2018 PA Super 4

TIMOTHY STANGE	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
v.	:	
	:	
JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; JANSSEN RESEARCH & DEVELOPMENT, LLC; EXCERPTA MEDICA INCORPORATED AND ELSEVIER, INC.	:	
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APPEAL OF: JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; JANSSEN RESEARCH & DEVELOPMENT, LLC,	:	No. 739 EDA 2016

Appeal from the Judgment Entered February 10, 2016,
in the Court of Common Pleas of Philadelphia County
Civil Division at No. April Term 2013 No. 1984

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APPEAL OF: TIMOTHY STANGE	:	No. 1549 EDA 2016

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Civil Division at No. April Term 2013 No. 1984

BEFORE: PANELLA, J., DUBOW, J., AND FORD ELLIOTT, P.J.E.

OPINION BY FORD ELLIOTT, P.J.E.: **FILED JANUARY 08, 2018**

Timothy Stange ("Stange"), plaintiff in the court below, and defendants, Janssen Pharmaceuticals, Inc. ("Janssen"), Johnson & Johnson, and Janssen Research & Development, LLC,[1] have taken cross-appeals from the judgment entered in favor of Stange in the amount of $535,106.17. Stange, who suffers from Tourette's syndrome, was prescribed Risperdal[2] and subsequently developed female breasts, a condition known as gynecomastia. Eventually Stange had to have surgery to remove his breasts. Stange alleged that Janssen negligently failed to adequately warn of the risk of gynecomastia associated with Risperdal use. Stange is one of over 5,500 claimants from around the country who chose to file suit in the Court of Common Pleas of Philadelphia County. Stange's case was coordinated in Philadelphia's Complex Litigation Center as a member case under the master docket captioned ***In Re: Risperdal Litigation***, March Term 2010 No. 296, Case Management Order 1, docketed May 26, 2010. All of the cases in this mass tort involve male plaintiffs who allege they developed gynecomastia as a result of ingesting Risperdal. After careful

[1] Janssen is a wholly owned and independently managed subsidiary of Johnson & Johnson. For ease of discussion, we will refer to the defendants collectively as "Janssen."

[2] Risperdal is the trade name for the generic medication risperidone.

review, we affirm in part, reverse in part, and remand for further proceedings.

The trial court has briefly summarized the facts and procedural history of this case as follows:

> In January 2006, Mr. Stange was twelve years old and living in Wisconsin. At that time, he began seeing Edward H. Kovnar, M.D. ("Dr. Kovnar"), a pediatric neurologist, for his Tourette syndrome. On February 7, 2006, Dr. Kovnar prescribed Risperdal to Mr. Stange. In February 2009, Dr. Kovnar discontinued Mr. Stange's use of Risperdal.
>
> In August 2007, Mr. Stange's mother, Mrs. Stange, called his pediatrician, David Mueler, M.D. ("Dr. Mueler") to report that Timothy Stange was experiencing a stabbing pain in his left nipple. In April 2011, Dr. Mueler diagnosed Mr. Stange with gynecomastia and referred him to a plastic surgeon. In 2011, Dr. John H. Jensen ("Dr. Jensen"), a plastic surgeon, saw Mr. Stange and diagnosed him with gynecomastia. On July 16, 2012, Dr. Jensen performed a bilateral mastectomy on Plaintiff. The surgery was successful; however, Mr. Stange has permanent scars and has experienced pain in his chest. Prior to his surgery, Plaintiff was often teased by his classmates about having breasts.
>
> In October 2006, the Federal [Food and] Drug Administration ("FDA") approved Risperdal, an antipsychotic drug, in pediatric and adolescent populations for symptoms associated with Autism. Prior to 2002, the Risperdal label did not convey a risk of gynecomastia. In 2002, the label indicated that Risperdal elevated prolactin levels but that, although disturbances such as gynecomastia may occur, the clinical significance is unknown for most patients. The ADVERSE REACTIONS section of the label indicated that gynecomastia was rare. In October 2006, the Risperdal label was updated as it was approved for children and adolescents. The

label did not mention gynecomastia in the WARNINGS section. In the PRECAUTIONS section, the label indicated that Risperdal is "associated with higher levels of prolactin elevation than other antipsychotic agents." The label stated that gynecomastia has been "reported in patients receiving prolactin-elevating compounds." In August 2007, this information was included in the WARNINGS section. In both the October 2006 and August 2007 labels the "Pediatric Use" section stated: "In clinical trial in 1,885 children and adolescents with autistic disorder and other psychiatric disorder treated with risperidone . . . gynecomastia was reported in 2.3% of risperidone-treated patients."

Janssen knew that Risperdal elevated prolactin in children and adolescents and caused gynecomastia. In November of 2000, the interim results of one long-term open label trial (RIS-INT-41) established that 3.75% of boys taking Risperdal developed gynecomastia. In August 2001, the final results of RIS-INT-41 established that 5.5% of boys taking Risperdal developed gynecomastia. In September 2002, in a related study (RIS-INT-70), which was a year extension of RIS-INT-41, 12.5% of boys in the trial reported new or ongoing gynecomastia. These results indicated that gynecomastia was a frequent adverse event.

In 2002, Janssen conducted a ***post hoc*** meta-analysis of five trials studying prolactin levels in children and adolescents, including RIS-INT-41. In May 2002, as put forth in Table 21 of this meta-analysis (hereinafter, "Table 21"), the data showed that there was a statistically significant association ($p=0.0158$) at weeks 8-12 of Risperdal use in children and adolescents whose prolactin levels were above the upper limit of normal with the risk of subsequently developing gynecomastia. The findings contained within Table 21 were included in the July 2002 draft of the article but were excluded from a subsequent draft of the article in October 2002 after the "statistical documentation protocols"

> were changed. The changed protocols resulted in the disappearance of a statistically significant association. The final article, published in November 2003, stated that there was "no correlation found between SHAP and prolactin levels even when male gynecomastia during puberty was included."[Footnote 1]
>
> [Footnote 1] "SHAP" refers to "side effects hypothetically attributable to prolactin."
>
> Janssen did not report the information in Table 21 to the FDA in its application process. Instead, the Defendants reported that there was no specific or significant finding of concern relating to prolactin elevation. Prior to Risperdal's indication for use in adolescents in 2006, the Defendants promoted the use of Risperdal in children and adolescents. Following the FDA's approval for Risperdal in pediatric and adolescent populations in October of 2006, sales representatives were instructed to give out brochures referred to as "Leave-Behind" material. The Leave-Behind material discussed the new autism approval in children but failed to contain the new safety information from the updated label, and actually contained information contrary to the 2006 label.

Trial court opinion, 5/23/16 at 2-5 (citations to the record omitted).

> On April 12, 2013, Plaintiff, Timothy Stange ("Mr. Stange"), commenced the above-captioned action by filing an Abbreviated Individual Complaint for Risperdal Litigation and Adoption by Reference ("Short-Form Complaint"), which alleged that Defendants, Janssen Pharmaceuticals, Inc. ("Janssen") and Johnson & Johnson, failed to provide an adequate warning as to certain risks associated with the use of Risperdal, a brand name for the prescription drug risperidone. Plaintiff pled various theories and counts, including negligence for design defect, and fraud, strict product liability for failure to warn and design defect, breach of express and

implied warranties, violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, violation of the Wisconsin Deceptive Trade Practices Act, and conspiracy.

