2018 PA Super 398

PHILLIP PLEDGER, BY BENITA PLEDGER, AS GUARDIAN OF HIS PERSON AND CONSERVATOR OF HIS ESTATE, Appellee v. JANSSEN PHARMACEUTICALS, INC.,; JOHNSON & JOHNSON; AND JANSSEN RESEARCH & DEVELOPMENT, LLC, Appellants	:	IN THE SUPERIOR COURT OF PENNSYLVANIA No. 2088 EDA 2016

Appeal from the Judgment Entered June 8, 2016
in the Court of Common Pleas of Philadelphia County
Civil Division at No(s): April Term, 2012 No. 1997

PHILLIP PLEDGER, BY BENITA PLEDGER, AS GUARDIAN OF HIS PERSON AND CONSERVATOR OF HIS ESTATE, Appellant v. JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON CO., AND JANSSEN RESEARCH & DEVELOPMENT, LLC, Appellees	:	IN THE SUPERIOR COURT OF PENNSYLVANIA No. 2187 EDA 2016

Appeal from the Judgment Entered June 8, 2016
in the Court of Common Pleas of Philadelphia County
Civil Division at No(s): 1997 April Term, 2012

BEFORE: STABILE, J., STEVENS, P.J.E.* and STRASSBURGER, J.**

* Former Justice specially assigned to the Superior Court.

** Retired Senior Judge assigned to the Superior Court.

OPINION BY STRASSBURGER, J.: **FILED OCTOBER 31, 2018**

Janssen Pharmaceuticals, Inc., Janssen Research & Development, LLC, and Johnson & Johnson Company (collectively, Janssen)[1] appeal from the judgment of $2.5 million entered on June 8, 2016, after a jury found in favor of Phillip Austin Pledger (Austin), and his mother, Benita Pledger (collectively, the Pledgers), and against Janssen in this pharmaceutical failure to warn case. In addition, the Pledgers appeal from the July 11, 2014 order granting partial summary judgment in favor of Janssen on the Pledgers' punitive damages claim.[2] After review, we affirm in part, reverse in part, and remand for proceedings consistent with this opinion.

We provide the following background. Austin was born in 1994. In 2000, Austin, who was living with his parents about an hour outside of Birmingham, Alabama, was diagnosed as having autism.[3] "In April 2002, Mrs. Pledger took Austin to meet Dr. Jan Mathisen, a pediatric neurologist in

[1] "Janssen Pharmaceuticals, Inc. and Janssen Research & Development, LLC, are wholly owned companies of Johnson & Johnson." ***Murray v. Janssen Pharmaceuticals, Inc.***, 180 A.3d 1235, 1238 n.1 (Pa. Super. 2018). For ease of discussion, we will refer to these entities collectively as Janssen.

[2] The Pledgers have filed an application for leave to file a post-submission communication. Janssen has filed a response to that motion setting forth objections. Upon review of the motion and response, and based upon our conclusions *infra*, we deny the application as moot. The information provided in the motion was not used, nor was it needed, to aid us in our disposition.

[3] "Autism is a developmental disorder that impairs the ability of a child to communicate. It also results in impairment in social interactions, and it can cause a lot of behavioral issues." N.T., 1/26/2015 (p.m.), at 38.

Birmingham[,]" in an effort to "relieve behavioral symptoms including temper tantrums." Trial Court Opinion, 8/11/2017, at 3; ***see*** N.T., 1/26/2015 (p.m.), at 44. Dr. Mathisen first saw Austin on April 22, 2002, and Dr. Mathisen and Mrs. Pledger discussed Austin's autism diagnosis and the potential for medication that may help him. At Austin's next visit, on June 17, 2002, Dr. Mathisen prescribed Risperdal[4] to Austin.[5] Dr. Mathisen warned Mrs. Pledger "that weight gain was possible" as a side effect of taking Risperdal. Trial Court Opinion, 8/11/2017, at 4 (citing N.T., 1/26/2015 (p.m.), at 57. Mrs. Pledger believed, however, that "this [risk] was acceptable because she thought [weight gain] could be mitigated by diet." ***Id***.

Austin did indeed gain weight, and Mrs. Pledger noticed that about two-and-a-half months after Austin began taking Risperdal, he "started getting heavy around his nipples." N.T., 2/6/2015 (a.m.), at 71. A 2005 photograph

[4] Risperdal, also known by its generic name, risperidone, is an "atypical antipsychotic []. It was initially released for the treatment of schizophrenia in adults with psychosis, and then that evolved into treatment of bipolar disorders, and then eventually it was approved for the use in children with autism." N.T., 1/26/2015 (p.m.), at 43. Risperdal was developed, marketed, and sold through Janssen.

[5] Risperdal was not approved by the Federal Drug Administration (FDA) for use in children in 2002. However, according to Dr. Mathisen, such "off-label" use began happening within a few years of Risperdal's release into the market in 1993. N.T., 1/26/2015 (p.m.), at 43. Dr. Mathisen testified that he was among "a large group of pediatric practitioners who were using [Risperdal] to treat children with a variety of conduct disorders." ***Id***. at 54. Risperdal was approved for use for children with autism in October 2006.

of Austin with his shirt off reveals enlargement in his chest area. ***See*** Plaintiff's Exhibit 71.

Around November 2006, Mrs. Pledger sought to switch Austin to a different doctor, Dr. Donald Paoletti. Dr. Paoletti discontinued Austin's use of Risperdal in April 2007. The last time Austin saw Dr. Mathisen was in October of 2006, and Dr. Mathisen's last refill for Austin's Risperdal occurred on January 19, 2007.

Around October 2011, Mrs. Pledger saw a commercial on television about the potential for Risperdal to cause a condition called gynecomastia.[6] She called the telephone number for the law firm on the television, and then sent in pictures of Austin as she was asked to do. It was at that time she learned that there may be a connection between Austin's Risperdal use and his large breasts.

In April 2012, the Pledgers filed a complaint against Janssen, which included claims asserting *inter alia*, Janssen's negligence in failing to warn physicians and patients that Risperdal could cause gynecomastia.[7] That

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[6] Gynecomastia is "a condition where female breast tissue grows in males." ***Murray***, 180 A.3d at 1238. Gynecomastia can be caused by an increase in levels of the hormone prolactin (hyperprolactinemia), which can lead to the development of breast tissue in males.

[7] The Pledgers' case was filed in Philadelphia County, and coordinated with Philadelphia's Complex Litigation Center as a member case in the mass tort program captioned at ***In re Risperdal Litigation***, March Term 2010, No. 296. "[Austin] 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…. All of the cases in this mass tort involve male plaintiffs who allege they have developed

complaint also contained a count for punitive damages. On February 10, 2014, Janssen filed a global motion for partial summary judgment with respect to several of the claims common to all cases, including the punitive damages claim. On July 11, 2014, the trial court granted partial summary judgment on *inter alia*, the punitive damages claim as to all cases.

