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IN RE: RISPERDAL® LITIGATION	
T.M. et al., Plaintiffs, v. JANSSEN PHARMACEUTICALS, Inc., et al. Defendants.	**PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION** **MAY TERM 2013** **No. 1076**

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THE MOTION FOR POST-TRIAL RELIEF

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Plaintiffs Thomas Moroni and Brenda Tinkham respectfully file this memorandum of law in support their motion for post-trial relief. They seek the removal of the nonsuit entered against them and a new trial on all issues of compensatory damages as to defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC.

FACTUAL AND PROCEDURAL BACKGROUND

I. Thomas Moroni developed gynecomastia as a result of ingesting Risperdal, following Janssen's negligent failure to warn.

Plaintiff Thomas Moroni ("Tommy") was born in February 1997 and is now 20-years old. Plaintiff Barbara Tinkham is his mother. They are a U.S. Air Force family who lived on military bases throughout the United States when Tommy was a child. In 2004, at age seven, Tommy's family moved to the Sheppard Air Force Base in Wichita Falls, Texas. Tommy began acting out in school. Tommy was referred to a pediatric psychiatric clinic on base, the Rose Street Mental Health Clinic. Tommy would eventually be diagnosed with attention deficit disorder, attention deficit hyperactivity disorder, and oppositional defiant disorder. He also suffered from depression because of childhood trauma. N.T., 12/6/2016, at 42-48; N.T., 12/8/2016, at 43.

In December 2004, Tommy visited pediatric psychiatrists Harvey Martin, M.D. and Bryan Wieck, M.D., at the Rose Street Clinic. Tommy was also evaluated by physician's assistant John Dewar and nurse practitioner Cynia

Menzik. Mr. Dewar described to Tommy and his mother the therapeutic benefits they anticipated with Risperdal, and described possible side effects limited to those noted in the label. Ms. Tinkham agreed to start Tommy on a Risperdal course. *See* Martin Dep., 5/4/2016, at 7-11, 16; Wieck Dep., 3/30/2001, at 8; Dewar Dep., 7/14/2016, at 9-18; N.T., 12/6/2016, at 52-69; N.T., 12/8/2016, at 44-47.

Sometime in 2006, Tommy developed gynecomastia, which is the development of female breast tissue in males. His gynecomastia was initially masked by significant weight gain caused by Risperdal. However, photographs of Tommy from 2006 and 2007 clearly showed his breasts developing over time. Tommy discontinued Risperdal in April 2008, but his breasts persisted and became increasingly more visible. N.T., 12/6/2016, at 70-95; N.T., 12/8/2016, at 72-73, 99-100.

During a November 2010 visit at the Moscati Health Center in Hastings, Nebraska, a primary care physician noted Tommy's gynecomastia. According to another clinical note, Tommy reported he began noticing his developing breasts four years earlier, in 2006. He also reported occasional pain in his breasts. In February 2012, Tommy was formally diagnosed with gynecomastia by plastic surgeon Joel Atchison, M.D., who recommended reduction surgery. N.T., 12/6/2016, at 90-95; N.T., 12/7/2016, at 49.

II. After close of Plaintiffs' case, the trial court granted Janssen's nonsuit motion.

In May 2013, Plaintiffs Thomas Moroni and Brenda Tinkham filed suit against Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC. (together, "Janssen"). Janssen manufactures, promotes, and sells Risperdal. Plaintiffs also asserted claims against Excerpta Medica, Inc. and Elsevier, Inc., which provided medical communication services to the pharmaceutical industry and were in the business of publishing scholarly books and journals in many fields of science. On March 11, 2015, Plaintiffs filed a praecipe to discontinue action with prejudice against defendants Excerpta and Elsevier. The dismissal left the Janssen defendants as the only remaining defendants in the case.

In July 2016, Janssen moved for summary judgment as to all of Plaintiffs' claims. Plaintiffs responded and Janssen filed a reply in support of their motion. On November 23, 2016, Judge New entered an Order partially granting and partially denying Janssen's summary judgment motion. Judge New permitted Plaintiffs' claims for negligent failure to warn, strict liability failure to warn, and fraud to proceed to trial.

Trial began with jury selection on November 28, 2016. Plaintiffs presented the testimony of breach of duty expert David Kessler, M.D.; causation expert Mark P. Solomon, M.D.; treating physicians Dr. Martin and

Dr. Wieck; treating physician's assistant Mr. Dewar; and Tommy's mother Ms. Tinkham.

On December 7, 2016, Janssen objected to the testimony of Dr. Solomon on grounds that his opinion exceeded the fair scope of his report. The trial court sustained the objection and precluded Dr. Solomon from addressing pending questions about medical literature upon which he relied to draw his causation opinions. N.T., 12/7/2016, at 52-57.

On December 9, 2016, at the close of Plaintiffs' case, Janssen moved for nonsuit. *See* Janssen's Motion for non-suit dated Dec. 9, 2016 (attached as Exhibit "A"). Plaintiffs responded. *See* Plaintiffs' response, dated Dec. 11, 2016 (attached as Exhibit "B").

On December 13, 2016, the trial court granted the motion on grounds that, under Texas law, "Dr. Solomon's testimony is legally insufficient to prove causation in this case." N.T., 12/13/2016, at 4.

On December 22, 2016, Plaintiffs timely filed their Motion for post-trial relief pursuant to Pa.R.C.P. 227.1(c). This brief in support of the motion follows.

STATEMENT OF QUESTIONS PRESENTED

1. Was the evidence at trial, viewed in the light favorable to Plaintiff, sufficient to send Plaintiffs' claims to the jury?

2. Did the trial court err in sustaining Janssen's objection Dr. Solomon's testimony on "fair scope" grounds?

Questions 1-2 should be answered in the affirmative.

STATEMENT OF THE SCOPE AND STANDARD OF REVIEW

Removal of nonsuit and new trial. In Pennsylvania, the "trial court may enter a compulsory nonsuit on any and all causes of action if, at the close of the plaintiff's case against all defendants on liability, the court finds that the plaintiff has failed to establish a right to relief." *Scampone v. Highland Park Care Center, LLC*, 57 A.3d 582, 595 (Pa. 2012). Nonsuit may be entered only where the lack of evidence to sustain the action is "so clear that it admits no room for fair and reasonable disagreement." *Vicari v. Spiegel*, 936 A.2d 503, 509 (Pa. Super. 2007), *aff'd* 989 A.2d 1277 (Pa. 2010). The trial court should give "the benefit of every reasonable inference and resolv[e] all evidentiary conflicts in [plaintiff's] favor." *Scampone*, 57 A.3d at 595. The compulsory nonsuit is otherwise properly removed and the plaintiff is entitled to a new trial. *See id.*

New trial (evidentiary rulings). The trial court determines whether a new trial is warranted through a two-part exercise. First, the trial court determines whether, over the defendant's timely and appropriate objection, it made a mistake under the standard of review applicable to that purported error. *See Marsico v. DiBileo*, 796 A.2d 997, 999 (Pa. Super. 2002). Second, the trial court determines whether the error was prejudicial to the moving party. *See id.* An error is prejudicial only if the Court determines that a new trial would produce a different verdict. *Pennsylvania Dep't of Gen. Servs. v. U.S. Mineral Prods.*, 898 A.2d 590, 604 (Pa. 2006).

ARGUMENT

I. The trial court should remove nonsuit and re-list the case for trial.

On December 9, 2016, Janssen moved for nonsuit on several grounds. *See* Exhibit "A." Plaintiffs responded and opposed the motion. *See* Exhibit "B." On December 13, 2016, the trial court granted the motion for nonsuit. The trial court reasoned that "under Texas law, Dr. Solomon's testimony is legally insufficient to prove causation in this case." N.T., 12/13/2016, at 4. The trial court is wrong. Plaintiffs introduced ample evidence to permit the jury to conclude that (1) Janssen failed to warn Tommy's prescribing physicians of known risks associated with Risperdal; and (2) Janssen fraudulently induced Tommy's physician to prescribe Risperdal to Tommy. Plaintiff also introduced sufficient evidence that this failure caused Tommy's gynecomastia to permit those claims to move forward. Key evidence and arguments are set forth below.

A. Legal framework

Under Texas law, a plaintiff seeking to establish negligence must demonstrate the defendant breached its duty to warn, and that the breach caused his injuries. *See Alm v. Aluminum Co. of America*, 717 S.W.2d 588, 591 (Tex. 1986). In the context of claims alleging a negligent failure to warn about the risks of prescription drugs, the manufacturer's duty is to adequately warn the treating physician or other prescriber. *See id.* at 591-92; *Wyeth-Ayerst*

Laboratories Co. v. Medrano, 28 S.W.3d 87, 93 (Tex. App. Texarkana 2000) (advanced practice nurse considered learned intermediary). Texas law permits a physician's assistant to prescribe medication, under the supervision of a physician. *See* Tex. Occupations Code § 157.0511.

In 2003, the Texas legislature enacted Texas Civil Practice and Remedies Code § 82.007, which expressly addresses prescription drug failure to warn claims, as follows. Section 82.007(a) creates a presumption that a drug manufacturer is not liable with respect to the allegations involving failure to provide adequate warnings if the warnings that accompanied the drug were those approved by the U.S. Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act. *See* Tex. Civ. Prac. & Rem. § 82.007. The plaintiff may rebut this presumption with evidence that the drug manufacturer "recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the [FDA]," and the plaintiff was injured by use of the drug as recommended, promoted, or advertised. *See id.* If the plaintiff introduces relevant rebuttal evidence, the presumption is neither treated as evidence nor weighed by the jury. *See Gen. Motors Corp. v. Saenz*, 873 S.W.2d 353, 359 (Tex. 1993). "The evidence on the issue is then evaluated as it would be in any other case." *Id.*

In this context, the manufacturer's duty is to warn of hazards associated with its product "if a reasonably prudent person in the same position would

have warned of the hazards." *Alm*, 717 S.W.2d at 591–92. "[W]hen the warning to the prescribing physician is inadequate or misleading, the prescription drug manufacturer remains liable for the injuries sustained by the patient." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012) (citing *Alm*, 717 S.W.2d at 592). A warning is adequate if "given in a form that could reasonably be expected to catch the attention of a reasonably prudent person in the circumstances of the product's use; and the content of the warnings and instructions must be comprehensible to the average user and must convey a fair indication of the nature and extent of the danger and how to avoid it to the mind of a reasonably prudent person." *Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 179 (Tex. 2004) (quoting Texas standard jury instructions). The adequacy of a warning is a question of fact to be determined by the jury. *See id.*

With respect to causation, the plaintiff must establish that the "defect in the manufacturer's warning was a substantial cause of the plaintiff's injury." *Centocor*, 372 S.W.3d at 170 (quoting *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 209 (5th Cir. 2008)). "Where the physician would have adequately informed a plaintiff of the risks of a disease, had the label been sufficient, but fails to do so on that account, and where the plaintiff would have rejected the drug if informed, the inadequate labeling could be a 'producing' cause of the injury,

because it effectively sabotages the function of the intermediary." *Id.* (quoting *McNeil v. Wyeth*, 462 F.3d 364, 373 (5th Cir. 2006)).

B. Plaintiffs introduced ample evidence that Janssen's negligence caused Tommy's injuries to submit case to the jury.

Against this backdrop, Plaintiffs introduced sufficient evidence to survive a nonsuit motion and permit a jury to consider Janssen's liability. To establish a *prima facie* case for breach of duty, Plaintiffs relied on testimony from David Kessler, M.D., who served as Commissioner of the U.S. Food and Drug Administration between 1990 and 1997. To establish a *prima facie* case for causation, Plaintiffs primarily relied on expert Mark. P. Solomon, M.D. and Tommy's Risperdal prescribers Mr. Dewar, Dr. Martin, and Dr. Wieck.

1. Janssen's inadequate warning

Dr. Kessler testified that, in December 2004 (when Mr. Dewar prescribed Risperdal to Tommy under the supervision of Dr. Martin and Dr. Wieck), the Risperdal label completely failed to inform these treaters of the specific risks known to Janssen associated with the drug. Dr. Kessler testified that the revised October 2006 label was likewise inadequate, as follows.

Dr. Kessler testified that Risperdal is a second-generation antipsychotic drug designed and sold by Janssen since 1994. Risperdal is a powerful drug that acts upon the central nervous system by changing brain chemistry. The FDA approved Risperdal for limited use: for adult use only until October 2006;

in October 2006, for treatment of irritability associated with autism in children 5-16 years; and in August 2007, to treat manifestations of schizophrenia for children 13-17 and for short-term treatment of acute manic or mixed episodes associated with bipolar I disorder in children 10-17 years. These uses, efficacy, and risks of use are listed in the prescribing insert, or "label." Janssen is the author and owner of the Risperdal label. Importantly, a prescription drug's label is the most effective means of conveying warnings about known safety risks to treating physicians and patients. Kessler Tr. Dep., 5/19/2015, at 7-8, 13-22.

Dr. Kessler testified further that in February 2006, the Risperdal label indicated that Risperdal had no better or worse effect on prolactin levels than other drugs in its class, that hyperprolactinemia or elevated prolactin had generally unknown clinical significance, and that gynecomastia was an endocrine disorder rarely associated with Risperdal. The Risperdal label defined "rare" as an observed incidence of fewer than 1 in 1000 patients, compared to "frequent," which describes an observed incidence of more than 1 in 100 patients. In October 2006, Janssen revised the Risperdal label to reflect its first FDA-approved pediatric indication. Janssen warned of a hyperprolactinemia class-effect, qualified for the first time by an additional statement that "Risperidone is associated with higher levels of prolactin elevation than other antipsychotic drugs." Janssen continued to indicate that

the incidence of gynecomastia was "rare," although its label elsewhere reported for the first time a 2.3% incidence rate of gynecomastia among Risperdal-treated patients. *Id.* at 13-29.

According to Dr. Kessler, Janssen dramatically understated Risperdal's risks in the label, and in its communications with the FDA, physicians, and the public. Based primarily upon review of internal Janssen documents and clinical trial data, Dr. Kessler testified that, by 2002, Janssen knew Risperdal was associated with:

- higher levels of prolactin elevation than other antipsychotics;
- prolactin elevations even at the recommended low doses;
- "frequent" incidences of gynecomastia under Janssen's own definitions; and
- 4 to 5 cases of gynecomastia in every 100 patients.

But the Risperdal label did not reflect these risks, even though Janssen had aggressively marketed Risperdal for off-label treatment of conditions in children and adolescents, and though Risperdal had become widely prescribed for these unapproved populations. *Id.* at 195-99; P-18.

In the late 1990s, Janssen sought FDA approval to introduce pediatric dosing information in the Risperdal label and to use Risperdal in children to treat "conduct disorders." Risperdal had been on the market since 1993, for use by adults only. The FDA rebuffed both efforts, expressing concerns about

off-label promotion to children and about the insufficiency of safety and efficacy data supporting Janssen's new drug application. In response, Janssen began several pediatric clinical trials. As Dr. Kessler explained, two studies are notable for purposes of this litigation. Study RIS-INT-41 was a long-term clinical study paying special attention to gynecomastia and other prolactin-related adverse events in children. Study RIS-INT-70 was a one-year extension of RIS-INT-41. *Id.* at 30-56, 79-81, 197-98.

By 2000, interim analysis of RIS-INT-41 data showed an incidence of 3.7% gynecomastia in male patients (13 cases/266 boys). By 2001, Janssen obtained additional data: the gynecomastia rate was actually 5.5%. When RIS-INT-41 ended in 2002, Janssen released a final report showing an incidence rate of gynecomastia of 5.5% (23 cases/419 boys). It reported further that in 3.6% of patients, gynecomastia did not resolve by the end of the 48-week clinical trial. In the related study, RIS-INT-70, Janssen further reported that, for children who were on Risperdal for a second year (having also participated in RIS-INT-41), the incidence of new and ongoing gynecomastia cases was an astonishing 12.5%. Yet publication of RIS-INT-41 and RIS-INT-70 results was delayed for years. *Id.* at 46-72.

Dr. Kessler explained high rates of gynecomastia in clinical trials are significant against the background of millions of pediatric prescriptions written during this time. "[T]hat number is frequent… that's real to a physician or a

parent because that means some of these children in your practice are likely to develop it." *Id.*

In the early 2000s, Janssen conducted eighteen open-label (no placebo) and double-blind (placebo) clinical studies with pediatric participants concerning Risperdal. Ten were multi-week studies and six were studies up to six months. RIS-INT-41 and RIS-INT-70 were the only long-term studies, and also the only studies giving special attention to prolactin-related adverse events and gynecomastia. These eighteen studies included 1,885 patients. Children ranged from 5 to 18 years old. Dr. Kessler emphasized two results in his testimony: (1) in the double-blind studies, children on placebo reported *zero* cases of gynecomastia; and (2) eight of nine cases of gynecomastia cases came from long-term studies. Dr. Kessler testified that, as these studies made clear, gynecomastia took time to manifest and would not be captured by short-term studies. *Id.* at 72-79; P-17.

In May 2002, five of the eighteen studies were included in a pooled *post hoc* statistical analysis of prolactin-related adverse effects. RIS-INT-41 was included, but RIS-INT-70 was not included. Janssen's analysis showed a 4.4% gynecomastia rate (22 cases/489 boys). *Id.* at 90-94; P-22.

The May 2002 statistical run generated another notable result: Table 21. Dr. Kessler testified that Table 21 answered the question of whether, in children who have prolactin levels higher than the upper limit of normal, there

is an association with adverse events like gynecomastia. Participants had their prolactin measured before the clinical trial (at baseline), and every four weeks during the trial. In one passage of his testimony, Dr. Kessler summed up what Janssen found in Table 21 that is vitally important in this case – that Janssen had found a causal correlation between Risperdal and prolactin-related side effects, and that this correlation was statistically significant, meaning there was a 98.5% likelihood that the side-effects did not happen by chance. Indeed, in internal communications, Janssen scientists freely acknowledged the significance of this finding and of Table 21. *Id.* at 95-105; P-24, P-25.

Based on his experience as FDA Commissioner and as a physician, Dr. Kessler testified that Janssen had the obligation to warn, by reasonable means and within a reasonable time, about risks associated with hyperprolactinemia and gynecomastia that Janssen knew Risperdal posed. He testified that "[w]hen you market a drug for a use, there's no question that you have a duty to tell the risks and the benefits," and provide the full set of data. Then clinicians can analyze and discuss the data, make judgments about clinical significance, and factor risks in their decisions to prescribe. Dr. Kessler testified that Table 21 should have been submitted to the FDA and "highlighted as an important finding." *Id.* at 64, 116, 135, 143-45, 151-77.

Dr. Kessler testified that although Janssen had an obligation to warn treating physicians, it failed on every level to do so. He identified five different failures by Janssen in this regard.

First, Dr. Kessler testified that Janssen failed to disclose the Risperdal-prolactin-gynecomastia risk to the FDA, as required by federal law. In December 2003, when Janssen sought FDA approval for a first pediatric use (irritability associated with autism), Janssen failed to disclose the significant Table 21 findings. The FDA rejected Janssen's new drug application and specifically expressed safety concerns pertaining to prolactin elevation, the consequences of prolonged exposure to increased prolactin, and prolactin-related adverse events. Janssen responded by telling the FDA that: "A review of the safety information did not show a correlation between prolactin levels and adverse events that are potentially attributable to prolactin." Janssen made this statement while omitting mention of Table 21 and pretending it did not exist. Dr. Kessler testified that Table 21 was highly relevant to the FDA's inquiry, and "a very important piece of information" that should have been provided. He testified that Janssen's response to the FDA was misleading. *Id.* at 177-84; P-43.

Second, Dr. Kessler testified that Janssen did not provide complete prolactin-related data (including Table 21) and actual gynecomastia incidence rates to its advisory board of child and adolescent clinicians. These outside

consultants met in 2002 in New York and Toronto to scrutinize Risperdal's prolactin-related safety. One result of Janssen's holding-back of this critical information was that critical safety findings were not publicized. Another result was that the advisory board (lacking that critical information) recommended against physicians performing prolactin monitoring at baseline or subsequently. *Id.* at 145-49; 230-31, P-36.

Third, Dr. Kessler testified that, both before and after October 2006, Janssen's label contained only the incomplete information provided the FDA and the advisory board. Janssen did not warn of Risperdal's actual risk profile. Dr. Kessler testified that Janssen should have specifically warned in the label: (1) about the "frequent" not "rare" association of gynecomastia to Risperdal; (2) about the 5 to 6% incidence of gynecomastia developed in clinical trials, such as RIS-INT-41 and 70; (3) about more incidence of hyperprolactinemia and greater elevations of prolactin at low doses than with drugs in the same class; and (4) about all prolactin findings, and especially the statistically significant Table 21 analysis. Dr. Kessler added that, post-2006, Janssen should have warned specifically about Table 21 and recommended prolactin monitoring. *Id.* at 244-46.

Fourth, Dr. Kessler testified that Janssen funded a misleading article in the Journal of Clinical Psychiatry, which purported to describe the known risks associated with Risperdal, specifically by reporting Janssen's *post hoc* analysis

results (the "Findling article"). This article denied the existence of a causal relationship between Risperdal, prolactin, and gynecomastia, and completely failed to warn about Risperdal's actual risks. Dr. Kessler testified that the Findling article was false and misleading in numerous respects. He testified that:

- The data reported in the article was "misleading," and the article's abstract wrongly represented there was no correlation between prolactin elevation and "symptoms hypothetically associated with prolactin"
- The article denominated gynecomastia by a vague nomenclature, "symptoms hypothetically associated with prolactin," even though Janssen specifically tracked "prolactin-related adverse events" in its clinical studies.
- Janssen chose Dr. Findling as nominal author of this misleading study because, according to Janssen personnel, he would "do/say whatever you want him to." *Id.* at 101-14; P-25, P-27.
- The article actually was drafted by Janssen medical and marketing personnel who concealed their role in the publication

- Janssen's personal wrote the article so that it misleadingly conveyed that prolactin elevations were transient and not related to adverse events like gynecomastia.
- When the clinical data contradicted the message Janssen wanted to convey in the article, Janssen simply changed the data.

This last point – Janssen changed the data to suit its message – is astonishing but true. The risk of gynecomastia from ingesting Risperdal is expressed as a ratio of gynecomastia cases to patient population. The higher the ratio, the greater the risk. And the converse is equally true. Dr. Kessler testified that, in 2002, Janssen reanalyzed pooled data set forth in Table 21 by decreasing the numerator of this ratio (gynecomastia cases) and also by increasing the denominator of the ratio (patient population). This manipulation caused the number of gynecomastia cases relative to patient population to become small enough so as to disappear as a statistically significant finding. *Id.* at 117-69; P-31 to P-40.

How did Janssen to this? Janssen included in the numerator only gynecomastia cases in boys younger than ten years. This manipulation significantly reduced the numerator from 22 to 5. Significantly, this step to exclude boys older than ten years from the analysis was taken against the advice of Janssen's advisory board, which commented that omitting these boys would

be "hiding data." As for the denominator, Janssen included all 592 children and adolescents in the denominator, and not just the 255 boys younger than ten years. Thus, Janssen compared apples to oranges – counting only the condition in boys younger than ten years against an all age male and female population, while comparing that figure to all children whatever their age. *Id.*

Janssen's 2002 reanalysis resulted in a gynecomastia incidence rate of less than 1% compared to the actual rate of 4.4%. Janssen employed similar manipulations of data to derive a 2.2% rate for all adverse events rather than the higher rates revealed by proper analysis. The 2.2% adverse event rate was the only rate disclosed in article's abstract. *Id.*

Fifth, Dr. Kessler testified that Janssen had multiple opportunities to warn in every communication to physicians – publications in medical literature; medical education seminars Janssen conducted; advisory board meetings; sales calls; and "Dear Doctor" letters to physicians and other healthcare professionals. Instead, Janssen worried that disclosing hyperprolactinemia and its association with clinical symptoms like gynecomastia was a "major disadvantage" in the drug's $340 million (in 2001) market. This would have led child psychiatrists to look at other available drugs. Indeed, in the early 2000s, before any pediatric use was approved, Janssen stated as its marketing objective to grow Risperdal's share in children and adolescents. As Dr. Kessler testified, the strategies approved by Janssen's Board of Directors and senior executives

included training medical staff/consultants to promote pediatric use of antipsychotics and Risperdal specifically; making regular sales calls to pediatricians, pediatric psychiatrists, and pediatric neurologists, social workers, state hospitals, etc.; generating new data in key diagnostic symptom areas; disseminating reanalyzed data; and neutralizing safety concerns. In terms of "neutralizing" safety concerns, the strategy was to say "okay to clinicians, it causes hyperprolactinemia, that's established, but in essence, don't worry, it doesn't cause gynecomastia, there is no correlation, there is no association." *Id.* at 81-91, 200-31; P-5, P-19 to P-22.

Dr. Kessler testified that three items were absent from Janssen's communications with physicians: the rate of gynecomastia was in fact "frequent"; Risperdal increased hyperprolactinemia more than other drugs in its class; and a summary of the statistically-significant data in Table 21. He testified further that Janssen's promotional materials emphasized the opposite of the truth, suggesting "infrequent" incidence and omitting already-mentioned relevant safety information. *Id.* at 231-44; P-51.

Dr. Kessler concluded that Janssen had multiple opportunities to tell physicians about Risperdal's red flag and Table 21's safety signal. "There are multiple avenues, right, where a company can warn. And a company can always warn about safety." Rather than warn, Janssen dissembled. It

minimized documented safety concerns. It lied to physicians, and through them to the general public. *Id.* at 230-31.

2. Janssen failed to warn Tommy's prescribers.

Plaintiffs also offered testimony from Tommy's Risperdal prescribers and treating physicians – Mr. Dewar, Dr. Martin, and Dr. Wieck, to establish Janssen's negligent failure to warn was the proximate cause of his injuries.

Dr. Martin and Dr. Wieck testified they are psychiatrists who treat children and adolescents in their private practice at the Rose Street Clinic. *See* Martin Dep. at 2; Wieck Dep. at 2. In December 2004, Dr. Martin and Dr. Wieck supervised and "directed" the practice of Mr. Dewar, a physician's assistant with privileges to prescribe medication at the Rose Street Clinic. Dr. Martin, Dr. Wieck, and Mr. Dewar testified consistently that they were unaware that Risperdal elevates prolactin in the body more than other drugs in its class. They were also unaware that gynecomastia occurred "frequently" not rarely in Risperdal patients. And they were unaware that a statistically-significant causal relation existed between ingestion of Risperdal, prolactin levels, and gynecomastia. Martin Dep. at 5-10, 18; Wieck Dep. at 7-13; Dewar Dep. at 4-5, 9-11, 17.

Tommy's treaters did not recall specific conversations with Tommy and Mrs. Tinkham. But each testified that he discussed as a routine part of their practices any known risks of a drug, treatment options, and determine any

course of action with the minor patient's parents. Tommy's treaters added they rely upon the drug manufacturer to provide truthful, accurate, and complete information about the drug, including any risks known to the manufacturer. The testified that a manufacturer's failure to warn them about a drug's risks impaired their ability to communicate those risks to the parent, and impaired the parent's ability to make a decision. Dr. Martin, Dr. Wieck, and Mr. Dewar confirmed each would have communicated gynecomastia-related risks to Ms. Tinkham, as Tommy's mother and guardian. Martin Dep. at 3-4, 10, 16-17; Wieck Dep. at 3-6, 20-21; Dewar Dep. at 6-8, 10-11, 13-14.

Dr. Martin and Dr. Wieck testified that, between 2003 and 2005, Janssen sales representatives visited their clinic to promote use of products in his practice, including Risperdal for children and adolescents. They testified that these sales representatives did not offer any warning that gynecomastia is a frequent side-effect in children ingesting Risperdal. In November 2004, Dr. Wieck also attended Janssen's Risperdal Primary Care Physicians Advisory Forum in Miami, Florida. Dr. Wieck received a $1,000 honorarium for attending, and complementary transportation and accommodations. The event included lectures on use of Risperdal in children. Janssen followed up with Dr. Wieck in December 2004 to remind him Risperdal was appropriate for use "in agitation and anxiety for younger kids." In December 2004, at the direction of Dr. Martin or Dr. Wieck, Mr. Dewar prescribed six refills of Risperdal to

Tommy. Martin Dep. at 13-16; Wieck Dep. at 7, 13-20; Dewar Dep. at 8-11, 13-15.

Ms. Tinkham testified that none of her son's treaters discussed gynecomastia with her before prescribing Risperdal or afterwards. She testified that she would not have allowed her son to take the drug had she known the significant risks of gynecomastia. N.T., 12/8/2016, at 44-47.

3. Janssen's causal responsibility

Plaintiffs also called an expert witness, Dr. Solomon, to demonstrate that Risperdal was the cause of Tommy's gynecomastia. Dr. Solomon was amply qualified as Plaintiffs' expert in surgery, plastic surgery, the physiology, biology, and pathology of the breast regarding certain medicines. In fact, Janssen did not cross-examine Dr. Solomon on voir dire, and it did not object to Dr. Solomon's qualifications to testify. *See* N.T., 12/6/2016, at 16-38; N.T., 12/7/2016, at 72-121.

Dr. Solomon testified that he examined Tommy and confirmed the diagnosis of gynecomastia earlier given by Tommy's physician in 2012. He testified that he reviewed Tommy's medical and pharmacy records; multiple photographs; the deposition testimony of Tommy, his mother, and his physicians, and that he also reviewed Janssen documents and published literature relating to Risperdal and its association with gynecomastia. Dr. Solomon opined with reasonable medical certainty that Tommy had

gynecomastia, that he developed gynecomastia during his ingestion of Risperdal, and that his ingestion of the drug as an offending agent caused the gynecomastia. Dr. Solomon testified that he based his opinion on the materials he reviewed and on his experience as a physician to make a differential diagnosis and form his opinion. N.T., 12/6/2016, at 37-39, 52; N.T., 12/7/2016, at 29-32, 45-46, 62-68.

Notably, Dr. Solomon testified that Tommy suffers from "true" gynecomastia that became visible as early as 2006. He testified that in May 2010, Tommy underwent a physical exam by Dr. Kurian; his physician noted that Tommy exhibited breast mounds and he was Tanner 3 stage. Normally-developing boys are generally Tanner 1 stage, meaning no breasts. But in November 2010, Tommy's nurse at the Moscati Health Center in Hastings, Nebraska, documented that Tommy had observed breast development about four years earlier in 2006. The nurse noted Tommy had stopped the Risperdal course a year and a half earlier, in 2008 but that he continued to have breasts. In February 2012, Dr. Atchison, a plastic reconstructive surgeon in Kearney, Nebraska, diagnosed Tommy with "true" gynecomastia. Dr. Solomon testified that Tommy now exhibited Tanner 4 stage breasts, based on his physical exam. Photographs of Tommy taken in 2006 through 2016 confirm the progression of Tommy's condition. N.T., 12/6/2016, at 67-75, 94-99; N.T., 12/7/2016, at 49-50, 65-68; P-5218, 5093, 5125, D-144.

Dr. Solomon testified that Tommy's condition developed and manifested while he was on Risperdal. In several 2006 to 2008 photographs shown to the jury, Dr. Solomon traced and pointed to Tommy's breast development, from Tanner 1 stage in July 2006 through the Tanner 2 stage in July 2007 and December 2008 photographs. By 2010, Tommy had Tanner 3 stage breast growth. Dr. Solomon testified that Ms. Tinkham described Tommy's growing breasts during the same period, which were to some degree masked by his excessive weight gain (also caused by Risperdal). Dr. Solomon testified that by the time Tommy's breasts became visible as Tanner 3 stage at his 2010 physical, they had already been developing for some time. Dr. Solomon noted Tommy's physicians Dr. Kurian and Dr. Atchison agreed with his assessment that Tommy's breast development had taken years. By mid-2006, Tommy had been on Risperdal for nearly two and a half years. N.T., 12/6/2016 at 76-88; N.T., 12/7/2016, at 142-43; N.T., 12/8/2016, at 99-100; P-5218, 5093, 5125, D-144.

Dr. Solomon specifically opined that Tommy's gynecomastia was caused by his ingestion of Risperdal. In his testimony, he explained the entire causal pathway, summarized the key evidence, and concluded that Risperdal caused Tommy's gynecomastia. He testified that "gynecomastia is an increase in the cellularity of the breast." He added that, consistent with studies and medical literature, Risperdal acted as a stimulus for increase in the hormone prolactin.

Prolactin signals breast cells to grow in women and men. The growth is slow over time. Dr. Solomon also testified that even when you stop Risperdal, breast continues growing until the cells receive appropriate hormonal signal to stop growth. N.T., 12/7/2016, at 50-51, 70-71, 143-45.

Significantly, in performing his differential diagnosis and reaching a causation opinion, Dr. Solomon ruled out potential alternative causes of Timothy's gynecomastia. N.T., 12/6/2016, at 98-99; N.T., 12/7/2016, at 29-45, 58-62, 68-70.

Especially when viewed in light most favorable to Plaintiffs, this evidence was sufficient for the trial to proceed to a jury and for the jury to enter a verdict on negligence and causation in favor of Plaintiffs under Texas law. *See Scampone*, 57 A.3d at 595. Plaintiffs do not suggest they were entitled to a directed verdict in their favor. But the Court erroneously entered nonsuit, where Plaintiffs presented sufficient evidence to establish a *prima facie* case on each element of their claim for failure to warn. *See Vicari*, 936 A.2d at 509.[1]

[1] This evidence was also sufficient to send Plaintiffs' fraud claim to the jury. Under Texas law, "a plaintiff establishes actionable fraud if the defendant makes a material representation, that is false, either known to be false when made or is asserted without knowledge of its truth, that is intended to be and is relied upon, and that causes injury." *American Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 436 (Tex. 1997). When the defendant has a duty to warn, "silence itself can be a false representation." *Id.* As the evidence illustrates, Janssen fraudulently failed to warn Tommy's prescribers of Risperdal's risks as described by Dr. Kessler. Tommy's prescribers relied upon Janssen's silence to prescribe Risperdal to Tommy. Janssen's fraud was the medical and legal cause of Tommy's injuries. *See Centocor*, 372 S.W.3d at 169-73.

C. The Court erroneously entered nonsuit.

The Court entered its nonsuit on the basis that, "under Texas law, Dr. Solomon's testimony is legally insufficient to prove causation in this case." N.T., 12/13/2016, at 4. Janssen earlier had moved for nonsuit on several grounds. As to Dr. Solomon, Janssen claimed that Plaintiffs "failed to introduce sufficient evidence of both general and specific causation." *See* Exhibit A at 13-23. This is the only ground that the Court identified as a basis for nonsuit and therefore is the focus of this analysis.

The Court erroneously entered nonsuit for several reasons. *First*, the Court mistakenly embraced Janssen's false conflation of admissibility and sufficiency as a basis for analyzing the nonsuit motion.

Janssen argued that Plaintiffs failed to meet their burden of proof for general causation as a matter of Texas law because Dr. Solomon had not presented "at least two studies" that demonstrate "a statistically significant doubling of the risk." For this proposition Janssen relied upon *Merrell Dow Pharm., Inc. v. Havner*, 953 S.W.2d 706 (Tex. 1997); *Merck & Co. v. Garza*, 347 S.W.3d 256 (Tex. 2011); and *Cerny v. Marathon Oil Corp.*, 480 S.W.3d 612 (Tex. App. Oct. 7, 2015). *See* Exhibit A at 13-19.

At the outset, neither Texas case law nor the Texas Products Liability Act requires a plaintiff to introduce evidence of epidemiological study (let alone two of them) to make a *prima facie* case of negligent failure to warn. *See* Tex.

Civ. Prac. & Rem. § 82.007; *Centocor*, 372 S.W.3d at 170. If the Texas legislature had intended to foreclose all negligent failure to warn claims where epidemiological studies were unavailable, it certainly could have articulated this defense in the statute. It did not. *Id.*

Under Texas law, a plaintiff's burden with respect to causation is simply to introduce evidence that the "defect in the manufacturer's warning was a substantial cause of the plaintiff's injury." *Centocor*, 372 S.W.3d at 170. Plaintiffs certainly met that standard here. Plaintiffs introduced expert testimony from Dr. Solomon, who opined with reasonable medical certainty that Tommy had gynecomastia, that he developed gynecomastia during his ingestion of Risperdal, and that his ingestion of the drug as an offending agent caused the gynecomastia. Plaintiffs also elicited testimony that Janssen's inadequate warning to Tommy's treating physicians was a substantial factor in their decision to prescribe Risperdal, and the proximate cause of Tommy's injuries. Especially when viewed in light favorable to the non-moving party, this evidence was sufficient to establish a prima facie case of causation under Texas law. *See id.*; *see also Scampone*, 57 A.3d at 595; *Vicari*, 936 A.2d at 509.

In moving for nonsuit, Janssen did not address the sufficiency of Dr. Solomon's testimony as it was actually admitted in Court. It instead focused on the "reliability" of Dr. Solomon's testimony and the appropriateness for the testimony be admitted in the first place. *See* Exhibit A at 13-23. There is a

basic difference between the admissibility of evidence (an evidentiary issue) and the sufficiency of the admitted evidence to establish a *prima facie* case for an element or cause of action (a substantive issue). Janssen's nonsuit motion conflated these distinct issues, and cleverly urged the Court to reach a sufficiency finding based on Janssen's perspective about whether Dr. Solomon's testimony should have been admitted in the first instance. *See Commonwealth v. Schrader*, 141 A.3d 558, 565 (Pa. Super. 2016). The Court failed to recognize that discrete decisions were at issue – the procedural issue of evidence on one hand, and the substantive issue of sufficiency on the other – and then reached its decision on an improper legal foundation. *See Betz v. Pneumo Abex*, 44 A.3d 27, 54 (Pa. 2012).

Janssen's conflation of procedure and substance is apparent from its motion. Janssen moved for nonsuit relying primarily upon decisions that address the admissibility of expert testimony under Texas Rule of Civil Evidence 702 and *Daubert v. Merrill Dow Pharmaceuticals*, 509 U.S. 579 (1993). *See Havner*, 953 S.W.2d at 712; *Garza*, 347 S.W.3d at 262-64 (applying *Havner*); *Cerny*, 480 S.W.3d at 620 (same). In *Havner* and *Garza*, the Texas appellate courts also vacated jury verdicts in favor of the plaintiffs under a Texas "no evidence" procedure that does not exist in Pennsylvania and is inconsistent with Pennsylvania law. *See Havner*, 953 S.W.2d at 711 & 714; *Garza*, 347

S.W.3d at 262; *see also Cerny*, 480 S.W.3d at 615 & 617 (affirming trial court's "no evidence" summary judgment).

Havner illustrates Texas procedure in this regard. In *Havner*, the Texas Supreme Court vacated a jury verdict in favor of the plaintiffs and entered judgment for defendant Merrell Dow. The plaintiffs filed a negligence action in which they claimed Merrell Dow's drug Bendectin caused their daughter's birth defect. *Havner*, 953 S.W.2d at 708-09. To prove causation, the plaintiffs introduced the testimony of experts who relied upon epidemiological studies to conclude that Bendectin increased the risk of the child's birth defect. *Id.* Merrell Dow challenged the "reliability" of this evidence in pre-trial motions to exclude witnesses, and the trial court held an extensive hearing. *Id.* at 709. The trial court permitted the evidence and, at the conclusion of the liability phase, the jury entered a verdict and award in favor of the plaintiffs. The intermediate appellate court affirmed. *Id.*

On further appeal, the Texas Supreme Court reversed and held that the opinions of the plaintiffs' causation experts were unreliable and inadmissible under Texas Rule of Civil Evidence 702, as applied under *E.I. Du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, 558 (Tex. 1995). *Robinson* incorporates the *Daubert* standard for admissibility of expert testimony into Texas law. *Id.* at 712-14. Applying a *Daubert* framework the Texas Supreme Court found the experts' causation opinions unreliable and inadmissible

because they were based upon epidemiological studies that did not meet the Court's threshold of statistical confidence. *Id.* at 721-30. Having found the experts' testimony unreliable, the Court applied a "no evidence" procedure to enter judgment in favor of Merrell Dow. *Id.* at 711 & 714. This Texas "no evidence" procedure permits an appellate court to vacate a jury verdict upon finding that "the court is barred by rules of law or evidence from giving weight to the only evidence offered to prove a vital fact," such as causation. *Id.* Under this procedure, a court "reviews a no-evidence summary judgment first, and then proceeds to address a traditional summary judgment only if necessary." *Cerny*, 480 S.W.3d at 617.

With Janssen's clever conflation of different legal concepts, the Court mistakenly applied Texas law (rather than Pennsylvania law) to Janssen's challenge to the admissibility of Plaintiffs' evidence. Of course, the law of Pennsylvania governs all procedural matters in Pennsylvania courts. *Commonwealth v. Sanchez*, 716 A.2d 1221 (Pa. 1998). And evidence is procedural law, as are the standards for reviewing and deciding dispositive motions. *Commonwealth v. Dennis*, 618 A.2d 972, 980 (Pa. 1992); *Hileman v. Pittsburgh and Lake Erie R. Co.*, 685 A.2d 994, 997 (Pa. 1996). As the Superior Court has explained: "Substantive law is the portion of the law which creates the rights and duties of the parties to a judicial proceeding, whereas procedural law is the set of rules which prescribe the steps by which the parties may have their

respective rights and duties judicially enforced." *Sheard v. J.J. DeLuca Co.*, Inc., 92 A.3d 68, 76 (Pa. Super. 2014).

With respect to Dr. Solomon, Pennsylvania law alone would have to govern whether his testimony should have been admitted. Pa.R.E. 702 governs the admissibility of expert testimony where scientific, technical, or other specialized knowledge beyond that possessed by a layperson will assist the trier of fact to understand the evidence or to determine a fact in dispute. Pa.R.E. 702. As relates to expert testimony, Pennsylvania has adopted the test in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). *See Commonwealth v. Topa*, 369 A.2d 1277, 1281 (Pa. 1977). It emphatically has not adopted *Daubert*. *See Grady v. Frito-Lay, Inc.*, 839 A.2d 1038, 1045 (Pa. 2003).

Under Pennsylvania law, *Frye* scrutiny is not triggered every time science comes into the courtroom. *Frye* applies only to proffered expert testimony involving "novel" scientific evidence. *Commonwealth v. Dengler*, 890 A.2d 372, 382 (Pa. 2005); Pa.R.C.P. 207.1; Pa.R.E. 702 (comment). When novel scientific evidence is presented, the *Frye* test examines whether the expert's methodology "is generally accepted by scientists in the relevant field as a method for arriving at the conclusion the expert will testify to at trial." *Grady*, 839 A.2d at 1045. The focus of the "general acceptance" inquiry lies strictly on the expert's methodology. The proponent of the testimony need not prove that the

expert's conclusion is also generally accepted. *Id.*; *Cassell v. Lancaster Mennonite Conference*, 834 A.2d 1185, 1190 (Pa. 2003).

Trial courts applying *Frye* grant considerable deference to experts on the methodology underlying their scientific reasoning. *Grady*, 839 A.2d at 1044. As the Supreme Court explained, "deferring to those in the best position to evaluate the merits of a scientific theory is the better way of ensuring that only reliable expert scientific evidence is admitted at trial." *Id.* Deference also promotes consistency and predictability in judicial rulings, because "the decisions of individual judges, whose backgrounds in science may vary widely, will be similarly guided by the consensus that exists in the scientific community on such matters." *Id.*

The deference mandated by a *Frye* analysis contrasts with the "gatekeeper" approach that federal judges perform under *Daubert*. *Daubert* requires district courts to become a direct participant in the scientific debate and make *de novo* determinations about the quality of an expert's reasoning and conclusions. In contrast, *Frye* is "focused exclusively" on the presence of novel scientific evidence and, in that context, asks only the threshold question of whether the expert's methodology is generally accepted so as to satisfy the bare threshold for admissibility under Rule 702. *Id.* at 592 n.11. Pennsylvania law leaves the testing of weight and credibility to cross-examination and allows the

jury to decide the persuasive value of an expert's reasoning. *See Trach v. Fellin*, 817 A.2d 1102, 1118-19 (Pa. Super. 2003).

Here, Janssen might have formulated a challenge to the admissibility of Dr. Solomon's testimony by filing a *Frye* motion under the standards articulated above. Plaintiff believe that the any such challenge would have failed, but we need not speculate about that point. The fact is that Janssen did *not* challenge the admissibility of Dr. Solomon's testimony either pre-trial via a *Frye* motion or following voir dire. They made no objection at all to his right to testify under *Frye* and Rule 702 principles as developed in Pennsylvania. *See* N.T., 12/6/2016, at 16-38; N.T., 12/7/2016, at 72-121.

Janssen instead waited for Plaintiffs to rest and then moved for compulsory nonsuit premised upon arguments that the causation expert's testimony was unreliable and inadmissible under *Daubert*. *See* Exhibit A at 14-15, 21-23. In other words, it waited until after Dr. Solomon had left the witness stand to articulate a challenge to whether his testimony should have been admitted in the first place.

Under Pennsylvania law, a defendant challenging the admissibility of evidence must make a specific and timely objection to the admission of evidence, either by pre-trial *Frye* motion or following *voir dire*. *See Schrader*, 141 A.3d at 565; *see also Vicari*, 989 A.2d at 1289 & n.1 (Saylor, J. concurring, joined by Eakin, J.). A defendant's challenge to the admissibility of an expert opinion

via objection on sufficiency grounds after the expert completed his testimony and the plaintiff's record was closed is neither specific nor timely. *Schrader*, 141 A.3d at 565; *Vicari*, 989 A.2d at 1289.

That Janssen's nonsuit motion is in actuality an improper and too-late challenge to the admissibility of Dr. Solomon's testimony is further illustrated by Janssen's reliance upon several federal court decisions which apply *Daubert* criteria, rather than the *Frye* analysis that applies in Pennsylvania. Janssen acknowledges in footnote that these decisions are not binding on the trial court, but claims the outcomes should nevertheless be followed because consistent with Pennsylvania law. *See* Exhibit A at 16-19 & n.24. Janssen is wrong. Janssen relies upon federal decisions as basis for asking the trial court to participate in the scientific debate and make determinations about the quality, credibility, and weight of Dr. Solomon's reasoning and conclusions. Janssen asks the court to erode the roles of the expert and the jury under Pennsylvania law. That may be a sound approach under *Daubert*. But *Daubert* is clearly not Pennsylvania law. *Grady*, 839 A.2d at 1044. Pennsylvania law explicitly leaves the testing of weight and credibility to cross-examination and allows the jury to decide the persuasive value of an expert's reasoning. *See Trach*, 817 A.2d at 1118-19.

For all of these reasons, the trial court erred in entertaining Janssen's nonsuit argument and granting compulsory nonsuit. Not only was the

evidence sufficient to establish a *prima facie* case, and Dr. Solomon's testimony was properly allowed as a threshold matter, but the only basis for relief was an untimely objection to the reliability and admissibility of Dr. Solomon's expert opinion. The nonsuit should be lifted for these reasons alone.

Several additional considerations further support the removal of the nonsuit and allowance of a new trial. Initially, Janssen made an incorrect *evidence* argument about whether Dr. Solomon's testimony should have been admitted from the outset, arguing that Dr. Solomon's conclusion that Risperdal caused Tommy's gynecomastia was inadmissible under *Frye* because Dr. Solomon did not consider dose and dose-response, and because no physician observed breasts before 2010.

As an evidence argument, the argument is defective because it is well-established that *Frye* does not "require an optimal methodology, just an accepted one." *Cassell*, 834 A.2d at 1190. Here, Dr. Solomon applied a differential diagnosis to conclude to a reasonable degree of medical certainty that Risperdal caused Tommy's gynecomastia and to exclude other possible causes. Dr. Solomon explained the methodology and bases for his causation opinion, and for excluding other potential causes. Any issue of Dr. Solomon's credibility and weight of his testimony were exclusively for the jury. *Sanchez*, 36 A.3d at 39; *Reeves v. Middletown Athletic Ass'n*, 866 A.2d 1115, 1130 (Pa. Super. 2004). Further, Janssen had the opportunity at trial (and in fact did) cross-

examine Dr. Solomon consistently with its arguments in the motion for nonsuit and more. N.T., 12/7/2016 (P.M.), at 72-121.

Janssen dismisses a photograph from 2007 of Tommy's breasts as insufficient to establish with medical certainty Tommy had gynecomastia at that time. *See* Exhibit A at 21-23. While the argument fails within the framework of evidence, it is also incapable of justifying a nonsuit in Pennsylvania because Dr. Solomon *was* allowed to testify and he *did* give testimony that established a prima facie case of causation at trial. Whether Janssen liked the evidence or not, and whether the Court was persuaded by the evidence or not, are both immaterial to whether the evidence sufficed to allow the jury to do its job. The jury should have been given the opportunity to consider and weigh the evidence. Janssen's *Daubert*-type and weight arguments were neither a proper basis upon which to discount evidence that was admitted properly and without objection, or a proper basis upon which to grant compulsory nonsuit.

Even assuming Janssen raised a proper sufficiency argument (which it did not), Janssen's reliance upon *Havner* is misplaced because the case is distinguishable on the facts. In *Havner*, the Texas Supreme Court noted that plaintiffs could rely on epidemiological studies to establish causation because direct experimentation on unborn children to determine whether the drug in fact causes birth defects "cannot be done." *Id.* at 714-15. Epidemiological studies are described as indirect evidence from a retrospective case comparison,

from which the "finder of fact is asked to infer that because the risk is demonstrably greater in the general population due to exposure to the [drug], the [plaintiff's] injury was more likely than not caused by the [drug]." *Id.* at 714-15, 721. The Court distinguished such indirect evidence (which it regarded with circumspection) from "direct" evidence of causation based on "controlled scientific experiments." *Id.*

Here, Plaintiffs did need to rely on extrapolations from data through epidemiological study. They introduced into evidence testimony about RIS-INT-41 and RIS-INT-70, two long-term clinical studies that investigated and demonstrated a direct causal relation between Risperdal ingestion and prolactin-related adverse events in children, including gynecomastia. RIS-INT-41 showed a gynecomastia incidence rate of 5.5%, and RIS-INT-70 reported an astonishing 12.5% incidence of gynecomastia. Janssen itself found a causal relation between Risperdal and prolactin-related side effects, upon running the statistical analysis of Table 21. The result was statistically significant, meaning there was a 98.5% likelihood that the gynecomastia side-effects in Janssen's clinical studies did not happen by chance. In internal communications, Janssen scientists freely acknowledged the significance of this finding and of Table 21. Kessler Dep. at 30-72, 79-81, 95-105;197-98; P-24, P-25.

Indeed, Risperdal's direct relation to development of gynecomastia in children and adolescents is generally accepted. Janssen's *current* copyrighted

Risperdal label acknowledges the connection. According to Janssen, Risperdal is "associated with higher levels of prolactin elevation than other anti-psychotic agents"; "gynecomastia . . . ha[s] been reported in patients receiving prolactin elevating compounds." *See* P-53 (2007 Risperdal label).

In addition to this direct evidence of causation generated by Janssen's own employees and agents, Dr. Solomon was permitted to rely upon Dr. Kessler's testimony and other evidence of record addressing clinical trials in forming his opinions. *See* Pa.R.E. 703. Dr. Solomon also performed a traditionally-stated and supported differential diagnosis of T.M.'s affliction. Differential diagnosis is a standard medical procedure routinely used by doctors in their daily practice to distinguish a particular condition from others that may present similar symptoms. *See*, *e.g.*, *Bindschusz v. Phillips*, 771 A.2d 803, 808 (Pa. Super. 2001). *Havner* did not purport to impose a "two epidemiological study" requirement where evidence from clinical trials is available and where the drug manufacturer acknowledges the causal relation. *See Havner*, 953 S.W.2d at 714-15. In the end, Dr. Solomon had an evidentiary foundation that was both broad and deep to support his causation analysis – with or without epidemiology studies to further bolster his opinion.

As a final matter, Janssen improperly claimed that Dr. Solomon failed to identify the complete bases for his opinions under Pa.R.E. 705. *See* Exhibit A at 17-20. Pa.R.E. 705 provides as follows: "If an expert states an opinion the

expert must state the facts or data on which the opinion is based." Pa.R.E. 705. Janssen never objected on this basis at trial, and raised the issue for the first time in its motion for compulsory nonsuit, after Dr. Solomon completed his testimony and Plaintiffs rested. Janssen's objection was untimely, waived, and not a proper basis for compulsory nonsuit. The belated objection was not calculated to draw out the bases for Dr. Solmon's opinions, as it offered no opportunity for Plaintiffs or the trial court to cure the purported evidentiary shortfall. *See Schrader*, 141 A.3d at 565.

In any event, the objection was meritless. Rule 705 calls for the expert to state the facts or data upon which his opinion is based. That the terms are set in the disjunctive illustrates that not every expert opinion calls for rote listing of data to meet some quota of citations to medical literature. S*ee*, *e.g.*, *In re D.Y.*, 34 A.3d 177 (Pa. Super. 2011), *appeal denied* 47 A.3d 848 (Pa. 2012). The expert "may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Pa.R.E. 703. "Once expert testimony has been admitted, the rules of evidence then place the full burden of exploration of facts and assumptions underlying the testimony of an expert witness squarely on the shoulders of opposing counsel's cross-examination." *D.Y.*, 34 A.3d at 183.

Here, Dr. Solomon identified specific facts upon which he formed the opinion that Tommy suffered from true gynecomastia caused by his ingestion

of Risperdal. These facts included evidence of record, such as Dr. Kessler's testimony, the Risperdal label, internal Janssen documents, Janssen clinical trials, Janssen statistical analyses (Table 21), and Risperdal's mechanism of action – all of which indicated Risperdal causes gynecomastia generally. They also included Tommy's physical presentation and his medical history. Premised upon these facts, Dr. Solomon concluded Risperdal caused Tommy's gynecomastia specifically. N.T. 12/6/2016, at 38-99; N.T., 12/7/2016, at 27-72, 121-46. Dr. Solomon plainly met Rule 705 requirements, and this was not a proper basis for nonsuit either.

II. Plaintiffs are entitled to a new trial because the preclusion of Dr. Solomon's testimony was prejudicial.

Plaintiffs' evidence, as it was admitted, was itself sufficient to establish a *prima facie* case under Texas law that Janssen negligently failed to warn of known Risperdal risks that caused Tommy's injuries. Nonsuit should be removed on this ground alone. But there is another ground on which Plaintiffs are entitled to a new trial—the Court's decision to sustain Janssen's objection on fair scope grounds, which improperly curtailed Plaintiffs' examination of Dr. Solomon regarding the medical literature upon which he relied in forming his opinions. *See* N.T., 12/7/2016, at 52-54. The Court abused its discretion in precluding this testimony, which would have supplied all of the testimony the Court said was missing in granting nonsuit. In other words, if nonsuit was

properly granted on the evidence as it was admitted (and it was not), then the improper preclusion of key portions of Dr. Solomon's testimony on fair scope grounds was undoubtedly prejudicial because it prevented Plaintiffs from reaching the evidentiary hurdle to survive the nonsuit motion.

A. Legal framework

The principles governing the fair scope doctrine are well settled. Pennsylvania Rule of Civil Procedure 4003.5 provides that a defendant may obtain in discovery "facts known and opinions held by an expert… acquired or developed in anticipation of litigation or for trial." Pa.R.C.P. 4003.5(a). The defendant may require the plaintiff to identify each person plaintiff expects to call as a witness and the subject matter on which each expert is expected to testify. *Id.* Also, the defendant may require the plaintiff to "state the substance of the facts and opinions to which the expert is expected to testify and a summary of the grounds for each opinion." *Id.* The plaintiff may submit a report of the expert in answer to interrogatories. *Id.* Rule 4003.5 also provides, as follows:

> (c) To the extent that the facts known or opinions held by an expert have been developed in discovery proceedings under subdivision (a)(1) or (2) of this rule, the direct testimony of the expert at the trial may not be inconsistent with or go beyond the fair scope of his or her testimony in the discovery proceedings as set forth in the deposition, answer to an interrogatory, separate report, or supplement thereto. However, the expert shall not be prevented from testifying

> as to facts or opinions on matters on which the expert has not been interrogated in the discovery proceedings.

Pa.R.C.P. 4003.5(c). The Supreme Court's commentary states that "[i]f the expert report is unclear as to the facts upon which the expert relied, upon motion of a party, the trial court should order the filing of a supplemental report that complies with Rule 4003.5(a)(1)." Pa.R.C.P. 4003.5 (explanatory comment – 2014).

The Superior Court has explained that, where a "fair scope" objection is concerned, "the accent is on the word 'fair,'" and whether the omission from the report surprises and is prejudicial to the adversary. *Keffer v. Bob Nolan's Auto Serv., Inc.*, 59 A.3d 621, 655 (Pa. Super. 2012); *Hickman v. Fruehauf Corp.*, 563 A.2d 155, 157 (Pa. Super. 1989). Prejudice in this context means a "substantial diminution" of the adversary's ability to properly present its case at trial. *Keffer*, 59 A.3d at 655. It means "more than simply damage" to the adversary's cause. *Id.* The salient question is whether "the discrepancy between the expert's pretrial report and his trial testimony is of a nature which would prevent the adversary from preparing a meaningful response, or which would mislead the adversary as to the nature of the appropriate response." *Hickman*, 563 A.2d at 157. The rule requires "sufficient notice of the expert's theory to enable the opposing party to prepare a rebuttal witness." *Id.* Prejudice is not presumed to

exist, and the burden to prove "actual harm" is upon the party objecting to admission of the testimony. *Keffer*, 59 A.3d at 655.

The fair scope rule is flexible. Fair scope "contemplates a reasonable explanation and even an enlargement of the expert's written words." *Hickman*, 563 A.2d at 157; *Andaloro v. Armstrong World Indus., Inc.*, 799 A.2d 71, 84-85 (Pa. Super. 2002). The expert's trial testimony is admissible if it could reasonably have been anticipated from the content of the expert's report. *See Butler v. Kiwi, S.A.*, 604 A.2d 270, 276 (Pa. Super. 1992). The purpose of the expert report is to apprise the adversary of the "expert's theory." *Schaaf v. Kaufman*, 850 A.2d 655, 666-67 (Pa. Super. 2004). "The expert is not required to give a basic primer on medicine in his or her report or draft it for a complete neophyte in the field. An expert is entitled to expect that the report will be read by qualified experts on the other side." *Id.* The expert is permitted to demonstrate the basis for his opinion, even using demonstrative tools which were not expressly described in the report. *See Pascale v. Hechinger Co. of Pa.*, 627 A.2d 750, 754-55 (Pa. Super. 1993).

Superior Court decisions illustrate application of these principles. For instance, in *Schaff*, the defendant's expert submitted a report in which he stated the opinion that the plaintiff's stroke was not the result of atrial fibrillation. The report also listed other possible causes of the stroke. At trial, the expert testified that the stroke could have originated in other parts of plaintiff's body.

The plaintiff objected on fair scope grounds, and the trial court overruled the objection. The Superior Court affirmed. The Court reasoned that the expert's trial testimony was properly admitted where the expert explained the basis for his opinion that something other than atrial fibrillation caused the stroke. The Court added "[o]ne would expect that the plaintiff's experts would know the other possible causes as well as [defendant's expert] and prepare accordingly." The expert's opinion was not beyond the fair scope of the report. *Id.*

And in *Coffey v. Minwax Co.*, 764 A.2d 616 (Pa. Super. 2000), the plaintiffs objected to the trial testimony of defendant's expert "as to the scientific tests, personal tests, and electrostatic discharge information relied upon for his opinion." *Id.* at 620-21. This testimony was not included in the report, where the expert had opined that there was insufficient evidence to conclude the fire had been caused by static electricity and that a more likely cause of the fire was the energization of an electrical appliance. The trial court overruled the objection, and the Superior Court affirmed. The Superior Court reasoned that the plaintiffs had ample notice of the expert's opinion to prepare a meaningful response. *Id.*

B. The Court abused its discretion by sustaining Janssen's "fair scope" objection.

In this case, on May 31 and June 1, 2016, Dr. Solomon authored two causation reports, one of which described his examination of Tommy and

conclusions from the examination. *See* Solomon reports, dated May 31, 2016 & June 1, 2016 (attached as Exhibit "C"). In his second report, Dr. Solomon determined that Tommy suffered from gynecomastia; that Tommy developed gynecomastia while he treated with Risperdal; and that ingestion of Risperdal caused his gynecomastia. Dr. Solomon relied upon his extensive training and experience to offer a differential diagnosis for Tommy's condition and the cause of his condition, and he offered his opinions to a reasonable degree of medical certainty. *Id.* Dr. Solomon's report also referenced "known literature regarding the drug" which describes the mechanism of action by which prolonged exposure to Risperdal acts to increase prolactin and stimulate the growth of female breast tissue in boys like Tommy. *Id.*

Janssen did not subpoena Dr. Solomon for deposition in this case. At trial, Janssen acknowledged that it did not request Dr. Solomon's deposition. *See* N.T., 12/7/2016, at 56.

Of course, Dr. Solomon had been deposed and then testified in three prior Risperdal cases. As a result, Janssen did not suffer any actual surprise and prejudice from his testimony and any suggestion to the contrary is baseless. In fact, this matter is among approximately 2,000 cases involving claims that the ingestion of Risperdal caused gynecomastia, which the First Judicial District coordinates under a master docket captioned *In re: Risperdal® Litigation*, March Term 2010, No. 296. Five cases in this mass tort program have been submitted

to juries on the same negligent failure to warn theories as this matter. Dr. Solomon was deposed and then testified as to causation in three of these cases, as follows: *Pledger v. Janssen Pharmaceuticals*, April Term 2012, No. 1997; *Stange v. Janssen Pharmaceuticals*, April Term 2013, No. 1984; and *Yount v. Janssen Pharmaceuticals*, April Term 2013, No. 2094. (Janssen only motion to preclude Dr. Solomon under *Frye* was denied in *Stange*.)

In the trial of those cases, Dr. Solomon testified about Risperdal's mechanism of action and discussed medical articles that support his description. Janssen knew that Dr. Solomon had not personally performed Risperdal research and that he relied upon publications of research results by other authors. Among them were two epidemiological articles: George M. Anderson, *et al.*, "Effects of Short- and Long-Term Risperidone Treatment on Prolactin Levels in Children with Autism," *Biological Psychiatry*, 61: 545-550 (2007); and Mahyar Etminan, "Risperidone and Risk of Gynecomastia in Young Men," *Journal of Child and Adolescent Psychopharmacology*, Vol. 25, Issue 9: 671-73 (2015). In those trials, Janssen's counsel (the same as here) cross-examined Dr. Solomon extensively on the medical literature upon which he relied to draw his causation conclusions, including the Anderson and Etminan articles. *See Stange* N.T., 10/21/2015 (A.M.), at 72-78; N.T., 11/3/2015 (P.M.), at 16-43, 69-75 (attached as Exhibit "D"); *Yount* N.T., 6/22/2016 (P.M.) at 183-93 & N.T., 6/23/2016 (A.M.) at 55, 72-86 (attached as Exhibit "E");

Pledger N.T., 2/9/2015 (A.M.) at 43-44; N.T., 2/9/2015 (P.M.), at 91-95 (attached as Exhibit "F"). Thus, Janssen and its counsel knew full well that Dr. Solomon had relied on those articles and what he had to say about them.

In this case, on October 24, 2016 – nearly five months after Dr. Solomon served his reports and more than a month before trial started – Janssen moved to preclude Dr. Solomon from testifying at trial on fair scope grounds based on its purported surprise and prejudice at what Dr. Solomon might say. *See* Janssen's motion in limine, dated Oct. 24, 2016 (attached as Exhibit "G"). Plaintiffs responded, and the trial court denied Janssen's motion without prejudice. *See* Plaintiffs' Response, dated Nov. 7, 2016 (attached as Exhibit "H"); Order, dated Nov. 29, 2016 (attached as Exhibit "I"). Notably, Janssen did not request any clarification of Dr. Solomon's opinion, and the trial court did not order the filing of a supplemental report as the Supreme Court recommends in commentary to Rule 4003.5. *See* Pa.R.C.P. 4003.5 (explanatory comment – 2014).

At trial, Dr. Solomon testified that Tommy suffered from gynecomastia; that Tommy developed gynecomastia while he treated with Risperdal; and that ingestion of Risperdal caused his gynecomastia. Dr. Solomon developed his opinions and bases for his conclusions by describing Tommy's medical records and Risperdal course. Dr. Solomon also described Risperdal's mechanism of action. *See* N.T., 12/6/2016, at 16-101; N.T., 12/7/2016, at 26-145. But,

when Plaintiffs asked Dr. Solomon about the medical literature upon which he relied to form his opinions – specifically the Anderson and Etminan articles, Janssen objected on grounds that the testimony went beyond the fair scope of his report. Janssen knew full well what he had to say, and there was no conceivable surprise. But the Court sustained the objection. N.T., 12/7/2016, at 52-57. The Court reasoned as follows: "It's not a big surprise, but I can't keep allowing you and allow this guy to testify about things that aren't in his report." *Id.* at 55.

