2019 PA Super 348

A.Y. AND B.A.Y.	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
v.	:	
JANSSEN PHARMACEUTICALS INC., JOHNSON & JOHNSON, JANSSEN RESEARCH & DEVELOPMENT, LLC; EXCERPTA MEDICA, INC., AND ELSEVIER INC.	:	No. 3058 EDA 2016
APPEAL OF: JANSSEN PHARMACEUTICALS INC., JOHNSON & JOHNSON, JANSSEN RESEARCH & DEVELOPMENT, LLC	:	

Appeal from the Judgment Entered September 8, 2016
In the Court of Common Pleas of Philadelphia County Civil Division at
No(s): April Term, 2013 No. 2094

A.Y. AND B.A.Y.	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
Appellant	:	
v.	:	
JANSSEN PHARMACEUTICALS INC., JOHNSON & JOHNSON, JANSSEN RESEARCH & DEVELOPMENT, LLC; EXCERPTA MEDICA, INC., AND ELSEVIER INC.	:	No. 3059 EDA 2016

Appeal from the Judgment Entered September 8, 2016
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No(s): April Term, 2013 No. 2094

BEFORE: PANELLA, P.J., KUNSELMAN, J., and STEVENS*, P.J.E.

OPINION BY STEVENS, P.J.E.: **FILED NOVEMBER 26, 2019**

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* Former Justice specially assigned to the Superior Court.

Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, and Johnson & Johnson Company (collectively, "Defendants/Appellants" or "Janssen") appeal from the judgment of $70 million entered on September 8, 2016, after a jury found in favor of A.Y. and his mother, B.A.Y. (collectively, "Plaintiffs/Appellees") and against Janssen in this pharmaceutical failure to warn case. In addition, Plaintiffs/Appellees have filed a cross-appeal from the June 10, 2016 order granting partial summary judgment in favor of Defendants/Appellants on Plaintiffs/Appellees' punitive damages claim.

On Defendants/Appellants' appeal, we affirm. On Plaintiffs/Appellees' cross-appeal, we reverse and remand for the trial court to consider conflict-of-law principles with respect to New Jersey and Appellees' home state of Tennessee in a manner consistent with this decision.

The trial court opinion aptly sets forth the record-based procedural history and relevant facts, as follows:

PROCEDURAL HISTORY

> On April 15, 2013, Plaintiffs A.Y. and [B.A.Y., "Mother,"] filed a Complaint against Defendants Janssen Pharmaceuticals Inc., Johnson & Johnson, Janssen Research & Development, LLC, Elsevier, Inc., and Excerpta Medica Inc. Appellees' Complaint alleged the following thirteen causes of action: (1) negligence, (2) negligent-design defect, (3) fraud, (4) strict product liability – failure to warn, (5) strict product liability – design defect, (6) breach of express warranty, (7) breach of implied warranty, (8) violation of Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 P.S. § 201-1 et seq., (9) unfair and deceptive trade practices, (10) conspiracy, (11) punitive damages, (12) medical expenses incurred by parent, and (13) loss of consortium.

By Order dated May 2, 2014, the Honorable Arnold L. New ruled that New Jersey Law applied to the issue of punitive damages and that New Jersey law barred the award of punitive damages. On June 2, 2014, Plaintiffs filed a Motion for Reconsideration of the Honorable Arnold New's May 2, 2014 Order barring the award of punitive damages. On June 9, 2014, Defendants filed an Answer to Plaintiff's Motion for Reconsideration. On July 18, 2014, Plaintiff's Motion for Reconsideration was denied.

On November 4, 2015, the Honorable Arnold New approved a stipulation dismissing the action as to Defendants Excerpta Medica, Inc., and Elsevier Inc. On April 14, 2016, remaining Defendants, Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC, filed a motion for summary judgment.

On May 5, 2016, Plaintiffs filed an Answer to Defendant's Motion for Summary Judgment. On May 11, 2016, Defendants filed a Reply.

On June 10, 2016, the Honorable Arnold New ruled that Tennessee Law applies to Plaintiffs' substantive claims [because Plaintiffs live in Tennessee and allege causes of action arising in Tennessee]. Plaintiffs' claims for: negligence, negligent design defect, strict liability—failure to warn, strict liability—design defect, breach of express warranty, breach of implied warranty [were deemed] subsumed into two claims: (a) Product Liability action because Risperdal was defective and (b) Product Liability action because Risperdal was unreasonably dangerous.[]

The Honorable Arnold New further ruled that Defendants' Summary Judgment [motion] was granted as to the following causes of action: (A) product liability action because Risperdal was defective, (B) fraud, (C) Pennsylvania's Unfair Trade Practices and Consumer Protection Law, (D) unfair and deceptive trade practices (under the Tennessee Consumer Protection Act), (E) conspiracy, and (F) loss of consortium. Defendant's Motion for Summary Judgment was denied as to all other causes of action.

On June 16, 2016, a jury trial commenced in this matter; the Honorable Paula A. Patrick presided. On July 1, 2016, the jury returned a verdict in favor of the Plaintiffs. The jury found that Defendants negligently failed to adequately warn Plaintiffs of the risk of gynecomastia associated with Risperdal™ use and

Defendants' negligence was a cause in bringing about A.Y.'s gynecomastia. The jury awarded Plaintiffs compensatory damages in the amount of $70,000,000.00 (seventy million dollars). On July 5, 2016, the jury's verdict was entered.

On July 8, 2016, Plaintiffs filed a Post-Trial Motion for Delay Damages. On August 10, 2016, Plaintiffs' Motion for Delay Damages was granted. Plaintiffs were awarded $6,661,027.40 in Delay Damages. The jury verdict of $70,000,000.00 was molded to add Delay Damages of $6,661.027.40 for a total verdict of $76,661,027.40. On September 7, 2016, judgment was entered in this matter.

On September 9, 2016, Defendants filed an Appeal to the Superior Court from decisions dated July 1, 2016, July 5, 2016, July 25, 2016, and August 10, 2016. On September 13, 2016, Plaintiffs filed a cross-appeal to the Superior Court from decisions dated May 2, 2014, July 18, 2014, and July 25, 2016. On September 22, 2016, Plaintiffs filed a Statement of Errors Complained of on Appeal pursuant to Pa.R.A.P. 1925(b). On October 12, 2016, Defendants filed a Statement of Errors Complained of on Appeal pursuant to Pa.R.A.P. 1925(b).

FACTUAL BACKGROUND

Risperdal (risperdone) is an antipsychotic medication belonging to a class of drugs which [has] become known as "atypical" or "second generation" ("SGA") antipsychotics. Risperdal was originally developed and approved for use in the treatment of symptoms associated with schizophrenia. The adverse effects associated with Risperdal are: rapid weight gain, hyperprolactinemia, gynecomastia (abnormal development of breasts in males), galactorrhea (lactation), pituitary tumors, microadenomas of the pituitary gland, breast cancer, osteoporosis, decreased bone mineral density, metabolic syndrome, dyslipidemia, hypertension, diabetes mellitus, diabetic ketoacidosis (DKA), hyperosmolar coma, hyperglycemia, glucose dysregulation, insulin insufficiency, insulin resistance, pancreatitis, tardive dyskinesia, extrapyramidal symptoms, involuntary movement disorders, dyskinesia, dystonia, akatisia, parkinsonism, neuroleptic malignant syndrome (NMS) and/or other related conditions. Risperdal is designed, developed, tested, labeled, packaged, distributed, marketed, and sold throughout the United States by the Janssen Defendants.

On December 29, 1993, Janssen obtained approval from the Food and Drug Administration ("FDA") to market Risperdal oral tablets for the treatment of "manifestations of psychotic disorders" (schizophrenia) in adults. In September 2000, the FDA requested that the label be changed to more clearly indicate that Risperdal was only approved for use in treating schizophrenia in adults. In October 2006, Risperdal was approved for the treatment of irritability associated with autistic disorder in children and adolescents (between the ages of 5 and 16), including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums and quickly changing moods. Risperdal has not been approved for children younger than 5 or those older than 16 years old for irritability associated with autistic disorder.

The prescribing of drugs "off-label" occurs when a drug is prescribed by a medical professional for use beyond those contained in the drug's FDA-approved uses. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or treating a different patient population. An example of off-label use is the treatment of a child with the drug when the drug is approved to treat adults.[]

Plaintiff A.Y. was born in 1999. [A.Y.] was diagnosed with Attention Deficit Hyperactivity Disorder (ADHD) and Oppositional Defiant Disorder (ODD). In August of 2003, when A.Y. was four and a half years old, he was prescribed Risperdal by Dr. Deniz Eker, a pediatric psychiatrist. Eker Dep. 2/8/16, at 31-32. At the time Dr. Eker prescribed Risperdal to A.Y., she did not warn A.Y.'s mother about the risk of gynecomastia. Dr. Eker stated that she would have warned A.Y.'s mother, but Dr. Eker did not know at the time that there was such a significant risk of gynecomastia from elevated prolactin. *Id.* at 56, 61.

In January 2004, four months after [A.Y.] began taking Risperdal, A.Y.'s mother went to Doctor Eker and expressed concern that A.Y's breasts were enlarging. *Id*. at 65. Dr. Eker then began tapering the Risperdal because she was concerned about gynecomastia. *Id*. at 66.

