Kenneth A. Murphy
kenneth.murphy@dbr.com
Attorney Identification No. 58162
Melissa A. Graff
melissa.graff@dbr.com
Attorney Identification No. 90363
Thomas F. Campion (admitted *pro hac vice*)
thomas.campion@dbr.com
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
Telephone: (215) 988-2700
Facsimile: (215) 988-2757

Diane P. Sullivan (admitted *pro hac vice*)
diane.sullivan@weil.com
Adam S. Tolin
adam.tolin@weil.com
Attorney Identification No. 91424
Allison M. Brown
allison.brown@weil.com
Attorney Identification No. 202227
WEIL, GOTSHAL & MANGES LLP
301 Carnegie Center, Suite 303
Princeton, NJ 08540
Telephone: (609) 986-1100
Facsimile: (212) 310-8007

Attorneys for Defendants
Janssen Pharmaceuticals, Inc.;
Johnson & Johnson; and
Janssen Research & Development, LLC

IN RE RISPERDAL® LITIGATION

P.P. *et al.*,

Plaintiffs,

v.

Janssen Pharmaceuticals, Inc.;
Johnson & Johnson;
Janssen Research & Development, LLC;
Excerpta Medica, Inc.; and
Elsevier Inc.,

Defendants.

PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION

APRIL TERM 2012
NO. 1997

DEFENDANTS JANSSEN PHARMACEUTICALS, INC.; JOHNSON & JOHNSON; AND JANSSEN RESEARCH & DEVELOPMENT, LLC'S
MOTIONS FOR POST-TRIAL RELIEF PURSUANT TO PA.R.C.P. NO. 227.1

Defendants Janssen Pharmaceuticals, Inc.; Johnson & Johnson; and Janssen Research & Development, LLC (collectively, "Janssen"), by and through their undersigned counsel, respectfully move this Court, pursuant to Rule 227.1 of the Pennsylvania Rules of Civil Procedure, for the entry of an order granting judgment notwithstanding the verdict or, in the alternative, granting a new trial on the claim tried or modification of the verdict and remittitur on damages awarded. In support of this Motion, Janssen relies on the testimony, documents, court submissions, legal arguments, and memoranda that were addressed during pre-trial and trial proceedings and in argument by Janssen, and further states:

I. PROCEDURAL HISTORY

1. On April 18, 2012, Plaintiff Benita Pledger, on behalf of herself and her then minor son, Austin Pledger, commenced this action by filing an Abbreviated Individual Complaint for Risperdal Litigation and Adoption by Reference ("Short-Form Complaint"), which alleged that Janssen failed to provide an adequate warning as to certain purported risks associated with use of Risperdal, a prescription medicine approved by the federal Food and Drug Administration ("FDA").

2. In particular, Plaintiffs alleged that Janssen failed to warn them and Mr. Pledger's prescribing physician, Jan Mathisen, M.D., about certain purported risks associated with Risperdal that caused Mr. Pledger's alleged gynecomastia and weight gain. Plaintiffs pleaded various theories and counts, including negligence, negligence – design defect, fraud, strict product liability – failure to warn, strict product liability – design defect, breach of express and implied warranties, violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, violation of Alabama's unfair and deceptive trade practices act, conspiracy, medical expenses incurred by parent, loss of consortium, and punitive damages. *Id.*

3. In an Order dated July 11, 2014, this Court granted in part Janssen's Motion for Summary Judgment, dismissing all of Plaintiffs' claims except for the negligent failure-to-warn claim.

4. Accordingly, the only claim presented at trial and submitted to the jury was the negligent failure-to-warn claim.

5. Trial commenced on January 23, 2015. At the close of Plaintiffs' case-in-chief on February 9, 2015, Janssen presented an oral motion for compulsory nonsuit, which the Court denied. On February 10, 2015, Janssen filed a brief in support of its motion for compulsory nonsuit.

6. At the close of all the evidence on February 19, 2015, Janssen presented an oral and Johnson & Johnson and Janssen Research & Development, LLC presented a written motion for directed verdict, which the Court also denied.

7. On February 24, 2015, the jury returned a verdict finding that Janssen was negligent in failing to provide an adequate warning to Dr. Mathisen, Mr. Pledger's prescribing physician, of the risk of gynecomastia associated with Risperdal use and that Janssen's negligent failure to provide adequate warnings was a cause of Mr. Pledger's injuries. The jury awarded compensatory damages in the amount of $2.5 million. *Id.*

II. LEGAL STANDARDS

A. Judgment Notwithstanding the Verdict Pursuant to Pa.R.C.P. No. 227.1(a)(2)

8. In ruling on a motion for judgment notwithstanding the verdict, the evidence must be considered in the light most favorable to the verdict winner. *Moure v. Raeuchle*, 604 A.2d 1003, 1007 (Pa. 1992) (citing *Broxie v. Household Fin. Co.*, 372 A.2d 741, 745 (Pa. 1977)); *Griffin v. Univ. of Pittsburgh Med. Ctr.-Braddock Hosp.*, 950 A.2d 996, 999 (Pa. Super. 2008) (citing *Buckley v. Exodus Transit & Storage Corp.*, 744 A.2d 298, 304-05 (Pa. Super. 1999)).

9. A judgment notwithstanding the verdict may be entered on two bases: "(1) where the movant is entitled to judgment as a matter of law; and/or, (2) the evidence was such that no two reasonable minds could disagree that the verdict should have been rendered for the movant." *Griffin*, 950 A.2d at 999 (quoting *Buckley*, 744 A.2d at 304); *accord Moure*, 604 A.2d at 1007; *Simon v. Wyeth Pharm., Inc.*, 989 A.2d 356, 365 (Pa. Super. 2009).

10. On the first basis, the Court reviews the record to determine whether, making all factual inferences adverse to the movant, the law nonetheless requires a verdict in the movant's favor. *Moure*, 604 A.2d at 1007. On the second basis, the Court reviews the evidentiary record to determine whether the evidence makes a verdict for the movant "beyond peradventure." *Id*.

B. <u>New Trial Pursuant to Pa.R.C.P. No. 227.1(a)(1)</u>

11. A new trial "is warranted to achieve justice in those instances where the original trial was tainted, unfair, or marred by error." *Klaus v. Kirkland*, 16 Pa. D. & C.5th 1, 12 (Phila. Cnty. Ct. Com. Pl. 2010) (citing *Harman v. Borah*, 756 A.2d 1116, 1121 (Pa. 2000)). There is a "two-step process that a trial court must follow when responding to a request for a new trial." *Lockley v. CSX Transp. Inc.*, 5 A.3d 383, 388 (Pa. Super. 2010).

> First, the trial court must decide whether one or more mistakes occurred at trial. These mistakes might involve factual, legal, or discretionary matters. Second, if the trial court concludes that a mistake (or mistakes) occurred, it must determine whether the mistake was a sufficient basis for granting a new trial. . . .

Id. (citation omitted).

12. To obtain a new trial, "the moving party must demonstrate to the trial court that he or she has suffered prejudice from the mistake" or mistakes. *Id.* (citation omitted). A new trial is appropriate even if the trial court has taken "affirmative steps to attempt to cure harm" following an objection when "no curative instruction can adequately obliterate the taint." *Siegal v. Stefanyszyn*, 718 A.2d 1274, 1277 (Pa. Super. 1998).

13. Further, the law must be "clearly and accurately" conveyed to the jury. *Cooper v. Lankenau Hosp.*, 51 A.3d 183, 185 (Pa. 2012); *King v. W.A. Brown & Sons, Inc.*, 585 So. 2d 10, 12 (Ala. 1991) ("[A] party is entitled to proper jury instructions regarding the issues presented . . . ." (internal quotation marks omitted) (citation omitted)). "Where the trial court's jury instructions are at issue, a new trial is appropriate where the instructions were fundamentally in error and might have been responsible for the verdict." *O'Brien v. Martin*, 638 A.2d 247, 248 (Pa. Super. 1994) (citation omitted). "A jury charge must be 'clear and precise and so couched as not to confuse the jury,'" and a new trial is called for when an "omission by the trial court may have confused and misled the jury in such a way as to have been prejudicial." *Murphy v. Cartex Corp*., 546 A.2d 1217, 1221 (Pa. Super. 1988) (citations omitted).

C. Modification of the Verdict Pursuant to Pa.R.C.P. No. 227.1(a)(4)

14. Remittitur is appropriate "in those cases where the court can clearly see that the verdict has been reached on account of bias, passion, prejudice, corruption, or other improper motive or cause." *Aspinwall v. Gowens*, 405 So. 2d 134, 137 (Ala. 1981).

15. Although the courts give "great deference to the jury's award of compensatory damages for mental anguish, we have not hesitated to remit such damages where the plaintiff has produced little or no evidence indicating that he has suffered such mental anguish." *Slack v. Stream*, 988 So. 2d 516, 532 (Ala. 2008) (citation omitted).

III. GROUNDS FOR POST-TRIAL RELIEF

A. Janssen is Entitled to Judgment Notwithstanding the Verdict, or in the Alternative, a New Trial, Because Mr. Pledger Failed to Prove Causation.

16. A plaintiff must prove both medical (factual) causation and warnings (proximate) causation to establish a prima facie case of a negligent failure-to-warn claim. *See, e.g.*, *Tidwell v. Upjohn Co.*, 626 So. 2d 1297, 1300 (Ala. 1993) (recognizing that to establish medical

causation the plaintiff must offer evidence that his treatment with the subject medicine caused his injuries); *Barnhill v. Teva Pharm. USA, Inc.*, 819 F. Supp. 2d 1254, 1262 (S.D. Ala. 2011) (defining warnings causation: "The burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff.").

1. Janssen is entitled to judgment notwithstanding the verdict because Mr. Pledger failed to prove that Risperdal caused his alleged injuries.

Places of Preservation of the Record: Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC's Motion for Compulsory Nonsuit, Feb. 10, 2015 (Control No. 15021476), at 5-10; Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC's Motion to Exclude the Testimony of Mark P. Solomon, M.D., Feb. 9, 2015 (Control No. 15021115); Janssen Pharm., Inc.'s Answer to Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Johnson & Johnson's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Janssen Research & Dev., LLC's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Examples from Trial Listed Below.

17. To establish medical causation, an expert must consider and rule out other possible causes. *See In re Harriett Cooper v. Diversey Corp. (Ex parte Diversey Corp.)*, 742 So. 2d 1250, 1255 (Ala. 1999) (affirming summary judgment where the plaintiff's "theory of causation [was] just as consistent with the theory that sodium hypochlorite caused [plaintiff's] injuries as it [was] with the theory that one or more of [defendant's] products caused her injuries").

