IN THE COURT OF COMMON PLEAS
COUNTY OF PHILADELPHIA
CIVIL TRIAL DIVISION

PHILLIP PLEDGER, by BENITA PLEDGER, as GUARDIAN OF HIS PERSON AND CONSERVATOR OF HIS ESTATE	:	**APRIL TERM, 2012**
Plaintiff	:	**NO. 01997**
	:	**2088 EDA 2016**
v.	:	**2187 EDA 2016**
JANSSEN PHARMACEUTICALS, INC., et al	:	
Defendants	:	

OPINION

Djerassi, J. **August 10, 2017**

A jury awarded damages to an autistic man who developed gynecomastia as a child. Plaintiff Phillip Pledger ("Austin") was almost eight years old in June 2002 when his doctor in Birmingham, Alabama prescribed Risperdal off-label to treat temper tantrums and related autistic behaviors.

After a three week trial in January and February 2015, a jury found Risperdal's manufacturer and distributor, defendants Janssen Pharmaceuticals Inc. ("Janssen") and affiliated Johnson and Johnson companies liable for negligent failure to warn. Janssen had not warned Austin's doctor, or anyone else in the medical community, of known danger that boys like Austin were likely to develop gynecomastia at higher rates than explained on the drug's 2002 FDA label.

The jury found Janssen failed to report this risk during the years 2002-2006 even though the company knew Risperdal was being prescribed to children off label by doctors across

America. The manner that Janssen misled the public was explained through expert testimony from plaintiff witness Dr. David Kessler, a former Commissioner of the FDA.

Janssen's negligence was a substantial factor causing Austin's gynecomastia either alone or as a concurring cause. The damage award was $2,500,000 based on plaintiff's embarrassment and humiliation factored over a lifetime.

I. PROCEDURAL HISTORY

On April 18, 2012, Plaintiff Benita Pledger, as guardian and conservator of her son Phillip "Austin" Pledger, filed a complaint against defendant Janssen and affiliated companies which had developed, produced and marketed the Risperdal ingested by Austin beginning when he was eight years old.

On July 11, 2014, following extensive discovery, the Honorable Arnold L. New denied in part and granted in part Janssen's motion for summary judgment. Judge New dismissed with prejudice plaintiff claims for strict liability, conspiracy, medical expenses, loss of consortium, negligent design defect, breach of implied warranty, breach of express warranty, deceptive trade practices under the Alabama Deceptive Trade Practices Act, fraud, violations of Pennsylvania's Unfair Trade Practices and Consumer Protection Law, and punitive damages. At trial, only the claim for negligent failure to warn remained.

Following jury selection and oral argument on motions *in limine*, a jury trial took place s from January 23 through February 24, 2015.

On March 6, 2015, Defendant filed post-trial motions. Plaintiff filed a cross-motion for post-trial relief on March 13, 2015. By agreement of the parties, the 120-day deadline was waived pursuant to Pa. R.C.P. 227.4(1) (B), and oral argument was held on both motions on October 22, 2015. After post-trial motions were denied, judgment was entered on June 8, 2016.

Defendant filed a timely notice of appeal from the denial of post-trial motions on July 5, 2016. Plaintiff filed a timely cross-appeal raising only the denial of punitive damages.

II. SUMMARY OF FACTS

When Austin was six years old living with his parents near Birmingham, Alabama, he was diagnosed with autism.[1] Two years later, his mother sought medical treatment to try to relieve behavioral symptoms including temper tantrums. In April 2002, Mrs. Pledger took Austin to meet Dr. Jan Mathisen, a pediatric neurologist in Birmingham. Austin was prescribed Risperdal by Dr. Mathisen who was aware the drug carried a risk of elevated prolactin levels and substantial weight gain. At the time that Dr. Mathisen prescribed Risperdal for Austin, the drug was FDA approved for adults only. Dr. Mathisen, though, was familiar with off-label use of medications and particularly anti-psychotics like Risperdal. From his own experience and study, he knew that many anti-psychotic medicines carry a risk of prolactin elevation, and this risk was also stated on Risperdal's adult FDA label. (N.T. 1/26/15, p. 43-44.) Dr. Mathisen was familiar with relevant medical literature and was unaware that Risperdal's use among children bore a risk of gynecomastia any higher than the "rare" designation on the adult label. (N.T. 1/26/15, p. 51, lns. 16-20.)[2]

Dr. Mathisen told the jury that in 2002, he had been in regular direct contact with a Janssen sales representative named Jason Gilbraith who gave him off-label Risperdal samples to treat autistic children like Austin. Initially during his own testimony, Gilbraith denied that he knowingly gave Risperdal samples to Dr. Mathisen for off label use on children, but Gilbraith later admitted he knew Dr. Mathisen is a pediatric neurologist. Gilbraith testified that he was not

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[1] Austin was born on July 15, 1994.
[2] According to testimony, a "rare" occurrence is one in a thousand or more.

allowed by Janssen to share any information about Risperdal, whether on safety or efficacy, unless approved by Janssen. (N.T. 2/4/15, Morning Session, p.29. lns. 10-14, p. 32 lns. 16-18, p.65, lns. 12-17, p. 66, lns. 7-10.)

Mrs. Pledger testified she first brought Austin to Dr. Mathisen in April, 2002. At a second appointment, on June 17, 2002, Dr. Mathisen prescribed Risperdal for Austin at a dose of .25 grams b.i.d. (twice a day). (N.T. 1/26/15, p. 60.) Mrs. Pledger said Dr. Mathisen warned her that weight gain was possible, but she said this was acceptable because she thought it could be mitigated by diet. (N.T. 1/26/15, p. 57)

Soon after Austin began taking Risperdal, he indeed gained weight rapidly. Mrs. Pledger noticed the appearance of female-looking breasts and attributed these to the weight gain she had been told to expect. (N.T. 2/6/15, p. 58.) She testified she never knew about the existence of a disease called "gynecomastia" until years later when she saw a television commercial sponsored by a plaintiff law firm, but this was many years after Austin had stopped using Risperdal in 2007.[3] (N.T. 2/6/15, pp. 61-63, lns 6-7.) Mrs. Pledger told the jury that she would "never have put him on it" if she had known of the risk of gynecomastia because she would fear as a mother that Austin would be embarrassed and targeted by bullies. (N.T. 2/6/15, pp 45-47, 49-50, p. 66, ln.13, pp. 70-71).

In his testimony, Dr. Mathisen said that when he was prescribing Risperdal to Austin, he had anticipated that Austin would gain weight. He also knew from experience in the 1990's when prescribing first generation anti-psychotics like Haldol to children that Risperdal might

[3] Austin stopped taking Risperdal in the spring of 2007.

increase Austin's prolactin levels.[4] When prescribing to Austin, Dr. Mathisen said he also relied on the existing adult FDA label and said neither medical literature at the time nor the FDA had associated first generation anti-psychotics with the development of gynecomastia in boys at any statistically significant level.

When deciding to prescribe Risperdal to Austin, Dr. Mathisen testified that he had anticipated Risperdal may raise the boy's prolactin levels based on what he knew from first generation anti-psychotics. (N.T. 1/26/15, p. 51.) But he was unaware that Janssen had studied Risperdal between 1997 and 2002 and did not know Janssen had discovered a statistically significant risk of gynecomastia among boys who ingested Risperdal for eight (8) through twelve (12) weeks and had demonstrated elevated prolactin levels while taking the drug.

This Janssen study was summarized in a chart known at trial as "Table 21" and marked into evidence as P-34(A)[5]. (N.T. 1/29/15, Afternoon, p. 11.) Nearly 300 children had been monitored by Janssen for "adverse events" that could be associated with the use of Risperdal. Plaintiff expert Dr. David Kessler, FDA commissioner at the time Risperdal was first approved for adults in 1997, testified as an expert in the fields of pediatric medicine and biostatistics.[6] Dr. Kessler testified that data collected at Table 21 showed statistically significant side effect among children taking Risperdal between 8 and 12 weeks. In Dr. Kessler's opinion, Table 21 showed that children taking Rispedal within this time period, and had elevated prolactin levels, were 7.8

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[4] Prolactin is a hormone produced by the pituitary gland. In humans, prolactin in association with estrogen and progesterone stimulates breast development and the formation of milk during pregnancy. TABER'S CYCLOPEDIC MEDICAL DICTIONARY p. 1606 (17TH ed. Clayton L. Thomas edit. 1989).

[5] P-34A is a single page from an internal data report circulated as an email attachment among Janssen staff on May 15, 2002. The internal report is consists of 34 separate data tables each comprising a page and was admitted into evidence as P34. This internal data report is also captioned as "Long-Term Risperidone Ts vs... Prolactin—Statistical Documentation for Manuscript Support—May 15, 2002."

[6] Dr. Kessler was FDA Commissioner from 1991-1997 and Dean of the Yale Medical School from 1997-2003. (N.T. 1/28/15, p. 110.)

percent more likely to develop gynecomastia than children taking Risperdal whose prolactin level had remained normal. (N.T. 1/29/15, Afternoon, p. 30 lns 23-24, p. 31-35, p.35, lns. 4-6.)

Table 21 was never shared with the FDA according to defense witness, Dr. Lodewijk Iwo Caers, Janssen's team leader for Risperdal research from 2002-2009. (N.T.2/11/15, Afternoon, p. 114, lns. 22-24)

Unaware of Table 21, and believing any association between Risperdal and gynecomastia was rare, Dr. Mathisen did not check Austin's prolactin levels or check for gynecomastia. Over 29 visits by Austin, Dr. Mathisen's did not remove Austin's shirt to examine his chest and never discussed the possibility of gynecomastia with Austin's mother.

Asked at trial whether he would have discussed the relationship between Risperdal and gynecomastia with Mrs. Pledger had he known of the data in Table 21, Dr. Mathisen testified yes. Asked whether he would have given Mrs. Pledger a choice whether to use Risperdal on Austin, Dr. Mathisen said yes.

> Q. Would you have given her a choice?
> A. Yes.
> Q. And would you have laid out the precise risks and benefits as you knew them and understood them?
> A. Yes.
> Q. And if you knew the risk was really 2.3 in a hundred, was that something you roughly (sic) would have discussed with Mom?[7]
> A. Yes.
> Q. And if you knew that the increase in prolactin was worse than the other medications would you have discussed it with Mom and given her the choice?
> A. Yes.

(N.T. 1/26/15, p. 104)

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[7] This 2.3% figure is the incidence of gynecomastia among children taking Risperdal that appears in the FDA's 2006 label which approved Risperdal for use among children. The 2.3% figure originated from Janssen research that was submitted to the FDA before approval of the 2006 label. The submitted data did not include Table 21. Neither the 2.3% nor 7.8% results were known to Dr. Mathisen from 2002-2006.

After Austin began taking Risperdal, Mrs. Pledger tried to deal with her son's weight gain because she thought the breasts he was developing were due to fat. She encouraged Austin to exercise and modify his diet. She testified Austin was embarrassed by his weird breasts and she told the jury that Austin usually refused to go swimming without a shirt and often covered his chest with his hands when looking at himself in a mirror.[8] She thought Austin's breasts were a function of his weight.