Austin's case proceeded to a jury trial beginning January 20, 2015, and did not conclude until February 24, 2015. There were numerous issues in the case, all of which were vigorously contested by both the Pledgers and Janssen. By way of overview, the Pledgers sought to prove that Janssen "had discovered a significant risk of gynecomastia among boys who ingested Risperdal for eight through twelve weeks and had demonstrated elevated prolactin levels while taking the drug."[8] Trial Court Opinion, 8/11/2017, at 5. According to the Pledgers, despite Janssen knowing that information, it did not communicate this risk to the FDA or to doctors prescribing Risperdal. In support of this claim, the Pledgers presented testimony of their expert, Dr. David Kessler, Federal Drug Administration (FDA) commissioner from 1991-1997.

> Dr. Kessler testified that data collected at Table 21 showed [a] statistically significant side effect among children taking Risperdal between 8 and 12 weeks. In Dr. Kessler's opinion, Table 21

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gynecomastia as a result of ingesting Risperdal." ***Stange v. Janssen Pharmaceuticals, Inc.***, 179 A.3d 45, 49-50 (Pa. Super. 2018).

[8] As part of their evidence, the Pledgers presented a study by Janssen that "was summarized in a chart known at trial as 'Table 21' and marked into evidence as P34(A)." Trial Court Opinion, 8/11/2017, at 5.

> showed that children taking Risperdal within this time period, and had elevated prolactin levels, were 7.8 percent more likely to develop gynecomastia than children taking Risperdal whose prolactin level had remained normal.

Id. at 5-6 (citing N.T., 1/29/2015 (p.m.), at 30-35).

Janssen acknowledged that Table 21 was never shared with the FDA. N.T., 2/11/2015 (p.m.), at 114. Moreover, because this information was never shared with the FDA, and was not on Risperdal's label in 2002 at the time Dr. Mathisen prescribed Risperdal to Austin, Dr. Mathisen believed "any association between Risperdal and gynecomastia was rare" and never checked "Austin's prolactin levels" or examined him for gynecomastia. Trial Court Opinion, 8/11/2017, at 6 (citing N.T., 1/26/2015 (p.m.), at 104). Dr. Mathisen further testified that "he would have discussed the relationship between Risperdal and gynecomastia with Mrs. Pledger had he known of the data in Table 21." ***Id***. In addition, Mrs. Pledger testified that had she known about the risk of gynecomastia, she would not have permitted Austin to take Risperdal. N.T., 2/6/2015 (a.m.), at 58-59.

Janssen also vigorously contested causation; in other words, Janssen claimed that Austin's large chest area was not caused by his taking Risperdal. In order to prove that Austin did indeed have gynecomastia caused by Risperdal, the Pledgers presented the testimony of Dr. Mark Solomon.[9]

[9] It is the series of events leading up to Dr. Solomon's testimony, along with Dr. Solomon's testimony itself, that form the primary basis of this appeal. These issues will be discussed in detail *infra*.

> Dr. Solomon explained his medical opinion that the diagnosis of [] gynecomastia depends on the presence of breast tissue and he explained that breast tissue is biologically not the same as fat tissue. He showed the jury the difference using medical slides. Dr. Solomon stated breast tissue growth does not go away on its own since it does not come from obesity which is characterized by fat cells that grow and recede depending on weight. Dr. Solomon testified that his own physical examination of Austin confirmed the presence of breast tissue inside Austin's breasts. Dr. Solomon said Austin had been on Risperdal for several years and his medical records had reported no other causal agent. He said female breasts in boys develop from the center and then spread outwards. The areola grows first and then breast tissue multiplies around the areola to form gynecomastia. Dr. Solomon told the jury that a picture of Austin shows what he termed "end stage growth." Pointing at the 2005 picture of 11[-]year[-]old bare[-]chested Austin coming out of a swimming pool, Dr. Solomon testified, "That's a full breast. That's not a little nipple out pouch. In 2005, he was 11 that would be the beginning of puberty. So if it were pubertal in origin, you would see a little pouch of a nipple, not an outline of a breast." (N.T., 2/9/[20]15, [at] 66.)

Trial Court Opinion, 8/11/2017, at 27-28.

Janssen conceded that Austin had gynecomastia, but also contended that Austin had a condition called pseudogynecomastia, "a disease category diagnosed by some physicians who link obesity and fat to the development of feminine looking breasts in boys." ***Id***. at 28. According to defense expert, Dr. Tom Vaughn, III, an endocrinologist, Austin had both gynecomastia and pseudogynecomastia. N.T., 2/18/2015 (a.m.), at 105. Dr. Vaughn testified that pseudogynecomastia is "obesity … in the chest, and sometimes it can look very much like breast tissue." ***Id***. at 104. Dr. Vaughn stated that Risperdal caused Austin's weight gain, which caused his pseudogynecomastia. ***Id***. at 107. In addition, Dr. Vaughn testified that he could not tell from the 2005

picture whether Austin had gynecomastia or pseudogynecomastia at that point. N.T., 2/18/2015 (p.m.), at 13.

In addition to the foregoing, Janssen suggested that even if Austin's large chest area at that time were gynecomastia, it was not caused by Risperdal. Dr. Vaughn testified that Austin's gynecomastia was not caused by Risperdal, but instead was caused by puberty. N.T., 2/18/2015 (p.m.), at 33-37.

On the other hand, the Pledgers relied upon Dr. Solomon's testimony. He testified that

> to a reasonable degree of medical certainty … Austin's ingestion of Risperdal caused his gynecomastia. … Dr. Solomon said he based his causation opinion in part by performing a differential diagnosis and told the jury why he ruled out other causes. Dr. Solomon testified that in his opinion gynecomastia does not develop in pre-puberty boys absent an abnormality caused by disease or an outside agent such as a medication. Reviewing Austin's medical records, Dr. Solomon saw no evidence of a disease causing Austin's gynecomastia. He specifically ruled out other known causes which were not present in Austin's medical history including the absence of Kl[ine]felter's syndrome, thyroid abnormality, or either pituitary or testicular tumors. "Absent another cause, another drug, another tumor, another kind of anything, a normal 8[-]year[-]old boy has a zero incidence of gynecomastia." (N.T., 2/9/[20]15, [at] 106 []).
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> Dr. Solomon testified that in his medical opinion, based on all the evidence before him, Risperdal was the only remaining variable and he told the jury why:
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> > [S]o, briefly, Risperdal is a drug that among its side effects, it's a stimulant of prolactin which is this hormone that we talked about briefly that's secreted by the pituitary gland and acts on the breast tissue.

> He was exposed to this drug at the age of 8. If you review literature, in 8 to 12 weeks from exposure to the drug, prolactin goes up, significantly. And his response to that significant rise, time related according to his mom, was the development of some breast buds which she didn't rightfully connect, because she wouldn't. He stayed on that drug for five years. I believe until 2007. So that he had a constant stimulus with elevations in prolactin for some prolonged period of time that we can – I'm sure occurred. I have no reason not to think it occurred because of my knowledge of the drug, and therefore, it stimulated his breasts to grow.