18. An expert's opinion must also meet a minimum threshold of demonstrating that it is supported by some scientific authority. *See Snizavich v. Rohm & Haas Co.*, 83 A.3d 191, 197 (Pa. Super. 2013) ("The exercise of scientific expertise requires inclusion of scientific authority and application of the authority to the specific facts at hand. Thus, the minimal threshold that

expert testimony must meet to qualify as an expert opinion rather than merely an opinion expressed by an expert, is this: the proffered expert testimony must point to, rely on or cite some scientific authority – whether facts, empirical studies, or the expert's own research – that the expert has applied to the facts at hand and which supports the expert's ultimate conclusion."). When an expert fails to meet this threshold, "the trial court has no choice but to conclude that the expert opinion reflects nothing more than mere personal belief." *Id.*

19. In addition, the expert's methodology must be generally accepted, and the expert must utilize the methodology in a generally accepted manner. *See, e.g.*, *Trach v. Fellin*, 817 A.2d 1102, 1114 (Pa. Super. 2003).

20. Dr. Solomon, Plaintiffs' medical causation expert, opined that Risperdal causes gynecomastia generally and that Risperdal caused Mr. Pledger's gynecomastia specifically. *See, e.g.*, Tr. 104:19-24, 2/9/15 (a.m.) ("Risperdal is a drug that among its side effects, it's a stimulant – or it's a potent stimulant of elevations of prolactin which is this hormone that we talked about briefly that's secreted by the pituitary gland and acts on the breast tissue."); *id.* at 104:25-105:13 ("He was exposed to this drug at the age of 8. . . . I have no reason not to think it occurred because of my knowledge of the drug, and therefore, it stimulated his breasts to grow.").

21. These opinions do not satisfy the *Frye* standards of admissibility or the substantive requirements of Alabama law to establish medical causation.

22. For example, Dr. Solomon did not demonstrate that his opinion that Risperdal caused gynecomastia – let alone prepubertal gynecomastia – or that prolactin "acts on the breast tissue" was supported by any scientific authority. A review of his testimony shows that his opinion is entirely *ipse dixit*. *See, e.g.*, Tr. 60:4-8, 2/9/15 (p.m.) ("So what I relied upon was my knowledge as a practicing physician, that among the agents that can cause gynecomastia are

drugs and that among the drugs is Risperdal. And it really comes down to that fact. So that's what I have done, counsel.").

23. Dr. Solomon also failed to consider and rule out other possible causes of prepubertal gynecomastia in rendering his opinion that Risperdal caused Mr. Pledger's gynecomastia. Although he identified tumors, medications, and chromosomal abnormalities as potential causes of prepubertal gynecomastia, *see, e.g.*, Tr. 103:23-24, 2/9/15 (a.m.), he failed to consider and rule out obesity as a potential cause of Mr. Pledger's gynecomastia. Dr. Solomon testified that he has seen the literature that discusses the fact that obesity can cause gynecomastia. Tr. 54:14-24, 2/9/15 (p.m.); *see id.* at 49:21-50:14 (referencing Dr. Solomon's book, which discusses pubertal gynecomastia and gynecomastia from obesity). He also testified that Mr. Pledger was overweight throughout his life. *Id.* at 22:14-17, 25:5-8, 26:9-12. Further, Dr. Solomon testified that Mr. Pledger had fatty tissue in his breasts. *Id.* at 13:23-14:3. Despite acknowledging that obesity can cause gynecomastia, Dr. Solomon testified that during his examination of Mr. Pledger, he did not do anything to quantify the amount of fatty tissue in Mr. Pledger's breasts, and he did not definitively state whether he ruled out obesity as a cause of Mr. Pledger's gynecomastia. *Id.* at 14:4-12.

24. Dr. Solomon's conclusion that Mr. Pledger developed gynecomastia shortly after he began taking Risperdal lacked any medical record support. First, Mr. Pledger had a normal prolactin level at the time he transitioned off of Risperdal and onto other drugs, which themselves had some risk of gynecomastia. Second, despite seeing his pediatrician and his neurologist during the time he was on Risperdal, Mr. Pledger was not diagnosed with gynecomastia until much later. Nevertheless, Dr. Solomon was very specific in his dating of the onset of gynecomastia, based wholly on a discussion with Mr. Pledger's mother, a 2005

photograph, and his sense that "you don't go from zero to 60 like that." Tr. 86:16-22, 96:19-20, 2/9/15 (a.m.).

25. Plaintiffs' failure to present the required expert testimony on the issue of medical causation warrants judgment in favor of Janssen as a matter of law. As such, Janssen is entitled to judgment notwithstanding the verdict because Plaintiffs have not met their burden of establishing that Risperdal caused Mr. Pledger's injuries.

2. In the alternative, Janssen is entitled to a new trial on the issue of medical causation.

Places of Preservation of the Record: Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC's Motion for Compulsory Nonsuit, Feb. 10, 2015 (Control No. 15021476), at 5-10; Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC's Motion to Exclude the Testimony of Mark P. Solomon, M.D., Feb. 9, 2015 (Control No. 15021115); Janssen Pharm., Inc.'s Answer to Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Johnson & Johnson's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Janssen Research & Dev., LLC's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Proposed Points for Charge, No. 24, Feb. 17, 2015; Defs. Janssen Pharm. Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Proposed Verdict Form at 4, July 14, 2014; Examples from Trial listed below.

26. Even if Dr. Solomon's testimony were sufficient for the question to be submitted to the jury, which Janssen contends it is not, Janssen is entitled to a new trial because the Court: (1) improperly limited the scope of Janssen's cross-examination, (2) refused to charge the jury on medical causation, and (3) refused to include separate interrogatories on the verdict sheet as to whether Risperdal was the medical cause of Mr. Pledger's injuries. *See Cooper*, 51 A.3d at 185 (holding that the charge, taken as a whole, must "clearly and accurately" convey the law to the

jury); *King*, 585 So. 2d at 12 ("[A] party is entitled to proper jury instructions regarding the issues presented . . . ." (internal quotation marks omitted) (citations omitted)).

27. Moreover, appearing to rely on *Aldridge v. Edmunds*, 750 A.2d 292 (Pa. 2000), the Court prevented Janssen from cross-examining Dr. Solomon with scientific authority that would undermine his position. *See, e.g.*, Tr. 60:9-63:2 (p.m.). *Aldridge*, however, addresses the use of learned treatises in the *direct* examination, and it cites with approval the case of *Cummings v. Borough of Nazareth*, 242 A.2d 460, 466 (Pa. 1968) (plurality op.), which stated that "[i]t is entirely proper in examination and cross-examination for counsel to call the witness's attention to published works on the matter which is the subject of the witness's testimony." Janssen should not have been so limited in its cross examination of Dr. Solomon.

28. As stated above, to prevail under Alabama law, a plaintiff must offer evidence that his treatment with the subject medicine caused his injuries. *See, e.g.*, *Tidwell*, 626 So. 2d at 1299.

29. Defendants proffered the following charge on medical causation:

> You must decide whether the defendant's conduct caused Plaintiffs' harm. Thus, Plaintiff must prove that Defendants' failure to warn about the risk of gynecomastia associated with the use of Risperdal caused Mr. Pledger to develop gynecomastia.
>
> The conduct caused the harm if (1) the conduct naturally and probably brought about the harm and (2) the harm would have happened without the conduct. In order for Plaintiff to recover in this case, he must first show that Risperdal was the factual cause of his gynecomastia.

Ex. A, Defs. Janssen Pharm. Inc.; Johnson & Johnson; and Janssen Research & Development, LLC's Proposed Points for Charge, No. 24, dated Feb. 17, 2015.[1]

[1] Although this document is part of the Court's record, we attach it for convenience because it is not yet on the docket.

30. On July 14, 2014, Janssen submitted its proposed verdict form, which included the following question:

> Have Plaintiffs proven by a preponderance of the evidence that Risperdal was the factual cause of Mr. Pledger's gynecomastia?

31. The Court did not give a charge on medical causation. Instead, the Court said only:

> 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 prescribe the – to provide the prescribing physician with an adequate warning of the risks associated with a prescription product is not a 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.

Tr. 38:8-39:1, 2/20/15 (p.m.).

32. The Court also refused to include an interrogatory on the verdict sheet about medical causation. *See* Tr. 145:9-146:25, 2/19/15 (p.m.).

33. The Court's refusal to instruct the jury on medical causation and to include an interrogatory on the verdict sheet about medical causation, Tr. 145:9-147:1, 2/19/15 (p.m.); Proposed Point for Charge No. 24, fundamentally mischaracterized the law that applied and warrants a new trial of this matter. *See Vaughn v. Phila. Transp. Co.*, 209 A.2d 279, 282 (Pa. 1965) ("It is fundamental that the primary duty of a trial judge is clearly and correctly to define the issues to be resolved by the jury . . . . How could the jury possibly understand the issues to be determined, when the duty of the defendant involved was defined only in an incorrect

manner?"); *Gorman v. Costello*, 929 A.2d 1208, 1212 (Pa. Super. 2007) ("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."); *Price v. Guy*, 735 A.2d 668, 670-71 (Pa. 1999) ("Error will be found where the jury was probably misled by what the trial judge charged or where there was an omission in the charge which amounts to fundamental error." (footnote omitted)); *see also King*, 585 So. 2d at 12 (Ala. 1991) ("[A] party is entitled to proper jury instructions regarding the issues presented . . . ." (internal quotation marks omitted) (citations omitted)).

3. Janssen is entitled to judgment as a matter of law because Plaintiffs failed to show that Dr. Mathisen would have decided not to prescribe Risperdal if the 2006 warning had been on the 2002 label.

Places of Preservation of the Record: Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC's Motion for Compulsory Nonsuit, Feb. 10, 2015 (Control No. 15021476), at 2-5, 10-17; Motion for Summ. J. of Janssen Pharm., Inc, Johnson & Johnson, and Janssen Research & Dev., LLC, April 21, 2014 (Control No. 14042847), at 25-30; Oral Motion for Directed Verdict at Tr. 14:8-15:6, 2/9/15 (p.m.); Janssen Pharm., Inc.'s Answer to Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Johnson & Johnson's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Janssen Research & Dev., LLC's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Examples from Trial Listed Below.

34. Alabama recognizes the learned intermediary doctrine. *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984). Under this doctrine, the manufacturer's duty to warn "'is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use.'" *Stone*, 447 So. 2d at 1304 (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1264 (5th Cir. 1974)); s*ee also Wyeth, Inc. v. Weeks*, --- So. 3d ---, No. 1101397, 2014 Ala. LEXIS 109, at *57 (Ala. Aug. 15, 2014) ("A prescription-drug

manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug.").