Asked at trial what she would have done if Dr. Mathisen had told her that there was an increased risk of Austin developing gynecomastia by taking Risperdal, she said, "No. I did not know boys could develop breasts or it was a side effect from the medicine at all. I knew nothing about that." (N.T. 2/6/15, p. 58.)

> Q. If you knew that, would you have allowed your son to be on the drug?
> A. No.
> Q. Can you tell that to us absolutely and categorically?
> A. Absolutely not. I—I can—I can't fight breast growth. I felt like with the weight gain, we could exercise. I could get---keep him active. I could keep encouraging healthy food. You can't fight something like that. I didn't know that was a possibility."

(N.T. 2/6/15, pp. 58-59.)

In November 2006, the FDA approved Risperdal for use among children with autism but the label now had a warning that reported a 2.3 % incidence of gynecomastia among children on Risperdal. (N.T. 1/28/15, Afternoon, p. 14.) Around that time, Mrs. Pledger was in the process of changing Austin's doctor to Dr. Donald Paoletti, who discontinued Austin's use of Risperdal in April, 2007. (N.T. 1/26/15, p. 205) But before this discontinuance, on January 19, 2007, Dr.

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[8] The photograph introduced at trial as P-47 shows Austin's chest as a boy. Mrs. Pledger testified P-47 is the only photo the family has showing Austin's chest while he was treating with Risperdal. He was not on any other anti-psychotic medications at the time.

Mathisen authorized refills of Austin's Risperdal prescription. (N.T. 1/26/15, p. 176.) Dr. Mathisen approved the refill without seeing Austin or speaking with Mrs. Pledger since their last visit to his office in October 2006. (N.T. 1/26/15, pp. 175-181.) Dr. Mathisen testified it was his policy to refill prescriptions of patients within six months of their last appointments with him. But he admitted that he had neither read the new Risperdal 2006 FDA label nor heard from other sources that risk of gynecomastia was no longer "rare" among children taking Risperdal. (N.T. 1/26/15, p. 169-172, p. 185-186)

This failure to warn by Dr. Mathisen was discussed by defense trial attorney Diane Sullivan, Esquire during her closing argument:

> Dr. Mathisen had all the information and again made the decision to prescribe Risperdal to Mr. Pledger. And Mrs. Pledger said he didn't tell her even then about the elevated risk of prolactin or the risk of gynecomastia. But that's not on Janssen. They gave him the new label. He said he had it in his hand.

(N.T. 2/19, 2015, p 106, lns. 18-25, p. 107, ln. 2).

Two photographs admitted and published at trial, P- 72 and P- 76, show Austin's gynecomastia. P-72 is a picture of Austin's gynecomastia at the time of the trial on February 4, 2015. P - 76 is a picture of Austin taken in October, 2012. The photographs were admitted during testimony by plaintiff's medical expert Dr. Mark Solomon to explain the difference between male breasts formed by breast tissue which is gynecomastia, and those formed by fat tissue, which is not.

A. Facts relating to Failure to Warn

The key negligence issue decided at trial was whether Janssen's failure to share Table 21 and its medical implications with the medical community, specifically Dr. Mathisen, violated a duty to warn. As already noted, Dr. Lodewjk Iwo Caers, Janssen's team leader for Risperdal

research from 2002 through 2009, had failed to disclose Table 21 to the FDA. (N.T. 2/11/15, p. 114, lns.22-24)

Plaintiff expert Dr. David Kessler explained why Table 21 mattered and why Janssen covered it up. He testified the FDA approved Risperdal in 1997 for treatment of adult psychosis. In 2002, Risperdal was FDA approved to treat adult schizophrenia. The drug label at that time told doctors that gynecomastia side effects were "rare", meaning one in a thousand or less. (N.T. 1/28/15 Afternoon, p. 11.) He said off label use of Risperdal for children had begun in the 1990s and had risen to 20 percent of all sales by 2000. (N.T. 1/28/15 Afternoon, p. 31.) He testified that as FDA Commissioner in 1997, he told Janssen that more testing was needed before the FDA would extend label approval to children. Janssen then began large scale pediatric medical testing of Risperdal, and the studies began in November 2000. (N.T. 1/28/15, p. 67.) Children were tested over different intervals for up to two years and at different doses to evaluate side effects and compile data.

Two of these studies had statistically significant adverse findings according to Dr. Kessler. "RIS – 41" and its extension study known as "INT – 70" reported that 6 out of 48 children who had taken Risperdal for up to two years developed gynecomastia, a 12.5% rate. (N.T. 1/29/15, p. 32, ln. 19) However, Dr. Kessler pointed out that 3 males of these 48 developed

gynecomastia during the second year for a 6.3% rate.[9] Both results are higher than the 2.3 % rate Janssen reported to the FDA for the 2006 label.[10]

Janssen's non-disclosure of Table 21 was not accidental in Dr. Kessler's view. An important document he relied on to show how Janssen kept Table 21 from the medical community is Exhibit P-34, the May 15, 2002 internal data report which contains 34 tables. (N.T. 1/29/15 Afternoon, p. 10.)[11]

At the time, Janssen scientists were studying the relationship between elevated prolactin levels and a list of potential adverse side effects including gynecomastia. The May 15, 2002 data print-outs were a collection of clinical findings reporting what Janssen called "prolactin-related adverse events" ("PRAE"). (N.T. 11/29/15 Afternoon, p.10, N.T. 11/29/15, p. 7 ln. 14, p. 13, ln. 19.)[12] Because earlier first generation psychotropic medications like Haldol were known to cause elevated prolactin levels with associated adverse risks, Janssen was testing second-generation Risperdal to see if these undesirable associations were also present with Risperdal. If not, Risperdal would enjoy a powerful marketing/sales advantage over first generation drugs. If the

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[9] The arithmetic was presented as follows: The RIS-41 study included 504 boys and girls. RIS-41 was performed over a one year period. Of these 504 children, 48 were followed for a second year in an extension study named INT-70. This INT-70 study reported that 6 male children out of the 48 studied for a second year developed gynecomastia, a 12.5% rate. Dr. Kessler noted that among these six were three children who had developed gynecomastia during the first year, a 6.3% rate. Put another way, Dr. Kessler testified 6.3% all children who took Risperdal between 8 and 12 weeks developed gynecomastia in the first year and 12.5% had done so by the second year. (N.T. 1/29/15 Morning, pp. 25-34)

[10] The new FDA label was issued in the fall of 2006. This label advised doctors that Risperdal may be used to treat autistic children and the risk of developing gynecomastia is 2.3%. (N.T. 1/29/15, p. 43)

[11] See and compare data published in Exhibit P-27, which is the November 3, 2006 edition of Journal of Child and Adolescent Psychopharmacology. P-27, published four years later is a Janssen sponsored medical article whose data was used in its FDA application leading to the 2006 approval of Risperidone for children. Table 21 is not published in this 2006 article, captioned *Long-Term Use of Risperidone in Children with Disruptive Behavior Disorders and Subaverage Intelligence: Efficacy, Safety and Tolerability*, (N.T. 1/29/15 p. 36).

[12] Janssen changed its terminology for PRAE between 2000 and 2002. Its researchers and writers began using phrases such as "symptoms *hypothetically* attributable to prolactin" ("SHAP"). (italics added) (N.T. 1/29/15, p. 22, ln. 20). Janssen further refined its statistical reporting by dividing data results into "SHAP A" and "SHAP B". SHAP A was a statistical category Janssen established for boys ten years or older. SHAP B was for boys younger than ten.

relationship between elevated prolactin and gynecomastia were unfounded, Janssen would also be able to claim this in its application and case to the FDA that Risperdal should be approved for children.

The Janssen scientists who wrote the May 15 internal report set baseline normal and upper limits for pediatric prolactin levels. (N.T. 1/29/15, morning, p. 22) They then pooled five different medical studies of children, all of whom were taking Risperdal. Janssen compared "adverse results" to prolactin levels.

Table 21 reports adverse events among children who were ingesting Risperdal during weeks 8 through 12 of the overall study. Dr. Kessler testified that among this specific group, there was a statistically significant growth rate of gynecomastia. As already noted, the rate of increase was 7.8%. (N.T. 1/29/15 Afternoon, p. 30 ln. 14, pp. 31-32) This percentage was based on clinical testing of 499 children who had ingested Risperdal between 8 and 12 weeks. 257 of these 499 children had elevated prolactin. Of these 257, 20 developed gynecomastia between 8 and 12 weeks for a 7.8% rate. (N.T. 1/29/15, afternoon, p. 30, ln. 14, pp. 31-32)[13] This statistically significant measure is shown in Table 21 and was within a chi-square rate of .02, meaning within a 98% chance of certainty. In Dr. Kessler's opinion this is a statistically significant finding. (N.T. 1/29/15, afternoon, pp. p. 27, ln.2 10-11, p. 28, lns. 7-12)

Dr. Kessler testified that the 7.8% rate for the 8 to 12 week group was at the top of an escalating trend of prolactin level increases among children during the early stages of their Risperdal ingestion. Table 21 showed increases in gynecomastia development among children taking Risperdal during the preceding 4 to 7 week period, but Dr. Kessler testified that the data

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[13] Generally, Table 21 shows some of the children on Risperdal maintained normal prolactin levels but others were elevated. The classifications were based on the amount of weeks children were exposed to Risperdal—four to seven weeks, eight to twelve weeks, twelve to sixteen weeks, sixteen to twenty four, etc.

for this earlier period was not statistically significant like those in the 8 to 12 week period.[14] (N.T. 1/29/15, afternoon, pp. 37-39)

With the significance of the Table 21 data explained, Dr. Kessler showed that corporate Janssen's strategy involved revising this May 15, 2002 internal report without Table 21. The method involved pooling all children tested in all Risperdal studies so a smaller percentage of gynecomastia incidence could be shown. [15] Eventually Janssen submitted data showing a 2.3% incidence of Risperdal and gynecomastia among children and this is what appears on the 2006 label when the FDA approved Risperdal for treatment of children. The final version was published in the November 3, 2006 medical article in the Journal of Child and Adolescent Psychopharmacology. P.27.