Trial Court Opinion, 8/11/2017, at 26-27 (quoting N.T., 2/9/2015 (a.m.), at 104-105).

Finally, Janssen suggested that even if Austin had gynecomastia that was caused by Risperdal, Dr. Mathisen was primarily at fault because the label for Risperdal revealed that ingestion could increase prolactin levels.[10] While Janssen acknowledges that the label in 2002 stated that gynecomastia was "rare," that label also stated that Risperdal increased prolactin levels. ***See*** Plaintiff's Exhibit 10; N.T., 1/26/2015 (p.m.), at 120. Thus, according to Janssen, Dr. Mathisen had sufficient knowledge to discuss this risk with Mrs. Pledger prior to prescribing Risperdal for Austin.

Nevertheless, on February 24, 2015, the jury returned a verdict in favor of the Pledgers, concluding that Janssen was negligent in not adequately warning Dr. Mathisen about the risk of gynecomastia to Austin from his taking

[10] This defense, known as the "learned intermediary doctrine," will be discussed in greater detail *infra*.

Risperdal, and that this negligence was a cause of Austin's gynecomastia. The jury awarded Austin $2.5 million in damages. Janssen timely filed post-trial motions, which were denied on May 4, 2016. The Pledgers entered judgment on June 8, 2016, and both Janssen and the Pledgers timely filed notices of appeal. The trial court filed its opinion on August 11, 2017.[11]

Appeal of Janssen

On appeal, Janssen presents several issues for our review. ***See*** Janssen's Brief at 6-7. We begin with Janssen's contention that the trial court erred in denying judgment notwithstanding the verdict (JNOV) because the Pledgers "failed to prove that any alleged inadequacy in Risperdal's labeling" caused Austin's gynecomastia. ***Id***. at 41. In considering this issue, we set forth the following. "The standard which we employ when reviewing the denial of a motion of directed verdict and a motion for [JNOV] is the same. We will reverse the [trial] court when we find an abuse of discretion or an error of law that controlled the outcome of the case." ***Jones v. Constantino***, 631 A.2d 1289, 1292 (Pa. Super. 1993).

> We will review all of the evidence in the light most favorable to the verdict-winner and will give that party the benefit of every reasonable inference arising from that evidence while rejecting all unfavorable testimony and inferences. [JNOV] may be entered where: (1) the moving party is entitled to judgment as a matter of law and/or (2) the evidence is such that no two reasonable minds could disagree that the verdict should have been rendered for the moving party. Our scope of review is plenary concerning any questions of law. Regarding questions of credibility and the

[11] The trial court did not order the parties to file concise statements of errors complained of on appeal pursuant to Pa.R.A.P. 1925(b).

> weight accorded the evidence at trial, however, we will not substitute our judgment for that of the fact-finder. [JNOV] should be entered only in a clear case, and any doubts must be resolved in favor of the verdict winner.

Murray, 180 A.3d at 1241 (internal quotation marks omitted).

Under Alabama law,[12] in a pharmaceutical failure to warn case as in any negligence case, a "plaintiff bringing such an action must establish: (1) that the defendant had a duty; (2) that the defendant failed to provide adequate warnings of the hazards of a particular product, thereby breaching that duty; (3) that the breach was the proximate cause of the plaintiff's harm; [and] (4) that the plaintiff suffered injury as a result." ***Bodie v. Purdue Pharma Co.***, 236 F. App'x 511, 518 (11th Cir. 2007) (applying Alabama law).

Here, Janssen does not contest the fact that it owed a duty to the Pledgers. However, at trial and on appeal, Janssen contends that it did not breach that duty. In considering a breach of duty in the context of a pharmaceutical failure to warn case, "Alabama courts follow the learned-intermediary doctrine, and thus, a manufacturer's duty to warn a consumer about a drug is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use." ***Stephens v. Teva Pharm., U.S.A., Inc.***, 70 F.Supp.3d 1246, 1253–54 (N.D. Ala. 2014) (internal citations and quotation marks omitted). "Additionally, the plaintiffs must show that the manufacturer failed to warn the physician of a risk not otherwise

[12] The parties stipulated that Pennsylvania law governs procedure-related issues in this case and Alabama law governs liability-related issues.

known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury." ***Id***. at 1254. "Hence, the plaintiff must show not only that an inadequate warning was given, but also that an adequate warning would have prevented the injury." ***Id***.

Janssen contends that it warned Dr. Mathisen adequately of the risks of Risperdal. First, Janssen claims that "Dr. Mathisen was 'well aware' Risperdal may elevate prolactin and potentially cause prolactin[-]related side effects like gynecomastia." Janssen's Brief at 42. Thus, according to Janssen, Dr. Mathisen had all of the information he needed to warn the Pledgers, but he failed to do so.

"[T]he causal link between a patient's injury and the alleged failure to warn is broken when the prescribing physician had 'substantially the same' knowledge as an adequate warning from the manufacturer should have communicated to him." ***Christopher v. Cutter Labs.***, 53 F.3d 1184, 1192 (11th Cir. 1995). Here, the question then is whether the 2002 Risperdal label adequately warned Dr. Mathisen of the risk of gynecomastia.

At the time Dr. Mathisen first prescribed Risperdal to Austin, the warning label stated that gynecomastia was "rare," meaning it occurred "in fewer than 1/1000 [(.001%) of] patients." ***See*** Plaintiff's Exhibit 10. In addition, that label provided that "[a]s with any other drugs that antagonize dopamine D

[*sic*] receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration."[13] N.T., 1/28/2015 (p.m.), at 23.

At the time Dr. Mathisen initially prescribed Risperdal to Austin, Dr. Mathisen had no reason to believe that Risperdal would have any different effect on Austin's prolactin level than any other drug in its class. This is clearly not "substantially the same" knowledge that the risk of gynecomastia was 23 times what Dr. Mathisen reasonably believed it to be. Thus, viewing the testimony in the light most favorable to the Pledgers, we conclude that the trial court did not err in denying JNOV on this basis.

