IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

January 2018 Term

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SUPREME COURT OF APPEALS
OF WEST VIRGINIA

No. 17-0282

J.C., A MINOR BY AND THROUGH HIS MOTHER AND NEXT FRIEND, MICHELLE C., AND I.H., A MINOR BY AND THROUGH HER MOTHER AND NEXT FRIEND, ANGELA H.,
Plaintiffs Below, Petitioners

v.

PFIZER, INC., ROERIG, A DIVISION OF PFIZER, INC., AND GREENSTONE, LLC F/K/A GREENSTONE, LTD.,
Defendants Below, Respondents

Appeal from the Mass Litigation Panel
Circuit Court of Kanawha County
Civil Action Nos. 12-C-146 & 13-C-229
Honorable James P. Mazzone, Lead Presiding Judge
In Re: Zoloft Litigation
Civil Action No. 14-C-7000

AFFIRMED

Submitted: March 6, 2018
Filed: May 15, 2018

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JUSTICE LOUGHRY delivered the Opinion of the Court.
JUSTICE KETCHUM, deeming himself disqualified, did not participate in the decision in this case.
JUDGE WILKES sitting by special assignment.

SYLLABUS BY THE COURT

1. "A circuit court's entry of summary judgment is reviewed *de novo*." Syl. Pt. 1, *Painter v. Peavy*, 192 W.Va. 189, 451 S.E.2d 755 (1994).

2. "The determination of whether a defendant's efforts to warn of a product's dangers are adequate is a jury question." Syl. Pt. 4, *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603 (1983).

3. "[C]ompliance with the appropriate regulations is competent evidence of due care[.]" Syl. Pt. 1, in part, *Miller v. Warren*, 182 W.Va. 560, 390 S.E.2d 207 (1990).

4. "It is the general rule that in medical malpractice cases negligence or want of professional skill can be proved only by expert witnesses." Syl. Pt. 2, *Roberts v. Gale*, 149 W.Va. 166, 139 S.E.2d 272 (1964).

5. "'Where an injury is of such a character as to be obvious, the effects of which are reasonably common knowledge, it is competent to prove future damages either by lay testimony from the injured party or others who have viewed his injuries, or by expert testimony, or from both lay and expert testimony, so long as the proof adduced thereby is to

a degree of reasonable certainty.' Syllabus Point 11, in part, *Jordan v. Bero*, 158 W.Va. 28, 210 S.E.2d 618 (1974)." Syl. Pt. 9, *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603 (1983).

6. "In medical malpractice cases where lack of care or want of skill is so gross, so as to be apparent, or the alleged breach relates to noncomplex matters of diagnosis and treatment within the understanding of lay jurors by resort to common knowledge and experience, failure to present expert testimony on the accepted standard of care and degree of skill under such circumstances is not fatal to a plaintiff's *prima facie* showing of negligence." Syl. Pt. 4, *Totten v. Adongay*, 175 W.Va. 634, 337 S.E.2d 2 (1985).

7. The determination of whether expert testimony is necessary to sustain the burden of proof in complex cases involving matters of science, medicine, engineering, technology and the like is made on a case-by-case basis. When the issues involved are beyond the common knowledge and experience of the average juror, expert testimony shall be required.

LOUGHRY, Justice:

The petitioners (plaintiffs below), J.C., a minor by and through his mother and next friend Michelle C., and I.H., a minor by and through her mother and next friend, Angela H., appeal the order of the Mass Litigation Panel ("Panel") entered on February 15, 2017, through which summary judgment was granted in favor of the respondents (defendants below), Pfizer, Inc., Roerig, a division of Pfizer, Inc., and Greenstone, LLC f/k/a Greenstone, Ltd. (collectively "Pfizer"). The petitioners assert that the Panel's decision was erroneously based on the absence of expert testimony to support their claims that Pfizer failed to adequately warn of the risks of a prescription medication. The petitioners further assert that even if expert testimony were required, summary judgment was erroneous because Pfizer's experts could supply the necessary testimony. Upon our review of the parties' briefs, the arguments of counsel, the appendix record submitted, and the applicable law, we affirm the Panel's summary judgment ruling.

I. Facts and Procedural Background

This litigation commenced on July 11, 2012, when a complaint alleging products liability and negligence claims was filed by several unrelated mothers on behalf of their respective minor children. The petitioners alleged that the children had suffered birth defects that were proximately caused by their mothers' ingestion of the drug sertraline

hydrochloride (brand-name "Zoloft") while they were pregnant.[1] Zoloft is a prescription antidepressant manufactured and marketed by Pfizer.[2]

In seeking to recover damages, the petitioners alleged that Pfizer failed to adequately warn of the risks of birth defects from the use of Zoloft while pregnant and that adequate warnings would have prevented their injuries. The petitioners do not dispute that the federal Food & Drug Administration ("FDA")[3] has evaluated the safety of Zoloft for decades and that it remains approved as safe and effective.[4]

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[1]Following the referral of this action to the Mass Litigation Panel in January 2014, it has been before this Court on procedural matters. *See State ex rel. J.C. v. Mazzone*, 235 W.Va. 151, 772 S.E.2d 336 (2015) (addressing Panel's authority and issue of forum non conveniens); *State ex rel. J.C. v. Mazzone*, 233 W.Va. 457, 759 S.E.2d 200 (2014) (prohibiting enforcement of order transforming two civil actions into twenty-five separate actions). This Court also affirmed the Panel's summary judgment order entered in favor of Pfizer on the claim of a different plaintiff, M.M. *See M.M. v. Pfizer, Inc.*, 239 W.Va. 876, 806 S.E.2d 800 (2017) (finding that governing Michigan law foreclosed failure-to-warn claim).

[2]*See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, MDL No. 2342, 26 F. Supp. 3d 449, 452 (E.D. Pa. 2014) (Zoloft is "commonly used to treat depression, anxiety, and other mental health conditions. . . . Zoloft is one of a class of drugs known as selective serotonin reuptake inhibitors (SSRIs).").

[3]Drug labeling falls within the purview of the FDA, whose mission includes "protect[ing] the public health by ensuring that . . . (B) human . . . drugs are safe and effective[.]" 21 U.S.C. § 393(b)(2)(B) (2011); *see also* 21 C.F.R. § 201.56 (setting forth requirements on content and format of labeling for human prescription drugs and biological products).