Substantial evidence was admitted showing different ways that Janssen staff addressed the unfavorable data even before the May 15, 2002 internal report. Janssen staff emailed each other for "reanalysis" of unfavorable data. (N.T. 1/29/15 Afternoon, p. 15, lns. 3-5.) One of these was on July 16, 2002. (N.T. 1/29/15, p.p. 40, 44-55.) This email contains an attachment of the first draft of a new proposed Janssen report known in court as the "Findling paper" and more formally as "Prolactin levels in children and adolescents with long-term Risperidone use."("July 16, 2001 draft") (P-36. N.T. 1/29/15, afternoon, p. 54, lns. 20-21.) Written for members of the Janssen Publishing Team by lead author Robert Findling M.D.and a team including Janssen

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[14] For this 4 to 7 week period, Table 21 shows 21 children on Risperdal had elevated prolactin. Of these, 6 children developed gynecomastia for a 28.5% rate. The arithmetic was not statistically significant in Dr. Kessler's opinion because the rate of uncertainty, the chi square test, was over 5 percent. Dr. Kessler noted that the 4 to 7 week data was important, however, because it showed an upward accelerating trend toward gynecomastia among children whose prolactin became elevated during early weeks of Risperdal ingestion. "So, what you see is numbers are rising here, in this early period." (N.T. 1/29/15, morning, p. 39, lns.16-17)

[15] While focusing here on Table 21 and the 7.8% figure, jurors had also been shown that two specific clinical studies, "RIS-41" and its extension study "INT-70" had yielded adverse gynecomastia findings ranging from 6.3% in the first year to an aggregate 12.5% after two years. . (N.T. 1/29/15, p.43.) Discussed infra. at page 10.

Director of Medical Affairs Carol Binder, this draft starts with a semantic change. Exhibit P-36. No longer would an unfavorable scientific result be called a "prolactin-related adverse event" ("PRAE"); the new term was "side-effects hypothetically attributable to prolactin" ("SHAP") (italics added).[16] Concerning Table 21, Findling, Binder et al reported the unfavorable scientific data as follows:

> The percentage of children with SHAP was assessed for patients with prolactin levels above the upper limit of normal versus patients with prolactin levels within the normal range at the various analysis time periods.
>
> The proportions were all comparable *except for the weeks 8 to 12 period, in which 7.8 percent of the patients who had SHAP at some point during the trial, while 2.9 percent of patients with prolactin levels within the normal range at weeks 8 to 12 experienced SHAP at some time during the study.* (P-36 p. JJRE 14079740. (Italics added).[17]

The writers noted this finding— that 7.8 % of children with elevated prolactin levels during weeks 8 through 12 developed gynecomastia— was statistically significant by writing "P<0 .02" next to their report.[18]

Binder and Pandina then go on to review Janssen's already produced corporate "poster" denying correlation between elevated prolactin and gynecomastia to the "SHAP" in plain view at Table 21.[19]

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[16] This was also the first time Janssen professionals used the term "hypothetically" in relation to the association between elevated prolactin levels and unwanted side-effects. Previous studies and reports had used the straightforward phrase "adverse events".

[17] In layman's terms, this passage is saying that among those children who showed above normal elevations of prolactin during the eight to twelve week mark of Risperdal ingestion, 7.8 % showed a side effect like gynecomastia over the two year course of the clinical trial. By contrast, among children whose prolactin level was normal during the eight to twelve week, only 2.9 % had side effects like gynecomastia over the two year period. The inference is that the presence of elevated prolactin among children taking Risperdal during weeks eight trough twelve of the clinical trial was more likely to cause gynecomastia than previously known and was substantial at 7.8 %.

[18] P<0.02 is the chi-square rate reflecting a data outcome within a 98% chance of certainty.

[19] As defined by Dr. Kessler, a poster is a presentation of data at a meeting. (N.T. 1/29/15, p. Afternoon, p. 54, ln. 18.)

The poster had stated, "There was no correlation with prolactin elevation and SHAP" among children taking Risperdal. (N.T. 1/29/15, afternoon, p.54, lns. 20-21)

Dr. Kessler explained Janssen's dilemma in July, 2002 as follows:

"Somebody realizes who's reading the paper that there is a significant value here. They also state that they have---there's a poster that they put out that says there's no direct correlation, and in essence, this is saying we have a problem." (N.T. 1/29/15, p. 55, lns. 13-18) [20]

Over the next 4 months, Janssen's pediatric publishing team managed the adverse data by developing a new "Key Message":

"Prolactin rise is transient and not related to side effects hypothetically attributed to prolactin, EPS or efficacy response." (P-38, N.T. 1/29/15 Afternoon, p. 66, lns. 6-9.)

Commenting on the general importance of accurate warnings, Dr. Kessler told the jury:

> The most important thing for me, I mean, both at the FDA and as a doc, a physician, is, and as someone who sits on the boards of the pharmaceutical companies, is---the one thing that you have to do when you're dealing with all medicines, including very powerful medicines, is to tell the truth, and you tell the whole truth and make sure that the data support that—support what you're saying.
>
> A key message—and pharmaceutical companies have key messages, they have---what that means is what they want to convey. And what they want to convey here---and you'll see in their own words—don't match what the data show. And to me that's not telling the whole story, especially when you're talking about adverse events that are significant and have a relationship.
>
> So you just make sure that FDA knows that, make sure doctors know that. Tell them the whole story, the good and the bad. It's not statistically significant at every point, but it's statistically significant at one important time point. Tell them that, the good and the bad. And that's what I care about. And that's what went into my opinion. (N.T. 1/29/15, afternoon, p.p. 67-68.)[21]

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[20] The paper Dr. Kessler is referring to is Table 21 data disseminated on May 15, 2002.

[21] See Exhibit P-49, the published "Findling report" dated November 2006 which incorporated the SHAP A and SHAP B statistical subcategories without publishing Table 21 itself, and without reporting the 7.8% figure incidence of gynecomastia among children tested with elevated prolactin levels who took Risperdal for eight to 12 weeks. Robert Findling, M.D. was the lead author; Janssen's Carin Binder, M.B.A. was a co-author.

B. Facts relating to causation

Evidence and trial events relating to causation are summarized here in narrative form. There were four types of factual disputes that were litigated at trial.

The first relates to whether plaintiff's scientific evidence shows a causal relationship between Risperdal ingestion by children and a statistically significant risk of gynecomastia?

The second is, if such a relationship exists and was known to Austin's treating doctor, would he have changed Austin's Risperdal prescription or what he said to Austin's mother about the drug, and would Austin have been prescribed Risperdal after his mother was warned?

The third is whether plaintiff has gynecomastia?

The fourth is, if plaintiff has gynecomastia, was the Risperdal ingested by plaintiff a substantial causal factor?

The narrative begins approximately a year before trial in March, 2014 when David E. Goldstein, M.D., a pediatrician and endocrinology specialist licensed in Missouri, examined Austin at the request of the Sheller Law Group, a Philadelphia products liability plaintiff firm. The physical examination took place in Alabama.

Dr. Goldstein met 19 year old Austin and his parents on March 5, 2014 at a hotel in Birmingham, Alabama, not far from the family's home. He examined Austin and diagnosed him with gynecomastia. Austin's parents gave Dr. Goldstein an oral medical history.

On March 31, 2014, Dr. Goldstein signed an expert report based on the physical examination, the parents' oral history, written medical records and deposition testimony. Dr. Goldstein's report includes his opinion as an expert in pediatric endocrinology that "the treatment of children and adolescents with Risperidone causes gynecomastia"; that Austin has "very enlarged breasts primarily due to gynecomastia" and that Austin's treatment with

Risperidone between 2002 and 2007 is "a substantial contributing factor to the development of Austin's gynecomastia."

The Sheller firm disclosed Dr. Goldstein's expert report to defendants' Philadelphia attorneys at Drinker Biddle within the case management time frame set by Judge Arnold L. New, Mass Torts Supervising Judge. Soon after, on April 16, 2014, Dr. Goldstein appeared for a deposition conducted by Janssen attorney and Drinker Biddle partner Thomas Campion, Esq. Mr. Campion asked Dr. Goldstein whether he was "practicing medicine" on March 5, 2014 when he examined Austin. Dr. Goldstein said he was "hesitating" in saying he had not been "practicing medicine" but only because he had told Austin's parents "a couple of things that I would recommend they did, but not under my care, like go to your doctor and do this and do that." (N.T. 4/16/14, p. 43.)

During trial proceedings nearly ten months later, Mr. Campion's line of questioning and Dr. Goldstein's deposition response became relevant to a mid-trial Janssen motion to preclude Dr. Goldstein's entire expert testimony. On the morning of Monday, February 2, 2016, moments before the jury was to enter the courtroom for testimony, Drinker Biddle partner, Kenneth Murphy, Esquire addressed the court on behalf of Janssen. Mr. Murphy advised that plaintiff attorney Christopher Gomez, Esquire of the Sheller Law Firm had emailed him on Saturday, January 31, 2015 to state that plaintiff intended to proceed with Dr. Goldstein's trial testimony by way of deposition *de bene esse*. Mr. Murphy told the court he had received written notice of this intention from Mr. Gomez the next day, Sunday, February 1, 2015. Mr. Murphy said he was surprised by this because he knew Dr. Goldstein had been in Philadelphia the previous week during Dr. Kessler's testimony. (N.T. 2/2/15, p. 5. lns. 13-21.)

Responding immediately, we agreed with Mr. Murphy that Dr. Goldstein's testimony had to be in person before the jury. We said,

"I agree. Given the nature of the attention to this case, I think it should be live. But I also think a short videotaped deposition outside the presence of this Court on such short notice at this time is inappropriate, and frankly, we have three weeks to go in this trial, I am sure it can be fit in somewhere." (2/5/15, Morning, p. 6, lns. 5-12.) Plaintiff trial attorney Thomas Kline, Esquire then advised he was planning to bring Dr. Goldstein to court the next day for his testimony. (N.T. 2/15/ 15, Morning, p. 7.)

Approximately five hours later, just before afternoon testimony on February 2, Mr. Murphy filed a motion and bench memorandum to preclude Dr. Goldstein from testifying at all. Mr. Kline was surprised and said he had been handed today "for the first time a motion which has apparently been either filed with the Court or about to be given to Your Honor, which seeks to preclude his testimony." (N.T. 2/2/15 Afternoon, p. 5-6.)

We read the motion during a trial recess later in the afternoon and learned Mr. Murphy was basing his motion on a claim of incompetence. The argument was Dr. Goldstein could not testify because he was incompetent, having committed a felony grade offense by "practicing medicine" in Alabama without an Alabama license when he examined Austin in Birmingham. Mr. Murphy's bench memorandum claimed:

"Because his opinions are based on this improper medical examination, the admission of Dr. Goldstein's testimony would undermine the integrity of this proceeding. This Court should not sanction the violation of another state's law. As such, Dr. Goldstein's testimony should be excluded in its entirety." (Bench Memorandum, p. 2.)

After Dr. Kessler's testimony, the jury was excused and argument began on Janssen's motion to preclude. It was established that nine months earlier, on May 7, 2014, Drinker Biddle lawyers had filed a different pre-trial motion to preclude Dr. Goldstein's testimony. This was a *Frye* motion before Judge New but no issues were raised about Dr. Goldstein practicing medicine in Alabama in violation of state criminal law. (Control No. 53 – 14051053.)

On July 11, 2014, Judge New denied Janssen's pre-trial motion to exclude Dr. Goldstein expert testimony. (Control No. 53-14051053) The issue whether Dr. Goldstein had practiced medicine in Alabama illegally was never raised by Drinker Biddle until February 2, 2015 as there were no pretrial motions *in limine* on this issue.