Janssen also contends that because Dr. Mathisen's final refill for Austin occurred in January of 2007, after the updated October 2006 label was available, it was Dr. Mathisen's failure to read the updated warning that actually caused Austin's gynecomastia. Janssen's Brief at 43-44. In considering this issue, we point out that Janssen's own studies revealed that it was the elevation in prolactin during weeks eight through twelve of administration that was causally related to gynecomastia. ***See*** Trial Court Opinion, 8/11/2017, at 5. By 2006, Austin was well beyond this point. In fact, the 2005 photograph shown at trial reveals that Austin already had

[13] By way of comparison, the 2006 label provided the following: "In clinical trials in 1[,]885 children and adolescents with autistic disorder or other psychiatric disorders treated with risperidone, … gynecomastia was reported in 2.3% of risperidone-treated patients." ***See*** Plaintiff's Exhibit 10. In addition, the label provided that "[r]isperidone is associated with higher levels of prolactin elevation than other antipsychotic agents." N.T., 1/28/2015 (p.m.), at 25.

increased breast size. ***See*** Plaintiff's Exhibit 71. Accordingly, we conclude that the trial court did not err in denying JNOV based upon Dr. Mathisen's final refill for Risperdal because the evidence viewed in the light most favorable to the verdict-winner, the Pledgers, showed the damage from Risperdal had already been done to Austin.

Finally, Janssen argues it is entitled to JNOV because Dr. Mathisen still prescribes Risperdal to minors today, even though the label has been updated to identify the additional risks related to elevated prolactin and gynecomastia. Janssen's Brief at 42-43. However, the issue is whether an adequate warning in 2002 would have changed Dr. Mathisen's prescribing habits. Dr. Mathisen testified specifically that if he were aware of the 2.3% risk of gynecomastia in 2002, it would not have been a rare event and "[h]e would have brought up the potential for that problem." N.T., 1/26/2015 (p.m.), at 80. In fact, Dr. Mathisen testified that he tells patients about the risk of gynecomastia when prescribing Risperdal today. ***Id***. at 194, 207. Moreover, Mrs. Pledger testified that had she been warned of this risk, she would not have permitted Austin to take Risperdal. ***See*** N.T., 2/6/2015, at 58-59. Thus, the record supports the conclusion that a different warning in 2002 would have changed Dr. Mathisen's prescribing behavior and the injury to Austin could have been prevented. Therefore, we conclude the trial court did not err in denying JNOV in any respect based upon the conduct of Dr. Mathisen.

We now turn to Janssen's issues with respect to Dr. Solomon. ***See*** Janseen's Brief at 27-40. In doing so, we provide the following background. In March of 2014, Dr. David E. Goldstein, "a pediatrician and endocrinology specialist licensed in Missouri, examined Austin at the request" of his attorneys. Trial Court Opinion, 8/11/2017, at 15.

> Dr. Goldstein met 19[-]year[-]old Austin and his parents on March 5, 2014[,] at a hotel in Birmingham, Alabama, not far from the family's home. He examined Austin and diagnosed him with gynecomastia. Austin's parents gave Dr. Goldstein an oral medical history.
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> On March 31, 2014, Dr. Goldstein signed an expert report based on the physical examination, the parents' oral history, written medical records and deposition testimony. Dr. Goldstein's report includes his opinion as an expert in pediatric endocrinology that "the treatment of children and adolescents with [r]isperidone causes gynecomastia"; that Austin has "very enlarged breasts primarily due to gynecomastia" and that Austin's treatment with [r]isperidone between 2002 and 2007 is "a substantial contributing factor to the development of Austin's gynecomastia."
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> The [law] firm disclosed Dr. Goldstein's expert report to [Janssen's] Philadelphia attorneys at Drinker Biddle within the case management time frame set by Judge Arnold L. New, Mass Torts Supervising Judge. Soon after, on April 16, 2014, Dr. Goldstein appeared for a deposition conducted by Janssen attorney and Drinker Biddle partner Thomas Campion, Esq. Mr. Campion asked Dr. Goldstein whether he was "practicing medicine" on March 5, 2014[,] when he examined Austin. Dr. Goldstein said that he was "hesitating" in saying he had not been "practicing medicine" but only because he had told Austin's parents "a couple of things [he] would recommend they did, but not under [his] care, like go to your doctor and do this and do that." (N.T. 4/16/[20]14, p. 43).

Trial Court Opinion, 8/11/2017, at 15-16 (some citations omitted).

No issues were raised with respect to Dr. Goldstein's competency to testify during the period provided for in the case management order. However, several days into trial,[14] on the morning of Monday, February 2, 2015, one of Janssen's attorneys, Kenneth Murphy, Esquire, explained to the trial court that one of the Pledgers' attorneys, Christopher Gomez, Esquire, had emailed him on Saturday, January 31, 2015, stating that the Pledgers intended to proceed with Dr. Goldstein's trial testimony by way of deposition *de bene esse*.[15] N.T., 2/2/2015, at 5. The trial court ruled immediately that it would not permit Dr. Goldstein to testify by deposition. ***Id***.

Janssen subsequently submitted to the trial court a bench memorandum explaining why the trial court should exclude Dr. Goldstein's testimony altogether.[16] ***See*** Reproduced Record, Vol. II., at 968a; Bench Memorandum,

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[14] By this time, motions *in limine* had been presented and decided, the jury had been selected, opening statements had been given, and the jury had heard testimony from Dr. Kessler and Dr. Mathisen. ***See*** N.T., 1/20/2015 through 1/30/2015.

[15] In other words, the Pledgers sent notice to Janssen that they intended to present Dr. Goldstein's testimony by taking a deposition for use at trial, rather than bringing him to testify as a live witness.

[16] This bench memorandum is not included in the certified record; however, there is a copy of it in the Reproduced Record. ***See*** Reproduced Record, Volume II, at 968a. "While the general rule is that this Court generally may consider facts only if they are duly certified in the record, we [have] acknowledged that where the accuracy of a pertinent document is undisputed, the Court could consider that document if it was in the Reproduced Record, even though it was not in the record that had been transmitted to the Court." ***In re Fiedler***, 132 A.3d 1010, 1027 (Pa. Super. 2016) (internal citations and quotation marks omitted). Because neither party has disputed the accuracy

2/2/2015. According to Janssen, Dr. Goldstein violated Alabama law by practicing medicine in Alabama without being licensed to do so when he conducted an examination of Austin and gave the aforementioned medical advice to Mrs. Pledger.

According to Janssen, Alabama law provides that a doctor who is not licensed in Alabama may only practice medicine in Alabama in consultation with a physician licensed to practice medicine in Alabama. ***Id***. at 2-3; Ala. Code § 34-24-74. Janssen argued that Dr. Goldstein's failure to comply with Alabama law renders his examination improper, and therefore "the admission of his testimony would undermine the integrity of the proceeding." ***Id***. at 5. Jannsen also claimed that they did not raise this issue earlier because it did not come to light until the Pledgers requested the *de bene esse* deposition. N.T., 2/2/2015, at 130.

According to the Pledgers, they requested the *de bene esse* deposition to accommodate Dr. Goldstein's schedule. ***Id***. at 135. The Pledgers also informed the court that Dr. Goldstein was now unwilling to testify because of concern about his potential for criminal legal exposure, and he was unavailable to the Pledgers because he had left Pennsylvania. Thus, the Pledgers requested that the trial court permit them to re-open discovery, have Austin fly to Philadelphia with his father, and then be examined by a new expert. The

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of the bench memorandum included in the reproduced record, we will consider it.

trial court agreed to permit the Pledgers to switch experts mid-trial, and Janssen objected and moved for a mistrial, which the trial court denied. ***Id***. at 149; N.T., 2/3/2015, at 11.