35. To succeed on a negligent failure-to-warn claim, in addition to establishing that a label is inadequate, a plaintiff must show "that the manufacturer failed to warn the physician of a risk *not otherwise known to the physician* and that the failure to warn was the actual and proximate cause of the patient's injury. In short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient." *Wyeth, Inc.*, 2014 Ala. LEXIS 109, at *57 (emphasis added).

36. Moreover, the plaintiff must present substantial evidence that his prescribing physician would have actually read and heeded a different warning. *Deere & Co. v. Grose*, 586 So. 2d 196, 198 (Ala. 1991) ("[A] negligent-failure-to-warn-adequately case should not be submitted to the jury unless there is substantial evidence that an adequate warning would have been read and heeded and would have prevented the accident."); *see also Barnhill*, 819 F. Supp. 2d at 1262 ("The burden remains on the plaintiff to demonstrate that the additional non-disclosed risk was sufficiently high that it would have changed the treating physician's decision to prescribe the product for the plaintiff.").

37. Plaintiffs cannot meet their burden because Dr. Mathisen testified that he was aware of the potential side effects of elevated prolactin and weight gain at the time he prescribed Risperdal to Mr. Pledger.

38. Dr. Mathisen had been prescribing Risperdal for at least four years prior to first seeing Mr. Pledger, and he was familiar with Risperdal's risk profile. Tr. 44:6-11, 114:15-21, 1/26/15 (p.m.). In particular, Dr. Mathisen testified that he was well aware, in 2002, that Risperdal, like other antipsychotics, could elevate prolactin and potentially cause

prolactin-related side effects like gynecomastia. *Id.* at 121:4-122:7, 122:8-15, 123:18-124:5. In fact, he stated that it was pretty well known for decades that higher prolactin levels in the body can cause gynecomastia. *Id.* at 124:6-19. He also agreed that the 2002 label discussed the risk of gynecomastia with respect to adults, and he was aware that because the label indicated risks with adults there might be an increased risk with children because they are smaller. *Id.* at 116:25-117:6, 117:24-118:16, 125:25-127:9.

39. Further, Dr. Mathisen stated that the risk of weight gain was always in the label and that he was aware of this risk. In fact, the risk of weight gain was one of his primary concerns. *Id.* at 142:18-25.

40. Even though he recognized these risks, Dr. Mathisen continued to prescribe Risperdal to Mr. Pledger because it was the best option available. *Id.* at 127:10-13, 149:15-150:12.

41. Because Dr. Mathisen was aware of the risks of weight gain and gynecomastia before he began prescribing Risperdal to Mr. Pledger, any alleged failure to warn cannot be the proximate cause of Mr. Pledger's injuries.

42. In October 2006, Dr. Mathisen received the revised Risperdal label, which included FDA-approved warnings about Risperdal use in pediatric patients with autism. *Id.* at 179:12-17. The warnings in the label included that Risperdal elevates prolactin more than other antipsychotics and that 2.3% of children and adolescents in clinical trials experienced gynecomastia. *See* Trial Ex. P-9, Oct. 2006 Risperdal Label at 3-4. Dr. Mathisen continued to prescribe Risperdal to Mr. Pledger after receiving this warning. Tr. 178:21-179:17, 184:6-8, 190:9-13, 191:7-9, 216:6-10, 1/26/15 (p.m.); *see also* Trial Ex. D-11, WalMart Pharmacy Records. He did not change his warning to Ms. Pledger. Tr. 180:23-181:8, 1/26/15 (p.m.). In

fact, he views the rate of gynecomastia in children and adolescents as a "small" risk." *Id.* He continues to prescribe Risperdal to patients with autism today. *Id.* at 193:25-194:7. Because Dr. Mathisen continued to prescribe Risperdal to Mr. Pledger and did not change his prescribing decision after receiving an adequate warning, Plaintiffs cannot meet their burden of showing that Dr. Mathisen would have changed his actions had he received the warning Plaintiffs contend he should have received.

43. Plaintiffs failed to put forth any evidence to establish that Dr. Mathisen would have read and heeded an adequate warning and the only record evidence is to the contrary. Dr. Mathisen testified that he does not even read revised pharmaceutical labels, even if the drug was just approved for a new indication, because he assumes that FDA approval means the drug is safe and effective. Tr. 97:21-98:3, 1/26/15 (p.m.). When discussing the October 2006 label, Dr. Mathisen stated that when a drug is approved for a new indication he "would not necessarily have gone through every wording of the label." *Id.* at 170:20-171:24. Instead, he testified that he probably would "look at the very first part of" the updated label and not "necessarily look at every little detail embedded in the body of the label . . . ." *Id.* Further, he stated that he "may not have personally looked" at information in the Precautions section of the label, and he may have done a "quick overview" without actually reading the label. *Id.* at 175:15-21, 185:22-186:3. Because Dr. Mathisen did not read revised pharmaceutical labels, even if Plaintiffs could show that the 2002 label was inadequate or that the 2006 label should have been approved earlier, they cannot meet their burden of showing that Dr. Mathisen would have actually read a different warning.

44. More importantly, even if Plaintiffs could establish that Dr. Mathisen read revised Risperdal labels, Plaintiffs have not set forth any evidence to establish that Dr. Mathisen would

have changed his decision to prescribe Risperdal to Mr. Pledger if he was provided an adequate warning. In fact, Dr. Mathisen's testimony establishes that after he received the revised October 2006 warning, which Plaintiffs concede was adequate, he continued to prescribe Risperdal to Mr. Pledger.

45. Because Dr. Mathisen had knowledge of the risks about which Plaintiffs complain and he did not testify that he would not have prescribed Risperdal for Mr. Pledger, judgment as a matter of law is appropriate, and judgment notwithstanding the jury's verdict is warranted.

4. In the alternative, Janssen is entitled to a new trial on the issue of warnings causation.

Places of Preservation of the Record: Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC's Motion for Compulsory Nonsuit, Feb. 10, 2015 (Control No. 15021476), at 2-5, 10-17; Motion for Summ. J. of Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC, April 21, 2014 (Control No. 14042847), 25-30; Oral Motion for Directed Verdict at Tr. 14:8-15:6, 2/9/15 (p.m.); Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Proposed Points for Charge, No. 24, Feb. 17, 2015; Defs. Janssen Pharm. Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Proposed Verdict Form at 4, July 14, 2014; Janssen Pharm., Inc.'s Answer to Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Johnson & Johnson's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Janssen Research & Dev., LLC's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. No. 27; Examples from Trial Listed Below.

46. Even if Dr. Mathisen's testimony were sufficient for the question to be submitted to the jury, which Defendants contend that it is not, Janssen is entitled to a new trial because the Court gave erroneous, inadequate, unclear and/or confusing instructions and jury interrogatories on as to the issue of warnings causation. *See Cooper*, 51 A.3d at 185 (holding that the charge, taken as a whole, must "clearly and accurately" convey the law to the jury); *King*, 585 So. 2d at 12 ("[A] party is entitled to proper jury instructions regarding the issues presented, and an

incorrect or misleading charge may the basis for the granting of a new trial." (internal quotation marks omitted) (citations omitted)).

47. As previously stated, it was Mr. Pledger's burden to establish that Dr. Mathisen would have actually read and heeded a different warning. *Deere*, 586 So. 2d at 198 ("[A] negligent-failure-to-warn-adequately case should not be submitted to the jury unless there is substantial evidence that an adequate warning would have been read and heeded and would have prevented this accident."); *Demmler*, 671 A.2d at 1155 (affirming summary judgment where "the record [was] devoid of any evidence that a different warning would have altered [the plaintiff's] use of [the medication] in accordance with [the prescribing physician's instructions]").

48. During the charging conference, Janssen repeatedly asked for a warnings causation charge that would have clearly and accurately instructed the jury that Plaintiffs had to prove that if Defendants had provided different information to Dr. Mathisen, he would not have prescribed Risperdal to Mr. Pledger and the injury would have been avoided. Janssen also requested a separate interrogatory on the verdict form that addressed this issue. *See* Tr. 114:18-122:8, 124:25-128:6, 145:9-147:1, 2/ 19/15 (p.m.); Janssen's Proposed Points for Charge at No. 24, July 14, 2014; Janssen's Proposed Verdict Form, July 14, 2014; Ex. B, Janssen's Bench Memorandum Regarding Pl.'s Duty to Show Proximate Cause;[2] *see also* Tr. 4:9-5:20, 2/20/15 (a.m.).

49. Despite Janssen's efforts, the Court did not charge the jury properly on the issue of warnings causation. The Court instructed the jury:

> 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

[2] Although this document is part of the Court's record, we attach it for convenience because it is not yet on the docket.

> would not have happened without the conduct. The failure of a manufacturer to prescribe the – to provide the prescribing physician with an adequate warning of the risks associated with a prescription product is not a 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.

Tr. 38:8-39:1, 2/20/15 (p.m.); *see also id.* at 50:1-19; 51:22-52:1 (Janssen's objections to charge).

50. This charge completely ignores the fact that Mr. Pledger had the burden of putting forth evidence to establish that if Dr. Mathisen had been provided with what Mr. Pledger identifies as an adequate waning then he would have decided not to prescribe the medicine and the injury would have thereby been avoided.

51. This error was compounded by the Court's telling the jury, prior to the charge, to disregard Ms. Sullivan's accurate statement of Alabama law. The Court stated: "Now, this case is also not about something that was argued to you specifically by Ms. Sullivan, 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?" *Id.* at 18:1-8 (addressing closing argument, Tr. 111:12-20, 2/19/15 (a.m.)).[3]

52. In addition, although Janssen requested a verdict sheet that included separate interrogatories on whether the warning caused Mr. Pledger's injuries, Ex. _, Defs. Janssen

[3] Curiously, earlier in the trial, the Court had stated just the opposite. For example, the Court stated "the problem with this case is, again, that in order to prove an adequate Warning it has to be adequate to make the doctor change his decision." Tr. 61:18-25, 2/20/15 (a.m.). *See also* Tr. 127:22-128:6, 1/23/15 (p.m.) ("The causation in this case is would the doctor involved here have changed his prescription had he known of something."); Tr. 16:23-17:9, 1/26/15 (a.m.) ("[W]hat the additional Warning would have done to the treating physician's thought process or prescription is the core of the case."). In fact, Plaintiffs recognized the need to prove that the doctor would have read and heeded a different warning. *See* Tr. 24:15-24, 1/26/15 (a.m.) ("[T]his doctor is prepared to say if I knew that information I would have acted different, and I need to tie the case to the treating doctor, and I plan to ask him if he knew this would it have made a difference.").