After hearing argument, we initially denied the preclusion motion on grounds of untimeliness. The motion's filing had violated the Case Management Order set by Judge New. (N.T.2/2/15, p. 147.) Mr. Kline expressed concern, however, that his client may be chilled from testifying as a result of Janssen's accusations that he had committed a crime. It occurred to the court that, at the very least there could be potential Fifth Amendment implications giving rise to potential unavailability. Mr. Kline urged the court to consider a remedy involving a new expert witness if Dr. Goldstein were to become unavailable. (N.T. 2/2/15, p. 149, 1.ns. 1 – 9.) We advised the lawyers that we were inclined to do so if review warranted but for the moment, the motion was denied on grounds of untimeliness.

The next morning, argument resumed outside the presence of the jury. By then, we had studied the bench memorandum more thoroughly and researched Alabama law on the subject of practicing medicine there with an out-of-state license. Mr. Kline told the court he had lost his expert because Dr. Goldstein was no longer available to him to testify. Mr. Kline said Dr.

Goldstein had left Pennsylvania and was outside our jurisdiction. Mr. Kline then argued as follows:

> They are—they knew for a year about this problem. Let me just say—let me just lay it out. They knew for a year. For a year they claim that they knew what they claim to be a crime. Whether they're right about that or not is another story, and they did nothing, nothing.
>
> Number two, they've done nothing—they did nothing but come in here yesterday to chill a plaintiff's ability to obtain justice. And by the way, they did it by essentially in that paper using a threat that he was somehow subject to---that the plaintiff's expert was subject to some kind of criminal prosecution.
>
> Whether right or wrong, Judge, that is a violation. And I did research on that. That's a separate violation. And everyone knows what I'm talking about.[22]

(N.T. 2/3/15, pp 66-68.)

Realizing Austin's prejudice was real, we vacated the denial order based on untimeliness and held an evidentiary hearing to determine next steps.

This was done outside the presence of the jury. The threshold question on the merits was whether Mr. Murphy was correct that Dr. Goldstein was incompetent to testify because he may have violated Alabama law. For reasons, to be explained more fully later, we rejected his position that "protecting the integrity of the court" was a competency issue. We noted that witnesses tainted by criminal convictions are routinely permitted to testify in both civil and criminal courts, and ultimately juries determine how much weight to give their testimony. (N.T. 2/3/15, Afternoon, p. 8-12.)

We considered whether to grant a defense motion for mistrial if we denied its motion to preclude. This was not an outcome plaintiff desired, having just presented four days of testimony

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[22] Mr. Kline is likely referring to Pa. Rule of Professional Responsibility 4.4(a) ("In representing a client, a lawyer shall not use means that have no substantial purpose other than to embarrass, delay or burden a third person..."). Janssen's timing arguably suggested an intention to cause Dr. Goldstein to fear criminal prosecution and provoke him to leave the state.

from Dr. Kessler, and plaintiff objected. The issues were whether plaintiff should be given an opportunity to present his case through a new expert witness and whether this could be done timely without prejudicing Janssen.

The first question was under what circumstances do Pennsylvania rules of civil procedure permit reopening of discovery during trial. As will be explained below, we determined that plaintiff may be granted permission to reopen discovery of a medical expert upon cause shown by exceptional circumstances under Pa. R.C.P. No. 4003.5(2) and Pa. R.C.P. No. 4003.5(3).

Pledger's attorneys proposed that Austin be physically examined the next day in Philadelphia by a new potential expert witness. The idea was to fly Austin from Alabama for this examination. According to counsel, the proposal involved examination by Mark Solomon, M.D., a doctor who was already known to Janssen's Drinker Biddle attorneys. Dr. Solomon had previously been deposed by defense counsel in preparation for an earlier proposed Philadelphia Court of Common Pleas Risperdal bellweather case that had settled a few months earlier.[23]

We realized that if Dr. Solomon were able to examine Austin on Friday, February 5, 2015, and if Dr. Solomon concluded that he could offer an expert opinion and prepare his report by the following day, Saturday, February 5, we would then be able to order his deposition for Sunday, February 6, and have him testify in court on Monday, February 7. This proposed discovery procedure could be done with the loss of only one trial day, Thursday, February 4. We would order Dr. Solomon to be available for trial testimony on Monday, February 7. This timetable, if carried out, protected Janssen from unfair surprise. Janssen's would be ready for Dr. Solomon because Janssen's lawyers had already conducted a lengthy deposition of Dr. Solomon for Judge Overton's case. Dr. Solomon's credentials and methodology were known. The

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[23] *Banks v. Ortho-McNeil-Janssen Pharmaceuticals,* C.P. Phila., Jan. Term 2010, No. 618 (Overton, J).

proposed timetable also gave Janssen's medical experts between three days and a week to respond to Dr. Solomon's testimony without requiring them to file a supplemental expert report.

As for Mrs. Pledger, we ordered that she be subject to deposition on the circumstances of her trip to Philadelphia with Austin and to disclose her communications with Dr. Solomon when she brought Austin to his medical office outside Philadelphia.[24]

We granted plaintiff's motion to reopen discovery under Pa. R.C.P. No. 4003.5(2) because exceptional circumstances had caused the unavailability of Dr. Goldstein. These exceptional circumstances under Pa. R.C.P. 4003.5(3) were Janssen's late and prejudicial motion to preclude Dr. Goldstein, which caused unfair surprise to plaintiff and chilled the availability of his expert. As plaintiff had no other expert noticed for trial, plaintiff was facing non-suit unless a new expert could be proffered and testify with admissible evidence. (N.T. 2/3/15, pp. 112-116.)

Janssen objected and again moved for mistrial. Ms. Sullivan argued Dr. Solomon is a plastic surgeon and she was prejudiced because her case theory involved attacking Dr. Goldstein's endocrinology based opinion. We denied her mistrial motion for three reasons.

First, the discovery timetable gave Janssen's attorneys reasonable time to prepare Dr. Solomon's trial cross-examination. Transcripts show Ms. Sullivan was ready. She cross-examined Dr. Solomon on Monday, February 7, the day after his new deposition, and she used both depositions during her impeachment. The record shows she vigorously challenged Dr. Solomon's expertise and credibility.

Second, Janssen's trial experts had time to respond to Dr. Solomon's testimony.

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[24] Mrs. Pledger had already been deposed before by Janssen counsel during pretrial discovery in this case on November 8, 2013.

Third, to the extent Janssen's strategy was changed from challenging Dr. Goldstein's endocrinology to challenging Dr. Solomon's differential diagnosis, the blame stands on them.

In preparation for counsel's mistrial arguments and before permitting the trial testimony of Dr. Solomon, we reviewed the entire situation again. We reanalyzed whether discovery relating to medical expert witness testimony had been reopened fairly according to rules and whether the circumstances involving Dr. Goldstein were indeed extraordinary. We researched whether Dr. Solomon's medical expert testimony would be admissible if it were based on a different medical subspecialty. We reviewed documents and photographs including Dr. Solomon's written expert report and his curriculum vitae.

We read a "Patient Registration 2015" which recorded Mrs. Pledger's consent to Dr. Solomon's examination. We reviewed Dr. Goldstein's original expert report and compared it to Dr. Solomon's. We reviewed documents prepared by defense expert witnesses Glenn D. Braunstein, M.D., dated March 21, 2014 and April 30, 2014, and by T. Brooks Vaughn, III, M.D., dated May 9, 2014. Both Dr. Braunstein and Dr. Vaughn were potential defense medical experts who had examined Austin in Alabama.

These documents were reviewed in the context of Janssen's demand for complete exclusion of expert testimony by Dr. Solomon and Ms. Sullivan's characterization that he was "woefully unqualified to replace an endocrinologist in this case." (N.T. 2.5.15, p. 15) She had argued that because Dr. Solomon was a plastic surgeon, his medical opinion must be inadmissible because it was not based on endocrinology. Dr. Solomon's opinion was based on differential diagnosis. Ms. Sullivan argued Janssen was prejudiced by their different perspectives on causation.

Arguing plaintiff's side, Mr. Kline recounted the procedural and ethical circumstances that led to the unavailability of Dr. Goldstein. He repeated his argument that Janssen's lawyers had broken ethical rules, such as filing late and prejudicial motions with no substantial purpose other than to "embarrass, delay or burden a third person." [25] Mr. Kline had also claimed Janssen's attorneys violated Philadelphia ethical practice by which attorneys may not directly accuse other persons of criminal conduct to gain evidentiary advantage in court.[26] Mr. Kline noted Janssen attorneys stated in open court that that Dr. Goldstein had violated Alabama criminal law, though he had not been charged. Examples include Ms. Sullivan's statements:

"Your Honor, because they *violated* law ..." (N.T. 2/2/16, p.143, Ins. 14--15);

"Your Honor, they *violated* the law" (N.T. 2/4/15, afternoon, p. 63, lns. 10-11);

"Your Honor, we have never threatened criminal prosecution at Dr. Goldstein, what we did was simply advise the Court of what was accurate. There is a statute in Alabama that they violated." (N.T. 2/5/15, pp. 11 – 47, lns.. 3 – 7)(emphasis added).

Responding at that time to a court caution, Ms. Sullivan continued:

"One thing, the Plaintiffs have never stated was they weren't in violation of the statute." (2/5/15, p. 47, lns 14-61)

The legal relevance to Mr. Kline's ethics charge is whether "cause" had been shown under Pa. R.C.P. 4003.5(2) and whether "extenuating circumstances" had been shown under Pa. R.C.P. 4003.5(3).

We rejected Janssen's position that Dr. Goldstein's alleged violation in Alabama would have automatically precluded the admissibility of his expert testimony if it had been offered.

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[25] *See* Comment, Pa. Rule of Professional Conduct 4.4.

[26] Mr. Kline appears to be referring to Opinion 89 – 17, Ethics Opinion (September 1989), Phila. Bar Association.

Janssen cited no support for its proposition that the "integrity" of the *Pledger* trial depended on excluding Dr. Goldstein. We understood that even if Dr. Goldstein had been convicted of violating Alabama's criminal statute, and if he had been available, Dr. Goldstein's expert testimony would not have been precluded. He would have still been competent to testify subject to impeachment. We did not enter a forma denial of the motion to preclude, however as the motion had become moot by Dr. Goldstein's unavailability.

Defense attorney tactics, including failure to timely raise Dr. Goldstein's licensure issue had no substantial purpose "other than to embarrass, delay or burden a third party". The effect was to unfairly surprise Dr. Goldstein and put him in fear of potential criminal prosecution and self-incrimination if he testified. The timing and suddenness of Janssen's accusations meant he had not consulted a criminal defense attorney to counsel him on whether testifying at the *Pledger* trial was a personal risk. Only Janssen could benefit from this situation as the likely result was a voluntary non-suit.

(N.T. 2/2/15, p. 149, lns. 14-16; N.T. 2/3/15, p. 6, lns. 12-15; p. 10, lns 20-23; p.11. lns 4-11).