Austin was then examined by Dr. Mark Solomon, a doctor familiar to Janssen because Dr. Solomon was also an expert in another Risperdal case that had just settled. Trial Court Opinion, 8/11/2017, at 20 n.23. That examination occurred, Dr. Solomon was deposed, and Dr. Solomon testified live for the jury on Monday, February 9, 2015. At trial, Dr. Solomon testified as discussed *supra*.

On appeal, Janssen first argues that it is entitled to a new trial because the trial court erred or abused its discretion by permitting the Pledgers to substitute their expert mid-trial in violation of the rules of discovery. Janssen's Brief at 27-30. According to Janssen, Janssen "had nothing to do with Dr. Goldstein's refusal to testify and sudden unavailability; rather it was [Dr. Goldstein's] own failure to comply with Alabama law that presumably caused him to flee Pennsylvania." ***Id***. at 27. Thus, Janssen contends the trial court violated Pa.R.C.P. 4003.5(b) because Dr. Solomon was not disclosed as a witness prior to trial. ***Id***. at 28.

"Our standard of review in denying a motion for a new trial is to decide whether the trial court committed an error of law which controlled the outcome

of the case or committed an abuse of discretion."[17] ***Corvin v. Tihansky***, 184 A.3d 986, 992 (Pa. Super. 2018). "The admission of expert testimony is a matter within the sound discretion of the trial court, whose rulings thereon will not be disturbed absent a manifest abuse of discretion." ***Walsh v. Kubiak***, 661 A.2d 416, 419 (Pa. Super. 1995) (*en banc*). The rules for discovery of an expert witness provide that

> [a]n expert witness whose identity is not disclosed in compliance with subdivision (a)(1) of this rule shall not be permitted to testify on behalf of the defaulting party at the trial of the action. **However, if the failure to disclose the identity of the witness is the result of extenuating circumstances beyond the control of the defaulting party, the court may grant a continuance or other appropriate relief**.

Pa.R.C.P. 4003.5(b) (emphasis added).

Here, there is no question that Dr. Solomon was not disclosed to Janssen within the appropriate timeframe. Thus, the first hurdle the Pledgers had to overcome was to convince the trial court that the failure to disclose Dr.

[17] To the extent Janssen suggests that any error in the trial court's permitting the substitution of experts would permit the entry of JNOV, it is incorrect. ***See*** Janssen's Brief at 25 ("The law required a verdict for [Janssen] …".). An error regarding the trial court's decision to admit testimony based upon a discovery violation, as Janssen suggests occurred here, would result in the granting of a new trial. ***See Woodard v. Chatterjee***, 827 A.2d 433, 440 (Pa. Super. 2003) ("If the trial court made an erroneous evidentiary ruling that caused harm to the complaining party, the only remedy is to grant a new trial."); ***see also Brandon v. Peoples Natural Gas Co.***, 207 A.2d 843 (Pa. 1965) (reversing trial court's grant of JNOV where trial court determined evidence had been erroneously admitted; relief was new trial, not JNOV, because court cannot enter judgment on diminished record). Thus, we consider this argument in that context.

Solomon was the "result of extenuating circumstances" beyond the Pledgers' control. ***Id***. The trial court offered the following.

> The timing of Janssen's motion and nature of their accusation were extraordinary and seemed calculated for maximum surprise. If Janssen's late motion were granted, [the Pledgers] would have no choice but move for a voluntary nonsuit. If the motion were denied, then Dr. Goldstein would likely choose to take the Fifth Amendment or testify with predictable damage to his credibility. Either way, if the motion had been filed before trial, there would not have been extraordinary prejudice to [the Pledgers] who would likely have moved for a continuance before undergoing the expense of trial.

Trial Court Opinion, 8/11/2017, at 34.

The trial court's conclusion that Janssen purposely waited until the middle of trial to raise this issue is supported by the record. Despite Janssen's protestations to the contrary, it admitted it was aware of this Alabama law at the time it hired its own expert. ***See*** Bench Memorandum, 2/2/2015, at 5 n.1 ("Indeed, mindful of the limitations of Alabama law, [Janssen] retained a local Alabama endocrinologist to perform a physical examination of [Austin], rather than use a previously retained out[-]of[-]state endocrinologist with whom [Janssen] already had a relationship."). Thus, we agree with the trial court that it appears that the "timing of Janssen's motion and nature of [its] accusation were extraordinary and seemed calculated for maximum surprise." Trial Court Opinion, 8/11/2017, at 34.

Accordingly, the trial court did not err or abuse its discretion in permitting the Pledgers to change experts mid-trial due to "extenuating circumstances beyond the control of" the Pledgers. Pa.R.C.P. 4003.5(b).

Moreover, we conclude the relief granted by the trial court was appropriate under the circumstances. ***See id***; ***see also Rutyna v. Schweers***, 177 A.3d 927, 936 (Pa. Super. 2018) (*en banc*) (holding trial court abused its discretion by failing to grant continuance to plaintiffs in a medical malpractice case "where, through no fault of their own, their expert was precluded from testifying"). Here, the new expert, Dr. Solomon, was familiar to Janssen. The Pledgers were willing to have Austin examined, a report prepared, and a deposition taken in an expeditious manner at no cost to Janssen. Based on the foregoing, we conclude there was no abuse of discretion or error of law that would entitle Janssen to a new trial on this basis.[18]

We now turn to Janssen's next two contentions regarding Dr. Solomon. First, Janssen argues that Dr. Solomon, a plastic surgeon, was not qualified to opine on the causes of gynecomastia, and therefore the trial court erred on this basis.[19] Janssen's Brief at 30. In addition, Janssen contends that Dr. Solomon's methodology for diagnosing Austin with gynecomastia was not "generally accepted by scientists in the relevant scientific community." Janssen's Brief at 33 (citing ***Grady v. Frito Lay***, 839 A.2d 1038 (Pa. 2003)).

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[18] Additionally, if there were a new trial on this basis, the Pledgers would have more than enough time to obtain either Dr. Solomon or a new expert altogether to testify on the Pledgers' behalf.

[19] Again, it appears that Janssen contends the trial court erred in denying JNOV. However, the remedy for trial court error based upon the admission of improper expert testimony is a new trial. ***See Cummins v. Rosa***, 846 A.2d 148, 150 (Pa. Super. 2004).

This Court recently considered similar arguments by Janssen in ***Stange***, 179 A.3d at 53, and concluded the following.[20]

> 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*)], 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. [***Trach***,] 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***. [at] 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.***, 764 A.2d 1, 5 ([Pa.] 2000) (Cappy, C.J., dissenting)).