Pharm. Inc.; Johnson & Johnson; and Janssen Research & Development, LLC's Proposed Verdict Form at 4-5, dated July 14, 2014 ("Have Plaintiffs proven by a preponderance of the evidence that Risperdal was the factual cause of Mr. Pledger's gynecomastia?"), the verdict form failed to set forth a separate interrogatory as to the issue of proximate causation. With respect to causation, the verdict form simply stated: "Do you find that Janssen's negligent failure to provide an adequate warning was a cause of Austin Pledger's gynecomastia." *See* Verdict Form.

53. The repeated conflation of the role of the doctor and the role of the patient in a negligent failure-to-warn case only led to additional confusion about warnings causation. On numerous occasions, Plaintiffs muddied the water by improperly suggesting that Janssen had a duty to warn Mr. Pledger's mother rather than Mr. Pledger's prescribing physician. *See, e.g.*, Tr. 26:10-16, 61:19-62:9, 1/23/15 (p.m.); Tr. 104:22-105:2, 1/26/15 (p.m.); Tr. 58:19-59:4, 64:13-67:11, 2/6/15 (a.m.); Tr. 53:7-18, 2/20/15 (a.m.). This simply is not the law, and the Court refused to issue a curative instruction. Tr. 57:25-58:22, 2/20/15 (a.m.); Tr. 50:24-51:13, 2/20/15 (p.m.).

54. The Court's own misapprehension of warnings causation was made clear in its discussion of concurrent causation:

> MR. MURPHY: Okay. So the first issue, Your Honor, had to do with the issue of learned intermediary and Dr. Mathisen. There is uncontroverted testimony, Your Honor, that Dr. Mathisen understood what the risks were associated with Risperdal; that he appreciated that there was an association between the medicine and the condition now complained of.
>
> THE COURT: Which is why I'm going to grant a concurrent cause instruction in my jury instruction, sir.
>
> Move on. That's denied.

Tr. 14:19-15:5, 2/19/15 (p.m.); *see also* Tr. 39:2-18, 2/20/15 (p.m.); *id.* at 49:19-50:5 (Janssen's objection to charge); Tr. 8:11-10:24, 22:6-24, 2/23/15. The law, however, plainly states that

Defendants cannot be liable for failure to warn the prescribing physician when he is aware of the very risks complained of and proceeds to prescribe the medicine. The Court seemingly acknowledged in the above exchange that Dr. Mathisen was so aware, but it believed this was cause for a concurrent causation instruction. It was not; it was cause for a directed verdict.

55. Indeed, the Supreme Court of Alabama has explained that concurrent causation 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." *Gen. Motors Corp. v. Edwards*, 482 So. 2d 1176, 1195 (Ala. 1985) (emphasis added) (citation omitted), *overruled on other grounds*, *Schwartz v. Volvo N. Am. Corp.*, 554 So. 2d 927 (Ala. 1989). Plaintiffs, though, never argued that the actions of Janssen or Dr. Mathisen, by themselves, was insufficient to produce the injury. *See* Tr. 8:15-17, 9:4-11, 2/23/15 (a.m.) ("Plaintiff's counsel referring to the concurrent causation charge as a "superseding intervening charge"). Superseding or intervening cause and concurrent cause, however, are not interchangeable, and the charge was therefore improper.

56. The impact of giving this erroneous instruction is apparent from the jurors' question during deliberations: "We need Judge's charge regarding Alabama and PA law as regards to Dr. Mathisen." Tr. 7:22-24, 2/23/15. Further compounding the error, the Court then instructed the jury again as to causation, including reading the charge as to concurrent causation. Tr. 8:11-10:24, 22:6-24, 2/23/15.

57. The foregoing errors in the Court's jury instructions and verdict form fundamentally mischaracterized the law that applied and warrant a new trial. *See Vaughn*, 209 A.2d at 281-82 ("It is fundamental that the primary duty of a trial judge is clearly and correctly

to define the issues to be resolved by the jury . . . . How could the jury possibly understand the issues to be determined, when the duty of the defendant involved was defined only in an incorrect manner?"); *Gorman*, 929 A.2d at 1212 ("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."); *Price*, 735 A.2d at 670-71 ("Error will be found where the jury was probably mislead by what the trial judge charged or where there was an omission in the charge which amounts to fundamental error." (footnote omitted)).

B. Janssen Is Entitled to Judgment as a Matter of Law or, in the Alternative, a New Trial, Because Mr. Pledger Failed to Show – and the Court Failed to Instruct the Jury to Find – That Plaintiffs' Claim Was Preempted in Whole or in Part by Federal Law and Properly Subject to the Jurisdiction of the FDA.

1. Janssen is entitled to judgment as a matter of law because this Court does not have subject matter jurisdiction over this preempted claim.

Places of Preservation of the Record: Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC's Motion for Compulsory Nonsuit, Feb. 10, 2015 (Control No. 15021476), at at 17-18; Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Motion in Limine to Preclude Testimony by David A. Kessler, M.D. that Defendant Failed to Warn of a Serious Adverse Event, Jan. 27, 2015 (Control No. 15013128); Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Motion in Limine No. 15 to Preclude Plaintiffs from Introducing Argument, Evidence or Testimony that Gynecomastia is a Serious Adverse Event, Dec. 9, 2014 (Control No. 14121610); Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Proposed Points for Charge, Nos. 26-27, Feb. 17, 2015; Tr. 47:4-48:2, 2/20/15 (p.m.); Janssen Pharm., Inc.'s Answer to Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. Nos. 2, 16; Johnson & Johnson's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. Nos. 2, 16; Janssen Research & Dev., LLC's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. Nos. 2, 16; Examples from Trial Listed Below.

58. Impossibility preemption jurisprudence examines the interplay between, on the one hand, federal mandatory, permissive, and prohibitory statutes and, on the other, state tort law. Statutory construction presents questions of law for a court to resolve, and preemption questions are no different.[4] *E.g.*, *Yorty v. PJM Interconnection, L.L.C.*, 79 A.3d 655, 663 (Pa. Super. 2013). "Federal preemption is a jurisdictional matter for a state court because it challenges subject matter jurisdiction and the competence of the court to reach the merits of the claims raised." *Kiak v. Crown Equip. Corp.*, 989 A.2d 385, 390 (Pa. Super. 2010).

59. Under a long line of cases including, in particular, the three United States Supreme Court decisions of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), *Wyeth v. Levine*, 555 U.S. 555 (2009), and *PLIVA v. Mensing*, 564 U.S. ---, 131 S. Ct. 2567 (2011), Plaintiffs' claims were entirely preempted.

60. The relationship between the FDA and a pharmaceutical manufacturer is "inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Buckman*, 531 U.S. at 347.

61. It follows from that relationship that state tort law cannot interfere with the "somewhat delicate balance of statutory objectives" by using state tort law – or experts or juries – to define what amounts to fraud on the FDA. *Id*. at 348. Here, Plaintiffs repeatedly argued – and adduced testimony that suggested – that Janssen had not provided the required information to the FDA, or had not presented it in the form or at the time Plaintiffs believed it should have been submitted to the FDA. All of these are determinations that cannot be made under state tort

[4] Of course, there are times when factual questions arise. *E.g.*, *In re Reglan Litig.,* 72 A.3d 696, 706 (Pa. Super. 2013). When there is a factual question associated with preemption, that question goes to the factfinder. *See United Transp. Union v. Pa. Pub. Util. Comm'n*, 68 A.3d 1026, 1033 (Pa. Cmwlth. 2013).

law and Janssen proposed a jury instruction to this effect, but the Court rejected it. *See* Proposed Jury Instruction No. 27.

62. The circumstance that this case involves off-label use of a medicine does not change the law or preemption. "Off-label usage" (there, of a medical device), is "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman*, 531 U.S. at 351. The Court of Appeals for the Sixth Circuit has explained: "Off-label use does not violate federal law or FDA regulations because the FDA regulates the marketing and distribution of drugs in the United States, not the practice of medicine, which is the exclusive realm of individual states." *Planned Parenthood Cincinnati Region v. Strickland*, 531 F.3d 406, 408 (6th Cir. 2008).

63. A key element of the balance that the FDA has struck is to limit the communications that a pharmaceutical manufacturer can have with a doctor who is prescribing off-label. Thus, for example, Janssen could not provide information to doctors about off-label uses or side effects through labeling (a term defined by statute that is much broader than just a label), but it could distribute – as it did to Dr. Mathisen in 2002 – "authorized information" in the form of an "unabridged reprint or copy of an article peer-reviewed by experts" and "published in a scientific or medical journal" "about a clinical investigation with respect to the drug or device" "which would be considered to be scientifically sound by such experts;" or a reference publication. 21 U.S.C. § 360aaa-1 (2005); *see also* 21 U.S.C. § 321(m) (definitions). But because labeling must reflect approved uses, Janssen required the pre-approval of the FDA to provide the warnings Plaintiffs urge here. *Cf. Marcus v. Forest Labs., Inc*. (*In re Celexa & Lexapro Mktg. & Sales Practice Litig.*), No. 14-1290, 2015 U.S. App. LEXIS 2632, at *24 (1st Cir. Feb. 20, 2015) (applying *Wyeth* and *Mensing* and concluding: "Forest could not

independently change its label to read as plaintiffs say it should have read in order to comply with California law" and the claim was thus preempted).

64. A pharmaceutical manufacturer can call to the FDA's attention a prospective new use and seek permission to include that on the label (and Janssen did precisely that with Risperdal) or can ask to include other information on the label, but Janssen has no state-law duty to ask – or to ask differently or more frequently. *E.g.*, *In re Reglan Litig.*, 72 A.3d at 698 (recognizing that *Mensing* precludes state tort liability even where a manufacturer can "take steps to urge the FDA to change the warnings" at issue).

65. If the FDA has denied a manufacturer's request, there can be no state law duty to warn. *Wyeth*, 555 U.S. at 571. That happened here as well.

66. In sum, for a pharmaceutical manufacturer, there can be state law tort liability only for conduct that is either unregulated or that a manufacturer is permitted by federal law to undertake unilaterally. State law cannot define a company's liability for a failure to do what can be done only with FDA approval, *Mensing*, nor for what FDA has said cannot be done, *Wyeth*.

2. In the alternative, Janssen is entitled to a new trial on account of erroneous jury instructions and evidentiary rulings regarding preemption and/or the role of the FDA.

Places of Preservation of the Record: Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC's Motion for Compulsory Nonsuit, Feb. 10, 2015 (Control No. 15021476), at at 17-18; Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Motion in Limine to Preclude Testimony by David A. Kessler, M.D. that Defendant Failed to Warn of a Serious Adverse Event, Jan. 27, 2015 (Control No. 15013128); Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Motion in Limine No. 15 to Preclude Plaintiffs from Introducing Argument, Evidence or Testimony that Gynecomastia is a Serious Adverse Event, Dec. 9, 2014 (Control No. 14121610); Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Proposed Points for Charge, Nos. 26-27, Feb. 17, 2015; Tr. 47:4-48:2, 2/20/15 (p.m.); Janssen Pharm., Inc.'s Answer to Second Amended Master Long-Form Complaint and

New Matter, May 3, 2012, at Affirm. Def. Nos. 2, 16; Johnson & Johnson's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. Nos. 2, 16; Janssen Research & Dev., LLC's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. Nos. 2, 16; Examples from Trial Listed Below.