In February 2005, after the initial tapering, Dr. Eker noted that A.Y.'s breasts were getting big and that she was discontinuing Risperdal because A.Y. had gynecomastia. *Id*. Dr. Eker testified

that when she first noticed gynecomastia, she began tapering off from the Risperdal but would have stopped it immediately if she had been properly informed about the risk of gynecomastia from Risperdal. *Id*. Dr. Eker believed gynecomastia was much less frequent and that A.Y.'s development of female breasts (at five years old) was a rare occurrence. When Dr. Eker believed the gynecomastia had gone down, she put A.Y. back on Risperdal. *Id*. at 76-77.

Dr. Eker transferred A.Y.'s psychiatric care to Dr. Michael Hughes in the first half of 2005. *Id*. at 78. Dr. Hughes testified that the idea to put A.Y. on Risperdal originated with Dr. Eker, and he was simply continuing the treatment. *Id*. at 279-80.

Dr. Hughes could not say that he would have put A.Y. on Risperdal at all if Dr. Eker had not prescribed it first. *Id*. Dr. Hughes testified that if he had known that there was a statistically significant association between prolactin elevation from Risperdal use and gynecomastia this information would have had a significant impact in his thinking with regard to prescribing Risperdal. *Id*. at 266-267. Dr. Hughes stated that he would have pushed against Risperdal use if he had known of the additional significant concerns. *Id*. at 83-84. Dr. Hughes treated A.Y. from May 2005 through May 2011. *Id*. at 228-29. Dr. Hughes discontinued Risperdal at the request of A.Y.'s mother because A.Y. was gaining so much weight. *Id*. at 161-62.

Dr. Brian Bonfardin, a psychiatrist, began treating A.Y. in June 2011. *Id*. at 16. In June of 2012, A.Y. was struggling, and A.Y.'s mother suggested trying Risperdal again to Dr. Bonfardin. At that time, Dr. Bonfardin's prescription of Risperdal had already plummeted because he had learned prior to 2012 that Risperdal increased prolactin levels more than other antipsychotics. *Id*. at 48-49.

Dr. Bonfardin testified that he did not know of [Janssen's own clinical] studies showing a 5.5% and 12.5 % frequency of gynecomastia among children who used Risperdal. If he had such information, he would have warned A.Y.'s mother about this significant risk. Bonfardin Dep., 2/11/16, at 16.

A.Y.'s care was transferred to Dr. Gordon Greeson in October of 2012. Dr. Greeson took A.Y. off Risperdal once he took over care because A.Y. gained quite a bit of weight and had hypertension in

> the short period he had been put back on Risperdal. A.Y.'s mother requested he be put back on Risperdal [the] next month.
>
> In 2013, A.Y.'s mother saw an advertisement discussing gynecomastia from Risperdal use. A.Y. Mother Dep., 12/14/15, at 6-8. She got in contact with an attorney and then went to talk to A.Y.'s treating physicians about the problem. *Id*. Dr. Greeson learned of the gynecomastia from A.Y.'s mother in March 2013. Dr. Greeson immediately decided he needed to stop Risperdal because he feared making the problem worse.

Trial Court Opinion, 6/20/18, at 1-7.

Appellants raise the following questions for our consideration:

1. Were Defendants/Appellants entitled to JNOV because federal law preempts Plaintiffs'/Appellees state-law failure-to-warn claim?

2. Were Defendants/Appellants entitled to JNOV because Plaintiffs/Appellees failed to establish any inadequate warning was the proximate cause of A.Y.'s Risperdal use and gynecomastia?

3. Is a new trial required because the trial court erroneously excluded: (1) testimony of a treating doctor who continued to prescribe Risperdal for A.Y. at his mother's request and after she filed this lawsuit, which called into question whether a different warning would have changed the prescribing decision; and (2) testimony and evidence establishing A.Y.'s serious mental illness and the significant benefit of Risperdal therapy for him, which was relevant to the benefit/risk analysis made by A.Y.'s prescribers?

4. Is a new trial required because the trial court did not instruct the jury that under Tennessee's "learned intermediary" rule, the jury had to assess whether the warnings were adequate to warn A.Y.'s doctors, to whom Janssen owed a duty to warn?

5. Is a new trial or remittitur required because the trial court failed to apply Tennessee's $750,000.00 cap for non-economic damages?

6. Is a new trial or remittitur required because the jury's $70,000,000.00 compensatory-damages award was excessive?

Appellants' brief, at 6-7.

In their first two issues, Appellants contend they were entitled to judgment *non obstante veredicto* ("JNOV") because federal law preempts Plaintiffs/Appellees' state failure-to-warn claim that Tennessee law required Janssen to change labeling to reflect juvenile Risperdal users' heightened risk of gynecomastia. We set forth our standard of review from the denial of a motion for judgment n.o.v.:

> A motion for judgment n.o.v. is a post-trial motion which requests the court to enter judgment in favor of the moving party. There are two bases on which the court can grant judgment n.o.v.:
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> > [O]ne, the movant is entitled to judgment as a matter of law and/or two, the evidence is such that no two reasonable minds could disagree that the outcome should have been rendered in favor of the movant. With the first, the court reviews the record and concludes that even with all factual inferences decided adverse to the movant the law nonetheless requires a verdict in his favor, whereas with the second, the court reviews the evidentiary record and concludes that the evidence was such that a verdict for the movant was beyond peradventure.
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> ***Polett v. Public Communications, Inc.***, 83 A.3d 205, 212 (Pa.Super. 2013), ***reversed on other grounds***, 633 Pa. 445, 126 A.3d 895 (Pa. 2015). In an appeal from the trial court's decision to deny judgment n.o.v.,
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> > we must consider the evidence, together with all favorable inferences drawn therefrom, in a light most favorable to the verdict winner. Our standard of review when considering motions for a directed

> verdict and judgment notwithstanding the verdict are identical. We will reverse a trial court's grant or denial of a judgment notwithstanding the verdict only when we find an abuse of discretion or an error of law that controlled the outcome of the case. Further, the standard of review for an appellate court is the same as that for a trial court.

Id. at 211.

Drake Mfg. Co., Inc. v. Polyflow, Inc., 109 A.3d 250, 258–259 (Pa.Super. 2015).

> "Concerning any questions of law, our scope of review is plenary. Concerning questions of credibility and weight accorded the evidence at trial, we will not substitute our judgment for that of the finder of fact.... A JNOV should be entered only in a clear case." [***Advanced Telephone Systems, Inc. v. Com–Net Professional Mobile Radio, LLC***, 846 A.2d 1264, 1279 (Pa.Super. 2004), ***appeal denied***, 580 Pa. 687, 859 A.2d 767 (2004) (citation omitted)]. "[T]he entry of a judgment notwithstanding the verdict ... is a drastic remedy. A court cannot lightly ignore the findings of a duly selected jury." ***Education Resources Institute, Inc. v. Cole***, 827 A.2d 493, 497 (Pa.Super. 2003), ***appeal denied***, 577 Pa. 721, 847 A.2d 1286 (2004) (citation omitted).
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> ***Growall v. Maietta***, 931 A.2d 667, 670 (Pa.Super. 2007), ***appeal denied***, 597 Pa. 717, 951 A.2d 1164 (2008). Rule 702 of the Pennsylvania Rules of Evidence.

Stange v. Janssen Pharmaceuticals, Inc., 179 A.3d 45, 52-53 (Pa. Super. 2018).

"Federal 'preemption is an affirmative defense on which [the] defendant bears the burden of proof.'" ***Aaron v. Wyeth***, 2010 WL 653984, at *3 (W.D. Pa. Feb. 19, 2010) (quoting ***Cambridge Literary Props., Ltd. v. W. Goebel***

Porzellanfabrik G.m.b.H. & Co. KG., 510 F.3d 77, 102 (1st Cir. 2007), ***cert. denied***, 555 U.S. 815, 129 S.Ct. 58, 172 L.Ed.2d 25 (2008); citing ***Wyeth v. Levine***, 555 U.S. 555, ––––, 129 S.Ct. 1187, 1193, 173 L.Ed.2d 51 (2009) (characterizing a manufacturer's argument that federal drug law preempted the plaintiff's claims as a defense)) (hereinafter "***Wyeth***"). Our courts acknowledge a presumption against such a defense:

> We recognize a presumption against federal pre-emption of state law. ***Dooner v. DiDonato***, 601 Pa. 209, 971 A.2d 1187 (2009) (citing ***Altria Group, Inc. v. Good***, 555 U.S. 70, 129 S.Ct. 538, 172 L.Ed.2d 398 (2008)). In ***Kiak v. Crown Equipment Corp.***, 989 A.2d 385, 390 (Pa.Super. 2010), this Court attributed that presumption to the "dual jurisdiction" which "results from reasons of comity and mutual respect between the two judicial systems that form the framework of our democracy." ***Fetterman v. Green***, 455 Pa.Super. 639, 689 A.2d 289, 292 (1997); ***see also Cipollone v. Liggett Group, Inc.***, 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). As the United States Supreme Court noted in ***Altria Group, Inc.***, ***supra***: When addressing questions of express or implied preemption, we begin our analysis "with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." ***Rice v. Santa Fe Elevator Corp.***, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947). That assumption applies with particular force when Congress has legislated in a field traditionally occupied by the States. [***Medtronic Inc. v.***] ***Lohr***, 518 U.S. at 485, 116 S.Ct. 2240, 135 L.Ed.2d 700; ***see also*** [***Lorillard Tobacco Co. v.***] ***Reilly***, 533 U.S. at 541–542, 121 S.Ct. 2404, 150 L.Ed.2d 532 [(2001)] ("Because 'federal law is said to bar state action in a field of traditional state regulation,' namely, advertising, we 'work on the assumption that the historic police powers of the States are not to be superseded by the Federal Act unless that is the clear and manifest purpose of Congress'" (citation omitted)). Thus, when the text of a pre-emption clause is susceptible of more than one plausible reading, courts ordinarily "accept the reading that disfavors pre-emption." ***Bates v. Dow Agrosciences LLC***, 544

> U.S. 431, 449, 125 S.Ct. 1788, 161 L.Ed.2d 687 (2005). ***Altria Group, Inc.***, 555 U.S. at 77, 129 S.Ct. 538.