This was an abuse of discretion and wrong. Dr. Solomon's expert report fully apprised Janssen of his theory of causation and provided an ample basis for any enlargement of that testimony by reference to specific studies that were well known to Janssen. *Schaaf*, 850 A.2d at 666-67; *Hickman*, 563 A.2d at 157; *Andaloro*, 799 A.2d at 84-85; *Butler*, 604 A.2d at 276. Further, Dr. Solomon was entitled to expect that his report would be read by experts for Janssen and their counsel who were well versed in this litigation and Dr. Solomon's prior testimony. *Id.* He was not required to draft the report that listed each item of medical literature concerning Risperdal's mechanism of action, especially where Janssen's *current* Risperdal label acknowledges the causal relationship. *See id.* This is most especially true since the medical literature is not substantively admissible as evidence in Pennsylvania – it may serve to bolster an opinion, but

is not the opinion itself, which is the subject of the fair scope doctrine. *See Aldridge v. Edmunds*, 750 A.2d 292, 296 (Pa. 2000).

Further, any omission from the report of references to specific medical literature caused Janssen no "actual" surprise or harm. *See Keffer*, 59 A.3d at 655. The very notion of that in this litigation, after all these trials with Dr. Solomon as a testifying witness, borders on absurd and is certainly not credible. Janssen knew exactly what articles Dr. Solomon relied upon in forming his opinions on causation (including Anderson and Etminen), because Dr. Solomon testified and was cross-examined as to those same articles in three prior cases involving Risperdal-caused gynecomastia. In fact, Janssen relied upon substantially the same testimony and experts to defend the failure to warn claims in all four cases where Dr. Solomon testified: *Pledger*, *Stange*, *Yount*, and *Moroni*. Janssen's strategy did not change, which illustrates that any purported discrepancy between Dr. Solomon's pre-trial report and his trial testimony in *Moroni* affected neither Janssen's capability to prepare a meaningful response nor mislead Janssen as to the nature of the appropriate response. *Hickman*, 563 A.2d at 157. Janssen suffered no diminution, let alone a "substantial diminution" in its ability to properly present its case at trial. *Keffer*, 59 A.3d at 655. That the Anderson and Etminan articles undermined Janssen's litigation position was not sufficient to establish the type of prejudice necessary to

prevail on a fair scope objection. *Id.* For all these reasons, the Court erred in sustaining Janssen's Rule 4003.5 objection.

The Court's error was prejudicial to Plaintiffs, for two reasons. *First*, the trial court precluded Plaintiffs from proving its case by relevant and persuasive evidence of their own choice and presenting the jury with the full evidentiary force of the case. *See Commonwealth v. Philistin*, 53 A.3d 1, 14 n.8 (Pa. 2012). *Second*, the trial court's decision was especially harmful in conjunction with the trial court's erroneous application and interpretation of Texas law to require proof of two epidemiological studies in support of causation. The trial court deprived Plaintiffs of the ability to meet the (erroneously) heightened burden of proof, which ultimately may have led to the trial court's decision to enter nonsuit in favor of Janssen.

CONCLUSION

For the foregoing reasons, the Court should remove the nonsuit and order a new trial in this matter.

Respectfully submitted,

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Dated: March 29, 2017

CERTIFICATE OF SERVICE

The undersigned hereby certifies that he hereby served a true and correct copy of Plaintiffs' Motion for Post-Trial Relief upon the following persons:

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IN RE RISPERDAL® LITIGATION

T.M. et al.,

Plaintiffs,

v.

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

Defendants.

**PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION**

**MAY TERM 2013
NO. 1076**

MOTION FOR COMPULSORY NONSUIT OF DEFENDANTS JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, AND JANSSEN RESEARCH & DEVELOPMENT, LLC

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Filing Date: **December 9, 2016**
Response Date: **December 9, 2016**
Reply Date: **December 9, 2016**
Control Number:

IN RE RISPERDAL® LITIGATION
T.M. et al., Plaintiffs, v. Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Research & Development, LLC, Excerpta Medica, Inc., and Elsevier, Inc., Defendants.

PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION

MAY TERM 2013
NO. 1076

ORDER

AND NOW, this ___ day of _____, 2016, upon consideration of the Motion for Compulsory Nonsuit of Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC, and the response of Plaintiff, if any, it is **ORDERED** that the motion is **GRANTED**.

BY THE COURT:

_____
SEAN F. KENNEDY, J.

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December 9, 2016

VIA ELECTRONIC FILING AND HAND DELIVERY

The Honorable Sean F. Kennedy
Criminal Justice Center
Room 1415
Philadelphia, PA 19107

Re: *In re Risperdal® Litigation*, March Term 2010, No. 296
***T.M. v. Janssen Pharmaceuticals, Inc.*, May Term 2013, No. 1076**

Dear Judge Kennedy:

Please accept the following Motion for Compulsory Nonsuit of defendants Janssen Pharmaceuticals, Inc. ("Janssen"), Johnson & Johnson, and Janssen Research & Development, LLC, which seeks nonsuit as to Plaintiff T.M.'s ("Plaintiff") remaining claims—negligence, strict product liability – failure to warn, and fraud.[1]

EXECUTIVE SUMMARY

Plaintiff's remaining claims are premised on the theory that Risperdal, an FDA-approved prescription medicine, was not accompanied by adequate warnings.[2]

[1] *See* Am. Order, *T.M. v. Janssen Pharm., Inc.*, May Term 2013, No. 1076 (Phila. Cty. Ct. Com. Pl. Nov. 23, 2016) (New, J.) (Control No. 16073589) (granting summary judgment in favor of Defendants and against Plaintiff on his claims for negligence – design defect, strict product liability – design defect, breach of express and implied warranties, violation of the Pennsylvania Unfair Trade Practices and Consumer Protection Law, Texas Deceptive Trade Practices Act, conspiracy, and punitive damages and granting summary judgment in favor of Defendants and against Plaintiff Brenda Tinkham, T.M.'s mother, on her only claims in this action (medical expenses incurred by a parent and loss of consortium)).

[2] Even Plaintiff's fraud claim is based on Janssen's failure to warn. *See* Third Am. Compl. ¶¶ 171–180. To the extent that Plaintiff's fraud claim is based on Janssen's interactions with the U.S. Food and Drug Administration ("FDA"), such a claim is preempted. *See, e.g., Buckman v. Plaintiffs' Legal Comm.*, 121 S. Ct. 1012 (2001).

Defendants are entitled to compulsory nonsuit as to these claims.[3]

First, nonsuit is appropriate because Plaintiff did not carry his burden to rebut the presumption under the Texas Product Liability Act ("TPLA") that Defendants cannot be liable for failure to provide adequate warnings in connection with a label that was—like the ones at issue in this case—approved by the U.S. Food and Drug Administration ("FDA").[4] Specifically, Plaintiff did not introduce any evidence from which a reasonable jury could conclude that (1) Janssen promoted Risperdal to Plaintiff's prescribers for an indication not approved by the FDA (an "off-label use"); (2) Plaintiff used Risperdal for that off-label use; and (3) Janssen's off-label promotion caused the prescribers to prescribe Risperdal to Plaintiff for that off-label use.

Second, nonsuit is appropriate because Plaintiff did not introduce evidence to support essential elements of his claims. In particular, Plaintiff failed to establish that (1) the warnings that accompanied Risperdal were inadequate, (2) Risperdal caused his alleged gynecomastia, and (3) any alleged inadequate warning was the proximate cause of his injury.

Third, nonsuit is appropriate because federal law preempts Plaintiff's theory of liability. Specifically, federal law prohibits a pharmaceutical manufacturer—like Janssen—from warning

[3] Defendants also are entitled to compulsory nonsuit because Plaintiff obtained satisfaction for injuries to his chest subsequent to the development of gynecomastia and is therefore precluded from a double recovery in this action as explained more fully in Defendants' Motion for Compulsory Nonsuit filed on December 2, 2016, which remains pending before the Court. (Control No. 16120438).

[4] Judge New determined that Texas law applies to Plaintiff's substantive claims. *See* Am. Order, *T.M. v. Janssen Pharm., Inc.*, May Term 2013, No. 1076 (Phila. Cty. Ct. Com. Pl. Nov. 23, 2016) (New, J.) (Control No. 16073589).

about risks (1) relative to an unapproved population and (2) when there is clear evidence that the FDA would not have approved a change to labeling.

Fourth, nonsuit is appropriate because Plaintiff did not introduce evidence to support an essential element of his fraud claim. In particular, Plaintiff did not introduce any evidence that he or his prescribing physicians relied on any representation from Defendants in connection with Risperdal.

Fifth, nonsuit is appropriate as to Johnson & Johnson and Janssen Research & Development, LLC, in any event, because (1) they are not manufacturers or sellers as defined by the TPLA and (2) Plaintiff failed to introduce any evidence whatsoever as to any action by either Johnson & Johnson or Janssen Research & Development, LLC.

Because Plaintiff has failed to meet his evidentiary burden, Defendants respectfully request that the Court grant their motion for compulsory nonsuit.

I. BACKGROUND

During his case-in-chief, Plaintiff presented the live or videotaped testimony of a number of witnesses, including David A. Kessler, MD; David Solomon, MD; John Joseph Dewar, a physician assistant; and Ms. Tinkham.[5]

A. Dr. Kessler.

Dr. Kessler opined that the Risperdal label in effect when Plaintiff was first prescribed Risperdal was inadequate because it did not warn that Risperdal is associated with higher levels of prolactin than other antipsychotic medications or include incidence rates of elevated prolactin

[5] Plaintiff also presented the videotaped testimony of Harvey Martin, MD, and Bryan Wieck, MD. As their testimony has no bearing on the matters raised in this motion, it is not included here.

in children and adolescents.[6] According to Dr. Kessler, although Risperdal was not approved for use in children and adolescents, Janssen should have provided this information to physicians through its sales force, medical education, or a "Dear Doctor Letter."[7]

Dr. Kessler further opined that the October 2006 Risperdal label was inadequate because it did not include a recommendation for monitoring prolactin levels or information about a "statistically significant association" between Risperdal and gynecomastia.[8]

B. Dr. Solomon.

Dr. Solomon, Plaintiffs' only causation expert, opined (for the first time) that Plaintiff developed gynecomastia in 2007.[9] Dr. Solomon came to this conclusion based solely on his review of a photograph of Plaintiff.[10] According to Dr. Solomon, Risperdal was prescribed for Plaintiff in December 2004.[11] As of that time, there was nothing Plaintiff could do to reverse the alleged gynecomastia because his breast cells had been "signaled" to continue growing until maturity.[12]

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[6] Kessler Dep. 456:12–24, 457:17–459:5, May 20, 2015.

[7] *Id.* at 460:19–461:17.

[8] *Id.* at 452:19–455:2.

[9] Tr. 85:6–86:8, 87:2–5, 87:13–22, Dec. 6, 2016.

[10] *Id.* at 85:23–86:8.

[11] Tr. 79:7–10, Dec. 7, 2016.

[12] *Id.* at 51:4–7.

C. Mr. Dewar.

Mr. Dewar testified that he was well aware that gynecomastia was a potential side effect of Risperdal when he first saw Plaintiff in 2004 and that he "always talked about" it when prescribing Risperdal to a child.[13]

D. Ms. Tinkham.

Ms. Tinkham testified that she did not read any Risperdal label.[14]

II. APPLICABLE STANDARD

After the close of a plaintiff's case, compulsory nonsuit is warranted if the "plaintiff has not introduced sufficient evidence to establish the elements necessary to maintain an action." *Morena v. S. Hills Health Sys.*, 462 A.2d 680, 683 (Pa. 1983). Although the "plaintiff must be given the benefit of all evidence favorable to him" in the compulsory nonsuit analysis, a suit cannot reach the jury "on the basis of speculation or conjecture." *Id.* at 682–83. In the present case, Plaintiff has failed to meet his burden of establishing that inadequate warnings accompanied Risperdal, that his Risperdal use caused his alleged gynecomastia, or that any alleged failure to warn or fraud was the proximate cause of his alleged gynecomastia. The Court should therefore grant Defendants' motion for compulsory nonsuit.

[13] Dewar Dep. 57:3–17, July 14, 2016; *see also id.* at 59:20–21 ("I was aware that it was a side effect . . . ."); *id.* at 100:14–15 ("But what I can say is that I did know that it was a side effect.").

[14] Tr. 71:2–17, Dec. 8, 2016.

III. ARGUMENT

A. Plaintiff Failed to Rebut the TPLA's Presumption That Janssen Cannot Be Liable for Plaintiff's Claims.

The TPLA applies to "a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product." Tex. Civ. Prac. & Rem. Code Ann. § 82.007(a). The TPLA defines "products liability action" as "any action against a manufacturer or seller for recovery of damages arising out of personal injury, death, or property damage allegedly caused by a defective product *whether the action is based in strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories.*" *Id.* § 82.001(2) (emphasis added). The statute therefore applies to Plaintiff's remaining claims of negligence (Count I), fraud (Count III), and strict product liability – failure to warn (Count IV). *See, e.g.*, *Gonzalez v. Bayer Healthcare Pharm.*, 930 F. Supp. 2d 808, 816, 820 (S.D. Tex. 2013) ("[T]he Court agrees with Bayer that a review of Plaintiff's claims for defective design, marketing defect, breach of express and implied warranties, negligence and gross negligence demonstrates that they are in actuality disguised failure-to-warn, fraud-by-omission claims subject to Section 82.007 of the Texas Civil Practices and Remedies Code.").

Under the TPLA, "there is a rebuttable presumption that the defendant or defendants . . . are not liable with respect to the allegations involving failure to provide adequate warnings or information if . . . the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Section 301 et seq.) [(the "FDCA")]." *Id.* § 82.007(a)(1). The statutory preemption applies, unless Plaintiff can rebut it,

because Plaintiff did not (and could not) introduce any evidence that the Risperdal package insert was not at all times approved by the FDA.

There are five exemptions to the presumption. *See* Tex. Civ. Prac. & Rem. Code § 82.007(b). The only exemption that is potentially applicable here requires Plaintiff to establish that Janssen "recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration." *Id.* § 82.007(b)(3)(A). Under Section 82.007(b)(3)(A), Plaintiff must establish that (1) Janssen promoted Risperdal to Plaintiff's prescribers for an off-label use; (2) Plaintiff used Risperdal for that off-label use; and (3) Janssen's off-label promotion caused Plaintiff's prescribers to prescribe the drug to Plaintiff for that off-label use. *Lucas v. Abbott Labs.*, 3:12–CV–3654–B, 2013 WL 2905488, at *3 (N.D. Tex. June 13, 2013) (citing Tex. Civ. Prac. & Rem. Code Ann. § 82.007(b)(3)); *Anderson v. Abbott Labs.*, Civil Action No. 3:11–cv–1825–L, 2012 WL 4512484, *4–5 (N.D. Tex. Sept. 30, 2012). In other words, Plaintiff must prove that his prescribers were exposed to Janssen's alleged off-label promotion *and* that Janssen's alleged off-label promotion *actually caused* the prescribers to prescribe the drug to him for the off-label use. *Lucas*, 2013 WL 2905488, at *4–5; *see also Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 777 (S.D. Tex. 2008); *Burton v. Am. Home Prods. (In re Norplant Contraceptive Prods. Liab. Litig.)*, 955 F. Supp. 700, 703 (E.D. Tex. Mar. 4, 1997).

Plaintiff did not present any evidence from which the jury could reach this conclusion. Indeed, there was no evidence that Plaintiff's *prescribers* were exposed to any off-label marketing by Defendants. Plaintiff did not introduce any testimony from one of his prescribers that he or she recalled any such promotion. Moreover, Dr. Martin specifically testified that he

was not asked to prescribe Risperdal to children.[15] In addition, there is no evidence that any alleged off-label promotion *caused* Plaintiff's prescribers to prescribe Risperdal for him.[16]

The TPLA's other four exemptions also do not apply here. The statute says the presumption may be rebutted if "the defendant, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury," Tex. Civ. Prac. & Rem. Code § 82.007(b)(1), but Judge New previously has ruled that section 82.007(b)(1) is preempted as a matter of law, *see* Order at 1 n.2, *Banks v. Janssen Pharm., Inc.*, Jan. Term 2010, No. 618 (Phila. Cty. Ct. Com. Pl. Sept. 4, 2012) (New, J.) (Control No. 12060968); *see also Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 381 (5th Cir. 2012) (holding that Section 82.007(b)(1) of the TPLA is preempted by the FDCA "unless the FDA itself finds fraud"). The presumption also may be rebutted if "the pharmaceutical product was sold or prescribed in the United States by the defendant after the effective date of an order of the [FDA] to remove the product from the market or to withdraw its approval of the product," Tex. Civ. Prac. & Rem. Code § 82.007(b)(2), but Plaintiff did not introduce any evidence that the FDA has ordered Risperdal to be removed from the market or that the FDA has it withdrawn its approval of Risperdal. In addition, the presumption may be rebutted if "(A) the defendant prescribed the pharmaceutical product for an indication not approved by the [FDA]; (B) the product was used as prescribed; and (C) the claimant's injury was causally related to the prescribed use of the product." *Id.* § 82.007(b)(4). But this

[15] Martin Dep. 84:6–11, May 4, 2016.

[16] Dewar Dep. 51:11–13 ("But I don't think we rely on the pharmaceutical company to guide our treatment.").

exemption does not apply because the defendants are not healthcare providers. Finally, the presumption may be rebutted if "the defendant, before or after pre-market approval or licensing of the product, engaged in conduct that would constitute a violation of 18 U.S.C. Section 201 [relating to bribery of public officials] and that conduct caused the warnings or instructions approved for the product by the [FDA] to be inadequate," *id.* § 82.007(b)(5), but there is no allegation, much less any evidence, of that here.

Because Plaintiff did not carry his burden to rebut the presumption against liability, Defendants are entitled to compulsory nonsuit on his remaining claims. *Lofton*, 672 F.3d at 381 (affirming summary judgment on plaintiff's negligence and strict liability claims based on TPLA); *Ebel*, 536 F. Supp. 2d at 770 (granting motion for summary judgment on negligence, strict liability, and warranty claims).

B. Plaintiff Failed to Establish That the Warnings That Accompanied Risperdal Were Inadequate.

Under Texas law, a warning is adequate when it specifically mentioned the circumstances complained of. *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App. 1993); *see also Dickerson v. Abbott Labs.*, No. 05-97-00070-CV, 1999 WL 93117, at *3 (Tex. App. Feb. 25, 1999) (holding that warning was adequate because it warned of the same side effect the patient suffered).

The "Precautions" section *and* the "DOSAGE AND ADMINISTRATION" section of the pre-October 2006 Risperdal labels during the period that Plaintiff used Risperdal stated the following:

> **Pediatric Use**
> Safety and effectiveness in children have not been established.

. . . .

> **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.[17]

It is difficult to conceive of a more concise and direct warning as to the use of Risperdal in children. *See, e.g.*, *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 259–60 (E.D.N.Y. 1999) ("[W]hile the package insert did not expressly state that the TSRH System's spine screws had not been approved for use in the pedicles, or that any such use was experimental, the insert did contain the following warning: 'Except for the TSRH staples, all of the components of the TSRH Spinal System are intended for hook fixation/attachment to the spine and/or screw fixation/attachment to the sacrum or ilium only.' This warning, to an experienced doctor such as Dr. Weber, could only mean that the TSRH screws had not been approved for use in the pedicles.").

Plaintiffs' own expert, Dr. Kessler, admitted that the Risperdal labels always included a warning as to the risk of hyperprolactinemia and to the possibility of gynecomastia.[18] The fact that the label did not use different words or address the incidence of these possible side effects in particular studies did not render the warning inadequate under Texas law. *See, e.g.*, *Rolen*, 856 S.W.2d at 609 (affirming trial court's grant of summary judgment where the warning warned of the exact complained of side effect that the patient suffered); *Dickerson*, 1999 WL 93117, at *3 (same).

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[17] P2, Feb. 2002 Risperdal Label at 2, 4.

[18] *See* Kessler Dep. 41:24–43:2, 44:24–46:23, May 19, 2015; *see also* P2, Feb. 2002 Risperdal Label at 2, 4.

Plaintiff's claims also rely on Dr. Kessler's purported expert opinion about the adequacy of the warnings, but his failure to testify to what language would be necessary to make the label "adequate" is dispositive; merely declaring a label or warning "inadequate" without showing what additional or different language would be needed to make the warning "adequate" is insufficient. *See, e.g.*, *Bourelle v. Crown Equip. Corp.*, 220 F.3d 532, 539 (7th Cir. 2000) ("The fact that Pacheco never even drafted a proposed warning renders his opinion akin to 'talking off the cuff' and not acceptable methodology."); *Jaurequi v. Carter Mfg. Co.*, 173 F.3d 1076, 1084 (8th Cir. 1999) ("Neither [expert] had created or even designed a warning device which would have been more appropriate, much less tested its effectiveness."); *Milanowicz v. Raymond Corp.*, 148 F. Supp. 2d 525, 541 (D.N.J. 2001) ("[A]n expert's failure to design and test a proposed warning and inability to point to contrary industry practice renders the reliability of his testimony 'extremely questionable.'" (citation omitted)); *Miller v. Pfizer, Inc.*, 196 F.Supp.2d 1062, 1089 (D. Kan. 2002) ("Dr. Healy has not drafted any sort of proposed warning; without any data or research regarding their potential efficacy, he has merely offered phrases that he thinks might be reasonably included. This fact weighs heavily against a finding that Dr. Healy is a qualified warnings expert.").

The October 2006 Risperdal label also specifically warned about the potential side effect of gynecomastia and added additional specifics about the incidence of those side effects in pediatric studies:

> Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin elevating compounds. . . .
>
> . . . .

> In clinical trials in 1885 children and adolescents with autistic disorder or other psychiatric disorders treated with risperidone, galactorrhea was reported in 0.8% of risperidone-treated patients and gynecomastia was reported in 2.3% of risperidone-treated patients.[19]

In *Apel v. Johnson & Johnson*, Docket No. MID-L-010623-09-MT, Case No. 274 CIVIL ACTION, 2014 N.J. Super. Unpub. LEXIS 3106, at *38–47 (N.J. Super. Ct. Law Div. July 25, 2014) (attached hereto as Ex. A, the Superior Court of New Jersey held that this exact wording was adequate as a matter of law as to the potential side effect of gynecomastia as well as tardive dyskinesia). Its reasoning is persuasive and should be followed here.

And, as to the post-October 2006 Risperdal label, Dr. Kessler opines only that the label should have included a monitoring recommendation and that it should have referred to a "statistically significant association" between Risperdal use and gynecomastia at 8 to 12 weeks.[20] This is insufficient as a matter of Texas law to establish that the warnings were inadequate.

A "recommendation" for monitoring, like the one that Dr. Kessler opines should have been given in the post-October 2006 Risperdal label, inappropriately interferes with the physician–patient relationship because it infringes on the independent medical judgment of a treating physician. *See, e.g., Bergstresser v. Bristol-Myers Squibb Co.*, Civil Action No. 3:12-1464, 2013 WL 6230489, at *7 (M.D. Pa. Dec. 2, 2013) ("[T]o the extent that the plaintiff alleges that the Abilify package labeling does not provide adequate monitoring instructions to physicians regarding the symptoms of dystonia, the plaintiff's allegations overlook the fact that such judgments as to specific monitoring are better left to the physicians' discretion, as opposed

[19] P3, Oct. 2006 Risperdal Label at 3–4.

[20] Kessler Dep. 452:19-455:2, May 20, 2015.

to the disassociated drug manufacturer."); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 813–14 (N.D. Ohio 2004) ("The law does not mandate that pharmaceutical manufacturers and marketers provide such specific instructions that they leave little room for doctors' reasonable medical judgment."), *aff'd*, 447 F.3d 861 (6th Cir. 2006).

Furthermore, adequacy of the warnings does not depend on whether they state that the medicine *causes* a particular side effect, as Dr. Kessler suggests the Risperdal label should have done by referring to a purported "statistically significant association" between Risperdal use and gynecomastia at 8 to 12 weeks. It is sufficient to identify the potential side effect to the clinician. *See, e.g.*, *Ziliak v. AstraZeneca LP*, 324 F.3d 518, 521 (7th Cir. 2003) ("If a pharmaceutical manufacturer warns doctors that specific adverse side effects are associated with the use of a drug, then a causal relationship between use of the drug and development of potential side effects is implicit in the warning, as is the doctor's need to monitor the patient and to consider alternative therapies.").

C. Plaintiff Failed to Establish That Risperdal Caused His Alleged Gynecomastia.

Medical causation is an essential element of Plaintiff's claims. *Merrell Dow Pharm., Inc. v. Havner*, 953 S.W.2d 706, 708 (Tex. 1997). "[C]ausation in toxic tort cases is discussed in terms of general and specific causation. General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury." *Id.* at 714. Plaintiff has failed to introduce sufficient evidence of both general and specific causation.

1. Plaintiff failed to establish general causation.

Under Texas law, "a threshold requirement of reliability is that the evidence demonstrates a statistically significant doubling of the risk." *Merck & Co. v. Garza*, 347 S.W.3d 256, 265 (Tex. 2011); *Havner*, 953 S.W.2d at 724–26; *Cerny v. Marathon Oil Corp.*, 480 S.W.3d 612, 620 (Tex. App. Oct. 7, 2015) ("Absent direct, scientifically reliable proof of actual causation, *Havner* requires the proponent of causation testimony in the toxic tort context to demonstrate that exposure 'more likely than not' caused the injury by pointing to at least two epidemiological studies demonstrating a statistically significant doubling of the risk as proof of general causation."). In addition, Plaintiff must present at least two studies that meet these requirements. *Garza*, 347 S.W.3d at 267 ("But even if [the VICTOR study] qualifies under *Havner*'s test, it cannot do so alone. Another study is still necessary, but lacking here."); *Havner*, 953 S.W.2d at 727 ("[A]n isolated study finding a statistically significant association . . . would not be legally sufficient evidence of causation."). If the epidemiological evidence does not meet the *Havner* and *Garza* standards, expert testimony as to causation that is based on such evidence is legally insufficient to show causation. *Garza*, 347 S.W.3d at 268.

Plaintiff "must [also] show that he or she is similar to those in the studies . . . includ[ing] proof that the injured person was exposed to the same substance, that the exposure or dose levels were comparable to or greater than those in the studies, that the exposure occurred before the onset of injury, and that the timing of the onset of injury was consistent with that experienced by those in the study." *Havner*, 953 S.W.2d at 720; *accord Garza*, 347 S.W.3d at 265–66; *see also Cerny*, 480 S.W.3d at 620 ("To raise a fact issue on causation under *Havner*, a toxic tort plaintiff must not only present competent evidence of a doubling of the risk through epidemiological

studies, [but] the plaintiff must also present evidence that he or she is similar to the subjects in the studies."). Therefore, a study that shows a statistically significant risk at a higher dose of the drug or under different circumstances is irrelevant and is not considered evidence of causation. *Garza*, 347 S.W.3d at 266.[21]

Although this standard is a strict one, it must be applied here. *In re Asbestos Products Liability Litigation*, No. MDL-875, 2012 WL 760739 at *2, *4, *7–10 (E.D. Pa. Feb. 17, 2012) ("We are mindful of the rather onerous burden [that Texas] places on the asbestos plaintiff. However, we are bound by the law as set out by the Texas Supreme Court . . . ." (footnote omitted)). Where, as here, Texas law controls, expert testimony admissible under Pennsylvania law but inadequate to meet the substantive standards of Texas law is inadequate to meet the burden of proof. *Id.* at *8 n.10–11.

Plaintiff does not have legally sufficient evidence of causation under the *Havner/Garza* standard. The only causation expert Plaintiff called, Dr. Solomon, does not cite *any* medical literature or studies to support his opinions and does not offer any testimony that Plaintiff's dose, duration of treatment, age, or adverse event diagnoses are comparable to the experience of any participants in any study that might meet the *Havner/Garza* requirements. Having no evidence

[21] For example, in *Garza*, one of Merck's studies included "statistically significant results showing five times as many heart attacks for the patients on Vioxx compared to the patients on Naproxen." 347 S.W.3d at 266. The court, however, disregarded that study because it "involved a dosage of 50 mg and a median duration of 9 months—double the dosage Mr. Garza took (25 mg) and a much longer duration than Mr. Garza's 25 days." *Id.* The court ruled that "[t]he usage involved in a study need not match the claimant's usage exactly, but the conditions of the study should be substantially similar to the claimant's circumstances," and that the "Garzas simply cannot argue that the VIGOR study showed a statistically significant doubling of the relative risk for a person like Garza, who took a much smaller dosage of Vioxx for much less time." *Id.*

of causation that is sufficient to meet their burden of proof, Plaintiffs cannot avoid compulsory nonsuit.

Even if this Court were to find that Dr. Solomon satisfied the *Havner*/*Garza* requirements, Dr. Solomon's causation testimony was the classic circular opinion that has been rejected as insufficient to establish causation. Specifically, he leaped to the conclusion that Risperdal caused Plaintiff's alleged gynecomastia without making any effort to satisfy the requirement of general causation. *Leake v. United States*, 843 F. Supp. 2d 554, 564 (E.D. Pa. 2011) ("A properly performed differential diagnosis, therefore, is built upon a reliable general causation finding—it does not establish general causation."); *see also Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 516 (W.D. Pa. 2003) ("The Court agrees with Rule 706 experts Dr. Powers and Dr. Savitz that the differential diagnosis is not a reliable methodology for determining *general* causation for the reasons discussed below, although it has been recognized as a valid methodology for assessing *specific* causation (once general causation has first been established).").

According to Dr. Solomon, once an individual takes Risperdal and breast growth begins, the breast growth will not stop until the individual reaches maturity, even if the individual ceases all Risperdal use.[22] Dr. Solomon provides absolutely no support for this theory of causation.

These opinions run counter to the requirement that an expert must provide at least some scientific support for his or her opinions:

> The exercise of scientific expertise requires inclusion of scientific authority and application of the authority to the specific facts at hand. Thus, the minimal threshold that expert testimony must meet to qualify as an expert opinion rather than merely an opinion

[22] Tr. 50:14–21, Dec. 7, 2016; *see also id.* at 51:17–21, 143:12–144:5.

> expressed by an expert, is this: the proffered expert testimony must point to, rely on or cite some scientific authority—whether facts, empirical studies, or the expert's own research—that the expert has applied to the facts at hand and which supports the expert's ultimate conclusion.

Snizavich v. Rohm & Haas Co., 83 A.3d 191, 197 (Pa. Super. Ct. 2013). Further, "[w]hen an expert opinion fails to include such authority, the trial court has no choice but to conclude that the expert opinion reflects nothing more than mere personal belief." *Id.*; *see also Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904–05 (7th Cir. 2007) ("We agree with the district court that Dr. McKinley had no reliable basis for his expert opinion. He could not point to any epidemiological data supporting his opinion, and he was not able to articulate any scientifically physiological explanation as to how Remicade would cause arterial thrombosis. The mere existence of a temporal relationship between taking a medication and the onset of symptoms does not show a sufficient causal relationship.").

Moreover, it was Plaintiff's burden to identify, on direct examination, the complete basis for his expert's opinion. *Hansen v. Wyeth, Inc.*, 77 Pa. D. & C.4th 501, 510 (Phila. Cty. Ct. Com. Pl. 2005) ("To force the opposing party to explicate an adverse experts' factual basis is unacceptable because it unfairly shifts the burden particularly when pre-trial disclosure is limited, expert depositions are generally prohibited, and the cross-examiner runs the risk of the expert presenting otherwise 'inadmissible' information to the jury in an answer." (footnotes omitted)); *see also McMurdie v. Wyeth*, No. 1386, 2005 WL 1713004 (Phila. Cty. Ct. Com. Pl.

July 14, 2005). Other than vague and general references to unspecified "literature," Plaintiffs made no such efforts.[23]

A causation expert also cannot simply identify isolated literature, i.e. "cherry pick" studies; rather, a causation expert must account for the full universe of literature addressing the issue and specifically account for any contrary findings. *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, MDL No. 2342, 2016 WL 1320799, at *6 (E.D. Pa. Apr. 5, 2016) ("In other words, in order to successfully opine on general causation (*i.e.*, that Zoloft can cause birth defects), any expert must account for the findings reached in the full universe of epidemiological studies." (footnote omitted)); *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prods. Liab. Litig.*, MDL No. 2:14-mn-02502-RMG, 2016 WL 1251828, at *15 (D.S.C. Mar. 30, 2016) (holding that "cherry-picking" data and "failing to adequately account for contrary evidence is not reliable or scientifically sound."); *Pritchard v. Dow Agro Scis.*, 705 F. Supp. 2d 471, 489 (W.D. Pa. 2010), *aff'd*, 430 F. App'x 102 (3d Cir. 2011) ("Plaintiffs cannot rely on Dr. Omalu's bare assertions that 'studies' show that there is an association between chlorpyrifos, benzene derivatives, or organophosphates and NHL. His opinion as to chlorpyrifos exposure is based on a single epidemiological study, and the authors of the study found only a weak association which was not statistically significant. Dr. Omalu also failed to address contrary studies which were raised by Defendants or adequately explain the differences between his opinions and the findings of those studies. Accordingly, for all of these reasons, Dr. Omalu's

[23] *See, e.g.*, Tr. 144:8–15, Dec. 7, 2016 (stating that he performed a review of the "literature," but did not list specific articles).

opinion on general causation is unreliable.").[24] Here, Dr. Solomon fails to address any of the literature that would negate his opinions.

2. Plaintiff failed to establish specific causation.

Dr. Solomon testified without any support that the Risperdal Plaintiff took from 2004 through 2008 is the cause of his present-day gynecomastia. Judge Bernstein has observed:

> Where the expert has obtained facts from a review of the litigation record, such as, deposition, documents, or exhibits, the expert may simply identify the case-specific facts of record on which the opinion is based. He may not however obscure his factual predicate by merely identifying volumes of depositions, report, literature and records from which he has drawn the facts.
>
> The Rule 705 requirement of presenting the "facts and data" which form the basis of the opinion may not be satisfied by a mere formalistic recitation of the material reviewed or considered. That pro forma routine absolutely obscures what Rule 705 intends to clarify and tantamount to the clearly impermissible tactic of offering an opinion based on "all the evidence."
>
> . . . .
>
> . . . . A ritualistic identification of voluminous depositions, libraries of medical literature, and thousands of documents, while intended to impress the jury by quantity, in fact absolutely obscures what Rule 705 is intended to clarify. This presentation of quantity is the same as offering an opinion based on all the evidence prohibited precisely because it obscures the true basis of opinion.
>
> . . . .
>
> On direct examination Dr. Busch presented conclusory testimony that the medical literature contained descriptions of valvular heart disease in connection with serotonin, methysurgide

[24] Although these cases were decided pursuant to the *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), expert analysis applied by federal courts, they nonetheless are consistent with several of the substantive requirements under Pennsylvania state law and thus are persuasive authority.

> ergotamine, and carcinoid syndrome. Dr. Busch testified, without explanation, that the literature demonstrating that serotonin could cause valvular heart disease should have put the defendant on notice of Fen-Phen's propensities.
>
> . . . .
>
> Rule 705 was adopted in accordance with long standing Pennsylvania law upholding the sanctity of the jury role as fact-finder. Expert testimony is intended to assist not supercede [sic] the jury. Expert opinion testimony should explain and clarify the facts so that correct conclusions may be reached by lay jurors. Experts are not advocates regardless of how much a party pays them. The trial is a search for truth and may not be castrated and corseted into a battle of experts. The jury must be provided with the factual basis on which an expert grounds his opinion so that the jury remains the only finder of fact and the trial is not reduced to "a battle of expert".

McMurdie v. Wyeth, No. 1386, 2005 WL 1713004, at *10, *13, *18, *24 (Phila. Cty. Ct. Com. Pl. July 14, 2005).

Dr. Solomon never identified the basis on which he could reach a conclusion that Plaintiff's alleged gynecomastia was never resolved, which he was required to do on direct examination. *Hansen*, 77 Pa. D. & C.4th at 501, 508 ("Rule 705 requires that the jury clearly learn the factual basis of opinion evidence from the expert herself on direct examination."). Dr. Solomon's opinions are, like the one in *McMurdie*, based on conclusory testimony that does not satisfy Plaintiff's burden of proving specific causation. Indeed, there is no doubt that Dr. Solomon took it upon himself to assume the role of the "thirteenth super-juror," which the Pennsylvania Rules of Evidence were designed to preclude.[25] *McMurdie*, 2005 WL 1713004, at *7 (recognizing that Rule 705 was "needed to preclude an expert from becoming a thirteenth super-juror").

[25] Tr. 78:16–17, 97:9–13, 113:17–18, 113:22–23, Dec. 7, 2016.

In addition, Dr. Solomon was required to (but did not) consider the particular dose of Risperdal taken by Plaintiff in opining as to causation. *Howard v. A.W. Chesterton Co.*, 78 A.3d 605, 608 (Pa. 2013) ("[I]n cases involving dose-responsive diseases, expert witnesses may not ignore or refuse to consider dose as a factor in their opinions. Bare proof of some *de minimus* exposure to a defendant's product is insufficient to establish substantial-factor causation for dose-responsive diseases. Relative to the testimony of an expert witness addressing substantial-factor causation in a dose-responsive disease case, some reasoned, individualized assessment of a plaintiff's or decedent's exposure history is necessary." (citations omitted)).

Finally, no reasonable jury could conclude that Plaintiff developed gynecomastia while being treated with Risperdal. Plaintiff offered the testimony of Dr. Solomon, his sole expert on causation, to opine that Plaintiff has Risperdal-induced gynecomastia. There is no contemporaneous medical evidence of gynecomastia until Plaintiff's initial diagnosis in May 2010—two years after Plaintiff discontinued Risperdal therapy. Yet, Dr. Solomon opined that Plaintiff developed gynecomastia in 2007, based only on a review of a historic photograph of Plaintiff.[26] Dr. Solomon testified that he could diagnose gynecomastia in 2007 based solely on his review of the photograph.[27] In other words, according to Dr. Solomon, the photograph alone was sufficient to conclude to a reasonable degree of medical certainty that Plaintiff had gynecomastia in 2007. Such testimony fails to meet the standard for admissibility under Pennsylvania Rule of Evidence 702 and contradicts his prior testimony. As such, Dr. Solomon's

[26] Tr. 84:4–86:14, 86:18–87:5, Dec. 6, 2016.

[27] Tr. 113:24–114:2, Dec. 7, 2016.

opinion that Plaintiff had gynecomastia as of 2007 should be excluded and stricken from the record, and a curative instruction should be read to the jury.

Under Pennsylvania law, an expert may offer scientific opinion testimony at trial *only if* "the expert's methodology is generally accepted in the relevant field." Pa. R.E. 702(c); *see also Grady v. Frito-Lay, Inc.*, 839 A.2d 1038, 1045 (2003) (recognizing that the proponent of expert testimony must "prove that the methodology an expert used is generally accepted by scientists in the relevant field as a method for arriving at the conclusion the expert will testify to at trial"). Making a clinical diagnosis of gynecomastia based on examination of a photograph is not a method generally accepted in the medical community. Indeed, Dr. Solomon has testified that in his clinical practice, he would never base a gynecomastia diagnosis on a photograph. Rather, the "standard" practice in plastic surgery and medicine requires a "physical examination." *Timothy Stange v. Janssen Pharmaceuticals, Inc. et al.*, No. 1984, Tr. 41:7-42:12, Oct. 27, 2015 PM (Q. "[W]ith regard to gynecomastia, if you're going to confirm that there is gynecomastia, you need to do a physical examination?" Dr. Solomon: "That's the standard in plastics and, I believe, in medicine."). Yet Dr. Solomon's opinion that Plaintiff developed gynecomastia in 2007 is based *solely* on a historic photograph from which he purportedly could "diagnose" the condition. This results-driven opinion is at odds with the methodology Dr. Solomon would employ in his clinical practice and made only for the purposes of litigation. It is a bedrock principle that an expert may not offer opinions based on a novel methodology that he would never use when diagnosing and treating patients in his day-to-day medical practice. Accordingly, Dr. Solomon's testimony that Plaintiff developed gynecomastia in 2007—based on this faulty and unscientific methodology—should be excluded and stricken from the record as inadmissible pursuant to Rule 702. Without

the improper diagnosis by photograph, there is no evidence to support the conclusion that Plaintiff developed gynecomastia while on Risperdal.

D. Plaintiff Failed to Establish That Any Alleged Inadequate Warning Was the Proximate Cause of His Alleged Injury.

Under Texas law, "[g]enerally, a manufacturer is required to provide an adequate warning to the end users of its product if it knows or should know of any potential harm that may result from the use of its product." *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 153–54 (Tex. 2012) (citation omitted). However, "a prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has no further duty to warn the end users directly." *Id.* at 157 (citations omitted). Under the "learned intermediary" doctrine, "a patient-purchaser's doctor stands between the patient and the manufacturer, professionally evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use." *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 207 (5th Cir. 2008) (citation omitted) ("*Ackermann II*").

To avoid application of the learned intermediary doctrine, the "plaintiff must show that (1) the warning was defective, and (2) the failure to warn was a producing cause of the injury." *Ebel v. Eli Lilly & Co.*, 321 F. App'x 350, 355 (5th Cir. 2009) ("*Ebel II*") (citing *Ackermann II*, 526 F.3d at 208); *In re Norplant*, 955 F. Supp. at 710–11. "The failure to warn was a producing cause of the injury if 'the alleged inadequacy caused [the] doctor to prescribe the drug for [the patient].'" *Ebel II*, 321 F. App'x at 356 (quoting *Ackermann II*, 526 F.3d at 208). "If, however, 'the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury' and the

plaintiff's recovery must be denied." *Id.* (citations omitted); *Stewart v. Janssen Pharm., Inc.*, 780 S.W.2d 910, 912 (Tex. App. 1989) ("If he was aware of the possible risks involved in the use of this drug, yet chose to use it regardless of the adequacy of the warning, then, as a matter of law, the adequacy of the warning was not a producing cause of [the] injury."). "Even if the physician is not aware of a risk, 'the plaintiff must show that a proper warning would have changed the decision of the treating physician, i.e., that but for the inadequate warning, the treating physician would have not used or prescribed the product.'" *Ackermann II*, 526 F.3d at 208 (citations omitted); *see also In re Norplant*, 955 F. Supp. at 710–11.

Plaintiff only introduced the testimony of one of his prescribers, Mr. Dewar. He testified that he knew at the time he prescribed Risperdal for Plaintiff that he was aware of the risk of gynecomastia associated with Risperdal use.[28] Plaintiffs therefore cannot establish proximate cause of the injury by inadequate warnings. *See Stewart*, 780 S.W.2d at 912 (affirming summary judgment in favor of manufacturer because even if there had been a deficiency in the warning, such a deficiency was "not a producing cause of [plaintiff's] injury" because the prescriber was "fully aware of the risks" associated with the drug); *Centocor, Inc.*, 372 S.W.3d 140, 172–73 (finding that the learned intermediary doctrine barred plaintiff's claims because plaintiff's physicians were aware of the potential risk regarding lupus-like syndrome, but chose to prescribe the drug anyway in light of plaintiff's complicated medical history and severity of ailments); *Ebel II*, 321 F. App'x at 356–58 (granting summary judgment where plaintiff failed to establish that drug's warning was the producing cause of suicide because the prescriber was aware of drug's risks).

[28] Dewar Dep. 57:3–17, July 14, 2016; *see also id.* at 59:20–21 ("I was aware that it was a side effect . . . ."); *id.* at 100:14–15 ("But what I can say is that I did know that it was a side effect.").

E. Plaintiff's Failure-to-Warn and Fraud Claims Based on the Pre-October 2006 Risperdal Label Are Preempted by Federal Law.

1. Federal law prohibits Janssen from warning about risks relative to an unapproved population.

Plaintiff presented the testimony of Dr. Kessler—a former Commissioner of the FDA—to manufacture a duty on the part of Janssen to warn as to pediatric use prior to Risperdal receiving an indication for use by children and adolescents. According to Dr. Kessler, the pre-October 2006 Risperdal label inadequately warned physicians of the possibility that Risperdal is associated with higher levels of prolactin than other antipsychotic agents are and that Janssen knew of—but did not report—incidence rates associated with elevated prolactin levels in children and adolescents when compared to placebo-treated patients.[29]

This theory, however, is preempted because federal law *prohibits* Janssen from taking this action. *See Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013) (holding that "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" (citing 21 C.F.R. § 314.70(b)(2)(i))). FDA regulations in effect during the period at issue reflect that a warning concerning a risk as to an off-label use has to be initiated by the FDA. *See* 21 C.F.R. § 201.57(e) (Mar. 2006) ("A specific warning relating to a use not provided for under the 'Indications and Usage' section of the labeling *may be required by the Food and Drug Administration* if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated

[29] Kessler Dep. 456:12–24, 457:17–459:5, May 20, 2015.

with serious risk or hazard." (emphasis added)); *see also Guidance for Industry—Changes to an Approved NDA or ANDA*, 2004 WL 3199016, at *19 (Apr. 1, 2004) (stating that "[c]hanges based on postmarketing study results, including, but not limited to, labeling changes associated with new indications and usage" must receive prior approval from the FDA).

Because Plaintiffs' entire for failure-to-warn theory as to the pre-October 2006 label rests on the notion that Janssen should have provided warnings as to Risperdal relative to an unapproved population, an action prohibited by controlling law, the claim is preempted.

2. Federal law prohibits Janssen from warning about risks when there is clear evidence that the FDA would not have approved the labeling change.

Plaintiff's pre-October 2006 label claim is also preempted for a separate reason. Even if this Court were to conclude that Janssen generally could have made a label change without prior FDA approval to warn of the potential side effect of gynecomastia in connection with pediatric use, it is clear that at the time Plaintiff used Risperdal (before the pediatric indication was approved in October 2006) the FDA would not have approved Plaintiff's proposed label change. On August 15, 1996, Defendants proposed to the FDA to include in the Risperdal label information related to dosing of Risperdal for pediatric patients. Despite knowledge that Risperdal was being used off label in pediatric patients, the FDA denied Janssen's request because it believed that adding dosing information for an unapproved population would encourage use of the drug for off-label purposes.[30]

Relying on *Wyeth v. Levine*, 555 U.S. 555 (2009), courts have held that state law claims are preempted where there was clear evidence that the FDA would not have approved the

[30] Kessler Dep. 74:23–86:6, May 19, 2015.

labeling during the time period relevant to the lawsuit. *See Rheinfrank v. Abbott Labs., Inc.*, 119 F. Supp. 3d 749, 766 (S.D. Ohio 2015) ("Preemption is warranted because there is clear evidence the FDA would not have approved a change to the Depakote label adding a developmental delay warning prior to M.B.D.'s injury."); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 951 F. Supp. 2d 695, 703 (D.N.J. 2013) ("In May 2009 . . . the FDA sent Defendant a letter . . . denying the change to the Precautions section of the label. The FDA's rejection constitutes clear evidence that the FDA would not have approved a label change to the Precautions section of the label prior to Mrs. Glynn's injury."); *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1276–77 (W.D. Okla. 2011) ("The court finds the FDA's rejection of the pediatric warning added by Wyeth under the CBE regulations to be highly persuasive evidence."); *see also Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861, 873 (7th Cir. 2010) ("[I]t would be odd to think that McNeil had a legal duty to guarantee against a risk that the FDA thought not worth warning against.").

The same analysis applies here. Given the FDA's rejection of any information about pediatric use in the Risperdal label (except allowing Janssen to state for a *second time* that safety and effectiveness had not been established for pediatric patients), and the FDA's subsequent repeated approvals of the Risperdal label without any requested change as to pediatric use until the time of the autism indication in October 2006, Plaintiffs' failure-to-warn claim as to the pre-October 2006 label is preempted on this basis as well.

F. Plaintiff Failed to Establish an Essential Element of His Fraud Claim.

Plaintiff did not introduce sufficient evidence to establish that he or his prescribers relied on any representations by or conduct of Defendants, which is necessary to sustain a claim of

fraud. In particular, Ms. Tinkham testified that she never read any information about Risperdal,[31] and Mr. Dewar, the only healthcare provider whom Plaintiff introduced testimony from, testified that he does not rely on pharmaceutical companies.[32]

In addition, Plaintiff did not introduce any evidence that his prescribers reasonably relied on any relevant misrepresentation by Defendants because the only prescriber whose testimony he introduced testified that he was aware of the risk of gynecomastia when he decided to prescribe Risperdal to Plaintiff.[33] *See, e.g.*, *Sawyer v. E.I. DuPont De Nemours & Co.*, 430 S.W.3d 396, 401 (Tex. 2014) ("To recover for fraud, one must prove justifiable reliance on a material misrepresentation."); *accord Leonard v. Taro Pharm. USA, Inc.*, 10-cv-1341, 2010 WL 4961647, at *5 (W.D. Pa. Dec. 2, 2010) (dismissing fraud based on *intentional* misrepresentations and omissions because "Pennsylvania state and federal courts have interpreted *Hahn* broadly to bar all non-negligence based claims asserted against a manufacturer of prescription drugs").

G. Plaintiff Failed to Establish the Liability of Johnson & Johnson and Janssen Research & Development, LLC.

1. Johnson & Johnson and Janssen Research & Development, LLC, are neither manufacturers nor sellers and are therefore not liable under the TPLA.

The TPLA only imposes liability on a "manufacturer" or "seller" of a product. *See* Tex. Civ. Practice & Rem. Code § 82.001(2) ("'Products liability action' means any action against *a manufacturer or seller* for recovery of damages arising out of personal injury, death, or property

[31] Tr. 71:2–11, Dec. 8, 2016.

[32] Dewar Dep. 51:11–13 ("But I don't think we rely on the pharmaceutical company to guide our treatment.").

[33] Dewar Dep. 57:3–17, July 14, 2016; *see also id.* at 59:20–21 ("I was aware that it was a side effect . . . ."); *id.* at 100:14–15 ("But what I can say is that I did know that it was a side effect.").

damages allegedly caused by a defective product . . . ."). The TPLA defines a "manufacturer" as "a person who is a designer, formulator, constructor, rebuilder, fabricator, producer, compounder, processor, or assembler of any product or any component part thereof and who places the product or any component part thereof in the stream of commerce," *id.* § 82.001(4), and it defines a "seller" as "a person who is engaged in the business of distributing or otherwise placing, for any commercial purpose, in the stream of commerce for use or consumption a product or any component part thereof," *id.* § 82.001(3).

Plaintiff has not introduced any evidence that would tend to establish that either Johnson & Johnson or Janssen Research & Development, LLC, are "manufacturers" or "sellers" with respect to Risperdal. This is not surprising as Janssen is a separate legal entity from Johnson & Johnson and Janssen Research & Development, LLC. Janssen alone is the "manufacturer" of Risperdal. Because Plaintiff has not (and cannot) adduce evidence to establish that either of these entities are "manufacturers" or "sellers" as defined by the Tennessee Product Liability Act, Johnson & Johnson and Janssen Research & Development, LLC, are entitled to nonsuit.

2. In any event, Plaintiff failed to introduce any evidence from which the jury could pierce the corporate veil as to Johnson & Johnson and Janssen Research & Development, LLC.

a. Johnson & Johnson

Plaintiff has failed to establish a prima facie case against Johnson & Johnson. Johnson & Johnson is a holding company. It owns stock in different companies, like Janssen and Janssen Research & Development, LLC, that are independently managed. These operating companies are separate and distinct entities.

All of the evidence Plaintiff has introduced involves the conduct of Janssen, not that of Johnson & Johnson. It is well-settled that in order for Plaintiff to recover from Johnson & Johnson based on the acts of Janssen or Janssen Research & Development, LLC, he must show by a preponderance of the evidence that Janssen or Janssen Research & Development, LLC, is the "alter ego" of Johnson & Johnson (the parent), a theory they did not even plead in their complaint.

"The general rule seems to be that courts will not because of stock ownership or interlocking directorship disregard the separate legal identities of corporations, unless such relationship is used to defeat public convenience, justify wrongs, such as violation of the anti-trust laws, protect fraud, or defend crime." *Bell Oil & Gas Co. v. Allied Chem. Corp.*, 431 S.W.2d 336, 339 (Tex. 1968). "To 'fuse' the parent company and its subsidiary for jurisdictional purposes, the plaintiffs must prove the parent controls the internal business operations and affairs of the subsidiary. But the degree of control the parent exercises must be greater than that normally associated with common ownership and directorship; the evidence must show that the two entities cease to be separate so that the corporate fiction should be disregarded to prevent fraud or injustice." *Id.* (citations omitted).

Here, Plaintiff has not adduced any evidence suggesting that either Janssen or Janssen Research & Development, LLC, ceased to be separate entitled or that a fraud or injustice would operate if their separate legal identity was honored. In fact, Plaintiff has introduced no evidence relating to the conduct of Johnson & Johnson or Janssen Research & Development, LLC, at all.

Plaintiff has therefore failed to satisfy his burden, and Defendants are entitled to nonsuit.

b. Janssen Research & Development, LLC.

Plaintiff also has failed to establish a prima facie case against Janssen Research & Development, LLC. All of the evidence Plaintiff presented focused on the conduct of Janssen. Janssen Research & Development, LLC, is an entirely distinct entity from Janssen. There is therefore no basis on which to impose any liability on Janssen Research & Development, LLC.

CONCLUSION

For all the foregoing reasons, Defendants respectfully request that the Court grant their motion for compulsory nonsuit.

Respectfully submitted,

/s/ David F. Abernethy

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

CERTIFICATE OF SERVICE

I hereby certify that, on December 9, 2016, I caused a true and correct copy of the Motion for Compulsory Nonsuit of Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC, to be served via electronic mail on counsel of record as follows:

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Attorneys for Plaintiffs

/s/ Melissa A. Merk
Melissa A. Merk

Appendix B

Arnold & Itkin LLP
TRIAL LAWYERS

December 11, 2016

Via Electronic Mail & Hand Delivery
The Honorable Judge Kennedy
Criminal Justice Center, Room 1415
Philadelphia, PA 19107

RE: **T.M., et al. v. Janssen Pharmaceuticals, Inc., et al.**
May Term 2013, No. 1076

Dear Judge Kennedy:

Please accept this letter in response to Defendants' Motion for Compulsory Nonsuit. On behalf of the Plaintiff, we would point out that the substance of Defendants' arguments are cut and paste arguments from their Motion for Summary Judgment that was already denied. In addition, as this Court is aware from sitting through this trial, Defendants' recitation of the controlling facts is slanted and incomplete.

Defendants state five reasons for seeking compulsory nonsuit.

First, Defendants rely on the Texas Products Liability Act presumption that a warning approved by the FDA is adequate.[1] This argument is a rehash of an argument raised in Defendants Motion for Summary Judgment which was denied. (*See* Defendants' Mot. for Summ. J. at 16-20.) Plaintiff's response to that argument continues to apply and is incorporated by reference. (*See* Pl. Resp to Defs. Mot. for Summ. J. at 33-42.) As discussed in more detail in the briefing, the TPLA presumption is overcome by showing evidence of off-label marketing. Plaintiff provided evidence of an extensive nationwide off-label marketing scheme targeted toward children. The evidence also showed that the scheme manifested itself in the form of visits to Plaintiff's treating physicians. For example, Dr. Martin was shown Defendants' call notes where he was told to keep prescribing Risperdal to four year olds before the drug was approved for children. (Martin Dep. 84:9-85:1.) Dr. Wieck testified about an all-expense paid trip to a luxury hotel in Florida for the purpose of discussing use of Risperdal by children before the drug was approved for such use. (Wieck Dep. 104:7-104:25, 105:10-106:1, and 107:8-108:24, 109:15-16.) A sales representative went to Dr. Wieck's office following the trip to discuss prescribing Risperdal to children. (Wieck Dep. 110:21-112:4.) The same representatives visiting Wieck and Martin visited with Dewar, but more importantly, Dewar testified that Wieck or Dewar made the decision to prescribe Risperdal to Plaintiff, and he also testified he looked to

[1] Defendants presuppose Texas law applies, but the applicable law is in dispute. (*See* Defendants' Mot. for Summ. J. at 11-16 and Pl. Resp to Defs. Mot. for Summ. J. at 26-33.) For the reasons set forth in Plaintiff's cited response brief to Defendants' Motion for Summary Judgment, Plaintiff believes this Court should apply Pennsylvania law. In addition, Plaintiff was also prescribed Risperdal in Washington and consumed Risperdal in that state, so Washington law also applies with regard to those prescriptions and Defendants do not address any applicable Washington law.

them for guidance on what to prescribe and what risks to discuss with Plaintiff. (Dewar Dep. 34:19-37:2, 113:22-114:1, 118:14-119:3.) It is a jury question whether this intense marketing scheme led to use of Risperdal by Plaintiff.

The presumption is also overcome by evidence of misrepresentation or withholding of relevant and material evidence to the FDA. Tex. Civ. Prac. Rem. Code § 82.007(b)(1). Again, there is ample evidence of this. Indeed, Dr. Kessler spoke about this in depth particularly in connection with Table 21. Defendants argue that this exception to the presumption is pre-empted, and this was briefed in detail in response to Defendants' motion for summary judgment which was denied. (*See* Pl. Resp to Defs. Mot. for Summ. J. at 33-39.) Those arguments are incorporated by reference.

Finally, on this point, the presumption Defendants are relying on only applies to Defendants' failure to warn claims. *See* Tex. Prac. Civ. Rem. Code § 82.007(a) (stating that this presumption only applies to claims based on allegations of inadequate warnings.) Defendants do not address Plaintiff's fraud claim in this regard and the presumption is not a basis for nonsuit on that claim.

Defendants' second basis for seeking compulsory nonsuit is a claim that Plaintiff did not introduce sufficient evidence on his claims. They divide this into three subparts claiming that there is insufficient evidence of inadequate warnings, insufficient evidence that Risperdal caused Plaintiff's gynecomastia, and insufficient evidence that inadequate warnings led to Plaintiff's gynecomastia. Again, these exact arguments were raised in Defendants' motion for summary judgment. (*See* Defendants' Mot. for Summ. J. at 20-29, 34-39.) Plaintiff responded to these arguments and that response is incorporated by reference. (*See* Pl. Resp. Defs. Mot. for Summ. J. at 39-47, 50-57.) These arguments, then, were already considered in summary judgment and denied. As explained more fully in the summary judgment briefing, with regard to whether the warnings are inadequate, Plaintiff introduced evidence from Dr. Kessler, and the Defendants' labels (Px. 2 and Px. 3) that the pre-October 2006 label did not warn that prolactin elevation was higher with Risperdal than with other antipsychotics, that gynecomastia was a frequent adverse event with Risperdal, that there was a statistically significant association between prolactin elevation from Risperdal use and adverse events like gynecomastia, and that it did not advise clinicians to monitor prolactin levels. Indeed, the pre-October 2006 label indicated the opposite of these propositions (that Risperdal raised prolactin levels the same as other antipsychotics, that gynecomastia from Risperdal use as rare, and that the association between prolactin elevation from Risperdal use and adverse events like gynecomastia is unknown.) With regard to the post October-2006 label, Plaintiff introduced evidence that it continued to misrepresent the frequency of gynecomastia and continued to lack a warning about prolactin monitoring.

With regard to causation, Defendants argue that Plaintiff's failed to show Risperdal caused Plaintiff's gynecomastia because (1) there is insufficient evidence that Risperdal causes gynecomastia and (2) even if it does, there is insufficient evidence that Risperdal caused Plaintiff's gynecomastia. This issue was extensively briefed by Plaintiff in response to Defendants' motion for summary judgment which was denied. (*See* Pl. Resp. Defs. Mot. for Summ. J. at 58-63.) Those arguments are incorporated herein by reference. Defendants break up their analysis claiming first that there is inadequate evidence that Risperdal causes gynecomastia. In support of this contention, Defendants rely on two Texas cases *Havner* and

Garza. Defendant makes no attempt to show the applicability of Texas law on this point. As this Court is aware, the Pennsylvania choice-of-law inquiry applies as to each "particular issue before the court." *Griffith v. United Air Lines, Inc.*, 203 A.2d 796, 801-06 (Pa. 1964). Before plowing through on this issue under Texas law, Defendant needed to show that the issue was a substantive as opposed to procedural issue. In conflicts cases involving procedural matters, Pennsylvania will apply its own procedural laws when it is serving as the forum state. *Commonwealth v. Sanchez*, 552 Pa. 570, 716 A.2d 1221, 1223 (1998). *Havner* and *Garza* are about the admissibility of expert testimony under Texas' rules of evidence. *See Merrell Dow Pharm., Inc. v. Havner*, 953 S.W.2d 706, 714 (Tex. 1997) (In drawing conclusions about the reliability of expert testimony, "a court necessarily looks beyond what the expert said. Reliability is determined by looking at numerous factors including those set forth in *Robinson* [Texas's version of Daubert] and *Daubert*. . . . Whether it rises to the level of evidence is determined under our rules of evidence, including Rule 702.") In Pennsylvania, the rules of evidence and the reliability of evidence are procedural matters. *See Com. v. Dennis*, 421 Pa. Super. 600, 616, 618 A.2d 972, 980 (1992) ("The law of evidence, including the admissibility of specifically offered evidence, has traditionally been characterized as procedural law.") The question about what constitutes sufficient evidence on a matter is unquestionably procedural. "Substantive law is the portion of the law which creates the rights and duties of the parties to a judicial proceeding, whereas procedural law is the set of rules which prescribe the steps by which the parties may have their respective rights and duties judicially enforced." *Sheard v. J.J. DeLuca Co., Inc.*, 2014 PA Super 98, 92 A.3d 68, 76 (2014) (quotation marks omitted.) It strains reason to think that having a certain number of studies on a particular topic is a matter of substantive law. This is clearly a matter of what steps a party must take to have its rights enforced, a procedural rule.

Even if these cases dealt with substantive matters, they only apply when there is undisputed evidence that many instances of the harm complained are brought about by unknown causes. *Havner*, 953 S.W.2d at 714 (noting that the question before the Court is what proof is required when there is undisputed evidence that not all instances of the harm complained of are caused by the substance and that there are instances where the cause is unknown); *Merck & Co., Inc. v. Garza*, 347 S.W.3d 256, 263 (Tex. 2011) (stating that the standard set forth for epidemiological studies only applies when causation cannot be proved directly and must be proved indirectly by epidemiological studies.) In *Havner* and *Garza*, other causes of the harm complained of could not be eliminated and the plaintiffs were forced to prove causation by indirect evidence of an increased risk. In this case, however, Plaintiff offered evidence that there is no background rate for prepubescent gynecomastia and that Plaintiff's gynecomastia was prepubescent. In other words, unlike the plaintiffs in *Havner* and *Garza*, all instances of the harm complained of have an identifiable cause. Dr. Solomon methodically went through all possible causes of gynecomastia for prepubescent males and eliminated them. In addition, *Havner* and *Garza* only apply to the issue of whether or not a particular substance can cause the harm complained of (what they discuss as general causation.) *See Havner*, 953 S.W.2d at 714-15; *Garza*, 347 S.W.3d at 262. Unlike *Havner* and *Garza*, in this case, there is direct evidence in the form of repeated party admissions that elevated prolactin from Risperdal use causes gynecomastia. Indeed, one of the changes from the pre-October 2006 label to the October 2006 label is a change from stating that the clinical significance of elevated prolactin was unknown to a statement that adverse events, like gynecomastia, follow from the use of prolactin elevating compounds like Risperdal. (*Compare* Px. 2 *with* Px. 3.)

In addition, it is overstatement of Texas law to say that two epidemiological studies showing a doubling of the risk is a strict requirement in all cases that rely on epidemiological studies. As both *Garza* and *Havner* stated, the ultimate rule is a common sense one that "courts must make a determination of reliability from all the evidence. Courts should allow a party, plaintiff or defendant, to present the best available evidence, assuming it passes muster under *Robinson*, and only then should a court determine from a totality of the evidence, considering all factors affecting the reliability of particular studies, whether there is legally sufficient evidence to support a judgment." *Garza*, 347 S.W.3d at 266 (Tex. 2011) (quoting *Havner*, 953 S.W.2d at 720). Here, when all of the evidence is considered, including Defendants' own admissions, it is clear that there is sufficient evidence to show that increased prolactin from Risperdal use can cause gynecomastia. This is all the predicate that is necessary to proceed past *Havner* and *Garza*.

Finally, even if one assumes that this issue is a matter of Texas substantive law, that this is a case that must be proven by increased risk alone such that *Havner* and *Garza* apply, and that Texas has the strict requirement Defendants claim exists under *Havner* and *Garza*, at this point in the trial, there is evidence of at least two epidemiological studies showing a link between elevated prolactin from Risperdal use and gynecomastia. The first is the Findling Article, which, when properly analyzed as Dr. Kessler showed in his testimony, shows an increased rate of gynecomastia among prepubescent males. Indeed, the Defendants' purported reason for only including prepubescent males in the final Findling Article was to eliminate the background rate and only show instances of gynecomastia attributable to their drug. As discussed repeatedly, Table 21 shows the required statistically significant association. Solomon also relied on the Entiman Article showing a statistically significant association and a four times increased risk. This article has now been discussed and this information is in evidence. Assuming, then, that the *Havner* and *Garza* standard applies, there is sufficient evidence on the record to satisfy the standard.

With regard to Dr. Solomon's specific causation analysis, Defendants simply misstated Dr. Solomon's testimony. Defendants claim that Dr. Solomon relied on one photograph from 2007 for his argument that Plaintiff had gynecomastia caused by Risperdal, but Dr. Solomon repeatedly stated that his opinion was based on the totality of the evidence including, among other things, his own physical exam revealing long-term gynecomastia, numerous photographs, medical records indicating the long-term existence of the gynecomastia, accepted medical knowledge indicating the amount of time it takes to develop gynecomastia, pre-litigation medical records documenting the commencement of gynecomastia starting in 2006 to 2007, the opinions of Plaintiff's other treating physicians on the long-term nature of Plaintiff's gynecomastia, medical literature concerning Risperdal use and gynecomastia, etc. Dr. Solomon also methodically eliminated all other potential causes of gynecomastia.