On September 22, 2015, Judge Arnold New granted summary judgment in favor of Defendants and against Plaintiff on all of Plaintiff's claims except for negligent failure to warn and strict product liability for failure to warn claims.

A jury trial commenced on October 15, 2015, which was presided over by the Honorable Kenneth J. Powell, Jr. On December 11, 2015, the jury returned a verdict finding that the Defendants negligently failed to warn adequately of the risk of gynecomastia associated with Risperdal use and that the Defendants' negligence was a cause in bringing about Mr. Stange's gynecomastia. The jury awarded compensatory damages in the amount of $500,000.00.

All parties filed Post-Trial Motions, which this Court denied on January 5, 2016. That same day, this Court granted Plaintiff's Motion for Delay Damages and molded the jury's verdict to add delay damages in the amount of $35,106.17 for a total verdict of $535,106.17. On February 10, 2016, this Court approved the parties' stipulation that Plaintiff will not seek to execute on the judgment during the pendency of the appeal, and judgment was entered in favor of the Plaintiff in the amount of $535,106.17.

On March 7, 2016, the Defendants filed a timely Notice of Appeal. On March 8, 2016, this Court ordered the Defendants to submit a Statement of Matters Complained of on Appeal pursuant to Pa.R.A.P. 1925(b). On March 10, 2016, Plaintiff filed a Notice of Appeal. On March 17, 2016, this Court ordered Plaintiff to submit a Statement of Matters Complained of on Appeal pursuant to Pa.R.A.P. 1925(b). On March 28, 2016, Plaintiff

> submitted a timely Statement. On March 29, 2016, Defendants also submitted a timely Statement.

Id. at 1-2.

We will address Janssen's claims on appeal first. Janssen has raised the following issues for this court's review:

> 1. Did the trial court abuse its discretion by allowing an expert opinion that Risperdal® was the medical cause of Plaintiff's gynecomastia, where no evidence supported the expert's speculation that Risperdal® caused Plaintiff's gynecomastia by raising his prolactin to abnormally high levels, and the expert failed to use a scientific method to rule out puberty as a potential alternative cause?
>
> 2. Did the trial court abuse its discretion by refusing to grant judgment to Defendants, where the prescribing physician, Dr. Kovnar, acknowledged: (a) he was aware of the risk of gynecomastia and high prolactin associated with drugs such as Risperdal® at the time he first prescribed for Plaintiff in February 2006; and (b) he did not recall reading the Risperdal® labeling that was updated in October 2006, which would have provided him additional information about those potential risks?
>
> 3. Did the trial court commit legal error when instructing the jury on combined negligence, which gave the misimpression that Defendants could be held solely liable even if the jury found the prescriber contributed to Plaintiff's injury by prescribing with knowledge of the risks, or by failing to read the updated gynecomastia risk information?

Janssen's brief at 5.

In its first issue on appeal, Janssen argues that it was entitled to judgment ***non obstante veredicto*** ("JNOV") because the trial court erred in admitting the expert testimony of Dr. Mark Solomon. Janssen contends that Dr. Solomon's methodology, as applied, was not generally accepted in the relevant field, and that his conclusions were speculative. We disagree.

> 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.:
>
> > [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.
>
> ***Polett v. Public Communications, Inc.***, 83 A.3d 205, 212 (Pa.Super. 2013)[, ***reversed on other grounds***, 126 A.3d 895 (Pa. 2015]. In an appeal from the trial court's decision to deny judgment n.o.v.,
>
> > 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***, 859 A.2d 767 (Pa. 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).

Growall v. Maietta, 931 A.2d 667, 670 (Pa.Super. 2007), ***appeal denied***, 951 A.2d 1164 (Pa. 2008).

> Rule 702 of the Pennsylvania Rules of Evidence provides no particular rules for the qualification of experts. Instead, pursuant to Rule 702 an expert may be qualified to testify so long as he or she has "scientific, technical or other specialized knowledge beyond that possessed by a layperson" that will in some manner assist the jury in understanding the evidence presented. Whether or not an expert witness is qualified to testify is usually a matter left

> to the sound discretion of the trial court. ***See***, ***e.g.***, ***Jacobs v. Chatwani***, 922 A.2d 950, 956 (Pa.Super. [2007]), ***appeal denied***, 595 Pa. 708, 938 A.2d 1053 (2007).

Daniel v. Wyeth, 15 A.3d 909, 925-926 (Pa.Super. 2011), ***appeal dismissed as improvidently granted***, 82 A.3d 942 (Pa. 2013).

According to Janssen, Dr. Solomon failed to meet the standard set forth in ***Frye v. United States***, 293 F. 1013 (D.C.Cir. 1923), for admission of expert testimony. We disagree.

> As we held [] in ***Trach v. Fellin***, 817 A.2d 1102 (Pa.Super. 2003) [(***en banc***), ***appeal denied***, 577 Pa. 725, 847 A.2d 1288 (2004)], the ***Frye*** test sets forth an exclusionary rule of evidence that applies only when a party wishes to introduce novel scientific evidence obtained from the conclusions of an expert scientific witness. ***Trach***, 817 A.2d at 1108-1109. Under ***Frye***, a party wishing to introduce such evidence must demonstrate to the trial court that the relevant scientific community has reached general acceptance of the principles and methodology employed by the expert witness before the trial court will allow the expert witness to testify regarding his conclusions. ***Id.***, 817 A.2d at 1108-1109, 1112. However, the conclusions reached by the expert witness from generally accepted principles and methodologies need not also be generally accepted. ***Id.***, 817 A.2d at 1112. Thus, a court's inquiry into whether a particular scientific process is "generally accepted" is an effort to ensure that the result of the scientific process, ***i.e.***, the proffered evidence, stems from "scientific research which has been conducted in a fashion that is generally recognized as being sound, and is not the fanciful creations [sic] of a renegade researcher." ***See id.***, 817 A.2d at 1111 (quoting ***Blum v. Merrell Dow Pharms., Inc.***, 564 Pa. 3, 9-10, 764 A.2d 1, 5 (2000) (Cappy, C.J., dissenting)).

Reading Radio, Inc. v. Fink, 833 A.2d 199, 208 (Pa.Super. 2003), ***appeal denied***, 847 A.2d 1287 (Pa. 2004) (emphasis deleted).

> [A]s to the standard of appellate review that applies to the ***Frye*** issue, we have stated that the admission of expert scientific testimony is an evidentiary matter for the trial court's discretion and should not be disturbed on appeal unless the trial court abuses its discretion. ***See Commonwealth v. Zook***, 615 A.2d [1] at 11 [(1992), ***cert. denied***, 507 U.S. 974 (1993)]. An abuse of discretion may not be found merely because an appellate court might have reached a different conclusion, but requires a result of manifest unreasonableness, or partiality, prejudice, bias, or ill-will, or such lack of support so as to be clearly erroneous. ***Paden v. Baker Concrete Constr., Inc.***, 540 Pa. 409, 658 A.2d 341, 343 (1995).

Grady v. Frito-Lay, Inc., 839 A.2d 1038, 1046 (Pa. 2003). "[W]e emphasize that the proponent of expert scientific evidence bears the burden of establishing all of the elements for its admission under Pa.R.E. 702, which includes showing that the ***Frye*** rule is satisfied." ***Id.*** at 1045. "[I]n applying the ***Frye*** rule, we have required and continue to require that the proponent of the evidence prove that the methodology an expert used is generally accepted by scientists in the relevant field as a method for arriving at the conclusion the expert will testify to at trial." ***Id.***, citing ***Commonwealth v. Blasioli***, 713 A.2d 1117, 1119 (Pa. 1998).