[4]The Panel noted in its order being appealed that for reasons unrelated to the instant matter, the FDA is reviewing the Zoloft label and has proposed a change to the pregnancy (continued...)

FDA regulations require prescription medicine manufacturers to include one of five warnings in a drug's label which reflect the potential of a drug to cause birth defects if used during pregnancy.[5] Based upon information supplied by Pfizer,[6] the FDA determined that Zoloft should carry a Category C warning, which is required when animal studies show some risk in use of the drug during pregnancy; when there are no adequate, well-controlled studies in humans; and when the potential benefits of use during pregnancy may outweigh the potential risks. In 2003, when the petitioner mothers took Zoloft, the label stated:

> Pregnancy–Pregnancy Category C — Reproduction studies have been performed in rats and rabbits at doses up to 80 mg/kg/day

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[4](...continued)
section which states, in part, that "[t]he weight of the evidence from epidemiologic studies of pregnant women exposed to sertraline 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 sertraline."

[5]*See In re Zoloft*, 26 F. Supp. 3d at 453 n.7 ("The FDA has established 5 categories to indicate the potential of a drug to cause birth defects if used during pregnancy. Category A means that there are adequate, well-controlled studies which have failed to demonstrate a risk to the fetus. Few drugs are in category A because controlled studies of medication use during pregnancy are ethically prohibited. Category B means animal studies show no risk, but there are no adequate and well-controlled studies of use by pregnant women. Category C means that animal reproduction studies have shown an adverse effect on the fetus, but there are no adequate and well-controlled studies in humans, and so pregnant women should weigh the potential benefits against the potential risks. Category D is used when there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may still warrant use of the drug. Category X is the lowest category, used when use of the drug is not recommended for any pregnant women, as the risks clearly outweigh any benefits. One SSRI, Paxil, is a Category D drug, while all other SSRIs, including Zoloft, are Category C drugs.").

[6]The Panel found that the petitioners had not presented any evidence that Pfizer withheld relevant information from the FDA.

> 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.[7] 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.

Pfizer also included in the Zoloft label that patients should "notify their physician if they become pregnant or intend to become pregnant during therapy."[8]

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[7]A teratogen is "an agent or factor that causes malformation of an embryo." New Oxford American Dictionary (3d ed. 2010).

[8]The appendix record contains reports of studies conducted in the medical and scientific community evaluating the safety of Zoloft, which have concluded there is no causal link between Zoloft and birth defects. *See*, *e.g.*, Organization of Teratology Information Specialists, *Sertraline (Zoloft®) and Pregnancy* (Sept. 2014) ("Overall, the available information does not suggest that sertraline increases the risk for birth defects above the 3-5% background risk that is seen in the general population."); American Heart Association, *Diagnosis and Treatment of Fetal Cardiac Disease A Scientific Statement from the American Heart Association* (May 27, 2014) (finding that studies "indicate that there is no increased risk of CHD [congenital heart disease] associated with the use of most SSRIs" and noting that "paroxetine [Paxil] may be an exception."). In a 2015 press release, the Center for (continued...)

The petitioners alleged that Pfizer negligently failed to adequately warn them of the risk of birth defects through the ingestion of Zoloft during pregnancy.[9] In their expert witness disclosure filed on March 16, 2016, the petitioners designated Adam C. Urato, M.D., as their expert on the adequacy of the Zoloft label in 2003, specifically as it related to the use of Zoloft during pregnancy. The petitioners disclosed that Dr. Urato would offer opinions concerning the label to "a reasonable degree of medical and scientific certainty, as an expert in Maternal-Fetal Medicine and based on his education, training, experience, review of the relevant literature, and specialized knowledge[.]"[10]

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[8](...continued)
Disease Control and Prevention reported, "[r]eassuringly, researchers did not confirm links between sertraline, the SSRI used most often, and any of the birth defects observed in previous studies." https://www.cdc.gov/pregnancy/meds/treatingfortwo/features/ssrisandbirthdefects.html (last visited April 29, 2018).

[9]In 2016, the Legislature enacted West Virginia Code § 55-7-30, which provides, in part, that it is the "intention of the Legislature in enacting this section to adopt and allow the development of a learned intermediary doctrine as a defense in cases based upon claims of inadequate warning or instruction for prescription drugs or medical devices." This Court had previously declined to adopt the doctrine. *See* Syl. Pt. 3, *State ex rel. Johnson & Johnson Corp. v. Karl*, 220 W.Va. 463, 647 S.E.2d 899 (2007) ("Under West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers. We decline to adopt the learned intermediary exception to this general rule."). Because the case at bar was filed in 2012, the doctrine has no application here.

[10]The appendix record contains Dr. Urato's curriculum vitae, which reflects that he graduated from Harvard Medical School, where he later was employed as a Teaching Fellow in Obstetrics, Gynecology and Reproductive Endocrinology; that he is currently employed as an Associate Professor of Obstetrics and Gynecology at Tufts University School of Medicine in Boston, Massachusetts; and that he has authored more than twenty-five peer-reviewed journal publications, and given numerous presentations, concerning the use of (continued...)

Although Dr. Urato was scheduled for deposition on June 13, 2016, he became unavailable due to unspecified health reasons. Dr. Urato's unavailability prompted Pfizer to file a motion to exclude him from testifying as an expert witness in this matter. The petitioners opposed the motion, arguing that their labeling expert was a critical witness and their "key liability expert" without whom they would be severely prejudiced. The petitioners asserted that Dr. Urato was

> 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.

The petitioners advised the Panel that should Dr. Urato's medical situation prevent him from testifying, they would "seek to designate a new expert in his place, considering the importance of the liability topics on which he is designated to opine[.]"

During an August 8, 2016, hearing, the petitioners' counsel reiterated that "Doctor Urato is a key liability expert of ours. . . . 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."[11] Although the Panel ordered that Dr. Urato's deposition be taken no later than August 29,

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[10](...continued)
antidepressants during pregnancy.

[11]*See* ¶ 14, Panel's February 15, 2017, Order.

