN THE CIRCUIT COURT OF KANAWHA COUNTY, WEST VIRGINIA

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

THIS DOCUMENT APPLIES TO ALL CASES

ORDER REGARDING MOTIONS *IN LIMINE*

On August 15, 2016, Plaintiffs and Defendants filed motions *in limine* on a variety of matters, as listed below. Having reviewed and maturely considered the motions, responsive briefs, and supporting materials submitted by the parties, and having conferred with one another to ensure uniformity of their decisions as contemplated by Rule 26.07(a) of the West Virginia Trial Court Rules, the Presiding Judges unanimously issue the following rulings.

PLAINTIFFS' MOTIONS *IN LIMINE*

***Plaintiffs' Omnibus Motion in Limine* (Transaction ID 59427162):**

- Motion Nos. 1, 2 and 3 are **GRANTED** as agreed upon;
- Motion Nos. 4(a), 5, 6, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19(d), 21, 22, 23, and 24 are **GRANTED**;
- Plaintiffs' unnumbered motion to exclude argument or evidence concerning the use of Zoloft by Defendants' attorneys and witnesses is **GRANTED**;
- Motion Nos. 19(a) through (c) are **GRANTED**, except as to evidence that is permissible pursuant to West Virginia Rules of Evidence 607, 608 and 609;
- Motion Nos. 4(b) and 7 are **DENIED**;
- Motion No. 20 is **DENIED** as moot.

Plaintiffs' Motion in Limine No. 1 *to Exclude Evidence, Argument, and References to Certain Irrelevant Information about Plaintiffs' Background*, filed in *J.C. a minor by and through his mother and next friend Michelle C* Civil Action No. 12-C-146-WNE (Transaction ID 59427195) is **GRANTED** as agreed, unless the door is opened at trial regarding:

- Circumstances concerning custody of the Minor Plaintiff.
- Irrelevant injuries, including the Minor Plaintiff's broken femur.

- Michelle C 's psychiatric history after the Minor Plaintiff's birth.

Such evidence is not relevant and if found to be relevant, its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues or misleading the jury.

Plaintiffs' Motion in Limine No. 1 *to Exclude Evidence, Argument, and References to Certain Irrelevant Information about Plaintiffs' Background,* filed in *I.H., a minor by and through her mother and next friend Angela H* Civil Action No. 13-C-229 WNE (Transaction ID 59427217) is **GRANTED** as agreed, unless the door is opened at trial regarding:

- That David H and/or Angela H have tried illegal drugs.
- That David H has been arrested.
- That Angela H filed a disability claim.

Such evidence is not relevant and if found to be relevant, its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues or misleading the jury.

Plaintiffs' Motion in Limine No. 2 *to Exclude Any Evidence or Discussion Relating to Defendants' Alleged Good Reputation and/or "Good Acts"* (Transaction ID 59427057) is **GRANTED IN PART** and **DENIED IN PART**. The product at issue in this trial is Zoloft. Defendants will be permitted to provide a limited amount of corporate introduction or history as background information in the same fashion that Plaintiffs will be permitted to introduce themselves to the jury.

Plaintiffs' Motion in Limine No. 3 *to Exclude Evidence, Argument, and/or References Regarding Plaintiffs' Experts' Person or Company Worth and Other Financial Information Unrelated to Expert Services in Litigation* (Transaction ID 59427069) is **GRANTED**, except as to income derived from an expert witness's services in this or any other case. Evidence of Plaintiffs' experts' personal or company worth and other financial information unrelated to their services as an expert witness in litigation is not relevant to any issue in this case.

Plaintiffs' Motion in Limine No. 4 *to Exclude any Evidence, Argument, and/or References That a Drug Manufacturer Could Not Change the Warning Label, or Issue Warnings, on a Medication Without Prior FDA Approval* (Transaction ID 59425089) is **DENIED**. Pfizer does

not suggest prior FDA approval is required for all label changes, however, even changes under the CBE procedure are subject to the FDA's review and rejection.