Finally, Defendants claim that Plaintiff cannot overcome the learned intermediary argument because Plaintiff's treating physicians were aware that Risperdal posed some risk of gynecomastia. This argument has been repeated in every Risperdal trial and with every pre and post-trial brief filed in this litigation. It completely ignores Plaintiff's position and the testimony of every treating physician. It is not enough to warn that there is a hypothetical rare risk of a side-effect when there is evidence that the risk is not hypothetical and is in fact frequent. Plaintiff's treating physicians, to a person, testified that they were unaware of Risperdal's real

propensity to cause gynecomastia and that knowledge of the real propensity would have changed their prescribing practices and the warnings they gave parents about this risk. (*See e.g.* Dewar Dep. 64:20-65:1, 95:8-96:1, 96:15-97:15, 97:21-98:8, 105:10-16, 139:17-23; Wieck Dep. 58:10-59:11, 115:8-25, 150:12-13; Martin Dep. 43:8-20, 44:2-7, 72:2-24, 73:12-16, 76:11-77:14, 114:20-115:3, 115:4-15, 201:22-202:2, 202:6-202:25.) There is also undisputed testimony from Plaintiff's mother that additional warnings, which the doctors testified they would have given her with additional information, would have led her to seek alternative therapy and prevented the problem. Plaintiff has put forth sufficient evidence on causation.

Defendants' third point is an argument that Plaintiff has no claim because federal law prevented Defendants from providing adequate warnings. This purely legal point has been extensively briefed in every Risperdal case and universally rejected. It was briefed in this case, at the summary judgment phase. (*See* Defs. Mot. for Summ. J. at 29-34 and Pl. Resp to Defs. Mot. for Summ. J. at 45-53.) These arguments are incorporated by reference. In short, this argument was squarely addressed and rejected by the United States Supreme Court in *Wyeth v. Levine*, 555 U.S. 555, 570-71 (2009). The Supreme Court held that drug manufacturers are responsible for their own labels and they can always warn. This was also the testimony of Dr. Kessler based on his years of experience running the FDA.

For their fourth point, Defendants claim that Plaintiff did not introduce evidence of reliance so as to support his fraud claim. Defendants cannot contest that each of Plaintiff's physicians testified that they relied on Defendants' label in making their prescribing decisions. (*See* Dewar Dep. 48:3-9, 50:8-23; Martin Dep. 20:8-23, 43:2-8; Wieck Dep. 24:19-25:6, 25:18-26:1, 51:9-18, 53:6-10.) As explained above, there were numerous false and misleading statements in Defendants' label. Defendants' claim that this evidence is insufficient because Dewar testified that he knew Risperdal could cause gynecomastia, but they, again, ignore the fact that Dewar was not aware of the vast difference between the incidence rate reported in the label, rare or less than one in a thousand, and the true incidence rate which, according to Defendants own documents and studies, ranges from 2.3% to over 12%. Dewar testified that knowledge of the increased risk of gynecomastia would have impacted his prescribing decisions and the warnings he gave parents and that he would have looked to Dr. Martin for direction on what more to say. (Dewar Dep. 64:20-65:1, 95:8-96:1, 96:15-97:15, 97:21-98:8, 105:10-16, 139:17-23) Dr. Martin testified it would have affected his prescribing practices, the warnings he gave parents, and the direction he gave to Dewar as to what Dewar should tell parents. (Martin Dep. 43:8-20, 44:2-7, 72:2-24, 73:12-16, 76:11-77:14, 114:20-115:3, 115:4-15, 201:22-202:2, 202:6-202:25.) Plaintiff can show reliance.

Finally, Defendants' fifth and last basis for compulsory nonsuit is a request to nonsuit Johnson & Johnson and Janssen Research and Development, LLC. This request has been made and rejected in every Risperdal case. Contrary to Defendants' contention, the reality is that these Defendants worked hand-in-hand to manufacture and sell Risperdal throughout the country during the relevant time. The documentary evidence shows that Johnson & Johnson and Janssen Research and Development, LLC took part in the conduct complained of by Plaintiff. Their names, and their employees' names, are found on the various records introduced into evidence supporting Plaintiff's claims. The conduct of all three entities is indistinguishable in the records. As a practical matter, the three defendants are affiliated companies and are represented by the same counsel who has not bothered to present any evidence distinguishing the conduct of these

three entities. They have been consistently treated as a unified acting body throughout this litigation, and their documents have been treated as coming from one unified conglomerate. Nonsuit is improper as to any of the three entities.

This motion is, primarily, an attempt to revisit issues already decided at summary judgment in hopes of obtaining a different result. For the reasons stated, the Defendants' Motion for Compulsory Nonsuit should be denied.

Respectfully Submitted,

/s/ Jason A. Itkin

Jason A. Itkin

cc: Heidi Hilgendorff, Esq.
Melissa Graff, Esq.
David Abernathy, Esq.
John Winters, Esq.
Kenneth Murphy, Esq.
Ethel Johnson, Esq.

Appendix C

MARK P. SOLOMON, MD, FACS

PLASTIC SURGERY

Jason Itkin, Esquire
Arnold & Itkin, LLP
6009 Memorial Drive
Houston, TX 77007

May 31, 2016

Re: [redacted]

Dear Mr. Itkin,

At your request, I examined Mr. [redacted] in my office on March 1, 2016. At the time of my evaluation, he was 19 years old and reported that he took RIsperdal starting at about age 10 and continuing till about age 15. He noted breast growth starting after taking the drug along with a weight gain of about 30 pounds. He has occasional pain in his breasts. He states that he is harassed about his breasts and is often told that he is transgender while he is not. He will not wear certain types of shirts due to his breasts. He thinks his breast size contributes to back pain. Neither his brother nor his father has gynecomastia. He states that Risperdal was used in conjunction with other medications for treatment of manic depressive disorder. He does not know the names of the other medications. His mother gave him the Risperdal. He has been institutionalized several times for depression. He also has PTSD from rape by his older brother. He sees a therapist at this time for treatment. He saw a plastic surgeon in Nebraska in the past for evaluation. A prolactin level at that time was normal. He was offered surgery for gynecomastia but chose not have it. He has blurry vision in his left eye due to trauma, but he has no double vision or changes in smell. He is now off all medications. He is unaware of any pituitary disease clinically or diagnostic studies that included CT/MRI obtained for treatment of left facial fractures. He was treated for thyroid disease in the past, but was evaluated in Sept 2015 and told of normal thyroid function. He states that he is able to get erections and has normal sexual function. He has a history of supraventricular tachycardia and gout in the past. He has had surgery for a facial fracture and pectus excavatum in the past. His Nuss bar was removed. He notes allergies to penicillin mainfested by rash, itch, and epistaxis, and hydrocodone that causes rash and itch. He is also sensitive to iodine topically. He smokes 5-6 cigarettes daily. He states that he eats a mostly vegan diet and has lost 15 pounds in the past few months due to diet and exercise. He has a spinal injury due to a car accident.

Examination demonstrated bilateral enlarged breasts with increased breast tissue. There were no breast masses or enlarged lymph nodes. His chest demonstrates four surgical scars from his prior pectus surgery. Measurements of his breasts were made. He is Tanner 5 in appearance. His genitalia are uncircumcised and normal. His testes are 4.2 cm by cm on the left and 4 cm by 3 cm on the right. There are no hernias or testicle masses.

MEMBER, AMERICAN SOCIETY OF PLASTIC SURGEONS

MEMBER, AMERICAN SOCIETY FOR AESTHETIC PLASTIC SURGEONS

191 PRESIDENTIAL BLVD., SUITE LN24, BALA CYNWYD, PA 19004 TEL: 610.667.7070 FAX: 610.664.6664 www.marksolomonmd.com

It is my opinion, to a reasonable degree of medical certainty, that Mr. [redacted] has bilateral gynecomastia due to ingestion of Risperdal. Given his history and physical examination, this is the cause of his condition.

Photographs are enclosed that document his appearance in my office at the time of his visit to me.

Sincerely,

Mark P. Solomon MD FACS

MPS/jak
Enclosure: photographs

MARK P. SOLOMON, MD, FACS

PLASTIC SURGERY

Jason Itkin, Esquire
Arnold & Itkin, LLP
6009 Memorial Drive
Houston, TX 77007

June 1, 2016

Re: [redacted]

Dear Mr. Itkin,

I reviewed the following materials in this matter:

1. Rose Street Mental Health Care
2. Moscati Medical Records,
3. Central Plains Plastic Surgery
4. Central Nebraska Medical Clinic
5. OU Children's Hospital
6. Good Samaritan Hospital
7. Bryan LGH Medical Center
8. San Marcos Treatment Center
9. Shelly K. Boyce, LMHP
10. Richard H. Young Hospital
11. Sheppard Air Force Base Medical Records
12. Wholeness Healing Center
13. Express Scripts
14. Deposition of Brenda Tinkham
15. Deposition of [redacted]
16. Deposition of Dr. Joel Atchison
17. Deposition of Tamra Belz
18. Deposition of Shelley Boyce
19. Deposition of Dr. Harvey Martin
20. Deposition of Dr. Bryan Wieck

In addition, I performed an examination of Mr. [redacted] in my office that is the subject of my examination report provided separately. This report is a summary of facts regarding the development of gynecomastia in Mr. [redacted] based upon the evidence in conjunction with my findings.

According to the evidence, the first prescription for Risperdal provided to Mr. [redacted] was written on December 8, 2004 (Martin Deposition p. 53, l. 21). He remained on Risperdal until shortly April 10, 2008, according to the records of Sheppard Air Force Base Medical Center (p. 143). Therefore, he was on the Risperdal from the age of 7 until he was 11 years old. Records from Sheppard Air Force Base Medical Service (p. 182) demonstrate that his weight was 99 pounds and his height was 57 inches in August, 2006. The same record demonstrates his weight

MEMBER, AMERICAN SOCIETY OF PLASTIC SURGEONS

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was 118.8 pounds and his height was 59 inches in September, 2007. By January, 2008, his weight was 134.6 pounds and his height was 64 inches. His mother noted a weight gain in September, 2007 (Sheppard Medical p. 143). Of additional significance is the finding of May 19, 2010, at which Mr. [redacted] was found to have enlarged breasts that, if he was a girl would be Tanner stage 3, and is consistent with gynecomastia.

The record of the Moscati Center dated November 24, 2010, states that Mr. [redacted] noted breast development after being placed on Risperdal. He complained of this at that time, when he would have been 13 years old. At that time, his height was 67 inches, his weight was 183.8 pounds and his prolactin level was normal at 8.6 (Moscati Record p. 31).

In her deposition, Mr. [redacted] mother recalls noting breast enlargement at about 12 to 13 years of age (Tinkham deposition p. 128, l. 10-11). This condition persisted and Mr. [redacted] described severe bullying that contributed to his decision to leave school in the ninth grade ([redacted] deposition p.60, L. 10-13). His mother also noted that he had pain in his breasts (Tinkham deposition p. 143, l. 23-24). Mr. [redacted] was diagnosed with hypothyroidism in this time frame as well.

By 2012, his situation was so severe that he consulted with Dr. Atchison regarding his breasts. He saw Mr. [redacted] in February of 2012 and reported enlarged breasts including glandular enlargement that could only be treated with surgery. This procedure was planned to include direct excision, liposuction and placement of drains. Due to lack of insurance approval, Mr. [redacted] did not undergo surgery. His condition has persisted to this day, as evidenced by my finding of gynecomastia.

Given the totality of the evidence, Mr. [redacted] gynecomastia is due to his exposure to Risperdal. He has completed puberty. He clearly has no evidence of Klinfelter's Syndrome or testicular tumor. He has had brain imaging during his facial trauma in 2011 and there was no finding of pituitary tumor. He has no history of alcohol or drug abuse. His documented hypothyroidism can contribute to his noted weight gain, but would not cause breast tissue development. His normal prolactin levels do not exclude Risperdal as a causative factor since known literature regarding the drug demonstrates an early rise of prolactin within the first 12 weeks of exposure, which then declines to normal. Prolactin levels reported were obtained long after Mr. [redacted] was first exposed to the Risperdal, so his levels would be expected to be normal. Nevertheless, the only cause of persistent gynecomastia in Mr. [redacted] history is his prolonged exposure to Risperdal.

All of these statements are made to a reasonable degree of medical certainty.

Sincerely,

Mark P. Solomon MD FACS
MPS/jak

Appendix D

08:41AM

IN THE COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION
- - -

IN RE: RISPERDAL® LITIGATION

TIMOTHY STANGE, Plaintiff	:	APRIL TERM, 2013
vs.	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON; AND JANSSEN RESEARCH & DEVELOPMENT, LLC., EXCERPTA MEDICA, INC., AND ELSEVIER, INC., Defendants	:	NO. 1984

Wednesday, October 21, 2015

- - -

Courtroom 275-City Hall
Philadelphia, Pennsylvania

- - -

BEFORE: HONORABLE KENNETH J. POWELL, JR., J.,
and a Jury

- - -

MORNING SESSION

- - -

THE WITNESS: Excuse me, Judge. Is there any way we could take a break? I need to use the restroom.

MR. KLINE: I'm trying to finish up to get him out of here.

THE COURT: He has to use the facility.

We will take our morning break now, ladies and gentlemen. Remember, no discussing the case among yourselves or with anyone else.

- - -

(Whereupon, the jury was excused from the courtroom at 10:40 a.m.)

- - -

(Whereupon, a brief recess was taken at this time.)

- - -

(Whereupon, the jury entered the courtroom at 10:59 a.m.)

- - -

THE COURT: Jurors are all back and seated.

MR. KLINE: And you have your robe, Your Honor.

THE COURT: I do. I got it myself.

MR. KLINE: Just one housekeeping matter, Your Honor, which is -- which Mr. Gomez will explain, just so we don't have confusion.

MR. GOMEZ: Yes, Your Honor. The -- some of the exhibits got misnumbered. I just want to put on the record the correct order so we're all up to speed.

The 2007 PDR, Physicians' Desk Reference, is marked as P-65.

THE COURT: Uh-huh.

MR. GOMEZ: P-66, which we will provide at the end of the day were the callouts to the Mayo Clinic article that Mr. Kline pulled out on the screen.

THE COURT: Okay.

MR. GOMEZ: And P-67 is the 2007 PDR beginning at page 1676.

So our next exhibit, Your Honor, will be P-68.

THE COURT: Right. Okay.

MR. KLINE: Continuing, just a little bit more, and I'll be done with redirect examination.

THE COURT: Okay.

BY MR. KLINE:

Q. Sir, you will recall discussing with counsel for Janssen the question you were asked specifically, you never saw a study that says that Risperdal causes gynecomastia, and then you, I believe, answered to the effect that, no, but I have seen a study which says that it's associated. Do you recall?

A. That's correct.

Q. And I would like to mark the Etminan article, which I know you're familiar with.

MR. KELLY: Objection, Your Honor.

MR. KLINE: 2015 article.

MR. KELLY: Objection, Your Honor. This witness hasn't -- there's no foundation whether he's seen this.

THE COURT: He's going to have to ask that question, and I'll rule on the objection.

MR. KLINE: I know because I showed it to him.

BY MR. KLINE:

Q. Sir, I'm showing you an article. I just want you to take a moment to look at it. It's from the Journal of Child and Adolescent Psychopharmacology entitled "Risperidone and Risk of Gynecomastia in Young Men." Do you see that?

A. Yes.

Q. And just take a moment to look at the abstract to be able to confirm that you have seen this article.

Have you, indeed, seen it?

A. Yes, I have.

Q. And, sir, when you were telling defense counsel in direct response to his question as to whether you had seen an article which causes it, and you said association, shows an association?

A. Yes.

Q. This article is published in 2015, very recently, sir?

A. Yes.

Q. And it is by authors from institutions like McGill in Canada; is that correct?

A. That's correct.

Q. And does it say that gynecomastia, that the rate -- the risk of gynecomastia -- I'm looking at the very end of the abstract.

A. Yes.

Q. And are you focused in on that, the risk of gynecomastia?

A. Yes.

Q. And was this a very large study, sir?

A. It was a very large study.
Q. It says in the abstract that it -- in the cohort there was 401,924 males aged 15 to 25. Do you see?
A. Yes, I do.
Q. And there were 1556 cases of gynecomastia and 15,560 corresponding controls?
A. Correct.
Q. Is this a large epidemiology study?
A. It's a very large study.
Q. Sir, do you see where it says that when the analysis was stratified to children and adolescents, the risk of gynecomastia was five times higher than for non-users?
A. Yes, I see.
Q. Relative risk 5.44; do you see that?
MR. KELLY: Your Honor, I object. My question was none of this says it caused gynecomastia. This is just a backdoor way of getting in another study. It's nothing to do with causation. That was my question.
MR. KLINE: There will be epidemiologists who like to testify about this. They talk in terms of association. It says what it says. I have one question to go to.

THE COURT: I'll allow him to answer the question.
BY MR. KLINE:
Q. Sir, if a study like this had been done by Janssen and you knew that this drug was five times more likely to cause gynecomastia than for a non-user, then would you have prescribed it?
A. No, I would not have.
MR. KLINE: Nothing further.
MR. KELLY: Do you mind if I stand here, Your Honor?
THE COURT: No.
MR. KELLY: The podium was moved back.
THE COURT: It will move easy. It is on wheels.
- - -
RECROSS-EXAMINATION
- - -
BY MR. KELLY:
Q. Just finishing up with this article that Mr. Kline questioned you about, you agree with me nothing in this article says that Risperdal causes gynecomastia?
A. In an epidemiologic study, there's no attempt to make causal statements. It's an association.

Q. Right.
So you agree with me, that study, there's no statement of causation, correct?
A. Correct.
Q. And you've seen no study that ever suggested to you causation --
MR. KLINE: Objection, Your Honor. It's misleading. It's nomenclature that's used.
THE COURT: I will allow it. I think he's clarified it. I'll allow Mr. Kelly to ask the question.
BY MR. KELLY:
Q. Not this study, any study.
A. To do a causation study, you would need to do what's called a prospective randomized study, where you were giving patients placebo versus an active drug, which would never be considered ethical and never be approved by an IRB.
Q. So the answer is, you've never seen this study anywhere showing causation?
A. It will never be done because it's ethically inappropriate.
Q. So I guess that means yes?
A. Yes, I have never seen a study that --

Q. Thank you, sir.
A. -- that would prove causality.
Q. Thank you, sir.
Association is different than causality?
A. It's the best we have.
Q. Now, I'm not going to go through the records of Dr. Meuler, but Mr. Kline asked you about one record of August 7, '07 and he asked you if you were aware of it.
I'm going to ask you if you were aware that, according to Dr. Meuler's records, Mr. Stange saw him every visit after August 7, '07 while he was on the drug, he never made any breast complaints, are you aware of that?
A. I was not aware of that.
Q. Are you aware of the fact that Dr. Meuler examined Mr. Stange's breasts June 2nd, '08 and found the breasts normal, no masses?
A. I was not aware of that.
MR. KLINE: Your Honor, I was not allowed to do the records.
MR. KELLY: I'm not. I'm asking the same thing.
MR. KLINE: No, he's not. My question

went to whether he was told some information. When I was stopped about showing these documents, I then went to a totally different subject, albeit -- albeit nuanced. And my question then became, Were you told this, that, or the other?

Now he's being asked was -- did you know Dr. Meuler, did you know Dr. Meuler? We have Dr. Meuler's testimony.

MR. KELLY: I think we got the answer.

MR. KLINE: Does it matter? No, the jury is going to hear Dr. Meuler speak for himself.

THE COURT: Right.

MR. KELLY: We'll move on. I think we got the answer anyway.

BY MR. KELLY:

Q. Last time I'm going to show you records, just two more. Mr. Kline asked you about weight.

Just briefly, could you turn to the November 3, '05 note? I'm going to ask you about Mr. Stange's height.

A. That would be in my records?

Q. Yes, Your Honor -- I mean, yes, Doctor.

A. What page would that be?

Q. Page -- first record November 3, '05 -- and the brains here will tell you the page. Page 11.

A. Page 11.

Q. Does this show -- can you go to the part where you measured his height?

A. Yes.

Q. If we can blow that up. Is that four feet nine and a half inches?

A. Correct.

Q. And that's your first visit?

A. That's correct.

Q. Now, fast forward to February 27, '09, which is around the time Mr. Stange stopped taking --

MR. KELLY: What page, Melissa?

MS. GRAFF: 88.

BY MR. KELLY:

Q. 88.

A. Okay. I have it here.

Q. And that's his last visit while he was taking either the generic or the brand Risperdal, February 27, '09?

A. I'll have to check my notes here.

Q. Well --

A. Yes, yes, I see what you're saying.

Q. What's his height then?

A. His height then is five foot seven and a half inches.

Q. So four feet nine and a half to five feet seven and a half, that's about ten inches of growth, isn't it?

A. This would be -- correct, ten inches.

Q. And you expect kids to gain weight when they grow, correct?

A. Yes.

Q. Do you use a formula of six pounds per inch?

A. No, because it varies with age.

Q. Do you use any formula?

A. No, I looked at the chart itself.

Q. Now, when we talk -- you talked about PDR. I think you said that it was your Bible. I'm not putting words in your mouth.

Did you say it was your Bible?

A. If I said Bible, I think that would indicate how often I refer to it.

Q. But it's your go-to source --

A. It would be my go-to source.

Q. -- even though you said at your deposition that the PDR says side effects that they list are largely irrelevant and misleading, correct?

MR. KLINE: Objection; asked and

answered and not covered on direct -- redirect.

THE COURT: I'll overrule it.

THE WITNESS: The format with which it's presented is often confusing.

BY MR. KELLY:

Q. And it's still your Bible?

A. It is.

Q. But you didn't look at the PDR before you prescribed Risperdal in this case, did you, Doctor?

A. I can tell you that I referred to the PDR in a contemporaneous fashion, maybe not on the day that I saw Timothy, but I referred to the PDR whenever I used a new drug for a new purpose.

Q. So you're not sure whether you looked at the PDR?

A. On that particular day, I can't state that I pulled it out.

Q. At any time during the prescribing?

A. During the time I was treating Mr. Stange, I can assure you that I referred to the PDR many times.

Q. Well, let me pull up your deposition, page 247, please, line 17. Are you with me, Doctor?

A. Yes.

Q. Doctor, Counsel just showed you a PDR guide in

IN THE COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

- - -

IN RE: RISPERDAL® LITIGATION

TIMOTHY STANGE, Plaintiff	:	APRIL TERM, 2013
vs.	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON; AND JANSSEN RESEARCH & DEVELOPMENT, LLC., EXCERPTA MEDICA, INC., AND ELSEVIER, INC., Defendants	:	NO. 1984

Tuesday, October 27, 2015

- - -

Courtroom 275-City Hall
Philadelphia, Pennsylvania

- - -

BEFORE: HONORABLE KENNETH J. POWELL, JR., J., and a Jury

- - -

MORNING SESSION

- - -

APPEARANCES:

KLINE & SPECTER, P.C.
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-and-
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Counsel for Defendants

ALSO PRESENT:

KRISTEN LOERCH, ESQUIRE

INDEX

EXHIBITS

(Time noted: 9:03 a.m.)

- - -

(The following occurred in open court outside the presence of the jury:)

- - -

MS. GRAFF: Good morning, Your Honor. I just marked as exhibits the callouts that popped up on the screen from each witness and gave each one their own exhibit number. So D-34 is the callouts of the exhibits used for Dr. Kessler. D-35 is the callouts used with Dr. Kovnar. D-36 are the callouts used with Dr. Brown. D-37 are the callouts marked with Dr. Caers. And D-38 is a clip report from the designations that we played from Dr. Kessler.

THE COURT: Okay.

- - -

(Whereupon, Exhibits D-34 through D-37 were marked for identification.)

- - -

MS. GRAFF: So our next exhibit number is D-39.

MR. KLINE: Ms. Graff, these were used when you were cross-examining Dr. Kessler; is that what they are?

MS. GRAFF: There's one for each witness. So D-34 is the callout that popped up on the screen.

MR. KLINE: The popouts on the screen?

MS. GRAFF: Correct.

MR. KLINE: They just look very thick. I'm not doubting that what you're representing is correct. They just look like large documents.

MS. GRAFF: Would you like to look at them? We sent them to Kristen last night.

MS. LOERCH: No, maybe they're here now, but they weren't last night.

MR. KLINE: Subject to our looking at them, agreeing, we are not objecting. We want to look at them.

THE COURT: Sure.

MR. MURPHY: There is an issue that I wanted to raise regarding the direct examination of Dr. Solomon with the Court, and I'd like to raise it with the witness outside

of the room and before the jury comes in.
THE COURT: Okay.
Is he here, Dr. Solomon?
MR. KLINE: Yes.
Dr. Solomon, if you would excuse yourself for a moment until we discuss a legal issue.
(Witness excused.)
MR. MURPHY: Your Honor will recall that there were objections raised to aspects of Dr. Jensen's testimony wherein he made something of an opinion, a causation opinion, that was -- that objection was sustained.
And I just want to make sure that this witness does not blurt out or offer testimony regarding what is in Dr. Jensen's deposition. And so I think there ought to be an instruction along those lines and perhaps his counsel can direct him accordingly so that we don't have any mistakes on the stand.
MR. KLINE: Your Honor, Dr. Solomon has been advised of the Court's rulings, and we do expect him to testify as to items which are not excluded, including the records which contain contemporaneous statements that he,

obviously, has reviewed and uses as a basis of his opinion.
He will not be referencing those items which have been excluded. He will be, obviously, referring to items which are included and fair game.
THE COURT: He's an expert.
MR. KLINE: He is an expert, yes.
He's an expert in plastic surgery, the same field as the -- as the plastic surgeons who saw this young man, operated on him, and wrote notes about him. We will be referring to their records and the other plastic surgeons' records and their writing, which all, by the way, was confirmed in their depositions. But we will not be having him -- Dr. Solomon refer to those portions of the testimony which have been excluded.
MR. MURPHY: We'll take it as it comes.
THE COURT: Okay.
MR. KLINE: That is -- we're agreeing to abide by the ruling, and we are going to -- we are going to go to his -- the remainder of the records, which are fair game, we believe.

THE COURT: Okay.
Is he going on first?
MR. KLINE: Yes. We'd like to get him on and off. So we'll interrupt the testimony of Ivo Caers.
THE COURT: Okay.
MR. KLINE: Unless you get an objection because people are so riveted into it.
- - -
(Whereupon, a discussion was held off the record.)
- - -
(Whereupon, the jury entered the courtroom at 9:16 a.m.)
- - -
THE COURT: The jurors are here and they're all seated.
Mr. Kline.
MR. KLINE: Your Honor, good morning.
Good morning, all.
Plaintiff calls Mark Solomon, M.D.
We will, Your Honor, conclude the deposition of Ivo Caers following Dr. Solomon's testimony.

THE COURT: Okay.
MR. KLINE: Dr. Solomon.
THE COURT CRIER: Kindly state and spell your name, for the record.
THE WITNESS: Mark P., like Philip, Solomon, S-O-L-O-M-O-N, M.D.
- - -
...MARK P. SOLOMON, M.D., having been duly sworn/affirmed, was examined and testified as follows:
- - -
DIRECT EXAMINATION ON VOIR DIRE
- - -
BY MR. KLINE:
Q. Good morning, Dr. Solomon.
A. **Good morning.**
Q. Would you tell -- would you speak directly into the microphone, making sure that everyone furthest away in the jury can hear you.
A. **Yes.**
Q. You are speaking to the jury, and there's a juror back here and a juror back here -- two jurors back here. But, of course, your conversation is with me.
Good morning, again.

A. Good morning.
Q. You are Mark Solomon, M.D.?
A. That's correct.
Q. And what is your profession, sir?
A. I'm a plastic and reconstructive surgeon.
Q. Plastic and reconstructive surgeon. Are you the same profession as Dr. Jensen, who treated this boy in the state of Milwaukee -- the state of Wisconsin?
A. I am.
Q. And as part of your profession, sir, do you treat the condition of gynecomastia?
A. I do.
Q. Are you familiar with the diagnosis of gynecomastia?
A. Yes.
Q. Are you familiar with the condition of gynecomastia?
A. Yes.
Q. Are you familiar with the endocrine system by virtue of your treatment of gynecomastia?
A. Correct.
Q. Is that something that -- the knowledge of the endocrine system, is that something only within the ambit of, say, specialists in the endocrine system,

endocrinology?
MR. MURPHY: Objection; leading.
THE COURT: Sustained.
BY MR. KLINE:
Q. Sir, would you explain to the Members of the Jury how a surgeon needs to understand the endocrine system in order to do his or her job.
A. So if I may? What I need to describe is basically medical education for a few moments.
Q. Well, then let's save it. I want to qualify you.
A. It's all part and parcel of both medical education and surgical residency training, as well as plastic surgeon residency training, so it comes up in a number of different points in education and training.
Q. Let me ask you about your background and training. We'll mark your resume, your curriculum vitae as Plaintiff's Exhibit 86. I'll hand one to the Court. I'll hand one to you for ease of reference.
- - -
(Whereupon, Exhibit P-86 was marked for identification.)
- - -

BY MR. KLINE:
Q. Currently, sir, do you have a varied practice in plastic surgery?
A. I do.
Q. Would you explain to the Members of the Jury its breadth, what does it include? By the way, where do you practice? I didn't ask you that.
A. My main base is Bala Cynwyd, my office. And I operate here in the city. I have a satellite office in Manhattan.
Q. Have you been affiliated or are you affiliated with academic institutions?
A. Yes.
Q. And that would be where?
A. At the present time Shriners Hospital is my most academic institution. I also work at Pennsylvania Hospital, and I have an adjunct faculty appointment at Drexel.
In the past I've been chief of plastic surgery at Hahnemann and what was then the Medical College of Pennsylvania, and in those days I had faculty appointments at both of those medical schools as an associate professor of surgery.
Q. Let me get your background in front of the jury briefly.

Do you have a bachelor's degree from Franklin & Marshall College?
A. Correct.
Q. In what year, sir?
A. 1974.
Q. Seems like yesterday?
A. Yeah.
Q. A graduate medical degree, an M.D. degree, from what institution, sir?
A. New York University.
Q. In what year, sir?
A. 1978.
Q. Following that, did you do residency training in surgery and then in plastic surgery?
A. Correct.
Q. At what institution, sir?
A. I did general surgery at both the University of Pennsylvania and then completed my final two years in general surgery at Thomas Jefferson where I was chief resident. And I returned to Penn as a plastic surgeon resident in a two-year training program.
Q. Sometimes we hear the term, sir, "plastic surgery" and we think it's cosmetic surgery.
First of all, do you do cosmetic

surgery?
A. Absolutely.
Q. And do you do everything literally from breast enlargements to penile enlargements, literally?
A. Yeah, I operate from head to toe, literally.
Q. And do you also do reconstructive surgery?
A. Absolutely.
Q. Do you do surgery, for example, for women who have had mastectomies?
A. From time to time.
Q. And do you do the reconstruction of those women?
A. I do.
Q. Do you have extensive experience in operating on the breast?
A. Absolutely.
Q. That's what we're here to talk about with you today, sir. Tell us about your experience.
A. Well, in terms of the breast alone, it's extensive. First, because training in general surgery teaches you things like tumors of the breast, breast cancer surgery, lymph node dissections, and then in plastic surgery, you learn breast reconstruction. And we could spend hours discussing the different modalities of breast

reconstruction that I've used, as well as cosmetic surgery of the breast, which is primarily breast augmentation, breast lift and then other breast, what I describe as reconstructive procedures, both breast reductions for women and breast reductions for men, which leads us to this particular issue at hand here today, gynecomastia.
Q. Focusing on what you're here for today, have you -- have you diagnosed young men with gynecomastia?
A. Yes.
Q. Have you outside of litigation diagnosed young men with gynecomastia who were on Risperdal?
A. Yes.
Q. Have you diagnosed and operated on -- have you operated on young men with gynecomastia?
A. I have.
Q. Okay. Now, let me talk about the -- your academic appointments briefly.
From '78 to '81, you were an assistant instructor at Penn?
A. Correct.
Q. And you were from '83 to '85 an instructor in surgery at Penn?
A. That's correct.

Q. From '86 to '88 you were a clinical assistant professor of surgery at Penn?
A. Correct.
Q. From '88 -- it appears '88 you moved to Hahnemann. And from '88 to '94, you were a clinical assistant professor of surgery at Hahnemann?
A. Correct, I was, that's true.
Q. And then from '90 to '96, you were an associate professor of surgery at what was MCP at the time, Medical College of Pennsylvania?
A. Correct.
Q. There you were the chief of the Division of Plastic Surgery?
A. That's correct.
Q. And maybe you can tell us in just a moment what distinguishes the field of plastic surgery. Is there an actual field of medicine that's denominated plastic surgery?
A. So within all of organized medicine there are 24 specialty boards recognized by the American Board of Medical Specialties of which plastic surgery is one.
Plastic surgery is unique in the sense that it's not anatomically restricted. You know, there are cardiologists who are the internal

medicine side of heart disease and then there are cardiac surgeons. There are rheumatologists who are for bone and joint disease and then there are orthopedic surgeons for bone and joint disease.
Plastic surgery is different from all of those disciplines because it's really a system of thought that allows us to move throughout the body treating a number of problems. And it's that system of thought that unifies the field of plastic surgery.
Q. Thank you. Just continuing through this briefly. I'm doing it the quick way, I hope.
From '94 to '96, you were an associate professor at MCP and Hahnemann, correct?
A. Correct.
Q. From '96 to '98, you held a clinical associate professorship at Hahnemann and what was then the Allegheny University Health Systems, correct?
A. Correct.
Q. And then '99 to 2002 a clinical associate professor at MCP, correct?
A. Correct.
Q. From '02 to '07 you were a clinical associate professor of surgery at Drexel --
A. Correct.

Q. -- College of Medicine?
A. **That's correct.**
Q. In September '11, appears that you were given an appointment as adjunct clinical associate professor of surgery at Drexel?
A. **Correct.**
Q. You have various hospital affiliations, correct?
A. **Yes.**
Q. Are you a very active practicing surgeon?
A. **Yes, I am.**
Q. Today, you are an attending physician of Pennsylvania Hospital; is that correct?
A. **That's correct.**
Q. And other hospitals or just Pennsylvania?
A. **No longer St. Chris. Shriners Hospital for Children.**
Q. Now, you do work at Shriners Hospital; is that correct?
A. **Correct.**
Q. Would you tell the Members of the Jury your -- about your work at Shriners Hospital so they have a sense of what you do there.
A. **Shriners Hospital is an institution for children. The problems that we see at this**

particular Shriners Hospital that I do are all very intense reconstructive procedures for children with spinal deformities, orthopedic problems, from time to time I see breast issues that are congenital, congenital tumors that I manage, and late management of burn issues, burn scar deformities. And these are patients that come literally from all over the world that we treat.

The hospital has an extensive aggressive outreach program to bring people in regardless of their ability to pay, and we care for these kids for as long as we need them in the hospital, and we do what they need to get them well. It's really an amazing institution, frankly.

Q. How often did you do that, sir?
A. **In theory, it's 20 percent of my time. I'm there one day a week. But, in fact, I go there whenever I'm needed, so I'm there at least one day a week, and then I make rounds and take care of my patients throughout the week, as well. And I will, from time to time, operate if they need me on another day.**
Q. Do you consider that an important part of your -- of what you do as a physician and a surgeon?
A. **Absolutely. It's -- it's emotionally and**

intellectually gratifying, so I really am attached to it.
Q. You have been given over the years grants and have conducted studies?
A. **I have.**
Q. Your CV indicates that you have at points in your career published in the medical literature?
A. **I have.**
Q. Were any of those written by someone else, sir, any of those articles written by somebody else?
A. **Only with my coauthors, you know, we all have authorship, so everybody sort of writes either different pieces of it, and we put it all together, or one person writes it, sends it to the next person, and we basically tear it apart and write it again. So those are collaborative.**
Q. Sure.
A. **But there's no outside entity, who's not directly involved with the work, who does any of the writing.**
Q. Okay. And in your private medical practice, sir, you are compensated directly by patients in most cases?

MR. MURPHY: Objection, Your Honor; beyond the scope of qualifications.

THE COURT: I'll permit it.
THE WITNESS: Yes.
MR. KLINE: I just want to get to how much he's being paid honestly.

BY MR. KLINE:

Q. And do you charge commensurate here with what you make in the operating room, sir?
A. **Yes, I do.**
Q. Tell the Members of the Jury how much is being advanced by me on behalf of my client to you?
A. **On behalf of the Stanges, I've received so far $10,000 as a deposit to hold the day so that I didn't schedule surgery, and I'll get another $10,000 at some point after we submit a bill for the end of today's work.**
Q. And, sir, have you had an opportunity to review medical records relating to Tim Stange to offer opinions here after I ask the Court to qualify you, sir?
A. **I have.**
Q. Let me just see. Is there anything that I might be missing as a little scattershot about your curriculum vitae, at least in my head?
A. **No. I think we've accomplished discussing my academic achievements. We didn't talk a whole lot**

about residency and what that entails. I'm happy to discuss that if you want.

Q. The jury has heard about that from other witnesses. They know now what a residency and fellowship is.

A. Board certification.

Q. They know about Board certifications.

A. So I think we've hit the highlights.

MR. KLINE: Your Honor -- and to be -- Your Honor, at this point I offer Dr. Solomon as an expert in the field of surgery, plastic surgery, and -- and the pathophysiology and biology of the breast.

THE COURT: Do you have questions, Counsel?

MR. MURPHY: Brief voir dire, Your Honor.

THE COURT: Just so you know, ladies and gentlemen, when an expert is put on the stand, in order for me to determine that he's an expert, questions have to be asked to qualify him as an expert.

So Mr. Kline has just finished his qualifying direct examination. Now the other side has a right to cross-examine him on his

qualifications, and then the full testimony will begin after this cross-examination.

MR. MURPHY: May I proceed, Your Honor?

THE COURT: Yes.

MR. MURPHY: Good morning, everyone.

THE JURY PANEL: Good morning.

- - -

CROSS-EXAMINATION ON VOIR DIRE

- - -

BY MR. MURPHY:

Q. Good morning, Doctor.

A. Good morning.

Q. I just have a couple questions for you regarding the qualifications that Mr. Kline went over with you. But, first, I want to ask you about your time at Shriners Hospital.

If I heard you correctly, much of what you do there is constructive and cosmetic surgery for children in the area of craniofacial and burns, correct?

A. That's not what I said.

Q. I'm sorry. What is it that you do?

A. So that particular Shriners in Philadelphia has a focus on spinal disease, meaning things like

scoliosis, spinal tumors, meningomyeloceles, spina bifida, has a focus on spinal trauma patients, orthopedics, hand, cerebral palsy. So there are a number of reconstructive challenges that those children bring, and I treat those people.

We also do chronic burn reconstruction, the Shriners system does acute care burns in other cities, but the late reconstruction is done -- some of it is done in Philadelphia. And then to the extent that there are children with deformities that the system has that I can treat, they bring them to Philadelphia and I operate on them.

So, no, as a matter of fact, we don't do craniofacial. Although I am trained in craniofacial surgery and I have done craniofacial surgery, it's not something we do at this particular Shriners.

Q. Understood.

So we're here, and the jury understands, the folks at Shriners Hospital do not call upon you to come and render diagnosis for the cause of gynecomastia in any of those children that you see, correct?

A. I have treated an occasional -- seen an

occasional kid with gynecomastia.

Q. That wasn't quite my question.

My question was whether the folks at Shriners Hospital engage you to come and conduct diagnosis for the cause of gynecomastia in any of those kids that you see --

A. It --

Q. -- in 20 percent of your practice?

A. If a child -- first of all, I see patients with gynecomastia in my private practice. But at Shriners, if a child were to have gynecomastia, frankly, I'm the only person who would treat it. I've certainly treated a variety of different breast problems at Shriners because we treat children with chest wall and breast problems.

Q. With all due respect, and I'll move on, but my question was a bit more precise than that.

My question was whether the folks at Shriners engage you or call upon you to render a causation diagnosis or opinion with regard to children at Shriners whom you see?

A. Absolutely they do. That's my role as a treating physician. I make a diagnosis -- so that the jury understands the practice of plastic surgery, we are not -- if I may, sir?

Q. I didn't say anything.
A. You asked the question.
We're not robots. Part of being a physician is to take a history, perform a physical exam, make a diagnosis. Part of a diagnosis is causation. You really can't treat somebody without understanding the cause. That's the essence of medicine.
And I hold very dearly my privilege to practice medicine, which is really a wonderful gift that I have from the State and from all of you. And it's -- it's an awesome responsibility. So if I'm asked to see a child with any problem, it's incumbent upon me to make a diagnosis as to the causation before I would decide whether to operate on that child or not, which is an even bigger responsibility. So I hope that answers your question.
Q. Right.
And so we're here -- your testimony is that you are called upon to make gynecomastia cause, diagnosis opinions, for kids at Shriners Hospital?
A. Yeah. If there's a kid with gynecomastia, that's absolutely part of my job.
Q. You have done that?

A. I have seen kids with gynecomastia, that's correct.
Q. Going to your qualifications, you're not a neurologist, correct?
A. No, I'm not a neurologist.
Q. And you have never treated a child who was diagnosed with Tourette's syndrome, correct?
A. Not for Tourette's syndrome, no, that's correct.
Q. And you never have prescribed the medication here at issue, Risperdal?
A. That's correct.
Q. And you don't treat patients for endocrine disorders, do you?
A. I manage patients who have endocrine disorders. I'm not a primary endocrine treating physician. I have performed endocrine surgery in the past.
Q. And, as you've explained, what you do in large measure is plastic surgeries, reconstruction, and augmentation, things of that nature, correct?
A. I practice the entire scope of plastic surgery, that's correct.
Q. Head to toe?
A. As I said.

Q. Including breast augmentation?
A. Correct.
Q. You do facelifts?
A. Correct.
Q. Tummy tucks?
A. Correct.
Q. Penile enhancements --
A. Correct.
Q. -- from time to time?
A. From time to time.
Q. As you explain, you also perform breast reconstruction procedures in males who have gynecomastia?
A. Correct.
Q. Now, the patients who come to you for reconstructive surgery, for cosmetic surgery, they don't come to you seeking a diagnosis for their problem, do they?
A. I don't think you and I are communicating particularly well.
So part and parcel of what I do is to make a diagnosis. You can't operate without a diagnosis. If the diagnosis is that a patient has small breasts, for example, do they have a breast asymmetry, do they have a breast tumor, do they have

some endocrine problem that causes that?
It's incumbent upon me to answer those questions before I decide that I'm going to put a knife to their skin, which under any other circumstance would be not medicine but a criminal act.
So I take that responsibility to understand the patient and their problem very, very strongly.
Q. Just so we're clear, is it your testimony that for every male who has come to you for surgery to reduce or address breast tissue, you have constructed a differential diagnosis to determine the cause of the gynecomastia?
A. Correct. A differential diagnosis, again, is an integral part of the practice of medicine.
What's a differential diagnosis? It's a list of the potential causes of the problem that I'm seeing the patient for, whether it's gynecomastia or -- by the way, a facelift or eyelid surgery, you need to have a differential diagnosis to understand how the patient got to the point they are and how we're going to move them to the point they want to be.
Q. Now, we can agree that pathology is the

science of causes and effects of disease, correct?
A. The science of -- I'm not sure that's the precise definition.
Q. I'm happy to take your language. What is pathology, as you understand it, Doctor?
A. So the word gets used in a number of different ways. If you're talking about the specialty, the medical specialty, of pathology --
Q. Indeed.
A. -- that's related to be -- that's a laboratory science, and then there's anatomical and forensic pathology, which everybody knows from CSI and those kinds of things. So pathology is the study of cause, I guess, of disease, if that's what you're asking me, that's correct.
Q. You're not a pathologist, correct?
A. No, I'm not a pathologist.
Q. You have not had any formalized training in pathology, correct?
A. That's not correct.
Q. Well, what formalized training have you had in pathology?
A. I had a year of pathology in medical school, as we all do. I then had a month of pathology, actually forensic pathology, which is one of the

most memorable months of my life in the New York City Medical Examiner's Office.
And then as a general surgery resident, we had to know pathology because we had to know the pathology of the tumors we remove and the conditions we dealt with, so we'd look at the microscope frequently with the pathologist.
And then in plastic surgery, about a third or a quarter of my Board Examination, written Board Examinations, was nothing but pathology. And then, finally, when I was a more active reconstructive skin cancer surgeon, I would be in the lab looking at the specimens that I removed from people with the pathologist, so --
Q. With -- I'm sorry.
A. -- so I absolutely have an understanding of pathology.
And I read reports and I've looked at slides, and I certainly consider it part and parcel of what I do. Am I a board anatomic pathologist? No. Do I have to know pathology to do what I do? Absolutely.
Q. Just so that we're clear, you did say that you were in the lab reviewing the slides with the pathologist, correct?

A. Correct.
Q. Have you read, written any articles or book chapters addressing drug- or medicine-induced gynecomastia?
A. That's a pretty broad question.
Q. Sure.
A. I think if I understood --
Q. Sure. I'll break it down.
A. -- have I read, written --
Q. Have you written?
A. No, I have not written.
Q. You know what is meant by the term "mechanism of action," do you not? Mechanism of action.
A. I have my understanding of it. I don't know if you and I would have the same one.
Q. Let's see if we can get on the same page.
With regard to drugs and medicine, mechanism of action refers to the biochemical interaction by which a drug causes an effect; can we agree on that?
A. It's reasonable.
Q. You never have taken any courses or classes addressing the means or the way in which medicines may cause gynecomastia, correct?
A. Again, part of medical school's pharmacology

and pathophysiology, which absolutely addresses how medicines cause change in the body, so I would disagree with your statement there.
Q. My question was a bit more precise and focused then just diseases in the body.
A specific disease or a condition, gynecomastia, and my question was whether you had taken any classes or courses addressing the means or the way in which medicines may cause gynecomastia?
A. Sure. Again, pharmacology in medical school absolutely discussed that in relationship to hormone metabolism, for example, other drugs that even then could cause gynecomastia. This is not the first drug that's caused gynecomastia.
Q. Have you written any articles or book chapters on a mechanism of action or the way in which you say Risperdal causes gynecomastia?
A. I have not.
Q. So you haven't taken any classes specifically focused on the way in which Risperdal may cause gynecomastia?
A. Under that very narrow definition, that's correct.
Q. So that we're clear, during med school, you weren't trained about the relationship between

gynecomastia and Risperdal, correct?
A. There's a very good reason for that.
Q. Am I correct?
A. I'd like the jury to hear the reason. The reason is the drug didn't exist.
Q. Correct.
A. However, that doesn't mean -- if I may?
Q. You may.
A. That doesn't mean that I can't read the literature and understand it today and use my knowledge base to understand what's going on. And that's really, I think, the essence of our -- the discussion you and I are having.
Q. With all due respect, and I appreciate your right to answer the question fully and completely, but my question went to training in medical school, and you answered it.

And so am I also correct, Dr. Solomon, that in the course of your residency, you also did not have any training regarding the association between Risperdal and gynecomastia?
A. For the same reason, the drug didn't exist.
Q. And it would be the same with regard to your postgraduate work, by the time that you graduated from medical school, completed your residency,

Risperdal was not on the market, correct?
A. Correct.
Q. Now, you generated a report in which you offer a causation opinion in this case, correct?
A. Correct.
Q. And in that report, you don't identify any means by which you say Risperdal causes gynecomastia, correct?
A. I don't think I stated specifically, but I'm certainly happy to discuss it, and I'm sure we will, throughout the morning.
Q. And just to round this out, you are not a pharmacologist, correct?
A. Correct.
Q. Now, are you familiar with the hormone LH, known as luteinizing hormone?
A. I'm aware of it.
Q. You're aware of it.

Do you know what it does?
A. In women, it promotes growth of the follicle in the ovary. I don't recall what it does off the top of my head for men.
Q. You don't know what it does in men?
A. I don't recall. I'd need to review that.
Q. You can't tell the jury, as you sit here

today; is that what you're saying?
A. Not without looking something up.
Q. That's not something, that is, the hormone H -- the hormone LH is not something that you deal with on a regular basis in your practice, right?
A. That's correct.
Q. But you know that's something that endocrinologists do, right?
A. You know, I'm not a practicing endocrinologist. I'm aware that gynecologic endocrinologists deal with it often. I can't tell you pediatric endos or adult endos deal with it.
Q. Dr. Solomon, do you know what a normal LH level is?
A. No.
Q. Are you familiar with the hormone FSH, follicle-stimulating hormone?
A. Yes.
Q. Do you know what it does?
A. Again, it stimulates the follicle in the ovary.
Q. Do you know what it does in men?
A. Not off the top of my head.
Q. Do you know what a normal FSH level is?
A. No. But, again, different labs have different

reference levels. So that the jury understands, when we receive laboratory reports, the beautiful thing is certain things that we deal with that can affect patients, literally their lives, like blood count, certain electrolytes, certain what we call blood gases, those numbers I know off the top of my head because they're life-and-death numbers.

Hormone values, again, because they can differ from lab to lab, you get a report, and it gives you the result and what's called a range of normal. So -- and, in fact, the ranges for men and women differ, which you may not be aware of, but I am, and it will tell you which is in -- in range, out of range.

So those kinds of results, which are useful and allow you to think about a problem in a more nuanced way, I can get those results without any problem.
Q. Dr. Solomon, do you know whether LH and FSH levels are relevant in the diagnosis of a cause of gynecomastia in a boy going through puberty?
A. They may be.
Q. There may be?
A. They may be.
Q. But you don't know?

A. No, no, no. They might be part of the problem, but I'm -- I'm not suggesting that, you know, they're essential to understanding it for all patients.

Q. Can you tell the jury how they may be relevant?

A. To the extent that there's something going on other than what would be one of the typical reasons for gynecomastia, again, if I can refer to what I said earlier, as part of my job as a physician, we take a history, we do a physical examination. Those two items alone give me enormous information, quantities of information.

And as a surgeon who's been in practice for 30 years and operated on many, many, many patients with gynecomastia and seen many more who I've treated observationally, I can tell you on less than one finger the number of times I've needed to have LH or an FSH to determine the cause and the need for surgery.

Q. But just so that we're clear, you did tell the jury that you don't know how the LH hormone acts in a male, correct?

A. I did -- I absolutely said that.

Q. Right.

And you don't know how the FSH hormone acts in a male, correct?

A. In a normal physiologic circumstance, they're not significant, so I guess that's the most important thing to understand. That, I do know. In a pathologic state, they may be significant.

Q. And, to be clear, you can't tell the jury what a normal FH -- LH, excuse me, level is, correct?

A. I believe I answered that question already.

Q. Am I correct, you cannot tell me?

A. I answered that.

Q. And the same thing with regard to FSH, you can't tell the jury what a normal level is, correct?

A. Again, I answered that.

Q. Am I correct?

A. You're correct that I answered that.

MR. MURPHY: Your Honor, may we see you at sidebar, please?

THE COURT: Certainly.

- - -

(Whereupon, a discussion was held at sidebar as follows:)

- - -

MR. MURPHY: Your Honor, I object to the qualification of Dr. Solomon as being

someone qualified to offer a causation opinion here. It is abundantly clear that he has not had the type of training that allows him to testify to what things ought to be ruled out.

He has not had any type of training with regard to drug-induced gynecomastia. He hasn't had any training with regard to Risperdal and its association with gynecomastia or prolactin.

With regard to hormones that are known to be relevant to the diagnosis that I just queried him on, he knew their names. He doesn't know what a normal level is, and he only speculated as to whether they might be relevant in a diagnosis.

He is a plastic surgeon, yes, no question about that. But to suggest that he has a reasonable pretension to offer a causation opinion in this case, I don't think that he has satisfied that.

THE COURT: It really goes to weight. I mean, I think that anybody who gets through medical school has a reasonable pretension to knowledge in an area that we don't. And it's what you argue to the jury is, I would throw

that out the window. That's your argument. But in terms of it coming in, it's just a weight issue. That's the way I see it.

He's not offered as an endocrinologist -- as an expert in endocrinology but biopathology?

MR. KLINE: He's being offered as an expert in the breast.

THE COURT: Yeah.

MR. KLINE: He needs to understand the pathology. You can correct me if I'm wrong, Mr. Murphy. There was not an LH or FSH during the relevant time period on this boy.

MR. MURPHY: That's absolutely correct.

MR. KLINE: Yeah, that's the point. So there isn't even a blood test which is in this case. There's no one to point to that blood test to say that that blood test was a cause. I may have a fading recollection because this is now three weeks into it, but I don't recall their experts -- their experts opining that that's a basis in their reports for the ruling out the gynecomastia.

They may want to -- in fact, I don't

know that they're able to testify about it. I can tell the Court, having tried three of these cases now, that that's never been an issue. There's never been -- there's never been someone come to court and say, The reason that we can tell you this boy doesn't have gynecomastia induced by Risperdal is because of some FSH or LH level. That's never been part of it.

I think Your Honor has it correct, there's a lot about weight and, as you'll see, when they bring on whichever of the two endocrinologists you'll have testify, then you will see -- then you will see that there's plenty they don't know about the breast because they don't do this part of it.

I can tell Your Honor, as you're about to see, there are three surgeons in this case during the course and treatment of this boy who offered their diagnoses and causation, just like this man did. You're going to hear it in their testimony, not the excluded part, the included parts, and you're going to hear through his testimony.

So while they -- in the world of

Janssen, it's a strange and peculiar world --

MR. MURPHY: Mr. Kline, I don't begrudge your time to talk. Here we go ad hominem --

MR. KLINE: It's not ad hominem. I never do ad hominem with the lawyers, at least I try not to.

I can talk about the company that I bring your claim against. I can tell you that the world of Janssen is one of scientific convenience. And so now they say the only person --

THE COURT: That's not relevant now. I understand. The point I'm going to make is just that -- are you done?

MR. MURPHY: I am.

THE COURT: I'm sure you're going to have a couple questions on redirect and then you'll offer him.

I would probably, based on what he has, accept him, having a reasonable pretension of knowledge that we and the jury do not possess, and they'll decide how much weight to give him. That's just argument.

MR. MURPHY: I understand.

MR. KLINE: If you're going to use reasonable pretension language with this witness, I ask you use reasonable pretension with every witness.

THE COURT: I have.

MR. KLINE: You shouldn't single out.

THE COURT: I've done it with every witness.

MR. KLINE: Their witness, too.

THE COURT: I do.

- - -

(The following occurred in open court in the presence of the jury:)

- - -

THE COURT: Mr. Kline, do you have any questions on redirect as to qualifications?

MR. KLINE: Just a few little points.

- - -

REDIRECT EXAMINATION ON VOIR DIRE

- - -

BY MR. KLINE:

Q. Sir, on mechanism of action, have you in this Risperdal litigation rendered opinions and given testimony as to the mechanism of action as it relates to prolactin?

A. Yes, I have.

Q. And have you been privy to documents -- actually internal documents of Janssen Pharmaceuticals and things that they have said about the mechanism of action as it pertains to this drug causing gynecomastia?

MR. MURPHY: Objection, Your Honor; beyond qualifications.

THE COURT: I'll sustain that.

MR. KLINE: Objection. I need to get to what he notes and what he reviewed. I'll try, Your Honor, again.

BY MR. KLINE:

Q. Have you --

MR. KLINE: Maybe it was the form.

BY MR. KLINE:

Q. Have you reviewed internal documents of Janssen?

A. Yes, I have.

Q. And have you reviewed documents that pertain directly to mechanism of action as to this drug as stated by Janssen?

MR. MURPHY: Same objection, Your Honor.

THE COURT: Yeah, I think it's outside

the scope.
MR. KLINE: Outside scope of?
THE COURT: Qualifications.
MR. KLINE: Okay.
THE COURT: That may come in at another point. I think it's outside the scope.
MR. KLINE: Understood.
BY MR. KLINE:
Q. I'll ask it just generally then.
Are you familiar with mechanism of action as it relates to this drug, sir?
A. Yes, I am.
Q. And as part of your medical training from medical school through -- how many years are you a practicing surgeon now, sir?
A. I've been 30 in practice, more than that as a physician, 35 or 36 as a physician.
Q. Thirty as a practicing surgeon?
A. Plastic surgeon, yeah.
Q. As a plastic surgeon, you described the diagnoses that you make and causative diagnoses you make; is that correct?
A. I do -- or did.
Q. Does part of that have to do with understanding mechanism of action?

A. Absolutely.
Q. The other issue, sir, relates to this lengthy questioning that was asked about your knowledge of the LH hormone and FSH hormone.
Have you seen any blood tests on this boy relating to LH or FSH hormones in the time period that he was taking Risperdal?
MR. MURPHY: Objection, Your Honor; beyond qualifications.
THE COURT: No, I'll overrule that.
MR. KLINE: Thank you.
THE WITNESS: There were no such blood tests.
BY MR. KLINE:
Q. Is there anything in your opinion here to consider here that you'll be offering that deals with some blood test which was done relating to the LH hormone and the FSH hormone?
A. There is nothing in that regard.
MR. KLINE: I move to qualify him.
Everything else I have to do is on -- in the substance of my eliciting opinions, Your Honor.
THE COURT: Do you have anything else?
MR. MURPHY: I have nothing further,

Your Honor.
THE COURT: I'm going to find that Dr. Solomon is an expert in surgery, plastic surgery, pathophysiology, and the biology of the breast, as he was offered.
It's for you, ladies and gentlemen, to decide the weight you give to his testimony, as I've told you over and over.
You may proceed.
- - -
DIRECT EXAMINATION
- - -
BY MR. KLINE:
Q. Dr. Solomon, at the request of my -- the lawyers who are working on behalf --
THE COURT: Mr. Kline, I didn't finish that, I'm sorry, that's my fault, not yours.
As I've told you before and I'll tell you again, an expert, when I qualify someone as an expert, it means that he has a reasonable pretension to knowledge that we don't share, we don't have. That's what it means. And that's why I've accepted him as an expert.
Thank you.
THE WITNESS: Thank you, Your Honor.

BY MR. KLINE:
Q. Dr. Solomon, at the -- at our request on behalf of Tim Stange, did you review certain materials relating to his treatment and care as a patient?
A. I did.
Q. Let me mark some exhibits, if I can. Did you review -- and let me get your report in front of me -- did you review the medical records of -- from Aurora Healthcare System?
A. I did.
Q. In particular, did you review the records of Dr. Kovnar, the pediatric neurologist?
A. I did.
Q. Did you review records from Cedar Mills Medical Group?
A. Yes.
Q. John Jensen, M.D.?
A. Yes.
Q. Is John Jensen a surgeon like yourself?
A. He's a Board-certified plastic surgeon, yes, that's correct.
Q. Did you review, also, records from a doctor, I believe his name is, Mixter?
A. Mixter, M-I-X-T-E-R.

Q. Mixter.
A. **I did.**
Q. Is he a plastic surgeon, as well?
A. **He is also a plastic surgeon.**
Q. I believe that's from the Clinic of Plastic Surgery?
A. **I believe that's correct, yes.**
Q. You reviewed multiple photographs, according to your report?
A. **Yes.**
Q. You reviewed deposition testimony?
A. **Yes.**
Q. Including testimony of John Jensen, the surgeon, Teresa Stange, the mother of Tim Stange, the plaintiff in this lawsuit and the patient?
A. **Yes.**
Q. David Meuler, the pediatrician?
A. **Yes, I did.**
Q. You also reviewed a mammogram record, as well?
A. **Yes.**
Q. I'm sorry --
A. **No. I don't have my report in front of me.**
Q. Let's put your report in front of you.
MR. KLINE: We'll mark it, P-87.
- - -

(Whereupon, Exhibit P-87 was marked for identification.)
- - -
MR. KLINE: I think we're back in sync on numbers, Your Honor.
THE COURT: We are. I just have to get some information on a few of them, but yes we are.
BY MR. KLINE:
Q. And did you review also pharmacy records?
A. **Yes.**
Q. Did you -- do you have your report in front of you?
A. **I'm looking right at it.**
Q. Just confirm to me that you've reviewed all of those records. I know you have and I know you're familiar with it.
A. **Yes.**
Q. Can you put it down then, please?
Do you have an opinion, sir, with reasonable medical certainty, as to the -- as to whether Tim Stange has gynecomastia?
A. **I do have an opinion.**
Q. And did he have gynecomastia?
A. **Absolutely.**

Q. And was that gynecomastia something that occurred during his ingestion of the drug Risperdal?
A. **Yes.**
Q. And do you have an opinion, with reasonable medical certainty, as to the cause of his gynecomastia, sir?
A. **I do.**
Q. And what is the opinion, sir?
A. **My opinion is that his ingestion of the drug as an offending agent caused the gynecomastia.**
Q. Does the basis of your opinion include your review of the medical records?
A. **Correct.**
Q. Does it include your knowledge and 30 years of experience as a surgeon?
A. **Correct.**
Q. Does it include your review of any Janssen documents?
A. **Yes.**
Q. And we'll discuss that.
And does it include your knowledge of the medical literature?
A. **Yes.**
Q. Have you read and familiarized yourself with the articles in the published literature relating to

the drug Risperdal and an association with gynecomastia?
A. **I have.**
Q. Now, you were telling the Members of the Jury in response to the questions for -- of counsel for Janssen that as part of your reaching a diagnosis, you also look at the causative issue, that is to say, when you're treating a patient, you look and ask the question, is there a relationship? Do you recall giving that testimony --
A. **I do.**
Q. -- moments ago?
A. **Yes.**
Q. Did you review the records of the surgeons in this case, not the, frankly, hired experts, but the surgeons in this case when they were treating this young boy?
A. **Absolutely I did that.**
Q. Now, let's start with the -- among the records you reviewed, did you review the records of John Jensen, M.D.?
A. **I did.**
Q. Jensen -- and we're going to get his records out, if I can.
MR. KLINE: I'm going to mark Dr.

Jensen's records in full as Exhibit P-88.

Your Honor, we will be using selected records of these much larger records. I'm going to do it a different way, Your Honor.

Before we do that, I think I'm going to clutter up a record with ton of records, I'm going to do selected records. If it becomes some issue we don't have the complete records, I'll put them in.

I want to go to exhibit -- what number did I mark?

Let's mark the full thing as Exhibit 88, and I'm going to mark as Exhibit 88(a) a letter of Dr. Jensen, okay.

- - -

(Whereupon, Exhibits P-88 and P-88(a) were marked for identification.)

- - -

THE COURT: Is there a Bates stamp number on that?

MR. KLINE: Not on the one in front of me. I'm a little handicapped. I apologize.

THE COURT: Have you been able to get to that, Doctor, the letter?

(Pause.)

THE WITNESS: I have a letter. I'm not sure if it's the one you're referring to.

BY MR. KLINE:

Q. I'm going to put it in front of you, sir. I'm going to hand it up and put it in front of you, sir. Sorry we got a little behind this today.

THE COURT: Defense counsel has this, I would assume?

MR. KELLY: Yes, Your Honor.

BY MR. KLINE:

Q. Now that we've solved our internal differences, if you would look at the document with the jury.

Tell the Members of the Jury what this document is.

A. This is a letter from Dr. Jensen to the group Health Cooperative of South Central Wisconsin, which is an insurance -- health insurance entity, and it's sent to the appeals unit for --

Q. Just one --

A. -- insurance.

Q. It's a letter by this doctor. Can we look at the signature on the bottom?

A. Yes.

MR. KLINE: May we go to the bottom,

please, Cory? Thank you very much.

BY MR. KLINE:

Q. It's signed by John Jensen, correct?

A. Correct.

Q. I want to walk you through some of the things that Dr. Jensen during the treatment of this patient said.

First of all, he said, I've been in -- he said he is a 27-year-old --

A. Seventeen.

Q. I'm sorry. Seventeen-year-old male with -- and the date is October 3, 2011, correct?

A. Yes.

Q. And let's highlight "severe gynecomastia." Do you see that?

A. I do.

Q. Now, you saw photographs that were taken at the time of the surgery, correct?

A. Correct.

Q. And I plan to show them to the jury through you. You've examined those photos, correct?

A. Correct.

Q. As well as other photographs in this case?

A. Correct.

Q. Now, Dr. Jensen went on to describe Tim as a 5

foot -- and, by the way, is there any equivocation in his diagnosis of there being true gynecomastia here?

A. There's no equivocation. No, it's a very clear state -- declarative statement.

Q. And the next sentence says, and this is dated October 3, 19 -- 2011, next sentence says, "Timothy is 5'8" with a weight of 155 pounds. As you can see from his photos, his habitus is not obese." Do you see it says "his habitus is not obese"?

A. I do.

MR. KLINE: Can we highlight that please, Cory?

BY MR. KLINE:

Q. And do you see the next words he says, he says, the surgeon, he -- the words are used "true gynecomastia."

MR. KLINE: Can you highlight that, please, Cory?

BY MR. KLINE:

Q. Now, this is all information which you read in rendering your opinion, correct?

A. I read it and relied upon it, that's correct.

Q. And, also, is it the kind of statement that is being made by this doctor in his evaluation of this

patient?
MR. MURPHY: Objection, Your Honor.
THE WITNESS: Correct.
THE COURT: Hold on, Mr. Kline. Is there an objection?
MR. MURPHY: There was an objection.
THE COURT: To?
MR. MURPHY: He said evaluation. This is a letter to an insurance company. It's not an evaluation of a patient.
THE COURT: Okay. I mean, it's certainly an evaluation of what he believes is the condition, and that's in already.
You don't want the word "evaluation," is that what you're saying?
MR. MURPHY: I don't quibble with that, Your Honor. I quibble with the characterization of what the letter is. It is what it is. It's a letter to an insurance company.
BY MR. KLINE:
Q. Since we're talking about a letter to an insurance company, when you said a letter to an insurance company, do you have to explain what the diagnosis is in these situations, sir?