2016, the petitioners remained unable to produce him for deposition. Thereafter, the petitioners filed a motion seeking leave to designate a replacement expert, again describing Dr. Urato as their key liability expert without whom the plaintiffs would be prejudiced. In response, the Panel ordered the petitioners' counsel to file under seal, no later than September 7, 2016, an affidavit from Dr. Urato's treating physician that contained, *inter alia*, a medical diagnosis for Dr. Urato and an affirmation that he was not medically able to sit for deposition. By letter dated September 7, 2016, the petitioners' counsel advised the Panel that "we have had very limited contact with Dr. Urato and he has not supplied us with the affidavit from his treating doctor."

Through its September 9, 2016, order, the Panel found that the petitioners' counsel were aware, no later than June 9, 2016, that Dr. Urato was unable to be deposed, and that counsel had failed to either make Dr. Urato available for deposition on August 29, 2016, or submit an affidavit from Dr. Urato's treating physician, as previously ordered. Determining that good cause had been shown, the Panel granted Pfizer's motion to exclude Dr. Urato as an expert in these cases "due to his inability to appear for deposition in these cases now or anytime in the foreseeable future." The Panel further found that although the petitioners' counsel had "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[,]" it "would be unfair to punish the litigants for their counsel's lack of diligence."

Accordingly, the Panel granted the petitioners' motion for leave to designate a replacement expert and ordered that the replacement expert be designated no later than September 16, 2016.

In compliance with the Panel's deadline, the petitioners filed a supplemental disclosure of experts in which they identified David A. Kessler, M.D., as their expert on failure to warn issues. Dr. Kessler is a nationally known expert and former Commissioner of the FDA.[12] Dr. Kessler's deposition was noticed for November 17, 2016. The petitioners filed a motion seeking to limit Dr. Kessler's deposition to no more than three hours, asserting that Pfizer was well aware of his opinions. They referenced Dr. Kessler's 116-page report detailing his opinions and his deposition that was taken in 2015 in a federal Zoloft multi-district litigation case—MDL No. 2342. *See In Re: Zoloft (Sertraline Hydrochloride) Products Liability Litigation*, MDL No. 2342, 26 F. Supp. 3d 449, 452 (E.D. Pa. 2014) (granting motion to exclude expert witness). The petitioners stated that

> 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 . . . . 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

[12]The appendix record contains Dr. Kessler's curriculum vitae.

> 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.

On November 14, 2016, the Panel entered an order denying the petitioners' motion to limit the length of Dr. Kessler's deposition and ordered the petitioners to produce Dr. Kessler for deposition on November 17, 2016. Two days before the deposition was to be taken, the petitioners filed a supplemental expert disclosure in which they withdrew Dr. Kessler as their labeling expert without explanation.

Inasmuch as the petitioners no longer had their self-proclaimed key liability expert, Pfizer filed a motion for summary judgment, arguing that the petitioners could not meet their evidentiary burden on the alleged inadequacy of the 2003 Zoloft label. The petitioners filed a response in which they maintained that they could meet their evidentiary burden with Pfizer company documents that allegedly show Pfizer was aware of the risks associated with the use of Zoloft during pregnancy yet failed to provide an adequate warning of such risks on its label. They further argued that to the extent expert testimony was required on the applicable warning and labeling standards, it could be provided through Pfizer witnesses. Pfizer filed a reply, arguing, *inter alia*, that "[i]n 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 and, thereby, present such evidence not through a scientist, but an advocate not subject to cross-examination."

In its unanimous order entered on February 15, 2017, the Panel awarded summary judgment in favor of Pfizer. The Panel observed that whether the failure to adequately warn claim is based in strict liability or negligence, "the question is whether [Pfizer] acted reasonably under the circumstances."[13] Relying upon this Court's precedent, the Panel noted the importance of having an expert witness in failure to warn cases, particularly when there are "complex technical, scientific, and medical issues beyond the common knowledge and experience of the average person." The Panel found that "[w]hether Pfizer behaved as a reasonably prudent manufacturer would when warning about the use of

[13]The Panel based its observation on *Honaker v. Mahon,* 210 W.Va. 53, 552 S.E.2d 788 (2001), wherein this Court stated that "'[n]egligence' 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[,]" *Id.* at 58, 552 S.E.2d at 793, and on our holding that "'[n]egligence 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.'" *Id.* at 55, 552 S.E.2d at 790, syl. pt. 2 (citation omitted). The Panel also relied upon *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603 (1983), in which this Court stated that under 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.'" *Id.* at 443, 307 S.E.2d at 611 (quoting *Morningstar v. Black & Decker Mfg. Co.*, 162 W.Va. 857, 888, 253 S.E.2d 666, 682-83 (1979)).

Zoloft during pregnancy involves complex issues of science and medicine"; that "this is not a case where the label is silent regarding the alleged risk" because the label during the relevant time carried the Category C pregnancy warning; that "the FDA has repeatedly approved Zoloft's label"; that "numerous independent organizations have concluded that the evidence does not support a causal link between Zoloft and birth defects"; that the "inclusion of warnings that are not supported by the science can lead to unintended and adverse consequences for the patient"; and that the petitioners' "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.'"

The Panel also found that the subject matter of the documents cited by the petitioners in opposition to summary judgment, namely animal studies, epidemiology, adverse event reports, Core Data Sheets,[14] and FDA regulations, were "not within the common knowledge and experience of the average juror[.]" The Panel further found that "such evidence cannot substitute for expert testimony on the adequacy of the Zoloft label" and that "[n]either the interpretation of such studies nor the appropriate method for distilling

[14]In a memorandum of law filed below, Pfizer described a Core Data Sheet as an "internal document that may be maintained by pharmaceutical companies[,]" which contains "essential information for safe prescribing of a medicine and is used as a template for developing labels worldwide, subject to regulatory requirements and other variations among countries."

such lengthy and complex information into a prescription drug label is within the ordinary knowledge and experience of the average juror." The Panel ruled that under the facts of this case, the adequacy of Zoloft's label required expert testimony. Because the petitioners had withdrawn their warning/label expert, the Panel concluded they could not meet the burden of proof on an essential element of their claim. This appeal followed.