Plaintiffs' Motion in Limine No. 5 *to Exclude any Evidence, Argument, and/or References That Pfizer Was Not Negligent and Should Not Be Held Liable Based on FDA Approval of Zoloft* (Transaction ID 59427082) is **DENIED**. "[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 also, Syllabus Point 9, in part, *In Re: Flood Litigation*, 216 W.Va. 534, 548, 607 S.E.2d 863, 877 (2004)(landowner's compliance with appropriate state and federal regulations in extraction and removal of natural resources did not give rise to a presumption landowner acted reasonably or without negligence or liability to others in extraction and removal activities).

Plaintiffs' Motion in Limine No. 6 *to Exclude Any Evidence, Testimony, or Argument Regarding Regulatory Submissions to the FDA* (Transaction ID 59427107) is **DENIED**. Even where FDA approval is not conclusive on the issue of liability, it does not render FDA approval irrelevant. To the extent Pfizer's duty to inform the FDA diverges from its duty to warn doctors, the jury will be informed of those differences, and the parties can argue to the jury the respective weight that should be given to FDA approval.

Plaintiffs' Motion in Limine No. 7 *to Exclude Any Evidence or Reference to Plaintiffs' Failure to Call Certain Experts or Witnesses* (Transaction ID 59427119) is **GRANTED**. Plaintiffs' selection of experts does not establish any material fact or help prove a proposition in issue, and insinuates to the jury that Plaintiffs chose to withhold expert opinion testimony from them. Any argument that Plaintiffs failed to call certain experts and/or certain witnesses will unfairly prejudice Plaintiffs, confuse the issues, and waste time.

Plaintiffs' Motion in Limine No. 8 *to Exclude Any Evidence, Testimony, or Argument Regarding the FDA "Preamble"* (Transaction ID 59426199) is **GRANTED** as agreed. Pfizer has no intention of arguing that the FDA Preamble language establishes a floor and a ceiling for drug labeling.

Plaintiffs' Motion in Limine No. 9 *to Exclude Evidence, Argument and/or References to Any Conversations with, or Statements or Beliefs of, Treating Physicians about What Caused Minor Plaintiffs' Injuries* (Transaction ID 59426244) is **GRANTED**, except where a party has designated a treating physician as offering expert testimony. Treating physicians are not causation experts, unless they have been designated to offer expert testimony on causation.

Plaintiffs' Motion in Limine No. 10 *to Exclude Evidence, Argument, and/or References Regarding Pfizer's Proposed New Label for Zoloft* (Transaction ID 59426281) is **GRANTED**. The Zoloft label and associated warnings that existed at the time the Mother Plaintiffs were prescribed Zoloft are what is relevant in this failure to warn case.

Plaintiffs' Motion in Limine No. 11 *to Exclude Any Evidence, Argument, and/or References Regarding What the FDA Did, Might Do, Did Not Do, or Did Not Want* (Transaction ID 59427127) is **GRANTED** to the extent Pfizer has agreed not to introduce evidence regarding what the FDA might do. Evidence regarding what the FDA did or did not do is subject to the Panel's rulings regarding Motions *in Limine* Nos. 4, 5, 6, and 15. Defendants may not introduce speculative testimony concerning what the FDA did, might do, did not do, or did not want.

Plaintiffs' Motion in Limine No. 12 *to Exclude Evidence, Argument, and/or References Regarding Daubert Rulings in the Zoloft MDL and Trial Results in Other Zoloft Lawsuits* (Transaction ID 59427138) is **GRANTED.** Expert rulings in other Zoloft cases did not apply West Virginia Law and were based on expert reports, and in some cases experts, who are not before this Court. Such evidence is not relevant to any issues in this case.