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[20] ***Stange*** is also a member case in the ***In Re: Risperdal Litigation***, March Term 2010 No. 296. The plaintiff was prescribed Risperdal for his Tourette Syndrome from January 2006 to 2009 and developed gynecomastia. After a jury trial, damages were awarded to Stange. Janssen appealed to this Court, and on appeal, complained *inter alia*, that "the trial court erred in admitting expert testimony of Dr. Mark Solomon" because his "methodology, as applied, was not generally accepted in the relevant field, and that his conclusions were speculative." ***Stange***, 179 A.3d at 52.

Reading Radio, Inc. v. Fink, 833 A.2d 199, 208 (Pa. Super. 2003) [] (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. 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.

Grady[, 839 A.2d at 1046]. "[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***.

Dr. Solomon is a plastic and reconstructive surgeon with extensive experience operating on the breast. He is familiar with gynecomastia and has diagnosed and operated on young men with that condition. Dr. Solomon used differential diagnosis, a generally accepted scientific process, to conclude that Risperdal caused Stange's gynecomastia. 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 [Stange'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.
>
> There are table after table of these [*sic*] history of Tim, where he was given the drug in '06. [Stange's] Mom talks about change … 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 with 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 [Stange] gynecomastia[].

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,*** [] 846 A.2d [at] 151 [] ([holding] ***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.

See [] [T]rial [C]ourt [O]pinion, 5/23/[20]16 at 22–23 ("However, [Janssen] knew that Risperdal elevated prolactin and

chose not to recommend that prescribing doctors monitor prolactin levels of patients taking their medication. […] Now [Janssen] wish[es] to benefit from their own concealment by alleging that [Stange'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 [surgeon] 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.

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.

Stange, 179 A.3d at 53–56 (some citations omitted).

With this background in mind, we turn to Janssen's arguments in this case. We begin with Janssen's contention that even though

> Dr. Solomon is a board-certified plastic surgeon[,] … [that] may permit him to diagnose gynecomastia in an appropriate clinical setting, or to testify about treatment options, he is not qualified to offer an ***expert*** opinion about the ***causes*** of gynecomastia generally or in an individual. That would be within an endocrinologist's expertise, as Dr. Solomon conceded.

Id. (emphasis in original).

During *voir dire*, Dr. Solomon was questioned about his experience in diagnosing gynecomastia. He testified that he had "diagnosed patients with drug-induced gynecomastia." N.T., 2/9/2015 (a.m.), at 28. When asked "why it is necessary to understand the … endocrine system" when considering performing breast-related surgery, Dr. Solomon stated that "in order to operate on someone … you need to know if the problem is something you can treat surgically or nonsurgically." ***Id***. at 33-34. Dr. Solomon testified that he is an expert in the "physiology and pathology of the breast." ***Id***. at 38. After questioning Dr. Solomon about the fact he was not an endocrinologist qualified to diagnose gynecomastia, Janssen objected to Dr. Solomon being qualified as an expert in this case because he is not an endocrinologist. N.T., 2/9/2015 (a.m.), at 69. The trial court concluded that Dr. Solomon is an expert in the disease of gynecomastia, and it is up to the jury "to determine the weight … to give his opinion." ***Id***. at 70.

> Experts in one area of medicine have been ruled [to be] qualified to address other areas of specialization where the specialties overlap in practice, or where the specialist has experience in another related medical field. ***See***, ***e.g. Kearns v. Clark***, [] 493 A.2d 1358 ([Pa. Super.] 1985) (urologist qualified to testify against surgeon to evaluate surgeon's performance in hysterectomy where urologist was familiar and had assisted in performance of other hysterectomies); ***Pratt v. Stein***, 444 A.2d 674 ([Pa. Super.] 1982) (professor of pharmacology qualified to testify to post-operative care given by orthopedic surgeon with respect to drug administered to patient); ***Ragan v. Steen***, 331 A.2d 724 ([Pa. Super.] 1974) (surgeon permitted to testify in medical malpractice action as to causation against radiologist where surgeon was knowledgeable through experience as to x-ray treatments); ***Christy v. Darr***, 467 A.2d 1362 ([Pa. Cmwlth.] 1983) (neurosurgeon qualified to testify on causation in personal injury cases where plaintiff suffered double vision and hearing loss despite objection that such testimony concerned problems outside neurosurgical specialty); ***Workmen's Compensation Appeal Board v. Jones E. Laughlin Steel Corp.***, 349 A.2d 793 ([Pa. Cmwlth.] 1975) (orthopedist permitted to testify to causation, and urological and psychological effects of fractured pelvis). The rationale behind the standards enunciated in these cases is that the qualified witness need only have a reasonable pretension to specialized knowledge; the standard is not set so high as to exclude the kind of testimony ordinarily available.

McDaniel v. Merck, Sharp & Dohme, 533 A.2d 436, 442 (Pa. Super. 1987).

Based on the foregoing, we conclude the trial court did not err in permitting Dr. Solomon to testify about the potential causes of gynecomastia. We agree with the trial court that it was within the province of the jury to weigh Dr. Solomon's testimony as a board certified plastic surgeon, against the testimony of Janssen's expert, an endocrinologist.[21] Thus, we conclude

[21] As discussed *supra*, both Dr. Solomon and Janssen's expert, Dr. Vaughn, agreed that Austin had gynecomastia. Their disagreement focused on whether the gynecomastia occurred prior to or after puberty.

that Janssen is not entitled to relief on the basis that the trial court erred in qualifying Dr. Solomon as an expert in this case.

We next consider Janssen's contention that Dr. Solomon's diagnosis of Austin having gynecomastia by looking at a 2005 photograph of him is not a generally accepted method of diagnosis pursuant to ***Grady*** and ***Frye***. ***See*** Janssen's Brief at 33-34. Here, Janssen contends that Dr. Solomon's causation opinion should have been excluded pursuant to Pa.R.E. 702, which provides the following.

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge is beyond that possessed by the average layperson;
>
> (b) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; and
>
> (c) the expert's methodology is generally accepted in the relevant field.

Pa.R.E. 702.

Our review of the record reveals that despite Janssen's attempt to characterize Dr. Solomon's testimony otherwise, Dr. Solomon indeed relied on several factors, including a differential diagnosis, in concluding Austin had gynecomastia in 2002. Specifically, Dr. Solomon testified that Mrs. Pledger provided history about when "she first saw breast development," ***see*** N.T., 2/9/2015 (a.m.), at 86; he viewed the 2005 photograph, ***id***.; and he ruled

out other conditions which cause gynecomastia, such as Klinefelter's syndrome, ***id***. at 93. Dr. Solomon testified that he performed a "differential diagnosis" to "narrow down" other causes. ***Id***. at 101. Dr. Solomon expounded:

> So in putting together a picture of Austin [], I took a history. Part of that history was what things was he exposed to that might cause this condition. So in his history, to be brief, the only thing he was exposed to that would cause the condition in the time frame that it was described to me and in the time frame as evidenced by the photographs is Risperdal. That's number one.
>
> Number two, he has no evidence of any of the other causative factors of gynecomastia, such as – we briefly mentioned – Klinefelter's syndrome, which is a chromosomal abnormality, that he does not have. He does not have thyroid disease. He does not have – he's not an alcoholic and doesn't have alcoholic liver disease. He doesn't have a pituitary tumor, from which I can establish. He doesn't have any of the other – he doesn't have any testicular tumors because I examined his testicles. So he doesn't have any of the other major groups of conditions that can cause gynecomastia.