67. The role of the FDA and its regulations and their scope was a persistent theme through trial; indeed, the Plaintiffs brought a former FDA commissioner to testify, over the objection of Janssen. *See* Mot. *in Limine* to Preclude Testimony by David A. Kessler, M.D., that Defs. Failed to Warn of a Serious Adverse Event, filed January 28, 2015, challenging the ability of an "expert" to articulate a different opinion whether gynecomastia is a serious adverse event that the FDA has – and from that opinion to extrapolate a different duty than the one the regulating agency has imposed. The Court did not rule on the motion. Tr. 98:12-100:15, 1/28/15 (a.m.).

68. Instead, the Court ultimately instructed the jury that:

> And moreover, any reference to the FDA or anything like that, the government, was only in relation to the cause of action, the case here that we have, right here, right in the City of Philadelphia, state of Pennsylvania, applying Alabama law, and that is negligent failure to warn, nothing else. It's not about, you know, all the different CFRs and this and that, regulations of the FDA. It's not about that. It's about our own – actually Alabama's law on negligent failure to warn and causation and damages, if you get there, all right?
>
> So I want to take a lot of this stuff out that may have kept us here longer than we should have been. Just want to take all that out. Not to disregard the evidence that we have, but to know – be focused on what we're really talking about in this case.

Tr. 16:4-22, 2/20/15 (p.m.).

> And this is the case in Pennsylvania. It's the case in Alabama. This is the case. That's the situation, all right. It has nothing to do with the FDA. This is state law, state of Alabama law.

Id. at 35:12-16.

69. The Court erred in permitting Plaintiff, and in particular Plaintiff's expert, Dr. Kessler, to substitute his judgment for the FDA's and to testify extensively about his interpretation of the standards that FDA has construed and is applying to Janssen – while at the same time repeatedly refusing to allow Janssen's witnesses to explain that Dr. Kessler's testimony did not accurately set forth the relationship or communications between the FDA and Janssen and did not accurately set forth Risperdal's safety and efficacy. *Compare*, *e.g.*, Tr. 5:1-100:11, 1/28/15 (a.m.), *with* Tr. 81:1-83:4, 2/2/15 (a.m.); Tr. 34:21-40:7, 2/10/15 (a.m.); Tr. 96:11-133:14, 2/17/15 (a.m.); Tr. 8:5-35:1, 57:22-58:9, 63:1-64:4, 65:14-65:17, 2/17/15 (p.m.). Although a trial court has discretion to exclude evidence, it may not err and prejudice the defense by "alter[ing] and streamlin[ing] the essential history of the case." *Cicconi Auto Body v. Nationwide Ins. Co.*, 904 A.2d 933, 939 (Pa. Super. 2006).

70. For example, Plaintiffs asked Dr. Kessler "as far as measuring the conduct of the company and what they should do, which we've been talking about with you for four days, is that measured in part against how it was really being used and the population in which it was being used?" Tr. 98:19-24, 2/2/15 (p.m.). Dr. Kessler responded that "[i]f the drug is being marketed for children, that's the intended use." *Id.* at 98:25-99-1. When Janssen objected, the Court's response was that it would be for the jury to decide "what was going on in Dr. Mathisen's office." *Id.* at 99:5-18.

71. But "intended use" is a defined term – as is "safe and effective" and "serious adverse event" – all of which are purely federal questions within the authority of the FDA – but all of which Plaintiffs sought from the outset of the trial to litigate and define relative to state tort law duties. *Compare, e.g.*, *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133

(2000) ("Viewing the FDCA as a whole, it is evident that one of the Act's core objectives is to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use. This essential purpose pervades the FDCA." (internal citations omitted)), *with* Tr. 98:25-99:1, 2/2/15 (p.m.) (intended use); Opening argument, Tr. 28:19-25, 1/23/15 ("That's my introduction to tell you that's why we're here on this very serious, very important mission for this little boy – to prove to you that drugs should be safe and that drugs should be warned about and that this drug did not have the correct prescribing information"); *id.* at 34:4-9 ("The FDA actually relies on pharmaceutical companies to provide proof that a drug works; that it means that it's safe; that it has what's called efficacy, and that it's safe for the intended use."); Tr. 76:12-14, 2/2/15 (a.m.) ("And, doctor, do you consider gynecomastia to meet the Regulatory definition of serious adverse event?").

72. Likewise, Dr. Mathisen was permitted to testify that he should have received a black box warning in 2006, but Janssen as a manufacturer could not unilaterally enact a black box warning at any time. *Compare* Tr. 185-186, 1/26/15[5] *with Dopson-Troutt v. Novartis Pharm. Corp*., 975 F. Supp. 2d 1209, 1218-19 (M.D. Fla. 2013) (citing Federal Register and Code of Federal Regulations provisions).

73. Separately, the Court failed to acknowledge that judge of this Court that is managing the litigation as a whole has already recognized that the FDA is very much a part of this litigation. Prior to trial, Plaintiffs filed four motions *in limine* seeking to exclude evidence, arguments, and references (1) about the impact of the FDA's determinations upon Janssen's non-negligence and non-liability because of its compliance with FDA statutes and regulations; (2) about the FDA preamble; (3) that complying with FDA regulations absolved the defendants

[5] Counsel objected and asked for an instruction. Tr. 5:15-6:12, 1/28/15 (a.m.). The Court declined, calling it "a matter of evidence." *Id*. at 6:13-21.

from liability; and (4) that a drug manufacturer cannot change its label without FDA approval. Judge New denied Plaintiffs' motions, but permitted them to object to specific evidence at trial.

74. Notwithstanding Judge New's December 5, 2014 orders on these subjects, *see* Control Nos. 14062637, 14062613, 14062636, and 14062616, and without any basis for revisitng them, the trial court repeatedly refused Janssen's attempts to introduce evidence that Judge New had found to be generally admissible.

75. As the Supreme Court has explained, "judges of coordinate jurisdiction sitting in the same case should not overrule each other's decisions on the same issue" unless there are exceptional circumstances, "such as where there has been an intervening change in the controlling law, where there has been a substantial change in the facts or evidence giving rise to the dispute, or where the prior holding was clearly erroneous and would create manifest injustice if followed." *In re De Facto Condemnation & Taking of Lands of WFB Assocs., L.P.*, 903 A.2d 1192, 1207 (Pa. 2006). As with all of the "law of the case" doctrines, the coordinate jurisdiction rule is "'not only to promote the goal of judicial economy' but also: '(1) to protect the settled expectations of the parties; (2) to ensure uniformity of decisions; (3) to maintain consistency during the course of a single case; (4) to effectuate the proper and streamlined administration of justice; and (5) to bring litigation to an end.'" *Id*. at 1207-08 (citation omitted). No such exceptional circumstances were proffered here.

76. The Supreme Court has observed that "[i]f a jury can reconsider a determination of a trial court that is crucial to its ultimate legal conclusion in a later phase of the same litigation, the possibility exists that an adverse determination can undermine that initial legal conclusion and emasculate the principles underlying the 'law of the case' doctrine." *Id.* at 1210. That is precisely what happened here, where the jury was presented with a distorted view of the

FDA and Janssen's role vis-à-vis the FDA, and was then asked to undermine Judge New's conclusions.

C. Janssen is entitled to judgment as a matter of law or in the alternative, a new trial, because the Court permitted Mr. Pledger to substitute his causation expert mid-trial.

Places of Preservation of the Record: Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC's Motion to Exclude the Testimony of Mark P. Solomon, M.D., Feb. 9, 2015 (Control No. 15021115); Tr. 126:15-151:12, 2/2/15 (p.m.); Tr. 5:4-12:24, 2/3/15 (a.m.); Tr. 64:15-77:5, 2/3/15 (p.m.); Tr. 5:1-28:7, 2/4/15 (p.m.); Tr. 17:15-50:4, 2/5/15 (a.m.); Tr. 5:12-19:19, 2/6/15 (a.m.); Tr. 5:12-22:11, 136:7-157:1, 2/9/15 (a.m.). Additional examples from trial listed below.

77. Toward the end of their case, Plaintiffs sought to take a *de benne esse* deposition of David E. Goldstein, M.D., the medical causation expert, rather than present him to the jury live. Because of the unusual nature of that request, Janssen inquired whether the witness in question was in fact disqualified.

78. When Plaintiffs declined to allay Janssen's suspicions on this subject, Janssen drew the question to the Court's attention, recognizing that the Court had authority to fashion an appropriate remedy. For example, in *Ingalls v. SMTC Corp*. (*In re SMTC Manufacturing of Texas*), 421 B.R. 251, 264 n.2 (Bankr. W.D. Tex. 2009), an expert violated Texas's disciplinary requirements for accountants by agreeing to a contingent expert fee. The court refused to allow her to testify as an expert, but it did allow her to testify regarding exhibits she had prepared. *Id*. The Supreme Court has articulated the relevant principles this way within the context of a criminal case:

> It is universally accepted that the trial judge has the responsibility and authority to maintain in the courtroom the appropriate atmosphere for the fair and orderly disposition of the issues presented. In the judge is vested the power and authority to maintain the order and integrity of the judicial process.

Commonwealth v. Patterson, 308 A.2d 90, 94 (Pa. 1973).

79. Both Plaintiffs and this Court recognized that Janssen could have refrained from informing them and simply questioned the witness to determine whether Dr. Goldstein had, in fact, conducted a medical examination and given medical advice in Alabama, despite not being an Alabama doctor and not being under the supervision of Alabama's authorities.

> Plaintiffs: [T]hey presumably could have said to him, Dr. Goldstein, did you know – right here, right in this seat; they could have said, Dr. Goldstein, did you know that you were violating Alabama law? And they could have made him look foolish if they thought they could. They could have said a whole bunch of stuff. I would have objected. I think the Court would have kept it out . . . .
>
> The Court: No, no, no. The issue from – we researched this issue overnight. Unless there's some issue of competency, it would have been permitted in this Court most likely. . . . His testimony would have been permitted most likely since I have not seen anything that would have ruled out his competency to testify. The weight of it, absolutely, but not the competency.