Before allowing Dr. Solomon to testify, we also considered whether the proposed content of his expert opinion would be admissible. Janssen's lawyers had argued that Dr. Solomon was unqualified because he was a cosmetic surgeon whose expertise was irrelevant. As Ms. Sullivan phrased it, "he specializes in penile enlargement". (N.T.2/5/15, p. 19, ln.10.) She also argued that Dr. Solomon was unqualified because he has not "published or trained in any way, shape or form" in endocrinology or "prolactin elevation". (N.T. 2/5/15, p. 22, lns. 14-15.) She claimed she was unprepared for Dr. Solomon because his expert report and Dr. Goldstein's stated different medical reasons for their ultimate opinion that Austin's gynecomastia was caused

by taking Risperdal. As an example, Ms. Sullivan argued Dr. Goldstein's opinion was that obesity can cause gynecomastia while Dr. Solomon disagreed.

Counter-arguing, Mr. Kline highlighted Dr. Solomon's experience as a medical doctor and surgeon who has diagnosed and treated hundreds of cases of gynecomastia. (N.T. 2/5/5/15, pp. 32-36) He pointed out that Dr. Solomon's 30 year clinical career necessarily includes daily diagnoses of patient diseases based on differential diagnosis. Mr. Kline argued that Dr. Solomon's academic credentials include his co-editorship of a book entitled *Aesthetic Surgery for Males* which published a chapter on gynecomastia. He reminded the court that Janssen attorneys possessed a 200 page deposition from Dr. Solomon taken in preparation for Judge Overton's bellwether case which had settled. [27] In this deposition, Janssen lawyers familiarized themselves with Dr. Solomon and his career. This included questions testing Dr. Solomon's knowledge about gynecomastia, about his education and medical experiences, about his diagnostic methods, and about his familiarity with Risperdal and its side effects. [28]

Based on Janssen's familiarity with Dr. Solomon's medical qualifications and his opinions and methods directly related to the issues in this case, we concluded there was no unfair surprise to Janssen.[29]

Accordingly, we reaffirmed our earlier decision to reopen medical discovery, ordered that a new deposition of Mrs. Pledger take place and ordered Dr. Solomon to submit to a deposition before his trial testimony on Monday, February 9.

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[27] *Jacob Goldenberg v. Janssen Pharmaceuticals*, CP Phila. Feb. Term, 2013, No. 1719.
[28] Defense Exhibit 44, Deposition of Mark P. Solomon, M.D., August 20, 2014 in *Goldenberg v. Janssen*, , CP Phila., Feb. Term, 2013, No. 1719.
[29] In court, we specifically cited *Lira v. Pearlstine, 559 A.2d 550, 553* (Pa. Super. 1989) *alloc den.* 527 Pa. 635 (1990) for the proposition that experts in one area of medicine may be found qualified to address other areas of specialization where the specialties overlap in practice or where the specialist has had experience in a related field of medicine.

At trial, Dr. Solomon was qualified as a medical expert in the fields of surgery, plastic surgery and the disease of gynecomastia. He is a graduate of Franklin & Marshall College, received his M.D. at NYU, interned in surgery at the University of Pennsylvania-Presbyterian, completed a surgical residency at Thomas Jefferson University and is board certified in general surgery. (N.T. 2/9/15, p. 31)

Dr. Solomon testified that he had significant experience treating patients with gynecomastia; that he had edited a medical textbook with a specific chapter on the disease; that he was familiar with prolactin and its relationship to the development of breasts in males and females; and that he has diagnosed gynecomastia hundreds of times before performing surgery. He testified on direct examination that he has a plastic surgery practice in Bala Cynwyd, PA which includes cosmetic surgery for penis and breast enlargement. He testified that he is a specialist at Philadelphia's Shriners Hospital for Children where he regularly participates in complex rehabilitative surgery. He told the jury that he was scheduled to perform pediatric plastic surgery the next day at Shriners to affix a prosthesis for a child with a limb deficiency and was doing so in conjunction with a team of Temple Hospital orthopedic surgeons. (N.T. 2/9/15, p.29, lns 16 – 19.)

During direct examination, Dr. Solomon testified to a reasonable degree of medical certainty his opinion that Austin's ingestion of Risperdal caused his gynecomastia. Dr. Solomon told the jury he had physically examined Austin, reviewed his written medical history and received oral history from Mrs. Pledger. He also reviewed the FDA's 2006 Risperdal label and Janssen's unpublished data report that included "Table 21." (P-34)

Dr. Solomon said he based his causation opinion in part by performing a differential diagnosis and told the jury why he ruled out other causes. Dr. Solomon testified that in his

opinion gynecomastia does not develop in pre-puberty boys absent an abnormality caused by disease or an outside agent such as a medication. Reviewing Austin's medical records, Dr. Solomon saw no evidence of a disease causing Austin's gynecomastia. He specifically ruled out other known causes which were not present in Austin's medical history including the absence of Kleinfelter syndrome, thyroid abnormality, or either pituitary or testicular tumors. "Absent another cause, another drug, another tumor, another kind of anything, a normal 8 year old boy has a zero incidence of gynecomastia" (N.T. 2/9/15, p. 106 Ins. 10 – 12.)

Dr. Solomon testified that in his medical opinion, based on all the evidence before him, Risperdal was the only remaining variable and he told the jury why:

> [S]o, briefly, Risperdal is a drug that among its side effects, it's a stimulant of prolactin which is this hormone that we talked about briefly that's secreted by the pituitary gland and acts on the breast tissue.
>
> He was exposed to this drug at the age of 8. If you review literature, in 8 to 12 weeks from exposure to the drug, prolactin goes up significantly. And his response to that significant rise, time related according to his mom, was the development of some breast buds which she didn't rightfully connect, because she wouldn't. He stayed on that drug for five years. I believe until 2007. So that he had a constant stimulus with elevations in prolactin for some prolonged period of time that we can---I'm sure occurred. I have no reason not to think it occurred because of my knowledge of the drug, and therefore, it stimulated his breasts to grow. (N.T. 2/9/15, Morning, p. 104, lns. 19-25; p. 105, lns. 1-13.)

Dr. Solomon explained his medical opinion that the diagnosis of the disease of gynecomastia depends on the presence of breast tissue and he explained that breast tissue is biologically not the same as fat tissue. He showed the jury the difference using medical slides. Dr. Solomon stated breast tissue growth does not go away on its own since it does not come from obesity which is characterized by fat cells that grow and recede depending on weight. Dr. Solomon testified that his own physical examination of Austin confirmed the presence of breast

tissue inside Austin's breasts. Dr. Solomon said Austin had been on Risperdal for several years and his medical records had reported no other causal agent. He said female breasts in boys develop from the center and then spread outwards. The areola grow first and then breast tissue multiplies around the areola to form gynecomastia. Dr. Solomon told the jury that a picture of Austin shows what he termed "end stage growth." Pointing at the 2005 picture of 11 year old bare chested Austin coming out of a swimming pool, Dr. Solomon testified, "That's a full breast. That's not a little nipple out pouch. In 2005, he was 11 that would be the beginning of puberty. So if it were pubertal in origin, you would see a little pouch of a nipple, not an outline of a breast." (N.T. 2/9/15, p. 66.)

In contrast, the position of Janssen experts was that Austin has a condition called "pseudogynecomastia", a disease category diagnosed by some physicians who link obesity and fat to the development of feminine looking breasts in boys. On direct examination, Janssen experts disagreed with Dr. Solomon's opinion that obesity and its associated fat tissue do not cause gynecomastia. According to Janssen, Austin had pseudogynecomastia in the 2005 photograph and the breasts seen in the picture were neither gynecomastia nor related to Risperdal. However, defense expert Dr. Tom Vaughn, III, an endocrinologist, admitted on cross-examination that based on his own physical examination of Austin, plaintiff has gynecomastia. (N.T. 2/18/15, Afternoon, p. 18, lns. 17-19.) He agreed with Dr. Solomon that this diagnosis of gynecomastia depends on the presence of breast tissue. (N.T. 2/19/2015, Afternoon, pp 18-19.)

Austin was administered Risperdal when he was eight years old beginning in the summer of 2002. He took the drug for five years. Weeks 8 to 12 of his Risperdal use occurred after Janssen was aware of Table 21 which was among the other data tables that circulated within Janssen's offices on May 15, 2002. P-34.

III. LEGAL ANALYSIS

By stipulation, Alabama substantive law governs liability is case; Pennsylvania law governs procedure. New Jersey law was applied to the question of punitive damages before this trial began.

1. Factual Causation

A. The Learned Intermediary Doctrine Does Not Preclude Proof of Proximate Cause Under the Facts of this Case.

The relationship between negligent failure to warn, the learned intermediary doctrine and causation are intertwined in failure to warn cases. By May, 2002, Janssen knew that Table 21 reported a greater than rare risk that children will develop gynecomastia between weeks 8 and 12 of their exposure to Risperdal. Janssen's team leader for Risperdal research from 2002-2009, Dr. Caers, admitted keeping Table 21 from the FDA. Janssen also failed to warn doctors about the implications of Table 21 through timely medical publications or by presentations at medical conferences. Janssen did not use permitted Dear Doctor letters to disseminate information about Table 21 and Janssen never authorized its sales representatives like Jason Gilbraith to give warnings to the doctors they dispensed samples to.

Janssen now argues even if its warning was inadequate, Janssen is not liable because its negligence did not cause Austin's injury. Janssen argues it owed no duty to Austin's mother under the learned intermediary doctrine. Janssen relies on the absence of testimony from Dr. Mathisen that he would not have prescribed Risperdal to Austin if he had known the risk of gynecomastia was greater than "rare". The problem for Janssen is Dr. Mathisen also testified he would have warned Mrs. Pledger if he had known.

Law in the area of the learned intermediary doctrine and proximate causation does not support Janssen. This is because patients have the right to know about significant risks posed by a medication, and this right depends on a pharmaceutical company making full disclosure to the learned intermediary.[30]

In *Wyeth v. Weeks,* the Alabama Supreme Court addressed a federally certified question at summary judgment: whether a brand name drug company could be liable for an inadequate warning when there was no privity between the brand name company ("Wyeth") and the prescribing doctor. This lack of privity was due to the fact that plaintiff had taken generic pills, not Wyeth's brand name products. Wyeth was arguing it could not be liable because there was no proximate cause between itself and the doctor.