Plaintiffs' Motion in Limine No. 13 *to Exclude Any Evidence, Argument, and/or References to Dr. Gretchen Dieck Biemesderfer's Personal Experience of Having a Child Born with a Birth Defect* (Transaction ID 59426318) is **GRANTED**. Such evidence is not relevant, will not assist the trier of fact, and has no bearing on the case.

Plaintiffs' Motion in Limine No. 14 *to Exclude Evidence, Argument, and/or References to Alternative Causes Unsupported by Pfizer's Experts' Opinions* (Transaction ID 59427150) is **DENIED**. To prevail on their claims, Plaintiffs must prove Zoloft was, "that cause, which in

actual sequence, unbroken by an independent cause, produced the wrong complained of, without which the wrong would not have occurred." *White v. Wyeth*, 227 W.Va. 131, 139, 705 S.E.2d 828, 836 (2010). If Plaintiffs introduce causation evidence, then Defendants can introduce evidence of alternative causation.

Plaintiffs' Motion in Limine No. 15 *to Exclude Evidence, Argument, and/or References Regarding the FDA's Approval of New Indications Means that Zoloft is Safe and Effective* (Transaction ID 59426349) is **DENIED**. FDA approvals of Zoloft as safe and effective over a 24-year period are relevant and admissible to show the state of the art and science at the time of the warning at issue. See *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 443, 307 S.E.2d 603,611 (1983)(product liability arising from failure to warn is 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.") To understand the state of the art underlying the label's text, the jury must be informed of the label's regulatory history, including that labels are periodically revised through the FDA approval process as new science emerges.

Plaintiffs' Motion in Limine No. 16 *to Exclude Evidence, Argument, and/or References That Pfizer and the FDA Share Responsibility for the Content of Zoloft's Label* (Transaction ID 59426377) is **DENIED**. In *Wyeth v. Levine*, 555 U.S. 555, 571 (2009), the Supreme Court stated that, "through many amendments to the FDCA and to FDA regulations, it has remained a central premise of the federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." Nonetheless, the Supreme Court also acknowledged that, "the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it does in reviewing all supplemental applications." *Id.*

Plaintiffs' Motion in Limine No. 17 *to Exclude Evidence, Argument, and/or References That Untreated Anxiety and/or Depression Cause Birth Defects* (Transaction ID 59426412) is

DEFERRED until trial. Defendants intend to present evidence that untreated depression is associated with adverse pregnancy outcomes as the result of behaviors accompanying those diseases, and not that untreated anxiety and/or depression cause birth defects.

With respect to Plaintiffs' motions *in limine* addressing FDA regulations–Nos. 4-6, 8, 11, 15-16–the Panel holds that evidence and argument about the applicable FDA standards is admissible, but is not preclusive. In other words, Defendants' assertion that they complied with FDA standards does not preclude Plaintiffs from bringing claims for failure to warn. Compliance with a regulation 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 also, *Johnson v. Monongahela Power Co.,* 146 W.Va. 900, 919, 123 S.E.2d 81, 93 (1961)(power company may be negligent despite compliance with National Safety Code if plaintiff can show something more ought to have been prudently done); *Johnson by Johnson v. General Motors Corp.,* 190 W.Va. 236, 247, 438 S.E.2d 28, 39 (1993)(federal motor vehicle safety standards were admissible in crashworthiness action against automobile manufacturer as evidence of whether manufacturer's conduct was reasonable; however, jury was not required to find manufacturer's conduct was reasonable merely because it followed those standards); *In Re: Flood Litigation*, 216 W.Va. 534, 548, 607 S.E.2d 863, 877 (2004)(compliance with state and federal regulations did not give rise to presumption landowner acted reasonably or without negligence or liability to others in extraction and removal activities); and *Estep v. Mike Farrell Ford Lincoln-Mercury, Inc.*, 233 W.Va. 209, 221, 672 S.E.2d 345, 357 (2008)(manufacturer's alleged compliance with relevant federal motor vehicle safety standards did not raise rebuttable presumption that vehicle was reasonably safe and not defective; compliance with safety standards is a factor for jury to consider when determining issue of product defect). Of particular importance in the trial of these cases is the state of the art at the time the mother Plaintiffs ingested Zoloft during their pregnancies with the minor Plaintiffs. See *Ilosky Tire Corp. v. Michelin,* 172 W.Va. 435, 443, 307 S.E.2d 603, 611 (1983).