II. Standard of Review

We are called upon to determine whether the Panel erred in granting summary judgment in favor of Pfizer. "A circuit court's entry of summary judgment is reviewed *de novo*." Syl. Pt. 1, *Painter v. Peavy*, 192 W.Va. 189, 451 S.E.2d 755 (1994). Against this plenary standard, the parties' arguments will be considered.

III. Discussion

The petitioners assert that the Panel erred in awarding summary judgment on the basis that without expert testimony they could not meet their burden of proving that Pfizer failed to adequately warn women of childbearing age to use contraceptives when taking Zoloft. In the alternative, the petitioners argue that even if expert testimony were required, summary judgment was in error because Pfizer's experts could supply the necessary testimony. Finally, the petitioners contend that establishing a low threshold for requiring

expert testimony will impede meritorious claims because retaining experts can be time-consuming and costly. We address each of these issues, in turn, below.

A. Labeling Expert on Failure to Adequately Warn Claim

In seeking a reversal of the Panel's summary judgment ruling, the petitioners assert that expert testimony was not necessary to sustain their failure to adequately warn claim. Noting that "[t]he determination of whether a defendant's efforts to warn of a product's dangers are adequate is a *jury question*[,]" syl. pt. 4, *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603 (1983) (emphasis added), they contend a jury can answer that question once it is presented with "significant material evidence," including (1) the Zoloft "Core Data Sheet," which provided, in part, that "[w]omen of childbearing potential should employ an adequate method of contraception if taking sertraline"; (2) Pfizer's safety policies and procedures requiring that such safety information be communicated though its product label; and (3) the fact that this contraception warning was not included in the Zoloft label in the United States.[15] The petitioners assert that this evidence is within the knowledge of an average juror. Because the Panel has previously ruled that the petitioners' causation

[15]The petitioners refer this Court to pages in the appendix record for the "significant material evidence." The particular pages cited are not to evidence, but are pages in the petitioners' memorandum of law filed below in opposition to summary judgment. Our review of those pages refers the reader to attached exhibits; however, several of the documents referenced as attached exhibits are not in the appendix record. Moreover, the exhibits that are in the appendix record support the petitioners' prior recognition of their need for an expert on their inadequate warning claim.

experts can opine that Zoloft causes birth defects, the petitioners posit that a labeling expert is not needed for a jury to determine whether a reasonably prudent manufacturer would have disclosed in the product label that Zoloft can cause fetal harm, as required by FDA regulations.

In support of their position, the petitioners cite *Berg v. Johnson & Johnson Consumer Companies, Inc.*, 983 F. Supp. 2d 1151 (D.S.D. 2013), in which the court denied the defendants' motion for judgment as a matter of law where the trial evidence showed their awareness of studies indicating that talcum powder could be dangerous; where other companies selling talcum powder included warnings; and where a "layperson is in a position (if not the best position) to know whether a particular harm or possible harm is deserving of a warning." *Id.* at 1160. Similarly, the petitioners contend that a jury of lay persons could understand that a reasonably prudent pharmaceutical manufacturer would follow its own safety rules in communicating the risks posed by its products and would know that Pfizer's warnings were inadequate.

The petitioners also rely upon *Campbell v. Boston Scientific Corporation*, 882 F.3d 70 (4th Cir. 2018), wherein the defendant argued that the plaintiffs' failure to warn claim failed for lack of expert testimony on the adequacy of a manufacturer's warnings because such was beyond the common knowledge and experience of a lay juror. The Fourth Circuit

found that while expert testimony "may well have been helpful . . . that does not mean that it was required." *Id.* at 80. Likewise, the petitioners argue that while expert testimony on the adequacy of the warning on the Zoloft label may have been helpful, it was not required.

Responding in support of the Panel's decision, Pfizer argues that the petitioners' evidentiary burden was to prove that Pfizer acted unreasonably regardless of whether the failure to warn claim is based on strict liability or negligence. Pfizer asserts that in accordance with this Court's precedent, the Panel correctly determined that expert testimony was required because the facts and circumstances of this particular case are outside the common knowledge and experience of the average juror. Emphasizing the importance of expert testimony in product liability cases, Pfizer relies upon *Morningstar v. Black & Decker Manufacturing Company*, 162 W.Va. 857, 253 S.E.2d 666 (1979), wherein this Court stated that "in a product liability case, the expert witness is ordinarily the critical witness. He serves to set the applicable . . . labeling and warning standards based on his experience and expertise in a given product field." 162 W.Va. at 887, 253 S.E.2d at 682.

In addressing the cases relied upon by the petitioners, Pfizer argues that those authorities either recognize, as the Panel did here, that whether expert testimony will be necessary is dependent upon the facts of each case and whether the issue involved was within the common knowledge and experience of the average juror, or they addressed a claim of *no*

warning, as opposed to an *inadequate* warning. With specific regard to *Berg*, Pfizer notes that the product involved was talcum powder–not a prescription drug. Pfizer contends there was simply no need for a labeling expert in *Berg* because the label on the talcum powder contained no warning; therefore, a decision adverse to the manufacturer on causation would leave only the issue of feasibility under South Dakota law, which had been resolved through a stipulation. Because the Zoloft label contained the FDA-approved warning regarding the risks of Zoloft during pregnancy, Pfizer asserts that even if a jury were to determine that Zoloft can cause birth defects, a determination of the label's adequacy would remain dependent upon "the resolution of complex issues outside the common experience of the jury[.]"

In distinguishing *Campbell*, Pfizer argues that the Fourth Circuit does not appear to have been presented with facts similar to those in the case at bar, including that the FDA has repeatedly approved the Zoloft label for decades; that the petitioners repeatedly described their labeling expert as being critical to their case; and that a consensus has emerged in the scientific and medical community that the data does not support a causal link between Zoloft use during pregnancy and birth defects.[16] Further distinguishing *Campbell*, Pfizer notes that unlike the plaintiffs in that case, here, the petitioners cannot overcome the deficiency in their proof concerning the alleged inadequacy of the 2003 Zoloft label through

[16]*See supra* note 8.

their causation experts. Not only did the petitioners not make the opinions of those experts part of the summary judgment record before the Panel,[17] Pfizer adds that the petitioners do not contend that their causation experts are experts on labeling or that they are competent to testify concerning what constitutes sufficient human fetal risk to have warranted a change in the Zoloft label. Observing that the statement in *Campbell* concerning experts in failure to warn claims is "unaccompanied by any analysis," Pfizer asserts that this Court's precedent demonstrates that when matters are beyond the average juror's common knowledge and understanding, expert testimony is required.