Dr. Solomon is a plastic and reconstructive surgeon with extensive experience operating on the breast. (Notes of testimony, 10/27/15, a.m. session at 10, 14.) He is familiar with gynecomastia and has diagnosed

and operated on young men with that condition. (***Id.*** at 10, 15.) Dr. Solomon used differential diagnosis, a generally accepted scientific process, to conclude that Risperdal caused Stange's gynecomastia. (Notes of testimony, 10/27/15, p.m. session at 27-28.) Dr. Solomon explained,

> Let's break it down. First, I think you asked me the relationship between Risperdal as an agent creating a rise in prolactin, and that's very well-documented.
>
> Prolactin is a hormone secreted by the pituitary gland. I'm not sure if the jury heard about all of this. Pituitary gland is a gland that sits in your brain, and we know Tim's pituitary was normal because he had an MRI before he started on the medication.
>
> I think that's important, as we talk about this process.
>
> So Risperdal is well-known to stimulate the production of this hormone, prolactin. Prolactin has several ways it acts on the breast.
>
> It will cause the breast to grow. Then, in women -- and in men, it can do this too -- it will cause the breasts to secret[e] milk. That's the direct effect.
>
> There's also an indirect effect that's discussed, where it suppresses the testosterone, which boosts estrogen, which also acts upon the breast almost synergistically, meaning, the two together are a bigger punch than either one alone.
>
> So if you look at the data, what I see, the internal documents are also published, but the internal documents break down in a graphic way, patient takes the drug. Prolactin goes up and typically, at a period after some weeks of exposure to the drug, patient starts developing breasts.

Id. at 24-25.

> There are table after table of these [sic] history of Tim, where he was given the drug in '06. Mom talks about change -- talks about changes in '06. We have photos in '07 that are certainly consistent with gynecomastia, even though no one had made a diagnosis. It's plain as day.
>
> This is all consistent that that, plus the history, plus the subsequent finding of breast tissue, is all consistent with the fact that Risperdal was the insinuating agent to elevate prolactin, which has a direct effect on breast tissue which gave Tim gynecomastias.

Id. at 25-26.

There is nothing scientifically novel about using differential diagnosis to conclude that Stange's gynecomastia was caused by Risperdal. Certainly differential diagnosis is a generally accepted methodology; indeed, Janssen does not dispute the validity of differential diagnosis generally. ***See Cummins v. Rosa***, 846 A.2d 148, 151 (Pa.Super. 2004) (***Frye*** did not apply where the methodology employed by the plaintiffs' medical experts was generally accepted among the medical community for diagnosis and treatment; plaintiffs' experts analyzed plaintiff-wife's medical records and relied upon their personal expertise to reach a conclusion regarding the source of her injuries).

Janssen complains that Stange's prolactin levels were never tested while he was taking Risperdal and that Dr. Solomon could not rule out puberty as the cause of Stange's gynecomastia. However, Dr. Solomon

testified that prolactin testing was not necessary in order to render an opinion within a reasonable degree of medical certainty that Risperdal was responsible for Stange's gynecomastia:

> Because in anywhere from 25 times the control to up to 80 some percent of patients, depending upon the doses of Risperdal, prolactin goes up. In all the agents of this class of drugs, Risperdal is the greatest offender at increasing prolactin.
>
> So as part of my job as a physician is to take a set of the facts and come to a conclusion. If I can get an ancillary test -- and it's easy to get, you can certainly get it -- part of the thing that most of us are taught is it's not going to change our opinion. It's not even essential to do it.
>
> Here, we have a young man on a drug known to cause prolactin elevations who has gynecomastia.
>
> On top of that, there's no -- nothing in the package insert that says you should follow it along. Whereas certain drugs, they say you should check a blood sugar, a potassium, those are in that big red book there, the Physicians Desk Reference, package incident [sic].
>
> We can make a diagnosis using our fundamental knowledge as physicians and be absolutely certain that it's a clear correlation between taking the drug, prolactin, breast growth.

Notes of testimony, 10/27/15, p.m. session at 26-27. ***See also*** trial court opinion, 5/23/16 at 22-23 ("However, the Defendants knew that Risperdal elevated prolactin and chose not to recommend that prescribing doctors monitor prolactin levels of patients taking their medication. *** Now the Defendants wish to benefit from their own concealment by alleging that the

Plaintiff's doctors' differential diagnosis is insufficient because of a failure to perform prolactin monitoring.").

Regarding pubertal changes, Dr. Solomon was able to rule that out in this case because Stange's breast tissue was extensive, remained after puberty, and was not affected by weight gain or loss:

> So yes, there's something called pubertal gynecomastia. The time cause is self-limited. That's the majority of patients that I see as a plastic southern [sic] who are adolescents, boys with breasts.
>
> We encourage the family to be patient, because we know that pubertal gynecomastia will resolve with time and age. The breast tissue as the hormonal environment changes in puberty. That stimulus goes away, the breast tissue goes away.
>
> That's the vast majority of puberty gynecomastia. A small percentage may exist. But in a circumstance where you have a patient who took a drug that's known to be an offending agent, developed breast tissue in a reasonable time course in relation to that agent, lost his pubescent changes, his weight sort of went up and went down, but the breast tissue remained.
>
> And the breast tissue, as I have said before, was dysmorphic, in excess of his body shape. The cause of his gynecomastia was the drug, without a doubt in my mind.

Notes of testimony, 10/25/17, p.m. session at 28-29.

Janssen's arguments really go to weight and not admissibility. As stated above, differential diagnosis is a standard well-established methodology and is routinely used by doctors. The weight to be afforded

Dr. Solomon's testimony and whether to accept his conclusions was for the jury. The trial court did not abuse its discretion in permitting Dr. Solomon to testify regarding causation.

Next, Janssen argues that Stange failed to prove proximate cause, ***i.e.***, that an inadequate warning was the cause of Stange's injuries. Janssen argues that Stange's treating physician, Dr. Edward Kovnar, M.D., knew that neuroleptics such as Risperdal were capable of increasing prolactin levels and prescribed it anyway. Janssen contends that Dr. Kovnar was aware that all neuroleptics, including Risperdal, were associated with gynecomastia. (Janssen's brief at 33-34.) Janssen also claims that beginning in October 2006, the Risperdal label cautioned prescribers that it was associated with higher levels of prolactin elevation than other antipsychotic agents, and that Dr. Kovnar could not remember reading the label. (***Id.*** at 35-36.) Therefore, Janssen argues that it was entitled to JNOV where Stange failed to prove that additional risk information would have changed Dr. Kovnar's prescribing decision. (***Id.*** at 36.)

> To support [his] claim of negligence, [Stange] must establish that [Janssen] breached its duty to warn, and that the breach caused [his] injuries. ***See Gracyalny v. Westinghouse Elec. Corp.***, 723 F.2d 1311, 1316-17 (7th Cir. 1983) (claim of negligence, unlike claim of strict liability, requires plaintiff to prove specific acts of causal negligence); ***Dippel v. Sciano***, 37 Wis.2d 443, 459-60, 155 N.W.2d 55 (1967). With respect to the adequacy of a warning, the initial inquiry under both strict liability and negligence analyses is the scope of the manufacturer[']s duty to provide a warning.