DEFENDANTS' MOTIONS IN LIMINE

Defendants' Motion in Limine No. 1: *To Exclude Reference to Foreign Zoloft Labels and Foreign Regulatory Actions* (Transaction ID 59421450) is **DENIED**. Evidence of foreign study and regulatory action is relevant because it establishes Defendants' knowledge of Zoloft's risks to unborn children when taken by pregnant women. Likewise, Defendants can introduce evidence the FDA had knowledge of Zoloft's foreign labeling when it approved the Zoloft warning label.

Defendants' Motion in Limine No. 2: *To Exclude Testimony or Argument Comparing the Alleged Association between Zoloft and Birth Defects to the Causal Relationship between Smoking and Lung Cancer* (Transaction ID 59421028) is **GRANTED**. Permitting such testimony or argument would result in unfair prejudice that substantially outweighs any alleged probative value of the evidence.

Defendants' Motion in Limine No. 3: *To Exclude Evidence of, and Argument Concerning, "Ghostwriting" or Contributions to Medical, Scientific, and Financial Organizations and Institutions* (Transaction ID 59421028) is **DENIED**. Evidence concerning Pfizer's ghostwriting program allows the jury to weigh the validity of the science.

Defendants' Motion in Limine No. 4: *To Bar Evidence or Comment Relating to Defendants' Wealth* (Transaction ID 59423136) is **GRANTED**, except as to evidence of wealth generated from the sales of Zoloft. Evidence of Defendants' wealth in general is irrelevant to the issue of liability, unfairly prejudicial and not necessary for jury to decide the amount of punitive damages, if any.

Defendants' Motion in Limine No. 5: *To Exclude Changes to Food and Drug Administration ("FDA") Regulations Relating to Pregnancy Labeling and Pregnancy Categories* (Transaction ID 59421028) is **GRANTED**. FDA amendment of industry-wide regulations governing pregnancy labeling years after the minor Plaintiffs were born is not relevant to determining the adequacy of the warning contained in the Zoloft label at the time it was prescribed to the mother

Plaintiffs. Any relevance of such evidence is outweighed by the likelihood such evidence will confuse or mislead the jury, or unfairly prejudice the Defendants.

Defendants' Motion in Limine No. 6: *To Exclude Evidence of Irrelevant Government Actions That Have No Nexus to Plaintiffs or Their Prescribing Physicians* (Transaction ID 59421028) is **GRANTED** as agreed. Plaintiffs do not intend to introduce evidence or argument relating to the Grassley Investigation or the GAO Report.

Defendants' Motion in Limine No. 7: *To Exclude Evidence of Irrelevant Warning and "Dear Doctor" Letters That Have No Nexus to Plaintiffs or Their Prescribing Physicians* (Transaction ID 59421028) is **GRANTED**. Evidence of letters created years before the mother Plaintiffs were prescribed Zoloft is irrelevant, and does not relate in any way to the issue of whether the mother Plaintffs or their prescribers were adequately warned about the risks associated with the use of Zoloft during pregnancy.

Defendants' Motion in Limine No. 8: *To Exclude Reference to Civil Settlements or Corporate Integrity Agreements* (Transaction ID 59421028) is **GRANTED** for the first phase of trial, when the jury is determining liability and whether Plaintiffs are entitled to compensatory damages. Such evidence is irrelevant to prove liability for, or the validity of a claim, and would cause unfair prejudice and confusion of the issues at this state of trial. The Court will re-visit this motion at the punitive damages phase of trial.