As recounted above, the issue in a failure to adequately warn claim, whether based on strict liability or negligence, is what a reasonably prudent manufacturer would do.[18] Accordingly, the petitioners' burden was to prove that Pfizer acted unreasonably regarding the pregnancy warning on its 2003 Zoloft label, *i.e.*, the Category C warning mandated by

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[17]Pfizer maintains that the summary judgment record is contrary to the petitioners' assertion that Pfizer scientists concluded in reports that Zoloft posed a risk to the fetus. Pfizer notes that one of the reports cited by the petitioners, rather than supporting the petitioners' contention, actually concludes 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." Another report states that 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." The summary judgment record also contains deposition testimony from Pfizer witnesses that Pfizer's review of adverse event database and other evidence did not support a causal association between Zoloft and birth defects.

[18]*See supra* note 13.

the FDA, as well as the additional warning that patients should "notify their physician if they become pregnant or intend to become pregnant during therapy[,]" and that the failure to adequately warn proximately caused their alleged injuries.

The record before the Panel at summary judgment showed that the FDA has evaluated the safety of Zoloft and has approved the Zoloft label more than thirteen times over the last twenty-four years. While the FDA's approval does not resolve this issue of liability, "compliance with the appropriate regulations is competent evidence of due care[.]" Syl. Pt. 1, in part, *Miller v. Warren*, 182 W.Va. 560, 390 S.E.2d 207 (1990). As the Panel explained,

> 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 . . . indicat[es] that any alleged inadequacy of the Zoloft label is not so obvious that Plaintiffs can dispense with expert testimony.

Indeed, our precedent reflects that expert testimony will be necessary to sustain an evidentiary burden when the matters involved are beyond the common knowledge and experience of the average juror. As indicated above, this Court observed nearly thirty years ago that

> *[i]n 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 . . . *the adequacy of warnings and labels*[.]

Morningstar, 162 W.Va. at 887, 253 S.E.2d at 682 (emphasis added). Unsurprisingly, the petitioners conceded the critical importance of their labeling expert below.

As previously discussed, when Pfizer moved to exclude Dr. Urato as an expert witness due to the petitioners' inability to produce him for deposition, the petitioners implored the Panel to deny the motion, arguing that Dr. Urato was critical to their claim. They expounded upon his qualifications; his crucial importance to their claim; his forty-six-page expert report detailing his opinions and the bases for his opinions; and the "great deal of work" he had done to produce his report and to formulate the opinions set forth therein. The Panel agreed with the petitioners' position regarding the critical importance of their labeling expert, prompting the Panel to overrule Pfizer's strong objections and allow the petitioners to designate an expert to replace Dr. Urato. Although the Panel found that the petitioners' counsel had "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[,]" the Panel concluded it "would be unfair to punish the litigants for their counsel's lack of diligence." The petitioners then designated Dr. Kessler as their labeling expert only to withdraw him as an expert on the eve of his deposition without explanation. Although the petitioners now contend they do not need their self-described critical expert witness and that

a jury of lay persons can use common sense to decide their failure to adequately warn claim, their argument is unsupportable.

Notwithstanding the petitioners' u-turn after they voluntarily withdrew their key liability expert, evaluating whether the language in the 2003 Zoloft label was adequate based upon the scientific and medical information that was available at that time, including the science related to the risks of untreated depression during pregnancy, is well beyond the ken and experience of the average juror. Presumably, Dr. Urato, and later Dr. Kessler, would have drawn upon their advanced education and years of experience to guide a jury through the extensive and complex medical, scientific, and regulatory materials, as well as the considerations undertaken and medical judgments made in the development of the Zoloft label, after which they would have offered expert opinion and explanation as to why they believed Pfizer had not acted as a reasonably prudent manufacturer and why the pregnancy warnings in the 2003 Zoloft label were inadequate.

While we agree with the Fourth Circuit's statement in *Campbell* that our decision in *Morningstar* did not establish a bright line rule that expert testimony will always be required to establish a failure-to-warn claim, our precedent does demonstrate that whether

expert testimony will be necessary is determined on a case-by-case basis,[19] considering whether the facts and claims at issue are within the common knowledge and experience of the average juror.[20] For example, we found that "questions involving the . . . appropriate warnings for lifttrucks are not within the common knowledge and experience of a lay juror." *Watson v. Inco Alloys Int'l, Inc.*, 209 W.Va. 234, 243,545 S.E.2d 294, 303 (2001); *see also Crawford v. Gen. Motors Corp.*, No. 5:06CV62, 2007 WL 1960611, at *3 (N.D.W.Va. July 2, 2007) (noting that West Virginia courts "have not addressed whether expert testimony is required to prove that an airbag system was defective"; predicting that West Virginia would do so; 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

[19]West Virginia Rule of Evidence 702 addresses the admissibility of expert testimony, providing, in part, that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise." We disagree with the petitioners' contention that the Panel transformed Rule 702 into a bright line rule that would require expert testimony in all cases involving pharmaceutical products liability. Instead, the Panel's decision reflects an appreciation and application of our precedent in reaching its conclusion that expert testimony was necessary to sustain the petitioners' claim under the particular facts, claims, and issues involved. We do recognize, however, that the medical, epidemiological, scientific, and regulatory judgments involved in the formulation of a drug label, as discussed herein, will make the need for expert testimony on a failure to warn or failure to adequately warn claim likely.

[20]We agree with Pfizer that the cases from other jurisdictions cited by the petitioners in support of their argument that no expert testimony is needed here are either reiterations or variations of the concept that if the issue is within the common knowledge or experience of the average juror, no expert testimony is necessary, or the plaintiff's causation experts supplied the necessary evidence.

average layman."); *SBA Network Servs., LLC. v. Tectonic Eng'g and Surveying Consultants, P.C.*, No. 1:12CV164, 2014 WL 3797426, *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.").