A. Yes; you have to justify the medical need for the treatment. And in order to do that, you first have to have a diagnosis.
Q. You need to know what you're dealing with?
A. Correct.
Q. Let's go on. Let's see what else he said. He said "with projection of" -- and we're going to highlight the word -- "breast tissue."
Now, sir, we haven't had this discussion yet. What is breast tissue as distinguished from fatty tissue? What is breast tissue, first of all?
A. So breast tissue is a combination of what are called glands and ducts. The glands, both in men and women, have the ability to make what ultimately is milk. And the ducts are the way that the product gets from the gland to the skin surface. And it's, by the way, very clearly distinguishable from fatty tissue.
Q. How do you distinguish it as a surgeon when you examine either a woman's breast or male breasts?
A. So it feels different. That's the most honest way to describe it. It absolutely feels different. And it's not a -- there's no question in one's mind, if they've done enough breast exams over the years,

you can differentiate easily between breast tissue and fatty tissue.
Q. How, sir, please?
A. One of the mechanisms is called pinch test, in which you pinch the tissue, and if you pinch breast tissue, especially gynecomastia, versus the skin next to it, which has a little bit of subcutaneous fat, the breast tissue is firm, it has granularity or nodularity to it that the fatty tissue doesn't have.
Another way to do it -- may I stand for a moment to demonstrate something?
Q. Sure.
A. One of the tests that I have always used is to have the patient press on their hips like this, especially a man. What will happen is that the pectoral muscle contracts, it pushes out the breast tissue, and the fat goes to the side.
So, again, it's a way to demonstrate quite clearly, by the way, the margins of that tissue. And it's a test that I use when I operate on patients with gynecomastia so that I can mark the differences between breast tissue and fat because that informs my surgical plan. I need to know where the different tissue compartments are in order to

perform the surgery safely and effectively.
Q. Now, he also describes expansion of the nipple areolar complexes. We'll highlight that.
What is the -- what is the nipple areolar complexes and the expansion of it, as you read this here?
A. So the nipple areolar complex is that pigmented central area of the breast, again both in men and women. And in patients, male patients, with breast tissue, that normally type circled gets pushed out such that it gets -- it widens out, it also has projection. It's not flat.
Q. And he describes here that this young man has -- and I'm going to use the words here used by the surgeon himself, "clearly" -- you will highlight it -- "clearly palpable breast mounds."
And what is that description, sir?
A. That's consistent with what I just described to you, that the examining physician can feel the breast tissue in a discrete mass area separate from the surrounding skin.
Q. Now, he then goes on to say -- and you were asked questions about pathology by counsel for Janssen, not counsel for Jensen, that's this man -- it says here, "this young man has" -- and I'm going

to highlight the words -- "a pathological state."
Tell me what that is, if I can use the word, "surgeonspeak" for.
A. In this circumstance, a pathological state means not normal, abnormal, beyond the range of normal is pathologic.
Q. Does pathologic in this instance refer to breast tissue versus what would ordinarily be found?
A. Correct. The quantity, proportion, dimensions of the breast tissue are pathologic, meaning it's not -- it's not a normal amount of breast tissue. It's beyond that.
Q. By the way, we men, do we have breast tissue, as well?
A. Yes.
Q. It's not just women who have breast tissue?
A. Correct.
Q. But he describes here something called an overgrowth of breast tissue, correct?
A. Correct.
Q. And what is that -- what is that, sir? If we can highlight "overgrowth of breast tissue."
A. So the condition of gynecomastia is a disproportion, meaning that the breast tissue is disproportionate to the rest of the patient's body

habitus, their frame. So it's this enlargement of male breast tissue, this feminization of male breast tissue, which is the meaning of gynecomastia.
Q. Now, is the hormone -- you talked about LH, which you didn't see in the records, and FSH, which you didn't see in the records.
Is the hormone prolactin related to the growth of breast tissue?
A. That's correct.
Q. Is that a well-known phenomenon?
A. Correct.
Q. And in this case, did you see what eventually became, without my having to pull it out, the jury has seen it, the 2006 label, where it is stated that Risperdal increases prolactin more than any of the same drugs in the class? Did you read that?
MR. MURPHY: Objection, Your Honor.
THE COURT: I'll sustain the objection.
BY MR. KLINE:
Q. Did you read the label, sir, as to 2006 as to what it said as to prolactin?
A. Yes.
Q. I'll ask a better and non-leading question.
What does it say, sir?

A. It says that among all these class of drugs, Risperdal elevates prolactin in excess compared to all the others in a similar class of drugs.
Q. And, in fact, have you seen that in a different part of the label, as well, as to percentage comparisons, sir?
A. I have.
Q. And what did you see there?
A. Depending upon the dose utilized for the given condition that's in the labeling, it can be anywhere from 25 times higher to as much 87 or -- in the 80 percent range of patients will get a bump in their prolactin shortly after exposure to the drug that is sustained as long as they're on the drug.
Q. Back to this for a minute. We'll get to that later.
The letter says, goes on to say, "that it causes severe" -- if I may use the word here -- "severe psychosocial stress."
Let me pause for a minute. Is a purpose of operating on a patient cosmetically due to reasons like stated in this report?
A. So if I may correct you for one second? This is not cosmetic.
Q. Okay. I'm sorry.

A. That's, in fact, what Dr. Jensen's point was. Cosmetic, so we're clear -- and this is a definition not from Mark Solomon but from the American Medical Association -- cosmetic is surgery that takes normal and makes it above normal.
So the easiest way to think of is the woman who dislikes her breasts because they're small and we put implants in, somebody who dislikes a bump in their nose and we make it smaller, those are absolutely cosmetic procedures and they are very good reasons to do them, but they're not the subject of this case.
This is a young man who had female breasts as a teenager, and that's -- that's not a normal circumstance. And the consequences of the stresses created and the psychology of it make life in many circumstances unbearable for these kids.
So that what I've often said to people, you know, I'm a psychiatrist with a scalpel, that you could go talk to a therapist about your big breasts if you're a 17-year-old kid, but, ultimately, it's a lot easier to get rid of them and make you look like a guy and that solves the problem. That's what Dr. Jensen was trying to say here.

Q. So we have "severe psychological depressed." And it says here, "Moreover, that cosmesis" -- what's cosmesis?
A. Cosmesis, appearance.
Q. Appearance. -- "is the purpose of this intervention should be weighed against the fact" --
MR. KLINE: Could we pull out this paragraph, please, Cory, so we can read it better?
BY MR. KLINE:
Q. "Cosmesis is the purpose of this intervention should be weighed against the fact that this young man will end up with permanent scarring on his chest, a cosmetic defect that he is willing to accept to treat what is in effect" -- and the words here used are -- "a gross deformity of his habitus." Correct?
A. Correct.
Q. Now, let's put that down, the callout down.
And he signs -- after the last paragraph there, which is in front of us, he signs his name John Jensen, M.D., associate professor for the Department of Plastic and Reconstructive Surgery at the Children's Hospital of Wisconsin, correct?
A. Yes.

MR. KLINE: Now, that is marked as Exhibit 88(a).
I'd like to go to another part of Dr. Jensen, the surgeon's record, which is -- Your Honor, Mr. Gomez, Your Honor, would prefer to mark this as a separate number, which is 89.
- - -
(Whereupon, Exhibit P-89 was marked for identification.)
- - -
BY MR. KLINE:
Q. Now, you have read both the records of Dr. Jensen, as well as his deposition testimony, which gives some explanation here and there, correct?
A. Yes.
Q. As 89, which we will display, is there a history and physical examination before we can display it, a history and physical examination by the physician's assistant?
A. Yes.
Q. And did Dr. Jensen in his testimony say that he agrees with the statements made here by the physicians -- by the physician assistant?
A. He did state that.
Q. And does that happen in the practice of

medicine, where a physician assistant will do something and then the surgeon, the doctor -- the surgeon will come in and say, yes, this is what I agree with?
A. Right, because we had the opportunity, if we don't agree with it, to change it.
Q. Okay.
So let's see what's said in Dr. Jensen's record displaying Exhibit 89. First of all, let's look at the full document. It says History and Physical Examination. It's done on a History and Physical Examination form of the Children's Hospital of Wisconsin. Is that the document you see, sir?
A. That is.
Q. And we will --
MR. KLINE: Can we do it as a callout, please, everything on the top? That's it. There we go.
Now, Dr. Jensen's record says 18-year-old male with gynecomastia. Let's highlight gynecomastia and let's have chief complaint: gynecomastia.
All right. Now, if we can take that down on the highlighting and we'll start with a

clear one again.
BY MR. KLINE:
Q. According to the surgeon's record, "patient experienced a 30-pound weight gain while taking Risperdal which resulted in breast growth." Do you see that?
A. I do.
Q. "Which resulted in breast growth. After discontinuation of medication patient lost weight but breast size remained stable." Do you see that?
A. Yes, I do.
Q. "The patient is very self conscious about the breast size." Do you see that?
A. I do.
Q. Do you see the words "while taking Risperdal" --
MR. KLINE: If you can highlight from the words "while taking."
Highlight the words, Cory, "while taking Risperdal which resulted in breast growth."
BY MR. KLINE:
Q. This is in the medical record of the doctor who treated him, correct?
A. Yes.

Q. And there's another -- and, by the way, is this the kind of thought process that you were describing to the jury when on cross-examination on qualifications you were asked by counsel for Janssen Pharmaceuticals, Doctor, is this the -- do you look for cause when you're -- when you're treating a patient for surgery, is, in fact, this what you as surgeons do?

A. Absolutely. Absolutely.

Q. Do you think about why does this boy have female breasts?

A. Correct. That persists through weight loss, for example, as an issue.

Q. Is that of any importance to you, that the breasts persist after weight loss?

A. It supports the notion that it's a pathologic condition as opposed to normal. And with regard, by the way, to the causative factors, among the issues you look for in a patient are medical history things that may preclude doing a safe operation.

So if there are other issues that he had that would interfere with anesthesia, for example, he wouldn't be a candidate for surgery. So it's imperative to understand the causative factors of the problems that we're treating.

Q. By the way, from the initiation of the Risperdal 2/7/06, at that point -- I hope we can just confirm these numbers because they are numbers in charts, he was 110 pounds, did you read that and see that?

A. I did.

Q. And by 6/2/08, he was 166 pounds?

A. I read that, as well.

Q. That was roughly when the -- when he was finished with the brand name Risperdal and went on generic Risperdal?

A. That's my understanding.

Q. And then from 6/2/08, when he was 166 pounds through the next year, 6/16/09, did he go down to 152?

A. He did.

Q. So there's a weight loss from 6/2/08 of 166 to a year later, 6/16/09 of 152?

MR. MURPHY: Objection, Your Honor; leading.

THE COURT: I'll sustain the objection.

MR. KLINE: And the reason?

THE COURT: Leading.

MR. KLINE: I'm sorry. I'm working

off of their expert's chart to try to save a lot of time. But I guess we'll pull out all those records individually after the break if I'm not allowed to do it.

BY MR. KLINE:

Q. Maybe I can ask it this way: Can you confirm for me, was there significant weight loss in the year after he was off the brand name Risperdal?

A. That's correct. I did read that. It's well-documented.

Q. And was the weight loss, sir -- did the breasts persist despite the weight loss?

A. That's correct.

Q. Did the boy and his mother seek treatment with these -- with Dr. Jensen, among another doctor, to deal with the problem?

A. They did.

MR. KLINE: Now let's look at another record. I want to mark as P-89(a) the second page. I believe it's right after this page.

There's two pages to this document, Your Honor. 89(a) is the discharge communication document from Children's Hospital by Dr. Jensen.

- - -

(Whereupon, Exhibit P-89(a) was marked for identification.)

- - -

BY MR. KLINE:

Q. Sir, you've reviewed this document?

A. I have.

Q. And you've reviewed Dr. Jensen's deposition testimony, so you know whose handwriting is on this document?

A. I have reviewed that testimony, and I do know whose handwriting is on this document.

Q. I'm going to display the document to the jury. It is a discharge communication for a length of stay.

By the way, did Tim, indeed, have the surgery with Dr. Jensen?

A. He did.

Q. We're going to talk about the surgery for a moment.

What kind of surgery was it?

A. The surgery was described as what's called a simple mastectomy. It's removal of the breast tissue.

Q. Is it described as a mastectomy?

A. I believe I read that phrase somewhere in the

records.

MR. KLINE: Can we put down this for just a moment until we get some definitional stuff?

We'll be right back.

BY MR. KLINE:

Q. What is a mastectomy, briefly? Couple sentences.

A. Very briefly, "mast-" refers to breast, "-ectomy" refers to taking away, so it's taking out the breast tissue.

Q. By the way, gynecomastia, Greek and Latin. I told the jury, but I have to have evidence, not just what I said. "Gyneca-" and "-mastia"; "gyneca-," female?

A. Yes.

Q. Greek, I believe. "-mastia" Latin for breast?

A. That's correct. So it means female breasts in a man.

Q. Now, back to what is written in the Dr. Jensen record. Now, you see handwriting here?

A. I do.

Q. Do you see a signature at the bottom?

A. I do.

Q. Based on the testimony of Dr. Jensen, did he

have another surgeon working with him in this surgery?

A. He did.

Q. And what was that surgeon's name?

A. I believe it was Dr. Lao; L-A-O, I think, is how it's spelled.

Q. Dr. William Lao to be correct. Is he a plastic surgeon? Did you look him up?

A. I did. He is.

Q. So we have another plastic surgeon saying something here?

MR. KLINE: Can we go up to the top? We're not going to highlight any of this, but we are going to go through it. Can we take the top? Will it get bigger if you take the other top or will it be the same? Just the very top. Yeah. Thanks.

BY MR. KLINE:

Q. So we have 7/6/12 was the date of the surgery, discharge 7/6/12.

It was surgery under general anesthesia; is that correct?

A. Correct.

Q. And the discharge summary diagnosis was gynecomastia, correct?

A. Correct.

Q. And under this there's a reason for admission that's given, correct?

A. Correct.

Q. And would this be the thinking of that surgeon as to the -- as to what he was operating on and why he was operating?

MR. MURPHY: Objection, Your Honor; calls for speculation and lack of foundation.

THE COURT: I'll sustain the objection.

BY MR. KLINE:

Q. Let's see what this surgeon wrote. Maybe that's a better way to put it.

MR. MURPHY: That's an assumption, sir.

MR. KLINE: I don't think it's an assumption that he wrote it.

Can we look at this record? Can we highlight -- let's see -- let's not highlight yet -- "17-year-old male with history of Tourette's, developed gynecomastia while on Risperdal," and if we can highlight, "developed gynecomastia while on Risperdal."

BY MR. KLINE:

Q. Is this a record which you reviewed of this surgeon, Dr. Lao, who participated with Dr. Jensen?

A. It is a record of that, and if I can clarify what may be some confusion that you're having. If you look above, it says, please include brief history and physical and other findings. So this is, again, consistent with all of the records that we've seen previously.

Q. Let's see. You're referring to --

THE COURT: Mr. Kline, let me interrupt for a minute. The signature down at the bottom, what I see on here, is Jensen. Can you point me to where Lao's name is on this document?

I see Jensen at the top, Jensen at the signature line, and then there is a resident at the bottom, but I can't read that. Is that the one you're saying is --

MR. KLINE: I can go to the testimony, Your Honor, to clear it up, but I know I had read that Jensen had created this record, at least I believe so.

THE COURT: Jensen, not Lao?

MR. KLINE: Lao. And Jensen signed off on it.

THE COURT: Okay. If you can establish that he knows that somehow or another.

MR. KLINE: I think I can. Let me look at the record to figure it out.

Are we taking a morning break at some point soon?

THE COURT: In five minutes.

MR. KLINE: Let me come back to you after the break.

THE COURT: Okay.

MR. KLINE: I believe it is signed off on by Jensen. Let's leave it there so far, and I will get back to the Lao piece.

THE COURT: I know his signature is on here. The one at the bottom, I don't know what that is. You see the very final one?

MR. KLINE: I think that's William Lao. I remember reading it. I don't want to say anything incorrect.

May I approach the witness, Your Honor?

THE COURT: Sure.

BY MR. KLINE:

Q. You read the deposition testimony, as well,

some of the explanatory deposition testimony in the case?

A. Absolutely.

Q. May I approach? It will just be easier.

On page 110 of Dr. Jensen's deposition, it was stated, if you turn to the second page, that's the page we're referring to, I represent to the Court --

MR. MURPHY: Your Honor, with all due respect, may I have a copy of what he's showing the witness?

THE COURT: Why don't you come up and stand with him? Is it easier? Or do you have a copy?

MR. KLINE: We have another copy of the dep.

I can show you, it's just clearing up what His Honor asked. This is Bates stamped, Will Lao's handwriting, Dr. Lao is a physician, as well. He writes this in the admission date. It was 158 of this, which is this document.

So to clear up Your Honor's question -- and sometimes I get ahead of myself, Your Honor, so thank you.

BY MR. KLINE:

Q. If you turn to the second page, do you know what the handwriting is?

MR. KLINE: I represent to the Court we're referring to the top handwriting.

If you display it, please, Mr. Smith, the document we had up with the callout that we had up.

BY MR. KLINE:

Q. Yes. Is this Will Lao's handwriting?

Dr. Lao.

And Dr. Lao is a physician, as well?

Yes.

Do you see that?

A. I do see that.

Q. And are you also aware independently that Dr. Lao is a plastic surgeon?

A. I am.

Q. And is the document on the bottom, if you can display the full document, is the document signed off on by Dr. Jensen --

A. That's correct.

Q. -- as His Honor pointed out?

A. That's correct.

Q. Again, in terms of the questions you were asked during -- by counsel for Janssen, is this part

of the process of doctors not only grabbing the scalpel but thinking about the biophysiology behind the problem that they have in front of them?

MR. MURPHY: Objection, Your Honor; speculation.

THE COURT: I'll sustain the objection.

BY MR. KLINE:

Q. Do physicians look -- okay. Do physicians look at the biophysiology, sir?

MR. MURPHY: Same objection, Your Honor. He's --

MR. KLINE: I'll ask this way.

BY MR. KLINE:

Q. Did the physician here look at the biophysiology?

MR. MURPHY: Same objection.

THE COURT: If there's a basis for it. Will there be a basis?

MR. KLINE: The record.

THE COURT: Let me hear the question, subject to the strike.

BY MR. KLINE:

Q. Did the physician here, like you in your -- did the physician here look at the condition of the

patient, as well as the history of the patient?
A. He did, the physician did.
Q. And did the physician look at the situation, which included the ingestion of the drug Risperdal?
MR. MURPHY: Objection, Your Honor. There is no foundation for that.
THE COURT: Well, it's in the record, so I mean that's already been in. It's in the record and he's spoken about that.
MR. KLINE: Okay.
THE COURT: And I just want to know what he bases this on, that's what I'm waiting for, to rule on the objection.
BY MR. KLINE:
Q. Does this record -- is this one of the records you reviewed in the overall formulation of your opinion which you expressed to the jury?
A. Absolutely.
Q. Is your opinion consistent with the records that you have reviewed so far by the surgeons who saw this boy?
A. Absolutely.
Q. Now, in addition to this record, there is the record of the surgery itself --
MR. KLINE: I'm ready to either start

it or not.
THE COURT: We'll take our break so you can have everything set up.
MR. KLINE: Okay.
THE COURT: I'm going to give you your morning break now.
Remember, you can't talk about the case with anyone.
- - -
(Whereupon, the jury was excused from the courtroom at 10:44 a.m.)
- - -
(Whereupon, a brief recess was taken at this time.)
- - -
(Whereupon, the jury entered the courtroom at 11:08 a.m.)
- - -
THE COURT: The jurors are all here and seated.
Mr. Kline.
MR. KLINE: Continuing, Your Honor, continuing along.
I now want to turn our attention to another 2011 record. And, for the record, I

want to make sure that I have identified the prior documents marked 89 and 89(a) as documents which are dated 7/16/12, relating to the gynecomastia surgery, the mastectomy surgery, which takes me to my next document, which is the record of the operation itself, which is the op note. We'll hand the document up, per our usual.
THE COURT: Will this be No. 90, operative note No. 90?
MR. KLINE: P-90, Your Honor.
- - -
(Whereupon, Exhibit P-90 was marked for identification.)
- - -
MR. KLINE: Before cueing up P-90, I want to go to some earlier photos.
We are marking, Your Honor --
(Attorneys confer.)
(Pause.)
BY MR. KLINE:
Q. I am going to show you two photos, which we are going to display to the jury, much earlier in time, June 11, taken sometime June 11th through 15 of 2007. And I want you to assume that these photos

are taken during that time period, per testimony which we will hear from Mrs. Stange.
So I'm going to first -- we're marking P-91 and P-91(a), Your Honor, photographs which were taken at a water park in June of 2007 of Tim.
THE COURT: Are they going up?
MR. KLINE: They're going to go up on the board. I have small hand copies, but they're going to go up on the board.
- - -
(Whereupon, Exhibits P-91 and P-91(a) were marked for identification.)
- - -
BY MR. KLINE:
Q. I want to show you a document marked P-91, and we will publish it to the jury, Your Honor. This is a photo which you have seen, Dr. Solomon?
A. Yes.
Q. And I have it in hard copy, too, which I'm handling right now, a larger copy of the photograph, as well, from June, sometime June 11th through 15 of 2007.
A. Seven.
Q. Yes. And if I can just zero in on Tim and his face and chest.

Have you seen this photo, sir?
A. I have.
Q. And knowing what you know today, sir, does -- is this evidence of the breast growth which you have seen in the medical records?
A. Yes, it is.
Q. And is this consistent with the condition of gynecomastia that you see described in the medical records?
A. Absolutely.
Q. And are you aware of the fact that it is dated back to June of 2007?
A. Yes.
Q. And the young man went on the drug in February 7th, 2006, correct?
A. That's correct.
Q. And do breast mounds or breast tissue grow overnight, sir, generally?
A. No.
Q. Does breast tissue, this condition of gynecomastia, take some time to manifest itself?
A. Yes.
Q. Was Timothy Stange on Risperdal at the time that the condition in which we see him in these photographs -- was he on Risperdal at that time?

A. Yes, he was.
Q. And had he been on Risperdal for about the prior year and four months?
A. Yes, sir, that's correct.
Q. I'm going to show you an exhibit marked as 91(a) from the same day.
MR. KLINE: If I may, displaying the photo to the jury, but I think it actually -- you never know until you're in the courtroom. I think it works best up on the screen, as well.
Sorry, Cory. I showed everyone but the person who needs to put it up.
BY MR. KLINE:
Q. Again, I will represent to you -- or I could ask you, I want you to assume that we will hear from Terry Stange, the mother of this then youngster, that this was his condition on June the 11th through 15th of 2007.
MR. KLINE: If Cory can, again, show his head and his chest. Can you get a little further in? I know it may get blurry.
Make sure that we do that as a callout.
BY MR. KLINE:

Q. Sir, based on what you know, is this consistent with the medical record of female breast tissue which was later removed from this boy in 2011 by the surgeon whose records we were discussing?
A. It's absolutely consistent. I think it was removed in 2012, though. I think you said 2011.
Q. Thank you, sir. Yes, the surgery was in 2012, yes.
MR. KLINE: If I can go back to the water slide photo for one moment. We've now displayed P-90 and P-91. Again, if you would zoom in of the chest, sir, just the chest for right now.
BY MR. KLINE:
Q. I know we're dealing with an old photo and a photo that's blurry, as well, but have you considered this in the opinions which you are expressing to the jury today, this condition?
A. Yes.
Q. And when the doctor himself described it as "severe gynecomastia," do you agree?
A. Absolutely. It's well beyond any proportion. It's dysmorphic is the phrase.
Q. Now, would you explain to the Members of the Jury the difference, if you would, please, between

just having a size versus disproportionality?
A. Sure. May I use this pointer?
Q. Yes, sure.
A. So if I can call the jury's attention to -- these are really discrete breast mounds. You can see the edges of the breast tissue and whereas, you know, he's got a little adolescent fullness here, this is well beyond the proportion of the fullness of his tummy.
And I understand it may not be obvious to the jurors, but I can tell you from my eye this is breast tissue. If I were to put my fingers in this area, it would feel different than this area. No doubt in my mind.
This is subcutaneous fat. This is a breast mound. And if this were a girl instead of a boy, we'd say this is an adolescent girl's breast. I think that's perhaps the best way for you to focus in your minds that this is gynecomastia, not fat.
Q. And are you looking at this photo --
MR. KLINE: If I can again take the breast part, just the breast part, Cory, please, so we have that, the breasts?
Thank you.
BY MR. KLINE:

Q. In this case in formulating your opinion, are you looking at all the evidence, that would be to say, the doctor's -- the records, the ingestion of the drug, the temporal relationship as to whether -- where the breast -- when the breasts formed and the other medical information that you have?

A. Yes.

MR. MURPHY: Objection, Your Honor.

THE WITNESS: That's absolutely correct.

MR. MURPHY: Objection.

THE COURT: Objection to?

MR. MURPHY: Leading.

THE COURT: No, I'll allow that on an opinion question. I'll permit that.

BY MR. KLINE:

Q. Okay.

Now, we now get to a few years later and we have photos of the surgeon himself -- that are taken, correct?

A. Yes.

Q. Are taking photographs common in the practice of the field of plastic surgery?

A. Absolutely.

Q. And --

A. If I may? It's how we document what we do, because if you take a photograph of the patient with an issue, regardless of the issue, you operate on the patient, you want to watch the changes that occur through the healing process and you want to see the end result and, frankly, that's how we learn a lot about what we do.

Q. So Tim was -- we know he was born in '94 and we know these photos are in '97(sic), and now we're going to look at photographs from 2012, when he was 18, correct?

A. Yes.

Q. The photographs that we're -- his date of birth we established 3/28/94, and this photograph -- can we display the water park photo so I have a reference as I do this? -- so he was 13 years old at the time. Is that your understanding?

A. That's correct.

Q. And does he essentially have the breasts of a 13-year-old girl?

A. That's a very reasonable description.

Q. Now, fast forward to when he's 18 years old and we have some photographs. (Pause.)

The surgery, we will all agree, is 7/16 of '12, and I will show you the records of the

date of weight points. But on 7/16/2012, did you see the records with his weight and his height at that point?

A. Yes.

Q. His weight appears to be 162 pounds. I hate to lead, but I want to save some time, I don't think it's controversial. Is that your understanding?

A. I'll agree with what you say. I don't have the document in front of me.

Q. We'll get those data points out during the trial.

MR. KLINE: Now, I want to show you a packet of photographs which Mr. Gomez tells me to mark as Exhibit 92.

- - -

(Whereupon, Exhibit P-92 was marked for identification.)

- - -

BY MR. KLINE:

Q. I want you to assume, sir, at this time he was 68 inches and he was -- that would be 5'8" and he was 162 pounds at that time, and I'll get that confirmed. I want you to assume that.

A. Okay.

Q. Now, let me show you --

MR. KLINE: We can take down the other document. Thank you. I meant to take it down previously.

And I now want to look at the photographs which were done, and I'm going to come up to you since we're one copy short. It's one of those mornings.

I'd like to display to the jury the exhibit which is marked as P08, P08, please, among the general grouping which was marked as P-92.

Thank you.

BY MR. KLINE:

Q. And what do we see there, Doctor, Dr. Solomon?

A. This is a preoperative photograph taken by Dr. Jensen is my understanding and it's a, what we call, three-quarter view, demonstrating both his right and left breasts, demonstrating gynecomastia in which the breast mound is clearly visible, especially on the right side in this perspective.

Q. Is there anything else you are able to point out, able to move it or zoom in?

A. Can I use my pointer?

Q. Sure you can.

A. Again, from the jury's perspective, that

amount of projection is abnormal for a male. That's a young girl's -- an adolescent breast for a girl. That's not a boy's breast.

Q. All right. And if I can, I think we can go from the other side with P-15 and what are we looking at --

THE COURT: So this is actually -- just, Mr. Kline, for the record, this is actually P-92?

MR. KLINE: Yes.

THE COURT: Photo 15?

MR. KLINE: Yes.

THE COURT: Okay.

MR. KLINE: Is that an acceptable way to mark them, Your Honor?

THE COURT: Sure.

BY MR. KLINE:

Q. Go ahead, sir.

A. In this view now we're looking at the right breast from the other three-quarter view, and you can see the outline of the breast tissue clearly and you can see the projection of the left breast and to my eye it looks like the left was perhaps a wee bit smaller than the right. And I think the pathology, the amount of tissue removed, was consistent with

this.

Q. Next, I want to go to the operative procedure, so let's put the photos away for a moment and let's look at the operative report, and then we'll show the operation and the result of the operation.

MR. KLINE: So I'm now going to go to exhibit -- the next exhibit number, which is 93.

Ninety-three, Your Honor, is the operative report. We'll hand a copy. We will not display it until we show counsel. It's marked P-90. It was marked previously.

THE COURT: It is.

MR. KLINE: I'm sorry. I'm going to display it. Thanks, Mr. Murphy. I have a lapse in brain cells this morning.

BY MR. KLINE:

Q. Let's look at the exhibit. We have Dr. Jensen dictating the operative note. If we can look at the bottom of the page, we can highlight it and quickly see it. It's electronically signed by Dr. Jensen, as well.

We know that this procedure was done for bilateral, meaning both sides, correct, sir?

A. Yes, sir.

Q. Gynecomastia?

A. Correct.

Q. And the procedure was bilateral gynecomastia correction, bilateral nipple-sparing mastectomy; is that correct?

A. That's correct.

Q. Explain to the Members of the Jury what is this procedure called a bilateral nipple-sparing mastectomy, please.

A. So the nipple -- in a mastectomy, the nipple could be removed because that's an integral part of the breast tissue or it can be spared. And in this instance, it was spared so that his breast looks normal, and if you'd like, I can draw an illustration of it with the Court's permission.

Q. I think we're going to see it with the photos.

A. Okay. That's fine.

Q. I think we'll be okay. I'll demonstrate it with the photos.

A. Fine.

But, in essence, what happens is the nipple is lifted up and the breast tissue is removed sharply. I believe that, yes, he talks about sharp dissection with the scissors, so he describes cutting out the breast tissue from plane just

beneath the nipple down to the pectoral muscles.

Again, you can feel your pectoral muscles by going like this and pinching. That mass in your armpit is your pectoral muscle. It travels right down your chest wall to the midline underneath your breast.

So he lifted up the nipple, carved out the breast tissue, that was the operation.

Q. I'm going to take you up on your offer, sir. Can you briefly come down, with the Court's permission?

THE WITNESS: May I, Your Honor?

THE COURT: Sure.

(Pause.)

THE WITNESS: Can everybody hear me? So I'm going to draw you a view from the front first to orient everybody.

That's the nipple-areolar complex. Underneath it, this is the left -- excuse me, the right side. So you have pectoral muscle, which are fibers coming like this to the middle underneath the breast. Okay.

And then this is the surface, the breast mound, we're going to put in blue. So this is breast tissue, and I'm just going to

depict it in blue.

So the operation proceeds in the following way, and I'll draw you two views from the front and from the side so you get the three dimensionality of it: So if we look at the nipple-areolar complex, what was done was an incision was made from this position all the way over to this position.

BY MR. KLINE:

Q. The green is showing the incision?

A. This is the incision. This is my scalpel is green, okay. Then using my scalpel, I lift this lower half of the nipple up like a trapdoor, so now if I show you the side view, so this is the breast from the side and, again, we have breast tissue all here and chest muscle, pectoral muscle, there.

What's done is here's our incision point right here, so now we have made our incision and the nipple is lifted up in this direction, out, okay.

So there's access through this point to the breast tissue, which is, again, in blue. And taking the scissors, we can cut out the breast tissue, leaving the blood supply to the nipple intact coming from the skin above. And removing it,

as Dr. Jensen describes in his note, talks about the pectoralis fascia and cauterizing, meaning stopping bleeding, from down here. So this mound is removed and pulled out through that opening.

Does that make sense, Mr. Kline?

Q. Yes. And, sir, this is the procedure which is described in the operative note; is that correct, sir?

A. That's correct.

Q. And what you've described for us is an accurate depiction; is that correct, sir?

A. I believe that's correct.

MR. KLINE: And we'll mark it as Exhibit 93.

THE COURT: Ninety-four.

THE WITNESS: To the jury, I've a done the same operation, which is why it's pretty straightforward to draw the picture.

MR. KLINE: Thank you. If I can have you resume the stand.

BY MR. KLINE:

Q. Now, with Exhibit 94 marked and with this in mind, this doctor created a series of postoperative photos, correct?

A. Correct.

THE COURT: Let me just -- I hate to do this all the time. I'm at 93. So I did say 94, but it looks like I'm at 93. Do you have a 93 that I may have missed?

MR. KLINE: Ninety-three, they tell me, is the op note.

THE COURT: No, we didn't do that because that was marked as 90. Take 93 out. The drawing is 93 now, okay?

MR. KLINE: Yes.

THE COURT: I'm sorry about that, but I really have to keep track of this.

MR. KLINE: I have marked the drawing as 93, not 94.

- - -

(Whereupon, Exhibit P-93 was marked for identification.)

- - -

MR. KLINE: Now, I just want to get my photos, and we may need to use the elmo, or do we have them scanned? Okay. We're making another copy out of the back office here.

THE COURT: I see that.

MR. KLINE: It ain't easy.

In fairness to the lawyers, Your

Honor, both on the other side and who are working with me, I changed my mind and wanted to use additional photos.

THE COURT: Okay.

MR. KLINE: So it's all on me.

(Pause.)

BY MR. KLINE:

Q. Doctor, you're going to see them up on the screen.

MR. KLINE: Your Honor, here's the copy here. Mr. Murphy, do you want a copy? Do you have them?

MR. MURPHY: I don't know.

MR. KLINE: There you go.

THE COURT: I'll look at them on the screen. I'll get a copy at some point.

MR. KLINE: I apologize to everyone. This is too long and cumbersome. I apologize.

BY MR. KLINE:

Q. We know what the preop photos looked like. There are postop photos. Let's walk through them.

MR. KLINE: Exhibit number for the group of postop photos will be?

THE COURT: Ninety-four.

MR. KLINE: Ninety-four. Should we

call them (a), (b), (c), (d), and (e) because I'm going to run through them quickly? I want someone to tell me how to do the housekeeping.

THE COURT: That's good.

MR. KLINE: Ninety-four is the first photograph. It's marked PH001, Mr. Cory Smith, are you ready with us, too? I'm going to take them in order.

- - -

(Whereupon, Exhibit P-94 was marked for identification.)

- - -

BY MR. KLINE:

Q. Okay. What do we see there, sir?

A. What we see is a postoperative photograph of Tim's, looks like, his right breast. We know it's postoperative for several reasons.

If I may use the pointer again? These paper tapes are called steri-strips and they help support the incision which corresponds to the -- if I may, Mr. Kline?

Q. I'm getting out of the way.

A. I want to borrow my drawing for a second.

Q. Okay. I thought it was in the way.

A. Over there is fine. I'm sorry.

Just for the jury's understanding again, so this line, this green line, that I drew corresponds exactly to where those paper tapes cover the incision.

The other point that I would bring out is that this discoloration is blood pigment dissecting through the areas that were elevated by Dr. Jensen, so that tells me the extent of the breast tissue. You can see a little bit of a blush of that color here. This looks almost like the kind of line we draw as plastic surgeons to outline the resection. So that's consistent with the preoperative photograph with the amount of breast tissue that he removed.

Q. I'm looking at P02, we have a bunch of these to cover. Let me just display that.

That is a side view; is that correct?

A. Correct.

Q. So we see swelling there, as well?

A. Correct.

Q. What's the medical term for black and blue?

A. Ecchymosis.

MR. KLINE: Let me look at P03, which is a better photo, it's a straight-on photo. Can we zoom in on that, please, sir, Cory, on

each one of them, so we can see what we're looking at?

Thank you, sir.

BY MR. KLINE:

Q. What are we looking at briefly, sentence or two?

A. Same thing, paper tapes, steri-strips on the incision, discoloration corresponding to the extent of the dissection.

Q. P04 is another photograph, sir?

A. That may be a day or two later because the discoloration has resolved a bit.

Q. P05 might be a good one to see what's happening now. What is P05?

A. That looks like a photograph taken by Dr. Jensen demonstrating both breasts with the steri-strips intact. So it's taken after the surgery, and you can see that the nipple-areolar complexes are alive, they're viable, they're well perfused. Again, the swelling and discoloration are resolving.

Q. What are those marks on the bottom there? Is that where the breasts used to be?

A. Right there?

Q. Yes.

A. That's what's described as the inframammary crease. Under the microscope, the histology of that would be the skin changes from breast skin to abdominal wall skin. It's one of those things that we do have to learn when we study histology and pathology.

Q. What is the name of the fold that is underneath the frame?

A. It's called the inframammary fold. It means the fold beneath the breast. It's, obviously, important for women, but men have one, too.

Q. Now, P06 shows a resulting photo. And I see the nipple, sir. Would you tell us what we're looking at there?

A. So a couple things. First of all, this is the incision which is now a scar.

THE COURT: Where is that, Doctor, right?

THE WITNESS: Right there is a scar.

THE COURT: Underneath?

THE WITNESS: Right at the margin between the areola and the normal skin.

THE COURT: Okay.

THE WITNESS: Corresponding to that line right here, that's that line between the

areola and the normal skin.
BY MR. KLINE:
Q. For the record, you are referring to not only P6, which is displayed to the jury, but also you are making reference to your drawing of Plaintiff Exhibit 93, correct?
A. That's correct. And you can see a little bit of spreading of the scar here where the tissue is not normal skin, but it's a little spread scar.
Q. Okay.
A. And then there's a little saucerization, meaning that the -- now there's no breast tissue here, so then the nipple-areolar complex has collapsed somewhat in that area.
Q. Have you seen in the records that that became a permanent condition?
A. Yes.
Q. And let me go to P10, moving ahead as part of the -- as part of P-93. If I can zoom in on the right side of the nipple again.
A. That's the patient.
THE COURT: That's left.
BY MR. KLINE:
Q. Is that what you were describing earlier?
A. So there's the scar that's a little spread

tissue right there. The scar goes from the 9 o'clock position over to the 3 o'clock position, and you can see this discoloration and indentation of the areola. There's also a somewhat similar kind of finding on the left side.
MR. KLINE: We can take that down and move back to some medical records, sir?
THE COURT: Mr. Kline, just let me make something straight, for the record.
What we were going to do is 94(a), (b), (c), (d), and (e), which was fine, but we did, 001, 002, 003, 4, 5, 6 and 10.
MR. KLINE: I believe that's correct.
THE COURT: So that's consistent with how you've marked the other photos.
MR. KLINE: Yes, and it's also consistent with what the records were. Sorry to switch it up on you.
THE COURT: It's all right. I just want to get it straight.
BY MR. KLINE:
Q. Now, if I may, just for record purposes, go back to the op note, which even I now know is Exhibit 90.
MR. KLINE: If we can display it one

more time and display the part that says "description of procedure."
BY MR. KLINE:
Q. If I can go up above to a fact that I asked that I just need to confirm, anesthesia general with endotracheal intubation; is that correct?
A. That's correct.
Q. And the findings, if I can go to his findings, "discrete breast masses bilaterally, right slightly greater than left"; is that what you see, as well, sir?
A. I do.
Q. "With slightly expanded nipple-areolar complexes in otherwise non-obese habitus." Do you see that?
A. I do.
MR. KLINE: And if Cory would just highlight "non-obese" for me for a moment.
BY MR. KLINE:
Q. Non-obese habitus, what is habitus, sir?
A. That's the body shape.
Q. And then under description of the procedure in more surgical terms, did the surgeon describe what you described in more lay terms, if you will?
A. That's exactly correct.

Q. All right. Now, back to the next point.
In addition to the records that the jury has seen relating to Dr. Jensen, as well as his assistant, Dr. Lao, was this young man seen by a surgeon in consultation who didn't operate on him?
A. That's correct.
Q. And I'd like to mark as record --
MR. KLINE: We're marking as P-95 the records of Doctor -- actually, we're going to mark two different. They were subpoenaed twice and produced twice, so let's mark them as 95 and 96.
- - -
(Whereupon, Exhibits P-95, P-95(a) and P-96 and P-96(a) were marked for identification.)
- - -
MR. KLINE: Would you, Chris, for the record, identify dates of production of those two records?
MR. GOMEZ: Sure.
Your Honor, P-95 is April 22nd, 2014.
P-96 is December 5th, 2013.
MR. KLINE: I'm marking as P-95(a) a record of a physician.

BY MR. KLINE:
Q. Is the physician here Dr. Mixter?
A. **Roger Mixter, M-I-X-T-E-R.**
Q. And who do you understand Roger Mixter to be?
A. **He is a plastic surgeon in Milwaukee.**
Q. Did this plastic surgeon evaluate this young man in -- back in 2011?
A. **Yes.**
Q. And have you reviewed records relating to 5/25/11?
A. **Yes, I have.**
Q. Did you read the deposition of Dr. Mixter, as well?
A. **I did.**
THE COURT: There's no more 96. It's 95(a) now?
MR. KLINE: No. I misspoke. You see, what happened, Your Honor, it's a little confusing. Dr. Mixter's records were requested twice.
THE COURT: I see that.
MR. KLINE: And they were produced twice. And we have two different records, which I'm going to go over with the witness.
THE COURT: Oh, okay.

MR. KLINE: And Dr. Mixter was examined about it and, for whatever reason, it is what it all is, but I want to show the records that were produced and ask this doctor if he reviewed them.
THE COURT: So what is 95(a)?
MR. KLINE: 95(a) is a note within --
THE COURT: So it's the first page with a note?
MR. KLINE: Yes.
THE COURT: Of these records, the first page where there's something handwritten?
MR. KLINE: Bates number of 008 on the bottom.
THE COURT: That's it. So that's 95(a).
All right. I understand.
BY MR. KLINE:
Q. And P-95 -- so I'm now displaying to the jury P-95(a), which is what, sir, as you've read and understand this record?
A. **It is my understanding that this is the note written by Dr. Mixter when he saw Tim in consultation on May 25, 2011.**
Q. And does his record make a diagnosis of

gynecomastia?
A. **Yes.**
Q. Now, in addition to you, sir, how many surgeons in the course of the treatment that you know have reached a diagnosis of gynecomastia?
A. **By my count, we have three.**
Q. Three physicians so far?
A. **Yes.**
Q. Okay.
A. **In addition to myself.**
Q. And we haven't gotten to the pediatrician's records yet?
A. **That's correct.**
Q. And does this record, which was produced to us, also mention the word "Risperdal" in it?
A. **It does.**
Q. And would you tell us what the note says, sir, as both you read it and as you know the doctor read it in his deposition?
A. **Yes. It reads, "Tourette's syndrome plus gynecomastia now with gynecomastia, probably from previous Tourette's meds."**
Q. Let me -- and let me just stop for a second. Let's highlight that, "probably from previous Tourette's meds." Do you see that?

A. **I do.**
Q. Do you remember back in your discussion with Mr. Murphy the discussion that you had with him as to whether physicians like yourself make a causal connection, think in terms of what was -- what's going on here?
A. **I do remember that discussion.**
Q. And then there's this notation that says, question mark, Risperdal, question mark, correct?
A. **Yes.**
Q. And his records were from 2000 -- this is a record from 5/25/11, this would be about a year before he actually had the surgery, correct?
A. **That's correct.**
Q. Just to fill it in, there's actually a second record that he produced, December 5th of 2013. And his December 5th, 2013, production of documents to the lawyers, to the copy service that requested them is now marked as P-96, and this same document is going to be marked P-96(a), the photo that pertains to this day is marked P-96(a), and I'm marking that as Exhibit 96(a) Bates stamp 4 in that document.
And this document, if I can show it to the jury says simply "Tourette's syndrome" -- would you read the operative words on the front -- under

medical?
A. It says "Tourette's syndrome, plus gynecomastia, now with gynecomastia. Probably from previous Tourette's meds."
Q. Okay.
A. I think we lost your microphone.
Q. I will get my microphone.
So this is the -- Dr. Mixter, did he operate on the patient?
A. He did not.
Q. And that's that document. Okay, next.
I would now like to move back in time --
THE COURT: Do you think this is an appropriate place to take a break or do you have -- take our lunch break? It's up to you. You tell me.
(Pause.)
MR. KLINE: I won't argue. When we come back, we'll be moving to the records of previously -- the earlier records, so yes, this is a good time.
THE COURT: Okay.
All right, ladies and gentlemen. We're going to take our luncheon break now.

I'll ask you to come back at 1:15.
Remember, don't talk with anyone among yourselves or anyone else. If you see anything in the papers or what have you, just ignore it. Enjoy your lunch.
- - -
(Whereupon, the jury was excused from the courtroom at 12:01 p.m.)
- - -
(Whereupon, a luncheon recess was taken at this time.)
- - -
(Whereupon, the afternoon session was reported by Maureen McCarthy.)
- - -

C E R T I F I C A T I O N

I hereby certify that the proceedings and evidence are contained fully and accurately in the notes taken by me on the trial of the above case, and that this copy is a correct transcript of the same.

Danielle O'Connor, RPR, CRR
Official Court Reporter

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(THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY ANY MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR SUPERVISION OF THE CERTIFYING REPORTER.)

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IN THE COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

01:27:46PM

IN RE: RISPERDAL LITIGATION

TIMOTHY STANGE, Plaintiff VS. JANSSEN PHARMACEUTICALS INC., JOHNSON & JOHNSON AND JANSSEN RESEARCH & DEVELOPMENT, LLC, EXCERPTA MEDICA, INC., AND ELSEVIER, INC., Defendants	APRIL TERM, 2013 NO. 1984

Tuesday, October 27, 2015

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City Hall, Courtroom 275
Philadelphia, Pennsylvania

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B E F O R E:

THE HONORABLE KENNETH J. POWELL, JR.

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TRIAL - PM

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Maureen McCarthy, RMR, CRR

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(Continued) Direct Examination of Dr. Solomon - 10/27/2015

THE COURT: Good afternoon, Dr. Solomon.

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(Continued) DIRECT EXAMINATION

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BY MR. KLINE:

Q. Dr. Solomon, I'd like to go now chronologically forward, and in the same place but I want to move it forward.

You reviewed the medical records and included in the medical records are the pharmacy records; correct?

A. Yes.

MR. KLINE: I'm marking the pharmacy records as the next P number.

These records, Your Honor, contain Bates numbers in the records which would be our reference points within the P-marked document.

BY MR. KLINE:

Q. You told us earlier that you reviewed the records of Dr. Mueller, the pediatrician?

A. I did.

Q. And you reviewed the records of Dr.

(Continued) Direct Examination of Dr. Solomon - 10/27/2015

Kovnar who we heard in this courtroom.

You reviewed those as well?

A. Correct.

Q. Do you have your report in front of you, sir?

A. Actually, I don't.

Q. You don't have it?

A. I thought I did. I do not.

Q. We'll grab one quickly. We have it marked as P-87. Give me a second to get one in front of you, sir. P-87.

MR. KLINE: The Dr. Kovnar records.

BY MR. KLINE:

Q. The Dr. Kovnar records are previously marked P-59 and you reviewed those?

A. Correct.

Q. You can feel free to refer to your report, sir.

The starting of treatment of Risperdal was on what date, sir?

A. February 7, 2006.

Q. And I would like to show some of the records marked as the pharmacy records, P-97. We will display them.

(Continued) Direct Examination of Dr. Solomon - 10/27/2015

Tim was on the Risperdal. Did you learn the dosage?

A. I did.

Q. Did you learned that both from the pharmacy records as well as from the physician's records?

A. From Dr. Kovnar's records in particular, that's correct.

Q. Without searching for it, do you have a recollection, generally, of the dosage that he had was on during the period of time from '06, '07 through '08?

A. It varied, but started out, as I recall, at .25 milligrams and rapidly went to .25 milligrams twice a day and, at times, went to .5 milligrams twice a day.

Q. In the various points during the pharmacy records -- I just want to display some of the pharmacy records. I'm looking at a record of 306, which I am going to display. It is Bates number TMSWPC 0041; and if we look on the top, your eye will go to Risperdal .5 milligrams.

Do you see that?

A. Yes.

Q. You're familiar with the fact that these precipitations were made and then they were filled.

Is that correct?

A. Correct.

Q. Did he continue to fill Risperdal as a name brand product through August of '08?

A. That's correct.

Q. TMSWPC 0027. We'll see that in 8-08,^ he went to the generic form which, of course, is listed as Risperidone, not Risperdal, namely, the brand name.

Is that correct?

MR. MURPHY: Objection. May I approach?

(Sidebar as follows:)

MR. MURPHY: I don't know how much you're going to use these pharmacy records, but if your going to continue, I ask that you have Cory mask out the cost.

MR. KLINE: Okay. I won't even display them. As far as I'm concerned we're not class cost. We're not interested in the cost. ^.

(Open court.)

BY MR. KLINE:

Q. One more I believe that we know. I'm going to Exhibit Number 0036?

THE COURT: That's a Bates number?

MR. KLINE: Yes, Bates number within Exhibit Number 97. The date appears to be 3-6-08. I think we've cured the issue.

BY MR. KLINE:

Q. And that appears to be the last time that it was prescribed as Risperdal.

Does that conform to your understanding?

A. Yes, it does.

Q. 3-6-08?

A. Yes, he was getting .25 milligram tablets at that point.

Q. The Risperdal, I think you report in your report, as you understand it, he was on it from 2-06 to 3-08, the Risperdal as a name brand product?

A. That's correct.

Q. When he was on the Risperdal -- did you review the mom's testimony relating to what

she saw and observed in 2006?

A. Yes.

Q. Did you consider that in the formation of your opinion?

A. I did.

Q. Sir?

A. Yes, I did.

Q. I'd like to show you it. We'll give a copy to counsel as well. Page 39.

(Side bar as follows:)

MR. MURPHY: At this point, he wants to get the doctor to read this with the testimony that is in the deposition and ask him did you read this?

Mom is here. Mom is going to testify. Mom is in the courtroom. The simple lie. If you let her testify as to what, in fact, she saw, that should not come through.

MR. KLINE: Here's the problem. I can do it one of two ways. I can say, I want you to assume that mom is going to testify.

THE COURT: You can do it that way.

MR. KLINE: The other way I can do it, which I thought was more sensible and also fair game, is to say, among the materials you read -- he's an expert -- did you review the mom's testimony? And is this a piece of information you relied upon?

I'm not confronting him with anything. I'm simply asking him what is the documentation for your opinion and what pieces of documentation of his opinion that the to mom has said she was breast in '06. ^

So my point is to say, is this some material that you reviewed and did you consider this in reaching your opinion? I think it's appropriate to do it that way.

MR. MURPHY: We're hearing from him and mom again?

THE COURT: An expert's testimony cannot be considered cumulative with a lay or fact witness, because he has to say what he bases his opinions on, and

that's part of it, he gets that in, notwithstanding the fact that it's rank hearsay otherwise, but not through him.

MR. MURPHY: If we'll hear it twice, we'll hear it twice.

THE COURT: She's going to say it. You can anticipate that, but he has a right to also ask this doctor. So I'm overruling the objection.

(Open court.)

BY MR. KLINE:

Q. Among the many documents you reviewed, you reviewed the mom's testimony?

A. That's correct.

Q. That was taken January 7, 2014?

A. Yes.

Q. On page 39, which we'll display to the jury, I will ask you if you considered the following in reaching your opinion here.

He was asked the question on page seven, it starts: Did you first notice Timothy's breast growth? Down to line 15. The questions were asked by counsel for Janssen: Did you first notice Timothy's breast growth?

THE WITNESS: I would say yes.

QUESTION: From Janssen: When did you notice it?

ANSWER: Jan 7, 2014 as he started gaining -- I mean, as he gained weight, he just got bigger and everything. Somewhere in the first half a year again in '06.

Do you see that, sir?

A. I do.

Q. Did you consider that in rendering your opinion, at least as part of the information you had?

A. Yes, I did.

Q. Now, did there come a point in time where Tim had stabbing pain in the breast?

A. Yes, there did.

Q. Would you tell the members of the jury the significance in the development of gynecomastia and, as a breast surgeon, tell the members of the jury the significance in the development of gynecomastia of symptoms, including pain.

A. So pain, stabbing pain, tenderness,

irritation of the breast are all things that can occur as breast tissue grows in an abnormal or pathological fashion.

Q. Is it one of the pieces of information that you considered in rendering your opinion here today before the jury?

A. Yes, it is.

Q. Is the mom's testimony something you've considered?

A. Yes.

Q. Are the photographs something you've considered?

A. Yes.

Q. Now, there is a record dated 8-9-07, which we will mark as Plaintiff's Exhibit 98.

For the Court and jury's benefit, this is a record from Dr. Mueller's records, medical records, and we will display it to the jury.

First, now we have the top of it, which says Cedar Mills Medical Group in Cedarsberg, Wisconsin. Patient name is Tim Stange.

If we can look at the various addendum notes, they are acknowledged and signed by David G Mueller.

Do you see that, Doctor?

A. I do.

Q. He is the pediatrician?

A. Yes.

Q. Now, in the very top, we'll take this piece by piece, and enlarge certain areas, the full thing, please, Mr. Smith.

Then the stabbing pain piece, just if I could, please. I'd like collar as well.

Can you get me the date up there as well, sir? The date here is 8-9-07, and it's a phone call from mom, and it says: Patient complaining of stabbing pain?

A. Yes, that's what it says.

Q. In his left nipple about one to two times per week.

Do you see that?

A. Correct.

Q. And as an expert here, what is the significance of this? It goes further, and I'll ask the significance.

No redness or signs of inflammation, normal during puberty. That's a question the mom was asking, or should he be seen?

And let's just go through the record and then I'll ask you how you considered this and for what purpose.

THE COURT: If you would take that down, please, Cory, and show us the next part.

BY MR. KLINE:

Q. Can have normal swelling of tissue in that area, occasionally tender but probably okay to observe. Appointment if increased pain, redness, discharge, et cetera. Happy to see any time of concern, David Mueller. That's August 9 at 12:13 central daylight time.

Next, he says, also he's listed as JJR patient. In general, those can go to her box. Next, message left for mom to call back. Next, mom advise she will reevaluate. Mom says she had asked Tim previously, had asked previously that Tim be changed to DGM's patient.

Do you see that indication?

A. I do.

Q. Did you consider the stabbing pain as

part of the opinion which you rendered here as to when the gynecomastia developed?

A. Yes, I did.

Q. Did the gynecomastia develop when he was on Risperdal, sir?

A. Yes.

Q. Did it develop prior to this period of time from what you've seen by way of report as well as by way of photograph as now by way of symptom?

A. Yes. That's correct. This is a process. It's not an overnight explosion. So we have a progression with several points of data to confirm the diagnosis and the progression and the relationship between the taking of the Risperdal, the offending agent, and the end result, the growth of the breast tissue.

Q. Now, can you, based upon what you've seen with your own eyes, sir, in the photographs in the pool, would it be reasonable to say this boy didn't have gynecomastia at any time prior to 2009, '10 or '11?

A. It would not be reasonable at all to say that. He clearly had it.

Q. Would it be reasonable to say no doctor made the diagnosis and, therefore, he didn't have gynecomastia, golly, he was seen by all these doctors, Dr. Solomon?

MR. MURPHY: Objection.

THE COURT: I'll sustain the objection to form.

BY MR. KLINE:

Q. Dr. Solomon, recognizing that he had been seen by a pediatric neurologist, a pediatric pediatrician, would it be reasonable, in your view, to say, well, the doctors didn't make a diagnosis in '06, '07, '08, therefore, the gynecomastia didn't appear back then.

Would that be reasonable?

MR. MURPHY: Objection.

THE COURT: Sustained.

BY MR. KLINE:

Q. Do you hold that opinion, sir?

MR. MURPHY: Same objection, Your Honor.

THE COURT: I'd ask the question as a hypothetical. Then it can be leading if you make it a hypothetical.

BY MR. KLINE:

Q. I want you to assume that no physician had made a diagnosis until some time in '09.

If you assume that, would it be reasonable to assume that the gynecomastia didn't exist before '09?

A. No. The gynecomastia clearly existed before '09. Nobody made the diagnosis until that point in time.

Q. Would you expect a pediatrician neurologist to make this kind of diagnosis?

A. Never.

Q. Would you expect, because someone is putting a stethoscope in someone's chest, that they would make the diagnosis?

MR. MURPHY: Objection.

THE COURT: Sustained.

BY MR. KLINE:

Q. Is a stethoscope examination the same thing as a breast examination?

A. Absolutely not.

Q. In order to make a diagnosis of gynecomastias, what kind of examination needs to be done?

A. The patient has to be undressed. The patient is examined standing and/or sitting. Some physicians will actually have the patient lie down; and as I mentioned, what I have the patient do is press on their hip to accentuate the pectoral muscle and help delineate the tissue.

But there are a number of maneuvers, and some physicians talk about what's called a pinch test. Regardless, there are a number of maneuvers that are specifically utilized to make the diagnosis.

If you're routinely listening to heart and lungs, you're not examining the breast. You're focused on what's between your ears when you're listening, quite frankly.

Many of us listen with a stethoscope with our eyes closed, as a matter of fact. I know I do.

Q. Referring back to P-91, sir. If an examination had been done any time prior to 6-09 but after June of '07, would a diagnosis of gynecomastia have been available to be made at that time?

A. Yes.

MR. MURPHY: Objection.

THE COURT: Sustained.

BY MR. KLINE:

Q. Now, a diagnosis was made finally; correct?

A. Correct.

Q. Is that diagnosis, in your view, consistent with the findings of the surgeons who saw this patient later on in 2011 and 2012?

A. Absolutely.

Q. In fact, in 2009 -- we'll display to the jury and hear from mom tomorrow -- Exhibit 99, you're privy not only to the record but you were privy to Dr. Mueller's testimony interpreting his handwriting; correct?

A. Yes.

Q. I'd like to show you the record, which is dated June 16, '09. We will display it to the jury. It is marked as 99. It has a Bates number on it TMSCMM 149.

Right in the middle of the page, under Physical Examination, is there a diagnosis

that's made, albeit hard to read, but interpreted by the doctor for us, sir?

A. Yes.

Q. And what does the doctor -- what does Dr. Mueller say as to what he diagnosed?

A. Gynecomastia.

Q. And putting you aside, sir, this is doctor number one who has now diagnosed gynecomastia in this young boy?

MR. MURPHY: Objection.

THE COURT: I'll overrule the objection.

A. By my count, aside from me, it's physician number four.

Q. In the course of the treatment; correct?

A. Correct.

Q. I'd like you to give us some more explanation based upon what you saw in the photographs of June of 2007, the process that's involved here in terms of you mentioned it doesn't explode overnight.

Would you give us just some additional explanation there, sir?

A. Sure. The best analogy I can use that

everybody will be familiar with is a baby; meeting of an egg and a sperm, one cell that divides and divides and divides. The next thing you know, we're all sitting here in court.

The body is basically a replication of that process. Whether it's good pathology or bad pathology, something that's an overgrowth or a cancer, it's all the same concept, which is the cells have to divide. Until they reach a critical mass, we don't appreciate them as observers.

If I'm given the opportunity to look at something, I may appreciate it before you, the jury, because I have a trained eye, but in truth, it's going to take time for something to develop.

It's not, what we call, an all or none phenomenon. It's not absent one day and there the next. It's a gradual growth process.

Q. You've reviewed studies related to Risperdal.

Is that correct, sir?

A. Yes.

Q. You've reviewed Janssen internal documents?
A. Yes.
Q. Have you reviewed Table 21?
A. Yes.
Q. Have you reviewed the various Findling drafts?
A. I have.
Q. Have you reviewed the documentation in what we here know as Risk 41 and the gynecomastia rates?
A. Yes.
Q. Have you reviewed recent literature as to the chances of getting gynecomastias if you're on Risperdal versus not on Risperdal?
A. I have reviewed that literature.
Q. What's your understanding there?
A. You're five times more likely to get gynecomastia if you're on Risperdal than if you're not.
Q. Did you take all of this into consideration in rendering your opinion as to the cause of the gynecomastia and the timing of the gynecomastia here, sir?

A. The answer is yes to both of those questions.
Q. You mentioned gynecomastia.
Is gynecomastia associated with prolactin elevation, sir?
A. Yes.
Q. Is that something which you saw in the Janssen internal documents that we supplied to you?
A. Yes.
Q. In order to see those documents, did you need to sign the confidentiality agreement so you wouldn't go out and tell somebody or write about it?
A. I did sign such an agreement and was requested to do so.
Q. And tell us if you would, what's your understanding of Risperdal and how it relates to the rise in prolactin and cause of gynecomastia as it relates -- its association and correlation with gynecomastia as it relates to this case.
MR. MURPHY: Objection. Your Honor.
BY MR. KLINE:

Q. Doctor, tell us, if you would, what is your understanding of Risperdal and how it relates to the rise in prolactin and cause of gynecomastia, its association and correlation as it relates to this case?
THE COURT: Overruled.
A. If I may, that's a several-part question. It takes a few minutes for me to answer it.
Let's break it down. First, I think you asked me the relationship between Risperdal as an agent creating a rise in prolactin, and that's very well-documented.
Prolactin is a hormone secreted by the pituitary gland. I'm not sure if the jury heard about all of this. Pituitary gland is a gland that sits in your brain, and we know Tim's pituitary was normal because he had an MRI before he started on the medication.
I think that's important, as we talk about this process.
So Risperdal is well-known to stimulate the production of this hormone, prolactin. Prolactin has several ways it acts on the breast.

It will cause the breast to grow. Then, in women -- and in men, it can do this too -- it will cause the breasts to secret milk. That's the direct effect.
There's also an indirect effect that's discussed, where it suppresses the testosterone, which boosts estrogen, which also acts upon the breast almost synergistically, meaning, the two together are a bigger punch than either one alone.
So if you look at the data, what I see, the internal documents are also published, but the internal documents break down in a graphic way, patient takes the drug. Prolactin goes up and typically, at a period after some weeks of exposure to the drug, patient starts developing breasts.
This is reproducible. Things that are reproducible in science are -- that's how we make facts, you know, we know that the earth goes around the sun because it continues to go around the sun. It's a reproducible fact.
There are table after table of these kinds of events. This is consistent with the

history of Tim, where he was given the drug in '06. Mom talks about change -- talks about changes in '06. We have photos in '07 that are certainly consistent with gynecomastia, even though no one had made a diagnosis. It's plain as day.

This is all consistent that that, plus the history, plus the subsequent finding of breast tissue, is all consistent with the fact that Risperdal was the insinuating agent to elevate prolactin, which has a direct effect on breast tissue which gave Tim gynecomastias.

I think I answered that.

Q. I want to ask you a corollary and hit my loose ends and get documents and finish up.

Do you need a prolactin level to render your opinion here?

A. No.

Q. Tell the jury why.

A. Because in anywhere from 25 times the control to up to 80 some percent of patients, depending upon the doses of Risperdal, prolactin goes up. In all the agents of this class of drugs, Risperdal is the greatest

offender at increasing prolactin.

So as part of my job as a physician is to take a set of the facts and come to a conclusion. If I can get an ancillary test -- and it's easy to get, you can certainly get it -- part of the thing that most of us are taught is it's not going to change our opinion. It's not even essential to do it.

Here, we have a young man on a drug known to cause prolactin elevations who has gynecomastia.

On top of that, there's no -- nothing in the package insert that says you should follow it along. Whereas certain drugs, they say you should check a blood sugar, a potassium, those are in that big red book there, the Physicians Desk Reference, package incident.

We can make a diagnosis using our fundamental knowledge as physicians and be absolutely certain that it's a clear correlation between taking the drug, prolactin, breast growth.

Q. Is there something in medicine, sir, called a differential diagnosis where you do

every day of the week in the office?

A. Every day of my life. That's correct.

Q. Are you doing anything different here in terms of a diagnosis based upon the facts and the evidence that you have in front of you?

A. I'm doing exactly that process here for the Court.

Q. Now, sir, do boys get gynecomastia anyway in puberty?

A. Some.

Q. Is that the explanation here?

A. No.

Q. Tell the jury why not.

A. To use an old quote, to help it make some sense, when you hear hoofbeats, don't think zebras.

So yes, there's something called pubertal gynecomastia. The time cause is self-limited. That's the majority of patients that I see as a plastic southern who are adolescents, boys with breasts.

We encourage the family to be patient, because we know that pubertal gynecomastia will resolve with time and age. The breast

tissue as the hormonal environment changes in puberty. That stimulus goes away, the breast tissue goes away.

That's the vast majority of puberty gynecomastia. A small percentage may exist. But in a circumstance where you have a patient who took a drug that's known to be an offending agent, developed breast tissue in a reasonable time course in relation to that agent, lost his pubescent changes, his weight sort of went up and went down, but the breast tissue remained.

And the breast tissue, as I have said before, was dysmorphic, in excess of his body shape. The cause of his gynecomastia was the drug, without a doubt in my mind.

Q. Weight gain, you've seen patients with gynecomastia and weight gain?

A. Yes.

Q. Are you familiar, in fact, with a major study on gynecomastia in children and antipsychotic drugs where weight gain was discussed?

A. Yes.

Q. And how does weight gain figure into all of this with Tim? What was going on with his case in terms of the weight gain and the eventual gynecomastia diagnosis?