Id. at 103.

As we did in ***Stange***, we conclude that Dr. Solomon's methodology was not novel, and indeed is a generally accepted methodology in the medical community. Further, "Janssen's arguments really go to weight and not admissibility." ***Stange***, 179 A.3d at 56. Accordingly, we conclude that Janssen is not entitled to relief on this basis.

Finally, with respect to Dr. Solomon, Janssen contends that it is entitled to a new trial "because the [trial] court wrongly denied defense counsel the

opportunity to use learned treatises to cross-examine Dr. Solomon." Janssen's Brief at 37.

> The law in this Commonwealth is well-settled that an expert witness may be cross-examined on the contents of a publication upon which he or she has relied in forming an opinion, and also with respect to **any other publication which the expert acknowledges to be a standard work in the field**. In such cases, the publication or literature is not admitted for the truth of the matter asserted, but only to challenge the credibility of the witness' opinion and the weight to be accorded thereto. Learned writings which are offered to prove the truth of the matters therein are hearsay and may not properly be admitted into evidence for consideration by the jury.

Majdic v. Cincinnati Mach. Co., 537 A.2d 334, 349 (Pa Super. 1988) (*en banc*) (emphasis added; citations omitted).

With this standard in mind, we analyze Janssen's cross-examination of Dr. Solomon. Dr. Solomon testified that he did not cite any medical literature in his expert report. ***See*** N.T., 2/9/2015 (p.m.), at 59. He further stated that "the incidence of prepubertal gynecomastia is zero. It should never occur." ***Id***. at 59-60. Then, counsel for Janssen sought to show Dr. Solomon "an article … by Dr. Bachar, Dr. Phillip, and Dr. Klippert and Dr. Lazar from Clinical Endocrinology, dated 2004, talking about prepubertal gynecomastia." ***Id***. at 60. Counsel for Janssen told the trial court that it "is a learned treatise from a respected journal." ***Id***. Thus, it wished to "cross-examine [Dr. Solomon] on it." ***Id***. Counsel for the Pledgers objected and stated that "[Dr. Solomon] needs to agree it's authoritative." ***Id***. at 61. Counsel for Janssen argued that

she could "authoritate [*sic*] it with [her] experts."[22] ***Id***. Further, when asked when he was aware of the article, Dr. Solomon responded that he had not read it. ***Id***. at 62.

Putting this exchange into the context of the law set forth *supra*, it is clear the trial court did not err by not permitting counsel for Janssen to cross-examine Dr. Solomon about this article. Dr. Solomon specifically stated he had not read the article. Moreover, counsel for Janssen never even asked Dr. Solomon whether the treatise or the article was a standard work in his field; rather, she continued to ask Dr. Solomon questions about the contents of the article to which counsel for the Pledgers objected. Janssen complains on appeal that this was error because "[e]xploring Dr. Solomon's total lack of knowledge of the relevant medical literature would have shown that he was unqualified to offer his causation opinion, and that the opinion failed to take into account studies contrary to his view." Janssen's Brief at 40.

Janssen is correct that this would have been fertile ground for cross-examination of Dr. Solomon; however, counsel did not ask any of these questions at trial. Per ***Majdic***, counsel could have asked Dr. Solomon about any treatise it wanted, so long as it also asked whether the treatise was a standard work in the field. However, counsel did not do that.[23] Accordingly,

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[22] Although it does not affect our conclusions *infra*, during trial, Janssen's experts did not testify about the authority of this article.

[23] Janssen also cites to its re-cross examination of Dr. Solomon where counsel asked Dr. Solomon if he was "familiar with the [g]overnment study that showed no relationship in autistic kids between prolactin levels on Risperdal

we conclude that the trial court did not err in any respect by not permitting Janssen to question Dr. Solomon on this learned treatise.

We now turn to Janssen's final issue on appeal, which is a challenge to the trial court's causation jury instruction. ***See*** Janssen's Brief at 44-49. Specifically, Janssen complains the trial "court failed to give a complete instruction on proximate causation under Alabama law." ***Id***. at 44. Janssen also contends that the trial court erred by giving a "concurrent causation" instruction. ***Id***. at 47.

We address these claims mindful of the following.

> Our standard of review regarding jury instructions is limited to determining whether the trial court committed a clear abuse of discretion or error of law which controlled the outcome of the case. Error in a charge occurs when the charge as a whole is inadequate or not clear or has a tendency to mislead or confuse rather than clarify a material issue. Conversely, a jury instruction will be upheld if it accurately reflects the law and is sufficient to guide the jury in its deliberations.
>
> The proper test is not whether certain portions or isolated excerpts taken out of context appear erroneous. We look to the charge in its entirety, against the background of the evidence in the particular case, to determine whether or not error was committed and whether that error was prejudicial to the complaining party.

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and gynecomastia." Janssen's Brief at 38; N.T., 2/9/2015 (p.m.), at 93. Counsel for the Pledgers objected, and counsel for Janssen again brought up the "learned treatise rule." ***Id***. However, after some discussion about whether the question was outside the scope of the Pledgers' re-direct examination, Dr. Solomon testified that he was indeed familiar with that study and answered questions about the study. ***See*** N.T., 2/9/2015 (p.m.), at 95-96. Thus, we conclude there was no error here.

> In other words, there is no right to have any particular form of instruction given; it is enough that the charge clearly and accurately explains the relevant law.

James v. Albert Einstein Med. Ctr., 170 A.3d 1156, 1163–64 (Pa. Super. 2017) (quoting ***Krepps v. Snyder***, 112 A.3d 1246, 1256 (Pa. Super. 2015) (citations and internal punctuation omitted)).

Here, Janssen contends the following instruction, given by the trial court in response to Janssen's closing argument,[24] was in error: "Now, this case is also not about something that was argued to you specifically by [Janssen], and that is whether a different warning would have caused a doctor not to prescribe. I will give you the law on this. But I want to say up front, that is not the law that we are examining in this case, okay?" N.T., 2/20/2015 (p.m.), at 18.

Janssen then takes issue with the trial court's explanation of the Alabama law applicable in this case. The trial court offered the following causation instruction:

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[24] In her closing argument, counsel for Janssen stated the following.