Hassett v. Dafoe, 74 A.3d 202, 210 (Pa.Super. 2013). ***Accord***, ***Lake v. Memphis Landsmen***, LLC, 405 S.W.3d 47, 56 (Tenn. 2013)

In their preemption argument, Appellants insist Janssen's labeling at all relevant times was adequate as a matter of Tennessee law. Nevertheless, they posit that even if Tennessee law required Janssen to change labeling as Appellees propose, the federal law doctrine of "impossibility preemption" applies to Plaintiffs/Appellees' state-law negligent failure-to-warn claim, because it was "impossible for Janssen simultaneously to comply with its federal and state-law obligations" regarding Risperdal labeling of pediatric gynecomastia risks. ***See*** Appellants' brief, at 27 (quoting ***Strayhorn v. Wyeth Pharm., Inc.***, 887 F.Supp. 2d 799, 809-10 (W.D. Tenn. 2012) ("Impossibility preemption is a type of implied conflict preemption which occurs when 'state and federal law conflict [and] it is impossible for a private party to comply with both state and federal requirements.'"), ***aff'd***, 737 F.3d 378 (6th Cir. 2013) (quoting ***PLIVA, Inc. v. Messing***, 564 U.S. 604, 618 (2011)).

We have previously discussed controlling decisional law characterizing impossibility pre-emption as "a demanding defense." ***Hasset***, 74 A.3d at 210 (quoting ***Wyeth***, 129 S.Ct. at 1199). Similarly, Tennessee has observed:

> The United States Supreme Court has identified two fundamental principles that must guide any preemption analysis. First, no matter what type of preemption is at issue, "the purpose of

> Congress is the ultimate touchstone." ***Wyeth***, 555 U.S. 555, 565, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009) (quoting ***Medtronic, Inc. v. Lohr***, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996)). Second, in conducting any preemption inquiry, courts must "start with the assumption that the historic police powers of the States were not to be superseded by [federal law] unless that was the clear and manifest purpose of Congress"—particularly when the federal law in question pertains to "a field which the States have traditionally occupied." ***Id***. (quoting ***Medtronic***, 518 U.S. at 485, 116 S.Ct. 2240) (internal quotation marks omitted); ***see also Leggett***, 308 S.W.3d at 854; ***Morgan v. Ford Motor Co.***, 224 W.Va. 62, 680 S.E.2d 77, 83 (2009) ("Preemption of topics traditionally regulated by states—like health and safety—is greatly disfavored in the absence of convincing evidence that Congress intended for a federal law to displace a state law.").

Lake, 405 S.W.3d at 56.

In ***Wyeth***, the United States Supreme Court held that impossibility preemption did not apply to state claims based on a failure to warn of the risk of gangrene from Phenergan delivered by an IV-push method, where it was within the power of the defendant manufacturer, Wyeth, to comply with both state and federal law by unilaterally strengthening the label's warning. In so holding, the Court explained that the Federal Food, Drug and Cosmetic Act ["Act"] is premised upon the expectation that manufacturers are primarily responsible for drug safety through proper labeling. The presumption follows, the Court continued, that compliance with both state and federal labeling requirements is possible unless there exists clear evidence that the FDA would block a proposed change to the label.

With regard to ***Wyeth***, it has been observed:

> In holding that the FDA's approval of Wyeth's label did not provide a complete defense to the plaintiff's failure to warn claim under a federal preemption theory, the ***Wyeth*** Court emphasized that it

was Congress' intent that state law act as a "complimentary form of drug regulation" because "manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." ***Wyeth*** at 1202. The Court further emphasized:

> State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the [Federal Food, Drug and Cosmetic Act's] premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.

Id.

Moreover, the Court found no Congressional intent to vest the FDA with the sole authority to ensure drug safety and effectiveness, as would result from the preemption of state tort actions. ***Id***. at 1200. ***Wyeth***, however, does not render state law failure-to-warn claims immune to preemption in every case. The Supreme Court recognized that "some state-law claims might well frustrate the achievement of congressional objectives" in the federal regulation of drug labeling. ***Wyeth***, 129 S.Ct. at 1204. To prevail here, Wyeth "faces an exacting burden to establish preemption of state law claims because compliance with both state and federal requirements for drug labeling is not impossible 'absent clear evidence that the FDA would not have approved a change' in the drug's labeling." ***Forst v. Smithkline Beecham Corp.***, 639 F.Supp.2d 948, 953–954 (E.D.Wis.2009) (quoting ***Wyeth***, 129 S.Ct. at 1198).

Aaron, 2010 WL 653984, at *5.

According to Appellants, however, federal law set forth in the Act at 21 C.F.R. §§ 201.57(e) and 312.32 provides that only the Food and Drug Administration ("FDA") may require a warning concerning a risk of an off-label

or non-approved use, and even then only in the case of a "serious" risk, namely, one that threatens life or normal life functions, or requires hospitalization. Appellants acknowledge the regulations provide an exception to this general restriction, the "changes being effected," or "CBE" exception articulated at 21 C.F.R. §§ 314.70(c)(6)(iii)(A), but they maintain the facts do not bring the present case within the bounds of the exception.

Specifically, the CBE exception permits a manufacturer to change labeling without prior FDA approval only if (1) the manufacturer had newly acquired information about the drug (2) that showed a causal association (3) between the drug and an effect that warranted a new or stronger warning. 21 C.F.R. §§ 314.70(c)(6)(iii)(A). "[N]ewly acquired information is data, analyses, or other information not previously submitted to the [FDA that] reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3; ***see also Wyeth***, 129 S.Ct. 1197 (quoting 73 Fed.Reg. 49607).

Appellees argue that Janssen's extensive clinical studies culminating with data compiled in its "Table 21,"[1] discussed at length in the testimony of expert witness David Kessler, M.D., ***see*** *infra*, brought them within the

[1] Expert witness Dr. David Kessler, FDA commissioner from 1991-1997, testified that by the year 2000 or 2001, Janssen had collected data at Table 21 showing a statistically significant increase in both prolactin levels in children taking Risperdal for at least 8 to 12 weeks and in prolactin-related gynecomastia in children. Janssen, however, never shared this information. In his expert opinion, by the year 2000 or 2001, Janssen was marketing Risperdal for children and adolescents, and was, thus, obligated to share their studies at this time. N.T. 5/19/2015, at 88-127.

contours of the CBE regulations, as the studies supplied the manufacturer with newly acquired information showing a causal association between Risperdal and more frequent and severe gynecomastia in juvenile boys than had been observed in the adult male population.

Appellants, however, dispute that Janssen had the authority to change labeling to inform that: Risperdal is associated with higher prolactin levels than other antipsychotic medications; elevated prolactin "causes" gynecomastia in the pediatric population; and clinical studies show sufficiently higher rates of gynecomastia in the pediatric population to qualify the condition as "frequent" in that population, as differentiated from the "rare" occurrence reported in adults. This is so, they claim, because Risperdal was not approved for pediatric use—it was an "off-label" use—and only the FDA had the authority to warn about off-label uses.

Plaintiffs/Appellees assail Appellants' "off-label use" defense as also being inconsistent with governing statutory law as it existed at the time A.Y. began taking Risperdal. Specifically, Appellees accurately point out that 21 C.F.R. § 201.57(f)(9)(i), which pertained to "pediatric care," was in effect in 2003 and provided that any "specific hazard" associated with an unapproved pediatric use "shall be described in this subsection of the labeling. . . ." *Id*.

Appellants' position is out of step with controlling jurisprudence on drug manufacturers' responsibilities to act on their unique access to product information by adequately warning consumers of newly discovered heightened risks of injury associated with the drug. Indeed, as the United States Supreme

Court has recently reiterated, the CBE regulation contemplates that drug manufacturers bear ultimate responsibility to provide adequate descriptions of a drug's newly discovered risks to ensure consumer safety.[2] This was particularly so prior to 2007—the relevant period in the case *sub judice*—when the FDA lacked authority to order manufacturers to revise their labels:

> We also observed that "through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." ***Wyeth***, at 570–571, 129 S.Ct. 1187. A drug manufacturer "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." ***Id.***, at 571, 129 S.Ct. 1187. Thus, when the risks of a particular drug become apparent, the manufacturer has "a duty to provide a warning that adequately describe[s] that risk." ***Ibid.*** "Indeed," we noted, "prior to 2007, the FDA lacked the authority to order manufacturers to revise their labels." ***Ibid.*** And even when "Congress granted the FDA this authority," in the 2007 Amendments to the FDCA, Congress simultaneously "reaffirmed the manufacturer's obligations and referred specifically to the CBE regulation, which both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA approval." ***Ibid.***

Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1677, 203 L. Ed. 2d 822 (2019).

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[2] While the ***Wyeth*** Court acknowledged FDA regulations generally provide that a manufacturer may change a drug label only after FDA approval of a change application, as we note *supra*, it interpreted the misbranding provision of the regulations as proscribing not labels that enhance warnings but, instead, those that fail to include adequate warnings. Indeed, on this point, the High Court stated frankly, "And the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning . . . is difficult to accept." ***Wyeth***, 129 S.Ct. at 1197.