In *Addair v. Litwar Processing Co., LLC*, No. 11-0397, 2012 WL 2914980 (W.Va. Feb. 9, 2012) (memorandum decision), we affirmed summary judgment in favor of the defendants, finding expert testimony was needed where the alleged occupational diseases were not "simple ailments . . . result[ing] from common causes familiar to the average layperson[,]" rather, they were complex illnesses alleged to "have arisen from exposure to chemicals of which the average person has no knowledge or experience." *Id.* at *2. Federal courts have applied West Virginia law in granting summary judgment where the plaintiff lacked expert testimony on an essential element of their claim. For example, in *Muzichuck v. Forest Laboratories, Inc.*, No. 1:07CV16, 2015 WL 235226 (N.D. W.Va. Jan. 16, 2015), the plaintiff filed an action, alleging that the defendant drug manufacturer failed to warn her decedent-husband and his prescribing physicians of the suicide risk associated with its drug, Lexapro. After the plaintiff's expert conceded that the drug's label included an appropriate warning, the plaintiff then challenged the method of warning but had no expert testimony to support her position. In granting summary judgment to the defendant, the district court found

that the plaintiff's contention that under West Virginia law, whether a manufacturer's efforts to warn "were adequate is always for the jury regardless of the state of the evidence is erroneous[,]" and that the plaintiff had not submitted any "expert testimony supporting her proposed alternative means of warning[.]" *Id.* at *11.

Although the matter before us does not involve a medical malpractice claim, our precedent that such matters generally require expert testimony on the standard of care is particularly informative given that the development of a drug label involves, in part, medical judgments.[21] In syllabus point two of *Roberts v. Gale*, 149 W.Va. 166, 139 S.E.2d 272 (1964), we held that "[i]t is the general rule that in medical malpractice cases negligence or want of professional skill can be proved only by expert witnesses." We affirmed summary judgment in favor of a physician in *Farley v. Meadows*, 185 W.Va. 48, 404 S.E.2d 537 (1991), where the plaintiff, lacking expert testimony to support her medical malpractice claim, wanted to rely upon *res ipsa loquitor*. Concluding that expert medical expert testimony was needed, we distinguished the plaintiff's claim from those cases where *res ipsa loquitor* would apply, such as where a "surgical sponge or scalpel shows up in the chest of a veteran of open heart surgery, [and] the only inference that can be drawn is that the foreign

[21] *See also* W.Va. Code § 55-7B-7 (2015), in part ("(a) The applicable standard of care and a defendant's failure to meet the standard of care, if at issue, shall be established in medical professional liability cases by the plaintiff by testimony of one or more knowledgeable, competent expert witnesses if required by the court.").

object was left in the chest from the surgery." *Id.* at 50, 404 S.E.2d at 539. In *Moats v. Preston County Commission*, 206 W.Va. 8, 521 S.E.2d 180 (1999), we addressed certified questions from the circuit court, including whether West Virginia Code § 55-7B-7[22] required the plaintiff to have an expert to testify that Valley Comprehensive Community Health Center, Inc. had deviated from the standard of care. The plaintiff, whose decedent had committed suicide while awaiting admission to the county jail on an involuntary commitment, argued that expert testimony was not needed. We noted that the case involved "complicated medical issues" and that 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," the determination of "whether Valley deviated from the standard of care involves more complex issues that are not within the common knowledge of lay jurors." *Id.* at 16, 521 S.E.2d at 188; *see also In re B.S.*, No. 17-0739, 2018 WL 317056, *3 (Jan. 8, 2018) (memorandum decision) (observing that petitioner had not offered expert to testify that stomach medication was causing her to have false-positive drug screens); *Minnich v. MedExpress Urgent Care, Inc.-W.Va.*, 238 W.Va. 533, 539, 796 S.E.2d 642, 648 (2017) (finding that plaintiff had "pled her case in a manner that requires the introduction of expert evidence to address whether Mr. Minnich should have been permitted to climb onto the examination table unassisted" and observing that "[a]bsent expert witness' testimony, the jury will be unable to determine whether Ms. Hively breached the duty of care she owed as

[22]*See supra* note 21.

a 'health care provider' to Mr. Minnich"); *Pendleton v. Wexford Health Sources, Inc.*, No. 15-0014, 2015 WL 8232155, *3 (W.Va. Dec. 7, 2015) (memorandum decision) (agreeing with "the circuit court that expert testimony would be required to prove petitioner's theory of malpractice").

In matters involving medicine and science, we analyze whether the issue is within the common knowledge or experience of the average person. For example, we held in *Ilosky* that

> "[w]here an injury is of such a character as to be obvious, the effects of which are reasonably common knowledge, it is competent to prove future damages either by lay testimony from the injured party or others who have viewed his injuries, or by expert testimony, or from both lay and expert testimony, so long as the proof adduced thereby is to a degree of reasonable certainty." Syllabus Point 11, in part, *Jordan v. Bero*, 160 W.Va. 105, 210 S.E.2d 618 (1974).

Ilosky, 172 W.Va. at 437, 307 S.E.2d at 605, syl. pt. 9. In *Totten v. Adongay*, 175 W.Va. 634, 337 S.E.2d 2 (1985), we held that

> [i]n medical malpractice cases where lack of care or want of skill is so gross, so as to be apparent, or the alleged breach relates to noncomplex matters of diagnosis and treatment within the understanding of lay jurors by resort to common knowledge and experience, failure to present expert testimony on the accepted standard of care and degree of skill under such circumstances is not fatal to a plaintiff's *prima facie* showing of negligence.

Id. at 634-35, 337 S.E.2d at 2-3; *see also Roberts*, 149 W.Va. at 172-73, 139 S.E.2d at 276 (internal citations omitted) (recognizing that negligence can "be established by lay witnesses in cases where negligence or want of professional skill is so obvious as to dispense with the need for expert testimony").[23] Similarly, we have found instances where expert testimony was not required based on the facts and claims involved in non-medical matters. *See Adkins v. Slater*, 171 W.Va. 203, 209, 298 S.E.2d 236, 242 (1982) ("The process of moving a mobile home is not so complex that it is beyond the comprehension of the average juror. Therefore, expert testimony was not necessary in this case to establish a standard of care, and to show whether the appellees violated that standard.").