> ***Gracyalny***, 723 F.2d at 1318. Although the adequacy of a warning often presents a factual issue for a jury, that is not always so. ***Compare id.*** at 1321, with ***Alvarado v. Sersch***, 2003 WI 55, 29, 262 Wis.2d 74, 662 N.W.2d 350 (summary judgment in negligence is proper where no reasonable jury, properly instructed, could find defendant was negligent).

Kurer v. Parke, Davis & Co., 679 N.W.2d 867, 876 (Wis.App. 2004), ***review denied***, 684 N.W.2d 137 (Wis. 2004) (bracketed information added).[3]

> A plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or she would have altered behavior and avoided injury. ***Mazur*** [***v. Merck Co.***], 742 F.Supp. [239] at 262 [(E.D.Pa. 1990)]; ***see also Staymates v. ITT Holub Indus.***, 364 Pa.Super. 37, 527 A.2d 140, 147 (1987) (evidence must support a reasonable inference that the existence of an adequate warning may have prevented the injury). Even in the event that a warning is inadequate, proximate cause is not presumed. ***Mazur***, 742 F.Supp. at 262. Absent proof that a more complete or explicit warning would have prevented [Stange's] use of [Risperdal], [he] cannot establish that [Janssen's] alleged failure to warn was the proximate cause of [his] injuries.

Id. (bracketed information added).

> In cases involving the failure to warn of risks associated with prescription drugs, Pennsylvania courts apply the "learned intermediary doctrine."
>
> Under the learned intermediary doctrine, a manufacturer will be held liable only where it fails to exercise reasonable care to inform a physician of the

[3] It is agreed that the substantive law of the State of Wisconsin governs the claim in this case. (Janssen's brief at 32 n.12.)

> facts which make the drug likely to be dangerous. The manufacturer has the duty to disclose risks to the physician, as opposed to the patient, because it is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug.

Czimmer v. Janssen Pharm., Inc., 122 A.3d 1043, 1057 (Pa.Super. 2015), quoting ***Gurley v. Janssen Pharm., Inc.***, 113 A.3d 283, 292-293 (Pa.Super. 2015), in turn quoting ***Cochran v. Wyeth, Inc.***, 3 A.3d 673, 676 (Pa.Super. 2010), ***appeal denied***, 20 A.3d 1209 (Pa. 2011).[4]

There was ample testimony regarding the inaccurate and misleading nature of Janssen's warning labels. There was substantial evidence that Janssen intentionally downplayed the risk of gynecomastia for adolescent boys using Risperdal. The trial court aptly summarized:

> Here, the pre-October 2006 label stated that certain endocrine disorders like gynecomastia are "rare." The 2007 label stated, in the "USE IN SPECIAL POPULATIONS" section under "Pediatric Use," that "[i]n clinical trials . . . gynecomastia was reported in 2.3% of RISPERDAL®-related patients." The 2007 label also reported that gynecomastia occurred in less than 1% of adult patients and less than 5% of pediatric patients treated with Risperdal.

[4] There is no conflict between Pennsylvania and Wisconsin law on the scope of the learned intermediary doctrine. (Janssen's brief at 32 n.12; notes of testimony, 10/19/15, p.m. session at 3.) The trial court applied the law of Pennsylvania on the learned intermediary doctrine, and neither party challenged this determination. (***Id.***)

> Both of these warnings were inaccurate based on the scientific evidence that the Defendants possessed. Between 2000 and 2003, the Defendants had evidence from three studies that showed that 3.75%, 5.5%, and 12.5% of boys taking Risperdal developed gynecomastia. These results indicated that gynecomastia was a frequent adverse event, not "rare" as the pre-October 2006 label stated. Additionally, the 2.3% incidence rate reported in the 2007 label was based on the Defendants' having exercised a heavy hand with the data. These warnings were not accurate, strong, or clear. Instead, the warnings, to the extent they warned at all, were inaccurate and misleading about the risks of gynecomastia.

Trial court opinion, 5/23/16 at 16 (citations to the record omitted).

Furthermore, Dr. Kovnar, Stange's pediatric neurologist, testified that although he knew that all neuroleptic drugs increased prolactin levels, he understood this condition to be rare and temporary and that he would not have prescribed Risperdal to Stange had he been aware of the increased risk. Dr. Kovnar did not know that Risperdal elevated prolactin levels significantly more than other neuroleptic drugs. Dr. Kovnar testified:

> Q. Did you know that as a class these second-generation antipsychotics in general had some increase of prolactin levels?
>
> A. I was aware all of the neuroleptics were capable of increasing prolactin levels.
>
> Q. And were you aware that all of them had some association occasionally with the condition gynecomastia?
>
> A. Yes, I was aware of that.

> Q. Was this any secret to you or in the practice of medicine?
>
> A. No, it was -- it was well-known. My understanding, however, was that it was rare, and hopefully, temporary.

Notes of testimony, 10/20/15, a.m. session at 48-49.

> Q. Did you spend your evenings and nights reading pharmaceutical labels?
>
> A. No, I did not. We have a number of readily accessible sources of information about pharmaceuticals. One is called the PDR and the other is an online reference called Epocrates.

Id. at 50.

> Q. Did you know anything from PDR or Epocrates when you made this choice to prescribe this drug that there was a significant incidence of gynecomastia, like five percent? Did you know anything like that?
>
> A. No, I did not.
>
> Q. And you mentioned that at the time you believed the drug was -- the condition was rare; is that correct?
>
> A. Yes.
>
> Q. And having looked at the PDR, is that what the PDR said back then?
>
> A. I've had the opportunity to look back at that PDR that was available at the time, and what I think stands out is the comment that gynecomastia is a rare adverse effect.

Id. at 50-51.

> Q. Did you know that at the time that the drug increased prolactin levels more significantly than other -- than other drugs of the class?
>
> A. No, I didn't. I knew that every medication that blocks the effects of dopamine, which is the underlying mechanism of the drug, is capable of elevating prolactin levels. But I was unaware that there was anything special or unique about Risperdal that caused greater elevation of prolactin.

Id. at 55-56. Dr. Kovnar testified that if he had all of the information in February 2006, he would have chosen a different medication for Stange. (***Id.*** at 49-50.) Dr. Kovnar also testified that there was no reason to test Stange's prolactin levels, in the absence of a specific directive or warning. (***Id.*** at 56-57.) Janssen's sales representatives made visits to his office several times in the spring and summer of 2007 and never communicated any increased risk of gynecomastia. (Notes of testimony, 10/21/15, a.m. session at 65-69.)

The evidence fully supports a conclusion that due to Janssen's inadequate labeling and failure to warn, Dr. Kovnar was unaware of the specific heightened risks associated with the use of Risperdal and would have prescribed a different drug. It was at least sufficient to create a jury question on proximate cause. The trial court did not err in refusing to grant JNOV on this basis. This claim fails.

Finally, in its third issue on appeal, Janssen complains that the trial court erred in instructing the jury on the concept of combined negligence.

According to Janssen, the instruction gave the jury the misimpression that it could find Janssen liable for inadequate labeling even if it also believed that Dr. Kovnar contributed to the risk of injury by failing to read the updated labeling or by deciding to prescribe Risperdal with knowledge of the increased risks. (Janssen's brief at 38-39.) Janssen acknowledges that a combined negligence instruction was appropriate vis-à-vis the three named defendants and that the instruction accurately reflected Wisconsin law on joint and several liability. (***Id.*** at 37-38.) Nonetheless, Janssen argues that the instruction was misleading where Stange never argued that Dr. Kovnar was negligent and the issue of Dr. Kovnar's prescribing decision, either knowing the risks or having failed to read the updated labeling, was central to Janssen's defense. (***Id.*** at 38.)