Moreover, the High Court emphasized that impossibility preemption under the relevant regulatory scheme requires the manufacturer to have fully disclosed the need for the additional warning, only to be met with FDA refusal:

> The underlying question for this type of impossibility pre-emption defense is whether federal law (including appropriate FDA actions) prohibited the drug manufacturer from adding any and all warnings to the drug label that would satisfy state law. And, of course, in order to succeed with that defense the manufacturer must show that the answer to this question is yes. But in ***Wyeth***, we confronted that question in the context of a particular set of circumstances. Accordingly, for purposes of this case, we assume—but do not decide—that, as was true of the warning at issue in ***Wyeth***, there is sufficient evidence to find that Merck violated state law by failing to add a warning about atypical femoral fractures to the Fosamax label. In a case like ***Wyeth***, showing that federal law prohibited the drug manufacturer from adding a warning that would satisfy state law requires the drug manufacturer to show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning.

Merck Sharp & Dohme Corp., 139 S. Ct. at 1678. In the present matter, Janssen did not make such a showing of full disclosure to the FDA during the relevant time.

The FDA surely possesses the authority under the statutory scheme to reject a revised label submitted by Janssen or any other manufacturer. This fact, alone, however, does not insulate a manufacturer from state failure to warn claims where the CBE scheme is available to enable compliance with state law:

> Of course, the FDA reviews CBE submissions and can reject label changes even after the manufacturer has made them. ***See*** §§ 314.70(c)(6), (7). And manufacturers cannot propose a change

> that is not based on reasonable evidence. § 314.70(c)(6)(iii)(A). But in the interim, the CBE regulation permits changes, so a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both.

Id., 139 S. Ct. at 1679.

As such, viewing Appellants' defense in light of the above authority, we disagree that the regulatory scheme would have "clearly" prevented it from warning about the statistically significant increase in frequency and severity of gynecomastia in boys taking Risperdal. In fact, we view Appellants' "misbranding avoidance" argument offered to justify Janssen's withholding of additional warnings to be of the type effectively rejected in ***Wyeth*** and its progeny. Because Appellants, therefore, have not carried their burden of proof applicable to their preemption defense, we find that federal drug labeling laws did not preempt Appellees' Tennessee tort law claim.

In Appellants' next issue, they contend JNOV was required because Plaintiffs/Appellees failed to establish that the lack of a gynecomastia warning specific to juvenile risk was the proximate cause of A.Y.'s harm.[3] According

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[3] Proximate causation was but one of two forms of causation—cause-in-fact being the other—Plaintiffs/Appellees bore the burden of establishing at trial. ***See*** *infra*. The Tennessee Supreme Court has explained the distinction between the two causations, as follows:

> The distinction between cause in fact and proximate, or legal, cause is not merely an exercise in semantics. The terms are not interchangeable. Although both cause in fact and proximate, or legal, cause are elements of negligence that the plaintiff must prove, they are very different concepts. Cause in fact refers to the cause and effect relationship between the defendant's tortious

to Appellants, even if the Risperdal warnings were inadequate—a supposition they deny—the evidence showed that the label Plaintiffs/Appellees' advocated at trial would not have prevented A.Y. from taking Risperdal and developing gynecomastia.

A.Y.'s physicians were aware of a potential risk of gynecomastia when they decided to prescribe Risperdal for A.Y., Appellants maintain, and his parents either continued with or returned to Risperdal despite having learned of its causative role in A.Y.'s gynecomastia diagnosis. Moreover, Appellant posits that a plaintiff cannot prove the causation element when he or she elects to continue a medication after raising a failure-to-warn claim. It is undisputed that A.Y. continued to take Risperdal after filing the present action.

> conduct and the plaintiff's injury or loss. Thus, cause in fact deals with the "but for" consequences of an act. The defendant's conduct is a cause of the event if the event would not have occurred but for that conduct. In contrast, proximate cause, or legal cause, concerns a determination of whether legal liability should be imposed where cause in fact has been established. Proximate or legal cause is a policy decision made by the legislature or the courts to deny liability for otherwise actionable conduct based on considerations of logic, common sense, policy, precedent and "our more or less inadequately expressed ideas of what justice demands or of what is administratively possible and convenient."

White v. Lawrence, 975 S.W.2d 525, 529 (Tenn. 1998) (quoting ***Snyder v. Ltg. Lufttechnische GmbH***, 955 S.W.2d 252, 256 n. 6 (Tenn.1997) (citations omitted)). Appellants, however, challenge only Appellees' proximate causation proffer at trial.

To establish proximate causation in a pharmaceutical failure-to-warn case, under Tennessee law, a plaintiff must show that "had additional warnings been given, the plaintiff[] would not have sustained [his] injuries.' ***King v. Danek Med., Inc.***, 37 S.W.3d 429, 453 (Tenn.Ct.App. 2000). Because the flow of information in this context, however, runs through the treating physician, the law applies a "learned intermediary" doctrine, whereby the plaintiff must show that the absent warning, if given, would have altered the prescribing physician's actions and, thereby, averted the patient's injury. The purpose of the learned intermediary doctrine is to ensure that makers of "unavoidably unsafe products" with a duty to give warnings may "reasonably rely on intermediaries [often physicians] to transmit their warnings and instructions." ***Pittman v. Upjohn Co.***, 890 S.W. 2d 425, 429 (Tenn. 1994).

With respect to a plaintiff's burden to prove causation under the learned intermediary doctrine, the Tennessee Court of Appeals has held:

> In order to recover for failure to warn under the learned intermediary doctrine, a plaintiff must show: (1) that the defendant failed to warn the physician of a risk associated with the use of the product not otherwise known to the physician; and (2) that the failure to warn the physician was both a cause in fact and proximate cause of the plaintiff's injury.

Harden v. Danek Med., Inc., 985 S.W.2d 449, 451 (Tenn. Ct. App. 1998).

Appellants' learned intermediary argument asserts that Appellees presented insufficient evidence that A.Y.'s treating physicians would have refrained from using Risperdal had Janssen issued a different warning. To

support this position, Appellants provide numerous citations to the record, albeit it without any accompanying explanation of the testimony involved.

Our review of this record, however, brings us in accord with the trial court and its determination that Appellant's physicians amply testified they would have chosen a different course of treatment had Janssen disclosed on the Risperdal label the significantly heightened risk of prolactin-related gynecomastia that existed for juvenile boys. To that end, we adopt the trial court opinion's salient discussion of how Dr. Eker's and Dr. Hughes' respective reliance on inadequate Risperdal information supplied by Janssen, coupled with their lack of independent knowledge about juvenile, prolactin-related gynecomastia, defeated Janssen's learned intermediary defense. Additionally, the extensive videotaped deposition testimony of Dr. Kessler regarding Janssen's breach of duty to inform physicians under the learned intermediary rubric also supports the trial court's conclusion on proximate causation. ***See*** N.T., 5/19/15, at 15-317; N.T.,5/20/15, at 333-656.

Nevertheless, we discuss briefly the testimony pertinent to the issue of proximate causation. To carry its evidentiary burden with respect to causation, Plaintiffs/Appellees presented the testimony of, *inter alia*, A.Y.'s treating physician, pediatric psychiatrist Dr. Deniz Eker, treating phyisican, pediatric psychiatrist Dr. Michael Hughes, M.D., and expert David Kessler, M.D., who, as mentioned *supra*, served as Commissioner of the FDA between 1990 and 1997.

Specifically, Dr. Eker testified that she first prescribed Risperdal to A.Y. in August of 2003 to treat A.Y.'s ADHD and oppositional defiant disorder. She maintained she did not warn A.Y.'s mother about the risk of gynecomastia at the time because she was unaware there was such a significant risk from elevated prolactin. Eker Dep. 2/8/16, at 56, 61. Though Dr. Eker could not remember whether she had consulted the Risperdal label thirteen years ago, she testified that she would have checked the Physician's Desk Reference (PDR), which relies in part on drug labeling, for potential side effects associated with Risperdal. ***Id***. at 100.

Had Dr. Eker known of the risk, she testified, she would have warned A.Y.'s mother. ***Id***. at 61. A.Y.'s parents confirmed Dr. Eker did not discuss gynecomastia with them, and they testified they never would have agreed to the use of Risperdal if they had known the true risk of gynecomastia. N.T., 6/29/16, at 238-40,317; N.T., 6/24/16, at 23-24, 48. Dr. Hughes, who assumed care of A.Y. starting in 2005, also expressed in his deposition testimony the importance of knowing the actual risk of juvenile gynecomastia stemming from hyperprolactinemia in his making his prescription decision. Hughes Dep. 3/10/16, at 66-69. Furthermore, both doctors denied having meaningful training or experience with, or independent knowledge of, gynecomastia. N.T., 2/8/16, at 126-28; N.T., 3/10/16, at 91, 122-24.

At the time Dr. Eker first prescribed Risperdal to A.Y., according to the testimony of Dr. Kessler, Janssen already knew that Risperdal posed an

increased risk of gynecomastia to juveniles. ***See*** fn. 1, *supra*. Yet, the Risperdal label failed to warn of this increased risk.

Specifically, Dr. Kessler testified in his video deposition that in August of 2003, the Risperdal label indicated the drug's effect on prolactin levels was consistent with other drugs in its class, that hyperprolactinemia had unknown clinical significance, and that gynecomastia was a "rare" occurrence associated with Risperdal use, occurring in fewer than 1 in 1000 patients, compared to a "frequent" occurrence, defined as more than 1 in 100 patients. Kessler Tr. Dep., 5/19/2015, at 13-29.