In short, our case law demonstrates that the determination of whether expert testimony is necessary to sustain the burden of proof in complex cases involving matters of science, medicine, engineering, technology and the like is made on a case-by-case. When the issues are beyond the common knowledge and experience of the average juror, expert

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[23]The petitioners rely upon *Cross v. Trapp*, 170 W.Va. 459, 294 S.E.2d 446 (1982), an informed consent case in which this Court held that expert testimony was "not required under the patient need standard to establish the scope of a physician's duty to disclose medical information to his or her patient." *Id.* at 461, 294 S.E.2d at 448, syl. pt. 5, in part. Here, rather than challenging the scope of Pfizer's duty, the petitioners claim that Pfizer failed to adequately warn them of the risks associated with use of Zoloft during pregnancy. Therefore, under our holding in *Cross*, 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[,]" *id.*, expert testimony would be required.

testimony shall be required. Indeed, "[u]naided by the explanations and opinions of those with specialized knowledge or skill . . . . [and] [u]nless the jury is comprised of experts in the field, the verdict is based on mere conjecture. Such a verdict is worthless." *Dion v. Graduate Hosp. of Univ. of Penn.*, 520 A.2d 876, 881 (Pa. Super. Ct. 1987). As the Pennsylvania court aptly reasoned:

> [p]rescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. The terms and applications of a warning on such a drug, in order to have meaning, must be explained to the jury. This is a subject "so distinctively related to some science, profession, business or occupation as to be beyond the ken of the average layman." McCormick on Evidence 33 (E. Cleary, 3d ed. 1984).

Dion, 520 A.2d at 881; *see also Wyeth Laboratories, Inc. v. Fortenberry*, 530 So.2d 688, 692 (Miss. 1988) ("Where the adequacy of the warning is not obvious to the ordinary layperson it is necessary to have expert testimony as to this issue.").

Our consideration of the complex issues in the case at bar concerning what should and should not be included in a drug label demonstrates that this is a case where expert testimony is necessary. In fact, the materials in the appendix record leave us with the firm belief that the determination of whether the Zoloft label in 2003 failed to adequately warn of the risks of use during pregnancy is intensely complex. We agree with Pfizer that

> the proper interpretation of animal studies and how to distill hundreds of pages of data into a label statement that will provide meaningful prescribing information to physicians is beyond the experience of most jurors. Nor are jurors generally familiar with

> adverse event reporting or epidemiology and how that information should be captured in prescription labels, taking into account the downsides of warning of unproven risks, such as discouraging proper prescribing of medicine to patients who need it.

The development of the Zoloft label required the rendering of medical judgments as to whether essential information concerning risk is sufficiently conveyed; regulatory considerations; and how language in the label might be interpreted by physicians based upon how health services are provided in a given country. Accordingly, we readily reach the same conclusion articulated by the Panel: "[T]he 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 that "such evidence cannot substitute for expert testimony on the adequacy of the Zoloft label." To find otherwise, following our consideration of the facts, claims, and circumstances of this case, would be to invite an unsound, unintelligent, and speculative verdict based upon matters beyond the cognition and experience of the average juror.

B. The Petitioners' Evidentiary Burden Cannot be Met With Company Documents and Pfizer's Experts

Lacking their key liability expert of their own volition, and as indicated above, the petitioners now assert they can meet their evidentiary burden through "significant material evidence," including company documents and product labels in foreign countries, which they contend demonstrate that Pfizer knew Zoloft was not safe for pregnant mothers

and that the pregnancy warning in the U.S. label was inadequate. In particular, the petitioners contend that the deposition testimony of Dr. Pierre Raillard, a former senior director of safety and risk management at Pfizer, provides any expert assistance a jury would need concerning relevant standards and whether Pfizer "behaved as would a 'reasonably prudent' manufacturer in its efforts to warn U.S. prescribers and their patients of the risk posed by *in utero* exposure to Zoloft."

Expressing a countervailing position, Pfizer asserts that the petitioners' description of company documents concerning Zoloft and the intent of the authors of those documents, without expert testimony, are "nothing but argument and speculation" of their counsel, which is "not a substitute for testimony from a qualified expert." Pfizer discounts the snippets from depositions upon which the petitioners rely as being little more than out-of-context testimony of witnesses admitting that certain documents "say what they say[.]" For example, while the petitioners equate the contraception language in the Zoloft Core Data Sheet as being a contraindication against use of Zoloft during pregnancy, Pfizer notes that the Core Data Sheet specifically states that Zoloft is not a teratogen[24] and that it can be prescribed in pregnancy if the benefits outweigh the risk. As for Zoloft labeling in foreign countries, Pfizer points to the testimony of its witnesses who explained that Zoloft labels are not required to include verbatim language from the Core Data Sheet; rather, it is the essential

[24]*See supra* note 7.

safety information from that document that should be conveyed. Pfizer maintains that determining whether the Core Data Sheet and the U.S. label are consistent is not merely a comparison of words used but is a medical judgment as to whether the essential message regarding risk is conveyed appropriately considering the relevant governmental regulations and the physician practices in a particular country.

The appendix record contains excerpts from the deposition of Dr. Raillard, as well as the depositions of other Pfizer witnesses. These witnesses,[25] including Dr. Raillard, each testified 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 the use of Zoloft with their physicians before becoming pregnant. Dr. Raillard testified that Pfizer's Core Data Sheet for Zoloft summarizes scientifically-based information to be communicated to the prescriber. He agreed that the Core Data Sheet contains the statement, "women of childbearing potential should employ adequate method of contraception if taking sertraline"; that this statement "should be translated into the various document[s]"; and that he believed that "globally those two documents [the Core Data Sheet and the U.S. label] are consistent with each other, and the essence of the [C]ore [D]ata [S]heet is reflected in the US PI [U.S.

[25]It appears from the deposition excerpts in the appendix record that these witnesses are former Pfizer employees.

label][.]" He further testified that the "key message" reflected in the Core Data Sheet was that

> the physician[s] who are going to prescribe the drug . . . the important thing here is to conduct this thorough benefit/risk assessment of each patient that is pregnant in the first trimester, or will be pregnant or intend to be pregnant, and the decision of the physician will have to be based on the perceived benefit. And if those perceived benefit[s] outweighed the risk, the prescription of the drug is appropriate.