> So, the second question you are going to be asked to answer is: Do you find that Janssen's negligent failure to provide an adequate warning was the cause of Austin Pledger's gynecomastia?
>
> And there is [*sic*] a couple of parts to that the Judge is going to charge you. One part is would a different Warning have made a difference to Dr. Mathisen. And I am going to show you it wouldn't. Would a different Warning have changed his decision to prescribe.

N.T., 2/20/2015 (a.m.), at 99.

> You must decide whether Janssen's conduct caused Austin Pledger's harm. Janssen's conduct caused the harm if the conduct naturally and probably brought about the harm; and, two, the harm would not have happened without the conduct.
>
> The failure of a manufacturer to … provide the prescribing physician with an adequate warning of the risks associated with a prescription product is not the cause of the patient's injury if the prescribing physician has his own independent knowledge of the risks that should have been included in an adequate warning.
>
> In other words, if you find that the doctor was not given adequate warning, yet at the same time had independent knowledge on his own of the risk, then cause has not been shown.
>
> Now, the conduct of two or more persons, however, may cause harm. Two or more persons may cause harm in the sense of causation.
>
> Now, in this case you may find that Dr. Mathisen, though not named as a defendant here, engaged in wrongful conduct. If this is so, and you find that Janssen's negligence also caused injury to Austin Pledger, each is a cause of his harm, if it naturally and probably brings about the harm.
>
> The fact that Dr. Mathisen is not a defendant here does not relieve Janssen of responsibility for the harm if you find that Janssen's negligence caused [Austin] harm, all right? So that's causation.

N.T., 2/20/2015 (p.m.), at 38-39.

According to Janssen "[t]his statement is accurate but incomplete. The instruction did not describe [the Pledgers'] burden under Alabama law to prove that a different warning would have caused him to avoid injury." Janssen's Brief at 46. According to Janssen, "[t]his was particularly crucial here, where Dr. Mathisen never read the October 2006 labeling, and so could not have changed his prescribing decisions in response to additional risk information."

Id. Furthermore, Janssen suggests that the trial court should not have given the "concurrent causation" instruction at all because it is appropriate only "when 'an injury may have several concurrent proximate causes … including the actions of two or more tortfeasors, neither of whose action was sufficient in and of itself to produce the injury, who act, either together or independently, to produce it.'" ***Id***. at 47-48. Janssen suggests that since it did not contend that Dr. Mathisen was negligent and he did not appear on the verdict form, this instruction "left jurors with the misimpression that Dr. Mathisen's failure to read the labeling was irrelevant to [the Pledgers'] warning claim." ***Id***. at 48-49.

First, with respect to the combined or concurrent cause instruction, Janssen did not object to the trial court's including it at trial. ***See*** N.T., 2/19/2015 (p.m.), at 136-38. Thus, even though Janssen raised this issue in its post-trial motion, it failed to preserve this issue at trial, and it cannot raise it on appeal. ***See*** Pa.R.C.P. 227.1(b) Note ("If no objection is made, error which could have been corrected in pre-trial proceedings or during trial by timely objection may not constitute a ground for post-trial relief.").

Furthermore, upon our review of the jury instruction given by the trial court as a whole, we conclude there was no error. Janssen acknowledges that the instruction accurately reflected Alabama law. Moreover, we have already held that Janssen's arguments about Dr. Mathisen's failing to read the 2006 label prior to refilling Austin's prescription are without merit. The issue, as

reflected accurately in the jury instructions, was whether the information provided by Janssen to Dr. Mathisen in 2002 was adequate, and whether a different warning would have changed his prescribing behavior then. Based on the foregoing, we conclude that Janssen is not entitled to relief on the basis of its jury instruction issues.

Having concluded that Janssen has presented no issue on appeal entitling it to relief, we affirm the judgment as to Janssen.

Appeal of The Pledgers

The Pledgers have appealed from the July 11, 2014 order of the trial court, which granted summary judgment in favor of Janssen and against the Pledgers on the Pledgers' claim for punitive damages.[25] In granting Janssen's motion as to all plaintiffs involved in the Risperdal litigation, the trial court held the following: 1) "New Jersey had a greater interest than Pennsylvania in the application of its law on the issue of punitive damages," and 2) "the New Jersey Products Liability Act does not permit Plaintiffs to recover punitive damages." Trial Court Opinion, 10/22/2015, at 10.

This Court recently considered these issues in both ***Stange*** and ***Murray***. First, despite Janssen's arguments to the contrary in those cases, this Court concluded that the plaintiffs did not waive the issues and thus they are preserved on appeal. ***See Stange***, 179 A.3d at 64; ***Murray***, 180 A.3d at

[25] This was part of a global motion for summary judgment filed by Janssen against all plaintiffs in the Risperdal litigation. It was heard by the Honorable Arnold L. New. Judge New filed an opinion on October 22, 2015.

1248-49. Next, this Court concluded that there was a true conflict between New Jersey law and Wisconsin law (Stange's home state), ***see Stange***, 179 A.3d at 65, and between New Jersey law and Maryland law (Murray's home state), ***see Murray***, 180 A.3d at 1250. Then, this Court concluded that because "the trial court considered only whether New Jersey law or Pennsylvania law should apply, not the law of the individual plaintiff's home state," we were required to "remand for the trial court to consider conflict-of-law principles" with respect to New Jersey and the plaintiff's home state. ***See Stange***, 179 A.3d at 66-67; ***see also***, ***Murray***, 180 A.3d at 1251 (remanding "so that Mr. Murray may create an individual record pertaining to the distinct conflict-of-law principles at play in his particular case").

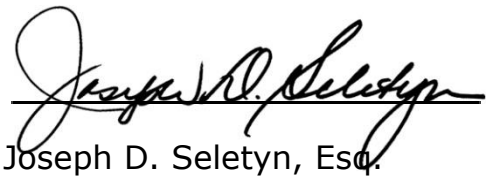
In this appeal, the Pledgers set forth the same arguments. ***See*** The Pledgers' Brief at 52-62 (arguing that there is a true conflict between New Jersey law and Alabama law regarding punitive damages and the trial court erred by concluding that New Jersey had a greater interest than Pennsylvania). Janssen sets forth the same counter-arguments. ***See*** Janssen's Reply Brief at 21-25 (arguing that the Pledgers waived this issue and development of an individualized record is unnecessary).

"[W]e have long held that as long as the decision has not been overturned by our Supreme Court, a decision by our Court remains binding precedent." ***Marks v. Nationwide Ins. Co.***, 762 A.2d 1098, 1101 (Pa. Super. 2000). Thus, as we did in ***Stange*** and ***Murray***, 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*** and ***Murray***.[26]

Judgment affirmed in part, reversed in part, and remanded for proceedings consistent with this opinion. Motion for leave to file post-submission communication denied as moot. Jurisdiction relinquished.

Judgment Entered.



Joseph D. Seletyn, Esq.
Prothonotary

Date: 10/31/18

[26] At oral argument, counsel for Janssen agreed that remand was appropriate.