Yet, Dr. Kessler explained, Janssen knew of Risperdal's increased risk from eighteen clinical studies it had conducted through the 1990's and into the 2000's to overcome its prior failed efforts to obtain FDA approval to introduce pediatric dosing information on the label. Two of the studies of boys ranging from 5 to 18 years old, in particular, showed a frequent occurrence of gynecomastia. The first was a long-term clinical study in which patients underwent a 48-week observation while taking Risperdal. An interim analysis in 2000 showed a gynecomastia incidence rate of 3.7% (13 cases/266 boys). The 2002 final analysis for the clinical study revealed an incidence rate of 5.5% (23 cases/419 boys).

The second study represented a one-year extension of the first study, by recording the incidence of new and continuing gynecomastia in boys who had participated in the first study and continued to take Risperdal for a second

year. The study found an incident rate of gynecomastia at 12.5%. Dr. Kessler testified the rate was "frequent." *Id*. at 46-72.

By Janssen's own 2002 internal analysis of its studies, there was a statistically significant correlation between Risperdal and prolactin-related gynecomastia in children. Dr. Kessler testified Janssen was obligated to warn about the risks at this time by submitting the results of its studies to the FDA as an "important finding," but it did not do so. *Id*. at 143-77. Instead, in December 2003, Janssen sought FDA approval of Risperdal for pediatric use without submitting the new data on gynecomastia risk. When the FDA denied Janssen's application for safety concerns regarding prolactin elevation, Janssen responded, "A review of the safety information did not show a correlation between prolactin levels and adverse events that are potentially attributable to prolactin." Dr. Kessler characterized Janssen's response as misleading. *Id*. at 177-84.

Accordingly, we agree with the trial court that the record belies Appellant's "learned intermediary" defense that A.Y.'s physicians prescribed Risperdal with knowledge of the heightened pediatric gynecomastia risks associated with the drug. ***See Pittman***, ***supra*** at 29 (indicating that an adequate warning to learned intermediaries must convey, *inter alia*, a warning with the degree of intensity required by the nature of the risk). ***See also Proctor v. Davis***, 291 Ill.App.3d 265, 682 N.E.2d 1203, 1214. (Ill.App. 1997) (holding drug manufacturer Upjohn could not rely on prescribing physicians as "learned intermediaries" when their off-label use occurred without

knowledge of dangerous side effects and was promoted through misleading information at time Upjohn possessed undisclosed, adverse information about drug).

Here, evidence showed that the label not only failed to state with the correct degree of intensity the nature of the risk, it failed altogether to state the heightened risk that Janssen, through administration of its own clinical trials, knew applied to juvenile boys.

Appellants also posit, however, that Appellees were precluded from establishing proximate cause because A.Y.'s mother elected to continue with Risperdal even after knowing about the gynecomastia risk. Our review of Appellants' court-ordered Pa.R.A.P. 1925(b) statement, however, reveals that Appellants did not raise this issue sufficiently to preserve this alternate argument against Appellees' proximate causation proffer at trial.

Specifically, Appellants' statement does reference that A.Y.'s mother acknowledged Dr. Eker told her that breast enlargement was a possible side effect of Risperdal, and she still requested that A.Y. stay on Risperdal, even after filing the present lawsuit. *See* Appellants' Concise Statement of Matters Complained of on Appeal, Paragraph 5. However, this reference is contained within a larger passage focused exclusively on the treating physicians' independent knowledge of Risperdal's risks, and as such appears to be offered as part and parcel of the argument that Dr. Eker knew of Risperdal's risks and conveyed them to A.Y.'s mother.

Indeed, the sentence immediately following the reference to A.Y.'s mother brings the issue to its conclusion by stating, "Where, as here, the prescribing physicians testified that they understood the risks of a medication at the time they prescribed it to their patient, they conveyed that risk to the patient (here the patient's mother), and there is no evidence that either prescribing physician even read the product label, any alleged deficiency in the label could not be the proximate cause of A.Y.'s injury. Judgment as a matter of law therefore should have been granted." Pa.R.A.P. 1925(b) Statement, at Issue 5.

Despite having conducted an exhaustive review of Appellants' Concise Statement, the trial court did not perceive in Issue 5 the question of whether Plaintiffs/Appellees were precluded by law from meeting their their proximate causation burden once A.Y.'s mother decided to continue with Risperdal even after she filed suit against Janssen. This was due not to the trial court's oversight but, instead, to Appellants' vague-at-best drafting of Issue 5, which appears dedicated solely to the issue of the physicians' knowledge. It is well-settled that a vague Rule 1925(b) statement fails to preserve a purported issue contained therein. ***See M.G. v. L.D.***, 155 A.3d 1083, 1099 (Pa.Super. 2017) (citing ***Reinert v. Reinert***, 926 A.2d 539 (Pa.Super. 2007) (issue raised on appeal waived where Rule 1925(b) statement was too vague for trial court review)). Therefore, we conclude Appellants have waived their claim as presented in this context.

Nevertheless, Appellants have preserved what amounts to essentially the same issue in its next Question Presented, where they ask whether a new trial is required for what they view as the trial court's erroneous evidentiary ruling excluding the testimony of one of A.Y.'s treating physicians, Gordon Greeson, M.D., who prescribed Risperdal to A.Y. in 2012. According to Appellants, Dr. Greeson's testimony was "uniquely important to rebut Plaintiffs/Appellees' theory that [A.Y.'s mother] would have refused Risperdal treatment for A.Y. if she had known it could cause gynecomastia." Appellant's brief, at 41. In that respect, Appellants maintain, the testimony would have shown the failure to warn was not the proximate cause of A.Y.'s gynecomastia, for Mother would have continued with Risperdal even had it contained an accurate statement of risk. We disagree.

With respect to the grant or refusal to grant a new trial upon allegations of error in the admissibility of evidence we have stated:

> Decisions regarding the admissibility of evidence are within the discretion of the trial court and will be reversed on appeal only if the trial court abused its discretion or committed an error of law. ... We will grant a request for a new trial based upon a trial court's evidentiary rulings only if those rulings not only are erroneous, but also are harmful to the complaining party. ... Evidence is relevant if it logically tends to establish a material fact in the case, tends to make the fact at issue more or less probable, or supports a reasonable inference or presumption about the existence of a material fact.

Phatak v. United Chair Co., 756 A.2d 690, 691 (Pa.Super. 2000) (citation omitted).

Dr. Greeson provided deposition testimony that A.Y.'s mother asked to restart Risperdal in June 2012—more than nine years after A.Y. first developed gynecomastia and more than one year after A.Y. had discontinued the medication in large part because of the gynecomastia effect. By March 2013, Dr. Greeson recommended that A.Y. switch from Risperdal to another antipsychotic, but Mother declined to follow the doctor's advice, even though she indicated she was prompted to file the present lawsuit against the manufacturer of Risperdal by advertisements pertaining to Risperdal/juvenile gynecomastia causes of action. At this point, Dr. Greeson testified in his deposition that he believed there was "no doubt" Mother was aware of the risk of gynecomastia from Risperdal at the time she asked him to restart A.Y. on the medication.

Appellants argue, "The only rational inference from Dr. Greeson's testimony is that a risk of gynecomastia would not cause Mother to refuse Risperdal—because A.Y.'s actual gynecomastia did not cause her to do so." They posit the doctor's testimony would have contradicted Mother's testimony that she resumed Risperdal only because A.Y.'s gynecomastia would not have resolved even if she discontinued the medication permanently.

Dr. Greeson explained in his deposition that his advisement to Mother included his concern that resuming Risperdal could make A.Y.'s gynecomastia worse. Mother's willingness to continue Risperdal in the face of this warning was thus relevant to the proximate cause element to the failure to warn case at bar, Appellants conclude, for it shows Mother would likely have disregarded

any risk-of-gynecomastia warning to obtain the antipsychotic benefits of Risperdal.

The trial court responds that Dr. Greeson's testimony was irrelevant to Plaintiffs' failure to warn claim, as Mother's willingness to resume Risperdal in 2013, after A.Y. had developed irreversible gynecomastia over the previous 10 years, did not have the tendency to make it more or less likely that Janssen's failure to warn proximately caused Mother to agree to Risperdal therapy for her then four-and-one-half year-old son. ***See*** Pa.R.E., Rule 401 ("Relevant evidence" means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."); ***Hennessey v. Moyer***, No. 905 EDA 2019, 2019 WL 4862183, at *6 (Pa. Super. Ct. Oct. 2, 2019) ("Relevant evidence is admissible if its probative value outweighs its prejudicial impact."). ***Accord*** Tenn. R. Evid. 401 ("'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence."); Tenn. R. Evid. 402 ("Evidence which is not relevant is not admissible."). The court further notes that the jury heard other evidence pertaining to Mother's request to resume Risperdal despite obviously knowing that her son had likely developed gynecomastia because of the medication.

We agree with the trial court's assessment. The proximate cause inference Appellants seek to make is simply too attenuated given the

significant passage of time and change in circumstances from when A.Y. began Risperdal treatment in 2003 to when he came under the care of Dr. Greeson in 2012-2013. Contrary to Appellants' contention, the proposed testimony would not have shed light on Mother's state of mind at the outset of A.Y.'s treatment, nor would it have "contradicted" Mother's statement that she requested continuation of the medication because A.Y. already had severe, irreversible gynecomastia by 2013. Under our standard of review, we cannot conclude that the ruling in question was both erroneous and harmful to the Appellants. Accordingly, we view this claim as meritless.