> In examining these instructions, our scope of review is to determine whether the trial court committed clear abuse of discretion or error of law controlling the outcome of the case. ***Williams v. Philadelphia Transportation Company***, 415 Pa. 370, 374, 203 A.2d 665, 668 (1964). 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. ***Glider v. Com. Dept. of Hwys.***, 435 Pa. 140, 151-52, 255 A.2d 542, 547 (1969). 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 fundamental error." ***Voitasefski v. Pittsburgh Rys. Co.***, 363 Pa. 220, 226, 69 A.2d 370, 373 (1949); A reviewing court will not grant a new trial on the ground of inadequacy of the charge unless there is a prejudicial omission of something basic or

> fundamental. ***Sweeny v. Bonafiglia***, 403 Pa. 217, 221, 169 A.2d 292, 293 (1961); ***Giorgianni v. DiSanzo***, 392 Pa. 350, 356, 140 A.2d 802, 805 (1958). In reviewing a trial court's charge to the jury, we must not take the challenged words or passage out of context of the whole of the charge, but must look to the charge in its entirety. ***McCay v. Philadelphia Electric Company***, 447 Pa. 490, 499, 291 A.2d 759, 763 (1972).

Stewart v. Motts, 654 A.2d 535, 540 (Pa. 1995).

The trial court gave the following instruction:

> You must decide if the defendants' negligence caused the plaintiff's injury. This question does not ask about the cause but rather a cause, because an injury may have more than one cause. Someone's negligence caused the injury if it was a substantial factor in producing the injury. An injury may be caused by one person's negligence or by a combined negligence of two or more people. The negligence of one person alone may produce an injury or the acts or omissions on the part of two or more persons or other conditions beyond anyone's control may jointly produce the injury.

Notes of testimony, 12/11/15, a.m. session at 39.

As Janssen concedes, the instruction was an accurate statement of Wisconsin law. ***Fischer by Fischer v. Ganju***, 485 N.W.2d 10, 17 (Wis. 1992); Wis.J.I.-Civil 1500. Furthermore, the instruction was appropriate where the trial court denied the motions for nonsuit of Johnson & Johnson and Janssen Research & Development, LLC, and so all three defendants remained in the case. As the trial court remarked, "Although the Defendants attempt to minimize Johnson & Johnson's involvement in this case, as discussed ***infra***, both Janssen and Johnson & Johnson acted (at a minimum)

negligently in failing to warn of the risks of Risperdal which caused Plaintiff's injury." (Trial court opinion, 5/23/16 at 25.)

Janssen complains that the jury was confused because Janssen's defense was that Dr. Kovnar prescribed Risperdal despite knowing the risks and/or failing to read the updated label. However, the trial court instructed the jury on proximate cause and the learned intermediary doctrine, and Janssen was free to argue that Dr. Kovnar violated a duty of care when he prescribed Risperdal. The trial court did not err in instructing the jury on combined negligence, in accordance with Wisconsin law.

We now turn to Stange's issues on cross-appeal. Stange has raised the following issues for this court's review:

> [1.] Did [Judge New] improperly grant a global motion [for] summary judgment on the claims for punitive damages of all Risperdal plaintiffs, including Timothy Stange, especially where ample evidence in this case supported a claim of punitive damages against Janssen and warranted the submission of that issue to the jury under either Wisconsin or New Jersey law?
>
> [2.] Did the trial court improperly fail to instruct the jury that [Stange] was entitled to all of the damages proximately flowing from Defendants' negligent acts and on [Stange]'s life expectancy?

Stange's brief at 4-5.

With respect to Judge New's order as coordinating judge,

> A trial court may dismiss an action pursuant to Rule 1035.2 of the Pennsylvania Rules of Civil Procedure governing summary judgment: After the

> relevant pleadings are closed, but within such time as not to unreasonably delay trial, any party may move for summary judgment in whole or in part as a matter of law (1) whenever there is no genuine issue of any material fact as to a necessary element of the cause of action or defense which could be established by additional discovery or expert report, or (2) if, after the completion of discovery relevant to the motion, including the production of expert reports, an adverse party who will bear the burden of proof at trial has failed to produce evidence of facts essential to the cause of action or defense which in a jury trial would require the issues to be submitted to a jury. Pa.R.C.P. 1035.2. A proper grant of summary judgment depends upon an evidentiary record that either (1) shows the material facts are undisputed or (2) contains insufficient evidence of facts to make out a ***prima facie*** cause of action or defense and, therefore, there is no issue to be submitted to the jury. Pa.R.C.P. 1035.2 *Note*. Where a motion for summary judgment is based upon insufficient evidence of facts, the adverse party must come forward with evidence essential to preserve the cause of action. ***Id.*** If the non-moving party fails to come forward with sufficient evidence to establish or contest a material issue to the case, the moving party is entitled to judgment as a matter of law. The non-moving party must adduce sufficient evidence on an issue essential to its case and on which it bears the burden of proof such that a jury could return a verdict favorable to the non-moving party. As with all summary judgment cases, the court must examine the record in the light most favorable to the non-moving party and resolve all doubts against the moving party as to the existence of a triable issue. Upon appellate review, we are not bound by the trial court's conclusions of law, but may reach our own conclusions. In reviewing a grant of summary judgment, the appellate Court may disturb the trial court's order only upon an error of law or an abuse of discretion. The scope of review is plenary and the appellate Court applies the same standard for summary judgment as the trial court.

Biernacki v. Presque Isle Condominiums Unit Owners Ass'n, Inc., 828 A.2d 1114, 1115-1116 (Pa.Super. 2003), quoting ***Grandelli v. Methodist Hosp.***, 777 A.2d 1138, 1143-1144 (Pa.Super. 2001) (citation omitted).

> The trial court must accept as true all well-pleaded facts relevant to the issues in the non-moving party's pleadings, and give to him the benefit of all reasonable inferences to be drawn therefrom. A grant of summary judgment is proper where the pleadings, depositions, answers to interrogatories, admissions of record and affidavits on file support the court's conclusion no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law.

Goldberg v. Delta Tau Delta, 613 A.2d 1250, 1252 (Pa.Super. 1992), ***appeal denied***, 626 A.2d 1158 (Pa. 1993) (citations omitted).

The coordinating judge briefly described the procedural history relating to the global order granting partial summary judgment in favor of the defendants on the issue of punitive damages as follows:

> On February 10, 2014, Moving Defendants filed a Motion for Partial Summary Judgment arguing New Jersey law barred the recovery of punitive damages. Moving Defendants argued a conflict existed between New Jersey's Products Liability Act,[5] which sharply limits the availability of punitive damages in pharmaceutical products liability cases, and Pennsylvania law, which permits the recovery of punitive damages in pharmaceutical products liability cases. They further argued New Jersey had a greater interest in the application of its law because New Jersey is where the "punitive conduct," i.e. the corporate decisions about Risperdal's design, manufacturing, marketing, selling, and labeling, allegedly occurred.

[5] NJPLA, N.J. Stat.Ann. § 2A:58C-5(c).