A. If we're thinking about the same study, I recollect a study in which the discussion was had that weight gain can mask gynecomastia. That's certainly something, again, I have seen in practice, but here, we have a boy who gained weight, lost weight, the breast tissue remained.

The gynecomastia might have been masked, but it was always there. A point that I try to make to patients when I operate on them about different things about their bodies, I have patients whom I do breast reductions, and they come in and are happy with my breast, but they say, what did you do to make my tummy so big?

And it's all a matter of perspective. I didn't do anything to make the tummy big. The breasts happened to be large enough that they obscured their tummy. We all suffer from a lack of perspective.

The longitudinal view that I have as a plastic surgeon and the reason we take pictures, for example, is to maintain the more objective perspective and see those changes over time.

Q. Just very briefly. Something that I had started before the lunch hour.

In terms of weight, just to add something here, in the records of Aurora Health, Tim was -- I want to get these records out. The first record is P-100, which is TMSAAH 0020. I want to make a brief chart. There are many weights in the chart. That's for sure, but can we display that to the jury?

On 2-7-06, his height was 4'8" and his weight, 110 pounds?

A. That's correct.

Q. My next exhibit number is 101, which is TMSCMM 0150. Exhibit 102, I think I can keep this straight.

On 6-2-08, he was 5'5", 166 .5 pounds. Is that your understanding?

A. I think I see 5'6". The weight is the same.

THE COURT: 66 inches is 5-6. I can't see the weight on this. What did you say it was?

MR. KLINE: 166. Certainly says 166 and a half.

BY MR. KLINE:

Q. The next one is 6-16-09. He was 5'6" and 152 pounds.

Is that your understanding, sir?

A. Again, I'm seeing 5'7", 67 --

Q. 103. The date of 7-02-12 at or around the surgery, he was 5'8" inches and 162 and a half pounds.

A. That's correct.

Q. There are many other data points?

A. Yes.

Q. We can sit here and go through 20 or 30 or 40 data points from these various records; correct?

A. Yes.

Q. But in terms of weight gain, he went from 5'8" to 5'6" in terms of height and 110 to 166 in these -- from '06 to '08 in the two years and four months he was on Risperdal; correct?

A. Yes.

Q. Then the diagnosis of Dr. Mueller, that finding was on June 16, 2009; correct?

A. Yes.

Q. At that point, he had lost 12 and a half pounds?

Is that correct?

A. Yes.

Q. Maybe 13 and a half?

A. 14 and a half?

Q. 14 and a half.

A. 14 and a half.

Q. Minus 14 and a half pounds.

At this point in time in '09, were there breasts on this boy?

A. Yes.

Q. 6-16-09; and in 6-2-08, were there female breasts on this boy?

A. Yes.

Q. In fact, in some time in '06 and '07, according to testimony and photos, was there gynecomastia in this boy?

A. Yes.

Q. Marking as Exhibit 104, I am marking as

an exhibit the letter dated 7-14-11 of Dr. Jensen to Dr. Mueller.

Do you have it in front of you, sir?

A. I do.

Q. We will display it to the jury. This is the very end of the line here in terms of surgery: Thank you for your referral of a 17-year-old man with gynecomastia and history of Tourette's. Take the first paragraph and pull it out, please, Cory.

The surgeon says to the pediatrician words, as you well know. Do you see that? We'll highlight that and then unhighlight it.

As you well know. Do you see that, sir?

A. Yes.

Q. Tim has no issues with breast growth until a rapid 30-pound weight gain some 30 years ago -- some years ago -- not 30 -- some years ago after being initiated on Risperdal. He was on the medication for two years before discontinuation. As he felt there was no significant improvement, and has actually been off the drug for a year and a half. He lost all of the weight that was associated with

that episode, but with weight loss, there was no resolution of his gynecomastia.

Do you see that?

A. I do.

Q. Dr. Jensen states in next paragraph, you may well be aware that appetite stimulation and weight gain associated with this class of drugs, and I believe the relative rapid gain and endocrinopathy -- what is?

A. Endocrinopathy.

Q. What is endocrinopathy?

A. An endocrine abnormality. A pathology of the endocrine system.

Q. Is that what we have here, sir?

A. That's correct. That's what we talked about a few moments ago when we discussed the relationship between the Risperdal, prolactin levels and the direct effect on breast growth.

Q. In fact, may be related to his gynecomastia. He denies pain but is somewhat bothered by the presence of breast tissue. He and his mother have discussed surgical correction in the past and, in fact, seek my opinion as a second plastic surgery opinion.

Dr. Mixter had evaluated him and said some questions as to the advisability of pursuing under light MAC -- that's monitored anesthesia -- in the office, and I believe his mother shared that concern.

You're aware of that fact?

A. Yes.

Q. And you're aware of the discussions we heard in this courtroom, the mom had with Dr. Kovnar about anesthesia choices?

A. I'm aware of all of that.

Q. In the large paragraph, near the bottom, it says, given this relatively rapid onset of the condition and association with rapid weight gain and the medication initiation, I'm concerned that its lack of resolution represents -- and then he uses a word here -- a pathological process.

We've discussed that; correct, sir?

A. Yes.

Q. You agree with that?

A. Yes, I do.

Q. I have suggested they be removed as excisional biopsies. In this case, I think it

can be performed safely through a -- would you tell me that?

A. Periareolar.

Q. Periareolar approach with direct incision and scissor. We discussed that as well; correct?

A. Yes.

Q. He recommended against liposuction?

A. Correct.

Q. And would you tell the members of the jury what was being removed and why you just couldn't liposuck out this?

A. Liposuction, by its very definition, means lipo, fat suction. So it's suction of fat.

In the patient with significant breast tissue -- and you may recall we talked a little while ago about the fact that the breast tissue is discrete and separate from the surrounding fat.

So Dr. Jensen is stating that he feels breast tissue. It's discrete. It's firm, and it's not going to be able to be removed with sucking out fat because it isn't fat. It's

breast tissue.

So he felt the need to use scissors to cut it out.

Q. Would you explain to the members of the jury, as you understand it, the relationship here -- we see some things in the records -- would you explain to us the relationship here to what's going on with his weight gain to what's going on with his breast growth?

Are they two different processes here fueled by two different things or are they the same?

A. I think the breast growth is ultimately separate from the weight gain. Weight gain, as I said, masked the changes in the breast and certainly, the weight gain is attributable to the Risperdal as well, as far as I know, it does cause rapid weight gain in patients.

But these are two separate but equal, I think is the best way to describe it, processes. You got breast growth being stimulated on the one hand and weight gain on the other.

The proof of it is as he loses the

weight, the breast tissue remains, which means it's not fat; it's breast tissue.

Q. You hold all your opinions to a reasonable degree of medical certainty?

A. I do.

MR. KLINE: Cross-exam.

THE COURT: Ladies and gentlemen, we'll take your afternoon break while they set up for cross-examination.

CRIER: Court is in recess to the call of the crier. Kindly rise while the jurors leave the courtroom.

(Jury panel departs courtroom at 2:19 p.m. until 2:41 p.m.)

- - -

CROSS-EXAMINATION

- - -

BY MR. MURPHY:

Q. I have follow-up questions for you based on the direct examination of Mr. Kline.

First, if I can direct your attention to what was marked as P-98. Do you have that in front of you, Doctor?

A. Yes.

Q. Can we put it up on the screen, please, P-98? And this is the document Mr. Kline visited with you on reflecting Ms. Stange's calling to the office reporting on the stabbing pain.

Do you remember that?

A. I do remember.

Q. And it indicates in the note that this had been going on for some time; right? It says one to two times per week.

A. Yes.

Q. This is something that Mrs. Stange was reporting based upon what Tim had told her.

Can we agree on that?

A. I would assume that to be correct. That's a yes.

Q. Now, is it your testimony, based upon that document, that is, the report of the stabbing pain, that Tim's gynecomastia actually onset before 2007? That is, August of 2007?

A. Well, we have, in addition to this, a photograph.

Q. My question is simple. Is it your

opinion that his gynecomastia started before August of 2007?

A. Before this date?

Q. Yes, sir.

A. Yes.

Q. With regard to the actual diagnosis of gynecomastia, did I understand you to explain to the jury that a full examination is required?

A. That's part of it.

Q. In order to confirm that a male has gynecomastia, that is, to confirm it, there ought to be a physical examination; correct?

A. Again, so, I guess I didn't make this clear, so I'll try and say it again.

The process of creating a diagnosis is multi-step. The first steps are take a history. Do a physical. Other things may or may not be necessary beyond that.

Q. My question to you -- I'll phrase it slightly differently and I think we might be able to get there.

In order to confirm, is it necessary to conduct a physical examination doing

palpation?
A. Let's make it a general rule. In order to make any diagnosis, you have to do a physical exam. Except unless you're a psychiatrist. That's a different specialty.
Q. Fair point. Again, with regard to gynecomastia, if you're going to confirm that there is gynecomastia, you need to do a physical examination?
A. That's the standard in plastic and, I believe, in medicine.
Q. I want to make sure I understood correct to tell the jury that with regard to your opinion that Risperdal caused Tim Stange's gynecomastia, it was not necessary for you to know what his prolactin level was at any given point?
A. I did state that, I believe.
Q. Now, you also told Mr. Kline that part of your opinion or, I should say, your opinion, in part, is based upon your review of certain company documents.
Do you recall that?
A. I do.

Q. Now, in your report that you generated in this case, which is in front of you as P-87, you identify a number of records and depositions that you reviewed; correct?
A. Yes.
Q. Photographs as well; correct?
A. Yes.
Q. But you don't make any reference to any literature or company documents that you relied upon in the course of generating your report or your opinion.
Is that correct?
A. Correct.
Q. When was it that you saw company documents that you rely upon in rendering your opinion today?
A. So as I think you're aware, there are a couple of other matters similar to this where I have had the opportunity to see documents that were secret, I guess is the best word I can use; and I was required to sign this document that basically said to me I had to keep it a secret.
So I'm keeping it a secret until Mr.

Kline asked me.
Q. I appreciate that. What my question is, with regard to this matter that brings us here today, and the report that you generated, wherein you set forth your opinion, when was it that you reviewed company documents?
Because you don't tell us that in your report.
A. Because I'm supposed to keep it a secret. But it was, you know, some time around or before -- this was January of 2015, and I started seeing documents when I was asked to review these matters and sign this nondisclosure.
And in order to follow the nondisclosure, I'm not disclosing. I can't tell you when I saw them. Candidly, I cannot. But I have seen a number of them over months when I first started seeing these cases.
Q. So we're clear, Dr. Solomon, your testimony to the jury is that you saw these company documents before you generated your report?
A. I don't know the date of the

nondisclosure off the top of my head. If you have it, we can confirm it easy enough. If you're asking a specific date, I don't have a recollection.
Q. I'm not -- I'm not trying to be obtuse with you. The question is whether you reviewed the documents before you -- let me finish -- before you generated the report?
A. My answer is I don't recall.
Q. Thank you. Another document that Mr. Kline visited with you on is P-88. P-88a. This was the letter sent to the insurance company.
Do you recall that?
A. I recall it and I need to see if I have it up here.
Q. I think we can display it to make it easy.
One of the things I don't think was covered in the course of the direct on this document is the purpose. That is, do you know why this document was written, that is, why, Dr. Jensen sent this letter in?
A. I can tell you what it says.

Q. If you don't know, you can say you don't know, we're fine, I'll move on.
A. The first sentence says inform of denial for services. I assume this is an appeal and it goes to appeals. If you look at the top part of the letter. That's what I assume.
Q. Given that, would you agree with me that this was Dr. Jensen's attempt to assist with getting insurance coverage for the surgery?
A. I believe it's Dr. Jensen's attempt to get the insurance company to support their client in doing their job to pay for healthcare.
I can tell you that in the Philadelphia marketplace, we never get to the second level in adolescents. It's covered immediately.
Q. I guess the answer to my question was yes, this was an effort toward getting coverage for the surgery?
A. For the patient.
Q. For the patient. I don't mean for the doctor. For the patient.
A. I'm sorry, I misheard you.
Q. Now, did you -- I believe the third

paragraph where it says this young man has a pathological state in the overgrowth of his breast tissue.
Do you remember that being highlighted?
A. Yes.
Q. And you said this was not normal; correct?
A. Correct.
Q. And it was not normal because he had gynecomastia?
A. Correct.
Q. So any young man who is diagnosed with gynecomastia would have that type of description; correct?
My question to you is, there's nothing special about Tim Stange's situation. This was just a young man with gynecomastia and there was a procedure that was proposed for him?
A. That's correct.
Q. So the pathological state and the overgrowth of his breast tissue, this is a descriptor that would be used for any young man with gynecomastia.

Is that fair to say?
A. I can't speak -- we're not -- unfortunately, I can't speak for any young man. I'm here to speak for Tim, actually, for this issue in this particular lawsuit.
So I don't think it's fair to ask me about any young man because I have taken care of lots of patients and patients are individuals. So I don't think it's right to sort of wastebasket the whole thing.
I'm happy to answer questions about Tim's conditions.
Q. No problem. With regard to patients that you see here in Philadelphia or elsewhere who present to you for breast reduction surgery, young men, that descriptor pathological state and the overgrowth of breasts would apply to them as well; correct?
A. Correct.
Q. Dr. Jensen in this procedure refers to the procedure as cosmetic.
Does he not? Let me orient you to the third sentence in the third paragraph where he begins, moreover, the cosmesis is the purpose

of this invention.
He's essentially saying the fact that he's saying this is a cosmetic procedure should be weighed against something else; correct?
A. That's his statement.
Q. That's what he says; right?
A. That's his -- that's exactly what it says.
Q. If I could draw your attention to P-89.
MR. KLINE: He already signed the disclosure. He would not be able to, under your confidentiality agreement, release it to the public either.
MR. MURPHY: It's actually ours, mine and yours.
BY MR. MURPHY:
Q. If I can again orient you to P-89.
Do you see it?
A. I see it, yes.
Q. This was the document that Mr. Kline showed you, P-89, and it is from Dr. Jensen's office.
Is that right?

A. It's from the Children's Hospital of Wisconsin.
Q. Understood. But do you remember that the question and answer between you and Mr. Kline regarding who it was that filled out this document?
A. I remember we had a question and answer about it. I don't remember the specifics.
Q. So that we can be properly oriented as to where this came from, this came from Dr. Jensen's office; right?
A. Perhaps we're not totally clear between you and me. But my understanding of reviewing records for a number of years and practicing at hospitals, when I see history and physical examination, and the notation Children's Hospital of Wisconsin, and where it says 7-16-12 in the upper right corner, this suggests to me this is a hospital document, a copy of what's contained in his records, but what I would say is a hospital record.
Q. The hospital records contained in the records of Dr. Jensen; agreed?
A. Yes.

Q. And acknowledging P-89 is P-89a.
Do you have that?
A. I don't have either of them at the present time.
THE COURT: Do you need them, Doctor?
THE WITNESS: I can work off the screen.
BY MR. MURPHY:
Q. P-89a. So P-89a and P-89 were used at the same time.
If you hook at the bottom of P-89a, you see Dr. Jensen's signature; right?
A. Yes.
Q. So you're comfortable in agreeing with me that this, too, is a document that comes out of the file of Dr. Jensen; correct?
A. Okay.
Q. So now, P-89 and 89a come from the file of Dr. Jensen; correct?
A. Okay.
Q. So I would now like to take you back to P-89.
With regard to P-89, you had a question

and answer with Mr. Kline regarding what is set forth in writing here.
Do you remember that? Patient experienced a 30-plus weight gain while taking Risperdal.
Do you remember that?
A. I remember we discussed it.
Q. Do you remember that discussion?
A. I remember the discussion, that's correct.
Q. This information, is it your testimony this was Dr. Jensen's opinion about what occurred?
A. I would have to go back and read the testimony again.
Q. I'm asking you right now, because I don't think what you're saying now would differ from what you said before.
A. Correct. I want to be consistent. My recollection is I said that.
Q. It's mine as well. It's your belief that Dr. Jensen was of the opinion -- and this reflects his opinion -- that the patient experienced 30-pound weight gain while taking

Risperdal, which resulted in breast growth; right?
A. Correct.
Q. If I can direct your attention to the top left aspect of this document, P-89 -- do you see where it says informant?
A. Yes.
Q. To the right of that, it says PT, and you know that's shorthand for patient?
A. Correct.
Q. And after that, mom?
A. Correct.
Q. So the informant, typically, in your industry is the person that provides the history.
Is it not?
A. Correct.
Q. So the informants were the ones who provided this history.
Isn't that right?
A. Again, the person who wrote it is writing their interpretation of that.
Q. And the person who wrote that wasn't Dr. Jensen. Was it?

A. I don't know if we established that.
Q. I'm asking you.
A. I don't recall what we said, but I'm happy to go back.
Q. I'm asking what your --
A. Again, I know we're not here to guess. I don't want to contradict myself. My recollection is that I said that this was Dr. Jensen's document, said it that way.
If there's evidence to the contrary, I'm happy to entertain it.
Q. It's saying that it was Dr. Jensen's document -- you didn't mean to suggest to the jury that Dr. Jensen wrote this. Did you?
MR. KLINE: We didn't say that.
MR. MURPHY: If the answer is no, he can say no. Don't testify.
MR. KLINE: It's not a matter of testifying. It's a matter of what the record shows.
BY MR. MURPHY:
Q. Do you remember my question?
A. Again, I'm not looking to get wrapped up in knots. We have a record. If you want to

go back and review the testimony, I'd be more than welcome to do that. I'd be happy to do that.
But I don't want to get in a position on contradicting myself because I don't understand the question.
Q. Doctor, very simple. I simply am asking whether it's your understanding that Dr. Jensen wrote that.
MR. KLINE: Objection. Asked and answered on direct.
THE COURT: Overruled, but I believe it was asked on cross. I think he's said it's his understanding that Dr. Jensen wrote that.
BY MR. MURPHY:
Q. That's correct? It's your understanding that Dr. Jensen wrote that?
THE COURT: I believe he did. I don't hear an answer.
A. I will defer to my previous discussion of this document, which we had a few hours ago. It's readily available. If you want to ask me about those statements, you should read the

record to me and I'm happy to answer it.
Q. Your testimony is what it is and it has been assessed appropriately. We will move on.
In P-89a, there's a section that reads reason for admission. Do you see that?
A. Yes.
Q. In parenthesis, it says: Please include brief H and P and other findings.
Do you see that?
A. I believe I pointed that out when I was being asked about it by Mr. Kline.
Q. What's included there is a history consistent with what we saw on page -- on P-89; correct?
A. No. That's not correct. That's the wrong interpretation of that statement.
Q. So a 17-year-old male with Tourette's Syndrome, gynecomastia, while on Risperdal, we didn't see that in the history aspect of P-89?
A. So to be very clear, if you look to the top left of that little banner we've outlined, reason for admission, 17-year-old male with history of Tourette's Syndrome developed gynecomastia while on Risperdal.

The statement speaks for itself. That's a doctor's opinion. You're saying this is a doctor's opinion -- I can tell you, having written many of these things, this is our opinion as to why the patient is there. It's not a guess. It's a diagnosis.
Q. So the reason why the patient comes is a diagnosis for the problem?
Is that what you're saying?
A. No. I think you fail to understand the process.
In order to treat a patient, you must make a diagnosis. In order to justify the treatment, the documentation justifies the treatment.
That's the diagnosis that, in layman's terms, is the reason for admission. Then it begs the next question, why does it say reason for admission? This document is a look at the top, discharge communication for length of stay less than 48 hours.
This is a document that's completed by the physician and given to the patient or, in this case, the patient's parent.

This is the physician's medical diagnosis.

Q. Let me just ask you. We see it was signed by Dr. Jensen; correct?

A. Yes.

Q. Did you ever speak to Dr. Jensen about any of the documents found in his file that you reviewed?

MR. KLINE: Objection, Your Honor. It's totally misleading as to the process.

THE COURT: I'll allow him to ask that question.

A. I have not spoken to Dr. Jensen.

Q. What you testified to about what you see here is your interpretation.

Is that right?

A. It doesn't take a lot to interpret a statement that's developed --

Q. Sir --

A. May I answer the question?

Q. If you would. I think it's a yes or no answer. What you're testifying to is based upon on your interpretation? Yes or no?

A. No. It's based upon my reading of the facts. That's a fact I'm reading it.

Q. You also were asked about an exhibit marked 91; and P-91 is a photograph of Mr. Stange going down a water slide.

Do you remember that photo?

A. Yes.

Q. You testified to, if I remember correctly, that what you see in a photo is consistent with the condition of gynecomastia.

Is that correct?

A. That's correct.

Q. And you know that this photograph, as represented by Mr. Kline, was taken between June 11, June 15, 2007; correct?

A. That's my recollection.

Q. Is there anything in the medical records that you reviewed indicating that anyone had done a physical examination of Tim Stange in June of 2007?

A. I don't recall.

Q. Are you offering the opinion that Mr. Stange had gynecomastia in June of 2007?

A. Without a doubt.

Q. And that's without the benefit of any physical examination; correct?

A. So part of what plastic surgeons do is observational, and photographs are part of a routine of things that -- tools I use to make a diagnosis.

That's a photograph that I would put into that scope of things that I would use to make the diagnosis.

Q. Now, in calendar year 2007, Mr. Stange was 13 years old; correct?

A. Correct.

Q. He was progressing through puberty. You know that to be true also; correct?

A. Correct.

Q. And because you've reviewed the various medical records that you discussed with Mr. Kline, you know that in April of 2007, he weighed 122 pounds; right?

A. I'd have to see that. If you have documentation, I'm happy to say yes or no.

Q. You don't dispute that?

A. I can't say yes or no. I don't know it. I haven't seen anything that says it.

Q. Well, let me ask you this: Based upon whatever it is that you reviewed, did you see what his weight progression was in calendar year 2007?

A. I have reviewed a number of documents that include tables and graphs that depict his weight over the years; but off the top of my head, I can't put a number to a date; but if you have it and want to show it to me, I'm happy to review and comment on it.

Q. P-92 is another photograph that I believe is a preop photograph.

Do you happen to have that in front of you?

A. I don't have any photographs.

MR. KLINE: I have some here. What number?

THE COURT: I have the packet ready. I'll just give to him.

BY MR. MURPHY:

Q. Doctor, you're looking at P-92 at this point?

A. Yes.

Q. And is that your signature this is a 2007

document; correct?
A. That's my understanding.
Q. And this is what Mr. Stange looked like before Dr. Jensen performed his procedure; right?
A. The document I'm reviewing is a number of photographs both pre and post operative.
Q. I'm on the first one. I'm sorry. P-92; and I think what we agreed to on the numbering convention is it be identified 8, 15 and the like.
I'm on the first page, 008.
A. That's not the one I'm looking at. Forgive me. Now I have the one that's labeled 008.
Q. Fair enough. So P-92, individual photo ending in 08, is a picture of Mr. Stange before his procedure; correct?
A. Correct.
Q. Is that what you're looking at, Dr. Solomon?
A. Yes, that's what I'm looking at.
Q. Again, so the jury is clear, this is Mr. Stange before -- immediately before surgery;

correct?
A. Correct.
Q. If you find a photo 0015?
A. I have it.
Q. Another picture or depiction at the same time.
Is that fair to say?
A. Yes.
Q. At this time, Mr. Stange is 18 years old; correct?
A. Yes.
Q. He is out of puberty; correct?
A. At the tail end of it, at any rate.
Q. Pardon me?
A. Tail end. There are other ways to evaluate it. He's at the end of puberty as opposed to beginning or middle.
Q. The pictures we saw of him going down the slide, he was 13 years old; correct?
A. Yes.
Q. And he was in the middle of puberty.
Was he not?
A. Beginning/middle.
Q. You say beginning/middle?

A. Again, there are a number of ways to evaluate it. It's not purely related to age. 13 is maybe middle, not the very beginning, not the end. Somewhere towards the beginning as opposed to 17, which is toward the end. It's a continuum.
Q. Having reviewed the documents, do you recall what -- first of all, you're familiar with Tanner stages.
Are you not?
A. Yes, I have some familiarity with it.
Q. Do you know what Tanner staging Mr. Stange was in June of 2007 when that photograph was taken?
A. I don't, off the top of my head.
Q. We'll get there.
You were also shown documents marked 96a and 95a respectively; and they were documents that come from the file of Dr. Mixter.
Do you have that in front of you, Doctor?
A. Yes.
Q. 95a and 96a.
A. I don't have them numbered that way but yes, I do have them in front of me.

Q. Just so we're clear, the first page on each one of these is 95, and if you page in one more on each of the exhibits, that's where the A comes in.
A. For clarification, I see a Bates number in the bottom right corner; one being 008 and one 009.
Q. Let's start with 008. I'll represent to you that that's what we have marked here as P-95a, and we can agree that it's your understanding that this is a document that comes from the file of Dr. Mixter; correct?
A. Yes.
Q. And for the benefit of the jury, who is Dr. Mixter?
A. He's a plastic surgeon that the Stanges consulted in May of 2007 regarding Mr. Stange's breast.
Q. My simple question to you, Dr. Solomon, is whether you ever had spoken to Dr. Mixter regarding any of the documents that you reviewed that were found in his file?
A. I have not.
Q. You've never spoken with Tim's mother

regarding his course of treatment with any of his doctors. Have you?
A. I have not, that's correct.
Q. And you've never spoken with Tim himself regarding his condition and his treatment with his doctors.
Is that correct?
A. That's not correct.
Q. When was it that you spoke with Mr. Stange?
A. Sunday, I had the opportunity to speak with Mr. Stange.
Q. Sunday?
A. Sunday.
Q. What did you learn from Mr. Stange when you spoke with him on Sunday?
A. I asked him about his general health. I asked him basic medical questions. Asked him -- I looked at his breasts, and that was the extent of it.
Q. You examined him?
A. Briefly.
Q. For what purpose?
A. For the purposes of informing my

knowledge of his present status with regard to this matter.
Q. Now, you testified earlier about your practice and your practice here locally. You maintain a website.
Do you not?
A. Yes.
Q. I want to make sure that what I have seen is an accurate representation of your website, the opening page.
MR. KLINE: May we see you at sidebar?
(Sidebar discussion was follows:)
MR. KLINE: I don't usually have the least bit of struggle.
Out of an abundance of a caution, the last time, at the first trial, Dr. Pledger trial, which Mr. Murphy participated in as counsel, the website is truly a side show. It goes to anything other than, not to -- it didn't go to the attempt to impeach the witness.
It went to the attempt to smear the witness. It's been well-known and

written about and publicized, he has a website which describes his plastic surgery services, doing things like penile augmentation and breast augmentations and things like that.
I would respectfully suggest to the Court that the prejudicial value far outweighs any probative value at a bear minimum.
I would request an offer of proof that Your Honor will see for yourself before we flash in front of this jury all kinds of stuff which was used in a prior trial, which was designed to create an impression that the witness was either -- was someone that you wouldn't like --
MR. MURPHY: With all due respect, we clearly have missed one another. I have no intention of doing anything like that.
My questions to him will be about what his website says about the condition of gynecomastia. That is all.
THE COURT: That's relevant.

MR. KLINE: I know what it says. I didn't know. I know what happened in the first trial. Albeit you were not lead counsel.
MR. MURPHY: We clearly haven't gotten to know better. Have we?
MR. KLINE: That would not be something I would expect from you.
(Open court.)
BY MR. MURPHY:
Q. Doctor, I'm going to hand to you what will be marked as D-39 formation.
THE COURT: I just would like to tell counsel for the defendant that I don't know what D-34 through D-38 are. We have to talk about that at some point.
BY MR. MURPHY:
Q. In front of you is D-39 for identification.
What I represent to you is that's a page from your website. Do you recognize it as such?
A. I do.
Q. May we display it?

What we're looking at here is a screen shot from your website; right?
A. Correct.
Q. At the website, you identify certain of the procedures that you perform. We talked about that earlier during qualifications.
Do you remember that?
A. I'm sorry. Say that again, please?
Q. Among other things that appear here are various procedures that you performed, things that you do for people who come and consult with you; correct?
A. Yes.
Q. And I said we talked about some of that earlier today?
A. Correct.
Q. One of the things we're looking at here is what your website addresses in terms of male breast reduction, one of the services that you provide; correct?
A. Correct.
Q. At your website, one of the things that you identity regarding gynecomastia is that it's a common medical condition characterized

by fat deposits; right?
A. In men, adult males.
Q. In men?
A. Adult males, not the nature of this case. Adult males. Apples and oranges, counsel.
Q. We'll come back to that.
A. That's -- we can't mislead these folks. I know you'd like to but we can't.
Q. With all due respect, don't do that. No, I would not like to mislead anyone and I think that you would either. I would not make that insinuation.
A. So we can agree to take this down because it's not relevant to this issue. These are adult males.
Q. Let me ask you this: There's another representation regarding gynecomastia, and you can tell me whether that applies to adult males only. Okay?
A. Go ahead.
Q. As we go through, to the extent it doesn't apply to adolescents, you can say so, and no one is being misrepresented or misled. Fair?

A. Absolutely.
Q. Now, one of the things you say is that in many cases of gynecomastia, the cause is unknown; right?
A. That's what it says there, that's correct.
Q. Now, is that a statement that's specific to adult onset gynecomastia only?
A. Again, this site is for adult males.
Q. I understand that. Let me take a step back because you -- you've now been qualified to talk about gynecomastia.
So with regard to gynecomastia in the child and adolescent population, is that statement true, that the cases of gynecomastia in children and adolescents, many of those causes are unknown.
A. In most children, we can figure it out.
Q. Did you understand my question?
A. I answered it to the best of my ability.
Q. In many of the cases, you can figure it out.
My question to you, does that then mean that in many of the cases, the cause is

unknown?
A. Again, I'm talking about gynecomastia in adolescents. You're talking about it in adult males.
It really is not applicable to Tim's case. If you want to have a discussion about gynecomastia in adults and children, I'm happy to have that discussion.
You have experts that are adult doctors in this case and you have them that are child doctors. I'm one of the few that is both. I can talk about both sides of the coin but I don't think it's fair to slide the rule -- the boundaries and create confusion that doesn't need to be created. This is an adult site.
Q. My question to you simply is this: With regard to gynecomastia, as it occurs in the child and adult population, are there many cases where the cause is unknown?
A. So you're saying child and adult. You just said child and adult.
Q. Sir, I think people heard me say child and adolescents. I'm saying child and adolescents, and I'll start all over again.

With regard to --

MR. KLINE: The question said child and adult, by the way.

BY MR. MURPHY:

Q. With regard to gynecomastia, as it occurs in a child and adolescent population, are there many cases where the cause is unknown?

A. No. Not in the child and adolescent population.

Q. How about the adolescent population?

A. Again, rarely, in my experience.

Q. Rarely is idiopathic.

Is that your testimony?

A. Idiopathic is another word for saying we don't know.

Q. Correct.

A. Right. So rarely.

Q. With regard to, at your website regarding male onset gynecomastia, one of the things that you state is that some men develop gynecomastia during puberty; right?

A. It does say that, correct. Some men get the condition during puberty.

Q. And the men who get the condition during

puberty don't all get it because of some drug-induced cause; right?

A. Correct.

Q. So there are men who develop, who developed gynecomastia while in puberty and that gynecomastia persisted into adulthood; correct?

A. A percentage of them, that's correct.

Q. A percentage. As you sit here today, did you dispute that that percentage has been documented as being upwards of 20 percent?

A. I have seen literature as low as five percent and as high as probably 18 to 20 percent.

Q. When you conduct a procedure to remove some part of a male breast tissue like what was done with Tim, you send that tissue to a pathologist; correct?

A. Generally, that's correct. Not 100 percent.

Q. You do that because the specimen may reveal that there's some pathologic cause for the problem; right?

A. Correct.

Q. When we talk about a pathological cause, explain to the jury what we mean by that.

A. We're using the word pathology in several different ways. So if I understand your question, the way that Dr. Jensen, in his letter --

Q. We're talking about you, Doctor.

THE WITNESS: Your Honor, may I finish my answer? I will answer the question, I promise. I have to use that -- I said we're talking about several ways. I'm going to clarify using those two examples.

Again, the word pathology as opposed to normal is one concept. The word pathology, meaning malignant, as opposed to benign is another concept. So using one word, we have at least three different concepts.

That's what I'm trying to explain; and if I can, by way of detail, my understanding of Dr. Jensen's concept is pathology was used as opposed to normal.

You're asking me, do we do

histology, microscopic exam to look for pathology for cancer as opposed to not cancer.

Q. So we're clear, your testimony, so the jury understands, in those instances when you send a tissue to pathology for analysis, you simply are trying to determine whether there is cancer or not?

That's the only reason?

A. I knew that when I said that, it was going to be an oversimplification. There are times to send tissue if it's a vascular malformation, a lymphatic malformation of the breasts, both of which I have seen, if it's isolated benign -- there are benign and malignant tumors. There are a variety of conditions of the breasts that are far beyond the scope or these issues.

But there are a number of things one can look for under the microscope.

Q. What we do know is Dr. Jensen did not send the tissue excised to any type of pathology; correct?

A. That's my understanding.

Q. You didn't see anything in the record?
A. I have not seen a report from a pathologist; that's correct.
Q. You testified earlier, I believe, that what you did was to conduct what's known as a differential diagnosis to reach your conclusion that Risperdal was the cause of Mr. Stange's gynecomastia.
Is that right?
A. Correct.
Q. And you identified all the potential causes of gynecomastia, and then you ruled them out until you were left with Risperdal as the cause.
Is that what you did?
A. That's the process by which it's done, that's correct.
Q. And that's what you did?
A. Correct.
Q. Now, with regard to pubertal gynecomastia, you know, by virtue of your readings and your research, that upwards of 70 percent of boys going through puberty develop gynecomastia; right?

A. Again, the number really varies considerably depending upon who you read. It can be roughly as low as 20 or 25 percent, and I know there's some reports in my head of 65 percent. So it's variable.
Q. And as we've discussed just a moment ago, you know that in certain of these young men who develop gynecomastia during puberty, it doesn't resolve. It persists into adulthood; correct?
A. I stated that.
THE COURT: What was the percentage?
MR. MURPHY: Previously, I identified 20 percent, and I think the doctor said he saw ranges up to 20.
THE COURT: I thought you said something else.
THE WITNESS: I said five.
BY MR. MURPHY:
Q. So we're clear, is it your testimony, Doctor, that with regard to pubertal gynecomastia that persists into adulthood, you've seen only five percent?
A. Of the patients that I have operated on.

In other words, it's a different way of looking at it. It's about five percent post patients who have gynecomastia that I see have pubertal, persistent pubertal gynecomastia.
That's a different statement than what you're asking me.
Q. Indeed. Let's go back to the statement I'm asking.
I'm asking about what you have seen in the literature. I believe that what you've seen in the literature is not five percent, but it's a range between five and upwards of 20 to 25?
A. Correct. Five to 20 is the range I believe I stated a few minutes ago.
Q. So did I. Between five and 20?
A. Yes, so we agree on that.
Q. Okay. You, in fact, have performed surgery on young men who have developed gynecomastia; correct?
A. Correct.
Q. And is it the case, Doctor, that for each of those young men on whom you performed a breast reduction procedure, you conducted a

differential diagnosis to determine what the cause of that gynecomastia was?
A. That's correct.
Q. In each one of them?
A. As I stated, that's part of the process. When a patient comes in, we take a history, do a physical, determine what other studies are needed to help, and we go from there.
Q. The cause of the gynecomastia, that is, what caused the gynecomastia that you now are about to address, is that important to you?
A. The answer is yes.
Q. So it has a bearing on how you might conduct the procedure or what type of procedure you might conduct.
Is that right?
A. That's a fair statement. If I'll operate at all, by the way.
Q. So what you're telling us is it's important to do a thorough differential diagnosis because that has a consequence; right?
A. Correct.
Q. So you would not diagnosis gynecomastia

based simply on review of a record and a photograph before you began a surgical procedure; correct?

A. I have certainly diagnosed it based upon a thorough history and a thorough physical with no other ancillary material.

In this case, we have even more than that.

Q. You would consider that a thorough differential diagnosis?

A. I'm happy to go through it with you.

Q. Pardon me?

A. The answer is yes. I have done a thorough differential diagnosis in this case.

Q. I believe that you have at some point.

My question was a bit more precise, and that is, whether you would be comfortable in relying on merely a review of records and review of photographs to reach a diagnosis, a cause diagnosis, before you went in and conducted a surgery?

A. So -- forgive me, but I'm confused, I have not been asked to operate on Tim. He already had his surgery.

If you're asking me, in this particular case, did I review photographs and records and go through differentials and come to a documentation, my answer is yes.

I'm pretty narrowly focused here. If you're trying to broaden me out, which I think you're trying to do, I would have to take that on a case-by-case basis.

Q. I'm quite precise with my language, if nothing else. My simple question to you is, if you were about to conduct a procedure on a young man for breast reduction, you would be comfortable on relying simply on a record of his treatment and photographs of him?

A. No. I would do a physical exam.

Q. Thank you. It's your opinion that prolactin elevation caused Mr. Stange's gynecomastia; right?

A. I believe that's part of the process, yes.

Q. In the course of your direct exam, I believe you referenced a percentage of 82 or 87 percent of patients taking Risperdal experienced prolactin elevation?

A. That's my recollection.

Q. Now, is it your understanding, Dr. Solomon, that all pediatric patients who take -- strike that.

Is it your understanding that 87 percent of all pediatric patients who take Risperdal will experience prolactin elevation?

A. To my recollection, because I'm trying to recall from the label where it says that, I think it's in one or two different parts of the label, and it may be either dose-related or basic diagnosis related.

Meaning, I'm not sure if it's autistics or schizophrenics, for example. If you show me the label, I'm happy to go over it with you.

Q. I will show you the label. But before we get to the label, I'm trying to get to your understanding of what the incidents of prolactin elevation in pediatrics who take the drug, because I think you just told us that you believe -- or you understand that 87 percent of all pediatric patients who take Risperdal will experience prolactin elevation.

A. I think that's a mischaracterization of what I said.

Q. Correct that, please.

A. What I said is that the risk of prolactin elevation in one part of the label talks about it being 25 times greater than placebo, and another portion of the label talks about 82 or 87 percent of patients in that protocol got an elevation in prolactin.

Again, I'm happy to review the label here before the jury so that you and I aren't having this back and forth when we can read it. It's easy enough to read.

Q. To be fair to everyone, we're going to do that. I simply was trying to establish your understanding. Let's take a look at P-53, which is the 2007 Risperdal label.

MR. MURPHY: Can we display that? May I approach?

THE COURT: Certainly.

BY MR. MURPHY:

Q. Dr. Solomon, you recognize this as the 2007 product label for Risperdal?

A. Correct.

Q. When you were referring to what you have reviewed regarding prolactin elevation and the incidents of same in the pediatric population, you were referring to this document?

A. I'm not sure which version. I have read so many of these at this point that I will confess I can't remember the 2002 from the 2005 to the 2006 to the 2007, but we can agree this is after Tim started the medication.

Q. Let me direct your attention to the Bates, the page with the Bates number 429 to the right.

THE COURT: Is this Exhibit D-53?

MR. MURPHY: No, P. It's the one that Mr. Kline wanted to use.

THE COURT: This one is marked D. Go ahead.

BY MR. MURPHY:

Q. You're at 429? Let me direct your attention to the column that says hypo ^anemia growth and sexual maturation.

Do you see that?

A. I do.

Q. And the second sentence reads: In double

blind placebo control studies of up to eight weeks duration in children and adolescents, age five to seven years, closed paren with autistic disorders or psychiatric disorders other than autistic disorders, schizophrenia or bipolar mania, 49 percent of patients who receive Risperdal had elevated prolactin levels compared to two percent of patients who received placebo.

Do you see that?

A. I do.

Q. You read that before?

A. That's how I come up with 25 times. Two goes into 50 25 times.

Q. So the two that you referenced is the two percent who receive placebo; correct?

A. Correct. I said it's from 25 times up to 82 to 87 percent, which is about two lines below where you highlighted.

I seem to have recalled it pretty clearly.

Q. We're going to get to what you actually recall.

A. It's right here.

Q. 49 percent of those who receive Risperdal had elevated prolactin levels; correct?

A. That's what that says.

Q. So that means that 51 percent of those who receive Risperdal did not experience any prolactin levels; correct?

A. Except for the 13 percent with schizophrenia who didn't have it. You can't -- with all due respect, sir --

Q. I have a question and I'm going to ask it.

THE WITNESS: Can I finish answering, Your Honor?

THE COURT: Answer his questions.

THE WITNESS: We have to read the entire label. You can't just pull out --

Q. Doctor, please.

49 percent of those who receive Risperdal had elevated prolactin levels, those in the study who were actually given Risperdal; right? 49 percent of those folks were shown to have elevated prolactin; correct?

You agree with that?

A. I agree that's what it says in that

portion of the label.

Q. Fair enough. So my question to you, simply is, would you then agree that of that group of people who, in this study, this patient population who are given Risperdal, the remainder 51 percent did not show elevated prolactin?

A. In that one study, that's correct.

Q. We agree.

Now, it goes on. This is one study with one group of people in a certain age cohort. Agreed?

A. Correct.

Q. The language goes on to address another age cohort and population.

Does it not?

A. Correct.

Q. Beginning with the word similarly. Can we pull that up? There, it reads, similarly, in placebo-controlled trials in children and adolescents, paren, age ten to 17 years, close paren, with bipolar disorder or adolescents aged 13 to 17 years with schizophrenia, 82 to 87 percent of patients who receive Risperdal

had elevated levels of prolactin compared to three to seven percent of patients on placebo. Increases were dose-dependant and generally greater in females than in males across indications.

Do you see that?

A. I do see that.

Q. Is this where you derive your 82 to 87 percent language?

A. Correct.

Q. Looking at this, you and I can agree the label doesn't say that 82 to 87 percent of all pediatrics who take Risperdal will experience elevated prolactin; correct?

A. Sort of like the blind man and the elephant. Feel the trunk, it feels one way. If you feel -- it feels another.^

We have two sentences there that speak for themselves. In all fairness to you, what I said in my testimony was, my recollection was it was something like 25 times more likely to go up and as high as 82 to 87 percent.

The simple solution here is for us to average it, and that's about 63, 64 percent,

if we take both of those lumps together.

So it's still more likely than not going to elevate prolactin.

Q. Just so we understand one another, you believe that it is appropriate scientifically to do averages on prolactin elevation between different age cohorts and different disease states?

You believe that's appropriate?

A. Again, I'm not sure where the underlying mental disorders have an effect on prolactin levels. It may be dose-related, number one.

Number two, if we look at Tim, when he started the drug, he's more in the second cohort than the first in terms of dose and in terms of age.

Q. What about disease state? He's not -- I'm asking a question.

A. Go ahead.

Q. What about disease state? He's neither bipolar nor schizophrenic. Is he?

A. I don't see his disease on there at all.

Q. Exactly. If we're going to be fair and apply the language appropriately, Tim Stange

is not reflected in either of these. Is he?

A. I disagree.

MR. KLINE: Objection.

THE COURT: Overruled. His name isn't used there.

MR. MURPHY: Exactly.

BY MR. MURPHY

Q. His profile, a young man with Tourette's Syndrome, is not reflected here. That is, the disease state, Tourette's Syndrome, is not reflected in either of those cohorts; correct?

THE COURT: Your objection is to that?

MR. KLINE: Yes. It's off-label.

THE COURT: You'll get there.

MR. KLINE: I have been calm and I'll do my redirect.

THE COURT: That's overruled. Go on.

A. I'm not sure I understand the question.

Q. The question was, the disease state of Tourette's Syndrome is not reflected in either the yellow discussion or the mint green discussion; correct?

A. Correct. There's no mention of Tourette's.

Q. Do you happen to know what the dose is for schizophrenic adults?

A. I don't recall it at the moment.

Q. Do you know what the dose is for schizophrenic adolescents?

A. I believe it starts at one or two milligrams a day. According to the label, it can be one to six milligrams a day for adolescents. And for adults, it can be four to 16 milligrams a day.

Q. Let me direct your attention to the first page of that exhibit. On the first page to the left aspect of it, there's the box that has the heading, dose administration.

Do you see that?

A. Yes.

Q. If we come down, and the second box on the left says schizophrenia adolescents.

Do you see that?

A. Yes.

Q. And we see that the target dose is 3 milligrams a day?

A. Yes.
Q. You saw from the past label that that data that was reflected indicated at the bottom there was a dose response that had to be considered; right?
A. I'm not sure I understand what you're referring to at this point.
Q. I'll ask you this and we'll go back to what I'm talking about.
The target dose for adolescent schizophrenia is 3 milligrams; correct?
A. That's what it says.
Q. Tim Stange never was prescribed 3 milligrams during his Risperdal therapy. Was he?
A. To my knowledge, that's correct.
Q. If we go down to bipolar mania in children, target dose.
Do you see that?
A. Yes.
Q. 2.5; correct?
A. Yes.
Q. And you read the records, saw the pharmacy records provided to you by Mr. Kline.

Mr. Stange was not prescribed 2.5 milligrams of Risperdal. Was he?
A. Correct.
Q. Are there studies that you relied upon for your opinion that prolactin elevation caused Mr. Stange's gynecomastia?
A. Yes.
Q. And I believe, during your deposition, you identified a study by Dr. Yvette Roke ^as one you relied upon?
A. That's one of several I reviewed.
Q. One of several?
A. Yes.
Q. And so the Roke study we're talking about is the study from 2012?
A. I don't remember if there's more than one from Roke, frankly.
Q. I'll show you and you can tell me.
THE COURT: Are you going into a lot of studies?
MR. MURPHY: Not a lot.
THE COURT: I know we're going to be going tomorrow.
MR. KLINE: I don't know yet.

Depends how soon he finishes up and I know the doctor has a surgery scheduled.
MR. MURPHY: It's a fine place to break. I'm not going to be done in ten minutes.
THE COURT: You have surgery scheduled tomorrow?
THE WITNESS: I have a very full day.
MR. KLINE: Maybe we can find out how long he has.
THE COURT: I'm going to leave this with the jurors. I'm going to ask them.
They want to get through the doctor's testimony. I know I promised you that we would leave at 4:00 every day.
Have any of you made arrangements that would prevent you from staying a little longer to finish the testimony?
THE COURT: Five of them. I'm not going to keep them. I hate to do this to you, Doctor, by the way.
THE WITNESS: I have no choice about

tomorrow. No choice. I'm booked for surgery. We've already moved folks.
THE COURT: I'm going to let you go. We'll work this out. Let me give you your instructions.
Would one of you like to give instructions? I'm sure you all know them by now.
Is 9:00 okay or do we need extra time? Come in at 9:30. Please remember you are not to discuss the case with yourselves or anyone else. You are not to discuss experiments or make individual investigations of the facts.
You're not to read, listen, watch any media accounts of the case. Please wear your jurors badges in a conspicuous place on your clothing at all times while you leave the courthouse.
Good evening everyone.
(Jury panel departs courtroom at 3:56 p.m.)
- - -
(Adjourned.)

CERTIFICATION

I hereby certify that the proceedings and evidence are contained fully and accurately in the notes taken by me on the hearing of the above cause, and this copy is a correct transcript of the same.

Maureen McCarthy

Maureen McCarthy, RMR, CRR
Official Court Reporter

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means unless under the direct control and/or supervision of the certifying reporter.)

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IN THE COURT OF COMMON PLEAS
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

IN RE: RISPERDAL LITIGATION

TIMOTHY STANGE, Plaintiff VS. JANSSEN PHARMACEUTICALS INC., JOHNSON & JOHNSON AND JANSSEN RESEARCH & DEVELOPMENT, LLC, EXCERPTA MEDICA, INC., AND ELSEVIER, INC., Defendants	APRIL TERM, 2013 NO. 1984

Tuesday, November 3, 2015

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City Hall, Courtroom 275
Philadelphia, Pennsylvania

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B E F O R E:

THE HONORABLE KENNETH J. POWELL, JR.

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TRIAL - PM

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Maureen McCarthy, RMR, CRR
Official Court Reporter

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A L S O P R E S E N T:

K R I S T E N L O E R C H, E S Q

M R. K E L L Y: Got back to the office. We were checking on Dr. Arrowsmith's availability, and I had e-mail exchange with Mr. Gomez and Mr. Kline. Then the thought occurred to me that she's testifying in the Murray case, and she'll be prepping for that and testifying for that. I didn't want her to run afoul of Your Honor's admonition; don't do anything about this case.

I figured I could argue, well, it's not this case, it's another case. But in an abundance of caution, Mr. Kline and I spoke and I said, what do you think about this issue?

And he said, I don't have a problem with her testifying in the -- and he can obviously speak for himself -- I don't have a problem with her testifying in the Murray case.

I wanted you to know that so I can disclose that and I don't view it as a violation of your injunction to her not

to do anything about this case. She's not doing anything about this case. She's in another case and she may be testifying, I think, Thursday of this week in that case.

Now, the question is, Mr. Kline is going to say, why can't she come back here afterwards? I don't know the answer to that offhand, but I do know she's available.

I gave him the 12th, and possibly the 13th, if we don't finish. That does put Dr. Braunstein and her on the same day, but we had the next day as a cushion if we don't phone finish.

That's where we are.

M R. K L I N E: I start with the proposition that I told Mr. Kelly that I did not view it as a violation if she's being prepared over there in another courtroom to testify.

I do think it's fair game that she's just, you know, their spokesperson all over the place and plans bring that out,

but I'm not objecting to her -- to being prepped and the like.

What I frankly don't understand -- and I'm not going to raise it and not going to go back on anything that I agreed to -- but I would call everyone's attention to the fact that we have an open witness on cross-examination who is going to be in town, and is going to be available, and we should take her before they take her.

Maybe Your Honor wants to talk to Judge De Nubile or something. I don't know. I'm not going to get in the way -- I'm not going to go back on everything I agreed to. I don't want to start a fistfight about any of that.

But I would point out that if I had my druthers -- I think the Court would see it this way -- I'd rather finish her before she gets to be opened up in another courtroom.

So that's just my general thinking.

The other thing that I said, I

Court is that I know we're all concerned about getting the case finished, and the thought that, well, we have her -- her and Braunstein, I don't think can be done in one day. I haven't touched her on direct at all and I have a ways to go with Braunstein on cross-examination.

And it strikes me that that automatically pushes the case into a sixth week, which I thought we were going to try to avoid.

So we have all of that. This isn't is a confounder, but it is something that I have given thought to last night and have made a decision that since our case is still open, which it is, they have Daniel Coppola, who is the new Evo Caers, as I call her, and she's, as I understand, ready and available on Monday.

And we will call her as a witness -- an adverse witness in our case on Monday. We know she's available and we will call her as we called other company witnesses.

So we will make her -- so we will not complete our case, and I had not told the Court that fact, and I want you to know.

By the way, we're ready to take her earlier to the extent they want to bring her in Thursday or Friday. But we plan to -- we plan to call Coppola.

We cut their witness, Deloria, and that would speed things up, I think, but it still raises the overall question as to Dr. Arrowsmith; and we are prepared, since we're off tomorrow, and since she's literally in town, we're prepared to take her on for cross-examination on Thursday, if that can be arranged.

If not, I will live with the arrangement that I have agreed to.

THE COURT: Did you discuss that with her?

MR. KELLY: Ken spoke to her. My understanding was she's already locked in, committed to testify in that trial Thursday, and --

THE COURT: If I talk to the judge and said we're way behind schedule for a lot of reasons, can you release her to come over here? I mean, have made your objections to that? I think Judge De Nubile, as a reasonable person would say, you had her on the stand, she's on cross, just have to let her go.

MR. KELLY: Haven't spoken to her that, but I'm happy to work on other options. But we're happy to have that discussion with her, I'm not optimistic. I don't know all the ramifications.

THE COURT: Tell me what you find out because you have colleagues over there, as do you, and then if I have to talk to the judge about it, I'm happy to be --

MR. KLINE: We don't control her. That case is being tried by lawyers who include Drinker lawyers as well, and I'm just baffled by why we can't finish her and why they would take precedence to her, to having a witness who's in town,

not only in town, for the purpose of testifying, and -- but I'm not going to --

THE COURT: If it can't be done, it can't be done. I think we should investigate.

MR. KELLY: We were asked to look into her availability next weekend.

THE COURT: Let me tell you something else that I have. On the 10th, which is a week from today, I have a hearing at 9th -- Marine Court, a hearing at 9:30. It will be 15, 20 minutes and I'm done so I'll bring the jury in at 10:00.

I hate to lose any time. There's some things we can't avoid. When we get this long, things we flip.

MR. KLINE: We lose Wednesday next week. It's a state holiday. Courts are closed.

THE COURT: We haven't lost the jury. They're even-tempered about this. At this point, we're okay. So I guess

it's in your best interest to move it along.

I have to stay here no matter what. Anyway, we can do that. I'm not asking to cut witnesses, give up questions or anything like that.

We have to be mindful of now. We've gotten to the point we have to be mindful.

MR. KLINE: No doubt.

THE COURT: Informationally, we got a visit from one of the legal assistants from the Itkin, Arnold firm, ^who is plaintiff's counsel in that case, lead plaintiff's counsel, and she told us that Dr. Arrowsmith was to -- they were -- they were told that Dr. Arrowsmith will be ready on Wednesday.

Now, we've also been told previously that it was over there it's Caers then Dr. Arrowsmith. So they may be counting on Dr. Arrowsmith going into Thursday. That may be what's in their mind.

In any event, I thought the more

information Your Honor knew, the better.

THE COURT: Okay.

MR. KELLY: My understanding is Caers is tomorrow. And given the length of prior -- even though it's Caers, she's Thursday.

Again, this is all hitting me -- we were asked to check availability next weekend. We did that. We'll work and do whatever we can.

THE COURT: We just have to be mindful of what's going on. I think we are now.

MR. GOMEZ: I'm going to replace Plaintiff 131. We had to ask, add stuff to it.

THE COURT: Okay.

(Jury panel enters courtroom at 1:21 p.m.)

THE COURT: We weren't doing legal argument, we weren't discussing anything, the machines were broken. It happens. I'm sorry for the delay. We thought we were on track to get stuff in. Still

will, but that's what happens.

We gave you lunch early and they've just been fixed. You came in as soon as we got it fixed. Bear with us.

As you know, we're trying all we can to not inconvenience you. Sometimes things are beyond our control. Thank you very much.

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(Video playing).

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MR. KLINE: I believe Dr. Solomon is back. He's ready to go on and have his cross-examination completed.

THE COURT: Okay. There he is. Ladies and gentlemen, you can put Dr. Solomon right up on the stand.

Does anybody need a break at this time? Should we just keep moving?

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(Con'd) CROSS EXAMINATION

- - -

BY MR. MURPHY:

Q. Good afternoon, Doctor.

I want to pick up where I left off with you, Doctor with the cross-examination.

Doctor, I want to clear up a couple things regarding fees. I thought I understood you to say that with regard to in court testimony, you charge a fee of $20,000 per day.

Is that correct?

A. That's correct.

Q. So this is your second day here. So in terms of days in court, you will have charged $40,000?

A. No. Frankly, I have not had this situation ever, so I can't -- I have not thought about what I'm going to do, candidly.

Q. You will charge something for your time here today?

A. Yes. I do get reimbursed for my time away from patient care and I have been doing patient care since about 7:00 this morning. It's been a hectic day.

Q. Understood.

Now, in addition to the time that you charge for in-courtroom testimony, time away

from your patients, there is time that you charge for review of the medical records in this case; correct?
A. Correct.
Q. You charge for that on an hourly basis?
A. Correct.
Q. In terms of the hourly rate for review of the record, what is that hourly rate?
A. We have a fee sheet and I don't have it committed to memory.
If I look at it, I can read it to you, but I don't recall it off the top of my head.
Q. You don't have a general idea whether it's $200 an hour, 200, 300 to review?
A. I don't recall, frankly.
Q. That's fair. Do you have an idea of how long it took you to review the records for Tim Stange in this case?
A. Hours, a long time is best I can tell you.
Q. No ballpark in terms of the number of hours?
A. Not off the top of my head, but I have spent hours on the weekend and hours in the

evenings.
It would certainly be ten or 15 hours. There's a considerable body of records, deposition testimony, medical records. Those are the things, and reports. Those add up to quite a lot of documents.
Q. Understood. In addition to reviewing the records, there's preparation of a report; that is to say, you prepared a report in this case; correct?
A. Correct.
Q. And there's a certain amount you charge per hour associated with the preparation of that report; correct?
A. Correct.
Q. Is it the same hourly rate that applies to review of the file?
A. I believe it is. Again, I have it written down and I think you have it. We can certainly look at it together if you'd like.
Q. With regard to the report, do you recall how long it took you to prepare the report that you generated in this case?
A. Again, it's a matter of hours. Hours is

what I can say.
Q. That's fair. I want to talk to you now about the opinions that you generated.
Dr. Solomon, it's your opinion that prolactin elevation caused Mr. Stange's gynecomastia; correct?
A. Correct.
Q. Now, are there any studies or articles that you relied upon for your opinion in that regard?
A. Yes.
Q. And what are they?
A. There's a statement and article by Anderson, some internal documents I have seen that draw a direct link between prolactin elevation and the occurrence of gynecomastia.
Q. Now, when you use the term internal documents, what are you referring to?
What type of documents?
A. There are documents I have reviewed as part of my review that you asked about a minute ago that were the subject of, I think the phrase is a confidentiality agreement that I signed? That presented data that was

available to the Janssen folks that was not available to the public; and it was not part of what ended up being in published literature absent the Anderson article.
And, in fact, I think I saw one document where the original article describes a direct link between prolactin and gynecomastia, and then in the final approved poster version of it, that material had been removed.
Q. In terms of internal documents, you're referring to Janssen-generated documents? Janssen documents?
A. That's correct. My understanding these are studies that were either performed by Janssen or supported by Janssen financially.
Q. In addition to those internal documents, you refer to the Anderson article?
A. My recollection, that's correct.
Q. Anything else you can recall?
A. Off the top of my head at this time, no.
Q. Let me step back for a moment. Ask you a question about fees. I think I have your schedule. $450 an hour for review of documents and generation of the report

Does that sound right to you?
A. Could I see the document so we're looking at the exact same thing?
Q. Absolutely, Doctor.
MR. MURPHY: May I approach?
THE COURT: Sure.
BY MR. MURPHY:
Q. My question to you is, is the hourly rate that you charge for review of documents and generation of your report $450?
A. That's what it says here. That's correct.
Q. With regard to the amount of time it took you to generate the report, does this at all refresh your recollection?
A. No. The report, I believe, it was a few months ago maybe, January, something like that? So it's a long time. I don't recall how long it took.
Q. That's fair. With regard to the amount of time it took you to review the records, does this refresh your recollection in any regard?
A. No.

Q. But we are clear that the amount that you charge -- that the hourly rate is $450?
A. That's correct.
Q. So now, I want to go back to your opinion.
You identified the Anderson article and certain Janssen internal documents that you reviewed as being the things upon which you rely to support your opinion in this case; correct?
A. Correct.
Q. Do you recall having testified at your deposition that you also relied on the Roke article?
A. Yes, I will.
Q. Is that also an article you relied upon?
A. Certainly something I reviewed as part of this litigation, that's correct.
Q. I want to show you the Roke article to make sure we're talking about the same thing.
You're going to be handed what we've marked D-50. You're familiar with this article?
A. Yes.

Q. This is one of the articles you rely upon to support your opinion in this case?
A. That's correct.
Q. This is the document written by Yvette Roke and others in 2012; correct?
A. Correct.
Q. This is an article that's the study of ten to 20-year-olds taking Risperdal a long time; right?
A. It says.
Q. Physically healthy ten to 20-year-old males.
Do you see that?
A. Yes, I do.
Q. So that was a cohort; right?
Ten to 20-year-old males.
A. Yes.
Q. Do you recall that in this study, only 47 percent of the study participants had elevated prolactin levels?
A. I believe we can look at the data.
Q. If we look at the results section, the extract is part of the article. On the first page of the article in the abstract section

under results.
It says: Hyperprolactinemia was present in 47 percent of subjects in group one.
Do you see that?
A. Correct.
Q. You understand that the group one were the folks who were exposed to Risperidone; correct?
A. Yes. They're the ones who took the Risperdal.
Q. If you look at the conclusion section, Dr. Roke and her authors concluded that hyperprolactinemia was not associated with gynecomastia; correct?
A. That's what it says.
Q. Okay. And one other thing that was noted -- I wonder if you recall this -- is that out of the folks who were not exposed to any antipsychotic, 21 percent of them reported gynecomastia.
Do you recall that?
A. I see that in the table of results.
Q. So in this study, amongst the folks who never even had or were exposed to Risperdal or

any other antipsychotic, 21 percent of them reported gynecomastia; right?
A. And twice as many who had the drug had it. It doubled the effect. Doubled the incidents.
Q. I want to ask you a question, Doctor, about the 2007 label, we talked about later in the litigation. For identification, it's marked P-53.
Doctor, you have in front of you what's been marked previously at P-53 is the 2007 Risperdal label.
Have you seen it before?
A. Yes.
Q. Now, I want to direct your attention to the section on hyperprolactinemia growth and sexual maturation under pediatric use; particularly 8.4, if you're looking for the numbers, it's also on your screen, might be easier to read.
Are you with me?
A. Yes, I'm with you.
Q. Do you see the second paragraph, in clinical trials? Do you see that language? I

think it's highlighted for you now.
A. I see that.
Q. Clinical trials in 1,885 children and adolescents, gallactorrhea was reported in .8 percent of Risperdal-treated patients and gynecomastia was reported in 2.3 percent of Risperdal-treated patients.
Can we agree that what is referenced here being reported upon is of those who were in trials, 1885, that is, 1,885 folks who participated in these trials, 2.3 percent of them reported gynecomastia.
Is that fair reading?
A. That's what it says.
Q. And thus, you'd agree with me then that the vast majority of this 1885 group did not report gynecomastia; right?
A. Again, it says that 2.3 percent had it. It doesn't say anything about the remaining group, whether it's self-reported or diagnosed by somebody treating them. It's sort of a vague label language.
It's above the average for people who, you know, who would be seeing it. It's more

prevalent in this treated group than the nontreated group, is my interpretation of this.
Q. I understand. I'll ask you this question, and either you can answer it or not.
If 2.3 percent of the 1885 people in the trial, in those various trials, reported gynecomastia, then the vast majority of the people participating in those trials did not report gynecomastia; correct?
A. I have one point of confusion I get from this.
My understanding is that Tim started on the drug in 2006 before the label was readily available. So this knowledge was not available to his physician.
MR. MURPHY: Objection. Move to strike. That's wholly irrelevant to the question I'm asking.
THE COURT: I'll strike that.
Answer the question, please.
BY MR. MURPHY:
Q. Do you need me to repeat the question? I will.

A. I can read that it says: Gynecomastia was reported in 2.3 percent of Risperdal-treated patients. I agree with that statement in that document, in that time period.
Q. So the answer to my question is what? the question I asked you then was: The vast majority of the folks who are in that 1885 did not report gynecomastia; correct?
A. To read a label, you read exactly what it says and we don't interpret what it doesn't say because that's an error, because there's literature that talks about the incidents as high as five percent that I'm aware of so. That data didn't make it into the label.
In other words, this is what whoever wrote this label chose to write at this time for whatever the FDA said.
But -- and so 2.3 percent had it. It doesn't really say what the others did. Nor does it say how that data was collected.
We don't know how accurate it is. We just know it's a statement. I can agree it says 2.3 percent of Risperdal-treated patients

in that group has gynecomastia.
My recollection is that in some of the previous labels, it was considered to be insignificant and we can agree to 2.3 percent is not insignificant. That's where the difference comes in.
MR. MURPHY: I'll object again and move to strike.
BY MR. MURPHY:
Q. If you tell me that you can't answer my question, that's fine.
A. I can say that 2.3 percent had it, according to that label.
Q. If you can't answer my question, simply tell me you can't answer it.
MR. KLINE: Your Honor, I think it was asked and answered.
THE COURT: I don't think it was answered.
MR. KLINE: Okay.
THE COURT: There's an excursion but not an answer.
A. Based on the way that question is framed, no, I cannot answer that question.

Q. That's fair. You testified that it's your opinion that prolactin elevation caused Tim Stange's gynecomastia?
A. Yes.
Q. But you haven't stated in your report how it is that prolactin elevation related to that?
A. I don't believe I went into the mechanism in the report. That's correct.
Q. One of the things you have said previously is that prolactin can directly stimulate the growth of glandular tissue?
A. Correct.
Q. You're not aware of any scientific study or medical texts that states or reports that prolactin directly stimulates breast growth. Are you?
A. I have read that and I'm trying to recall where I did. Off the top of my head, I don't recall at this moment, but I have absolutely read it and was aware of it going back to medical school, quite frankly.
Q. You recalled being asked that very question during your deposition?

A. I don't recall, but I can certainly look at the deposition if you have it.
Q. We'll go to your deposition at page 66, line 17 through 21.
Do you see that?
A. Can I look at it?
THE COURT: Does this have a number or will it be D-51?
BY MR. MURPHY:
Q. For the record, you have in your hand what's been marked D-51, and that's the deposition transcript. That was generated during your deposition in this case; right?
A. Yes.
Q. And at page 66, line 17, you were asked the same question I just now asked you; correct?
A. Correct.
Q. And your response was: Not off the top of my head.
So you aren't able to identify any support for that statement then and you are unable to offer support for that statement now; correct?