Appellants next challenge the court's evidentiary ruling excluding specific act evidence of A.Y.'s "biting, hitting, smashing windows out with his fist, persistent fighting with other children, refusal to follow instructions at school or at home, and on one occasion breaking a chicken's back." Appellant's brief, at 44. Appellants also contest the court's ruling limiting the testimony of expert medical witness, child psychiatrist Nadine Schwartz, M.D., whom Appellants had offered to speak on the Risperdal risk/benefit analysis conducted by psychiatrists, on her opinions regarding whether A.Y.'s treatment records reflected any evidence of significant emotional distress from gynecomastia.

> "The admission of expert testimony is a matter of discretion [for] the trial court and will not be remanded, overruled or disturbed unless there was a clear abuse of discretion." ***Blicha v. Jacks***, 864 A.2d 1214, 1218 (Pa.Super.2004). Indeed, admission of the disputed testimony "must be shown to have been not only erroneous but also harmful.... Evidentiary rulings which did not

> affect the verdict will not provide a basis for disturbing the jury's judgment." ***Detterline v. D'Ambrosio's Dodge, Inc.***, 763 A.2d 935, 940 (Pa.Super. 2000) (quoting ***Ratti v. Wheeling Pittsburgh Steel Corp.***, 758 A.2d 695, 707 (Pa.Super.2000)).

Helpin v. Trustees of Univ. of Pennsylvania, 969 A.2d 601, 617 (Pa.Super. 2009), ***aff'd***, 10 A.3d 267 (Pa. 2010).

According to the trial court, it committed no error in its evidentiary rulings excluding specific act evidence, as it did not preclude Dr. Schwartz from "testifying about Risperdal generally, the patients for whom Risperdal is appropriate, and the analysis a prescriber engages in when determining whether to prescribe Risperdal, including consideration of the risks and benefits. As the transcript demonstrates, Dr. Schwartz testified regarding these matters and more at trial." Trial Court Opinion, at 59-61.

The transcript shows the court permitted Dr. Schwartz to testify not only generally about Risperdal use in child psychiatry but also specifically about the risk/benefit assessment relevant in A.Y.'s case given his medical and behavioral history. For example, Dr. Schwartz discussed how a psychiatrist would approach a risk/benefit analysis, and she applied the approach to examine A.Y.'s particular case. She explained he had been diagnosed with ADHD, oppositional defiant disorder, and mood disorder (either depressed or bipolar) at various points, and offered her opinion that A.Y. exhibited "very serious symptoms." She confirmed that the severity of the condition is the most essential piece to the risk/benefit analysis. *Id*.

Dr. Schwartz went on to discuss how Risperdal would have benefitted A.Y. given his diagnoses. She primarily emphasized the drug's mood

stabilization properties as a way of helping such a patient with aggressive, explosive, violent, or impulsive outbursts, which, she opined, can be very quick and severe. Dr. Schwartz was permitted to restate these behaviors and the drug's corresponding benefits several times without objection or interruption by either opposing counsel or the court. N.T. 6/24/16 at 21-26, 54-56.

The trial court concludes:

> The above-referenced testimony belies Defendants' claim that this court limited Dr. Schwartz to only discussing the general benefits of Risperdal. As the transcript demonstrates, Dr. Schwartz testified about Risperdal as a treatment for certain mood disorders, the patients for whom Risperdal is appropriate, and the factors to be considered when prescribing such a medication. Dr. Schwartz also discussed A.Y.'s medical conditions, the seriousness of his symptoms, and why the severity of the conditions is relevant to a psychiatrist's risk/benefit analysis.

Trial Court Opinion, at 62.

We agree with the trial court and discern no error with its evidentiary rulings precluding specific act evidence, as Appellants still informed the jury, through expert testimony, that A.Y. demonstrated "very serious symptoms" and that Risperdal for juveniles with his diagnoses has been shown to help with highly aggressive, impulsive, explosive, and violent outbursts. This expert proffer, therefore, fairly characterized A.Y.'s condition and enabled Appellants to frame its theory of the case that Mother faced a dilemma between risking a relapse in A.Y.'s very serious mood disorder from Risperdal cessation and exacerbating A.Y.'s gynecomastia from Risperdal continuation.

As such, we discern neither error with, nor prejudice stemming from, the court's ruling precluding testimony regarding A.Y.'s specific acts manifesting his mood disorder.

Similarly, we reach the same conclusion with respect to the trial court's ruling precluding Dr. Schwartz from inferring from the record whether Appellant exhibited any evidence of significant emotional distress from his gynecomastia. Dr. Schwartz never met or treated A.Y. and, therefore, had no first-hand knowledge of how his gynecomastia affected him emotionally, psychologically, or socially, leaving her to speculate from records about such matters.

Appellants cite to ***McClain v. Welker***, 761 A.2d 155, 156 (Pa.Super. 2000) as supporting its position, but ***McClain*** is inapposite, as it addressed whether the trial court erred when it refused to qualify Dr. Theodore Lidsky, a neuroscientist, as an expert on plaintiff children's cognitive defects from ingesting lead paint because he lacked a medical degree. In reversing and remanding, the panel ordered, "Accordingly, on remand, Dr. Lidsky should be permitted to render an expert opinion within the guise of Pa.R.E. 702 as to the causation of cognitive disorders." ***Id.*** at 158.

The expert in ***McClain***, therefore, was permitted to clarify how ingesting lead can cause the particular cognitive defects exhibited by the plaintiff children. Such a scientific subject was clearly within the neuroscientist's scope of expertise. Appellants, in contrast, failed to establish that Dr. Schwartz's scope of expertise included the ability to interpret another doctor's notes to

gauge a patient's level of emotional distress and humiliation from a disfiguring diagnosis.

Again, we find the court's evidentiary ruling neither erroneous nor harmful. Under the circumstances, and with other witnesses expressing direct impressions of A.Y.'s emotional distress, the court committed no error in deeming Dr. Schwartz's inferences on A.Y.'s emotions incompetent for admission at trial.

Appellants next assert several challenges to the trial court's jury instructions. Our review of these claims is governed by the following standard:

> Error in a charge is sufficient ground for a new trial if the charge as a whole is inadequate or not clear or has a tendency to mislead or confuse rather than clarify a material issue. Error will be found where the jury was probably misled by what the trial judge charged or where there was an omission in the charge. A charge will be found adequate unless the issues are not made clear to the jury or the jury was palpably misled by what the trial judge said or unless there is an omission in the charge which amounts to a fundamental error. In reviewing a trial court's charge to the jury, we must look to the charge in its entirety.

Tincher v. Omega Flex, Inc., 180 A.3d 386, 397-98 (Pa.Super. 2018) (cleaned up).[4]

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[4] We note the parallel standard of Tennessee:

> [T]his Court has held that "[w]hether a jury instruction is erroneous is a question of law and is[,] therefore[,] subject to *de novo* review with no presumption of correctness." ***Nye,*** 347 S.W.3d at 699 (citing ***Solomon v. First Am. Nat'l Bank of Nashville,*** 774 S.W.2d 935, 940 (Tenn.Ct.App.1989)). As

Appellants contend that this Court should remand for a new trial because the trial court declined to instruct the jury on a key aspect to Tennessee's Learned Intermediary Doctrine. Specifically, Janssen proposed the following instruction, which it argued would clarify for the jury that for prescription medications, unlike other consumer products, the "user" to whom the warnings are directed is the physician, not the patient:

> In this action, because the product involved is a prescription medication that can only be taken with the doctor's prescription, the expected users of Risperdal, for purposes of any warnings, are the physicians who prescribed Risperdal for [A.Y.], *not* [A.Y.] or his family. This is because a prescribing physician is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment. In order to prevail, Plaintiff's must prove that Janssen failed to warn [A.Y.]'s healthcare providers of the risk of gynecomastia *and* that his healthcare providers were not already aware of the risks. If the risk of gynecomastia was apparent to [A.Y.]'s physicians, Janssen was not negligent even if Janssen gave no warning about it.

Appellants' First Amended Proposed Points of Charge, Proposed Instruction No.21, 6/29/16 (emphasis in original).

> indicated, in determining whether a trial court has imparted "substantially accurate" jury instructions, we review the charge in its entirety and consider it as a whole; we will not invalidate instructions that "'fairly define[ ] the legal issues involved in the case and do[ ] not mislead the jury.'" ***Id.*** (quoting ***Otis,*** 850 S.W.2d at 446). Moreover, we may consider the jury instructions in conjunction with the verdict form in determining whether the issues were presented to the jury "in a clear and fair manner." ***Hickson Corp. v. Norfolk S. Ry.,*** 260 F.3d 559, 568 (6th Cir.2001).

Payne v. CSX Transportation, Inc., 467 S.W.3d 413, 448 (Tenn. 2015).

The trial court opted instead to rely on the Tennessee Pattern Instruction Civil 10.12 for its instruction. The instruction went as follows:

> Supplier's duty to warn. A supplier who knows or reasonably should know that a product is likely to be dangerous for its intended use or foreseeable misuse has a duty to use reasonable care to warn of the product's danger or to reveal its unsafe condition.
>
> Warnings should be given to those persons whom the supplier should reasonably expect to use or to handle the product or be endangered by its use or handling if the supplier reasonably should believe those persons would not realize the danger without the warnings. The failure to fulfill this duty is negligence.