Tr. 92:11-93:10, 2/3/15 (p.m.). Nonetheless, Comment 12 to Pennsylvania Rule of Professional Conduct 3.3 (Candor Toward the Tribunal) imposes on lawyers "a special obligation to protect a tribunal against criminal or fraudulent conduct that undermines the integrity of the adjudicative process" . . . and "requires a lawyer to take reasonable remedial measures, including disclosure if necessary, whenever the lawyer knows that a person, including the lawyer's client, intends to engage, is engaging or has engaged in criminal or fraudulent conduct related to the proceeding." In the face of Plaintiffs' refusal to allay Janssen's concerns, Janssen considered it preferable – as a matter of deference, of candor, and of discretion – to call the situation to the Court's attention when all counsel were in chambers rather than to question the witness in front of the jury without prior notice.

80. Instead of responding to Janssen's private overtures or the not-yet-filed bench memorandum by clearing up any misconceptions, Plaintiffs unilaterally released Dr. Goldstein and afterward asked the Court to permit a substituted witness mid-trial, blaming Janssen for Plaintiffs' witness's conduct. The Pennsylvania Rules of Civil Procedure do not contemplate a voluntary relinquishment of a witness mid-trial, and they do not provide for the substitution that occurred here. Indeed, as the Court recognized, Dr. Goldstein could simply have been permitted to testify. See *United States v. Levenite*, 277 F.3d 454, 461 (4th Cir. 2002) (concluding that although the receipt of a fee from a prosecutor alleged to have violated statutory restrictions "create[s] fertile fields from which truth-bending or even perjury could grow, threatening the core of a trial's legitimacy," the veracity of the witness and credibility of his testimony is best tested through cross-examination and a properly instructed jury).

81. Under Rules 4003.5(b) and No. 4019(i), undisclosed witnesses are not to be permitted to testify on behalf of the defaulting party at the trial of the action. Both rules provide the same caveat: "*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. No. 4003.5(b) (emphasis added); Pa.R.C.P. No. 1019(i) (emphasis added). Rule 4010 (which governs examination of a person whose physical or mental condition is at issue) likewise provides that a court has the authority to "make an order against a party requiring delivery of a report on such terms as are just, and if an examiner fails or refuses to make a report the court shall exclude the examiner's testimony if offered at trial." Pa.R.C.P. No. 4010(b)(1). Because the exception to Rules 4003.5 and 4019(i) is triggered by "extenuating circumstances beyond the control of the defaulting party," Plaintiffs' premature action – without

waiting for this Court to act – warranted the exclusion of Dr. Solomon. *See* Pa.R.C.P. No. 4003.5(b); Pa.R.C.P. No. 4019(i).

82. As the Court twice recognized, the unilateral release of Dr. Goldstein meant that a key element of the cause of action was not established, which should have resulted in a nonsuit. Tr. 9:20-22, 2/3/15 (a.m.). ("Either they have the causation evidence or they don't. If they don't, it will be a nonsuit."); Tr. 66:18-25, 2/3/15 (p.m.). ("Then we may have to call – this case may be nonsuited or we may have to put it into an IME, because all of the research that I've seen about this case is . . . without the specific causation, we've got a problem here, according to the Superior Court two years ago.").

83. Plaintiffs countered that they were prejudiced by the "chilling" of their witness and demanded a "remedy" from the Court. Tr. 135:12-13, 141:9, 2/2/15 (p.m.). Just as speech cannot be chilled when the speech is contrary to law or public policy, a witness whose testimony is procured contrary to public policy cannot be aggrieved or establish a right to a remedy. *Cf. Bovino v. Bd. of Sch. Dirs.*, 377 A.2d 1284 (Pa. Cmwlth. 1977) (rejecting a First Amendment challenge to a termination "based directly upon words" but only insofar as they reflected on his conduct). The interest that Alabama has in preventing the unauthorized practice of medicine is at least as great as the interest Texas has in ensuring the integrity of its accountants. Moreover, the Court had made clear that it had not instructed that the witness be released, was prepared to let the witness testify and be impeached (if, indeed, that occurred) – and the unilateral decision of Plaintiffs to avoid the effect of that questioning is not a "right" and did not warrant a "remedy."

84. Although the Court had initially refused to consider Janssen's motion as untimely, the Court determined that Plaintiffs were entitled to relief and permitted them to substitute a witness midtrial. Tr. 73:21-74:7, 2/3/15 (p.m.). Because Plaintiffs had no right to relief, this was

error. Because Plaintiffs had decided to release and had refused to recall Dr. Goldstein, which, as the Court itself recognized, left Plaintiffs without an essential element of proof, Janssen is entitled to judgment as a matter of law.

85. In the alternative, Janssen is entitled to a new trial on this ground. This Court predicated its determination that a new witness could be brought to trial on its conclusions that (a) Janssen had hidden its knowledge of the violation; and (b) that the motion was untimely. Both conclusions were inaccurate.

86. On multiple occasions, Janssen explained to the Court that it was bringing to the Court's attention *new* information, gained after Plaintiffs sought to replace live testimony by a deposition while refusing to confirm that there had been no impropriety in the way his testimony was developed. *E.g.*, Tr. 130:6-25, 2/2/15 (p.m.); 107:9-108:1, 2/3/15 (p.m.); 25:6-25, 2/5/15. The Court did not set a hearing nor ask for any details from either side.[6] Accordingly, the Court did not have before it a factual record on which to conclude that *Janssen* had been hiding something. *Cf.* Pa.R.C.P. No. 4019(g) (contemplating an opportunity for a hearing in conjunction with sanctions). Indeed, in all the times during trial that the issue has come up, Plaintiffs have never asserted that Dr. Goldstein's testimony would have been properly received.

87. Although this Court has "[t]he general, inherent power of all courts to regulate their own practice, without control, on the ground of expediency," the local rules the trial courts create are not enforced to the extent they violate the Constitution or laws of the Commonwealth or United States, or statewide rules. *In re Appeal of Churchill*, 575 A.2d 550, 554 (Pa. 1990).

88. The substitution contravened not just the specific rules governing discovery but the very principles upon which the rules governing discovery are grounded. Taken together,

[6] Janssen timely filed a motion *in limine* to strike Dr. Goldstein's testimony on May 7, 2014. Had Janssen known then the facts that it learned later, it would certainly have included them in the motion *in limine*.

Rules 4003.5, 4010, and 4019 set forth a clear policy that there will be time pretrial to probe the claims and defenses that will be raised at trial and the expert testimony that will support them.

89. The Court's ruling deprived Janssen of two rights that the discovery rules were enacted to protect: Janssen was entitled to prepare to meet the actual expert opinions that were delivered at trial. Its experts – and its counsel – had spent time familiarizing themselves with Dr. Goldstein's report, deposition, and analysis. As the Superior Court has explained, it is not enough for a witness to be known; the full scope of the witness's opinion in that case must also be known. *See Corrado v. Thomas Jefferson Univ. Hosp*., 790 A.2d 1022, 1030 (Pa. Super. 2001) (opinion that the failure to perform a bronchoscopy was below the standard of care was outside the scope of the report, and the doctor "would have been prejudiced by the introduction of this portion of Dr. DeJager's testimony because he would have been placed in the position of having to cross-examine the doctor on the subject and prepare a meaningful response."). This was not a situation in which only one aspect of the testimony ambushed Janssen. Instead, Janssen was provided with Dr. Solomon's report just before a weekend, with a 90-minute deposition that Sunday and his testimony the next day.

90. Even when a known expert testifies beyond the fair scope of a report, a defendant is deprived "of the opportunity to adequately prepare for a meaningful response to [an expert's] testimony." *Woodard v. Chatterjee*, 827 A.2d 433, 442 (Pa. Super. 2003) (*quoting Feden v. Consol. Rail Corp.*, 746 A.2d 1158, 1162 (Pa. Super. 2000). In this case, the prejudice was many degrees of magnitude greater. Not only did the expert opinions of Dr. Goldstein and Dr. Solomon diverge on critical points – including when the gynecomastia began and what the role of Mr. Pledger's obesity was – everything significant was different. It may be true that Dr.

Solomon had given depositions in the cases of *other plaintiffs*, but Dr. Goldstein's examination was at a much earlier point in time than Dr. Solomon's.

91. Moreover, the contradictions between Dr. Goldstein and Dr. Solomon – which would have impacted the credibility of one or both – could not be developed. For example, Dr. Solomon testified that he had examined Mr. Pledger's genitals and found his testicles to be normal, Tr. 92:23-93:3, 2/9/15 (a.m.). The jury did not hear Dr. Goldstein's testimony, nor see the detail in his report which showed that Mr. Pledger's "right testis measured 5 cm. in length with volume approximately 25 ml (normal adult size)," while the "left testis measured 2 cm. in length with volume approximately 3 ml (average size of a testis in a 10 year old male)." David E. Goldstein, M.D., Expert Report on Phillip "Austin" Pledger, Submitted March 31, 2014, at 3. Given that Dr. Solomon's testimony was explaining why he was not considering other causes of the gynecomastia – and given the emphasis during closing on Dr. Solomon's being "a real doctor" – Tr. 50:5, 2/19/15 (a.m.), the jury should have been able to assess how detailed Dr. Solomon's examination actually was.

92. The measure of prejudice under Rule 4003.5 – articulated in response to that challenge to an expert's trial testimony as beyond the fair scope of his pre-trial report – centers on the word "fair." "The question to be answered is whether, under the particular facts and circumstances of the case, the discrepancy between the expert's pre-trial report and his trial testimony is of a nature which would prevent the adversary from making a meaningful response, or which would mislead the adversary as to the nature of the appropriate response." *Woodard*, 827 A.2d at 442 (quoting *Feden*, 746 A.2d at 1162).

93. The *Woodard* court found that the defendant there had "suffered prejudice by not having an adequate or fair opportunity to formulate rebuttal and present her own expert to

counter the testimony." *Id.* at 444. This Court should recognize that Janssen has suffered just such prejudice.

94. The prejudice was compounded by three other incidents at trial. The first incident was when Janssen sought to bring out the variances in Dr. Solomon's testimony. The Court stopped counsel, observing that in prior cross-examinations counsel had raised consistent statements and others that "were not based on fabrications." Tr. 117:2-7, 2/6/15 (a.m.). The Court then said it would "be watching this very carefully. I'm going to admonish you in front of the jury if necessary" and required counsel "if you have an inconsistency, you show it to counsel first, and that the witness then reads it ahead of time, just like you know how to do, and then ask the question." *Id*. at 117:8-11, 14-18. Accordingly, even such cross-examination as was possible on the reduced timeframe was constrained.