Defendants' Motion in Limine No. 9: *To Exclude References, Argument, and Any Evidence Regarding (1) Other Lawsuits Involving Pharmaceutical Products and (2) Public Relations Firms* (Transaction ID 59423418) is **GRANTED** as agreed. Plaintiffs do not presently intend to offer any evidence or argument regarding other claims, injuries or lawsuits, so long as Defendants agree not to argue this claim is isolated.

Defendants' Motion in Limine No. 10: To Exclude All Testimony or Argument Pertaining to Suicidality Risk in Children, Adolescents, and Young Adults (Transaction ID 59421028) is **GRANTED** as agreed. Such evidence is irrelevant to any issue in these cases, which do not involve pediatric use of Zoloft. Plaintiffs do not presently intend to offer any such evidence or

argument, but if Defendants argue Zoloft is more effective to treat depression than other drugs, Plaintiffs should be able to rebut such evidence with evidence Zoloft is not effective or safe to treat depression.

Defendants' Motion in Limine No. 11: *To Exclude Marketing Evidence That Has No Nexus to Plaintiff Laura Michelle L C or Her Prescribers*, filed in *J.C., a minor by and through his mother and next friend Michelle C* (Civil Action No. 12-C-146-WNE) (Transaction ID 59423667) is **GRANTED**. Such evidence is irrelevant because Plaintiffs cannot demonstrate any nexus between such evidence and the mother Plaintiff's decision to take Zoloft, the prescriber's decision to prescribe Zoloft to the mother Plaintiff, or the causation the jury must decide. Plaintiffs never saw or relied on Zoloft marketing materials and Plaintiffs have not shown otherwise.

Defendants' Motion in Limine No. 11: *To Exclude Marketing Evidence That Has No Nexus to Plaintiff Angela H or Her Prescribers*, filed in *I.H., a minor by and through her mother and next friend Angela H* (Civil Action No. 13-C-229 WNE) (Transaction ID 59421490) is **GRANTED**. Such evidence is irrelevant because Plaintiffs cannot demonstrate any nexus between such evidence and the mother Plaintiff's decision to take Zoloft, the prescriber's decision to prescribe Zoloft to the mother Plaintiff, or the causation the jury must decide. Plaintiffs never saw or relied on Zoloft marketing materials and Plaintiffs have not shown otherwise.

Defendants' Motion in Limine No. 12: *To Exclude Argument and Testimony Regarding Any Allegation that Pfizer Defrauded, Deceived, or Misled the FDA* (Transaction ID 59423343) is **GRANTED** as agreed. Plaintiffs do not intend to argue the Defendants defrauded the FDA.

Defendants' Motion in Limine 13: *To Strike Evidence of Future Medical Costs and Expenses Offered by Plaintiffs' "Life Care Planning" Expert, Cathlin Vinett Mitchell, R.N.* (Transaction ID 59423714) is **GRANTED**. Ms. Mitchell's projection is speculative and conjectural because she failed to conduct any real investigation into these cases, and admitted in her deposition that she failed to review the medical records of the minor Plaintiffs.

Defendants' Motion in Limine No. 14: *To Exclude Evidence of Injuries Not Attributed to Zoloft or The Alleged Injury*, filed in *J.C., a minor by and through his mother and next friend Michelle C* , Civil Action No. 12-C-146-WNE (Transaction ID 59423648) is **DENIED**. Defendants' motion attempts to preclude a broad category of potential evidence without the opportunity to consider the substance, context or purpose for which the evidence is offered.

Defendants' Motion to Remove Confidentiality and Privilege Branding from Exhibits Introduced or Shown to the Jury (Transaction ID 59448292) is **GRANTED**. Defendants will take the lead on removing the branding, and for that purpose, Plaintiffs shall identify a reasonable number of exhibits, originally branded by Defendants, at least fourteen (14) days (excluding court holidays) in advance of when Plaintiffs will introduce them into evidence.

The parties' objections and exceptions are noted and preserved.

It is so **ORDERED.**

ENTER: October 18, 2016.

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