Disagreeing, the *Wyeth* Court began by noting the familiar rule that "but for" an inadequate warning, "the prescribing physician would not have prescribed the medication to his patient".[31] But then the Court continued as follows:

> Wyeth's argument completely ignores the nature of prescription medication. The Weekses cannot obtain Reglan or any other prescription medication directly from a prescription-drug manufacturer. The only way for a consumer to obtain a prescription medication is for a physician or other medical professional authorized to write prescriptions (i.e., a learned intermediary) to prescribe the medication to his or her patient. This Court has adopted the learned-intermediary doctrine, which provides that *a prescription-drug manufacturer fulfills its duty to warn users of the risk associated with its product by providing adequate warnings to the learned intermediaries who prescribe the drug and that, once that duty is fulfilled, the manufacturer owes no further duty to the ultimate consumer. When the warning to the prescribing health-care professional is inadequate, however, the manufacturer is directly liable to the patient for damage resulting from that failure.* The substitution of a generic drug for its brand-name equivalent is not

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[30] *Wyeth, Inc. v. Weeks*, 159 So.3d 649 (Ala. 2014); *Fields v. Eli Lilly and Co.*, 116 F.Supp. 3d 1295 (M.D. Ala. 2015). *Fields* is directly on point and was decided soon after the verdict in *Pledger*.
[31] *Wyeth*, 159 So. 3d at 673-674.

> *liable to the patient for damage resulting from that failure.* The substitution of a generic drug for its brand-name equivalent is not fatal to the Weekses' claim because the Weekses are not claiming that the drug Danny ingested was defective; instead, the Weekses' claim is that Wyeth fraudulently misrepresented or suppressed information concerning the way the drug was to be taken and, as discussed, the FDA mandates that the warning on a generic-drug label be the same as the warning on the brand-name-drug label and only the brand-name manufacturer may make unilateral changes to the label.[32]

Wyeth held that a brand name manufacturer can be held liable for a fraudulently misrepresented label even though it was a generic company that made the actual drug.[33]

In *Fields v. Eli Lilly and Co.*, the *Wyeth* Court holding was applied to a negligent failure to warn case.[34] The Hon. W. Keith Watkins, Chief Judge of the U.S. Middle District of Alabama denied a summary judgment motion filed by Eli Lilly and Co. ("Lilly"). For purposes of the motion, Lilly had conceded it should have warned Prozac users in the mid-1990's that there was "an increased risk of birth defects from ingestion of Prozac during pregnancy." Lilly then argued it should not be liable regardless because the patient could not prove "the actual and proximate cause" of her injury. Plaintiff Mrs. Dana Fields argued that if Lilly had given her physician Dr. Jimmy D. Durden an appropriate warning, he would have had a duty to pass the warning to her. She had stated that if Dr. Durden had warned her, she would have stopped using Prozac while she was pregnant.

Citing *Wyeth,* Chief Judge Watkins denied Lilly's summary judgment motion, finding plaintiff had raised genuine disputes of material fact on 1) whether she took Prozac during her pregnancy and 2) whether factual causation exists. The Court held:

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[32] *Id.* at 674 (italics added).
[33] *Id.*, at 675 citing *Wyeth v. Levine* 555 U.S. 555 (2009) and *Pliva Inc. v. Mensing*, 564 U.S. 604 (2011)).
[34] *Fields v. Eli Lilly and Co.*, 116 F.Supp. 3d 1295 (M.D. Ala. 2015)

> [U]nder Alabama's learned intermediary doctrine, Mrs. Fields can demonstrate factual causation by proving that had Lilly given Dr. Durden a stronger warning about the association between the ingestion of Prozac during pregnancy and an increased risk of birth defects, Dr. Durden would have informed Mrs. Fields of the risk and his warning would have resulted in a different outcome for Mrs. Fields in that she would not have taken Prozac. *This theory is not predicated on the effect an adequate warning would have had on Mrs. Fields, but rather upon the effect an adequate warning would have had on Dr. Durden's prescribing practices."* (emphasis added.).[35]

Our jury instruction in *Pledger* explained the relationship between negligence, failure to warn, the learned intermediary doctrine and factual causation as follows:

> Negligence is the failure to use reasonable care to prevent harm to one's self or others. A person's conduct is negligent if he or she either does something that a reasonably prudent person would not do in a similar situation or he or she fails to do something that a reasonable person would have done in a similar situation.
>
> So you must decide in this case if Janssen was negligent in this situation. Now this case is about a duty to warn, okay, about a duty to warn by a drug company, a manufacturer. But this duty to warn goes, under what I'm about to tell you, under what we call the Learned Intermediary Doctrine, goes to the prescribing doctor, to the physician, okay. It goes to the prescribing physician.
>
> 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.
>
> A prescribing physician acts as the learned intermediary between himself or herself and the patient, or in this case the patient's guardian. This is because the law recognizes that the prescribing physician is in the best position to evaluate a patient's needs and to assess the risks and benefits of a particular course of treatment. We all know that.
>
> So in cases involving a brand name pharmaceutical manufacturer, such as Janssen with Risperdal, the drug company's duty to warn is limited, and it's limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use.
>
> This is because prescription drugs are likely to be complex medicines which are esoteric in formula and varied in effect. So we

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[35] *Id.* at 1307. (Italics added).

> rely on the expertise of the physician intermediary to bridge the gap in special cases where the product and the related warnings are sufficiently complex, so as not to be fully appreciated by the patient or patient's guardian, all right?
>
> The choice made by the doctor is an informed one, an individualized medical judgment on what he or she knows about the patient and the prescription drug. Pharmaceutical companies are, therefore, required to warn only the prescribing physician who is the learned intermediary between the manufacturer and the patient's guardian, all right? The duty to warn goes to the doctor, goes to the doctor."

The jury found Janssen owed Dr. Mathisen a duty to warn. Not only was the information about the implications of Table 21 relevant to Dr. Mathisen's prescription decisions on Risperdal for children, it was also relevant to his duty to warn his patient's mother about dangers of the drug he was prescribing.

Janssen argues that even if its duty to warn Dr. Mathisen was breached, there is no liability. This claim is based on the absence of testimony from Dr. Mathisen that he would not have prescribed Risperdal to Austin even if Dr. Mathisen had been adequately warned.

However, the jury heard Mrs. Pledger tell them that if Dr. Mathisen had told her about the link between Risperdal and gynecomastia, she would not have let Austin take Risperdal. Mrs. Pledger testified she would have feared for her son's embarrassment and humiliation.[36] The jury also heard Dr. Mathisen tell them that if he had been warned by Janssen, he would have told Mrs. Pledger.

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[36] Mrs. Pledger spoke of Austin's self-awareness of his breasts and his incapacity as an autistic person to ask her why he is different from other boys or men. She testified that he had been humiliated in school on account of his breasts. (N.T. 2/6/15 Morning Session, p. 49.)

Finding both Mrs. Pledger and Dr. Mathisen to be credible, proximate cause was proven. *Fields v. Eli Lilly and Co. supra.* citing *Wyeth, Inc. v. Weeks, supra.*[37] But for Janssen's failure to warn Dr. Mathisen, Austin would not have taken Risperdal.

B. Janssen was not prejudiced by the reopening of discovery after Dr. Goldstein's unavailability following exceptional circumstances.

After Dr. Goldstein became unavailable, the parties disagreed whether it was too late for plaintiff to substitute a new expert. Janssen attorneys had accused Dr. Goldstein of practicing medicine in Alabama without an Alabama medical license, a violation of Alabama criminal statutes.[38] The timing of Janssen's motion and the nature of their accusation were extraordinary and seemed calculated for maximum surprise. If Janssen's late motion were granted, plaintiff would have no choice but move for voluntary nonsuit. If the motion were denied, then Dr. Goldstein would likely choose to take the Fifth Amendment or testify with predictable damage to his credibility. Either way, if the motion had been filed before trial, there would not have been extraordinary prejudice to plaintiff who would likely have moved for a continuance before undergoing the expense of trial.

Cause was therefore established to give plaintiff an opportunity to avoid non-suit. Applied together, Pa. R.C.P. 4003.5(a) (2) (A) and Pa. R.C.P. 4003(a)(3) permit reopening of

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[37] Assuming this credibility finding, the proximate cause outcome should be the same under Pennsylvania law. *See Simon v. Wyeth Pharmaceuticals, Inc.* 989 A.2d 356, 368 (Pa. Super. 2009) ("In the duty to warn context, plaintiffs must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, **he would have altered his behavior** and the injury would have been avoided") citing *Demmler v. Smithkline Beecham Corp.*, 671 A.2d 1151, 1155 (1996) (emphasis added).

[38] Our research leans against Alabama courts considering Dr. Goldstein's examination of Austin for purposes of medical expert preparation to be "practicing medicine". Ala. Code 1975 Sec. 34-24-50; Ala. Code Sec. 34-24-74.; Ala. Code 1975 Sec. 34-24-51. Based on Dr. Goldstein's deposition in 2014, he examined Austin in Alabama in preparation for potential litigation. To the extent that he gave any medical advice to Austin's mother, he said it was limited to suggesting that Austin visit his own doctor to check on something Dr. Goldstein had observed. N.T. 4/16/14, p. 43.

Pa. R.C.P. 4003.5(a)(3), we set restrictions as to scope of discovery and provided for allocation of fees and expenses associated with the reopened discovery.[39]/ [40]

2. Expert Witness Qualifications

Janssen vigorously protested reopening discovery and giving plaintiff the chance to substitute his medical expert.

After receiving Dr. Solomon's expert report, Janssen attorneys argued his opinion would force them to change their trial strategy. Ms. Sullivan said she had told the jury in her opening that she would show them that Dr. Goldstein's opinion, based on endocrinology, was wrong. She claimed that Dr. Solomon's opinion, based on differential diagnosis, prejudiced her defense.

We analyzed her argument under Pennsylvania rules of evidence relating to expert witnesses. Pa. R.E. 702 provides that witnesses are qualified to offer an expert opinion by knowledge, skill, experience, training or education if (1) the expert's specialized knowledge is beyond that of a layperson, (2) the expert's specialized knowledge will help the trier of fact to understand the evidence or determine a fact in issue, and (3) the expert's methodology is generally accepted in the relevant field. This is an adoption of the seminal standard set forth in *Frye v United States.*[41]

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[39] Extenuating circumstances under rules of discovery existed because Janssen's actions had placed Austin in the same kind of position at trial as if he had not named his medical expert before trial. Generally, an undisclosed witness may not testify at trial but there are exceptions. When a party has not disclosed the identity of a witness before trial because of extenuating circumstances, trial courts have the discretion to grant a continuance or other appropriate relief under Pa R.C.P. 4017(i).

[40] Pa. R.C.P. 4003.5(a)(3) provides in pertinent part: "or except on order of court as to any other expert upon a showing of exceptional circumstances under which it is impractical for the party seeking the discovery to obtain facts or opinions on the same subject by other means, subject to such restrictions as to scope and such provisions concerning fees and expenses as the court may deem appropriate."

[41] *Frye v. U.S. 293 F.1013* (D.C. Cir. 1923); Comment of the Committee on Rules of Evidence, Pa. R.E. 702. Pennsylvania's approach to qualifying an expert witness is an explicit rejection of the federal test derived from *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). The Committee notes, "The rule applies the general acceptance test for the admissibility of scientific, technical, or other specialized knowledge testimony."