> In response, Plaintiffs made three arguments. First, Plaintiffs argued the law of the case doctrine required this Court to apply the law of the state where Risperdal was marketed, prescribed, and ingested. Second, Plaintiffs argued if the law of the case doctrine did not apply, then this Court should apply Pennsylvania law to the punitive damages claim. Finally, Plaintiffs argued they could recover punitive damages under New Jersey law because the New Jersey precedent relied on by Moving Defendants is inapplicable to the case ***sub judice***. By Order dated May 2, 2014, for the reasons set forth below, this Court granted partial summary judgment in favor of Moving Defendants on the issue of punitive damages.

Opinion by Judge New, 10/22/15 at 2-3.

Plaintiffs filed a motion for reconsideration on June 2, 2014, which was denied. Stange argues that a global order concerning punitive damages was inappropriate. Stange contends that Pennsylvania law requires a choice-of-law analysis of what state has the greatest relationship and interests in each individual plaintiff's case, which is necessarily fact-dependent. According to Stange, a Wisconsin resident, a choice-of-law analysis favors application of Wisconsin law in this case. Stange complains that rather than entering a global motion, the trial court should have allowed him to develop facts and state interests important to his particular circumstances. (Stange's brief at 55.)

Stange also argues that the New Jersey Product Liability Act, which allows a prescription drug manufacturer to defend against punitive damages by demonstrating that its drug was approved by the FDA, does not apply in

this case, where the FDA first approved Risperdal for pediatric use in October 2006, and Risperdal was never approved for treatment of Tourette's syndrome. Stange argues that because Risperdal was prescribed for an off-label use, it was not "approved" within the meaning of the NJPLA. Finally, Stange argues that the global order deprived individual plaintiffs of significant substantive rights and denied individual plaintiff's counsel the opportunity to present responsive argument pertinent to that particular plaintiff's case. (Stange's brief at 67.)

Janssen contends that the issue is waived because Stange's argument that Pennsylvania choice-of-law rules required application of Wisconsin punitive damages law was not preserved in the trial court. Pa.R.A.P. 302(a) ("Issues not raised in the lower court are waived and cannot be raised for the first time on appeal."). In their response to the defendants' motion for partial summary judgment, the plaintiffs argued that the law of the case doctrine required the trial court to apply the law of the state where Risperdal was marketed, prescribed, and ingested. (Opinion by Judge New, 10/22/15 at 4.) The plaintiffs argued that the coordinating judge was bound by his decisions in three previous cases, applying the punitive damages law of the

state where the injury occurred.[6] (***Id.***) In the alternative, the plaintiffs argued that Pennsylvania punitive damages law should apply to every case

[6] The conflict of law issue arises from three cases decided prior to the global order entered in the ***In Re Risperdal® Litigation***. Judge New applied the punitive damages law of the home domicile of the respective plaintiffs. In resolving the law of the case issue, Judge New stated:

> Plaintiffs' argument fails for two separate, yet equally important, reasons. First, the law of the case doctrine only applies to prior decisions in the same case. King, 999 A.2d at 600. Here, although they fall under the umbrella of the ***In Re Risperdal® Litigation*** mass tort program, the Banks, AB, and SB matters are individual, different, cases. Case Management Order No. 1 makes clear that each case retains its own identity as an individual case, and the ***In Re Risperdal® Litigation*** docket was established merely as a depository for the filing of pleadings and motions common to all cases. ***See In Re Risperdal® Litigation*** March Term 2010 No. 296, Case Management Order 1 at § 1. Since ***Banks***, ***AB***, and ***SB*** are separate cases, this Court's rulings concerning which state's law applies to the issue of punitive damages in those cases has no effect on this Court's ruling on the issue ***sub judice***. Second, assuming ***arguendo Banks***, ***AB***, ***SB***, and ***In Re Risperdal® Litigation*** are considered to be the same "case" for the purposes of the law of the case doctrine, the law of the case doctrine would still not apply because the undersigned issued the Orders in question in all four matters, ***Banks***, ***AB***, ***SB***, and ***In Re Risperdal® Litigation***. As the Superior Court made clear, "[a] trial judge may always revisit his own prior pre-trial rulings in a case without running afoul of the law of the case doctrine. ***Clearwater Concrete***, 18 A.3d at 1216. For both of these reasons, the law of the case doctrine does not apply in this matter.

Opinion by Judge New, 10/22/15 at 5 (footnote omitted).

in the litigation, where the defendants met repeatedly in Pennsylvania to make decisions regarding the activities giving rise to punitive damages. (***Id.*** at 5-10.) The coordinating judge stated:

> This Court notes Plaintiffs did not argue a choice of law analysis requires this Court to apply the law of the state where Risperdal was marketed, prescribed, and ingested by the individual plaintiffs. Rather, Plaintiffs made two separate and distinct arguments: 1) the law of the case doctrine required this Court to apply the law of the state where Risperdal was [] marketed, prescribed, and ingested, and 2) if this Court found the law of the case doctrine did not apply, then Pennsylvania law should apply.

Id. at 6 n.4.

According to Janssen, the plaintiffs' argument, that Pennsylvania law required a case-by-case assessment of the competing interests of all relevant jurisdictions and that the law of each state where Risperdal was prescribed and ingested should govern each individual case, was not raised in the plaintiffs' March 24, 2014 response in opposition to the motion for partial summary judgment. Janssen contends that the argument was raised for the first time in the plaintiffs' June 2, 2014 motion for reconsideration of the global order granting the defendants' partial summary judgment motion.

> Failure to raise an issue before the trial court, however, results in waiver of the issue on appeal. ***Dollar Bank v. Swartz***, 540 Pa. 369, 657 A.2d 1242, 1245 (1995) (citations omitted) ("It is a fundamental principle of appellate review that we will not reverse a judgment or decree on a theory that was not presented to the trial court"). Even if an issue "was included in [a] subsequently filed motion for reconsideration, issues raised in motions for

> reconsideration are beyond the jurisdiction of this Court and thus may not be considered by this Court on appeal." ***Rabatin v. Allied Glove Corp.***, 24 A.3d 388, 391 (Pa.Super. 2011) (citation omitted); ***accord*** Pa.R.A.P. 302(a).

Eisbacher v. Maytag Corp., 2017 WL 947606 at *5 (Pa.Super. March 9, 2017).

> Issues not raised before the trial court are not preserved for appeal and may not be presented for the first time on appeal. Pa.R.A.P. 302(a); ***Erie Insurance Exchange v. Larrimore***, 987 A.2d 732, 743 (Pa.Super. 2009). While the issue was included in the subsequently filed motion for reconsideration, issues raised in motions for reconsideration are beyond the jurisdiction of this Court and thus may not be considered by this Court on appeal. ***Prince George Center, Inc. v. U.S. Gypsum Co.***, 704 A.2d 141, 145 (Pa.Super. 1997), ***appeal denied***, 557 Pa. 640, 732 A.2d 1210 (1998), ***cert. denied***, 528 U.S. 810, 120 S.Ct. 41, 145 L.Ed.2d 37 (1999).

Rabatin, 24 A.3d at 391.

Furthermore,

> [a] decision to pursue one argument over another carries the certain consequence of waiver of those issues that could have been raised but were not. This proposition is consistent with our Supreme Court's efforts to promote finality, and effectuates the clear mandate of our appellate rules requiring presentation of all grounds for relief to the trial court as a predicate for appellate review.