Dr. Raillard emphasized that the important message was to conduct a "thorough assessment of the benefit/risk" and that he believed the Zoloft labeling is "adequate and appropriate."

Pfizer witness Mojgan Sadrarhami, Pharm. D., who was employed as Pfizer's regulatory affairs director, testified that the Core Data Sheet "has to be looked at in totality[,]" rather than just a single sentence, and that he believed the "message of benefit/risk weighing for the doctor" concerning Zoloft use during pregnancy was communicated in both the Core Data Sheet and the Zoloft label. He agreed that the single sentence regarding contraception in the Core Data Sheet does not appear in the U.S. label, but he believed that the information and message in the Core Data Sheet was nonetheless communicated in the Zoloft label:

> I think the message in the United States prescribing information, again, it provides the full detail of the information about animal studies. And also, under information for patients, it does advise that patients should talk to their physicians if they do plan to become pregnant or they are pregnant. So that conversation, that risk/benefit conversation, needs to take place between the

> physician and the patient. And I think both documents in essence are communicating the same message.

Explaining further, Dr. Sadrarhami testified that the U.S. Zoloft label

> tells you about adverse events that occurred in animals and what those adverse events were. The clinical significance of the effects are not known. There are no adequate and well-controlled studies in pregnant women. Because animal production studies are not always predictive of human response, sertraline should be used during pregnancy only if perceived benefits outweigh risk. . . . [and]
>
> • • •
>
> [t]hat the physicians should weigh the benefits and the risks of the drug given the information that's given [in the label].

Dr. Sadrarhami also testified that the FDA has never requested that the U.S. Zoloft label contraindicate for use in pregnancy.

Martha Brumfield, Ph.D., another Pfizer witness, testified there was no internal Pfizer requirement that the language in its labels had to be the same globally, and "there can be other factors that impact why wording might be slightly different in different parts of the world" depending upon "medical practice or culture . . . [and] how health services work in various countries." Dr. Brumfield expressed her belief that Pfizer's policy for drug labels required consistency, not the same words; that the Core Data Sheet and U.S. label were consistent with each other; and that

> one needs to look at the totality of the information that's available for any given section of the label. And all of these labels communicated basically the core principles, that the drug had not been shown to be a teratogen. There were not adequate

> studies - - adequate and well-controlled studies in humans. Animal studies cannot always be completely predictive of what will happen in humans. And that, therefore, the benefit of use of the product need[s] to be taken into consideration against the potential risk to the fetus.

The foregoing deposition testimony shows that the petitioners cannot sustain their evidentiary burden with Pfizer's witnesses. Although the petitioners assert that we must draw "any permissible inference [from this testimony] . . . in the most favorable light to"[26] them, as the party opposing summary judgment, "'[p]ermissible inferences must still be within the range of reasonable probability[.]'" *Williams v. Precision Coil, Inc.*, 194 W.Va. 52, 60 n.10, 459 S.E.2d 329, 336 n.10 (1995) (quoting *Ford Motor Co. v. McDavid*, 259 F.2d 261, 266 (4th Cir. 1958)). As recounted above, and contradicting rather than supporting the petitioners' claim, these witnesses each testified that the U.S. Zoloft label adequately conveyed the essential information in the Core Data Sheet, including the benefit/risk assessment to be conducted by the prescribing physician and the patient for use during pregnancy.

Moreover, it is informative that when the petitioners were fighting to keep their critical and "key liability" expert, they already possessed what they now refer to as

[26] *Williams v. Precision Coil, Inc.*, 194 W.Va. 52, 59, 459 S.E.2d 329, 336 (1995).

"significant material evidence"[27] that would obviate the need for expert testimony. While there may be factual disputes concerning this material evidence, resolution of those disputes is unnecessary to the determination that the animal studies, adverse event reports, epidemiological studies, Core Data Sheets, and FDA regulations relied upon by the petitioners required expert testimony. As the petitioners previously represented, the advanced education, experience, and expertise of Dr. Urato, and later Dr. Kessler, were necessary for an intelligent consideration and analysis of this "significant material evidence" and the myriad of factors involved in the formulation of the Zoloft label. The petitioners' argument that they do not need their key liability expert but can sustain their failure to adequately warn claim with Pfizer witnesses is plainly untenable.

C. Requiring Expert Testimony to Meet Evidentiary Burden in Complex Matters Is Not Unfair

Lastly, the petitioners assert that establishing a low threshold for requiring expert testimony "threatens to close the courthouse doors to all types of claims, no matter how meritorious[,]" because retaining experts can be both time-consuming and costly. In response, Pfizer submits there is no unfairness in requiring the petitioners to meet their

[27]While the petitioners relied upon portions of certain reports before the Panel to support their position, they failed to note that the ultimate conclusion in those reports was that there is nothing that would lead to a finding that sertraline has an adverse effect on pregnancy. *See supra* note 17. Moreover, the adverse event reports, how they are evaluated, and when they warrant inclusion in a drug label are matters clearly beyond the experience and knowledge of the average juror.

burden of proof with expert testimony under the facts and circumstances of this particular case, and they were given every opportunity to do so.

As discussed above, this Court's precedent shows that whether expert testimony will be necessary is dependent upon the facts, claims, and issues involved in a given case. Where matters and issues are within the common knowledge and experience of the average juror, no expert testimony is necessary; however, when a claim involves highly complex matters of science, medicine, engineering, technology and the like, which are beyond the common knowledge and experience of the average juror, expert testimony will be necessary.[28] Importantly, requiring a party to meet his or her evidentiary burden with expert testimony–where necessary–ensures that a jury's verdict has a sound evidentiary basis and has been intelligently rendered.

IV. Conclusion

For the foregoing reasons, the Mass Litigation Panel's February 15, 2017, order granting summary judgment in favor of Pfizer is hereby affirmed.

Affirmed.

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[28]As indicated *supra*, there can be matters involving science, medicine, technology, and the like where expert testimony may be unnecessary. *See*, *e.g.*, *Ilosky*, 172 W.Va. at 437, 307 S.E.2d at 605, syl. pt. 9; *Roberts*, 149 W.Va. at 172-73, 139 S.E.2d at 276 (recognizing that negligence can "be established by lay witnesses in cases where negligence or want of professional skill is so obvious as to dispense with the need for expert testimony").