A. I believe my support is different than saying not off the top of my head. What I learned in medical school doesn't necessarily mean I can quote an article.
Q. With respect to the specific question that was asked of you, any specific study or article that supports that proposition as you sit here today, you cannot identify any; correct?
A. I don't have a recollection of what I learned 40 years ago in terms of where I read it, that's correct.
Q. At your deposition, there was another question asked of you which was whether you were able to say how it is that Risperdal caused Tim's gynecomastia.
Do you recall that?
A. I don't. I'm sorry.
Q. You don't? Let me ask you this:
As you sit here today, are you able to say or do you have an opinion about how it is you say Risperdal caused Tim's gynecomastia?
A. It's not -- first of all, it's not just how I say; and second of all, it's the

relationship between Risperdal. It's suppression of dopamine and elevation of prolactin, which then acts on the breast through a couple different mechanisms.
Q. You used the term mechanism of action?
A. I think I just said mechanism, not mechanism of action.
Q. Mechanism. When you used the term mechanism, do you mean the way in which the drug causes an effect?
A. That's probably a reasonable way to say it.
Q. Let's take a step back and keep it simple.
Your opinion is that prolactin elevation caused the gynecomastia; correct?
A. Yes.
Q. And one of the questions I asked you is whether it's your opinion that the prolactin acts directly on breast tissue to cause growth; correct?
A. Correct.
Q. So my question is: Is it your opinion that prolactin acted differently on Tim

Stange's breast tissue to cause gynecomastia?
A. That's one mechanism, which has been described as a possibility that I'm aware of. There are others that I'm also aware of, and we can't know exactly which one of those mechanisms was at play in Tim's case.
Q. What I'd like to do is I'd like to deal with them in turn.
The first one we're talking about right now is the mechanism you identified that says prolactin acts directly on breast tissue.
My question, a little while ago, was whether there were any articles or studies that you could identify to support that.
As I understood your testimony, as you sit here today, you can't identify; correct?
MR. KLINE: Objection. It's a mischaracterization. 20 minutes ago, he mentioned Anderson.
THE COURT: I understand that. It really is testimony. I'm going to ask you to restate the question.
I'll sustain the objection.
BY MR. MURPHY:

Q. With regard to the mechanism that you identified that says prolactin acts directly to cause breast tissue to grow, are there any articles or studies that you're aware of that support that?
A. I can think of three documents sitting here. One is the Anderson study that I referred to. One is a presentation that's in the internal Janssen documents that discusses prolactin in particular and its interaction with breast tissue; and a third is what I believe was submitted as a poster presentation for a meeting.
Again, it's an internal document where the presentation specifically described the direct effect, and that when the reviewers from the Janssen company saw it, they edited that portion out.
So those are three pieces of information, two of which were until I saw them, protected by confidentiality, as internal documents and not available to the public.
And that's the interaction between Risperdal, prolactin and gynecomastia.

MR. MURPHY: Objection. I move to strike the last part of that. He identified the documents but the editorial at the end is wholly inappropriate.
THE COURT: I'll take it.
BY MR. KELLY:
Q. So Anderson is one of the articles that you say support the mechanism that prolactin acts directly on breast tissue to cause breast growth; correct?
A. Yes.
Q. Let's take a look at the Anderson article. This has been previously marked as P-116.
Is this the Anderson article you're talking about, Doctor?
A. Yes, sir.
Q. Couple things about this Anderson article. This article reported on the continuation of the Rupp study.
Do you recall that?
A. I do have a recollection but I couldn't tell you specifically beyond that right now.

Q. Do you recall that this study was conducted by NIMH, National Institute of Mental Health?
A. It so says. If I may ask, where are you getting that from in this article?
Q. Where do I find that?
A. I see on the bottom of page one of the article, okay.
Q. This study is not a Janssen study. It's not a Janssen-conducted study; correct?
A. That's what it says.
Q. One of the results from this article was that there was a finding that prolactin levels were not associated with adverse events; correct?
Do you recall that?
A. I don't recall it but we can -- if you give me a line and page, I'm happy to review it.
Q. Sure. This one you can actually find in the -- on the first page in the abstract under Results. You can look at the screen to be oriented.
A. We're looking at the abstract. I see

that.
Q. Do you recall that was one of the findings from this article?
A. I see it here.
Q. Is there anything in this article, Dr. Solomon, that supports your statement that prolactin directly stimulates breast growth?
A. If I can call your attention to on the very first page, the paragraph that I would describe as top right, about halfway down, if I can quote, there's a sentence that begins with the word: Direct. Direct effects of elevated prolactin on breast tissue --
MR. KLINE: Excuse me, Your Honor. Since we're doing this on the board, may we put that on the board what he's quoting?
MR. KELLY: That's fine.
A. You can see about a third of the way down right there where you see direct. Let's highlight that sentence; and if I may read it.
Q. Sure.
A. Direct effects of elevated prolactin on breast tissue lead to galactorrhea in females

and gynecomastia in males.
Q. So we're clear, you read that to mean that prolactin actually causes breast tissue to grow, so we're clear?
A. It's pretty clear to me that that's exactly what it says.
Q. That's what you read it to mean? Yes or no?
A. It's not just what I read it to mean. It's what the sentence means to anyone who would read that.
THE COURT: Please answer the question.
A. Yes, that's what I -- that's what it says.
THE COURT: There it is.
BY MR. MURPHY:
Q. Thank you. Now, another thing that the Anderson authors noted was that their findings were consistent with the findings in the Findling article; correct?
A. I would have to read that statement.
Q. Sure. I'll orient it to you. Page ending in .4, bottom right. It's also 548 of

the original right column toward the bottom of the first paragraph.
THE COURT: Okay. Thank you.
BY MR. MURPHY:
Q. Do you see the language, Doctor?
A. Yes. I'm just reading the paragraph. If you give me a second, please. I have read the paragraph.
Can you ask me the question again, please?
Q. My question was, to you, was: Dr. Anderson reported that their findings were largely consistent with the findings of the Findling paper; right?
A. That's what it says.
Q. You know that this Anderson paper was published in 2007; correct?
A. That's what it says.
Q. Four years after the Findling paper came out; correct?
A. Yes.
Q. So we see another group of doctors reaching the same conclusion as Dr. Findling?
MR. KLINE: Objection. No objection.

if it's the same conclusion as to increase in prolactin.

THE COURT: I understand what you're saying. I'm asking you to refine the question.

MR. MURPHY: That's fine.

BY MR. MURPHY:

Q. We've read the language fairly consistent with the largest previous study of effects of long-term Risperidone treatment in children and adolescents, Findling, et al; correct?

A. Yes, that's what it says.

Q. And these doctors report that their findings are consistent with Findling; correct?

A. Yes. Just to be clear, Findling is describing elevated prolactin, and this study does as well.

Q. Then I think we agree that this comes four years after Findling; correct?

A. Correct. Consistent with the thought that the drug increases prolactin. That's correct.

Q. Doctor, you don't have an opinion as to

whether Tim Stange's ratio of estrogen to testosterone was in any way altered by prolactin. Do you?

A. I don't have any biochemical data for that.

Q. So you don't have an opinion on that?

A. Again, I know he had gynecomastia. I know he had elevated prolactin. I can't tell you what the ratio of testosterone was, that's correct.

Q. With all due respect, did you say that's correct, you don't have an opinion?

A. I don't have any information in that regard.

Q. I'm just trying to get us down the road.

I asked you a simple question: Do you have an opinion? If you don't, say you don't.

MR. KLINE: Respectfully, on that one, I think he answered.

THE COURT: I disagree with you, Mr. Kline.

Answer the question, please, Doctor.

A. My opinion is we don't have the data to give the answer to that question.

Q. There's no data that you've seen speaking to our addressing estrogen or testosterone levels during the time he was on Risperdal therapy; correct?

A. There is no data for that, that's correct.

Q. You're also aware that gynecomastia can develop in the absence of prolactin; correct?

A. Yes.

Q. For those individuals who develop gynecomastia in the absence of prolactin elevation, something other than prolactin is the culprit for gynecomastia; correct?

A. There are other causes, that's correct.

Q. You don't know how long prolactin needs to remain elevated in order to cause gynecomastia, as you say. Do you?

A. I'm not aware of that data.

Q. You're not aware of any published articles suggesting that prolactin elevation continues after Risperdal therapy is discontinued. Are you?

A. I'm not aware of any articles that -- say that again? Prolactin elevation continues

after Risperdal therapy ends?

Q. Correct.

A. I'm not aware of that, that's correct.

Q. But you are aware that if a patient discontinues Risperdal therapy, their prolactin levels decrease over time; correct?

A. Yes.

Q. You know what Risperdal's half life is also. Don't you?

A. I don't recollect it at the moment. I know it's relatively short.

Q. You know that if the medicine is no longer in the patient's body, then the medicine cannot cause a physiologic problem; correct?

A. Not correct.

Q. So it's your understanding that if the medicine is no longer in the patient's body, it can cause physiologic changes?

A. I think that the way to understand that is that if a stimulus occurs on a group of cells, and those cells are now dividing, and that stimulus is gone, but the cells are in there, now, a relatively new program of cell

division, then you can get an end result such as gynecomastia in the absence of the drug.
Q. Are there any articles or studies that you cite in your report supporting that?
A. That I cite in my report? No.
Q. Now, earlier, when you were here, if I heard you correctly, you told us that you conducted a differential diagnosis to determine the cause of Mr. Stange's gynecomastia; correct?
A. Yes.
Q. I want to hand to you for the moment my copy of your report. May I approach, Your Honor?
Part of what you write there is, my opinion is based on a differential diagnosis that includes other causes of gynecomastia. These other causes include hormone therapy, pituitary disease, testicular tumor, alcohol and other drugs; correct?
A. Yes.
Q. Because --
A. Can I read the next sentence for completeness? That's how you get a

differential diagnosis. So the jury understands the differential diagnosis.
Q. If you want to read the next sentence, you can.
A. Thank you. I go on to write: Review of the medical records and deposition testimony rules out all other causes of gynecomastia in Timothy's case.
Q. You identified certain of the things that you ruled out; right? That's what you just read.
A. I did write some of them. Not all.
Q. Let's talk about some of what you did.
THE COURT: Hold on. I'm going to have to give the jury a break. It's now five after 3:00. I'm giving to give them a rest break.
Ladies and gentlemen, I'm going to give you your afternoon break. Please don't discuss the case among yourselves or with others.
(Jury panel departs courtroom at 3:05 p.m. and reenters at 3:21 p.m.)
BY MR. MURPHY:

Q. We were talking about the differential diagnosis that you conducted. I wanted to ask you about one of the known causes of gynecomastia that you did not identify, and that is pubertal gynecomastia.
Is pubertal gynecomastia something that you ruled in and then ruled out as part of your differential diagnosis?
A. Forgive me but --
Q. My question is whether pubertal gynecomastia is something that you ruled out in the course of your differential diagnosis.
A. Yes.
Q. You know that there is a high background rate of pubertal gynecomastia; correct?
A. There is a background rate.
Q. How high is that background rate pursuant to the literature with which you're familiar?
A. It can be -- varies pretty widely. Anywhere from 25 percent to the 60 or 70 percent range.
Q. Earlier, you told us that -- well, I'll just ask the question.
You're aware that with regard to some

young boys who have pubertal gynecomastia, it persists into adulthood; correct?
A. I believe I have testified to that.
Q. Indeed. Your understanding is that the range is somewhere between five and 20 percent for those who have persistent pubertal gynecomastia into adulthood; correct?
A. That comports with my recollection, that's correct.
Q. Now, you've reviewed the medical records, as you identified in your report, related to Mr. Stange; correct?
A. Yes.
Q. In those medical records, there's nothing that indicates or suggests that Mr. Stange had had delayed puberty; correct?
A. That's correct.
Q. How then, sir, did you rule out pubertal gynecomastia as a cause of Mr. Stange's gynecomastia?
A. Several reasons. First of all, the majority of pubertal gynecomastia subsides with the end of puberty. In those patients in whom it persists, there's typically not a

cause that we can identify.
But as a rule in medicine, when you make a differential diagnosis, you start with, here's the problem, here are the causes that could potentially be, and you rank them from one to whatever, and you go down the list and eliminate them.
So that in Tim's case, given the agent that he took, the Risperdal, given the time course of the drug, given his growth, given the history of the drug and its relationship between prolactin and gynecomastia that we've discussed, it becomes the obvious answer as to the cause of his gynecomastia as opposed to pubertal, which would have gone away on its own; or if it persisted into adulthood, it becomes what we call pathic, which means maybe it is and isn't.
If you got an offending agent, that's where in medicine you're obligated to go. If somebody comes in with a cough and fever and a chest x-ray that looks like pneumonia and coughing up green gobs of stuff, they have bacterial pneumonia.

That's how medicine works. The most likely thing is the most likely thing; or as we say, when you hear a hoof beat, you don't think of Zebras.
Q. When you hear hoof beats, you don't think Zebras?
A. Yes.
Q. When you hear a boy going through puberty who presents with gynecomastia, you don't think pubertal gynecomastia.
Is that your testimony?
A. When he's taking Risperdal, that's correct.
Q. And in this instance, you point to prolactin and its association with gynecomastia as the reason why you don't think pubertal gynecomastia; correct?
A. Correct.
Q. And with regard to the literature that you looked at, you know that not everyone who is diagnosed with gynecomastia presents with elevated prolactin; correct?
A. That's probably correct.
Q. And with regard to Mr. Stange, you

haven't seen any lab tests or results that reflect what his prolactin level was during the time he was on Risperdal therapy; correct?
A. That's correct.
Q. Yet, you conclude that prolactin must have been the cause of his gynecomastia; correct?
A. I said that Risperdal was the cause.
Q. Risperdal, which you say raised his prolactin; correct?
A. Not me. That's the literature of Risperdal, is it raises prolactin.
Q. I'm asking you about your opinion.
If what you're telling me is you rely on the literature, that's fine. But you're telling the jury that Risperdal raises prolactin and that is what led to his gynecomastia; correct?
A. That's the very short synopsis, that's correct.
Q. And so we're clear in the room, you say that notwithstanding the fact that there are no lab tests or values for prolactin levels on Mr. Stange during the time he was taken

Risperdal; correct?
MR. KLINE: Objection, asked and answered.
THE COURT: He asked and answered that. He said there are no lab tests.
MR. MURPHY: I understand that. I want to make sure we're clear.
THE COURT: It's out there.
BY MR. MURPHY:
Q. One of the things you also identify as potential causes and you identify in your report is other drugs; correct?
A. Yes.
Q. And you've seen in the records where, among other things, Mr. Stange was taking Clonidine; correct?
A. Yes.
Q. You're aware that gynecomastia is a reported side effect of some who have taken Clonidine; correct?
A. Yes.
Q. And yet you rule out Clonidine as a possible cause.
Is that right?

A. Correct.
Q. Have you seen the product label for Clonidine?
A. No.
Q. You didn't research it?
A. I don't recollect it. If you have it, I'm happy to review it. I don't remember.
Q. I'm simply asking what you did in the course of your differential diagnosis.
You don't recall having reviewed the product label?
A. Candidly, I have reviewed so much stuff, I don't remember.
Q. Well, I'll ask you this and we can get beyond it.
Do you have any doubt that the product label for Clonidine identifies gynecomastia as an adverse event experienced by some of those who took Clonidine?
A. As I recall, I believe it's described as a rare event, but I'm not sure of the exact language they use.
Q. But do you have that recollection?
A. It is mentioned. Gynecomastia is

mentioned in the product label but I don't know how it's quantified.
Q. Now, I want to talk about some of the records that you did review. You recall that Dr. Mueler, as we understand it's pronounced, mentioned gynecomastia and Mr. Stange's chart in June of 2009?
A. Correct.
Q. Let's take a look to orient ourselves.
If you can, this is an office visit where gynecomastia is initially mentioned. Do you see that?
A. Yes.
Q. That's one of the records you reviewed?
A. Yes.
Q. You also understand that by June of 2009, Mr. Stange had ceased taking Risperidone for at least five months; correct?
A. Yes.
Q. And by that time, he had been -- he had discontinued taking Risperdal for about a year?
Is that your recollection?
A. That's my recollection.

Q. To your knowledge, did Mr. Stange ever have a test for Klinefelter's Syndrome?
A. A test?
Q. Was he tested for the syndrome?
A. What test, if I may ask would you be thinking about?
Q. There are a couple of tests that one can conduct. I'm simply asking you whether you saw anything indicating that he was tested.
A. He was not tested and based on my -- you asked my differential diagnosis and I ruled out Klinefelter's.
Q. I'm simply asking whether he was tested. That's all I asked you?
A. One does not necessarily need that to make the diagnosis; but correct, that test.
Q. Did you see any test conducted on Mr. Stange during the time he was on Risperdal therapy?
A. I don't recall.
Q. Did you see any evidence of blood tests taken at the time he was diagnosed with gynecomastia?
A. I don't recollect.

Q. Did you see any evidence of a blood test taken at the time he underwent his corrective surgery?
A. I don't remember if they got a preoperative blood count frankly, and a coagulation profile. Some surgeons do. Some don't. I don't remember.
Q. You don't know when Mr. Stange entered puberty. Do you?
A. I believe I have testified to that in my deposition, as a matter of fact.
Q. The answer is no?
A. I said I didn't know.
Q. Do you recall what Mr. Stange's Tanner stage was at the time he was diagnosed with gynecomastia?
A. In 2009, it might have been Tanner 4, but I know it's in the records so we don't have to guess.
Q. Do you see the record, Tanner's 3? Can you make that out, Doc?
A. I see that's what it says. If you're calling that 3 -- yes, that's a Roman Numeral 3. I do see that.

Q. We can agree he was Tanner stage 3 when we first see the reference to gynecomastia in his chart. Fair?
A. That's fair.
Q. At this time, he was 15 years, going up to the top aspect of the document, 15 years, three months; correct?
A. That's what it says.
Q. And for a boy 15 years, three months, Tanner 3 is normal progression; correct?
A. If he's been through Tanner 1 and 2, then Tanner 3 is the next step, that's correct.
Q. My question, to be more precise is: For a 15-year-old boy to be at Tanner stage 3, that's normal, not abnormal. Is it?
A. That's correct.
Q. As you understand it, Tanner 3 is mid puberty?
A. That's a good way to describe it.
Q. Now, I'd like to show you the April 8, 2011 note from Dr. Mueler.
Can you make that out?
A. Yes.
Q. April of 2011, that's less than two years

after Dr. Mueler initially referenced gynecomastia; correct?
A. Yes.
Q. And at this point, Mr. Stange was 17 years old. If we can go back to the top of the document and pull out the age.
Do you see that?
A. Yes.
Q. At this time, he is Tanner stage 4, I believe, if we go down to the relevant section.
Do you see that?
A. Yes.
Q. So two years later, he's further progressing through puberty; correct?
A. Yes.
Q. Another note from Dr. Mueler, this 6-2-08 is about a year before there was that initial mention of gynecomastia; correct?
A. Correct.
Q. And if we go down to where their mention is of Tanner staging, we see he is Tanner stage 3; correct?
A. That's what it says.

Q. So a year before there was any mention of gynecomastia, he was Tanner 3; right?
A. Yes.
Q. A year later, when there was this initial mention of gynecomastia, he's still Tanner 3; right?
A. That's what that says.
Q. In this document from June of '08, there's no mention of breast pain, tenderness, pain or anything like that; correct?
A. Correct.
Q. You know that the only complaint of chest or nipple pain was reported by Mrs. Stange in 2007; correct?
A. I'm aware of that.
Q. This is the note reflecting the call by mom.
This you've seen; correct?
A. You're referring to this note, not the one previously on the screen; correct?
Q. What I have in front of you is the note reflecting Mrs. Stange's call reporting on the pain in Tim's chest.
A. Right, in August of 2007, that's correct.

Q. Now, in that note, do you see a reference to appointment if increased pain?
A. I see that.
Q. Is it your understanding that the office was suggesting that an appointment should be made if there was continued or increased pain in his chest?
A. That's what it says.
Q. In the records you reviewed, did you see any indication that there was a follow-up or subsequent complaint of chest pain or nipple pain after the call was made by mom?
A. Not that I recall.
Q. Do you recall, Dr. Solomon, having testified that Mr. Stange developed gynecomastia somewhere between 2006 and 2009?
A. Are you referring to my deposition testimony in this matter?
Q. I'll ask you. Is that what you testified to in your deposition?
A. Again, I have some vague recollection that may characterize it, but if I stated it and we got it written down, could I see it, please?

Q. We shall. I direct you to page ten. I believe it might be lines 15 to 17 of your deposition.

MR. KLINE: Your Honor, I don't see any impeachment. He went right to the deposition. To that extent --

THE COURT: The doctor asked for it. That's the only reason.

MR. KLINE: I see. I get it.

BY MR. MURPHY:

Q. Is that what you recall, Doctor? Is that the testimony you recall?

A. I stated some time between 2006 and 2009 is when he developed gynecomastia. That's what I testified to on page ten, line 16.

Q. At the time of the deposition, what you were able to say is some time between 2006 and 2009; correct?

A. That's what I stated.

Q. You testified here in court that Tim's gynecomastias started in 2007.

Did you not?

A. I don't recall if I said precisely 2007. I'm not sure that's an accurate

characterization of my testimony.

Q. Pardon me?

A. I'm sorry, that's an accurate characterization of my testimony.

Q. The record will reflect what it reflects, sir.

A. I might note by, the way, 2007 and between 2006 and 2009.

Q. I understand. So we're clear, we're clear, what you said in your deposition was the best you could say at the time 2006 to 2009; correct?

A. I stated that in my deposition, that's correct.

Q. We're clear.

Having read the records as well as deposition transcripts, you're aware that Mr. Stange testified that he first noticed breast development in the summer of 2009; correct?

A. I don't recall that.

Q. You don't recall that?

A. No, sir, I'm sorry, I don't.

Q. Now, you've also offered the opinion that Mr. Stange gained excessive weight while on

Risperdal.

Is that right?

A. I believe that's in my report.

Q. And you didn't create a growth chart for purposes of that opinion. Did you?

A. I did not.

Q. Growth charts aren't something that you routinely utilize in your practice.

Is that right?

A. In my adult practice, no.

Q. The opinion you gave regarding his weight gain is based on your comparison of his first weight on Risperdal and his last weight on Risperdal; correct?

A. I'm not sure if that's how I came to that conclusion, frankly.

Q. Do you recall how you did, in fact, come to that conclusion?

A. I believe I saw a number of data points of his weight, and I saw that his weight went up and he went on an attempt to lose weight, which he did, and his gynecomastia persisted. Again, supporting it was nonpubertal in its type.

Q. Your testimony is that you looked at various data points in coming to that conclusion?

A. That's correct.

Q. Do you know how many inches Mr. Stange grew during the time he was on Risperdal therapy?

A. That's from 2006 to 2009, I'd have -- I'm not -- I don't want to get -- I know I saw it then but I don't recall it now.

Q. Doctor, is it your opinion that Mr. Stange developed rapid weight gain after beginning Risperdal therapy?

Are you consulting your report?

A. Yes. I'm not sure I used the term rapid anywhere in my report or deposition.

Q. Is that your opinion? Because there's certain things that are not in your report that you hold as an opinion, so I want to be fair to you.

Is it your opinion that Mr. Stange experienced rapid weight gain immediately after beginning Risperdal therapy?

A. Again, I have never, to my knowledge, I

don't believe I have ever used the word rapid.
Q. You do not hold that opinion; correct?
A. I have used the word increased. I have never used the word rapid.
Q. So you do not hold that opinion; correct?
A. That's correct.
Q. Do you recall, when Mr. Stange began his Risperdal therapy, he weighed 110 pounds?
A. I don't recall off the top of my head but I'm sure we have it on the chart someplace. We've seen that graph before, the table, I think.
Q. I'm going to hand you, Doctor, part of what previously was marked as P-59. Part of the record, I'm sure you reviewed.
Do you see the document?
A. I do.
Q. You see that it reflects Mr. Stange's weight as 110 pounds on February 7th, 2006?
A. 110 pounds, eight ounces.
Q. And that is when he began Risperdal therapy; correct?
A. Yes.
Q. Now, I'll ask you, but I'll deal with it

this way. That was February of 2006. I now want to show you a part of Dr. Mueler's records. This is from 12-4-06.
Do you see that?
A. Yes.
Q. Do you see his weight in December was 119 pounds?
A. Yes.
Q. Can we agree that between February of '06 and 12 of '06, he gained about nine pounds?
A. Correct.
Q. That's not rapid weight gain. Is it?
A. I'm not -- again, I have never used that word, so I don't know -- I don't know how I would define that.
Q. Now, in calendar year '06, he was 12 years old; right?
A. Yes.
Q. Do you recall that it was in calendar year 2007 that Mr. Stange gained 30 pounds?
A. I don't recall.
Q. We can look at it.
A. We can see that if that exists.
Q. I want to show you a record from April

13th of '07.
Do you see that?
A. Yes.
Q. And April 13th of '07, he weighs how much?
A. 122.
THE COURT: It's Bates 212 from the doctor's deposition, Dr. Mueler.
BY MR. MURPHY:
Q. April 13th, '07 he's 122 pounds; correct?
A. Yes.
Q. I'd like to direct your attention to the note of August 14th, 2007. May I approach?
A. Yes.
Q. Have you seen that record before, Doctor?
A. Yes.
Q. As of August 14, 2007, he was 143 pounds; correct?
A. Yes.
Q. Now a record from the end of the year, November 26, 2007.
Have you seen that before, as well?
A. Yes.
Q. There, it reports that he was 155 pounds;

right?
A. Yes.
Q. So in April, he was 122 pounds. By November, he was 155 pounds; correct?
A. Yes.
Q. That's when he was going through puberty; correct?
A. Yes. That's a fair statement.
Q. And he was 13 years old at that time; correct?
A. Yes.
Q. Now, you've identified for me the articles that you relied upon, and generally speaking, to be fair to you, the Anderson article, the Roke article and certain materials that are company documents; correct?
A. Yes.
Q. And that's the entirety of which you relied upon in terms of articles and medical literature; correct?
A. Again, you asked me a very specific question. You asked the connection between Risperdal and gynecomastia and prolactin and gynecomastia, and those items were my

response.

MR. KELLY: Thank you. No further questions.

THE COURT: Mr. Kline?

MR. KLINE: Sidebar, please?

(Sidebar discussion as follows:)

MR. KLINE: I have by all accounts eight minutes left.

THE COURT: Correct.

MR. KLINE: The record should reflect that this witness doesn't have a second day. He was here 2:00 to testify. I believe it was going to be half an hour additional examination.

That's what was represented last week. We now are -- last time he was here. I'm now given seven or eight minutes because this jury leaves at 4:00 consistently.

I can't complete it in that time. I will have to try to figure out a way. I have a significant examination.

Is Your Honor willing to hold them?

THE COURT: Hold them? Yes. But as

you know --

MR. KLINE: That's not going to be popular.

THE COURT: As you know, I will ask before I hold. That is, have they made child care arrangements, as I have done in the past when we had to hold them.

I told them one thing that was, we were going to stop at 4:00 so they can get ahead of the traffic and make plans based on that.

We start at different times but end at the same time. But absolutely, I'll ask them that. I'm willing to stay. I'm sure all the parties are.

MR. KLINE: I don't think it's fair to my client, frankly, for me to try to -- I will use my four, five minutes, I guess, but I plan to do the examination -- have to figure out when he's available and figure out what the equities are to all of that.

THE COURT: He's available tomorrow.

MR. KLINE: He said he was

potentially available tomorrow. I have plans to do stuff tomorrow.

THE COURT: I get it.

MR. KLINE: I'm not sure when he's back. I don't want to have a consultation with him in front of the jury. I have to do it. I'm not going to forego my redirect examination. Nor am I going to voluntarily accommodate them to get my examination done.

THE COURT: I get it. Now, I would suggest that -- do you want to do something now in the next five minutes?

MR. KLINE: Yes.

MR. MURPHY: Before we get off the record, I want to be clear. I did not misrepresent anything about the amount of time I was going to take.

I believe the record will reflect I was not deleterious. I was expeditiously going through my cross-examination of the doctor.

MR. KLINE: To give an example of expeditious, he's holding a chart with

all of the weight gains, which was done by Braunstein. Of course, they don't want to put that into evidence because it will show Braunstein did a case specific evaluation of the case, but that could be done simply with Braunstein's chart. That's for starters.

THE COURT: They tried the case their way.

MR. KLINE: That's for sure. It's the throw it up, whatever hits the wall may land.

- - -

CROSS-EXAMINATION

- - -

BY MR. KLINE:

Q. Dr. Solomon, I will not be able to complete. I'm given five minutes and I will not be able to do it.

A. I understand.

Q. I will have to discuss with you your schedule when we're done here. I want to try to get through a couple of things very quickly.

You mentioned the things that you reviewed today with counsel for Janssen. I believe in your direct examination -- I believe in your cross-examination you did not refer to the Entimen article.

Have you reviewed that as well?

A. I have.

Q. Is that one of the things that you relied upon?

A. Yes.

Q. And I am not going to drag it out. It's right here, at the back.

You recall the results, generally speaking, of the Entimen article published in 2015 as to the relationship of gynecomastia for a teenager?

A. Yes, I do. I believe it was five times control. Fairly large study.

Q. Five times control. Meaning that if you're on the Risperdal versus a teenager who is not, you would have a five times more likelihood to get gynecomastia?

A. Yes.

Q. Sir, the Roke study, if we can quickly

get my copy of Roke, sir.

What you were referring to here in the results section, but which was not fully explained, sir, is that they compared the Risperdal group to the -- like Dr. Entimen did, they compared the Risperdal group to the nonRisperdal group; correct?

A. Yes, sir.

Q. On Risperdal, gynecomastia was present 43 percent. We're not interested in the sexual dysfunction part here. Highlight gynecomastia, Risperdal-treated, 43 percent compared to 21 percent in the control group; correct?

A. Yes.

Q. Two to one, if you're on the Risperdal; correct?

A. Yes.

Q. Was that one of your take-aways from the study?

A. Yes.

Q. Was that one of the reasons that you came to court and said that gynecomastia --

MR. MURPHY: Objection, Your Honor,

leading.

THE COURT: It is a leading question.

MR. KLINE: It's two minutes to 4:00.

THE COURT: It's actually 4:00.

BY MR. KLINE:

Q. I want to do two things, if everybody can indulge me less than five minutes.

Is that what this study says, sir?

A. Yes.

Q. The study further, if you go to page 435, there's a chart -- do you have a paper in front of you?

I guess you can also look on the screen?

A. I have it, sir.

Q. The screen we're going to highlight things as well, sir. Ask for a little latitude.

Do you see in this study, they did gynecomastia with physical examination.

Do you see that?

A. Yes.

Q. And let's look at the table. It says,

prevalence of hyperprolactinemia and prolactin-related side effects with Risperidone in autistic kids; correct?

A. Yes.

Q. That's what the study is about, treated with Risperidone.

Now, these authors are studying this; correct?

A. Yes.

Q. Are they studying it because they don't think this possibly could ever happen?

A. No.

MR. MURPHY: Objection, Your Honor.

THE COURT: I'll overrule the objection.

BY MR. KLINE:

Q. Go down here, you have -- you see .05?

A. Yes.

Q. Is that the level of statistical significance?

A. Yes. It's not a random occurrence, is what it means.

Q. Here, they found in the case control for gynecomastia physical examination, 22 versus

ten; correct?
A. Yes.
Q. They showed up with twice the number, twice the number of gynecomastias on Risperdal, Risperidone, versus the control group.
That's the sugar pill group; correct?
A. Yes.
Q. Did you see this in that study when you looked at it?
A. I did.
Q. By the way, do you know where you have in the label 47 versus 2 that we've been back and forth with many times?
A. Yes.
Q. The Roke study, if you look here, it says here, in the results, back to the results, first page, abstract, results: Hyperprolactinemia was present in 47 percent but only two percent of the subject group; correct?
A. Yes.
Q. So that comes out of -- was in the label, does it conform to what's in this study?

A. Yes.
Q. And my word, you have -- you put kids on a pill, and 47 percent get hyperprolactinemia and you know that increased prolactin anemia is in two percent of --
MR. MURPHY: Objection.
MR. KLINE: I'll get to a question.
BY MR. KLINE:
Q. Two percent of the control; correct?
A. That's exactly what it says.
MR. MURPHY: Objection.
THE COURT: Hold on. Let's stop here. Hold that thought. We'll come back to it.
I don't want to rush you to the point you don't ask the type of questions you want to ask. I think we're going to stop here and start fresh with Roke.
It's four after 4:00. You have one minute but I'm not going to give it to you. Taking it away. Teacher says no.
Ladies and gentlemen, we'll finish this at some point one way or another, I promise. So I'm going to let you go.

You're off tomorrow. We'll come back in on Thursday at 9:00. Is 9:00 for Thursday good? Okay. Let's see what I have. Let's see.
I'm going to let you go at this point and ask you to come back at 9:00 on Thursday. Tomorrow we will not have court.
Don't discuss this with anybody at home, any friends, anybody or among yourselves at any time.
If you should see something, hear something or read something in the press, television, radio, ignore it. Turn it off and walk away.
Don't do any investigations on your own. Don't look up anything on the Internet. You're just not allowed to. It's only what you hear in this courtroom you're permitted to evaluate.
Remember to wear your badge in a conspicuous place when you're in the courtroom, in the courthouse Thursday.
Good evening. Enjoy your day.

We'll see you Thursday.
(Jury panel departs courtroom at 4:05 p.m.)
MR. GOMEZ: I'm going to mark the chart as 132. Behind it 133. Handwritten chart on redirect of Dr. Solomon and page two will be the handwritten chart on redirect of Dr. Solomon.
- - -
(Adjourned.)
- - -

CERTIFICATION

I hereby certify that the proceedings and evidence are contained fully and accurately in the notes taken by me on the hearing of the above cause, and this copy is a correct transcript of the same.

Maureen McCarthy
Maureen McCarthy, RMR, CRR
Official Court Reporter

(The foregoing certification of this transcript does not apply to any reproduction of the same by any means unless under the direct control and/or supervision of the certifying reporter.)

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Appendix E

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

- - -

IN RE: RISPERDAL® LITIGATION :
A.Y., et al., : APRIL TERM, 2013
v. :
JANSSEN PHARMACEUTICALS, INC.,: NO. 2094
et al.,

- - -

WEDNESDAY, JUNE 22, 2016

- - -

COURTROOM 475
CITY HALL
PHILADELPHIA, PENNSYLVANIA

- - -

TRIAL - AFTERNOON SESSION - VOLUME III

- - -

B E F O R E: THE HONORABLE PAULA A. PATRICK, J.

REPORTED BY:
SHANNAN GAGLIARDI, RDR, CRR
REGISTERED DIPLOMATE REPORTER
CERTIFIED REALTIME REPORTER
OFFICIAL COURT REPORTER

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Karista Brown, Paralegal

W I T N E S S I N D E X

PLAINTIFF'S EVIDENCE

DEFENSE'S EVIDENCE

COLLOQUY

THE COURT: Do we have to discuss anything before the jury comes in?

MR. ITKIN: I don't think so, Your Honor.

THE COURT: Let me just say this. I know you all are from out of town, but, in Philadelphia, we have these concerts and shows and all these things out there. It can be quite annoying and they can get loud. Hopefully, they won't be loud. That's all I can say to you. I don't have any control over that. If I did, I would stop the whole thing, but I can't.

MR. ITKIN: We could hold them all in contempt, Your Honor.

THE COURT: I would like to, but some days we have to deal with this, especially in the summertime.

MR. ITKIN: Judge, I think where it is right now, it's fine. If it gets to be that it's some sort of heavy metal concert or something, we might approach.

THE COURT: It has happened.

MR. ITKIN: I just don't want it to be

COLLOQUY

where they can't hear.

THE COURT: When Stevie Wonder came, you should have been here that day.

MR. ITKIN: I would ask for a short continuance for Stevie Wonder.

THE COURT: Yeah, they have these pop-up concerts. I don't know.

THE COURT OFFICER: Please stand as the jurors enter the courtroom.

(The jury enters the courtroom at 12:50 p.m.)

THE COURT OFFICER: You all may be seated.

THE COURT: Okay. We have to contend with a concert or something outside, so please listen carefully. And we'll have counsel speak louder, I'll speak louder, and hopefully the witness will speak loud as well.

Okay. Your next witness.

MR. ITKIN: Thank you, Your Honor. We would like to call Dr. Mark Solomon as a live witness.

THE COURT: A live witness.

SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014

DIRECT ON VOIR DIRE - SOLOMON

THE COURT OFFICER: Can you state your full name, please?

THE WITNESS: Mark Solomon.

(Witness sworn.)

- - -

DIRECT EXAMINATION ON VOIR DIRE

- - -

BY MR. ITKIN:

Q. Please introduce yourself.

A. I'm Mark Solomon, MD. I'm a plastic surgeon here in Philadelphia. Been in practice for 31 years. It's hard to believe, frankly. I practice a broad array of plastic and reconstructive surgery, including the things that everybody thinks about as what we see on television for cosmetic surgery.

But I'm also blessed to be able to work at Shriner's Hospital for Children about 20 percent of my time and treating those children from all over the world with very challenging problems and hopefully making them better.

Q. Thank you, Dr. Solomon.

Do you need a bottle of water or anything before we get going?

A. That would be great. Thank you.

SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014

DIRECT ON VOIR DIRE - SOLOMON

Q. Dr. Solomon, where were you born?

A. In Philadelphia.

Q. Okay. And where did you go to college?

A. In Lancaster at Franklin & Marshall.

Q. What did you study in college?

A. I majored in biology, got an Honors degree after doing a thesis at college.

Q. And why did you choose biology as a field to study?

A. From a fairly early age, I was interested in medicine as a career, and the life sciences, in particular. So that biology was a natural fit for my goal of going to medical school. I trained in biology and enjoyed the science and then was able to successfully apply to medical school and get in.

Q. Where did you go to medical school?

A. New York University, NYU.

Q. That's a pretty well-known, high-end medical school?

A. I'm immensely proud of that institution. I think it's an amazing place. I think the education I got there was second to none, and I use things that I've learned there every day. So it was a great, great experience.

SHANNAN GAGLIARDI, RDR, CRR, (215)683-8014

Q. How long is medical school?
A. Four years after college.
Q. After college. So four years of college, four years of medical school, what do you do next?
A. You have a medical degree, but you're not really a doctor. To be a doctor, you have to do an internship. An internship is a hospital-based experience where you take care of patients, back then pretty much 24/7, to learn about how to care for people in a variety of disciplines.

So we rotated through surgery, medicine, gynecology, orthopedics, plastic surgery, to learn, with a bend towards surgery, but how to take care of sick people, and I did that at Penn, University of Pennsylvania.

Q. University of Pennsylvania.

How long is the internship?

A. The internship is one year.
Q. What do you do after that?
A. After that, you become what's called a resident, and I became a resident in general surgery, to be a general surgeon, because that's the pathway to be a plastic surgeon.

I decided I wanted to be a plastic surgeon,

actually, within the first year of medical school. I still remember the lecture that I saw, and I was so amazed by what they were doing. And I said this is for me.

So I trained in general surgery first at Penn, and general surgery back then was either five or six years. And because I wanted to do plastic surgery, I had the opportunity to go to Jefferson and knock a year off the training.

So I did three years at Penn, two years at Jefferson, the second year of which is called a chief resident year where you're pretty independent, taking care of patients with supervision, obviously, but you have a lot of responsibility managing what we call a service, inpatient care, operating room care, and so forth. Then I went back to Penn and did a residency in plastic surgery.

Q. So you did -- just to make sure I understand this, there's two residencies. There's one that's just general surgery, how to operate on all different parts of the body?

A. And all different disciplines, cardiac, general, plastics, transplant, vascular. Those are the main disciplines that we did.

Q. Then you did a second residency that trains you to be a plastic surgeon?
A. Correct.
Q. So all in all, how many years were you a resident?
A. Seven.
Q. So four years of college, four years of medical school, an internship for a year, and then?
A. Four more of general surgery and two of plastic, so a seven-year block.
Q. Sixteen years of schooling?
A. Well, and then I did a fellowship about two years later. I was invited to France to do a fellowship that actually pretty much mimicked what I do today, which is aesthetic surgery and pediatric plastic surgery, and I did that for six months.
Q. I think I heard you say that you were something called the chief resident?
A. The senior year of responsibility in both of those residency programs is a chief resident. As the chief resident, there are administrative roles in terms of organizing call and operating room time.

And then there are surgical cases that you get to do in a supervised way where you're doing the

surgery with somebody looking over you, but the patients are your patients as the chief resident.

So it's an intense learning experience that really sort of gives you the sense of what that responsibility is because, right after that, you're on your own.

Q. And being named chief resident is an honor; is that correct?
A. Yeah. Not everybody gets it because a lot of people can't finish the program.
Q. So after you completed your second residency, you became a plastic surgeon; is that correct?
A. I went into private practice, plastic surgery.
Q. You are something called board certified; is that correct, sir?
A. Correct.
Q. What does it mean to be board certified?
A. I'm actually board certified in two specialties, general surgery and plastic surgery. In each of those specialties, the track for certification is the same. First you take a set of written examinations, and, if you pass those, you can

then take the oral examinations. And once you've passed both sets of exams, you are certified.

In general surgery, they have, at the time that I got it, what's called a time-limited certificate for ten years. So ten years after I got my certificate, even though I wasn't practicing general surgery at that point, I was an academic professor at a medical school, so I felt it was worthwhile to maintain my certification. So I went and took another exam to recertify in general surgery even though it was something I wasn't practicing.

Q. You are board certified in general and plastic surgery as well?

A. Yes.

Q. And you have medical licenses both in Pennsylvania and New York; is that correct?

A. And Ohio and California.

Q. Okay. Four states?

A. Yes.

Q. Tell us a little bit about some of the hospitals that you have had privileges at, you've been allowed to operate in.

A. When I first went into practice, I was practicing at what was then called Graduate Hospital,

some of you probably don't even know what it is anymore, and also another hospital that's gone, Germantown Hospital.

And I was in private practice going between those places having privileges to do plastic surgery, taking care of trauma patients, cancer patients, and cosmetic surgery patients, and, actually, at the beginning, I did hand surgery as part of plastic surgery.

And then several years after that, I was invited to become the chief of plastic surgery at what was then called the Medical College of Pennsylvania, again, something that you may remember. There's been a lot of turmoil in the hospital world in Philadelphia, and it's buffeted my practice as well.

So I was chief there. They merged with Hahnemann, and I was chief there. And then in '96, I decided to go back into private practice because, as some of you may know, I had a feeling that what they were creating wasn't going to survive, and sure enough it didn't. So I wanted to maintain my independence and went into private practice, and I've been in private practice since operating at

Pennsylvania Hospital, a couple of the surgery centers. And then, starting in 2013, I was invited to join the staff at Shriner's and have been there, as I said, 20 percent of my time.

Q. Tell us a little bit about what Shriner's Hospital is.

A. Shriner's Hospital is a miracle. We treat children from all over the world with a variety of conditions, and this particular Shriner's Hospital has a focus in several areas. Those areas are spine, which includes spinal cord injuries and scoliosis, cerebral palsy, limb length discrepancies and upper extremity problems, and then a smaller amount is late burn reconstruction. And then I also see an assortment of other birth defects that flow from that in these kids who often have multiple birth defects.

Q. You spend 20 percent of your time there?

A. At least.

Q. When was the last time you were at Shriner's Hospital?

A. Yesterday, and I'll be there after we're done here. I have a patient to see.

Q. You also have your private practice; is that right?

A. Yes.

Q. Tell us a little bit about your private practice.

A. So, again, my private practice has evolved over the years because, in plastic surgery, we do a broad array of things. And as time has progressed, I've been fortunate enough that I can focus on what's called cosmetic surgery because it's fun. It's challenging. I like doing it. I get, I think, good results and I enjoy it. So I've been fortunate enough to build a practice of primarily cosmetic surgery, and that's what I do.

Q. What different parts of the body do you treat?

A. Plastic surgery is a discipline that goes head to toe. Most other medical and surgical disciplines are what we call anatomically bound. There are heart surgeons. There are bone surgeons. There are brain surgeons. Plastic surgery is a system of thought about surgery, about how we handle problems, so, consequently, I operate head to toe.

So the cosmetic stuff is facelifts, breast surgery, body surgery, genital surgery, and the reconstructive stuff is facial reconstruction, breast

reconstruction. Even in birth defects there are breast issues, extremity reconstruction for kids with traumatic or congenital deformities of their extremities.

Q. Do you, in your practice, ever have occasion to see patients with something called gynecomastia?

A. Absolutely.

Q. Okay. Ballpark it. How many patients in your practice, not in the courtroom, just in your practice, private practice, have you seen with gynecomastia?

A. Hundreds, literally, because in 30 some years of practice, it's a pretty common thing that I see.

Q. Outside of the courtroom, have you diagnosed patients with gynecomastia?

A. Absolutely.

Q. Have you diagnosed patients with what caused their gynecomastia?

A. When we can find out, yes.

Q. Have you authored any articles?

A. A number of them.

Q. Okay. When you authored those articles,

did anybody ever write those articles for you or were you the actual person who wrote them?

A. The articles I've written, I've written generally with other authors, but authorship is amongst all of us. We all write either different sections or we review and re-edit things and examine the data together. It's a team effort.

Q. You never hired outside consultants to do your authorship, though?

A. Never.

Q. You've gotten grants in your business; is that correct?

A. I have. It's been a while, but yes.

Q. Including, I know it's not related to this case specifically, but you've gotten grants dealing with the breast; is that correct?

A. Actually, breast cancer research.

Q. Sir, you have extensive knowledge of the endocrine system?

A. Yes, endocrine diseases, endocrine health. First of all, it's certainly basic stuff that you learn in medical school. And then as part of my general surgery training, we did surgery of the adrenal glands, of the thyroid glands, for example.

And, actually, at Penn, in plastic surgery, I don't think it's that way anymore, but in the '80s when I was there, we did our lion's share of thyroid surgery, parathyroid surgery. That was part of our training.

Q. Why do you have to know about the endocrine system for the work that you do?

A. The endocrine system is basic to the care of any patient. I mean, I probably see patients with thyroid disease every week. I have to know that they have it. I have to know their thyroids are well controlled. If I'm going to operate on them and their thyroid is not properly managed, they can get very sick very quickly. Diabetes is a very common endocrine disorder, and I've certainly done my share of pancreatic surgery.

Q. It's something you deal with in your practice literally every day?

A. Yes.

Q. Tell us about your knowledge of the breast. Do you have knowledge of the breast?

A. Yes.

Q. Do you understand the breast anatomy, physiology, those sort of issues?

A. Absolutely. I treat breast conditions, again, every day of the week.

Q. Okay. You know about the development of the breast in both males and females?

A. Yes.

Q. How many breasts do you think you've examined over the years?

A. Thousands.

Q. You're in a courtroom; is that correct?

A. Yes, sir.

Q. In full disclosure, I've retained you as an expert in this case; is that right?

A. Correct.

Q. Let's just get it out of the way.
Are you here for free today, sir?

A. No, I'm not.

Q. Okay. How much do you charge for courtroom testimony?

A. So courtroom testimony is charged at the rate of what it would be for me to be working in my office operating on people. So I take in about $20,000 for the day in court.

Q. And that's your -- how long has that been your fee?

A. Years.
Q. Okay. You've given depositions before?
A. Correct.
Q. Do you normally work on the plaintiff's side or the defense side when you're doing litigation consulting?
A. Frankly, in the past, many years it's been more for the defense, probably 60 to 70 percent, than for the plaintiff. But my general rule is I evaluate the cases as I see them, and I decide if they have merit and if I want to be involved.
Q. And no matter what you say today, I still owe you for your bill; is that right?
A. Correct.

MR. ITKIN: Your Honor, at this time we would tender Dr. Solomon as an expert in plastic surgery, the endocrine system, breasts, medicine generally, general causation, and specific causation.

THE COURT: Any objection?

MR. ABERNETHY: Voir dire, Your Honor.

THE COURT: Yes, voir dire.

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CROSS-EXAMINATION ON VOIR DIRE

- - -

BY MR. ABERNETHY:
Q. Good afternoon, Dr. Solomon.
A. Good afternoon.
Q. You testified that you have treated patients in your practice with gynecomastia; correct?
A. Yes.
Q. It would be correct, would it not, that 5 percent or less of your practice involves the treatment of gynecomastia?
A. That's probably a fair assessment.
Q. Now, endocrinology is a medical specialty, is it not?
A. That's correct.
Q. And endocrinology is the medical specialty that deals with hormones like prolactin and hormone-related diseases?
A. Partly.
Q. You are not an endocrinologist, are you?
A. That's correct.
Q. You are not board certified in endocrinology?
A. That's correct.
Q. You don't belong to any professional

organizations in the field of endocrinology?
A. That's correct.
Q. You don't review regularly the medical literature in the field of endocrinology?
A. That's correct.
Q. Now, you perform plastic surgery on patients with endocrine-related conditions, don't you?
A. Correct.
Q. But you don't provide the primary treatment for that, for the endocrine conditions. That's provided by an endocrinologist, isn't it?
A. Correct.
Q. And you also perform plastic surgery sometimes on patients with something called hypogonadism; is that right?
A. Correct.
Q. But you don't provide the primary treatment for hypogonadism itself; is that right?
A. What would you describe as the primary treatment for hypogonadism?
Q. Well, you've testified, haven't you, that you don't treat hypogonadism as a primary entity; you provide treatment as a plastic surgeon?

A. That's a correct statement.
Q. The primary treatment for someone with hypogonadism would come from an endocrinologist or a urologist or a gynecologist, for a female patient, wouldn't it?
A. Again, endocrinologists may or may not provide endocrine treatment. Urologists, I'm not aware of many that treat hypogonadism medically. They tend to treat it surgically.
Q. In terms of endocrinology or urology, you don't practice in those specialties, do you, sir?
A. I practice plastic surgery as it relates to urology.
Q. But you don't hold yourself out to patients as an endocrinologist or a urologist, do you?
A. No. I'm a plastic surgeon.
Q. Now, you're here to testify today about a drug used for psychiatric and behavioral conditions called Risperdal; correct?
A. That causes gynecomastia, correct.
Q. We're going to get to that later. We're talking about qualifications now.
You're not a psychiatrist, are you?
A. I often tell patients I'm a psychiatrist

with a scalpel, but I'm not trained as a psychiatrist, if that's what you mean.
Q. You don't practice and hold yourself out to patients as a psychiatrist?
A. Correct, I don't perform psychiatry.
Q. And you're not board certified in psychiatry?
A. Correct.
Q. You don't prescribe atypical antipsychotics like Risperdal in your practice, do you?
A. I do not.
Q. In fact, you don't recall ever prescribing Risperdal for a patient, do you?
A. That's correct.
Q. And you don't treat the condition for which Risperdal is used?
A. Correct.
Q. I want to ask you -- Mr. Itkin asked you a little bit about your publications.
You were the editor of a textbook, were you not, on male aesthetic surgery?
A. That's correct.
Q. And that book included chapters that were written by various authors, some of which discussed

gynecomastia; correct?
A. Correct.
Q. Leaving aside editing that book, you've never published in the peer-reviewed literature on gynecomastia or its causes, have you, sir?
A. To my knowledge, that's correct.
Q. And you've never published anything in the peer-reviewed literature on Risperdal, have you?
A. I have not.
Q. You've never published in the peer-reviewed literature on pubertal development, have you?
A. Not that I recall.
Q. And you've never published in the peer-reviewed literature on hypogonadism, have you?
A. Correct.
Q. And you have not published in the peer-reviewed medical literature on prolactin elevation or its effects, have you?
A. Not to my knowledge.
Q. You're not a pharmacologist, are you?
A. I'm a plastic surgeon.
Q. Different than a pharmacologist?
A. Correct.
Q. And you've never published in the

peer-reviewed literature on medicine-induced or drug-induced gynecomastia, have you?
A. Correct.
Q. You are familiar with the term "mechanism of action," are you not?
A. Correct.
Q. And in relation to a drug like Risperdal, mechanism of action would refer to how the drug causes a therapeutic effect or how it causes an adverse effect; would that be fair?
A. That's a fair statement.
Q. You've never published in the peer-reviewed medical literature on any mechanism of action by which Risperdal or any other drug causes gynecomastia, have you?
A. Correct.
MR. ABERNETHY: Your Honor, the defendants accept the proffer of Dr. Solomon as an expert in the field of plastic surgery and in the field of the breast as it relates to plastic surgery.
We object to the proffer insofar as it relates to the endocrine system or to general or specific causation, which I

assume means testimony about the causation of gynecomastia by a drug or the effects of prolactin elevation or hypogonadism. In those areas we would object.
THE COURT: Your response.
MR. ITKIN: Your Honor, he's testified that he knows about the endocrine system. He's diagnosed drug-induced gynecomastia. I can clean up a couple questions, if you want. He has a pretension of knowledge on these subjects.
THE COURT: Objection is overruled. He will be qualified as an expert.
MR. ABERNETHY: Thank you, Your Honor.
THE COURT: Go ahead.
- - -
DIRECT EXAMINATION
- - -
BY MR. ITKIN:
Q. Dr. Solomon, you've read lots of literature, I assume, about how -- you mentioned, I think you said, that Risperdal can cause gynecomastia?
A. I did.

Q. Is there scientific literature that people in your profession read that talk about that?
A. Correct.
Q. Are you familiar with that literature?
A. Correct.
Q. Do you understand it?
A. I do.
Q. Something you read in your normal practice?
A. Correct.
Q. You've diagnosed drug-induced gynecomastia in your private practice?
A. I have.
Q. Outside of litigation, outside of courtrooms?
A. Before we ever met.
Q. Fair enough.

Let's talk about gynecomastia a little bit. First of all, I've got a little slide here. What is gynecomastia?

A. So gynecomastia is defined as feminization of the male breast. And you've got the roots up there, Gyne meaning, women go to gynecologists, it refers to a female doctor, and the mastia refers to the breast. So the definition is in the word.

Q. Fair enough.

Doctor, I want to show you, I don't know if this would be helpful or not, but I want to show you something I found online. Tell me if you can help us explain a little bit about the breast physiology. We'll put it up on the screen here for you maybe.

Is this something that could be helpful to us?

A. Absolutely.
Q. If you'd like, Your Honor, with the Court's permission, Dr. Solomon, I've got a laser pointer, if you want to come down and sort of describe.

THE COURT: Sure. Whatever is easier.

MR. ITKIN: Maybe I'll give you this laser pointer.

THE COURT: Okay. Just be aware, Doctor, because you are down there, you're not up on the stand, you have to speak loud enough so the court reporter can hear you and everyone is able to hear you.

THE WITNESS: Yes, I will.

THE COURT: You may want to stand down further so the jury is able to hear you so your back is not toward the jury.

THE WITNESS: I'm going to go back and forth just so you folks can see what I'm pointing to.

BY MR. ITKIN:

Q. Maybe I'll ask the questions, Doctor. If I say something stupid, just let us know. It won't be the first time.

Left side we've got a normal male breast tissue?

A. Correct.
Q. So tell us what we're looking at on the left side.
A. So this is an anatomic slice if you cut something literally down the middle and you're looking at their chest wall. So what you see are ribs, that white shape, muscle, and this is fat under the skin of a male.

This picture is pretty accurate but not completely accurate because men do have a little bit of breast tissue, a few cells of breast tissue, but women have more of it. And these granules here that are a different color than this yellow fat are actually dispersed throughout this breast tissue.

Q. So I don't mean to interrupt, but the

yellow is fat that we all have, men with normal chests have in our breast?

A. Correct.
Q. And where it says glandular tissue and it's a little kind of different color, that's not fat; am I understanding that correct?
A. That's breast gland. Everybody knows the gland secretes milk. That's the biologic purpose of the gland. So that glandular tissue is dispersed throughout the breast in women. In men, there tends to be a small amount of glandular tissue right under the nipple, and that's the difference.
Q. In a normally developed breast in a man or a boy, they don't have very much glandular tissue?
A. Correct.
Q. In a man or a boy with gynecomastia, I assume they have glandular tissue?
A. It looks much more -- again, these glandular elements are spread out, and they cause enlargement of the breast.
Q. That's why it looks like a female breast on a boy?
A. Correct. And the other thing that I want to note is this muscle is your pectoral muscle, your

chest muscle. So the breast sits entirely overtop of that. When we go a little later, you'll see why that's important to remember.

Q. Okay. Perfect. I think that answers my questions about the breast. We may come back to that in a moment.

Doctor, as you're getting back on the stand, on touch, on a physical examination, can a doctor who is, you know, trained and knows what they're looking for, can they tell the difference, on touch, between what we looked at as the fat or the normal breast versus the glandular tissue?

A. Absolutely. And the key is that glandular tissue is firm. Fatty tissue is soft, somewhat mushy, and certainly women who do self-exam, breast self-exam, can absolutely know the difference between breast tissue and non-breast tissue or fatty tissue within the breast.

Q. Okay. Now that we kind of got that out of the way, I want to shift gears and talk about Andrew.

You've met my client Andrew; is that right?

A. Yes.

Q. How is it that you came to meet him?

A. Your firm asked me if I would perform an

evaluation of Andrew to determine if he had gynecomastia. You arranged for him to come to my office. I met him with his mother, and I performed a medical history and physical examination of him to determine, among other things, if he had gynecomastia.

Q. And I don't want to short circuit to the end of the story, but what did you find out when you examined him? Did he have gynecomastia?

A. Yes.

Q. In addition to getting to meet Andrew and examine him, we also sent you some medical records?

A. Correct.

Q. And some deposition testimony; is that right?

A. Correct.

Q. My notes have it that Andrew was born -- I'd like to talk about some of the medical records and kind of give us some history.

My notes indicate that Andrew was born December 17, 1998; is that right?

A. Yes, sir.

Q. So I'm going to write some things down just to help us keep it straight.

MR. ITKIN: Your Honor, can I ask if the jury can see?

THE COURT: You actually can move it closer.

MR. ITKIN: Is that blocking the screen?

THE COURT: You can move it right there, if you want, just so they can see it.

MR. ITKIN: I'm going to promise you I'm going to knock this down at least once during the testimony. It's already stuck in my pant leg. Here we go.

MR. ABERNETHY: Your Honor, it's okay if I move around a little to see that, if need be?

THE COURT: Absolutely.

BY MR. ITKIN:

Q. DOB, that's shorthand for doctors for date of birth?

A. Yes.

Q. 12/17/98; right?

A. Correct.

Q. So did you review the records from a

Dr. Eker?

A. Yes.

Q. And I'm going to hand you what's been previously marked as PX5003. This is a -- I'll identify, mark, and offer into evidence the July 18 note.

MR. ABERNETHY: May I have a copy?

MR. ITKIN: I've redacted it per the Court's instructions.

THE COURT: What is that marked as?

MR. ITKIN: This is PX5003, and it's had the privacy information we discussed previously taken out.

THE COURT: Okay.

MR. ITKIN: Your Honor, with the Court's permission, I'd like to publish the exhibit on the screen.

THE COURT: Is there any objection?

MR. ABERNETHY: No, Your Honor.

THE COURT: Okay.

BY MR. ITKIN:

Q. You received the records from Dr. Eker; is that right?

A. Yes.

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Q. And Dr. Eker was, my understanding -- what type of doctor was Dr. Eker?
A. A psychiatrist.
Q. And it looks like this visit is July 18, 2003; is that right?
A. Correct.
Q. So how old is Andrew at that time?
A. Four and a half.
Q. Four and a half-ish. And he's there to be evaluated for some psychiatric issues; is that right?
A. Correct.
Q. At this time he is on what medications?
A. None.
Q. Okay. So let's move a little bit forward in time because at that appointment he was prescribed, if we go to the next page of that record, there's the plan; right?
A. Yes.
Q. Help me a little bit with this, Doctor.
I realize all doctors, I assume, take their notes and records a little bit different; is that right?
A. Correct.
Q. But there are some things that, when we

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read through these records, that may trigger to you, as a doctor who sees them, that helps you understand what the doctor is going through process-wise?
A. Yes.
Q. So, for example, when they have the section of the plan, what does that mean in the medical record?
A. That's the outline of the physician's care plan for the patient, what steps are going to be implemented to help the patient, whether it's medication, surgery, physical therapy, whatever.
Q. So we have a 30-minute appointment, four-and-a-half-year-old boy, Andrew, and the plan is start the patient on clonidine. And then at the bottom of that paragraph it says: I explained to the mother the side effects of clonidine, including sedation, dizziness, and decrease in blood pressure.
Do you see that?
A. I do.
Q. Clonidine is a medicine?
A. It's a medicine that has multiple uses in adults. It can be used for people with elevated blood pressure.
Q. That's what they started Andrew on as a

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result of that 30-minute appointment?
A. Correct.
Q. Let's fast forward in time a little bit, and it looks like I'm going to hand you what is PX -- part of PX5003. This is an August 1 -- this looks like a follow-up appointment from August 1, 2003.
A. Correct.
MR. ITKIN: Your Honor, we'd like to offer and introduce the August 1 record into evidence. I think maybe for ease of the record, what we might do is label them going forward instead of what they were marked.
THE COURT: Any objection?
MR. ABERNETHY: I don't object to this page, Your Honor.
THE COURT: Okay. It's admitted.
MR. ITKIN: May I publish it, Your Honor?
THE COURT: Yes.
BY MR. ITKIN:
Q. This is August 1, 2003; is that right?
A. Yes.
Q. Same doctor, Dr. Eker, the psychiatrist;

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right?
A. Yes.
Q. It looks like this is a 15-minute visit?
A. Correct.
Q. Still about four and a half years old?
A. Yes.
Q. It says patient is four and a half years old, if I can read the record, with a diagnosis of ADHD; is that right?
A. Yes.
Q. The other highlighted part says: The mother wants the patient to be tried on Strattera as she heard it from her husband's doctors, and she is concerned that clonidine might affect the blood pressure.
Do you see that?
A. I do.
Q. What do you take away from that?
A. That there was some discussion between Dr. Eker and Andrew's mother about using additional medication because of her concerns related to the clonidine that had been prescribed initially.
Q. Now we go to the plan section, and if we can maybe show the rest of the plan section so we can

kind of get the full picture.

I will start the patient on Strattera as the mother does not feel comfortable with the clonidine for the blood pressure issues. I explained the possible side effects, including sedation, dizziness, extrapyramidal symptoms and -- we're on the wrong visit. We switched visits here on you. You went forward a page. We screwed up. I'm showing you the wrong medical record, Doctor. I'm sorry.

At any rate, while we're getting that pulled up, they switched him to the Strattera; is that right, Doctor?

A. Yes.

Q. And it states: I stated the medication is not indicated for usage in children younger than six.

Do you see that?

A. I do.

Q. But we can give it a trial?

A. Correct.

Q. So the psychiatrist prescribed this. This would be called an off-label prescription?

A. Correct.

Q. They figured we'll give it a try?

A. Yes.

Q. Now let's forward ahead to about two or three weeks later. This is the next visit I have in the records of August -- it's actually two visits ahead, but I want to kind of move through this to the August 22, 2003 visit. This is also part of P003.

MR. ITKIN: Your Honor, we'd like to offer, mark, and introduce, barring any objection, publish this to the jury.

THE COURT: Any objection?

MR. ABERNETHY: Not for this page, Your Honor, no.

THE COURT: Okay.

BY MR. ITKIN:

Q. So last visit was August 7 I think we went. Now we're two weeks forward, 14 days; is that right?

A. Yes.

Q. And once again we're talking about Andrew, and how long was the visit?

A. Fifteen minutes.

Q. Another 15-minute visit. Plan is: I will discontinue the Dexedrine.

Do you see that?

A. I do.

Q. We didn't go over the record. There was

another record where they prescribed Dexedrine?

A. That's correct. I'm familiar with it.

Q. What is Dexedrine?

A. Dexedrine is a stimulant, an amphetamine-class drug.

Q. Then it says here, I want to draw your attention to it: I will start the patient on Risperdal solution, 1 milligram per milliliter, 0.25 milligrams in the morning, two-week supply with zero refills.

Do you see that?

A. I do.

Q. What does that tell us?

A. So just so you read it correctly for the jury, it was actually twice a day at that point because it says po in the morning and po qhs. Qhs means at bedtime. So it's twice a day for two weeks.

Q. Where would -- are you familiar with drug labels?

A. Yes.

Q. Do drug labels contain dosing information?

A. Yes.

Q. Have you reviewed the Risperdal drug labels in this case?

A. I have.

Q. Was there any dosing information for children that are four and a half years old as of 2003?

MR. ABERNETHY: Objection, Your Honor. It's beyond the scope of the report, not a disclosed opinion.

MR. ITKIN: It's a fact. I mean, I can show him the drug label. It's not in there, Your Honor.

THE COURT: It's overruled. You can answer.

THE WITNESS: I've reviewed the label. There was no indication for the use of this drug in children at that time.

BY MR. ITKIN:

Q. Okay. So it wouldn't have the dosing information?

A. Correct.

Q. But the doctor prescribes 0.25 milligrams in the morning and at night?

A. Correct.

Q. Next sentence: I explained the possible side effects, including sedation, dizziness -- and

I'm struggling with this word again -- extrapyramidal symptoms and tardive dyskinesia to the mother.

Do you see that?

A. I do.

Q. What is tardive dyskinesia?

A. It's easier for me to demonstrate it than to explain it. It's a neurologic response. It can be twitching. It's called pill rolling. A number of things that can occur because of the interference with neuromuscular transmission from the drug.