95. The second incident occurred in closing. Plaintiffs said: "They consulted with, on the one key point, high level, true pediatric endocrinologists, not the fellow that they dragged up here from Alabama . . . ." Tr. 27:24-28:4, 2/20/15 (a.m.). And, a few minutes later: "The only reason I went through all that paid stuff with them is to show you Dr. Alabama and his 30,000 dollar job coming up here as a substitute." *Id.* at 36:17-20. That direct attack on Janssen's compliance with the very law that Mr. Pledger was allowed to disregard was then accompanied by a "fumble forward" in their characterization of Dr. Solomon:

> He is a plastic surgeon. Oh, yeah, we can all giggle. Pardon me, giggling is over. Yes, he does that procedure, and he does breast enhancement, breast reductions and, my word, he has on his website about gynecomastia. And, oh, yes, he was expensive, and oh, yes, I thought he was important to bring in here, somebody who actually knows the breast. And I don't apologize for doing it, for bringing in a real doctor who reconstructs breasts, who knows breast tissue, who showed you the pathology of the breast under a microscope, who talked about the breast, and who did everything that you would want to know about the breast, and told you the

> logical conclusion, that this boy had gynecomastia, he had true gynecomastia, he lost weight, there is some tissue hanging there, connective tissue, adipose tissue, might have some fat in it, of course.

Id. at 49:19-50:15.

96. The third incident occurred at the end of closing arguments. Plaintiffs complained about Janssen's closing, and the Court expressed its concern that the argument that Dr. Solomon was the best Plaintiffs could come up with was "egregious." *Id.* at 189:2-190:10. In response to the Court's observation that it might comment, Janssen explained that that would be "very prejudicial." To which the Court responded, "I understand that." *Id*. at 190:14-16; *see also id*. at 192:22-24 (same). [7] Nevertheless, when instructing the jury, the Court charged:

> Now, this case is not about something argued to you specifically by Ms. Sullivan, 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?
>
> Also, this is not about whether the plaintiff could not find an endocrinologist to testify in this case. It is not about that.
>
> Now, it was suggested to you again by Ms. Sullivan that the plaintiff could not produce an endocrinologist and suggested that they could not because they could not.
>
> You are instructed to disregard that line of argument in its entirety as it is not accurate and it's disingenuous based on matters of law that occurred outside of your presence.

Tr. 18:1-21, 2/20/15 (p.m.).

97. In isolation or taken together, these remarks, with their singling out of Janssen's counsel as telling the jury what is "not the law" and "is not accurate" and is "disingenuous" go

[7] Later, the Court said, "Regarding something that was submitted to me now, I think by Mr. Kline, regarding a pediatric endocrinologist, I just – I'm going to be giving some remarks and I hope that covers the whole situation, and we will proceed." Tr. 8:8-25, 2/20/15 (p.m.). The Court then said that it did not have the testimony in front of it and was not ruling. When Janssen followed up to ask whether the Court was planning on remarking on the endocrinologist, the Court answered "No." *Id.*

beyond "[p]roper instructions on the elements of liability and damages [which] are adequate to focus the jury's attention on the issues to be decided" and instead "can serve only to create sympathy for the plaintiff and potential prejudice against the defendant." *Hileman v. Pittsburgh & Lake Erie R.R. Co.*, 685 A.2d 994, 997-98 (Pa. 1996) (recognizing that prejudice from differentiating FELA from workers' compensation suggested an unfairness of result).

98. Under the circumstances, the Court did not grant either an adequate continuance or the "other appropriate relief" required by Rules 4003.5 and 4019(i) – even assuming that there were extenuating circumstances beyond Mr. Pledger's control. Accordingly, Janssen is entitled to a new trial.

D. Janssen Is Entitled to a New Trial Because Counsel Repeatedly Invoked Prejudice in Ways that Cannot be Squared with Pennsylvania Law or Judge New's Orders Affirming that Law.

Places of Preservation of the Record: Janssen Pharm., Inc., Johnson & Johnson, and Janssen Research & Dev., LLC's Motion for Compulsory Nonsuit, Feb. 10, 2015 (Control No. 15021476), at at 17-18; Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Motion in Limine to Preclude Testimony by David A. Kessler, M.D. that Defendant Failed to Warn of a Serious Adverse Event, Jan. 27, 2015 (Control No. 15013128); Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Motion in Limine No. 15 to Preclude Plaintiffs from Introducing Argument, Evidence or Testimony that Gynecomastia is a Serious Adverse Event, Dec. 9, 2014 (Control No. 14121610); Janssen Pharm., Inc.; Johnson & Johnson; and Janssen Research & Dev., LLC's Proposed Points for Charge, No. 26, Feb. 17, 2015; Tr. 47:4-48:2, 2/20/15 (p.m.); Janssen Pharm., Inc.'s Answer to Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. Nos. 2, 16; Johnson & Johnson's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. Nos. 2, 16; Janssen Research & Dev., LLC's Answer to Plaintiffs' Second Amended Master Long-Form Complaint and New Matter, May 3, 2012, at Affirm. Def. Nos. 2, 16; Examples from Trial Listed Below.

99. Judge New had granted outright and without caveat Janssen's motions to preclude evidence of Janssen's 2013 guilty plea and civil settlement and its motion to preclude Mr. Pledger from introducing expert testimony and other evidence of corporate intent. This was an unassailable ruling, and the plaintiffs never proffered any motion for reconsideration or other basis for revisiting the ruling. Under Pennsylvania Rule of Evidence 404(b)(1), evidence of a "crime, wrong, or other act is not admissible to prove a person's character in order to show that on a particular occasion the person acted in accordance with the character." This is true in both criminal and civil actions, because a person cannot prove the doing of one act by reference to another. *Commonwealth v. Etzel*, 86 A.2d 64, 66 (Pa. 1952) (quoting *Veit v. Class & Nachod Brewing Co*., 64 A. 871, 872 (Pa. 1906)). Indeed, it is a general rule that admission of "manifestly prejudicial" evidence is reversible error. *Whyte v. Robinson*, 617 A.2d 380, 384 (Pa. Super. 1992).

100. Likewise, having an expert testify about the "intent" of the defendant or the FDA is not just prejudicial; it usurps the function of the jury. *In re Diet Drugs Prods. Liab. Litig*., MDL No. 1203, 2001 U.S. Dist. LEXIS 1174, at *6 (E.D. Pa. Feb. 1,2001); *see also In re Rezulin Prods. Liab. Litig*., 309 F. Supp. 2d 531, 546–47 (S.D.N.Y. 2004) (finding that expert testimony regarding corporate intent is improper because "it describes 'lay matters which a jury is capable of understanding and deciding without the expert's help'" (citation omitted)); *In re Diet Drugs Prods. Liab. Litig*., MDL No. 1203, 2000 U.S. Dist. LEXIS 9037, at *29 (E.D. Pa. June 20, 2000) ("The question of intent is a classic jury question and not one for experts . . . .").

101. Nevertheless, the trial court repeatedly required Janssen to "choose" between introducing the evidence that Judge New had properly excluded and forfeiting a critical aspect of Janssen's defense. At one point, the Court threatened Janssen that it was prepared to sidestep

Judge New's pre-trial ruling and permit "some kind of rebuttal . . . about government action against Johnson & Johnson in the last year or so on a particular drug named Risperdal." Tr. 74:24-75:4, 1/30/15 (p.m.).

102. And Plaintiffs repeatedly circumvented Judge New's rulings. For example, in examining Mr. Gilbreath, at the pertinent time a Janssen sales representative, Plaintiffs asked about a gap in delivery of samples:

> A. I only suggest that he didn't request them, because I would have provided them had he requested them as I always had.
>
> Q. I am going to suggest something different to you. I am going to suggest that the company admonished people and told them there was a new policy here?

Tr. 25:11-17, 2/4/15 (a.m.). After a sustained objection, Plaintiffs asked:

> Q. The company cracked down, correct, sir?
>
> A. Not in my opinion it was a crack down, we had had the policy in place all along, it was just a formal way to capture it at this point.
>
> Q. And the company knew they were in trouble, correct?

Id. at 25:24-26:5. After another sustained objection, Plaintiffs asked,

> Q. Did you read the newspapers at that time, sir? Were you reading the newspapers?

Id. at 26:10-11. At recess, Janssen asked for a curative instruction, and the Court told the jury:

> The other thing is a reminder that questions by any attorney who is asking any questions at any time, that is not evidence. Just remember that. That is not evidence. Only testimony from the witness stand or other things that have been admitted pursuant to these rules over here, the Rules of Evidence, that's evidence. Questions are not. Okay?

Id. at 46:17-24.[8]

103. Similarly, Mr. Pledger repeatedly sought to associate Janssen with "big," "corporate," and "dollars" – all attacks that the Superior Court has found prejudicial. *See e.g.*, Tr. 70:19-20, 2/6/15 (a.m.) (describing documents "the company lawyer handed over here"); Tr. 57:23-25, 2/18/15 (p.m.) (Q. "What did you fly, did you fly commercial or did you fly on the company jet? A. "U.S. Air."); Tr. 20:20-20:22, 2/20/15 (a.m.) ("You know about the experts, you know the case is literally awash with money"); *id.* at 25:10-13 ("I don't see their former Commissioner of the FDA in the courtroom, one of the biggest pharmaceutical companies in the world."); *id.* at 29:2-5 ("They don't just go on selling, selling, selling, selling, selling the drug. And selling the drug"); *id.* at 52:9-17 ("I am not a corporate lawyer . . . . I am a courtroom lawyer, I confess, 37 years here, City Hall, William Penn, him and me, I guess, and the Judge has been around a long time.").[9] In rebuttal, Mr. Pledger said, "One of the biggest pharmaceutical companies in the world didn't bring a pediatric endocrinologist when they rested their case on pediatric endocrinology. *Id*. at 138:21-24.

104. The Superior Court has clearly held that the only remedy for such prejudice is a new trial.

> We have held that when a party intentionally violates a pre-trial order, the only remedy is a new trial, in order to promote fundamental fairness, to ensure professional respect for the rulings of the trial court, to guarantee the orderly administration of justice, and to preserve the sanctity of the rule of law. Here, counsel for both Mirab[e]l and Latin Express admitted at trial that they

[8] Fortunately, counsel were not in open court when Plaintiffs' views of Janssen were manifested most clearly: "That's right, we don't want the truth. You want the truth. You heard the truth here today. You heard the truth about off-label promotion where a company was fined 2.8 million billion dollars. $2.2 billion. . . . Attorney General Holder said that Janssen Pharmaceuticals and Johnson & Johnson's conduct – Johnson & Johnson's conduct as to children – as to children was shameful. . . . Shameful. That's who you represent." Tr. 118:9-119:6, 2/3/15 (p.m.).

[9] Janssen objected that this was not a punitive damage case, but the court found that the language was "not over the top." Tr. 57:17-58:13, 2/20/15 (a.m.).

> discussed the wealth and size of Comcast in their closing to highlight the economic disparities between the parties. These statements were in clear violation of a pre-trial order; thus, Schulgen and Comcast are entitled to a new trial because of these statements.