The test is "whether the witness has any reasonable pretension to specialized knowledge on the subject under investigation."[42] A person is deemed an expert if he or she "possesses knowledge not within the ordinary reach, and because of this knowledge, is qualified to speak upon a particular subject." [43] Regarding expert medical doctors, courts recognize overlap among doctors in their specialized knowledge. The same ultimate opinion may derive from doctors working in different medical fields.[44] Therefore, two doctors practicing medicine in different but overlapping specialties may each qualify to give an expert medical opinion on the same causal issue.[45] It is only when the scope of a medical expert's experience and education do not embrace a particularized subject matter should a trial court decline to admit an opinion from an expert whose familiarity with the subject is limited to general medical knowledge.[46]

When an expert witness is qualified to give an opinion based on a particular medical field or specialty, it is up to the factfinder whether "to believe all, part, or none of the evidence and to determine the credibility of the witnesses."[47]

During voir dire on his expert qualifications, Mark B. Solomon, M.D. testified that he regularly addresses endocrinal issues because "endocrine surgery is a separate subset of general

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[42] *Miller v. Brass Rail Tavern, Inc.*, 664 A.2d 525, 528 (Pa. 1995).
[43] *Pratt v. Stein*, 444 A.2d 674, 707(Pa. Super. 1982) quoting *Ercshen v. Pennsylvania Independent Oil Company*, 393 A.2d 924, 926 (Pa. Super. 1978).
[44] *Rittenhouse v. Hanks*, 777 A.2d 1113, 1116 (Pa. Super. 2001) *rearg den.* ("Appellants' contention that Dr. Meller was not qualified because he is not a radiation oncologist is unavailing since experts in one area of medicine may be found qualified to address other areas of specialization where the specialties overlap in practice or where the specialist has had experience in a related field of medicine. *See, e.g., Lira v. Albert Einstein Medical Center*, 559 A.2d 550 (Pa. Super.1989) (neurologist with some training in otolaryngology competent to render expert testimony on conduct of otolaryngologist).
[45] *Bindschusz v. Phillips*, 771 A.2d 803, 808-09 (Pa. Super. 2001) citing *Estate of Pew*, 598 A.2d 65, 69 (Pa. Super. 1991) ("in the area of medicine, specialties sometimes overlap and a practitioner may be knowledgeable in more than one field").
[46] *Wexler v. Hecht*, 847 A.2d 95, 99-100 (2004), aff'd, 593 Pa. 118, 928 A.2d 973 (2007) (holding that a non-M.D. podiatrist was not competent to testify as an expert to contradict a M.D. orthopedic surgeon regarding an orthopedic surgeon's standard of care).
[47] *Brown v. Trinidad*, 111 A.3d 765, 770 (Pa. Super. 2015).

surgery because it not only deals with breast disease but also thyroid disease, adrenal disease, the pancreas..." (N.T. 2/9/15, p. 32.) Dr. Solomon was asked why it's necessary to understand the underlying endocrine system when performing breast surgery. He answered, "[b]ecause in order to operate on someone, before you make the decision to operate, you need to know if the problem is something you can treat surgically or non-surgically. So I need to understand the causes of the problem". (N.T. 2/9/15, p. 33, lns. 22-25, p. 34 lns. 1-9.)

He was qualified to testify as an expert in the fields of surgery, plastic surgery and the disease of gynecomastia. (N.T. 2/9/15, p. 60.)

But the admissibility of his opinion also depended on whether Janssen had been unfairly surprised and therefore prejudiced. Evaluating prejudice is case by case.[48] The factors are "1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified, 2) the ability of that party to cure the prejudice, 3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case, and 4) the bad faith or willfulness in failing to comply with the court's order.[49]

We conclude now, as we did at trial, that the balance weighs heavily in favor of the admission of Dr. Solomon's testimony and opinion.

There was no undue surprise to Janssen. Its lawyers had deposed Dr. Solomon a few months earlier and possessed a 200 page transcript with his answers on medical causation between Risperdal and gynecomastia in children. (N.T. 2/9/15, p. 153). Janssen's lawyers also deposed Dr. Solomon the day before his trial testimony and had another 137 pages of transcript, this time relating to Austin's case specifically.

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[48] *Feingold v. Se. Pennsylvania Transp. Auth.*, 517 A.2d 1270, 1273 (Pa. 1986).
[49] *Curran v. Stradley, Ronon, Stevens & Young*, 521 A.2d 451, 457-458 (Pa. Super. 1987) citing *Feingold*, 517 A.2d at 458.

The trial record shows Janssen's trial lawyers were prepared. Ms. Sullivan challenged Dr. Solomon's credibility and opinion vigorously. Janssen's own expert causation witnesses did not testify in Janssen's case-in-chief until nearly a week later, and their expert testimony disagreeing with Dr. Solomon was received without supplemental reports. Ten days after Dr. Solomon's testimony, Tom Brooks Vaughn, III, M.D. was qualified as a defense medical expert in the fields of pediatric and adult endocrinology. While agreeing that Austin had gynecomastia, Dr. Vaughn testified Austin also has a condition called "pseudogynecomastia," defined as "our word for fatty disposition of the chest". (N.T. 2/18/15, Morning, p. 77, lns. 15-16.) Dr. Vaughn's opinion was that Austin's disease is "what we call benign pubertal gynecomastia, which is kind of a long word for the kind of gynecomastia that about 70 percent of kids may get, and then a percentage of those may persist into adulthood. But that's what he has". (N.T. 2/18/15, Morning, p. 77, lns. 19-24.) During cross-examination, Dr. Vaughn conceded that the diameter of breast tissue underlying Austin's gynecomastia was at least 10 1/2 centimeters, more than the diameter of a softball. (N.T. 2/18/15, Afternoon, Vol. XVII, p.78, lns. 12-21, pp. 79-80.) This concession severely undercut his credibility.

Even so, there was important debate whether Austin's gynecomastia developed before or after onset of his puberty. Dr. Solomon affirmed testimony he gave at both depositions. He explained that gynecomastia exists when a boy develops breast tissue that forms into female size breasts. He told the jury that hormonal changes during a boy's puberty can cause gynecomastia, but in Austin's case, the disease developed before puberty. Dr. Solomon based this opinion on Mrs. Pledger's oral history, the boy's written medical records and the 2005 photo of Austin coming out of a swimming pool. This picture was taken when Austin was eleven years old at a time that Dr. Solomon testified was at an early stage of his puberty. The photo shows Austin

with a large set of female looking breasts. Dr. Solomon testified the picture showed "end-stage growth", meaning a "full breast." His medical opinion was that if Austin's breasts as shown in the 2005 photo had actually begun to grow during the early stages of Austin's puberty, "you would see a little pouch of a nipple, not an outline of a breast." (N.T. 2/9/15, p. 66, lns. 9-15.) In Dr. Solomon's opinion, the full sized breasts in the picture were not the result of hormonal changes that commonly occur during puberty. Ruling out all other potential causes as explained in our factual summary, Dr. Solomon concluded that Risperdal caused Austin's gynecomastia.

3. Jury Instruction

Janssen raises one other prejudice claim based on the admission of Dr. Solomon's opinion. This focuses on our response to a statement by Ms. Sullivan during her closing argument. Ms. Sullivan told the jury the following:

> And what did your common sense tell you when you heard that the only expert who could support their case that Risperdal caused Plaintiff's enlarged breasts wasn't an endocrinologist at all, I mean, we are in spitting distance of four major hospital systems, Penn, CHOP, Jeff, St. Chris. *They couldn't find an endocrinologist not only in Philadelphia, they couldn't find an endocrinologist who specializes in hormones anywhere in the country, anywhere in the world to support their case.* The only expert they brought to say that Risperdal caused Plaintiff's gynecomastia was a cosmetic plastic surgeon, who testifies a lot, over 60 times for plaintiff's lawyers, including since the 1990s for the plaintiff's firm, here, and who, as you heard, on his website is better known for turning Philadelphia into the penile enlargement capital of the world. *What did your common sense tell you when you heard that's the only scientist and doctor they could get to support that claim. (*emphasis added*).*

(N.T. 2/19/15, p. 67).

During trial and outside the presence of the jury, we had directed both parties not to comment on the exceptional circumstances leading to Dr. Solomon's testimony. (N.T. 2/9/15, pp. 142-144.) Ms. Sullivan had objected, arguing she needed to refer to Dr. Goldstein because she had told the jury in her opening that she would discredit his endocrinology opinion. Ms. Sullivan

said she could do this by using Dr. Goldstein's original expert report to impeach Dr. Solomon. She wanted to ask Dr. Solomon whether he agreed with Dr. Goldstein's opinion. Ms. Sullivan said she should be allowed to do this because Dr. Solomon had relied on Dr. Goldstein's report. She referred to a statement at the end of in Dr. Solomon's expert report, "[a]fter forming my opinions, I also reviewed the report of Dr. David E. Goldstein, M.D. that relates to Austin Pledger. I agree with that report." (N.T. 2/9/15, p. 144).

Considering all the circumstances that had led to Dr. Solomon's testimony, we declined to let Ms. Sullivan use Dr. Goldstein's report to impeach Dr. Solomon. [50]

The general rule is an expert report is inadmissible hearsay unless the proponent is available for cross-examination.[51]

An exception is when the expert has relied on the report of another expert to reach his own opinion.[52] In this case, Dr. Solomon's written expert report does not state he relied on Dr. Goldstein's report as a basis for his own opinion. Dr. Solomon's opinion was based on differential diagnosis not endocrinology.

In addition to hearsay, Dr. Goldstein's expert report was inadmissible under Pa. R.E. 403.[53] Janssen planned to attack Dr. Goldstein's endocrinal conclusions through its own experts. Janssen did not need to bring in Dr. Goldstein's endocrinology analysis to present its case. The

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[50] 2013 Comment of the Committee on Rules of Evidence *Pa. R.E. 703* ("An expert witness cannot be a mere conduit for the opinion of another. An expert witness may not relate the opinion of a non-testifying expert unless the witness has reasonably relied upon it in forming the witness's own opinion.) citing *Foster v. McKeesport Hospital*, 394 A.2d 103 (1978).

[51] *See Rox CoL Co. v. Workers' Comp Appeal Bd.*, 807 A.2d 906, 924 (Pa. 2002) (A party should not be able to get inadmissible hearsay into evidence in an indirect way.).

[52] *Lower Makefield Tp. V. Lands of Dalgewisc*, 4 A.3d 1114, 1112 (Pa. Commw. 2010), *af'd*, 67 A.3d 772 (Pa. 2013) citing *Primavera v. Celetex Corp.* 608 A.2d 515 (Pa. Super.1992).

[53] Pa. R. E. 403 provides, "The Court may exclude relevant evidence if its probative value is outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence".

only apparent reason Ms. Sullivan wanted to do this was to buttress her own experts by attacking Dr. Goldstein's expertise at a trial where he could not explain himself. Any probative value to Janssen was outweighed by the prejudice which mentioning Dr. Goldstein would cause. If a reference was made to Dr. Goldstein, then plaintiff would likely be compelled to leave Dr. Goldstein's absence unexplained or risk a mistrial. Given Janssen's own role in causing his unavailability, admitting Dr. Goldstein's report was denied under Rule 403 as well.