Q. In the list of possible side effects, do you see breast growth anywhere?

A. I do not.

Q. Do you see the word "gynecomastia"?

A. I do not.

Q. Do you see the words "weight gain"?

A. I do not.

Q. Not listed in the side effects?

A. Correct.

Q. When you do your medical records in your private practice, do you list potential complications, I assume?

A. Absolutely.

Q. And do you try to give those as a complete

and accurate list of the ones that you know about?

A. That's correct.

Q. Why is that?

A. In order to make an informed decision about whether to proceed with a medical treatment, whether it's medication or surgery, patients should have the best information that we can provide them with to help them make that decision to determine if it's in their best interest or their child's best interest.

Q. At least in what's listed in the medical record, no mention of breast, no mention of weight gain; fair?

A. Correct.

Q. I want to show you a picture that is Plaintiff's Exhibit 5079. Bear with me for one second, Doctor.

Doctor, that's a picture you've reviewed in forming your opinions in this case?

A. I have.

Q. Okay. And, Doctor, do you have an understanding as to when that picture was taken?

A. I do.

Q. What is your understanding of when that picture was taken?

A. It is my understanding that this is approximately Christmastime 2003.

Q. So let's get some more dates up on my chart that I'm starting. I may have lost my black marker, but Karista is here to save me.

So we've got Risperdal. Risperdal was started on what date?

A. August 22, 2003.

Q. 8/22/2003; right?

A. Yes, sir.

Q. He's about four and a half years old?

A. Correct.

MR. ITKIN: Your Honor, I'd like to introduce the Christmas picture that is Exhibit 50799.

THE COURT: Any objection?

MR. ABERNETHY: No, subject to a foundation being established as to the date, Your Honor.

THE COURT: Okay.

MR. ITKIN: Your Honor, may I publish it to the jury?

THE COURT: Uh-huh.

BY MR. ITKIN:

Q. Now, I'm going to call this 12/25/03, but, Doctor, that may be a day or so. But it's in the Christmas time frame is your understanding of that picture; is that right?

A. That is absolutely my understanding.

Q. Andrew would be about five years old at this time; is that right?

A. Correct.

Q. Because he's got a December 17 birthday?

A. Yes.

Q. Doctor, what is -- cute kid, huh?

A. Yeah.

Q. What, if anything, strikes you about this picture?

A. What's striking is he's got a large breast for a five-year-old boy.

Q. And are we talking about this breast or this breast?

A. Well --

Q. That was a bad question.

A. Yes.

Q. The right breast or the left breast?

A. You can certainly clearly see the outline of the left breast, and, frankly, since we know he

doesn't have any anatomic birth defects, it's going to be bilateral. It's going to be both sides.

Q. Tell us, and this might be -- can you diagnose gynecomastia from a picture?

A. Yes.

Q. Is this just -- what about this picture -- like, I can see, I think, that his left breast looks like it's big.

But from a medical perspective, from someone who is trained, tell us some of the things that you notice that might not -- that I might not catch looking at this.

A. So we've talked about that gynecomastia is enlargement of the breast. That enlargement is out of proportion to the rest of the patient.

So if you look at that breast, you can see the contour and you can almost see a shadow of it on his upper arm in that photograph, the left breast. That's out of proportion to his height and weight. That's a dysmorphia, is what we call it, and anything that's dysmorphic means it's out of proportion to the rest of the patient.

Q. Maybe I don't understand this. If someone gets gynecomastia, do they just wake up the next day

and they've got a full set of female breasts?

A. No.

Q. How does it happen?

A. So something you can think of is a pregnancy. You know, women get pregnant, but they don't wake up with their tummies stuck out the next day. It takes time for biology to do what biology does.

In the case of Andrew here with his gynecomastia, something stimulated his breast tissue, because we talked about the fact that even boys have a few cells of breast tissue, and caused that breast tissue to grow beyond the normal boundaries.

Q. In a female, for example, how does the breast grow? In a female or a man with -- a male who has gynecomastia, what is the pattern of breast growth? How does it form?

A. So breast growth, if we can shift gears to girls for a minute, has a pattern of growth in which -- may I stand, Your Honor?

THE COURT: Yes.

THE WITNESS: So I'll demonstrate on myself. The nipple and areola in the center of the breast, where the breast

cells are initially, first protrudes. And then, in a girl, those breast cells proliferate and enlarge, going out peripherally or radially, and that's how the breast grows.

Girls are what we call Tanner staged, meaning there are stages of growth from puberty to adulthood, and that describes the development of the breast from that central mound to a full-grown breast.

And in gynecomastia, in Andrew's case, we certainly see that same process going on. That's a breast that, if you were to cut everything away and just look at that body, it looks like the breast of an 11- or 12-year-old girl who is just starting puberty.

MR. ITKIN: Your Honor, can we dim the lights a bit so we can get a little better resolution on this picture?

BY MR. ITKIN:

Q. So you're saying what we see here in this picture is what you would expect for a female who is beginning to go through puberty and have her breasts

grow?

A. Correct.

Q. It's the same pattern of breast growth?

A. Correct.

Q. Let me ask you, Doctor, at this point, at this point -- I'm going to ask you a hypothetical because Andrew continued to take Risperdal for a period after this; is that correct?

A. Correct.

Q. Let's say we stop the Risperdal right here at this picture, last day he took it. I know that didn't happen, but if he stops the Risperdal at that point, is that going to stop the breast growth?

A. No. The breast is already -- the match has been lit to light the fire, and the cells have started doing what they're going to do. They are going to continue to grow disproportionately to the rest of him.

Q. So this may be a bad example. It's like preprogrammed?

A. Well, obviously -- well, the word I would use is pathologically programmed, meaning shifted into an abnormal pattern of growth.

Q. Once that pattern is established, it's

going to continue throughout his growth until he reaches his --

A. Maturity.

Q. -- maturity?

A. Yes, sir.

Q. Is there a pill that you can take at this point that would stop the breast from growing until he reaches maturity?

A. No.

Q. At this point is there anything that Andrew or his dad or his mom could have done to prevent this from happening?

A. No. At this point he now has a surgical condition. Whether he gets surgery or not is a different part of the discussion, but the treatment for this condition is surgery.

Q. Are you saying you'd operate on him?

A. No. Let me be clear. I am not saying that. But this is the kind of situation where I would observe him periodically at intervals once a year until he reaches maturity and until his breasts are at some stable position, and then I would undertake or at least begin a discussion of surgical options for correction of the problem.

Q. Okay. Let's kind of move forward a little bit through some of these medical records. I want to go to the January 12, 2004 office visit with Dr. Eker. That's part of 5003. We'll offer, mark, and introduce that.

MR. ITKIN: Your Honor, with your permission, I would publish that to the jury.

THE COURT: Any objection?

MR. ABERNETHY: Not for this page, Your Honor.

THE COURT: Okay.

BY MR. ITKIN:

Q. So this is January 12, 2004; is that right?

A. Yes, sir.

Q. So a couple weeks after Christmas?

A. Correct.

Q. A couple weeks after the picture we just saw?

A. Right.

Q. Another one of these 15-minute visits with Dr. Eker?

A. Correct.

Q. The record states: He's not been

aggressive, but mother also expressed concern as patient's breasts have been enlarging. He has also been continuing to gain weight.

Do you see that?

A. I do.

Q. Couple questions. Breast enlarging, mother expresses concern, what is your takeaway from that?

A. His mother is observing what we all just observed in that photograph.

Q. Okay. Second thing. What is the significance of he also has been continuing to gain weight?

A. One of the side effects of the Risperdal is weight gain, and that's one of the things that happens in patients on that medication.

Q. Okay. We're going to come back to weight gain in a minute.

So we go back to the plan section, right, what the doctor's going to do, and she's going to continue Risperdal it looks like; is that right?

A. Yes.

Q. But then she says: I will gradually taper the Risperdal to be discontinued as the patient is gaining weight and has possible, question mark,

gynecomastia.

Do you see that?

A. I do.

Q. So, first of all, what does it mean to taper the Risperdal?

A. What I interpret that to mean is she wrote a month's supply with zero refills, meaning that she gave the mother instructions to reduce the dose over time.

For example -- and, again, I'm not suggesting this was exactly how it was done, but, commonly, if you have a drug that you're taking twice a day, you would then go to once a day, then you would go to every other day, then perhaps every third day, and then stop it.

Q. So if you take a powerful antipsychotic medicine, or really any kind of strong medicine, you slowly get off it instead of just stopping cold turkey sometimes. That's what tapering is?

A. That's correct.

Q. And then it looks like they're going to start Andrew on something called Abilify?

A. That's correct.

Q. Another drug; is that right?

A. Yes.
Q. Same class of medicines?
A. Yes.
Q. And it looks like she explains the side effects of insomnia, agitation, has not been studied in young children.
Do you see that?
A. I do.
Q. Okay. I want to focus on something down here on seven, weight is 61 pounds.
Do you see that?
A. I do.
Q. And if, at Andrew's age -- you've had a chance to sort of look at his weights over the years, is that right, in his medical records?
A. Yes.
Q. He's on and off Risperdal and on various drugs, different drugs.
What is kind of generally -- is he a skinny kid, a medium-sized kid? How is his weight?
A. He's in the upper echelon of weight class consistently through his growth curve.
Q. Okay. Go ahead.
A. I mean, that's just his -- some people tend

toward the higher percentiles of weight distribution. Some people are thinner.
The thing that I think the jury needs to remember is, even if he was a little toward the higher side in that Christmas photograph, his breasts were beyond that. They were out of proportion to that. And it is my determination, based on the records, the photographs, and my own physical examination, that that pattern has continued into his present-day status.
MR. ABERNETHY: Your Honor, I object and move to strike. It's beyond the scope of the report.
MR. ITKIN: Your Honor, the report is about that he has gynecomastia, that caused the gynecomastia.
THE COURT: It's overruled. Go ahead.
BY MR. ITKIN:
Q. So if we go back to the picture we were just looking at, what you're saying is, even though Andrew might be a little bit on the bigger side for a five-year-old, these breasts are out of proportion for what you would expect if it was just, like, and I hate to use the expression, but like a fat kid with

breasts; right?
A. The word my mother used to use was husky to describe both me and my son. But they're disproportionate to the level of the rest of his body shape. That's the key.
Q. I guess you can kind of see that by that shadow coming right there between the left arm and the breast; am I getting it right, Doctor?
A. Yes. When you see that shadow on his upper arm, that means the light is stopped at the projection of his breast casting a shadow on his arm.
Q. Let's keep going through these medical records a little bit. Let's go to February 9, 2004, so about a month after the January visit.
MR. ITKIN: Your Honor, we'd like to mark, offer, and identify the February 9, 2004 visit, put it into evidence and publish it to the jury.
THE COURT: Is there an objection?
MR. ABERNETHY: Not for this page, Your Honor.
THE COURT: Okay.
BY MR. ITKIN:
Q. Actually, Doctor, I want to add a couple of

things to our chart before we get to this, but we can leave that up there for now.
January 12 was the record we just looked at where they talk about gynecomastia; is that right?
A. Yes.
Q. And now we are on February 9. This is another one of those 15-minute visits with Dr. Eker, the psychiatrist; is that right?
A. Yes, sir.
Q. If we go to the subjective section of this, I want to kind of focus on the first kind of three sentences before we have the privacy issues.
So it says: Patient is a five-year-old diagnosed with ADHD who came accompanied by his mother for a medication check. Mother reports that he has been gaining weight on the Risperdal.
Do you see that?
A. I do.
Q. That was consistent with what we saw on the previous visit; right?
A. Yes.
Q. And it looks like right down there it says: He has gained approximately 13 pounds on Risperdal.
Do you see that?

A. I do.
Q. That's a big weight gain for a five-year-old boy; fair?
A. It is.
Q. It says: Mother has been giving Risperdal 0.25 milligrams in the morning.
So it looks like he's still on it. Maybe they're doing that tapering we were talking about.
A. Yes.
Q. Let's go down to plan. By the way, subjective, what does that mean in a medical record?
A. Subjective in a medical record is also known as history. It's what the patient tells you. It's their interpretation of what's going on.
Q. So you go to the doctor's office, and they ask you how many times a week do you work out, how many alcoholic beverages do you have. And you report to the doctor, and that's what they write down in the subjective.
A. Yes, and where is your pain, how would you describe your pain, for example. Those are all subjective things.
Q. Got it. So we get to the plan, and it says: I will discontinue Risperdal as the patient is

continuing to gain weight on it. He also has gynecomastia.
Is that right?
A. That's correct.
Q. Those are the plans, what the doctor puts down; is that right?
A. That's correct.
Q. And that is on the 2/9/04. I've already written it down, gynecomastia; is that fair?
A. Yes.
Q. Okay. Now, 2/9/04, stopping the Risperdal. This is the doctor is saying we're taking him off the Risperdal.
If they stop the Risperdal, do they stop the gynecomastia from continuing to form?
MR. ABERNETHY: Objection. Beyond the scope.
THE COURT: Overruled.
THE WITNESS: It does not stop it.
BY MR. ITKIN:
Q. Is there some pill, some treatment, some shock, anything that we have medically available to us in 2004, or even today, that Dr. Eker could have done on February 9, 2004 to stop the gynecomastia?

A. No. Once you've started that process, once the cells have been stimulated to do what they're going to do, they're now beyond the scope of normal control, and there are no medications, as I stated previously, that would change that course.
Q. The match has been lit is what I think you said.
A. Yes. The match is lit. The fire is going.
Q. You say that, Doctor. I want to challenge you on that a little bit; okay?
A. Okay.
Q. I want to hand you a record from a Dr. Phillips, March 22, 2004. This is Plaintiff's Exhibit 530.
MR. ABERNETHY: I'm sorry. What exhibit?
MR. ITKIN: PX5030.
Your Honor, we'd like to offer, mark, introduce, and publish to the jury.
THE COURT: Any objection?
MR. ABERNETHY: Could I just have a moment, Your Honor?
THE COURT: Sure.
MR. ABERNETHY: No objection, Your

Honor.
THE COURT: Okay.
BY MR. ITKIN:
Q. Dr. Solomon, this is one of the records we sent you; right?
A. It is.
Q. And it's from the Phillips Medical Group?
A. It is.
Q. Dr. Phillips, my understanding, was a pediatrician?
A. That's correct.
Q. That's his primary care doctor; right?
A. That's my understanding as well.
Q. This looks like a visit, March 22, 2004; right?
A. Yes.
Q. So that's about a month after the gynecomastia, six weeks?
A. Six weeks, yes.
Q. If I look through this record page by page, word by word, I don't see a mention of female breasts, gynecomastia, anything of the sort.
Do you?
A. I do not.

Q. Well, Doctor, you've told us he's got gynecomastia. You told us from the picture.

How do you explain that Dr. Phillips doesn't mention it down there?

A. Well, to begin with, at the very top of this note, which you have highlighted up there, it says "sick" and the date. So this is what is called a problem-focused visit. It's a child who is ill. He is taken to the doctor, not for a general well-being physical exam, but for an exam focused on the cause of his illness.

And in this case, if you go down to where it says history, HPI, mom says that he started complaining of his right ear hurting this a.m. So this is a visit to the doctor for an earache.

Q. So help me with this, Doctor. I mean, I guess I get it. You go to the doctor. You complain of the earache. They don't do a -- is there a special exam that needs to be done to diagnose gynecomastia?

A. Yes, an exam to determine the presence of gynecomastia is, by definition, an exam of the breasts. You don't go for an earache to get a breast exam. You don't go -- women don't go to their family

practitioner with complaints of a sore throat or pneumonia to get a breast exam. Their gynecologist does the breast exam.

Q. Assume Dr. Phillips took out the old stethoscope, put it under the shirt, put it down there.

Wouldn't that be enough for Dr. Phillips to know whether there's gynecomastia or not?

A. No. His stethoscope is not the tool that we use to determine whether somebody has gynecomastia. A stethoscope is used to listen to the heart and lungs.

And, more importantly, when one puts a stethoscope on the chest, first of all, it's not directly on the breast. There are a number of well-described anatomic locations for placement of that stethoscope, and, in fact, they skirt the breast. That's Number 1. That's assuming that he listened to all seven to eight points that we use the stethoscope on the front.

And, more importantly, in putting a stethoscope on, you would compress the tissue you're listening to, again, not directly on the breast, but under it and to the side of it.

Q. So in other words, this might be something that, if the doctor is focused on the ear and even if they use a stethoscope, the doctor is not doing the squeezing or the type of breast exam that needs to be done, the pinch test, to check the breast tissue; is that fair?

A. That's correct.

Q. And one other thing I wanted to point out, Doctor, in this, if we go down to the weight, 64 pounds, 2.3 ounces; right?

A. Yes.

Q. To be clear, weight gain, we know today weight gain is a known side effect for children on Risperdal; fair?

A. Yes.

Q. I don't think that will be disputed by Janssen; fair?

A. That's my understanding. That's correct.

Q. What about weight gain can somehow sometimes -- how does weight gain -- I want to ask this as fairly as possible.

Can weight gain play any role, good or bad, in complicating the diagnosis of gynecomastia?

A. Complicating is a very useful word here.

It can certainly obscure it or make it difficult to diagnose. And, again, in a physician who is doing what I would describe as a focused examination, who is not thinking about gynecomastia, for whom the mother hasn't said there's no breast growth, or that there is breast growth, one would not anticipate, expect, or otherwise think about gynecomastia as an issue. And the weight gain is certainly -- has certainly been described, even in the literature, to obscure the findings of gynecomastia.

Q. So I want to keep going forward in time a little bit more with these medical records. I want to go forward about a year to March 9, 2005. We're going to go back to Dr. Eker's records.

MR. ITKIN: Your Honor, we'd like to mark, offer, introduce, and publish, subject to no objections from defense counsel.

THE COURT: Any objections from defense?

MR. ABERNETHY: No objection to this page, Your Honor.

THE COURT: Okay.

BY MR. ITKIN:

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Q. So March 9, 2005, it's another one of those 15-minute visits with Dr. Eker; right?
A. Yes.
Q. How old is Andrew at this point?
A. Six and a quarter maybe.
Q. About six; right? And it looks like, if you go down to the plan section, I will restart Risperdal solution, and it looks like they're going back on that same dose of 0.25 twice a day; am I reading it correctly?
A. Actually, it looks to me just once a day to start, 0.25 po qhs, meaning at bedtime.
Q. Take the Risperdal at night, 0.25?
A. Yes.
Q. It says: It was helpful to the patient in the past, but he developed gynecomastia.
Do you see that?
A. I do.
Q. She goes: I stated to the mother that I will not continue the medication if he has breast enlargement.
Do you see that?
A. I do.
Q. Now, his weight in part five is 71 and a

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half pounds?
A. Correct.
Q. Let me ask you something: Any chance that, between February 9, 2004 and March 9, 2005, that the gynecomastia disappeared and went away?
MR. ABERNETHY: Objection. Beyond the scope.
THE COURT: Overruled.
THE WITNESS: No chance whatsoever.
BY MR. ITKIN:
Q. Continuing to gain weight, though, on the medicines; fair?
A. Correct.
Q. So go forward about two months. We're going to switch doctors now. I want to hand you what is Plaintiff's Exhibit 5003 from the May 26, 2005 visit from a Dr. Hughes.
MR. ABERNETHY: I'm sorry. What's the exhibit number?
MR. ITKIN: Still part of P003.
With the Court's permission, I'd like to mark, offer, introduce, and publish.
THE COURT: Any objection to that?
MR. ABERNETHY: No objection to this

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page, Your Honor.
THE COURT: Okay.
BY MR. ITKIN:
Q. Why don't we go to the top first. We've got Andrew, May 26, 2005, 15-minute visit; right?
A. Yes, sir.
Q. This time we got a new doctor, Dr. Hughes; is that right?
A. Correct.
Q. What is your understanding as to why the switch-up in doctors?
A. It is my understanding that Dr. Eker went out on maternity leave.
Q. I want to talk about the subjective, that section a little bit.
Remind us, that's what the patient tells the doctor?
A. Yes.
Q. Okay. So this probably would have come from Andrew's mom?
A. Correct. In fact, it says with mom, seen with mom.
Q. First sentence: Patient was seen with mom. At this point Risperdal is the most helpful for him

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than anything he's tried. Would like to continue it. She does report history of gynecomastia in the past and stated he is eating dramatically at this point.
Do you see that?
A. I do.
Q. I reviewed a note previously stating there was no evidence of gynecomastia on a previous exam.
Do you see that?
A. I do.
Q. Is he talking about, if we can go back to the Dr. Eker exam, the previous one we just saw?
A. Yes.
Q. Does that record show anything about no evidence of gynecomastia?
A. It does not.
Q. Does that comport with any medical record that you have seen?
A. None that I can identify at all.
Q. Okay. He says: We will draw a prolactin level today.
Do you see that?
A. I do.
Q. What does that mean?
A. Prolactin is a hormone secreted by the

pituitary gland that, in the presence of Risperdal, goes up above normal levels and is associated with the presence or production of gynecomastia.

Q. Prolactin is in all of our bodies?

A. Yes.

Q. What happens in boys if their prolactin levels get too high?

A. They get breasts, among other things.

Q. That is called hyperprolactinemia I think we've heard?

A. Yes, that's correct.

Q. I'm getting better at pronouncing some of these words.

So they do this prolactin test; is that right?

A. That's correct.

Q. One other thing I want to -- two other things I want to point out. One is it says kind of towards the bottom of this paragraph: I asked to see him without his shirt on today and he would not do so.

Do you see that?

A. I do.

Q. In your practice, you treat people with

gynecomastia from time to time; is that right?

A. I do.

Q. What are some of the things that you see in typical patients with gynecomastia?

A. Well, among them, they wear clothes to hide it. They are unhappy about it. They're shy about it. And I certainly have patients who don't even want to show it to me because it's a source of embarrassment, and these are adult males who are not psychiatrically stressed.

Q. Andrew here at six and a half, seven, doesn't want to take his shirt off in the exam; fair?

A. Correct.

Q. He's also already up to 84 pounds; right?

A. Correct.

Q. Okay. Let's look at the prolactin test results. Let's see what we've found out. This is -- we had a stapling error, but it's part of the same exhibit. You should have it, Doctor. It's the second page.

A. I do.

Q. Let's look at that together.

MR. ITKIN: Your Honor, if I may publish that to the jury?

THE COURT: Any objection?

MR. ABERNETHY: No, Your Honor.

THE COURT: Okay.

BY MR. ITKIN:

Q. If we look in the top left corner, the date here is 5/27/2005.

Do you see that?

A. I do.

Q. And these are, I guess, the lab results?

A. The lab result is on the line that says result name and then the highlighted 23.7. That's the actual result.

Q. Just kind of understanding, you draw the blood, they send it to the lab, they do whatever analysis, and the doctor gets a medical record back?

A. Correct.

Q. What do the prolactin results come back at?

A. It's highly abnormal, even though it's under the column normal. That's an error. It's outrageously high.

Q. All right. 23.7, help us put that in context, if you can.

A. So it's 23.7 milligrams per milliliter. That's the quantity of the hormone per milliliter, or

cubic cc, that's what a milliliter is, of blood circulating in his body. We have a six-and-a-half-year-old boy at this point.

When you look at those reference ranges, you know, when they call that normal there, it's normal for a non-pregnant woman or a pregnant woman.

So the lab doesn't distinguish the age or the sex of the person they're getting the specimen from. Adult males have a normal range of 2 to 18 milligrams per milliliter. That's an adult male.

Q. Let me make sure because this, I think, is important. Maybe we could pull this out. We've got something here called the reference range right here.

Do you see that?

A. I do.

Q. That's typical, when you get lab results back, whether they're checking your cholesterol, whatever, they tell you what's the range of normal?

A. Yes.

Q. For females, we've got postmenopausal. That's going to be women; right?

A. Correct.

Q. We have pregnant.

That's also going to be women; right?

A. Correct.
Q. And we've got non-pregnant, which I assume would also go to women here; right?
A. Correct.
Q. In women, prolactin, the range is 3 to 30; right?
A. In non-pregnant women, correct.
Q. Okay. Andrew is a boy; fair?
A. A little boy.
Q. Right. I mean, in 2005, he's six and a half years old; right?
A. Correct.
Q. All right. We've got the reference ranges for men, for males; right?
A. Correct.
Q. This is not for children. This is for adults; is that right?
A. Correct.
Q. For adult males, the range is 2 to 18.
Do you see that?
A. I do.
Q. So that would be what is normal; fair?
A. For an adult male.
Q. He is a six-and-a-half-year-old boy?

A. Correct.
Q. His numbers are what?
A. 23.7.
Q. Highly elevated prolactin; is that right?
A. It's highly elevated for an adult male. For a young boy, for whom the reference range is probably 10 to 12 at most, it's more than double. And, in fact, I've seen data from the Janssen folks where the reference range is 7, so that would be triple what the company describes as normal.
Q. So, Doctor, we've got a six-and-a-half-year-old boy.
He's been on Risperdal for how long?
A. At this point he was started back on it for maybe a month, I think. He had been on it and off it, and now he's been back on it March.
Q. You've got the March 9, '05 Dr. Eker record in front of you?
A. Yes, right. He was put back on it March 9. And this is now May 25 was his visit with the doctor, and it's the 27th they got the specimen.
Q. About how many weeks?
A. Ten, if I'm counting right, nine.
Q. We've --

A. Eight and a half, something like that.
Q. Would you agree it would be somewhere within eight to twelve weeks that we see this elevated prolactin?
A. Correct.
Q. Doctor, before you testified, we heard some information about prolactin levels rising with children on Risperdal at weeks eight to twelve.
Have you seen any of that information yourself in preparing for your testimony?
MR. ABERNETHY: Objection. Beyond the scope of his report.
MR. ITKIN: Your Honor, he's reviewed the literature.
THE COURT: Yeah, he has. Overruled. You can answer.
THE WITNESS: Yes, I've read that literature many, many times.
BY MR. ITKIN:
Q. What we're seeing here, when Andrew restarts the Risperdal, is he fits within that kind of area, right, eight to twelve weeks?
A. He is the textbook example of the person who gets that response when challenged with that

medication, that agent. He responds and it flies right up.
Q. Well, Doctor, would I be correct then in leaping to the conclusion that, because we see this rise in prolactin eight to twelve weeks back in 2005, that must be when the gynecomastia starts; is that right?
MR. ABERNETHY: Objection. Same objection.
THE COURT: Well, the objection would be different. I'm going to sustain the objection.
Could you rephrase that?
MR. ITKIN: I will rephrase the question.
THE COURT: Yes.
BY MR. ITKIN:
Q. Doctor, does this high prolactin level mean the gynecomastia started in 2005?
MR. ABERNETHY: My objection is it's beyond the scope of his report, Your Honor.
THE COURT: I understand your objection. That objection is overruled. He can answer that question.

THE WITNESS: I forgot the question.

MR. ITKIN: I'll try it again. Sorry, Your Honor.

THE WITNESS: I'm sorry.

BY MR. ITKIN:

Q. Does that high prolactin level mean the gynecomastia started in 2005?

A. It does not, no. We already know it started in -- around Christmastime of 2003, and we have evidence of it then. So it started then.

Q. So if I tried to argue that it started in '05, that would be wrong or misleading; fair?

A. It would certainly be incorrect based on the evidence that we've reviewed already in the court.

Q. What significance then can we draw from the elevated prolactin test in 2005?

A. The evidence that we can draw is that, when this young man is exposed to the Risperdal, his prolactin level goes up at any age.

Q. He's sensitive to the medicine?

A. Correct.

Q. Because not -- fair point not everybody that takes Risperdal will end up with gynecomastia;

right?

A. Correct.

Q. Medicines affect different people in different ways?

A. Correct.

THE COURT: Counsel, I think it's a good time now to take a break.

MR. ITKIN: Perfect, Your Honor.

THE COURT: Give the jury a brief comfort break for about 15 minutes. Of course, the rules I've given before still apply. You're still under oath, so there's no communications about this case whatsoever. Please stand while the jury exits for about a 15-minute break.

(The jury exits the courtroom at 2:13 p.m.)

THE COURT: Okay. Doctor, you can take a break as well. You can't have any conversations with the attorney.

THE WITNESS: Thank you, Your Honor.

(Whereupon a brief recess is taken.)

THE COURT OFFICER: All rise. Court

is now in session. Please cease all conversations.

(The jury enters the courtroom at 2:33 p.m.)

THE COURT OFFICER: You all may be seated.

THE COURT: Okay. We'll continue with the direct examination.

MR. ITKIN: Thank you, Your Honor.

BY MR. ITKIN:

Q. Dr. Solomon, are you ready to keep going?

A. Yes, sir.

Q. We can put that 5/27/05 record back on. And I think where we left off, and I don't want to put words into your mouth, but by this point, even though we've got this elevated prolactin, it's your testimony that the damage is already done?

A. Yes.

Q. I'm just going to write that on there so we can remember it for later on.

So we're going to keep marching through Andrew's history, and from this point to about 2007, without going through every medical record, is he basically on Risperdal?

A. Yes.

Q. And I think they try him on a couple of other medications like Depakote and maybe lithium?

A. Yes.

Q. Any of those have any causative role in his gynecomastia?

A. No.

Q. Okay. So what I've written here is from May 2005 to 2007 on Risperdal, but no role in causing the gynecomastia.

Do you agree with that?

A. I do.

Q. I want to show you what's been previously marked as Exhibit 5079, which is a photograph of Andrew.

MR. ITKIN: Your Honor, I'd like to offer, introduce, mark, identify, and publish the photograph to the jury.

THE COURT: Any objection?

MR. ABERNETHY: No, subject to establishing the foundation on the date.

MR. ITKIN: Your Honor, can we dim the lights?

THE COURT: Yes.

DIRECT - SOLOMON

BY MR. ITKIN:

Q. You reviewed this photograph as part of your preparation?

A. I did.

Q. And the jury has already seen this picture in opening statements, and this is dated, the date is kind of cut off, but it's a March 3, 2007 photograph?

A. Correct.

Q. How old is he at this point?

A. Eight and a quarter, eight and a half, around there.

Q. I don't know if we can zoom in or crop in. I want to focus on the right side of Andrew here.

Now, obviously, Andrew is looking a little husky in this picture; fair?

A. Yes.

MR. ITKIN: Your Honor, with your permission, I might just publish this. I think it's a little difficult to see from the screen, if the jury could pass it around.

BY MR. ITKIN:

Q. Maybe while the jury is passing this around, you can describe what you see through the

DIRECT - SOLOMON

doctor's eye, not through what I might focus on as a layperson. I want to focus you on the right side of his chest.

A. Yes. So we can see a developed breast. If you were to blot out, as we are about to do, the rest of him, you wouldn't know -- you certainly wouldn't think it's a boy. It could be a teenage girl breast. It's pretty well-developed and looks like a breast.

Q. Any doubt that those are female breasts, gynecomastia?

A. It's gynecomastia without a doubt. And again, the characteristics that it has demonstrated are the volume and mass of the tissue, the size of the nipple areolar complex, which is enlarged beyond what it should be for a boy of eight years old, and a well-defined inframammary crease or fold, which is that line, that fold that traps the breast tissue on the chest wall on which the breast then can fall.

Q. That breast is on an eight-year-old boy; is that right?

A. Yes.

Q. And is it your testimony, Doctor, that that female breast, the triggering event for that was way back in 2003?

DIRECT - SOLOMON

A. Correct.

Q. And this is the natural progression as he's getting older as how the breast develops?

A. Absolutely correct.

Q. Now, after this photograph to 2013, Andrew continues to see doctors regularly; fair?

A. Yes.

Q. Continues to take different medicines; is that right?

A. Correct.

Q. I think I saw that he was on Prozac, Abilify, Risperdal, generic Risperdal.

By the way, generic Risperdal, that's the same chemical as Risperdal, just a different manufacturer?

A. Correct.

Q. Same thing?

A. Same exact thing.

Q. So he's on all these various medicines from 2007 to 2013, those six years.

Any of those medicines cause the female breast that we see on the screen right now?

A. No. It already existed.

Q. Have anything to do with it?

DIRECT - SOLOMON

A. It had nothing to do with it.

Q. If I argue or counsel argues and someone stands up and says, oh, well, it must have been the Abilify that he took in 2008 or the Depakote or the lithium, to your medical expert opinion, does that make any sense?

A. Not a bit.

Q. Why?

A. Again, because the stimulus for the growth of his breast tissue occurred in 2003 and was documented first, we can see it in that photograph, the Christmas photograph I'll call it, and in the subsequent visit with Dr. Eker, when discussions about gynecomastia were first entertained, when his mom said he was growing breasts.

Q. Okay. Doctor, I want to hand you what is marked as Exhibit 5079. We're going to look at another picture.

MR. ITKIN: And, Your Honor, I would like to mark, offer, identify, and publish a portion, a cropped portion of this picture to the jury first. Then I'll show the whole picture.

THE COURT: Any objection?

MR. ABERNETHY: No, again, subject to a foundation on the date.

BY MR. ITKIN:

Q. Doctor, before we show this to the jury, this picture, have you seen this picture?

A. I have.

Q. Have you reviewed this picture?

A. I have.

Q. And the jury has heard, in opening statements from counsel, that the Younts saw a commercial for a lawyer, filed a lawsuit, eventually ended up with my firm.

One of the things I will tell you, this picture was taken -- as part of the lawsuit, we asked for a picture. This is a picture taken in the 2013/2014 time period; okay?

A. Yes.

Q. You saw this picture? I provided this picture to you?

A. Yes.

Q. Okay. I want to show you a portion of the picture, first of all.

What are we looking at right there?

A. That's a breast.

Q. All right. I want to show you the full picture.

That's Andrew?

A. That's Andrew with his breast, and the breast itself has a lot of characteristics of an aesthetically ideal female breast because that's something I know about.

Q. Okay. Why don't we -- why don't you tell us -- why don't we go to -- it doesn't really matter.

Why don't we go to the cropped version, and you can tell us why you would say this looks like a female breast.

A. So can I borrow your pointer and step down? Because it's easier that way.

MR. ITKIN: Absolutely, if it's okay with the Court.

THE WITNESS: May I, Your Honor?

THE COURT: Yes.

THE WITNESS: So I will make sure everybody can hear me. Can everybody hear me? So when we look at a breast from an aesthetic or beauty point of view, which is part of my training, expertise, and background, which, I might add, no other

expert will tell you because none of the other experts from any side of this case are plastic surgeons.

So, first of all, the nipple in the ideal breast should be at the high point of the breast. This is the high point. And it's not the center, but it's the most projected point off the body. So that's a characteristic of an aesthetically pleasing female breast.

There should be a slope. We call this the upper pole. It should have a slope. It shouldn't be flat. It should have some fullness, but it shouldn't be super projected.

There should be a roundness to the lower pole with an inframammary crease. The nipple should not drop below the inframammary crease, so it should be above that, which it is.

So this is the perfect female breast. The only problem is it's on a man.

BY MR. ITKIN:

Q. Thank you, Dr. Solomon.

This picture, and we can zoom out to the normal view of it, this picture was taken before you saw Andrew; is that right?

A. That's correct.

Q. And you saw -- even on the pictures taken before you saw Andrew, we didn't send it to you until after you saw him; fair?

A. Correct.

Q. We sent him up to see you, and you did an independent evaluation; is that right?

A. That's correct.

Q. Okay. Here in Philadelphia at your office?

A. Correct.

Q. Tell us, kind of briefly walk us through, we don't need every detail, but walk us through basically what happened in the examination.

A. So in my office I met with Andrew and his mother, and I took the history of his exposure to the Risperdal, of the development of his breasts, of his other medical issues, which we talked about and I put in my report.

And I asked about his exposure to other drugs, both legal and illegal, other habits, drinking, for example, which can contribute to

gynecomastia, which he does not do, nor does he have any illicit drug history that I could elicit from him.

So I did basically a standard medical intake exam, allergies, medications, any kind of surgery that he underwent, and then I did an exam that I would describe as problem-focused but focused toward the issues related to exposure to Risperdal.

Q. Let me stop you for one second.

Is the history you took similar to the same history you would take of a patient that showed up at your office outside of the courtroom, outside of litigation?

A. Correct. A medical history is a medical history. You may tilt it one way or the other, depending upon what we call the chief complaint, the concern of the patient when they show up.

So in his case, the concern was enlarged breasts, so I knew I was to evaluate him to determine did he have enlarged breasts and what was the cause. So that's how it was focused. But that leads to a series of questions in a general way toward his background and then, in a more specific way, towards that condition.

Q. Then you actually did a physical examination of him?

A. Yes. At that point his mother left the room. I examined his breasts. I made measurements of his breasts. I photographed his breasts. I also examined his genitalia.

Q. Why did you examine his genitalia?

A. One of the side effects of the Risperdal is something called hypogonadism, and I wanted to determine, among other things, has he reached full sexual maturity, does he have sexual function, did the Risperdal interfere with that in any way, and also to rule out something else called Klinefelter syndrome, which is a condition that could cause gynecomastia.

Q. Were you able to rule out Klinefelter syndrome?

A. I was.

Q. Has he reached full sexual maturity?

A. Correct.

Q. You said you took some pictures?

A. I did.

Q. Let's look at those pictures. I want to understand why the different pictures you took.

MR. ITKIN: Your Honor, we're going to mark, identify, offer, introduce, and hopefully publish to the jury shortly the pictures that Dr. Solomon took.

THE COURT: Any objection?

MR. ABERNETHY: No, Your Honor. I assume he's going to identify these as his photos.

BY MR. ITKIN:

Q. Are those the photographs that you took?

A. They are.

Q. And I think we have black-and-whites, but I think we'll be able to show them on the screen in color.

MR. ABERNETHY: Counsel, what's the exhibit number?

MR. ITKIN: It's Plaintiff's 132.

MR. ABERNETHY: Thank you.

BY MR. ITKIN:

Q. So let's take a look at these photographs. This looks like one that's just straight on; is that right?

A. Correct.

Q. Why do you take the one that's just

straight on?

A. So, first of all, if I can establish that I have a photo studio in my office. Photographs are to a plastic surgeon what x-rays are to an orthopedic surgeon. They're an integral part of the diagnostic testing, if you will.

So I have standardized photographs for all my patients. So these are my standard breast photos, meaning they demonstrate the breasts in relation to the body. So this is what we call a frontal or front view. It establishes, first of all, the proportionality in relation to the body, and it shows us the breasts from the front.

Q. Let's go to the second picture then.

A. You may recall, when we spoke earlier about the anatomy, I talked about the importance of the pectoral muscle. So one of the things that I've learned to do to demonstrate the presence of breast tissue, you may at some point hear about something called a pinch test, which is basically having the patient sit or lie on the exam table, and the physician pinches the breast tissue to really feel the extent of the breast tissue.

But one of the useful tools for

visualization for the court is that -- may I stand, Your Honor?

THE COURT: Yes.

THE WITNESS: If I have the patient standing, the initial photograph he's standing with his arms behind his back. In this photo, I have him press on his hips, which makes his chest muscles, his pectoral muscles, tighten. And what it does is it eliminates the fatty tissue of the skin and projects out the breasts themselves. So what you see there is basically his breasts projected by his contractile motion of his pectoral muscles.

BY MR. ITKIN:

Q. I want to go forward in your pictures to, I think it's the sixth picture, kind of a side view.

Why do you have his hands above his head?

A. Again, that's another way to isolate the breast tissue on the chest wall by getting everything else sort of lifted out of the way. The breasts, you can see the outline of the breast tissue, especially on his left, just because of the way the lighting shows it.

Q. Let's go to the next picture.

A. Profile view of his left breast, again, demonstrating the breast tissue, the tight inframammary fold, and the position of the nipple relative to that.

Q. We're going to take that down. I want to show you -- when did you see Andrew?

A. November 2015, to my recollection.

Q. You actually put your hands on him; is that right?

A. Absolutely.

Q. Were you able to feel the glandular tissue you described at the beginning of your examination?

A. Yes.

Q. You're sure this isn't just fat?

A. It's breast tissue. It's gynecomastia beyond any doubt.

Q. Okay. Did you need to do, like, a biopsy or a mammogram or something like that to confirm it?

A. No.

Q. If you're doing a -- if you're evaluating someone for gynecomastia in your office outside of litigation, do you do mammograms or biopsies or x-rays or anything else to confirm?

A. Never, no. For example, the indication for a biopsy would be what I would call an isolated mass. Women are used to this. If you feel a lump, you might biopsy the lump before you do the gynecomastia surgery.

As far as mammography, there's absolutely no indication for it. I've been doing this for 30-something years. I can examine a man's breast and, in fact, routinely have to determine, unlike any other physician who is going to testify, who should be a patient for surgery, who is going to have a knife put on their skin and that tissue removed.

Q. Doctor, I want to show you one more medical record.

You saw him in 2015?

A. Toward the end of it, yes.

Q. I want to show you a February 2016 medical record, so just a couple months, we're almost in July, five months ago.

MR. ITKIN: Your Honor, we'd like to mark, identify, and introduce, and I'm about to give an exhibit number in a second, the Knox County Children and Youth, we can do it on a break, records from

February 22, 2016.

THE COURT: What exhibit is that? You don't know?

MR. ITKIN: I lost track. I will get a number for us on the break.

THE COURT: Any objection to that?

MR. ABERNETHY: No, Your Honor.

MR. ITKIN: May I publish it to the jury, Your Honor?

THE COURT: Yes.

BY MR. ITKIN:

Q. The top here we see it's from the Knox County Children and Youth Clinic?

A. Yes.

Q. Andrew is about 16 at this time; right?

A. Correct. Seventeen, I think.

Q. '98, 2008?

A. Seventeen.

Q. Okay.

A. I think. Math is not my strong suit.

Q. Mine either, Doctor.

I want to focus on the note here from the doctor. It says: Has obvious breasts when asked to pull up shirt today.

Do you see that?

A. I do.

Q. That's similar to what you described; is that right?

A. Correct.

Q. Here's a little bit of a question for you.

You've diagnosed him with gynecomastia; right?

A. Yes.

Q. And we saw back in '03/'04 gynecomastia noted in the records; right?

A. That's correct.

Q. But if we kind of go through the records, we see a lot of talk about weight gain but not someone talking about breasts or gynecomastia until you diagnosed him and until this visit where he takes his shirt off in February 2016.

How do you explain that, Doctor?

A. So forgive me if I repeat myself, but one of the things we learned in medical school is, if you don't take a temperature, you don't find a fever. If nobody asks the question, if nobody says to the physician, you know, I think my son has breasts, can you look at them, nobody's going to look.

And a routine exam, as we talked about, of the heart and lungs, for example, and we've all had this experience, the doctor listens to your heart, listens to your lungs, does not squeeze your breasts.

Q. Well, it's your testimony, if I understand it, this all began back in '03; fair?

A. Correct.

Q. So I want to -- I think you mentioned before the break that there's kind of a natural progression?

A. Correct.

Q. Andrew's ending -- is he through puberty now, close to the end?

A. Yes.

Q. I want to see how the natural progression, see if your testimony holds water. I'm going to test you on this; okay, Doctor?

A. That's fair.

Q. Let's look at -- I want to compare the Christmas picture and your pictures, and tell us if you can see, explain to us where the natural progression comes from; okay?

A. Okay. Yes.

Q. I put this together. Can we publish those

two exhibits? Tell us how you can say that it's a natural progression.

A. So, again, the Court may recall that we talked about, in young women, breasts go through a natural progression of first there is something called a breast bud underneath the nipple areolar complex, which protrudes out. Then you get radial growth, meaning outward from the center of breast tissue.

In essence, we have two 3-quarter views, one when he's five years old, four and a half, and another in my office in November. And if I were to look at a standard textbook of breast growth for young women, the picture on your right is phase one. The picture on the left is full maturity.

Q. Hold on a second. By the pictures, we've got them at kind of similar angles.

Is that what you're saying?

A. Yes.

Q. So we can compare his left breast as a five-year-old to his left breast as a 16/17-year-old?

A. Yes.

Q. And what you're saying is that we see the start of the breast formation in that first picture

and the sort of end result in the picture from your office?

A. Correct. And you can certainly imagine in your minds the progression where first the breast bud starts and the areola sticks out and then the tissue gets bigger.

And then, frankly, as he grows, that dysmorphism, that relatively large breast for that body, grows as well, but always stays bigger than the rest of him.

Q. Does the -- how would you describe the shape of his breast there?

A. So his breast has sort of a ptotic tuberous shape. Tuber meaning it's kind of like a tuber, which is like a sweet potato, sort of elongated and it's hanging. The nipple is now hanging below that crease. So from that picture we discussed in 2013 to now the end of 2015, his breast has continued to mature and is now draping over his chest wall like a normal breast.

Q. Natural progression from age five, five-year-old boy on Risperdal, to where he's at today?

A. Right.

Q. Even though he's been off the Risperdal for a couple of years now?
A. Correct.
Q. Let's look at one more of these. Let's look at a head-on shot. We'll go with the holding the baby. You already got it. You're there. Okay.
A. Again, anyone can look at this picture, certainly the jurors can see, that that is the same breast with the same anatomic landmarks, that crease above it that defines it, the crease below it that defines it, and the breast tissue sort of right underneath the nipple areolar complex.
Q. When you say the crease -- so crease, right here, this is him in '07; right? So eight, nine years old?
A. Yes.
Q. This is the crease area you're talking about?
A. There are two creases. That's the upper one in his case.
Q. He's got an upper crease right there too?
A. Right. That defines where the breast takes off from the chest wall. That bulge going toward his armpit is the chest muscle that we talked about.

Q. So this is chest muscle, but the crease right here outlines the breast?
A. Yes, and that crease below the breast is what we call the inframammary crease, and the other one is just a crease between the chest wall and the breast.
Q. So this crease right here underneath the breast has a name?
A. Yes, sir.
Q. What is it called?
A. Inframammary, meaning below the breast.
Q. Inframammary. Okay.
A. It actually has some unique characteristics under the microscope that aren't relevant to our discussion.
Q. And you see that inframammary crease right there?
A. Yes, sir.
Q. This, once again, a natural progression of the breast from when he was five to eight to now 16, 17 years old; is that right?
A. Without a doubt.
Q. Help, because it's a little difficult for us to tell from the pictures.

I realize men don't wear bras, but what size breast are we talking about here?

MR. ABERNETHY: Objection. Beyond the scope of the report.

THE COURT: Overruled. He can testify.

THE WITNESS: So I made measurements of his breasts, as I testified and talked about in my report, and those measurements are part and parcel of what allows me to determine breast size.

And breast size or bra size, if you will, is the combination of the diameter of the base of the breast and the difference between the circumference, the breast band, which is the number size for women, you know, 32, 36, 40, whatever, and the circumference of the nipple.

So his numbers turn out to be a C to a D, depending what size strap you wear, if it's a 40 or a 42.

BY MR. ITKIN:
Q. C to a D?
A. Yes, sir.

Q. Somewhere right in that range?
A. Yes. As I recall, his breast is at least 15 centimeters wide, which is a very wide base.
Q. Dr. Solomon, is there a pill or, like, physical therapy or some easy treatment that Andrew can do to get rid of this dysmorphic female breast?
A. No, sir.
Q. Is Andrew a candidate for a surgery?

MR. ABERNETHY: Objection. Beyond the scope of the report. Nothing about it in the report, Your Honor.

THE COURT: Let me see counsel at sidebar.

(In-camera proceedings as follows:)

THE COURT: Okay. I called you back here because is there going to be some evidence or discussion about a surgery or some type of treatment as a result of what your client's going through?

MR. ITKIN: Yeah. I think what the doctor will say is that he's not a candidate due to his mental health issues.

THE COURT: Okay.

MR. ITKIN: I want to be clear. We have a limine on mastectomy. I want to be clear. I'm not opening the door on his mental health issues. I do think it's important for the jury to know at least this doctor will not treat him as a candidate for surgery on those issues.

MR. ABERNETHY: I understand the proffer. My problem is none of this is discussed in the report. There's two reports totaling three pages, and I have them if you want to look at them. There's no opinion in here that he developed gynecomastia in 2003, first of all.

Second, there's no discussion at all, as there often is in his reports, because he's in all these cases, he writes a lot of these reports, there's no discussion for surgery, whether he's a candidate for surgery, what the surgery would be.

He's giving a lot of opinions that were never disclosed. Pennsylvania law, I think, is very clear. You have to disclose the opinions and the grounds in the report.

It's just not here.

MR. ITKIN: Your Honor, briefly, I think the opinions are disclosed. Typically, Mr. Abernethy, for example, deposed Dr. Solomon for about four hours in another case. They did not take his deposition in this case, but he's testified in all these cases. And this is not -- there's nothing new or novel to anybody in terms of surprise about his testimony. I could probably do his cross-examination for him, in fact.

MR. ABERNETHY: But this is case-specific.

THE COURT: Correct.

MR. ABERNETHY: I don't have to take a deposition so that he can disclose all the things that he's supposed to do in the report.

THE COURT: I agree. And it's not your case.

MR. ABERNETHY: Right. He has to tell me in the report, and it's not in the report. So I couldn't have told, from a

deposition, a report in a prior case about a different boy.

THE COURT: Moreover, even if you're reading the report, you wouldn't know that he would recommend a surgery unless he says it. I agree with you. I think defense is right. You can't say anything further about it if it's not in the report.

MR. ITKIN: Okay. That's fine, Your Honor. We'll move on.

THE COURT: I will instruct the jury to disregard anything about surgery.

(End of in camera proceedings.)

THE COURT: Okay. I will instruct the jury to disregard any testimony you heard about any surgery.

MR. ITKIN: Thank you, Your Honor. May I proceed?

THE COURT: Yes.

BY MR. ITKIN:

Q. Ready, Dr. Solomon?

A. I am.

Q. I want to talk to you about your kind of ultimate conclusions in the case. We could probably

take that picture down.

You have testified you reviewed the medical literature about Risperdal; right?

A. Yes.

Q. You reviewed Andrew's medical history; right?

A. Yes.

Q. You've examined Andrew?

A. Yes.

Q. You've talked with his mother as well?

A. Yes.

Q. Looked at the photograph evidence?

A. Yes.

Q. You have brought to bear your training, your knowledge, and experience in evaluating Andrew; correct?

A. Yes.

Q. Do you have opinions about whether or not he has gynecomastia?

A. I do.

Q. What is your opinion about whether he has gynecomastia?

A. He absolutely has gynecomastia.

Q. Okay. Do you have an opinion as to what

caused his gynecomastia?
A. I do.
Q. And in reaching that opinion, did you rely upon all those things you've described, the medical records, your knowledge of the scientific research, your training, your experience, the whole gamut of expertise that you bring to bear on this?
A. That's correct.
Q. I assume you didn't just consider the good parts and the bad parts.
You considered everything; is that right?
A. Correct, the totality.
Q. For example, I mean, did you consider whether the gynecomastia was caused by puberty?
A. I did.
Q. How do we know the gynecomastia was not caused by puberty?
A. Because at the age of four, he wasn't in puberty when he got breasts.
Q. Four-year-olds aren't in puberty; right?
A. By definition.
Q. So we can eliminate that as a cause; fair?
A. Correct.
Q. You mentioned something called Klinefelter

syndrome; is that right?
A. Yes.
Q. Can you rule out Klinefelter syndrome as a cause of his gynecomastia?
A. I did.
Q. How?
A. Based on the fact that he is sexually mature. Patients with Klinefelters have a different hair pattern in their gonads. They have breast tissue but they tend to be thin.
And, again, he has sexual maturity. He's achieved sexual function. And I examined his gonads, as I said, and, well, he had an undescended testicle. That's a different discussion. But he certainly has a normal penis and testicle, and, except for the undescended one, he's normal.
Klinefelters often have small gonads, small testes, for example, and pubic hair does not look like adult male pubic hair.
Q. He also has facial hair?
A. He has facial hair. He has acne, consistent with his issue of puberty on his chest.
Q. Can we rule out Klinefelters as a potential cause of his gynecomastia?

A. Correct.
Q. What about family history? Does he have anybody in the family that's got -- you know, his dad, his mom, did you look into that?
A. Again, that's part of the questions I routinely ask, and the answer is there's no family history.
Q. Not showing in the records a history of gynecomastia in the family?
A. Correct.
Q. Can we rule that out?
A. Yes.
Q. We talked about this a little bit already, but he's been on some other medications; right?
A. That's correct.
Q. How do we know -- well, first of all, how do we know it wasn't the other medications?
A. Because the only medication he was on when he first got the condition was Risperdal.
Q. And, I mean, I can -- I'm circling here the December 25, '03 picture.
At that time he was only on the Risperdal; is that right?
A. That's correct.

Q. That was the triggering event?
A. That's correct.
Q. So all these other medicines -- Risperdal, Depakote, lithium, Abilify -- can you rule those out as the cause?
A. After the trigger event, that's correct.
Q. What about issues with his thyroid?
A. Again, he's got a number of measurements of thyroid function throughout the chart, the medical records that I read, I believe even up to the exam of February 2016. They're all normal.
Q. So we can eliminate that as well?
A. Yes.
Q. I hear people with chronic liver disease can get gynecomastia.
A. Correct.
Q. Does Andrew have chronic liver disease?
A. He has no history of hepatitis. He does not drink. His liver function studies that I saw in the chart that were drawn periodically throughout his life have all been normal.
Q. Can we rule chronic liver disease out?
A. Correct.
Q. I hear people with chronic kidney disease

can also end up with gynecomastia.
A. Rarely, but yes.
Q. Does Andrew have chronic kidney disease?
A. He has no evidence of kidney disease either in history or biochemical assays that are, again, present in the chart.
Q. We rule that out; is that right?
A. Correct.
Q. That leaves us with Risperdal?
A. That's correct.
Q. Can we rule out Risperdal as the cause of his gynecomastia?
A. No. It's the culprit.
Q. So based on the records you've reviewed, your training, your experience, your examination, your knowledge of the scientific literature, can you tell us to a reasonable degree of scientific and medical certainty what caused Andrew's gynecomastia?
A. Andrew's exposure to Risperdal at a very young age is the direct and proximate cause of his gynecomastia.
Q. Doctor, all your opinions have been to a reasonable degree of medical and scientific certainty?

A. Absolutely.
MR. ITKIN: Your Honor, at this time we will pass the witness.
THE COURT: Okay. Cross-examine.
MR. ABERNETHY: Your Honor, before I begin, can I ask to hand up to the doctor a binder with a few documents we might use? Some of these might be put on the screen at some point. Some of them might be just shown to him.
THE COURT: Okay.
MR. ABERNETHY: From the binder.

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CROSS-EXAMINATION

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BY MR. ABERNETHY:
Q. Dr. Solomon, I'll get into those documents later, but let me ask you a couple of other questions first.
You gave some testimony near the end of your direct examination about your examination, your physical examination of Andrew in your office; correct?
A. Correct.

Q. And you also mentioned the report or actually reports that you wrote as an expert in this case; correct?
A. Yes.
Q. And, in fact, you wrote two separate reports relating specifically to Andrew Yount, didn't you?
A. Yes.
Q. And if you take a look at the binder, can you confirm for me that the document at Tab 1 of that binder is the first report that you wrote as an expert in this case on December 8, 2015?
A. That's correct.
Q. And this report relates to the physical examination and history in your office which you testified about a few minutes ago; correct?
A. Correct.
Q. And it's a one-page letter to the Arnold and Itkin firm; right?
A. That's correct.
MR. ABERNETHY: If we can mark that, Your Honor, for identification as Defense Exhibit 701?
THE COURT: Okay.

BY MR. ABERNETHY:
Q. And if you turn to Tab 2, can you confirm for me that this is the second expert report that you wrote for plaintiff's counsel in this case?
A. That's correct.
Q. And this was a two-page letter dated February 17, 2016; is that right?
A. That's correct.
Q. I'm not sure if I asked you, the first one, the one-page letter, that was dated December 8, 2015; correct?
A. Correct, December 8, 2015.
Q. And it documents your examination of Andrew, which happened on November 30, 2015?
A. That's correct.
MR. ABERNETHY: The second report at Tab 2, if we could mark that for identification, Your Honor, as Defense Exhibit 702?
BY MR. ABERNETHY:
Q. The second report lists a number of medical records and depositions that you read relating to Andrew's case; correct?
A. Correct.

Q. Am I correct that you wrote the first letter in December, after you did the examination but before you reviewed the medical records and depositions?
A. Correct.
Q. And then after the December 8 report, you read all the medical records and depositions that are listed in Defense Exhibit 702, the February report?
A. Correct.
Q. Okay. And these reports are not the first expert reports, not the first reports you've written as an expert witness, are they?
A. In my life, no, they're not.
Q. You've been in a number of other cases as an expert witness, haven't you?
A. Yes.
Q. And, in fact, you've been in several gynecomastia cases retained by the same law firm that retained you in this case; is that right?
A. I believe this is the first one that's come to trial.
Q. I'm sorry?
A. This is the first case that I've been in court with this law firm.

Q. Okay. This law firm or other law firms, you've written several prior reports as an expert in gynecomastia cases, haven't you?
A. Correct.
Q. In each case retained by one of the firms representing the plaintiff suing Janssen; right?
A. Correct.
Q. And in each of those cases, you've written the same general kind of expert report or reports, haven't you?
A. I'm not sure what you mean by general.
Q. Well, you've written expert reports in those other cases; right?
A. Correct.
Q. And they've documented your examination in those prior cases; right?
A. Correct.
Q. In all of the gynecomastia cases in which you've been retained as an expert, you did a physical examination of the individual whom you decided had gynecomastia, did you not?
A. That's correct.
Q. And your physical examination was done in the same general way in each of those cases, wasn't

it?
A. Correct.
Q. And you documented it in your expert reports in the same general way, did you not?
A. To the extent that I understand the term "general way," yes.
Q. And you understood, in all of these cases, as you understand in this one, that the expert report is supposed to give the opinions you're going to testify to as an expert and the grounds for those opinions; correct?
A. That's more or less correct.
Q. Is that not your general understanding of what an expert report is?
A. So the grounds for my opinion are not necessarily -- between the two reports, the entire picture flows. So I would say it that way.
Q. Right. I didn't mean to confuse the issue.
The two reports that we just talked about constitute your total expert report in this case, don't they?
A. Yes.
Q. And you understood that those reports would set forth the opinions you were going to testify to

as an expert and the grounds for those opinions between the two documents; correct?
A. Correct.
Q. Okay. Now, you testified several times on direct examination to an opinion that Andrew Yount developed gynecomastia in 2003, did you not?
A. Correct.
Q. Would you agree with me, Doctor, that neither of your expert reports, which we just looked at, state an opinion that Andrew Yount developed gynecomastia in 2003?
A. So we're clear, the report of the physical exam is a documentation that he has gynecomastia. The other report, that I would refer to as a causation report, establishes that the Risperdal exposure is the causative factor. Beyond that, I did not specify the time because, again, we have a photograph now that absolutely documents that.
Q. My question to you, sir, is -- and I think you just agreed with this, but I just want to be clear -- even your second report on causation did not state an opinion that Andrew Yount developed gynecomastia in 2003, did it?
A. My second report stated that he has

gynecomastia due to the exposure to Risperdal. His exposure to Risperdal began in 2003. Therefore, that's when his gynecomastia began.

Q. Well, let's take a look at it, if we may.

MR. ABERNETHY: And, Your Honor, if there's no objection, I'd like to bring up the February 17 report for a moment, Defense Exhibit 702.

THE COURT: Okay. Is there an objection?

MR. ITKIN: I mean, I don't have a problem showing his report.

MR. ABERNETHY: It's Tab 2. And could you just bring up call-out number 7 so we can take a look at what Dr. Solomon said?

BY MR. ABERNETHY:

Q. So it says: Andrew had bilateral gynecomastia.

And that was the conclusion you drew in the original physical exam; correct?

A. That's what I just stated a couple minutes ago.

Q. Okay. One question at a time. The next sentence says: Based upon the information reviewed

above, it is clear that the cause of his gynecomastia was exposure to Risperdal starting in 2003 and ongoing at intervals until 2013.

That's what you wrote in your report, is it not?

A. Correct.

Q. Would you agree with me, based on your review of the medical records, that Andrew was on and off Risperdal at various times between 2003 and 2009?

A. Correct.

Q. And would you also agree with me that he did not take Risperdal or risperidone for about a three-year period between 2009 and 2012?

A. I don't recall, but I'll -- I think the word is stipulate to that.

Q. Did you also see in the medical records that Andrew took generic risperidone made by another company at various times in 2012 and 2013?

A. That's correct.

Q. So when you are describing the cause of his gynecomastia as exposure to Risperdal starting in 2003 and ongoing at intervals until 2013, what you've written right here, that exposure from 2003 and ongoing at intervals until 2013 includes exposure to

Janssen's Risperdal and also exposure to the generic risperidone?

A. So for the jury's purpose, you're mischaracterizing the report because on page 2 --

Q. I --

A. If I may, sir, on page 2, I absolutely state unequivocally that he had breasts in the medical record in 2004. That's stated right here, confirmed by my direct testimony. We can agree on that it's in the report; correct?

Q. Can you --

A. Correct?

Q. Sir, I'm asking you questions.

A. I understand.

Q. And my question wasn't what you just told me, so let me try it again.

A. But I cannot allow you to mischaracterize the report for the jury.

MR. ABERNETHY: Your Honor, could I have the witness be responsive to the questions, please?

THE COURT: Just ask the question.

BY MR. ABERNETHY:

Q. The question is, when you're referring here

to the exposure to Risperdal starting at 2003 and ongoing at intervals until 2013, you do agree, don't you, that that exposure over that ten-year period includes exposure to Janssen's Risperdal but also exposure to risperidone.

Is that true or isn't it?

A. There's exposure to generic risperidone. It is not the causative effect.

MR. ABERNETHY: Move to strike.

THE COURT: The first part of his answer stays. The last part I'll strike.

MR. ABERNETHY: Thank you, Your Honor.

BY MR. ABERNETHY:

Q. We'll come back to this issue, I think, a little bit later, but I want to ask you a little bit about some of the other things.

You testified about the history that you took in the first examination in November 2015; do you recall that?

A. Correct.

Q. And that's what's documented in the first report at Tab 1, the December 8 report; is that right?

A. Correct.

Q. And in the first report, you say in the second paragraph there, if you look at the second sentence: He had a long history of behavior problems for which he had been on several medications.

Do you see that?

A. Correct.

Q. That's taken from the history that you took from Andrew and his mother at the examination?

A. Correct.

Q. Now, you subsequently learned from your complete review of the medical records -- and let me just stop there for a second.

Is it your understanding that you were given complete medical records from all of the doctors who treated Andrew for his psychiatric and behavioral conditions?

A. Yes, it is my understanding.

Q. And, in fact, in your second report, you've got a pretty long list of 26 items on the first page; is that right?

A. Correct.

Q. And that list includes all the medical records from the different practices that treated him for his psychiatric conditions; correct?

A. Correct.

Q. It also includes medical records from his regular pediatrician; correct?

A. Correct.

Q. And pharmacy records, so you looked at the pharmacy records on the medications he got?

A. Correct.

Q. And it also includes the depositions of Andrew and his mother and several of his doctors; correct?

A. Yes.

Q. And so with respect to the treatment for the psychiatric conditions and the medications he was on, it's your understanding that you got a complete set of the medical and pharmacy records; right?

A. That's my understanding.

Q. And when you reviewed those records after the December 8 report, after the examination, you confirmed that Andrew, in fact, had been on a large number of medications at one time or another for his psychiatric condition; correct?

A. Correct.

Q. You confirmed that he was on Abilify for a period of time; correct?

A. Yes.

Q. And that's another antipsychotic, atypical antipsychotic?

A. I believe we testified to that earlier today.

Q. And you also confirmed that he was on Fanapt for a period of time?

A. I believe that's now.

Q. Right, a period of time up to today; correct?

A. It's in the past couple years is my recollection.

Q. That's also an atypical antipsychotic; correct?

A. Correct.

Q. Also treated with Zyprexa?

A. Yes.

Q. And Seroquel?

A. Yes.

Q. And Geodon?

A. Yes.

Q. Those are atypical antipsychotics, aren't they?

A. Correct.

Q. Also treated with a drug called Trileptal?

A. Don't recall that one, but I have no reason to doubt you.

Q. It would be reflected in the medical records if he got it; right?

A. Again, I reviewed a huge number of records in this matter, and I don't remember all the details. But I remember certainly Abilify, Zyprexa, and so forth.

Q. Fair enough. And you reviewed all the medical records listed in your second report; correct?

A. Correct.

Q. You know that he was treated with Paxil at certain periods of time; correct?

A. I don't recall that one.

Q. You do recall that he was treated with clonidine. You testified on direct that that was the first medication that was prescribed by the psychiatrist.

A. Yes.

Q. You also confirmed, didn't you, that he was treated for a period of time with a drug called Tenex?

A. Yes.
Q. And also treated for a period of time with Ritalin?
A. I believe briefly.
Q. And treated for a period of time with Strattera. That was one of the early drugs that you talked about on your examination; correct?
A. We discussed that, right.
Q. And treated with Dexedrine, which you also mentioned on direct?
A. We already discussed.
Q. And treated for a period of time with Prozac?
A. I have a recollection of that.
Q. Also Zoloft?
A. I don't recall that.
Q. Also lithium. You mentioned that?
A. I do recall that.
Q. And also Depakote?
A. Yes.
Q. Now, your complete knowledge of the medical records and the medications that he took came from your review of the medical records after you had taken the history and done the examination; correct?