Mirabel v. Morales, 57 A.3d 144, 151 (Pa. Super. 2012) (internal quotation marks omitted) (citations omitted).

105. Indeed, the Superior Court went further:

> Statements regarding the size and wealth of Comcast would have been grounds for a new trial even if the trial court did not issue a pre-trial order excluding it. In the absence of punitive damages, it is "irrelevant, improper, and prejudicial" for a jury to consider the defendant's wealth. Thus, discussion of the wealth of a defendant during closing can warrant a new trial. While a curative instruction can overcome the prejudice of these types of statements, no such instruction was given here. Thus, Schulgen and Comcast would have been entitled to a new trial regardless of this pre-trial order.

Id. at 151 n.7 (internal citation omitted).

106. In contrast to the offense taken by the Superior Court, the trial court in this case appeared to take similarly offensive statements in stride. For example, when Plaintiffs' counsel said as an aside to a witness, "By the way, the documents show that in the early 2000s it was a two-billion-dollar drug in sales," Tr. 59:22-24, 2/11/15 (a.m.), the Court took Janssen's immediate objection under advisement, *id.* at 59:25-60:7. When Janssen followed up, the Court said, "The difficulty you have on that point is that Johnson & Johnson is a known company in the public. So, you, know, it's known as a Fortune 500 company, so what's the prejudice?" *Id.* at 105:1-5. Plaintiffs then complained: "But the fact of the matter is it, of course, is relevant. It's, of course, relevant. They're working on a billion-dollar franchise. . . . And my hands are tied by not being able to show that all of this conduct is motivated by them and what they see and what they know about the use of the drug, the numbers of kids on the drug and the like." *Id*. at

106:12-22. The Court reiterated: "I know that I sustained the objection. And I don't see the prejudice for the reasons I've just stated. Johnson & Johnson is known to the public as a large corporation. So I'm not sure what prejudice yet." *Id*. at 107:9-14.

107. Comcast is, of course, a large company as well. But far from being equivocal, the Superior Court recognized that there are times when the prejudice from such statements is so great that even curative instructions are inadequate. *Mirabel*, 57 A.3d at 150-51 (internal quotation marks omitted) (citations omitted). Here, as noted above, the Court had only taken the objection under advisement, leaving Janssen without even a sustained objection.

108. In these circumstances, where Judge New had already determined that the prejudice attendant on disclosure of Janssen's guilty plea and settlement warranted a blanket exclusion of any testimony, argument, or evidence in this regard, and counsel repeatedly ignored his order without any attempt to make the showing required to overrule a prior judge's considered order, the fact that the Court sustained some objections and cautioned counsel once was not adequate to overcome the prejudice and taint from counsel's persistent comments.

109. In sum, looked at from any of the rationales used in *Mirabel* or in *Condemnation*, counsel's conduct deprived Janssen of a fair trial and did so in violation of the coordinate jurisdiction doctrine. Accordingly, Janssen is entitled to a new trial.

E. Remittitur Is Warranted in This Case.

110. At a minimum, the Court should grant remittitur of the damages award. Remittitur is appropriate "in those cases where the court can clearly see that the verdict has been reached because of bias, passion, prejudice, corruption, or other improper motive[s]." *Aspinwall*, 405 So. 2d at 137. "We give stricter scrutiny to an award of mental anguish where the victim has offered little or no direct evidence concerning the degree of suffering he or she has experienced." *Kmart Corp. v. Kyles*, 723 So. 2d 572, 578 (Ala. 1998).

111. "[T]he party claiming damages has the burden of establishing the existence of and amount of those damages by competent evidence. The award of damages cannot be made upon speculation, and the plaintiff has the burden of offering evidence tending to show to the required degree, the amount of damages actually suffered." *State Farm Fire & Cas. Ins. Co. v. Lynn*, 516 So. 2d 1373, 1376 (Ala. 1987) (quoting *Johnson v. Harrison*, 404 So. 2d 337, 340 (Ala. 1981)).

112. In this case, Mr. Pledger was awarded $2.5 million for permanent disfigurement and mental anguish. In determining whether the evidence supports the award of damages, the Supreme Court of Alabama has observed that "[w]hen a plaintiff's testimony amounts to little more than the obvious notion that dealing with the traumatic event was 'hard' or 'humiliating,' we have consistently remitted damages." *Slack*, 988 So. 2d at 532 (quoting *Delchamps, Inc. v. Bryant*, 738 So. 2d 824, 838 (Ala. 1999)). "Additionally, when a plaintiff testifies merely that he suffered 'a lot' of mental anguish, we have similarly remitted damages." *Id.* (quoting *Oliver v. Towns*, 770 So. 2d 1059, 1061 (Ala. 2000)).

113. The Supreme Court of Alabama has made plain that excessive compensatory damages awards not supported by the trial record cannot stand. *See, e.g.*, *Slack*, 988 So. 2d at 532 ("Despite our great deference to the jury's award of compensatory damages for mental anguish, we have not hesitated to remit such damages where the plaintiff has produced little or no evidence indicating that he has suffered such mental anguish."); *Hobart Corp. v. Scoggins*, 776 So. 2d 56, 66 (Ala. 2000) (affirming remittitur of compensatory damages verdict from $510,000 to $250,000 where "Scoggins suffered the traumatic amputation of a substantial portion of his right index finger and as a result was unable to work for approximately three months. Repair of the remaining portion of his finger required reconstructive surgery, after physicians' attempts to reattach the severed portion were unsuccessful. Subsequently, physicial

therapy was required. Scoggins is permanently disfigured. In what had been Scoggins's customary sports activities, he is now either unable to engage at all or able to engage only with substantial difficulty. Even more significant is the effect of his injury on his ability to engage in his profession."); *Kmart Corp.*, 723 So. 2d at 577-78 (remitting damages for mental anguish from $100,000 to $15,000 where "only evidence of Kyles's as to alleged mental suffering was her husband's testimony she cried on one occasion – when she telephoned him to say that she had been arrested"); *Sears, Roebuck & Co. v. Harris*, 630 So. 2d 1018, 1033-34 (Ala. 1993) (ordering remittitur of compensatory damage awards for victims of carbon monoxide poisoning, including remittitur of a $2,000,000 award of compensatory damages to $500,000 for a plaintiff who suffered "long-term effects of carbon monoxide poisoning" that "aggravated the hypertension for which she had received treatment before the accident").

114. The only testimony adduced at trial as to Mr. Pledger's alleged damages was that of his mother, Benita Pledger. She testified that Mr. Pledger "knows" that his chest is different but "doesn't have the capacity to ask [her] why," Tr. 47:16-21, 2/6/15 (a.m.); Mr. Pledger wears a shirt when he is swimming, *id.* at 47:6; Mr. Pledger covers his chest when he gets out of the shower and "admires himself in the mirror because he can see hisself [sic] without his breasts," *id.* at 46:25-47:1; and Mr. Pledger cried once when a teacher said or did something, *id.* at 49:2-21.

115. Moreover, it is clear that the jury was confused about what it was supposed to find by way of damages, i.e., that the award was based on speculation. For example, the Court originally charged the jury that Mr. Pledger was seeking damages for permanent disfigurement, mental anguish, and embarrassment and humiliation. *Id.* at 41:5-42:7, 2/ 20/15 (p.m.). These categories were presented as three separate bases for an award of damages in this case; mental

anguish and embarrassment and humiliation, however, are not different categories of damages. *See Slack*, 988 So. 2d 531 ("Mental anguish includes anxiety, embarrassment, anger, fear, frustration, disappointment, worry, annoyance, and inconvenience." (quoting another source)). The Court also explained during its instruction to the jury that there were "no economic damages that [are] being claimed in this case" – only non-economic damages. *Id.* at 42:18-23. While deliberating, however, the jury asked the Court three questions, one of which was: "What is the average amount for surgery for breast reduction?" Tr. 8:3-4, 2/23/15. Because neither party had put in evidence as to that, the Court simply instructed the jury that there was no evidence on that point. *Id*. at 13:11-17, 23:22-24:3 ("You also asked, what is the average amount for surgery for breast reduction. And that, ladies and gentlemen, we do not have any evidence on in this case. So I cannot answer that for you."). Finally, the Court accepted Mr. Pledger's request to take judicial notice of the life expectancy tables after the close of the evidence, even though he acknowledged that Alabama law, the law governing damages in this case, required them "to be presented during evidence, during the case." Tr. 13:9-10, 2/22/15. Even though the life expectancy tables should not have been admitted at all, the Court gave an erroneous instruction as to their use. Rather than instructing the jury that it should consider them life expectancy table together with other evidence to determine how long *this* plaintiff may live, a charge required by both Alabama and Pennsylvania, the Court said only:

> There's been some discussion about life expectancy in this case. I'm going to leave it at that. You figure it out for yourselves what the life expectancy is. I believe that – I can give you judicial notice of it that it's about 75.4 years is the actual life expectancy of Austin Pledger, and you take away his 19 years and you come up with a number. But that's up to you to figure out, okay?

Tr. 42:8-17, 2/20/15 (p.m.). This instruction did nothing to inform the jury about how they should use the chart or whether they should even consider whether *this* plaintiff may survive to

75.4 years. This, too, was error. *See Helm v. Eagle Downs-Keystone Racetrack*, 561 A.2d 812 (Pa. Super. 1989) ("Since mortality tables are not to be applied rigidly, failure to adequately instruct the jury on their use constitutes reversible error and warrants the grant of a new trial on the issues of damages.").

116. Consideration of Benita Pledger's testimony in light of the decisions of the Supreme Court of Alabama, particularly *Hobart Corp.* and *Sears, Roebuck & Co.*, and of the obvious confusion that plagued this jury, demonstrates that the evidence does not support the jury's exorbitant award of compensatory damages of $2.5 million. Consequently, remittitur is appropriate.

WHEREFORE, for all of the reasons set forth above and in the evidence and exhibits incorporated herein by reference, Janssen respectfully requests that this Court grant judgment notwithstanding the verdict or, in the alternative, a new trial on the claims tried or modification of the verdict for remittitur on the damages awarded.

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Respectfully submitted,

/s/ Kenneth A. Murphy
Kenneth A. Murphy
Melissa A. Graff
Thomas F. Campion (admitted *pro hac vice*)
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996

Diane P. Sullivan (admitted *pro hac vice*)
Adam S. Tolin
Allison M. Brown
WEIL, GOTSHAL & MANGES LLP
301 Carnegie Center, Suite 303
Princeton, NJ 08540

Attorneys for Defendants
Janssen Pharmaceuticals, Inc.;
Johnson & Johnson; and
Janssen Research & Development, LLC