Seconds after admission of Dr. Goldstein's report was denied, Janssen's attorneys proposed the following jury instruction as a curative:

> In their opening statements, both parties referred to an expert witness from Missouri, an endocrinologist named Dr. David Goldstein. Dr. Goldstein examined plaintiff in a hotel room in Alabama for this lawsuit at plaintiff lawyer's request. Dr. Goldstein is not going to appear at this trial. Plaintiff has substituted a new expert, Dr. Mark Solomon in place of Dr. Goldstein.

(N.T. 2/9/15, p. 155.)

This was denied as well. N.T. 2/9/15, p. 156.

Days later in her closing argument, Ms. Sullivan told the jury that plaintiff could not find a single "*endocrinologist...anywhere in the country, anywhere in the world to support their case.*"

We read the following curative instruction among dozens of other instructions during the general jury charge:

> Also this is not 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 plaintiff could not produce an endocrinologist and suggested that they did not because they could not. You are instructed to disregard that line of argument as it is not accurate and it's disingenuous based on matters of law that took place outside your presence.

(N.T. 2/20/15, p. 18.)

Janssen argues this instruction was an abuse of discretion, a claim which requires clear proof from the complete record, not dependent on "sentences plucked out here and there." [54] In *Gbur v. Golio*, an overzealous attorney in a medical malpractice case engaged in trial conduct that had led to repeated court admonishments advising counsel to adhere to relevant testimony and appropriate argument. [55] In closing argument, the attorney asked the jury, "Why is it that the plaintiffs could not find an urologist in the country to support their claims?"[56] The trial court responded by issuing a cautionary instruction including telling them it did not matter where the expert came from. Holding there was no abuse of discretion, the Superior Court held, "[N]evertheless, Appellant's counsel persisted with these inappropriate attacks. Consistent with the trial court's duty and obligation to control the proceedings in the courtroom and to assure that the jury was presented with only legally relevant and germane testimony and arguments of counsel, the trial court below appropriately exercised its discretion in informing the jury of Appellant's counsel's misleading and improper argument.[57]

In our case as in *Gbur* and in *Dadonna v. Thind*,[58] our duty to control the proceedings required "a more direct effort at control by the trial court". In light of the record, this point was reached when counsel argued that plaintiff could not find an "endocrinologist...anywhere in the country, anywhere in the world to support their case."

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[54] *Kensworthy v. Burghart*, 361 A.2d 335, 338 (Pa. Super. 1976) citing *In re Pusey's Estate*, 184 A.844, 850 (Pa. 1936).
[55] *Gbur v. Golio*, 932 A.2d 203, 213-14 (Pa. Super. 2007), *aff'd,* 963 A.2d 443 (Pa. 2009).
[56] *Id.* at 213, n. 9. The plaintiff's expert in Gbur was a radiation oncologist from Alabama, not a Pennsylvania urologist.
[57] *Id.*
[58] *Dadonna v. Thind*, 891 A.2d 786, 802 (Pa. Cmmwlth. 2006) ("Plaintiff's counsel's persistent refusal to adhere to the trial court's rulings required a more direct effort at control by the trial court").

4. Concurrent Causation

In their post-trial motion, Janssen argues for a new trial on grounds that we abused our discretion when delivering the following concurring cause instruction:

> Now, the conduct of two or more persons, however, may cause harm. Two or more persons may cause harm in the sense of causation.
> Now, in this case you may find that Dr. Mathisen, though not named as a defendant here, engaged in wrongful conduct. If this is so, if this is so and you find that Janssen's negligence also caused injury to Austin Pledger, each is a cause of his harm, if it naturally and probably brings about the harm.
> The fact that Dr. Mathisen is not a defendant here does not relieve Janssen of responsibility for the harm if you find that Janssen's negligence caused Mr. Pledger's harm. (N.T. 2/20/15 p.m., p. 38-39.) .[59]

A defendant's negligence "need not be the sole cause of injury in order for an action to lie against that defendant; it is sufficient that the negligence concurred with other causes to produce injury."[60] A defendant can be liable for negligence, "notwithstanding the fact that others, who are not his [or her] agents, could be liable for their own negligence."[61]

We explained our reasoning on the record during the charging conference:

> Now, the reason that I'm proposing [Alabama Pattern Jury Instruction 33.01 Combined and Concurrent Causes] is because there was evidence, at least by inference in this case alluded to, that the conduct of Dr. Mathisen himself may have been below the standard of care. It wasn't stated outright, but I would expect that it might be argued. It it's not going to be argued, then I wouldn't use this standard – this at all.
> But it could be argued here that Dr. Mathisen either should have known about the risk of gynecomastia based on the existing warning or that he, as Dr. Robb

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[59] Alabama Pattern Jury Instruction ("APJI") 33.01 provides, "The conduct of two or more [persons, entities, etc.] may cause harm. Each [person's, entity's, etc.] conduct is a cause of harm if it naturally and probably brings about the harm. [Add if appropriate]: The fact that one or more [person, entity, etc.] is not a defendant in this case does not relieve the other [person, entity, etc.] of responsibility for the harm".
[60] *Breland ex rel. Breland v. Rich*, 69 So. 3d 803, 825 (Ala. 2011)
[61] *Marsh v. Green*, 782 So. 2d 223, 227 (Ala. 2000).

> would put it, failed to – failed to advise of rare risks. I think that was the testimony.[62]
> So this particular instruction – as I follow a case called *Breland versus Rich* at 69 So.3d 803, 2011 – this particular causation charge covers that situation...
> ...I don't think it comports necessarily with the plaintiff's theory of the case. But it may involve a potential argument that I want to advise the jury of that I expect the defense to make...
> ...It depends in the end how this case is argued. But if Ms. Sullivan or anybody who's arguing this case from the defense makes an argument putting down or in some way denigrating the conduct or the competence of Dr. Mathisen, this instruction will be given.

(N.T. 2/19/15, p. 136-138.)

In her closing argument, Ms. Sullivan indeed argued that after the FDA approved Janssen's new Risperdal label in 2006, Dr. Mathisen failed to read it and continued to refill Austin's Risperdal prescription. (N.T. 2/20/15, Morning, p. 106.) Ms. Sullivan read to the jury the portion of Dr. Mathisen' s testimony relating to his failure to read the new 2006 FDA label, and she concluded, he "didn't do [his] responsibility in terms of reading every word in the [2006] label." (N.T. 2/20/15, Morning, p. 106.)

Ms. Sullivan went on to invite the jury to conclude that if Janssen were negligent for providing an inadequate warning, "it didn't make a darn bit of difference" because Janssen was not the cause of Austin's gynecomastia. (N.T. 2/20/15, p. 106, lns.13-25.)

Hearing argument that Dr. Mathisen was negligent, it was up to the jury to decide if he was. And if they found Janssen and Dr. Mathisen were both negligent, it was also up to the jury to decide whether the harm of either naturally and probably brought about the harm. [63] If they

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[62] Adelaide S, Robb, M.D. testified as a defense expert in adult psychiatry, clinical trials and autism. N.T. 2/13/17,

[63] *Breland, id.* at 826 (A particular defendant's negligence need not be the sole cause of injury in order for an action to lie against the defendant; it is sufficient that the negligence concurred with other causes to produce injury...however it is still necessary that the plaintiff prove that the defendant's negligence proximately caused the injury.

found that Janssen was both negligent and a proximate cause of Austin's injury, regardless of their finding on Dr. Mathisen, Janssen is liable.

5. Federal Preemption

Finally, Janssen claims federal law preempts a state cause of action for negligent failure to warn. Jansen argues a pharmaceutical company cannot comply with the FDA and state law at the same time. Federal law does not support this proposition and Janssen's preemption claim therefore has no merit.[64]

Preemption analysis requires a comparison between state tort law and federal statutes. Under the U.S. Constitution's Supremacy Clause, federal law preempts state law when it is impossible for a party to comply with both state and federal law. There is a strong presumption however against preemption in recognition that states are "independent sovereigns in our federal system," and "Congress does not cavalierly preempt state-law causes of action."[65]

As discussed earlier in the context of the learned intermediary rule, Alabama courts hold drug companies owe a duty to provide an adequate warning.[66] The *Pledger* jury found this meant that Janssen should have adequately warned Dr. Mathisen of a statistically significant finding that Risperdal has more than a rare chance of causing gynecomastia in children during weeks 8 to 12 of drug ingestion when their prolactin level is also elevated. [67] Janssen had many opportunities to warn Dr. Mathisen and the broader medical community but declined. These chances included instructing its sales and marketing representatives like Jason Gilbraith to tell

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[64] *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).
[65] *Id.* at 628.
[66] *See Bodie v. Purdue Pharma Co.,* 236 F. App'x 511, 518 (11th Cir. 2007) (under Alabama law plaintiff in a negligent failure to warn case must prove "that the defendant failed to provide adequate warnings of the hazards of a particular product, thereby breaching that duty").
[67] *Id.*

doctors about the data findings at Table 21 and their implications for child safety. Janssen also chose not to send Dear Doctor letters, or produce accurate posters to explain risk at medical conferences. And Janssen never published Table 21 nor explain its significance in medical journals anywhere. [68]

It was perfectly lawful for Janssen to comply with state law and conform to FDA rules: "[T]through many amendments to the FDCA and to FDA regulations, it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times.... and *with ensuring that its warnings remain adequate as long as the drug is on the market* (emphasis added).[69]

6. Punitive Damages

We incorporate by reference the Opinion filed by the Honorable Arnold New at *In Re: Risperdal Litigation Applicable to All Cases* at Philadelphia CP, March Term 2010, No. 296.

7. Remitter

During trial neither party introduced evidence of the cost of potential remedial surgery. The jury assessed non-economic damages for embarrassment and humiliation based on Austin's life expectancy. At approximately $30,000 a year, the emotional damage is within reason.

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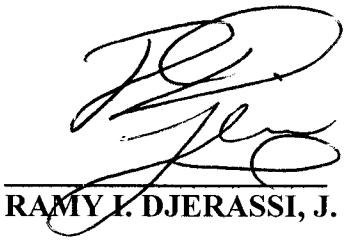
[68] The FDA's CBE regulation permits drug manufacturers to unilaterally update and strengthen warnings and safety information in its label without receiving prior FDA approval. 21 C.F.R. § 314.70(c)(6) (iii)(A), (C); *see also Gurley v. Janssen Pharm., Inc.*, 113 A.3d 283, 290 (Pa. Super. 2015) (citing *Wyeth*, 555 U.S. at 568 (2009)).
[69] *Wyeth*, 555 U.S. at 568–571 (reviewing history of Federal Food and Cosmetic Act, .21 U.S.C.A. § 301 et seq).
[69] *Id.* at 570.

IV. CONCLUSION

For the reasons explained here and those incorporated by reference, it is respectfully requested that judgment be affirmed.

BY THE COURT:



RAMY I. DJERASSI, J.