N.T. 6/30/16, at 171.

Furthermore, the court directs us to the questions it presented to the jury on the verdict sheet, which the court also read to the jury before deliberation. According to the court, this reading instructed the jury specifically that the manufacturer's warning was required to be directed to A.Y.'s healthcare providers:

> Now, as you deliberate, you will receive the verdict sheet. I'll read it to you. There are four questions you must answer. The first question: Was Janssen negligent by failing to provide an adequate warning to [A.Y.'s] healthcare providers about the risk of gynecomastia from taking Risperdal? There's a line to check yes, a line to check no. If you answer yes to Question 1, please proceed to Question 2. If you answer no to Question 1, plaintiff cannot recover. Do not answer any further questions and return to this Courtroom.

N.T. 6/30/16, at 182.

The trial court opines that the explanation provided on the verdict sheet, coupled with the jury instruction regarding Defendants/Appellants' duty to

warn, accurately reflected the law applicable to the present case. Appellants disagree, as they claim the court's instruction and reading of the jury sheet simply gave the jurors "contradictory" charges that could only have misled or confused them.

We disagree with Appellants' position. Viewing the court's charge as a whole, we view no key omission, fundamental error, or inherent conflict, as the jury was sufficiently apprised of a manufacturer's duty to direct its warning to healthcare providers, consistent with the learned intermediary doctrine. Therefore, Appellant is due no relief on this claim.

Next, Appellants posit that the trial court committed reversible error when it failed to apply appropriately the Tennessee Civil Justice Act Damages Cap of 2011, which imposes a limit on non-economic damages in the amount of $750,000 per plaintiff. Tenn. Code Ann. § 29-39-102(a)(2), "Civil Actions; awards" (2018).

It is undisputed that the cap applies to the present case, but Plaintiffs/Appellees argued that the facts brought this case under a statutory exception to the cap. The exception provides:

> (h) The limitation on the amount of noneconomic damages imposed by subdivision (a)(2) and subsections (b)-(e) shall not apply to personal injury and wrongful death actions:
>
> …
>
> (2) If the defendant intentionally falsified, destroyed or concealed records containing material evidence with the purpose of wrongfully evading liability in the case at issue; provided, however, that this subsection (h) does not apply to the good faith

> withholding of records pursuant to privileges and other laws applicable to discovery, nor does it apply to the management of records in the normal course of business or in compliance with the defendant's document retention policy or state or federal regulations.

Tenn. Code. Ann. § 29-39-102(h)(2).

Appellants maintain, without reference to either rules of statutory interpretation or pertinent authority, that the statute targets only spoliation of evidence during discovery, and there was no spoliation "in the case at issue."

They note Plaintiffs/Appellees did not allege that Janssen engaged in falsifying, destroying, or concealing records during the course of discovery in this case. Because, they reiterate, the statute in question is aimed at discovery conduct within a given case and not at alleged pre-litigation manipulation or concealment of documents from non-party actors, even if the documents may one day become evidence in a potential future litigation, the exception does not apply to the present matter.

The trial court found no merit to Defendants/Appellants' argument at trial, where Appellants invoked the statute when Plaintiffs/Appellees requested the following instruction:

> You must determine whether the Defendants intentionally falsified, destroyed, or concealed records pertaining to this case[.]
>
> For you to find that Defendants intentionally falsified, destroyed, or concealed records pertaining to this case, the Plaintiff must prove by a preponderance of the evidence the following elements:

1. That Defendants intentionally falsified, destroyed or concealed Defendants' records to wrongfully evade liability in the case at issue; and

2. That Defendants' records contained material evidence pertaining to this case.

See Plaintiffs' Amended Proposed Points for Charge, 6/29/16.

Specifically, Plaintiffs/Appellees provided the following argument in support of its proposed points of charge:

> [**Plaintiffs' Counsel**]: Your Honor, let me give you globally what's going on. This case is going to be decided under Tennessee law, and I don't profess to be a total expert on Tennessee law. But the defendants are going to raise an issue, if there's a jury verdict and if it exceeds, I believe, $750,000, they will try to claim that there's some sort of damage cap in Tennessee. [Counsel then explains there is an exception in cases of concealment of evidence.] So what you see here is the instruction about what that means, and then later on in the verdict form we propose a question on it.
>
> So the two issues of concealment, there's two things they did. One is they locked up Table 21 from 2002 until 2015. That's a big part of our case. And then you also have the Bilker issue [referring to person Janssen allegedly hired to provide an alternate interpretation of the clinical studies discussed, supra]. So there's two issues of concealment because, even though they gave Table 21 to the FDA in October 2015, our claim goes to 2003. So we think this comes in, and we think you need this instruction so that we can get a jury finding on this issue in case, you know, we're fortunate enough.

N.T., 6/30/16, at 9-10.

Appellants countered:

> [**Defendants' Counsel**]: No, but it has to do – falsified, destroyed, or concealed to wrongfully evade liability in the case at issue. Your Honor, obviously we haven't had briefing on this, but I think it's clear from the statute and from the instruction itself

> that this is about concealing evidence in this litigation. It's not about whether you should or shouldn't have given facts to other people outside litigation. This is just extremely prejudicial, and it's not appropriate to this case. And to be suggesting to this jury that we destroyed evidence and kept it out of litigation just is irretrievably prejudicial to the defendants.

N.T., 6/30/16, at 12-13.

The trial court explains it rejected Defendants/Appellants' argument and, therefore, read Plaintiffs/Appellees' proposed charge to the jury, because ample evidence demonstrated that Appellants intentionally falsified and concealed records in this case:

> "To reiterate, Plaintiffs presented evidence that Defendants concealed Table 21, an internal Janssen document, that demonstrated a statistically significant link between Risperdal and gynecomastia. Instead of submitting this information to the FDA during the approval process, Defendants withheld and concealed the results for more than a decade. In addition, Plaintiffs presented evidence that Defendants hired Dr. Warren Bilker, a biostatistician, to perform a reanalysis of Table 21. The only specifics given to Dr. Bilker, who was under the control and direction of Dr. Findling and Dr. Daneman, were to refute the results in Table 21. N.T., 6/27/16, at 179. According to Plaintiffs, Dr. Bilker intentionally manipulated and retested the data multiple ways to get the results Defendants wanted. Once Dr. Bilker was able to refute the results in Table 21, the reanalysis was submitted as a letter by Dr. Daneman and Dr. Findling to The Journal of Clinical Psychiatry and published. These results, according to Plaintiffs, were inaccurate, inadequate, and misleading.

Trial Court Opinion, at 85.

We agree that such intentional conduct, if proven, was fairly contemplated within the exception set forth in subsection (h) of the statute in question. A reasonable inference arises from the record that Appellants persisted in its alleged concealment of the clinical study results recorded in

Table 21 not only with an eye toward future litigation in general but also to frustrate existing lawsuits such as Plaintiffs/Appellees'. This alleged conduct was compounded by Appellants' manipulation of the data collected in Table 21 and publication of the altered results during the relevant time.

The court, therefore, properly informed the jury that it was to decide a question of fact whether Plaintiffs proved its allegations of such conduct occurring after the present lawsuit had commenced, and that if it decided in the affirmative then the damages cap no longer applied. As Appellants develop no persuasive argument to upset the court's considered interpretation of the statute, we decline to find error with the instruction at issue.

Relatedly, Appellants claim the court committed reversible error when it gave an allegedly incomplete special interrogatory on what Appellants call the spoliation issue. Specifically, the verdict form read:

> Did Janssen intentionally falsify, destroy, or conceal records containing material evidence in this case?

Trial Work Sheet/Verdict Sheet, 7/5/16.

According to Appellants, the omission of the clause, "with the purpose of wrongfully evading liability in the case at issue," deprived the jury of clear guidance on how to make the proper finding required under the law, and, therefore, prejudiced Appellants in the process. Our review of the record, however, reveals that the court provided the following jury instruction just minutes earlier:

> **Trial Court**: Intentional falsification, destruction, or concealment. You must determine whether the defendants intentionally falsified, destroyed, or concealed records pertaining to this case. For you to find the defendants intentionally falsified, destroyed, or concealed records pertaining to this case, the plaintiffs must prove, by a preponderance of the evidence, the following elements: Number one, that the defendants intentionally falsified, destroyed, or concealed defendant's records *to wrongfully evade liability in this case at issue*. . . .

N.T., 6/30/16, at 173. (emphasis in original).

Contrary to Appellants' contention, the court instructed the jury that it was required to consider whether Defendants/Appellants had acted in such a way to wrongfully evade liability in this case. As the record belies Appellants' assertion, we find it without merit.[5]

In Appellants' final issue, they contend the trial court should have granted a new trial or remitted what they perceive as an excessive damages award. We disagree.

Under Tennessee law, a trial court "may set aside a jury's verdict and order a new trial when justice so requires." ***Palanki v. Vanderbilt Univ.***, 215 S.W.3d 380, 386 (Tenn.Ct.App. 2006). The role of the trial judge in this regard is well-settled:

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[5] Also germane to this issue is the well-settled legal precept that failure to object to a flawed jury verdict prior to a jury's dismissal precludes a challenge to the verdict in post-trial motions. ***See Stapas v. Giant Eagle, Inc.***, 198 A.3d 1033, 1041 (Pa. 2018) (holding that where both parties to litigation approved verdict sheet and did not object to verdict before jury dismissed, post-trial objections to verdict were waived); Pa.R.C.P. 227.1(b)(1) ("post-trial relief may not be granted unless the grounds therefore, (1) if then available, were raised in pre-trial proceedings or by motion, objection ... or other appropriate method at trial.").