Id. at 392, quoting ***Devine v. Hutt***, 863 A.2d 1160, 1169 (Pa.Super. 2004) (footnote omitted).

Stange argues in his reply brief that waiver is inappropriate in the mass tort context since appointed liaison counsel is not class counsel and

does not represent all Risperdal plaintiffs. (Stange's 4th-step reply brief at 8 n.1.) Stange argues that ***Rabatin***, ***Devine***, and similar precedent were developed in "one-off" cases. (***Id.*** at 10.) Stange complains that this was his first opportunity on his individual record to litigate the question of punitive damages. (***Id.*** at 8.)

After carefully reviewing the plaintiffs' response in opposition to the defendants' motion for partial summary judgment, we deem the punitive damages issue to be adequately preserved. While the plaintiffs did cite the law of the case doctrine and argue that the coordinating judge should follow his earlier rulings, the plaintiffs argued more generally that the law of the plaintiffs' various home states should apply to punitive damages. The plaintiffs relied on several other decisions applying the punitive damages law of the state of the injury, ingestion, and marketing of a pharmaceutical drug. (Plaintiffs' response in opposition to defendants' motion for partial summary judgment, 3/24/14 at 8-10; RR, Vol. 1 at 163-165.) The plaintiffs argued that although Janssen is a Pennsylvania corporation, the trial court should recognize the strong interests of the state where the plaintiff's injuries occurred, the drug was prescribed, and where the defendant has affirmatively and actively marketed and sold the drug. (***Id.***) The plaintiffs did not limit their argument to the law of the case doctrine. Although the plaintiffs did ask the coordinating judge to respect his earlier rulings, that argument was couched within a broader argument that the law of the state

where a particular plaintiff was prescribed Risperdal and suffered injury should apply. We decline to find waiver.[7]

> In addressing which substantive law to apply, we employ the conflict-of-law principles that our High Court framed in ***Griffith v. United Air Lines, Inc.***, 416 Pa. 1, 203 A.2d 796 (1964). In ***Griffith***, our Supreme Court altered its approach in determining which substantive law to apply in tort cases. Prior to that decision, Pennsylvania followed the ***lex loci delicti*** rule, which applied the substantive law of the place where the tort was committed. ***Id.*** at 801. However, the High Court abandoned that mechanical approach in favor of a methodology that combined the "government interest" analysis and the "significant relationship" approach of sections 145 and 146 of the Restatement (Second) of Conflicts, which we reproduce ***infra***. ***Id.*** at 801-06; ***Troxel v. A.I. duPont Inst.***, 431 Pa.Super. 464, 636 A.2d 1179, 1180–81 (1994).

Marks v. Redner's Warehouse Markets, 136 A.3d 984, 987 (Pa.Super. 2016) (footnote omitted).

> ***Griffith***, ***supra***, addressed the choice of law question in an action brought by the executor of a Pennsylvania resident killed in a plane crash during a landing in Denver on a flight from Philadelphia, Pennsylvania to Phoenix, Arizona. ***Id.*** at 797. Concluding that the plane crash in Colorado was "purely fortuitous" and that Pennsylvania had a greater interest in the executor's recovery, our

[7] We do agree with Janssen, however, that the issue regarding whether Risperdal had been "approved" within the meaning of the NJPLA is waived. In their motion for reconsideration of the global order granting the defendants' partial summary judgment motion, the plaintiffs argued, for the first time, that the NJPLA did not preclude punitive damages because Risperdal did not achieve FDA approval for any pediatric use until October 2006. The plaintiffs argued that many cases involved Risperdal ingestion by minor children before the October 2006 approval. (Plaintiffs' motion for reconsideration, 6/2/14 at 5; RR, Vol. 1 at 209.)

> Supreme Court discarded the ***lex loci delicti*** rule for a flexible methodology that permitted courts to conduct an "analysis of the policies and interests underlying the particular issue before the court." ***Griffith***, ***supra*** at 805.

Id. at 987-988.

> Section 145(2) of the Restatement (Second) of Conflicts sets forth the contacts to be considered in applying the analysis required under ***Griffith***. They include:
>
> (a) the place where the injury occurred;
>
> (b) the place where the conduct causing the injury occurred;
>
> (c) the domicile, residence, nationality, place of incorporation and place of business of the parties; and
>
> (d) the place where the relationship, if any, between the parties is centered.
>
> Restatement (Second) of Conflict of Laws § 145 (1983).
>
> We evaluate these four factors mindful of the overarching choice-of-law principles enumerated in § 6 of the Restatement (Second). Those considerations include the following:
>
> (a) the needs of the interstate and international systems;
>
> (b) the relevant policies of the forum;
>
> (c) the relevant policies of the other interested states and the relevant interests of those states in determination of a particular issue;
>
> (d) the protection of justified expectations;

> (e) the basic policies underlying the particular field of law;
>
> (f) certainty, predictability and uniformity of result; and
>
> (g) ease in the determination and application of the law to be applied.
>
> ***Id.*** § 6.

Id. at 988.

As stated in ***Marks***, the first step in our analysis is to decide whether there is a true conflict between the laws of New Jersey and Wisconsin.

> A true conflict occurs where an analysis of the policies underlying each of the conflicting laws reveals that, in each case, application of the respective state's law would further its corresponding policy. ***Id.*** at 855. If a true conflict exists, we then proceed to determine which jurisdiction has the greater interests, considering the qualitative contacts of the states, the parties and the controversy. ***Cipolla***, ***supra*** at 856.

Id.

Here, a true conflict exists where the NJPLA does not permit the imposition of punitive damages in pharmaceutical products liability cases where the drug was approved by the FDA. Wisconsin caps punitive damages at twice the amount of any compensatory damages or $200,000, whichever is greater, but does not otherwise limit punitive damages in pharmaceutical cases. Wis.Stat.Ann. § 895.043(6). Wisconsin clearly has an important interest in protecting its citizens, such as Stange, against tortious conduct;

New Jersey's Products Liability Act reflects its policy of shielding its pharmaceutical industry from imposition of punitive damages. As such, there is a true conflict of law and the trial court must determine which state, New Jersey or Wisconsin, has the most significant relationship to the parties and the occurrence to determine which jurisdiction's substantive law applies.[8]

Stange argues that Wisconsin law should apply because he was prescribed Risperdal in Wisconsin and developed gynecomastia in Wisconsin; Janssen's inadequate warnings reached Dr. Kovnar in Wisconsin; Janssen's salespeople visited Dr. Kovnar in Wisconsin on multiple occasions over many years and failed to disclose Risperdal's actual risks; and his medical and legal injuries all occurred in Wisconsin. (Stange's brief at 53.) Stange also argues that Wisconsin has the greater governmental interests where he is a Wisconsin resident and Wisconsin has a strong interest in regulating the activities of pharmaceutical companies that choose to do business within its borders. (***Id.*** at 54.) Stange contends that Wisconsin's overriding interest in regulating corporate entities conducting business there and punishing outrageous behavior is greater than New Jersey's interest in maintaining the profitability of its pharmaceutical industry. (***Id.***)

[8] As stated above, Stange does not argue on appeal that Pennsylvania punitive damages law should apply.

According to Janssen, the critical punitive damage contacts weigh in favor of New Jersey law because the defendants' principal places of business were in New Jersey, the Risperdal labeling was developed and distributed from New Jersey, Janssen's overall Risperdal marketing and sales strategy was developed in New Jersey, and communications with the FDA and the medical community occurred in New Jersey. (Janssen's brief at 43.) Janssen also argues that New Jersey has an interest in preserving its local economy, protecting its pharmaceutical industry, and policing its own corporate citizens. (***Id.*** at 45-47.) Janssen characterizes Wisconsin's punitive contacts as "minimal" and argues that the coordinating judge correctly found that New Jersey punitive damages law applies globally, to all Risperdal cases in the mass tort program.

We disagree. As discussed above, we decline to find that Stange waived the choice-of-law argument because the plaintiffs' response to the defendants' motion for partial summary judgment included a discussion of the law of the case doctrine. Stange's argument on appeal that the law of Wisconsin, his home state, should apply to the issue of punitive damages in his particular case is preserved. However, the trial court did not fully address the issue, finding that the plaintiffs' argument was limited to the law of the case doctrine. Therefore, the trial court only considered whether New Jersey or Pennsylvania law should apply, not the law of the individual plaintiff's home state. We agree with Stange that it is necessary to remand

for the trial court to allow Stange to develop an individual record on choice-of-law as it relates to his unique circumstances and to set out the facts and state interests important to his particular case. As such, it is necessary to reverse the order granting partial summary judgment for the defendants on the punitive damages issue and remand for the trial court to consider the conflict-of-law principles developed in ***Griffith***, ***supra***.[9]

Finally, Stange contends that the trial court erred in refusing to instruct the jury on future damages including future emotional distress due to the bullying and ridicule he endured because of his breasts. Stange argues that he introduced evidence at trial that he was continually bullied because of his condition, which was confirmed by medical records. (Stange's brief at 69.) Stange's mother corroborated his testimony regarding the extreme anguish and embarrassment he suffered for years. (***Id.***) According to Stange, this led to a reasonable inference that he would continue to suffer mental anguish for the rest of his life as a result of the bullying. (***Id.*** at 69-70.) Therefore, Stange argues that under Wisconsin law, an instruction on future damages was warranted. (***Id.*** at 70.) The trial court charged the jury on noneconomic damages, including emotional

[9] We note that the recent case of ***Bristol-Myers Squibb Co. v. Superior Court of California***, ___ U.S. ___, 137 S.Ct. 1773 (2017), in which the United States Supreme Court held that out-of-state plaintiffs failed to establish specific jurisdiction over Bristol-Myers since there was no significant link between the claims and Bristol-Myers' conduct in California, has no impact on this case, where Janssen is a Pennsylvania corporation.

distress, but refused Stange's requested instruction on future emotional distress, finding that Stange failed to present any evidence of mental anguish from bullying in the future. (Trial court opinion, 5/23/16 at 9-11.)

The Supreme Court of Wisconsin has set forth the applicable law regarding future damages, including for future emotional distress proximately flowing from the defendant's negligence, as follows:

> The law is clear that when the tortfeasor's conduct causes bodily harm for which he or she is liable, the tortfeasor is also liable for mental distress (including fear and anxiety) resulting from the bodily harm. Where the "plaintiff can demonstrate physical injury at the time of the accident, plaintiff may also prove and collect damages for emotional injury arising from the accident." ***Rennick v. Fruehauf Corp.***, 82 Wis.2d 793, 805, 264 N.W.2d 264 (1978). The burden on the person claiming damages is to convince the jury, by the greater weight of the credible evidence to a reasonable certainty, that he or she has sustained or will sustain the mental distress and physical harm claimed as a result of the tortfeasor's negligent conduct. In other words, recovery may be had for reasonably certain injurious consequences of the tortfeasor's negligent conduct, not for merely possible injurious consequences. Thus the jury was instructed in this case that it was to compensate the plaintiff for worry and mental distress, if any, which the plaintiff had endured and was reasonably certain to endure in the future as a consequence of his injuries. Wis. J.I.-Civil No. 1750A (1982).

Brantner v. Jenson, 360 N.W.2d 529, 532 (Wis. 1985).

The Supreme Court of Wisconsin affirmed a published decision of the court of appeals, ***Brantner v. Jenson***, 352 N.W.2d 671 (Wis.Ct.App. 1984), which articulated a rule that "if there is a reasonable basis for the fear of

future harm and the possibility of that harm developing was increased as a result of the negligently caused injury, the mental distress is compensable." ***Brantner***, 352 N.W.2d 671.

> The court of appeals articulated a rule setting forth two elements a victim must establish by a preponderance of the evidence to prove that he or she is reasonably certain to endure mental distress as a consequence of the injury: (1) the possibility of the feared harm must have increased as a result of the negligently inflicted injury, and (2) the victim must have a reasonable basis for the fear of future harm.

Brantner, 360 N.W.2d at 534.

> The two-part test, which is merely another way of stating the general rules of causation and damages in negligence law, recognizes the distinction between damages for reasonably certain anxiety over a possible future occurrence of the consequence and damages for the probable future occurrence of that consequence and looks to the totality of circumstances surrounding the plaintiff's alleged mental distress to determine whether the distress is reasonably certain.

Id. at 534-535. ***See also Meracle v. Children's Serv. Soc'y of Wisconsin***, 437 N.W.2d 532 (Wis. 1989) (plaintiffs could not recover future damages for medical expenses and emotional distress based upon their fear that their adopted daughter might contract Huntington's Disease; she had only a 25% chance of developing the disease and a plaintiff must demonstrate that the anticipated damages are reasonably certain to occur).

The trial court explained that while Stange testified to past incidents of bullying, there was no evidence that he currently suffers any mental anguish or was likely to suffer mental distress in the future:

> At trial, Mr. Stange described multiple instances of his being bullied in high school because of his breasts. It is clear that the bullying based on his breasts ceased after Mr. Stange's surgery and he is not currently being bullied. Mr. Stange did not testify that this past bullying caused any permanent mental problems for him other than the fact that he has memories of the events. Mr. Stange did not testify that he currently suffers any mental anguish from any residual effects of past bullying. Mr. Stange did not indicate that he believed that he would suffer any mental anguish from bullying in the future. Further, [Stange] did not proffer an expert to opine on the possible long-term effects of bullying on mental health. Accordingly, [Stange] did not present sufficient evidence to support a finding that [he] would suffer mental health problems in the future; thus, it would be inappropriate for the jury to award damages. Therefore, this Court did not err in refusing to instruct the jury that it could award damages for future emotional distress.

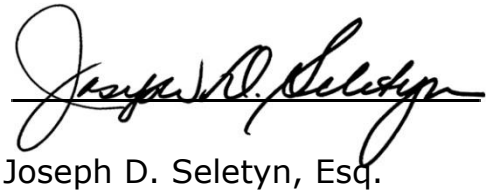
Trial court opinion, 5/23/16 at 11 (references to the transcript omitted; citation omitted). We agree. Stange's argument that the jury could make a "fair inference" that he will continue to experience the effects of past bullying is too speculative. Stange failed to demonstrate that future damages for emotional distress were "reasonably certain." Therefore, the trial court did not err in refusing to instruct the jury on damages for future emotional distress.

Affirmed in part and reversed in part; remanded for further proceedings consistent with this Opinion. Jurisdiction relinquished.

Panella, J. joins this Opinion.

Dubow, J. did not participate in the consideration or decision of this case.

Judgment Entered.



Joseph D. Seletyn, Esq.
Prothonotary

Date: 1/8/18