> Although the amount of an award is primarily a consideration for the jury to determine, the trial court may suggest a remittitur when the amount of the verdict is excessive, beyond the range of reasonableness, or is excessive as the result of passion, prejudice, or caprice. ***Poole v. Kroger Co.,*** 604 S.W.2d 52, 54 (Tenn. 1980). However, there is no precise mathematical formula which the court can use to assure that judgments in negligence cases are uniform. ***S. Ry. Co. v. Sloan,*** 56 Tenn.App. 380, 407 S.W.2d 205, 211 (1965). Said the Court:
>
> > There is no exact yardstick, or measurement, which this court may use as a guide to determine the size of verdicts which should be permitted to stand in cases of this kind. Each case must depend upon its own facts and the test to be applied by us is not what the amount the members of the court would have awarded had they been on the jury, or what they, as an appellate court, think should have been awarded, but whether the verdict is patently excessive. The amount of damages awarded in similar cases is persuasive but not conclusive, and, in evaluating the award in other cases, we should note the date of the award, and take into consideration inflation and the reduced value of the individual dollar.
>
> ***S. Ry. Co.,*** 407 S.W.2d at 211.

Palanki, 215 S.W.3d at 386.

> Pennsylvania is largely in accord:
>
> The assessment of damages is peculiarly within the province of the factfinder and an award will not be upset on appeal unless it is so excessive as to shock the conscience of the court or it is clearly based on partiality, prejudice or passion. ***De Simone v. City of Philadelphia***, 380 Pa. 137, 110 A.2d 431 (1955). Generally, under Pennsylvania law, damages need not be proved with mathematical certainty, but only with reasonable certainty, and evidence of damages may consist of probabilities and inferences. ***See, e.g.***, ***Morin v. Brassington***, 871 A.2d 844, 852 (Pa. Super. 2005), ***quoting J.W.S. Delavau Inc. v. Eastern America Transp. & Warehousing, Inc.***, 810 A.2d 672, 685 (Pa. Super. 2002); ***James Corp. v. N. Allegheny Sch. Dist.*** 938 A.2d 474, 494 (Pa. Cmwlth. 2007); ***E.C. Ernst, Inc. v. Koppers Co.,***

> *Inc.*, 626 F.2d 324, 327 (3d Cir. 1980). Where the amount of damages can be fairly estimated from the evidence, the recovery will be sustained even though such amount cannot be determined with entire accuracy. ***Mass. Bonding & Ins. Co. v. Johnston & Harder***, 343 Pa. 270, 22 A.2d 709, 713–14 (1941). We review a trial court's decision whether to grant a new trial based on alleged excessiveness or inadequacy of the verdict for an abuse of discretion. ***Botek v. Mine Safety Appliance Corp.***, 531 Pa. 160, 611 A.2d 1174, 1176 (1992). Judicial reduction of a jury award is appropriate only when the award is plainly excessive and exorbitant. ***Haines v. Raven Arms***, 536 Pa. 452, 640 A.2d 367, 369 (1994).
>
> The refusal of a remittitur is peculiarly within the discretion of the trial court and will not be reversed absent an abuse of discretion or error of law. ***Id.***, ***citing Scaife Co. v. Rockwell–Standard Corp.***, 446 Pa. 280, 285 A.2d 451, 456–57 (1971).

Bailets v. Pennsylvania Tpk. Comm'n, 181 A.3d 324, 336 (Pa. 2018).

Appellants contend that such precepts should guide this Court to find that the verdict in the present case is so excessive relative to the harm suffered that a remittitur would effectively "destroy the jury's verdict," thus necessitating a retrial. ***See Guess v. Maury***, 726 S.W.2d 906, 912 (Tenn.Ct.App. 1986).

Appellants note that, under Tennessee law, "[w]hen asked to determine whether a verdict should be set aside based on the amount of the damages award alone, the courts must consider the nature and extent of the plaintiff's injuries, the pain and suffering the plaintiff experienced, the expenses the plaintiff incurred as a result of the injuries, the impact the injuries have had on the plaintiff's enjoyment of life, and the plaintiff's age and life expectancy." ***Duran v. Hyundai Motor America, Inc.***, 271 S.W.3d 178, 212 (Tenn.Ct.App. 2018).

"Gynecomastia[,]" Appellants submit, "is not a life-threatening condition, and Plaintiffs presented no evidence of physical pain and suffering." Appellants' brief, at 54. While surgical correction of gynecomastia is possible, Plaintiffs/Appellees did not choose to pursue this option. Appellants further stress that Plaintiffs/Appellees similarly presented no evidence of economic damages, hospital bills, and did not argue that gynecomastia would affect A.Y.'s future earnings. *Id*.

Thus essentially limited to psychological and emotional, non-economic damages, Appellants continue, Plaintiffs/Appellees' award of $70,000,000 was grossly disproportionate to the evidence. Appellants maintain the extent of such evidence was that A.Y. was bullied at school and work, teased, and never went outside without a shirt. They conclude such a proffer simply did not support a compensatory damages award nearly 30 times larger than the next largest compensatory verdict in Philadelphia, $2,500,000 in ***Pledger v. Janssen Pharmaceuticals***, ***Inc.***, 198 A.3d 1126 (Pa.Super. 2018).

The trial court opines that the verdict was not excessive, as the jury was free to infer from the evidence that A.Y.'s pain and suffering, embarrassment, loss of enjoyment of life, and the inability to engage in normal activities in the future was considerable. In that vein, the court notes that the jury was charged to consider both economic and non-economic damages, and Tennessee law holds that a "jury has wide latitude in assessing non-economic damages." ***Meals ex rel. Meals***, 417 S.W.3d at 425.

Indeed, the court notes, the jury charge instructed the jury that "no definite standard or method of calculation is prescribed by law by which to fix reasonable compensation for pain and suffering, permanent injury, disfigurement, and the loss of enjoyment of life, nor is the opinion of any witness required as to the amount of such reasonable compensation." Trial Court Opinion, at 92 (quoting N.T. 6/30/16, at 175-76). Because the courts have recognized that such damages are not easily quantified and do not lend themselves to easy valuation, the amount of these damages is appropriately left to the sound discretion of the jury. ***Id***. (quoting ***Duran***, 271 S.W.3d at 210-211).

We discern no reversible error with the jury's award of damages, as we do not view it as inconsistent with the evidence. A.Y. was just 4 ½ years old when first prescribed Risperdal, and he has never since known life without gynecomastia. At sixteen years of age when the jury considered its award, A.Y. was living with severe and permanent disfigurement. The undisputed record confirms he has been routinely bullied and teased by peers and is too humiliated to ever remove his shirt in recreational or social situations where it would be customary for boys to do so when enjoying ordinary pleasures of youth.

The jurors were free to call upon their personal experiences and sensibilities to assess such intangible harms, and their valuation could reflect the length of time A.Y. would reasonably be expected to live with this

disfiguring, embarrassing condition. Under such facts, the jury exercised sound discretion. Accordingly, we will not disturb the damages award.

APPELLEES' CROSS-APPEAL

In Appellees' cross-appeal, they contend the trial court erred by granting Janssen's motion for partial summary judgment on Appellees' claim for punitive damages. In entering its global order granting summary judgment as to all plaintiffs in the Risperdal litigation, the trial court determined that New Jersey had a greater interest than Pennsylvania in the application of its law on the issue of punitive damages, and the New Jersey Products Liability Act does not permit Plaintiffs to recover punitive damages.

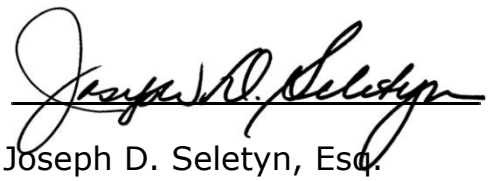
This Court has subsequently considered the trial court's two determinations in ***Murray v. Janssen Pharmaceuticals, Inc.***, 180 A.3d 1235 (Pa.Super. 2018), ***Stange***, 179 A.3d at 49-50, and ***Pledger***, 198 A.3d 1126 and held in each that we were required to remand for the trial court to consider conflict-of-law principles with respect to New Jersey and the respective plaintiff's home state, which it had not done. ***See Stange***, 179 A.3d at 66-67 (remanding for consideration of conflict between Wisconsin and New Jersey); ***Murray*** (180 A.3d at 1248-49 (remanding for consideration of conflict between Maryland and New Jersey); ***Pledger***, 198 A.3d at 1148 (remanding for consideration of conflict between Alabama and New Jersey).

Here, Appellees present the same arguments made by the plaintiffs in the aforementioned cases, and both parties agree the decisions by our Court remain binding precedent. ***See Marks v. Nationwide Ins. Co***, 762 A.2d

1098, 1101 (Pa.Super. 2000) (acknowledging as long as a decision by this Court has not been overturned by our Supreme Court, it remains binding precedent). Thus, as we have done previously, we reverse the order of the trial court granting partial summary judgment in favor of Janssen and remand for proceedings consistent with those in ***Stange***, ***Murray***, and ***Pledger***.

Judgment affirmed in part, reversed in part, and remanded for proceedings wherein the trial court shall consider conflict of law principles with respect to Tennessee and New Jersey and how they bear on Plaintiffs/Appellees' punitive damages claim. Jurisdiction relinquished.

Judgment Entered.



Joseph D. Seletyn, Esq.
Prothonotary

Date: 11/26/19