A. Yes.
Q. You didn't go through 20 different medications in the history with Andrew and his mother, I take it?
A. Correct.
Q. Now, in your review of the medical records, the history says that he was on Risperdal at the age of three and remained on it until the age of 11.
Do you see that?
A. Yes.
Q. That was the history also, I take it, the recollection that you got from Andrew and his mother?
A. That's correct.
Q. And we've now confirmed from the medical records that, in fact, he was prescribed Risperdal for the first time at four and a half; correct?
A. Correct.
Q. Okay. And you also confirmed from the medical records that he was on and off Risperdal a number of times between 2003 and 2009; correct?
A. I believe I confirmed that, yes.
Q. And on those occasions when he went off Risperdal, he typically went on another medication.
That's what the medical records show, isn't

it?
A. Yes.
Q. And frequently during that period, he would go off that other medication and go back on Risperdal; correct?
A. Yes.
Q. And that was because the doctor and Andrew's mother concluded that whatever the other medication was wasn't working for him?
A. That's what the record states.
Q. Or had some side effect that was not acceptable?
A. I don't recall that concept.
Q. Do you recall that, when you read the medical records about one of the early drugs, Dexedrine, that his mother reported that it made him hyperactive instead of helping him?
A. Correct.
Q. And that's why he went on Risperdal for the first time; correct?
A. I have to go back to those notes to be sure, but that sounds about right.
Q. Now, I'd like to go back to some of the medical records that you reviewed with plaintiff's

counsel from the treatment by Dr. Eker.
Do you recall testifying about those in your direct?
A. I do.
Q. We're going to talk about those and also perhaps one or two that you didn't see.
I'm going to, for simplicity, go back to, hopefully, the records in the form that plaintiff's counsel showed them to you during direct.
This is the record from August 22, 2003, that you looked at earlier; correct?
A. Yes.
Q. And this is where it's documented that the doctor stopped the Dexedrine and put Andrew on Risperdal for the first time; correct?
A. Yes.
Q. And it referred, as counsel asked you, to a number of side effects that the doctor, Dr. Eker, discussed with the mother at that first visit.
Do you recall that?
A. I do.
Q. Now, counsel asked you about the fact that gynecomastia is not listed there.
Do you recall that?

A. I do.
Q. Let me ask you a question about your own practice, Doctor.
When you advise a patient about medication, do you always list, for every patient, every single side effect that's been reported or listed in the labeling for the drug?
A. I do not.
Q. I'm sorry?
A. I do not.
Q. And, in fact, for most drugs, there is a very long list of side effects, some more serious, some less serious, correct, that are reported in the labeling?
A. Certainly.
Q. And some that are more common and some that are less common; correct?
A. Yes.
Q. Now, do you recall looking at the record from the next visit with Dr. Eker?
A. I'm happy to review it with you here.
Q. I may have to dig for it a bit, but let me ask you something that might refresh your recollection.

Do you recall that at the next visit with Dr. Eker she asked Andrew's mother whether there had been any breast discharge?
A. Again, if I have it here, I'll find it. If not, I'd like to see it.
Q. Okay. I may need to look for that, so we'll perhaps come back to that.
Let me ask you now about the record. I think you also saw this on direct examination, and I'm going to try to find and put up the one that we looked at earlier during your direct examination.
So this is the record from the January 12, 2004 visit; correct?
A. Yes.
Q. Which you looked at earlier?
A. Yes.
Q. And this is the record that confirms that mother is expressing concern about enlarged breasts and weight gain; correct?
A. Yes.
Q. And at this point Dr. Eker indicates that she's going to taper the Risperdal because the patient is gaining weight and has possible, she writes, question mark, gynecomastia.

Do you see that?
A. I do.
Q. Now, you know, from your review of Dr. Eker's testimony and the other records, that she did not do a physical examination of Andrew's breasts at this visit; correct?
A. I don't recall at which visit she did examine him, so I can't tell you, from my recollection, whether she did it now or at some other point.
Q. So do you have a recollection, sir, that Dr. Eker did a physical examination of Andrew's breasts in connection with diagnosing gynecomastia?
A. My recollection is, in her testimony and her deposition, she talks about looking at him. She did not touch him. And that's the extent to which, at the moment, I recall her deposition testimony.
Q. Okay. Actually, if you look at your report, Tab 2, the second report, on the second page, if you look at the second page, the first full paragraph, there you cite her deposition testimony that she examined his breasts visually; correct?
A. Page 70, line 5 of her testimony, that's correct.

Q. It's not your recollection, is it, that she ever conducted a physical examination or touched Andrew's breasts?
A. To be clear, it is my recollection she states that she did not touch him, but she examined him, meaning she looked at him. Part of a physical exam is looking. Part of it.
Q. Right. She looked but didn't touch; correct?
A. That's correct.
Q. It's also correct, isn't it, that there's nothing in any of the records from Dr. Eker's examinations or treatment with any finding of glandular tissue in Andrew's breasts; correct?
A. Again, she examined his breasts visually. That's what she said.
Q. Okay. I think I asked you a slightly different question.
Can we agree that there's nothing in Dr. Eker's records that document any finding of glandular tissue in his breasts?
A. In these records that we're reviewing at the moment of her visits with him in the office?
Q. You reviewed all of Dr. Eker's records,

didn't you?

A. Yeah. Well, records meaning the office records. I want to make sure we define records. I'm talking about records, meaning medical records as a psychiatrist, her psychiatric evaluations of him. Is that what you're referring to?

Q. The second item on your report, your second report, where you list all the things you reviewed, are the medical records from Cherokee Health System.

Do you see that?

A. Yes.

Q. And Dr. Eker treated Andrew through Cherokee Health System; correct?

A. Yes.

Q. And all of Dr. Eker's records that you saw were in the Cherokee Health System records that were provided to you; correct?

A. Yes.

Q. And there was nothing in any of the Cherokee Health System records that were given to you that recorded any finding of glandular tissue in Andrew's breasts; is that correct?

A. No. If you look at her deposition where she said he had gynecomastia with the medication

Risperdal, that was her testimony. Gynecomastia is glandular breast tissue, as we spent a fair amount of time discussing.

Q. So your interpretation of her testimony is that she examined him and found glandular tissue in the breasts?

A. My interpretation is she made a diagnosis of gynecomastia. Gynecomastia is defined as feminization of the male breast. That feminization can only occur with proliferation or growth of glandular tissue. So if you're asking me is the word "glandular tissue" in her records, no. But is the finding there, absolutely.

Q. It's not in her testimony either, is it, the word "glandular tissue"? She never says that, does she?

A. She says gynecomastia.

Q. I didn't ask you that, sir. Please listen to my question.

She never used the word or the term "glandular tissue" in her records or in her testimony, did she?

A. So that we are clear for the jury, gynecomastia means glandular tissue. That's the only

thing it can mean. So in answer to your question, she does not use the word "glandular." That's correct. She instead uses the appropriate medical term "gynecomastia." Without a doubt those are her words.

Q. Never used the term "glandular tissue"; correct?

A. Correct, gynecomastia.

Q. And you testified earlier, did you not, that one of the things you do in the physical examination, where you touch a patient's breasts, is to feel for glandular tissue; correct?

A. What I do as a plastic surgeon examining breasts, correct. I also stated it would be inappropriate for a psychiatrist to touch a patient's breast, which, by the way, she testifies to in her deposition as well.

Q. And, in fact, you would agree with me, wouldn't you, that a psychiatrist is not typically the specialist who examines a patient and diagnoses gynecomastia? Would you agree with that?

A. It's a rare circumstance, but if they see it, they can make the diagnosis.

Q. But it's not a typical diagnosis for a

psychiatrist; correct?

A. Again, I'm not here as a psychiatry expert.

Q. You also saw, did you not, in Dr. Eker's records, that when she made a reference to gynecomastia, she referred Andrew to his primary care physician to further evaluate him? Do you recall that? Let me ask you to take a look at a document, Tab 24.

THE COURT: Are you going to withdraw the question you had on the floor?

THE WITNESS: Can I finish answering your previous question?

BY MR. ABERNETHY:

Q. I'm withdrawing the question because I want to try to orient you with a document, if you wouldn't mind looking at it for me. Would you look at the document at Tab 24?

MR. ABERNETHY: And if there's no objection, perhaps we could put this up.

THE COURT: Okay.

MR. ITKIN: No objection, Your Honor.

THE COURT: Okay. No objection.

MR. ABERNETHY: So if we could put up Tab 24.

CROSS - SOLOMON

BY MR. ABERNETHY:

Q. This is another Cherokee Health System record, right, from Dr. Eker?

A. Yes.

Q. And here you see on 3/11/04, March 11, '04, she writes: Patient will see PCP.

That's primary care physician; correct?

A. Yes.

Q. For enlarged breasts. They continue to be enlarged even though Risperdal was DC'ed.

That means discontinued; right?

A. Yes.

Q. Would you agree with me that this is a note where Dr. Eker, who has made a notation in her file about possible, question mark, gynecomastia, is now referring him to his primary care physician to be seen for that?

A. Referral to me is a specific word meaning a specific action. I think that she's just noting that they're going to see the primary care physician. I'm not sure she made a quote/unquote referral. She basically left it in the hands of the mom to take Andrew to the primary care physician for an evaluation.

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Q. For enlarged breasts is what she writes here; correct?

A. Yes.

Q. And you know from the medical records, don't you, that, in fact, Andrew saw his primary care physician at Phillips Medical Group only 11 days later on March 22?

A. Do you have that note?

Q. Yeah. Actually, I think it may be the same -- I'm not a hundred percent sure, but I think it may be the same one that we looked at on your direct examination.

Would you take a look at Tab 25?

A. I have it.

Q. And this is the same note from March 22 that you looked at on direct, isn't it?

A. Right, the sick child visit.

Q. Right. So this is Andrew seeing his primary care physician 11 days after the note by Dr. Eker that we just saw; correct?

A. For an ear problem, as we discussed.

Q. You would agree with me, wouldn't you, that the record doesn't reflect that Andrew or his mother raised the issue of enlarged breasts with

CROSS - SOLOMON

Dr. Phillips at that visit?

A. That's correct. They raised ear problems.

Q. And there's nothing in the record indicating that Dr. Phillips noted anything unusual about Andrew's breasts; correct?

A. He didn't examine his breasts.

Q. Actually, Dr. Phillips never evaluated Andrew for gynecomastia, did he?

A. I believe he testified he never examined his breasts.

Q. And he never diagnosed him with gynecomastia; correct?

A. If you don't examine somebody, you can't make a diagnosis. He never examined him, so it's a moot point.

Q. You would agree with me, would you not, Doctor, that in all of the time that Andrew saw his primary care physician at various times in the years following Dr. Eker's evaluation, none of the pediatricians or other practitioners in that practice ever saw anything indicating abnormal breast growth; correct?

A. No. That's a mischaracterization of the record.

CROSS - SOLOMON

Q. Is there any diagnosis of gynecomastia by anybody in the primary care practice?

A. There's no exam of the breasts in the primary care practice ever. There's no note you can show me that says a normal breast exam.

Q. There's no referral, is there? Andrew was never referred to an endocrinologist to evaluate this condition, was he?

A. Correct.

Q. And he was never referred to a plastic surgeon to evaluate it either; correct?

A. Correct.

Q. Obviously, you're a plastic surgeon and you saw him, but you're not treating him as a physician; correct?

A. I'm not a treating physician in this case, that's correct.

Q. You evaluated him as a retained litigation expert for this case?

A. I examined him for the purposes of determining if he had a condition that merited pursuing the litigation. It's a different point than what you are suggesting.

Q. You examined him after being retained to do

so by the lawyers who represent him in this lawsuit; correct?

A. That's incorrect. I examined him at the request of the attorneys to determine if he had a diagnosis of gynecomastia. If he did not have a diagnosis of gynecomastia, that would have been the end of the whole issue.

Because, in fact, there have been patients that I have seen where I've said the history, examination, and so forth do not rise to the level of this kind of litigation.

Q. I think perhaps my question was unclear.

Did somebody other than the plaintiff's lawyers retain you in connection with this case?

A. Again, retaining me is different than having me evaluate the patient.

Q. You saw Andrew at the request of the lawyers; correct?

A. That's correct.

Q. Who were representing him in a lawsuit that was then already pending alleging that he had gynecomastia; is that correct?

A. Probably. I don't know the legal matters until after I do the exam.

Q. Let me go back for a minute, if I could, and ask you a few more questions about the physical examination.

You described, when counsel had the diagram up on the screen, the glandular tissue that's seen in a female breast and how it contrasts with a normal male breast.

Do you recall that?

A. Yes.

Q. And I think you told us, but I want to be sure I'm clear on this, that when you do a physical examination of the breast, it's called palpation; right?

A. Yes.

Q. When you do the palpation of the breasts, you're palpating the breasts to determine whether glandular tissue is there; correct?

A. Among other things, that's correct.

Q. That's at least one of the purposes of the examination, to determine glandular tissue?

A. Correct.

Q. And you did that in Andrew's case when you saw him on November 30, 2015?

A. Correct.

Q. And you don't specifically use the terms "glandular tissue," but you use the term "gynecomastia," which you have told us means the same thing?

A. Correct.

Q. Doctor, would you agree that, in order to confirm a diagnosis of gynecomastia, which you said I think can only -- I think you said -- let me make sure I -- let me start over. One of those late-day questions that just never get started right.

I think I understood you to say a few minutes ago that you can't have gynecomastia without detectable glandular tissue; is that right?

A. Correct.

Q. Okay. And would you agree with me that in order to confirm a diagnosis of gynecomastia, you have to do a physical examination of breasts and confirm the presence of glandular tissue?

A. Not necessarily.

Q. Do you recall testifying in another trial involving gynecomastia about eight months ago that, in order to confirm a diagnosis of gynecomastia, you have to physically examine the breasts?

A. I don't remember my exact words, but I also

remember a discussion about could I do it on visual inspection from a photograph. And I believe I said that one could do that as well.

Q. Let me, so that we're focused together, let me ask you to take a look at the prior testimony that I was asking you about. This is from the October 27 p.m. session.

I thought you said earlier, and I may have misunderstood you, that you didn't recall ever testifying in a prior gynecomastia case that came to trial.

Did I mishear you on that?

A. That's a complete mischaracterization of my testimony.

Q. Well, I didn't intend to mischaracterize it. I misunderstood you, obviously, so I apologize.

This is a transcript of testimony that you gave in a prior gynecomastia trial in this courtroom on October 27, 2015; is that correct?

A. For a different law firm, correct.

Q. Different case too; right?

A. Yeah, absolutely.

Q. But you were being asked questions about gynecomastia and the physical examination involved in

diagnosing gynecomastia, were you not?

A. That's correct.

Q. Okay. Could I ask you to direct your attention specifically to page 41, line 12? Let me ask you specifically about these questions and answers.

Question: In order to confirm that a male has gynecomastia, that is, to confirm it, there ought to be a physical examination; correct?

MR. ITKIN: Your Honor, I'm going to object to the improper hearsay. The witness should be allowed to -- there's a process for impeachment and this is not it.

THE COURT: Let him read it first and then you can ask him questions.

BY MR. ABERNETHY:

Q. Can I first ask him if he gave this testimony?

THE COURT: Absolutely.

MR. ABERNETHY: All right. That's what I was about to do, Your Honor.

BY MR. ABERNETHY:

Q. These are the questions. I want to know if this is your testimony.

A. So --

Q. Wait, wait. I want to ask you --

A. You just asked me if it's my testimony. You said is it my testimony. I'm looking at it to confirm.

Q. In this testimony, you indicate on pages 41 and 42, do you not, that in order to confirm gynecomastia, you need to do a physical examination?

A. So on page 42 I said: In order to make any diagnosis, you have to do a physical exam.

Q. And that's the standard; correct?

A. That's the practice of medicine.

Q. And that's what you do; correct?

A. Correct.

Q. Let me go back for a minute, if I could, to your second report, the report dated February 17. That's at Tab 2.

MR. ABERNETHY: And if we could bring up again Defendant's 702, the February 17 report, and if you could bring up call-out number 7 for me.

BY MR. ABERNETHY:

Q. I think we looked at this before. Here at the bottom of the first page and beginning of the

second, we looked at this a little earlier. It says: Based upon the information reviewed above, it is clear that the cause of his gynecomastia was exposure to Risperdal starting in 2003 and ongoing at intervals until 2013.

Do you see that?

A. I do see it.

Q. And when you wrote here "based upon the information reviewed above," were you referring to the 26 items that were listed above that on the first page?

A. That's correct.

Q. And that's all the medical records and depositions, pharmacy records, et cetera?

A. We discussed that already, I believe.

Q. So based on that information, you concluded that the cause of his gynecomastia was exposure to Risperdal?

A. That's clearly what I've stated.

Q. In fact, Dr. Solomon, hadn't you, in fact, already decided, before you read any of that material that you're referring to here, that you were going to express an opinion that Risperdal was the cause of his gynecomastia?

A. I don't know what opinion I'm going to make until I formulate it, and part of my job for the court is to review all the materials. So what I decided prior to my completing this review was that he had gynecomastia. I hadn't made a causal link until I reviewed all the supplementary data.

Q. Well, you told us, didn't you, that you read all this material, the deposition testimony and the records and all that, after you did the examination and after you wrote the first report?

A. Right.

Q. Didn't you, in fact, say in the first report, before you ever read any of these materials that you list in the second report, that you were going to give the opinion that Risperdal caused his gynecomastia?

A. Right. I say at the end of that it is my impression at that time that the Risperdal caused his gynecomastia based on the history and the physical exam. This further material absolutely confirms that.

Q. Let's bring up Defendant's Exhibit 701 for identification and take a look at what you wrote. That's Tab 1.

MR. ABERNETHY: Can you blow up the last paragraph?

BY MR. ABERNETHY:

Q. Here you write: It is my impression, to a reasonable degree of medical certainty, that Andrew has bilateral gynecomastia due to his exposure to Risperdal; correct? That's what you wrote?

A. Correct.

Q. That, we established, is before you read any of the medical records and any of the depositions; correct?

A. Correct. That's based on my history and physical, ruling out Klinefelter, thyroid disease, liver disease, alcohol, and the host of other things that we went over in my direct testimony, as causes.

All that other information absolutely buttressed it in terms of confirming historical basis of gynecomastia from Dr. Eker's medical records, her deposition testimony. Those things all support everything I said there. That is a conclusion based on history and physical exam.

Q. And it's a conclusion stated, according to your report, to a reasonable degree of medical certainty?

A. Absolutely.

Q. The same thing you said in the second report; correct?

A. Correct.

Q. And the same thing you said today?

A. I'm consistent.

Q. You are consistent.

Now, do you need more water?

A. No, I'm good. Thank you.

Q. Toward the end of your direct examination, you testified, I believe, that you had excluded all other potential causes of Andrew's gynecomastia besides Risperdal.

Did I understand that correctly?

A. Correct.

Q. And you acknowledged that there are a number of other causes of gynecomastia; right?

A. Correct.

Q. And one of those other causes is drugs; correct?

A. Correct.

Q. And, in fact, there are a lot of different drugs that can cause or have been associated with gynecomastia, aren't there?

A. Not to the extent of Risperdal, but that's correct.

Q. And you are aware that Andrew was on many different medications over a period of years; correct?

A. I believe I testified to that both with you and with Mr. Itkin.

Q. And in your reports, you didn't discuss any of the other drugs that he was on and why you excluded them as a cause of gynecomastia, did you?

A. I don't believe I wrote that, that's correct.

Q. And in the courtroom today, you've told us that you basically excluded all of them because, as you've said today, he had gynecomastia in 2003, and, therefore, no drug after that could have caused it; is that right?

A. And it's so stated in my report that he had it as of January 2004, according to Dr. Eker and so forth. All the facts flow together to create a picture. The picture is he had gynecomastia at a very young age and it persists.

Q. It is correct, isn't it, Doctor, that you didn't go through the labeling and literature about

any of the other drugs that Andrew was on to determine whether any of them were associated with gynecomastia?

A. I'm aware that some of them may be, but, again, not to the extent that statistically Risperdal is, Number 1. Number 2, based on the time line of exposure, the only drug he had before he had breasts was Risperdal.

Q. Can we agree that there is nothing in either of your reports, Doctor, that specifically discusses any of the other medications that Andrew was on or that discusses any of the labeling or literature relating to whether they're associated with gynecomastia? Would you agree with that?

A. And that he never took them prior to the development of his gynecomastia, correct.

Q. I did not ask you that.

A. I want to be complete for the purposes of court. So the answer is, yes, you are right, but, again, he didn't take them before he got gynecomastia. We can agree on that too.

Q. Well, we're not agreeing on that, but I understand your testimony, sir.

A. Well, one of us is entitled to make a

medical diagnosis. I am.

Q. And the other witnesses will testify, Doctor. I'm not trying to quarrel with you. I'm just trying to get the facts about what you said in your report and what you've said here.

You testified that you excluded Klinefelter syndrome based on your physical examination; correct?

A. Correct.

Q. There is, is there not, a specific chromosomal test that definitively establishes or rules out the existence of Klinefelter syndrome?

A. Correct.

Q. To your knowledge, that test was never performed on Andrew; correct?

A. Correct.

Q. And you certainly didn't order such a test in connection with your work in this case, did you?

A. Correct.

Q. I'd like to ask you some questions now, Doctor, relating to a subject that you discussed earlier in your direct, which is prolactin. And if you'll bear with me for a minute, let me see if I can find the document that Mr. Itkin showed you. Okay. I just wanted to get a clean copy here.

MR. ABERNETHY: Can we go back to the Elmo? Thank you. That was not the document, though. I'm not so good with the Elmo. There we go.

BY MR. ABERNETHY:

Q. This is the prolactin test report that you referred to during your direct examination; correct?

A. Yes.

Q. And if I heard you correctly, you testified that Andrew is recorded here as having a prolactin result of 23.7 milligrams per milliliter and that that result is outrageously high.

Did I hear you correctly?

A. I believe that's an accurate statement of my testimony, that's correct.

Q. Okay. Would you take a careful look at the document, and I can hand you a paper copy if it's easier to read.

Isn't the measurement reported here a measurement in nanograms per milliliter, not milligrams per milliliter?

A. I mean, I'm reading from a distance with a copy. It looks like an M. It could be an N. I'm not sure that makes a huge difference in the fact

that the standard is 2 to 18 in those same units. That's how these tests are run. If I misspoke about the N versus the M, I apologize to the Court.

Q. Isn't it a fact, Doctor, that prolactin measurements are typically done in nanograms per milliliter?

A. Again, I'm reading from that document, which we, I think, can agree it's hard to tell whether that's an M or an N. I have no problem if it's nanograms per milliliter. It's still three times the normal for a six-year-old boy.

Q. Where did you take the normal range for a boy of that age that you testified to on direct examination?

A. In a paper that you would call Findling, they refer to the average range of prolactin in boys as 7.3, I believe it is.

Q. So your understanding is that the -- well, the reference range that's listed in the document for males is 2 to 18; correct?

A. That's what it says.

Q. And you would understand that to mean, would you not, that 18 nanograms per milliliter, assuming I'm right about nanograms, we'll ask the

endocrinologist, but 18 nanograms per milliliter is the upper limit of the normal in this range; correct?

A. For an adult male.

Q. And your testimony is that the scientific literature indicates that the upper limit of normal for males of this age is 7 nanograms per milliliter?

A. No, that's not what I said, so let me be clear again. The Janssen literature, the literature that was supported by the Janssen defendants here in research they did, states that the average, average, not upper limit, average level is, I believe, 7.3, but it's in the 7 range, and that's in the Findling paper.

Q. But endocrinologists who look at prolactin levels typically look at whether those levels are above the upper limit of normal, don't they?

A. Only in the Findling paper. That's a useful tool that the Janssen folks have used to figure out when prolactin is elevated, but if you look at the average range for children as opposed to adults, it differs. And the data supports me, not your characterization.

Q. Respectfully, I'll move to strike that as nonresponsive because I don't think I asked you any

of that.

A. You did, sir.

Q. My question, sir, is whether endocrinologists, in typical practice, who are looking at whether prolactin levels are elevated, look at whether the level is above the upper limit of normal? Is that what endocrinologists typically do?

A. So, again, there are adult endocrinologists and pediatric endocrinologists. There are different values for different populations. So I would respectfully suggest that you direct that question to an endocrinologist.

Q. And you would expect, since you've testified that this is outrageously high, that any capable endocrinologist would agree with that?

A. Again, given the data in the Janssen literature with an average level of 7, 23 is more than three times that level. So even if it's not outrageously high, we can agree it's elevated.

Q. You would not agree that it's slightly elevated?

A. Twenty-three minus seven, again, I said I wasn't great with math, I think that's about 16. So that's almost the entire reference range. In other

words, it's significantly beyond the norm for a child.

Q. And you would expect endocrinologists to find this highly elevated, would you or wouldn't you? That was my question.

A. I think if the average is 7 and he's 23, the answer speaks for itself.

Q. Now, this record that we just looked at was a record of the prolactin test that was taken by Dr. Hughes on May 26, 2005, on that visit by Andrew to him; correct?

A. I think it's -- it's dated May 27 and the visit is the 26th. So I don't know when it was drawn, so it's somewhere between those two dates.

Q. Let me just try to get my dates correct here.

This document says received 5/26, reported 5/27; correct?

A. Correct. That's what I was trying to recall.

Q. And the first page, which I think you also looked at on direct examination, that's the actual note from Dr. Hughes; correct?

A. That's correct.

Q. And it refers to drawing a prolactin today right there about in the middle of the note.

Do you see that?

A. Yes, I see that.

Q. And you testified on direct, I believe, that prolactin elevation is associated with gynecomastia; correct?

A. I believe that's correct.

Q. And you have testified also on direct, in reference to some of the other notes, that gynecomastia had been an issue that was raised when Dr. Eker was treating him; correct?

A. I believe we discussed that, that's correct.

Q. Right. And there's a reference here, in fact, in this note: She does report some history of gynecomastia in the past.

Do you see that? I'm sorry. It's about four lines down in the note.

A. I'm assuming you would agree with me that "she" refers to the mother.

Q. Right. This is mother talking to Dr. Hughes about the same issue, gynecomastia, that she had talked with Dr. Eker about in the previous

visits; right?

A. And that Dr. Eker confirmed, that's correct.

Q. Now, would you agree with me that the purpose here of drawing a prolactin test was to determine whether Andrew was at some risk of gynecomastia?

A. Again, I can't read what Dr. Hughes was thinking, but I think he was documenting that Andrew had elevated prolactin. I think he was concerned that he might have elevated prolactin because he had gynecomastia. That's my interpretation of that note.

Q. He writes here that he talked to Andrew's mother that there would probably be an elevated prolactin level; right?

A. That's what it says.

Q. After that, it says the important thing would be to watch it over time and see if there was any association with her concerns about gynecomastia; correct?

A. That's what it says.

Q. Now, Doctor, would you agree with me that, if Andrew already had gynecomastia and it wasn't going to go away, there wasn't really any purpose to

taking a prolactin test in connection with potential gynecomastia?

A. Again, I don't know what Dr. Hughes' understanding is of the relationship between prolactin and gynecomastia. I'm speaking for me. But I can tell you that, once again, we clearly have a situation where Andrew had been presented with or challenged with, if you will, the offending agent, the Risperdal, and I think Dr. Hughes was looking to see what his biologic response to that would be. And sure enough, his response was consistent with data that we now have well established that it elevates prolactin.

Q. Well, he writes here, specifically, doesn't he: The important thing would be to watch it over time and see if there was any association with her concerns over gynecomastia.

That's what Dr. Hughes writes here; correct?

A. Again, we are on sort of a limb here in my estimation, but he's treating the mother's concerns over gynecomastia. That's the best I can get out of this.

Q. I'm asking you what he wrote. I'm asking

you what he wrote.

A. We can agree that's what he wrote. What we're talking about is what does it mean. Perhaps you and I have different interpretations, but the fact remains his prolactin was elevated and he had gynecomastia. I've testified to that. The photographs demonstrate it and the lab data demonstrates it.

Q. If he already had gynecomastia, there wouldn't be any reason why you would need to take a prolactin test to watch over time and see if there is any association with gynecomastia, would there?

A. Again, it seems to me that question is better directed to Dr. Hughes as to asking him what his plan was for management of Andrew's established gynecomastia at the age of six.

Q. I think you were also asked another question about this record where it says a line or two up: I have reviewed a note previously stating that there was no evidence of gynecomastia on previous exam.

Do you see that?

A. I do see that.

Q. And I think you testified on direct,

correct me if I'm wrong, that you didn't see any note to that effect.

A. I don't recall any note to that effect.

Q. Would you take a look at Tab 27?

MR. ABERNETHY: And I'll ask if counsel could take a look at it and if there's any objection to us publishing it and putting it up on the screen.

THE COURT: Is there any objection, Counsel?

MR. ITKIN: No objection, Your Honor.

THE COURT: Okay.

MR. ABERNETHY: So could we put up Tab 27, please?

BY MR. ABERNETHY:

Q. This is a note from a March 23, 2005 visit with Dr. Eker.

Do you see that?

A. Yes.

Q. And this is part of the Cherokee Health System records, so you reviewed it in connection with your work as an expert in this case, did you not?

A. Correct.

Q. You were not shown this record on direct

examination, were you?

A. I don't recall.

Q. Well, let's take a look at what it says. We just looked at Dr. Hughes' note where he said he reviewed a note previously stating that there was no evidence of gynecomastia on previous exam.

Now, this is back earlier with Dr. Eker treating, and at the top it says: Patient is a six-year-old Caucasian male with disruptive behavior disorder, NOS, who came in accompanied by mother for a medication check.

Do you see that?

A. I do.

Q. Then it says: Mother reports he seems better on the Risperdal.

That's, again, history, mother reporting what she's seeing at home; right?

A. Right.

Q. It then says: He does not have any physically aggressive episodes at school and at home. His sleep is good.

Do you see that?

A. Correct.

Q. Then it says: His appetite seems to be

increased.

Do you see that?

A. Yes.

Q. Then it says: He does not have any evidence of gynecomastia.

Do you see that?

A. That's what his mother said.

Q. And after that history is taken, Dr. Eker writes, under plan, just pull up the section labeled plan, she writes: I will continue Risperdal solution, 1 milligram per milliliters, 0.25 milligrams.

I think you said that meant at bedtime?

A. Yes.

Q. And so this is Dr. Eker prescribing Risperdal in 2005 after the prior notes she made referring to gynecomastia; correct?

A. After the note that she made at a previous visit.

Q. Right. She made notes in her records in 2004 about gynecomastia; correct?

A. Correct.

Q. And now here in 2005 she's prescribing Risperdal; correct?

A. Correct.

Q. And then in the second sentence under plan, it says: I stated to the mother that patient had increased appetite, weight gain, and gynecomastia with the medication, the Risperdal. I would like to keep it at the lower dosage.

Do you see that?

A. I do.

Q. Does that indicate to you that Dr. Eker is concerned about weight gain and the potential for gynecomastia and, therefore, wants to keep him on a lower dose of Risperdal?

A. So it doesn't say the potential for gynecomastia. It says he has gynecomastia. And I think that Dr. Hughes, in his subsequent note, mischaracterizes that which we call the subject, meaning the mom may or may not have said anything about his breasts, but Dr. Eker certainly believes he has gynecomastia from the medication. She confirms it right there, consistent with everything else that we've discussed.

Q. When she talks about gynecomastia and weight gain, she says I want to keep it at the lower dosage; correct?

A. She does -- no, that's a separate sentence.

Q. It says: I stated to the mother that patient had increased appetite, weight gain, and gynecomastia with the medication, the Risperdal. I would like to keep it at the lower dosage.

That's what she wrote; correct?

A. That is what she wrote, that's correct.

Q. Now, we already talked about briefly that you have referred to elevated prolactin as a basis for concluding that Risperdal caused Andrew to develop gynecomastia.

Do you recall that?

A. Yes.

Q. And that's what you say in your report as well; correct?

A. That it's attributed to prolactin specifically in my report?

Q. Well, let's take a look at the report, the second report.

MR. ABERNETHY: If you could bring back Defense Exhibit 702, and call-out number nine.

BY MR. ABERNETHY:

Q. On May 26, 2005, Andrew was found to have

an elevation in his prolactin level.

Do you see that?

A. Yes.

Q. And then, if we could call out ten, this is additional evidence of the effect of Risperdal on Andrew's metabolism. This effect of Risperdal on prolactin is well-described.

Do you see that?

A. I do.

Q. So we can fairly read this to suggest that you find elevated prolactin to be evidence that Risperdal was a cause of Andrew's gynecomastia?

A. Just so we're clear, what I wrote is: This effect of Risperdal on prolactin is well-described. I'm not, in that sentence, making any further connections. I'm saying just what it says.

Q. Do you believe that elevated prolactin is associated with the development of gynecomastia?

A. I do.

Q. And do you believe that elevated prolactin is an explanation for Andrew's development of gynecomastia resulting from exposure to Risperdal?

A. I believe that's the mechanism, that's correct.

Q. Now, you would agree with me, would you not, that not everyone who takes Risperdal will have elevated prolactin?

A. Probably true.

Q. And you can't tell us how much prolactin has to be elevated in order for gynecomastia to result, can you?

A. I'm not aware of data that quantifies it.

Q. And you're not aware of any literature that would answer that question; correct?

A. That's correct.

Q. You also can't tell us how long prolactin has to be elevated in order for gynecomastia to result, can you?

A. For the same reasons we just discussed.

Q. Again, there's no literature that provides any answer to that question; correct?

A. Correct.

Q. By the way, the only prolactin test that you refer to in your report is the one on May 26, 2005; correct?

A. Correct.

Q. And you didn't cite or refer to any other test showing elevated prolactin; is that right?

A. Correct.

Q. You would agree with me, would you not, that you can have elevated prolactin and still not develop gynecomastia?

A. Probably.

Q. And, in fact, you testified in a previous proceeding, didn't you, that you don't think it's true that all males with elevated prolactin develop gynecomastia?

A. I would need to see that testimony to confirm or deny that.

Q. Okay. Could we take a look at the March 24, 2015, deposition in Stange? This is a transcript of your deposition in another case, isn't it?

A. Correct.

Q. And would you take a look at page 90, lines 16 to 18?

A. Go ahead.

Q. And having read that, would you agree with me that you've testified before that you don't think it's true that all males with elevated prolactin develop gynecomastia?

A. If I may, just let me read the question,

because I don't understand yours.

Line 16, question: Do all males with elevated prolactin develop gynecomastia?

Answer at line 18: I don't think that's true.

Q. Okay. Fair enough. You would agree, would you not, that some males develop gynecomastia without any prolactin elevation at all?

A. Probably.

Q. And you also know, from the literature, don't you, Doctor, that some males develop gynecomastia in puberty with no drug causation at all?

A. Correct.

Q. And I think you've testified that the percentages range, in the literature, anywhere from 15 to 65 percent of pubertal males developing gynecomastia without a drug exposure?

A. That's my recollection of the literature, that's correct.

Q. And the reports and the literature also suggest, don't they, that some percentage of those cases will persist past puberty; correct?

A. Yes.

Q. And you've read the reports and the literature anywhere from 5 to 18 or 20 percent?

A. Again, there are variations in that number.

Q. In that range?

A. I don't want to guess, but I know there's a variation in the number.

Q. And some of the cases persist into adulthood, but many of the cases resolve and don't persist into adulthood; correct?

A. That's a reasonable statement.

Q. Okay. Now, I want to go back for a moment to the question of prolactin elevation and gynecomastia. You do talk about prolactin elevation and gynecomastia in your report. We just looked at it.

You don't cite any literature, medical literature, in support of the statement that elevation in Andrew's prolactin level is evidence that Risperdal caused it.

A. If I understand your question, I think what you're asking is do I cite any literature in my report, and the answer is no.

Q. And, in fact, you've written a number of reports in gynecomastia cases, and it's your practice

not to list specific literature that supports your opinion in any of those reports, isn't it?

A. Correct.

Q. Nonetheless, you have testified in prior cases, in depositions and trials, that you relied on certain specific literature in forming your opinions as an expert in these cases, have you not?

A. I believe that's consistent.

Q. And do you recall that one of the articles that you testified that you relied on as an expert was the Findling paper from 2003?

A. I certainly, as we talked about, I'm familiar with it.

Q. Did you testify in a prior deposition that it's one of the articles that you relied on as an expert?

A. Again, with all due respect, if you're going to ask me about prior testimony, the easiest thing is to show it to me. I can confirm or deny it, depending upon the testimony.

Q. I'm happy to show it to you. I just wanted to see if you remembered.

This is a deposition that you gave in a prior gynecomastia case; correct?

A. Yes.

Q. On February 8, 2015?

A. Correct.

Q. And if you turn to the back, let me find the specific question near the end. If you take a look at page 132, line 7, did you find it?

A. Yes.

Q. And here you were asked a question about whether you relied on a number of articles that Mr. Gomez put on the record in your deposition in forming your expert opinion in the case in which you were testifying; correct?

A. Yes.

Q. And if you turn back a couple of pages, starting on page 130, Mr. Gomez marks and refers to a number of papers in the medical literature, which you then testify on page 132 you relied on; is that right?

A. That's correct.

Q. And one of them, if you look at page 130, line 14, was the Findling paper from 2003; correct?

A. Yes.

Q. And then one of them was the Reyes paper from 2006?

A. Yes.

Q. And one of them is the Anderson paper from 2007, if you look at page 131, line 3?

A. Correct.

Q. And one of them is the Roke paper from 2012, if you look at line 11?

A. Correct.

Q. And these are several articles in a longer list of articles that you were asked about that are referred to; correct?

A. These are in a longer list, that's correct.

Q. And then on page 132, you testified that you relied on all of these articles that Mr. Gomez listed in forming your opinions as an expert; correct?

A. Correct.

Q. So you would agree with me that these are papers that you could rely on as an expert in testifying on the subject of gynecomastia; correct?

A. More specifically, Risperdal-induced gynecomastia, that's correct.

Q. It's correct, isn't it, that all of these papers that you testified you relied on to form opinions as an expert concluded that elevated

prolactin had not been established to be associated with gynecomastia?

A. That's not my interpretation of those articles.

Q. Okay. So let me ask you to take a look at a couple of specific references in the papers. Would you turn to page 39? I'm sorry, Tab 39.

This is the Reyes paper, which is from 2006, which is one of the papers that you testified in that prior deposition you relied on as an expert; correct?

A. Correct.

Q. And would you turn to page 266 in the left-hand column about two-thirds of the way down?

MR. ABERNETHY: Could we bring this up on the screen, if there's no objection?

THE COURT: Any objection?

MR. ITKIN: No objection, Your Honor.

THE COURT: Okay.

MR. ABERNETHY: This is Tab 39, and if you could bring up call-out number one.

BY MR. ABERNETHY:

Q. So in this paper that you testified you relied on to form expert opinions, the authors say:

Importantly, as has been previously observed, citing Findling et al. 2003, occurrence of gynecomastia was not related to increases in serum prolactin levels.

That's what the authors say; correct?

A. I believe that's a mischaracterization of what I've testified to in the past.

Q. I'm not asking you whether it characterizes what you testified to in the past. You've told us a minute ago that this is a paper that you relied on as an expert in gynecomastia litigation.

All I'm asking you now is, following up on my earlier question, don't the authors write in this paper that occurrence of gynecomastia was not related to increases in serum prolactin levels? That's what these authors concluded; correct?

A. No, that's absolutely incorrect. They are referring to Findling. If you want to have a discussion of that, we need the Findling paper from 2003. That's their interpretation of the Findling data. That's not their finding as a conclusion.

Q. Well, it says "as has been previously observed," and they cite Findling; correct?

A. Again, they are referring to Findling. So if we're going to talk about Findling, I'm happy to

discuss it, but this is their interpretation of Findling.

MR. ABERNETHY: Bring up call-out number two, please, same paper. This is page 269, call-out two. Oh, I'm sorry. You are there. I apologize. I got a little misoriented.

BY MR. ABERNETHY:

Q. Here the authors write: Importantly, elevated prolactin levels were not correlated with the three cases of gynecomastia.

No reference to Findling here; right?

A. Nor do they tell us when the prolactin was drawn and in what time period that is in relation to when the gynecomastia was discovered.

Q. This is what the authors wrote; correct?

A. May I finish?

Q. I'm asking you --

A. May I finish?

Q. No. I'd like you to answer my question first, please.

A. I will not allow the jury to be misled by a poorly phrased question. I will give you an answer that requires an interpretation of scientific data,

which I'm confident I'm the only expert in this room that I can really adequately do. At the time being, I'm the scientist. That is not completely true. That's what they wrote, but it doesn't give you all the facts you need to come to the conclusion. You're asking me to make a conclusion based on what they wrote, and we need more data.

Q. That is not what I asked you.

A. That is exactly what you asked me.

Q. I'm not going to quarrel with you, sir. That's what they wrote. I'll move on.

Let's just be clear, this is one of the articles that you cited in your prior deposition was a paper that you relied on to form expert opinions.

That's correct, isn't it?

A. Out of a number of them and in the totality of my decision-making process, examining all of the data, not just that one sentence. You can't cherry-pick. It's not fair to the jury or to Andrew.

Q. Sir, I'm not inviting argument from you, sir. Would you answer my questions, please?

A. I'm answering your questions to the best of my ability so we get all the facts out in front of everybody. I just want to have the facts out.

MR. ABERNETHY: Tab 37, please. I'm sorry. This is the Anderson paper.

Can we put this up, Counsel?

MR. ITKIN: That's fine, Your Honor.

BY MR. ABERNETHY:

Q. Tab 37, this is the Anderson paper, one of the other papers that you mentioned you relied on in forming expert opinions; correct?

A. Yes, it's one of the papers I reviewed.

Q. And, in fact, there is the sticker. It was marked as an exhibit at your prior deposition; correct?

A. Yes.

Q. And if we could take a look at call-out number one from the abstract: Prolactin levels were not associated with clinical complaints or physical examination findings.

And then there's a reference to several specific items, including gynecomastia; correct?

A. That's what it says.

MR. ABERNETHY: And if we look at the -- is that call-out one? Could you give me the -- sorry. I got a little mixed up on my calls. Can you go back to the

abstract on the first page?

BY MR. ABERNETHY:

Q. And this is from the abstract: Prolactin levels were not associated with adverse effects; correct? That's what the authors wrote in the abstract of this paper?

A. That's the abstract. So the jury understands, an abstract is a brief summary of their findings, but it is not a thorough analysis of their findings.

Q. And the other quote that I just showed you a minute ago was not from the abstract. It was from the text of the paper; correct?

A. Again, it mischaracterizes the paper, but we can discuss that, I suppose, later.

MR. ABERNETHY: Tab 36, please. This is the Roke paper.

I'm sorry. Can we bring it up, unless there's an objection?

MR. ITKIN: No objection, Your Honor.

BY MR. ABERNETHY:

Q. This is the Roke paper, also one of the ones that you listed as a paper you relied on in forming expert opinions; correct?

A. Yes.

MR. ABERNETHY: Can we look at call-out number one?

BY MR. ABERNETHY:

Q. This reports in the abstract: 46 percent of subjects in group one had asymptomatic hyperprolactinemia.

That finding is consistent, isn't it, with the notion that you can, in some cases, have elevated prolactin levels without any symptoms or adverse effects connected with it?

A. Again, this is their statement in that group one that 46 percent had elevated prolactin without symptoms that they could find. That's what they're saying.

MR. ABERNETHY: And in the same results paragraph of the abstract, could you bring up call-out number two?

BY MR. ABERNETHY:

Q. They write: Gynecomastia was not significantly associated with hyperprolactinemia; correct?

A. Yes, but that contradicts their results later on in the paper.

Q. And hyperprolactinemia is elevated prolactin; correct?

A. Yes.

MR. ABERNETHY: Could you bring up call-out three?

BY MR. ABERNETHY:

Q. Here again in the conclusions they write: Although gynecomastia was two times more common in the risperidone group, hyperprolactinemia was not associated with gynecomastia.

The authors' conclusions of this paper; correct?

A. That's in their conclusions, that's correct.

Q. Now, all these papers that we've just been talking about were published in peer-reviewed medical literature; correct?

A. Correct.

Q. And peer-review means that other experts in the same field review the article to determine whether or not the analysis is sound and the article worthy for publication; correct?

A. That's a generally correct statement.

Q. And all of these papers that we've just

been talking about were peer-reviewed.

You know that; correct?

A. I believe that's correct.

Q. And accepted by the editors of reputable journals; correct?

A. They were accepted for publication, that's correct.

Q. And published in those journals; correct?

A. Yes.

Q. You were not an author or peer-reviewer on any of these papers, were you?

A. Correct.

Q. You don't know anything about the peer-review process for any of these papers, do you?

A. Incorrect.

Q. I'm sorry. What was your answer?

A. That's incorrect. I know about the peer-review process. It's pretty similar across the board. I've reviewed a number of papers over the years for peer-review process.

Q. My question wasn't clear. I'm not suggesting you're not familiar with the peer-review process. You don't have any knowledge of the peer-review that was done for these specific

articles, what the peer-reviewers concluded or what --

A. That is true.

Q. Sorry if I asked a confusing question. It's late in the day.

Now, you testified earlier about weight gain as a side effect for Risperdal; correct?

A. I believe that's correct.

Q. And weight gain, in fact, was referred to in the labeling for Risperdal from the very beginning, was it not?

A. I believe it's in the 2002 or 2003 label.

Q. And you know, from your review of the medical records, that Andrew's doctors were well aware of the weight gain issue connected with Risperdal, weren't they?

A. There's evidence to that effect.

Q. In fact, there are a number of medical records that we've been looking at this afternoon, that Mr. Itkin showed you and that I showed you, where it records that the doctors talked to Andrew's mother about weight gain with Risperdal; correct?

A. Yes.

Q. And you know from your examination of the

medical records, don't you, that there were a number of occasions over a course of years when Andrew was taken off Risperdal and put on other drugs instead of Risperdal because of concerns about weight gain; correct?

A. I'm not sure that was the only reason, frankly. I just don't recall.

Q. Well, let's take a look at some of the records. Would you take a look at Tab 5?

This is actually a record we looked at before from the January 12, 2004 visit with Dr. Eker; correct?

A. Yes.

Q. And plan item two specifically says that she's going to taper him off Risperdal because he's gaining weight, and she also refers to possible, question mark, gynecomastia; correct?

A. That's correct.

Q. So it's clear that weight gain was an issue, and she's taking him off the drug, in part, because of weight gain; correct?

A. In part, that's correct, and gynecomastia is the other part.

Q. And Tab 17.

A. I'm sorry. What number?

Q. I'm sorry, Tab 17.

A. One-seven?

Q. Yes, one-seven, I apologize.

MR. ABERNETHY: Counsel, can we put this one up? This is not redacted, but I don't think there's anything in it that would be.

MR. ITKIN: Your Honor, this document is fine.

THE COURT: Okay.

MR. ABERNETHY: Okay. Can we put up Tab 17, please?

BY MR. ABERNETHY:

Q. I don't think you saw this before in your direct examination, but this is another note from Dr. Hughes; correct?

A. Yes.

Q. And this is from September 19, 2005?

A. Yes.

MR. ABERNETHY: And if we could bring up call-out three?

BY MR. ABERNETHY:

Q. Mom is concerned about the weight gain

Andrew is having on Risperdal.

Do you see that?

A. Yes.

Q. So it's clear to you from this record that weight gain is a concern to mom, and she's talking about it with the doctor; correct?

A. As caused by the Risperdal, that's correct.

MR. ABERNETHY: And if we could bring out call-out number four.

BY MR. ABERNETHY:

Q. Given this, mom is motivated for a change to a medicine which potentially may have less chance for weight gain.

Do you see that?

A. That's what it says.

Q. So here the doctor and mom are talking about weight gain as a concern with Risperdal and, in fact, looking for another medication to do what Risperdal did but without as much weight gain?

A. That's correct.

MR. ABERNETHY: And Tab 18 -- and, Counsel, is Tab 18 okay to put up?

MR. ITKIN: Yeah, I think this document is consistent with the Court's

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orders, Your Honor.

THE COURT: Okay.

MR. ABERNETHY: So you can just put that up for a moment and bring up call-out number two, please.

BY MR. ABERNETHY:

Q. So here this is another note from Cherokee Health Systems; correct?

A. Yes.

Q. This is from 2006, the following year; correct?

A. Yes.

Q. And here the note says: He is now out of school for the summer, and mom talked about weight concerns with Risperdal again. They are motivated for a trial of Depakote to see if it can help him with mood stabilization and at the same time not increase appetite as much as Risperdal.

Do you see that?

A. I do.

Q. And then at the bottom of call-out number one, it shows that, in fact, Depakote sprinkles are prescribed.

That's the plan; correct?

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A. Yes.

Q. So here's yet another example where Andrew is on Risperdal. Mom knows weight gain is an issue. She's concerned about it, and she and the doctor are looking for a different medication; correct?

A. Yes.

Q. You know, in fact, from the medical records, that they looked at -- they tried Depakote, and Depakote wasn't effective for him. And he later went back on Risperdal; correct?

A. That's my understanding.

Q. So you would agree with me, would you not, that there are numerous examples in the medical records where weight gain is identified as a concern, Andrew is taken off Risperdal and put on something else, that something else doesn't work for him, and he goes back on Risperdal, even though weight gain is identified as an issue? You would agree with that, would you not?

A. Yes.

THE COURT: Counsel, I think this is a good point to stop.

MR. ABERNETHY: Thank you, Your Honor.

THE COURT: Okay. Members of the

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jury, I'm going to excuse you for the evening, and you are to return back here tomorrow morning at 9:00 a.m.

Please remember not to discuss this case amongst yourselves or with anyone else, and you are not to conduct any experiments or make any individual investigations. You are not to read or listen to media or Internet accounts about this case.

Please remember to wear your juror badges conspicuously so you can get in the correct door as you come in in the morning. Please stand as the jury exits. Have a good night.

(The jury exits the courtroom at 4:45 p.m.)

THE COURT: Doctor, you can step down.

THE WITNESS: Thank you, Your Honor.

THE COURT: You can be seated in the back.

I wanted to find out how many more witnesses do you have for your case.

MR. ITKIN: So, Your Honor, we've got

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probably one more live witness, and then we've got the video testimony of these doctors that --

THE COURT: How many videos?

MR. ITKIN: Well, that's an issue that I'd like to raise with the Court at some point. We've got Dr. Eker, who to us is the key because that's the failure to warn.

THE COURT: Okay.

MR. ITKIN: We've got the next doctor who took the prolactin test, who I think is relevant because of some of those issues.

From our perspective, you could pretty much limit the other doctors. At that point it doesn't matter. I know they disagree with that. Every one of these depositions takes on this -- they're almost all the same when you go through the page lines. If you had known this, would you have changed your prescribing practice? And we get some good testimony. Then they walk them back and they get some testimony. Then it's, did you see breasts? Did you not see breasts? And here's a bunch of

stuff about him.

THE COURT: How long are the depositions?

MR. ITKIN: Our clips will be, like, 20 or 30 minutes each, but their clips, I think, are a lot more expansive. From my perspective of kind of getting our case done by Thursday, maybe Friday before lunch, we want to slim it down as fast as possible because I think it's time to get the case moving.

THE COURT: I agree. But it's moving. Go ahead, Counsel.

MR. ABERNETHY: Well, there are a number of issues, Your Honor, that we're going to have to hash out and probably ask for rulings on relating to some of these issues.

THE COURT: Okay.

MR. ABERNETHY: Mr. Essig has been going through their cuts on Dr. Eker, and I think he could talk about the specifics better.

But one issue that I have to tell you

we are going to raise, have to raise, is they have testimony from some of these doctors essentially saying, well, I didn't know this study showed X percent gynecomastia or Y percent gynecomastia. If I had known that, I would have talked to the mother about that issue, and we would have discussed it.

And they're clearly going to argue, and I assume try to present some testimony, that had that conversation occurred, the mother would have not let Andrew take Risperdal, and Andrew wouldn't then have been injured.

In our view, and I ask your indulgence for a minute or two because this is a critical issue in our view to our defense of this case, in my view, that testimony and that argument opens the door to -- and I don't know that any of this is relevant, but could we just ask the witness, whose testimony is in progress, if he could excuse us for a minute while we're arguing a legal issue?

THE COURT: Sure.

(Witness is sequestered.)

MR. ABERNETHY: In our view, this testimony opens the door to evidence that you have thus far excluded about the specific acts of conduct by Andrew at various points in time, and here's why.

They are going to argue to the jury, oh, if we had known it was 5 percent or 12 percent in a study, we would have told mom, and mom wouldn't have taken the drug.

A reasonable juror, who understands the specific extensive extreme conduct problems that Andrew had, might reasonably disbelieve that testimony and reject that argument and conclude that mom would have continued to give Risperdal, despite 5 percent in a study or 12 percent in a study, because it was clearly essential to deal with this extreme behavior.

And it's not -- they can't make a determination whether to draw that inference one way or the other without knowing the facts. Generalities about,

well, he had some aggressive behavior or he had some violent behavior without knowing any of the facts, they can't make a reasonable judgment about which inference to draw.

If they're going to argue the failure to warn caused this because mom wasn't given the medication with additional information, we have to show the facts that mom knew and was confronted with when she made the decision to, in fact, keep him on Risperdal even when there was a discussion of breast issues, gynecomastia, and weight gain.

And I understand that Your Honor concluded concern that this is prejudicial because it paints Andrew as a bad kid. Respectfully, I would suggest that's not a real issue here because nobody is contending, not us, not them, that any of Andrew's conduct is indicative of him being a bad person or bad actor.

THE COURT: Let me explain to you why I said what I said, why I'm not allowing

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it. Number one, this is not a standard of care case, nor is it a failure to diagnose case. All of those factors would come in if that were the case because any reasonable doctor would need to have all that information to make a diagnosis and to apply the proper standard of care.

This is not this case. It's clear that he was taking this drug and other drugs. It's clear that he had mental health issues. Fine. It's not a standard of care case, nor is it a failure to diagnose case. It's simply a failure to warn. That's all it is.

MR. ABERNETHY: I understand that completely.

THE COURT: I want you to understand that's why I made the rulings that I made.

MR. ABERNETHY: Fair enough, Your Honor. All I'm arguing is that, if the jury is being asked to infer whether additional warnings would or would not have caused Andrew's mother to stop or not use Risperdal, they can't decide how to make

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that inference, yes, she would have rejected Risperdal or, no, she would have kept him on it anyway, without knowing the actual facts that mother was confronted with.

THE COURT: That does not make any sense at all. I'll tell you, if the jury is sitting listening to the case, if that information comes in, they can make a decision either way based upon that.

But you wanting to get in all these specific acts and incidents of what this child was doing at different points in his life, being violent, being this, being that, none of that is really relevant because, as I said, it's not a standard of care case. It's not a failure to diagnose at all. We're way past that. That's not any issues here. And I think to put that information, of course, is prejudicial, but also I think it would be confusing for the jury.

MR. ABERNETHY: I understand Your Honor's ruling. I respectfully disagree

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but --

THE COURT: And you can disagree. I'm just letting you know those are the rulings and those rulings stand. So if they're putting in certain excerpts, I guess, of the doctor's testimony, they can do that, and you can do the same. I don't know how long these depositions are, but, you know, whatever. I'm just saying to you that none of the specific incidents are triggered by what he wants to put in.

MR. ESSIG: Just in terms of keeping things moving, we have their cuts for Dr. Eker, which we got late last night. I've communicated our counters to them. We'll try to confer tonight. I have a feeling we're going to need to take a couple issues up with you at some point tomorrow, either before or after Dr. Solomon is done, before that depo can be played. If they can send me the next cut they have as soon as they can tonight, that will get the process moving and getting another one ready.

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MR. ITKIN: Judge, just one question. I don't mean to be dense. My apologies in advance. Our case is that 2003, Dr. Eker was not -- Janssen did not warn Dr. Eker because it's a failure to warn to the doctor. That's our case.

There is -- I want to know this as we do our depo cuts tonight. That's why I'm asking. There is testimony in the depositions that's 2007, 2008, 2009, if you had known this, would you have done that, if you had known this.

To me, that testimony is not relevant to our case because I don't have a doctor, an expert, that links up any failures in 2006, '07, '08, or '09.

THE COURT: Any time thereafter, right.

MR. ITKIN: So in my mind, I would leave all of that out of my depo cuts because I don't think it's relevant.

Now, I don't know if they agree or disagree. I feel like right now it's in there as sort of a protective measure. If

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they're going to say it, we're going to say it, and back and forth. I don't know if it's a limine or a question for the Court. I think that all should just be excluded. It should be, what did you see, within the Court's ambience, what did you treat, did he have the breasts or not, just to know the Court's guidance. It would help us.

My question to the Court is, is it your -- I know you don't have it in front of you. I'm not asking for an advisory ruling, but generally I think it might help us, as we're working together, to know is sort of this failure to warn at a later date, does the Court find that to be relevant in light of today's testimony?

MR. ESSIG: Your Honor, I think you ruled on this this morning, actually. There is relevant testimony from the other doctors that we need to present that relates to our defense and part as to whether or not he truly had gynecomastia during the subsequent treatment that he was on the drug.

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So we're not at any interest to play any more video than has to be played, but nonetheless, I think you understood that this morning, Judge, there was other testimony from later doctors that we're going to need to play as part of our defense as to whether or not he had gynecomastia.

THE COURT: Well, I agree. My throat is scratchy. Right now I'm not going to limit it, so we'll see. We'll talk more about it.

MR. ESSIG: I think it might be easier, in the context of a specific deposition, specific testimony, for you to decide.

THE COURT: We'll be back tomorrow morning at 9:00.

Something else?

MR. ITKIN: Judge, the rule in Pennsylvania, not allowed to talk to witnesses; correct?

THE COURT: What?

MR. ITKIN: We're not allowed to talk

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to our witnesses?

THE COURT: You can talk to your witness. You can't talk to him while he's under cross-examination.

MR. ITKIN: Understood.

THE COURT: You have no conversation with Dr. Solomon.

MR. ITKIN: That was my question.

MR. ABERNETHY: And it's my understanding, Your Honor, that the only live witness we're going to have tomorrow is Mr. Yount, Andrew's father.

MR. ITKIN: If we get through the video, that will be who the witness will be.

MR. ABERNETHY: After we get through the video, there won't be another live witness.

THE COURT OFFICER: All rise. Court is adjourned until tomorrow morning at 9:00 a.m.

(Proceedings adjourned.)

CERTIFICATE

I, Shannan Gagliardi, Registered Diplomate Reporter in and for the Commonwealth of Pennsylvania, do hereby certify that the foregoing is a true and accurate transcript of the notes of testimony of said witness who was first duly sworn on the date and place hereinbefore set forth.

I further certify that I am neither attorney nor counsel for, nor related to or employed by any of the parties to the action in which this trial was taken, and further, that I am not a relative or employee of any attorney or counsel employed in this action, nor am I financially interested in this case.

SHANNAN GAGLIARDI
Registered Diplomate Reporter
Certified Realtime Reporter

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

- - -

IN RE: RISPERDAL® LITIGATION :

A.Y., et al., : APRIL TERM, 2013

v. :

JANSSEN PHARMACEUTICALS, INC.,: NO. 2094
et al.,

- - -

THURSDAY, JUNE 23, 2016

- - -

COURTROOM 475
CITY HALL
PHILADELPHIA, PENNSYLVANIA

- - -

TRIAL - MORNING SESSION - VOLUME IV

- - -

B E F O R E: THE HONORABLE PAULA A. PATRICK, J.

REPORTED BY:
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PLAINTIFF'S EVIDENCE

DEFENSE'S EVIDENCE

WITNESS	DIRECT	CROSS	REDIRECT	RECROSS

COLLOQUY

THE COURT: Good morning. You can be seated.

Are there some matters to discuss before the jury gets in?

MR. ITKIN: We might want to do the page/lines.

THE COURT: You can step down.

MR. ESSIG: Judge, for the record, Bill Essig. Dr. Eker is the first deposition they intend to play. We had things worked out --

THE COURT: We can't hear you.

MR. ESSIG: -- and then at 12:00 something a.m., I got cuts from them for three additional depositions that, obviously, I was already in bed, I hadn't had a chance to look at.

THE COURT: You were in bed by midnight, really?

MR. ESSIG: I try. I need my sleep, Judge. I get up early, though. So I took a look at them at 6:00 a.m. and realized that I was going to have to do some work this morning, which I will do while the

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other testimony is going on. But it's going to be hard for us, I think, to get to much more than maybe one other deposition today other than Eker because we need to go through the cuts.

THE COURT: Okay. All right.

MR. TAVARES: Your Honor, just in response, we gave them updated cuts based on your rulings. I would imagine that they should have been working on their updated cuts. I don't know why they were waiting for our cuts. I don't know why our cuts made such a difference to them.

It's just basically, as the rulings come, we just update our cuts to eliminate stuff that no longer is going to be available. So I don't understand why they don't have their cuts ready. We do plan on playing three witnesses today based on our cuts. We haven't designated new stuff. We just cut back. So I don't understand the difference, why he's saying he can't do that.

MR. ESSIG: Your Honor, obviously,

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we're countering to their cuts.

THE COURT: You want to read to see.

MR. ESSIG: Exactly.

THE COURT: He's saying they're streamlined now.

MR. ESSIG: It may go faster today, but it's hard to tell.

THE COURT: Okay. So what deposition are we ready with?

MR. ITKIN: The deposition that we need the Court's help with is the prescriber from '03, which is Dr. Eker.

THE COURT: That's going to be the deposition shown this morning?

MR. ITKIN: After Dr. Solomon.

THE COURT: Okay.

MR. ESSIG: These are their cuts for Dr. Eker.

MR. TAVARES: Your Honor, I have a binder here with both of ours highlighted, ours in yellow, theirs in green.

THE COURT: Okay.

MR. ESSIG: So first, Your Honor, sort of a more global issue before we get to

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specific page/line, we object to them seeking to play the cuts out of the order in which they were elicited in the deposition.

I think it's confusing to the jury when you jump around. I think it makes more sense to keep a deposition in the order in which it occurred. So that's one global objection that we have.

There are a couple of places where they move testimony around, and it's not running in the order in which the questions were originally asked. I don't know if you have a feeling about that, Your Honor, but we did want to raise that objection.

THE COURT: What is your response?

MR. ITKIN: Your Honor, these are experts that are not experts. They're doctors. They're under nobody's control. They usually ping-pong back and forth between, we ask questions, they ask questions, we ask questions. It's not like you're taking a question and not having the answer that goes with it.

What you're trying to do is, when you are trying to take a deposition that is, you know, more than almost 200 pages, and get it down to 30 minutes, is you try to group issues together where they go logically.

So on page 85, the person gives an answer that helps go to the failure-to-warn issue. Put it with the other failure-to-warn issue so it's not out of left field and makes more sense in the context of the deposition. That's all we did.

THE COURT: I'll let you do that. It's keeping the testimony together, even though the doctor testified to other things in between. I'll let you do that.

What other objection do you have?

MR. ESSIG: Your Honor, another sort of global objection, but it relates to some specific pages, and this is a bunch of testimony that starts at page 37, line 14, through page 40, line 4.

And there's a whole series of

questioning of Dr. Eker about the labels that were in effect at the time that she prescribed versus the label in 2006, which is after she stopped seeing the patient, and a series of would-you-like-to-have-known questions.

We object on grounds of relevance in that she testified that she never had any recollection of reviewing the Risperdal label at any time prior to prescribing the medication for Mr. Yount.

So the questioning is all speculative and irrelevant in terms of what was in the label, when she had other sources of information that she acquired information about Risperdal, but had no recollection of ever reviewing the Risperdal label at the time that she was prescribing for Mr. Yount.

THE COURT: Your objection is relevance?

MR. ESSIG: Yes.

THE COURT: What is your response?

MR. ITKIN: Your Honor, this is a

witness who is testifying some 12 years after the fact that she prescribed medicine to one patient out of however many patients she has. She said that she doesn't remember one way or the other if she looked at it.

But the questions, the testimony elicited that goes to the heart of the case is, you know, if you had known what they put in 2006, what they put in 2003, if you had known the risk was higher, if you knew that the prolactin elevation was higher, would that have changed your prescribing decision?

That's what we need to prove in the case, and that's the testimony that is elicited. It's not irrelevant. It's directly relevant to the issues in the case.

THE COURT: It is relevant so I will allow it.

What else? What is your other objection?

MR. ESSIG: Your Honor, I think that

takes care of many of our objections. Similarly, for the record, objections we had on Dr. Eker also were 42-20 to 43-22; 44, lines 15 to 23; page 46, line 25 to page 53, line 4; page 57, line 22 to page 58, line 24; and this is an out-of-order cut, page 45, line 3 to page 46, line 10; back to 59-20 to 60, line 6; page 61, lines 4 to 14; page 77, lines 14 to 17; page 81, lines 3 to 8, 11 to 15, 17 to 19; page 82-6 to 83-6; and page 196, line 2 to line 18.

One other objection, Your Honor, that we had, on page 41 starting at line 11, there's some speculative questioning of Dr. Eker about whether she treats patients who have body image issues and does that cause a risk of psychiatric problems to the patient. This goes through page 41, line 21.

Obviously, there's no other testimony that Dr. Eker ever treated Andrew Yount for body image issues. I think this is speculative and should be stricken.

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THE COURT: Your response?

MR. ITKIN: Your Honor, one of the issues in the case is damages. And, I mean, I think it's kind of obvious to everyone, but we need to put that evidence into the record.

THE COURT: What is the question?

MR. ITKIN: The question is --

THE COURT: Which page?

MR. ITKIN: I'm sorry, 41, line 14.

MR. ESSIG: Our objection starts at line 11, actually.

(Court is reading.)

MR. ESSIG: Question: Do you treat or have you treated patients who have body image issues?

Answer: Yes, I have.

Question: And obviously, it seems to me at least obvious, if you were a male who gets female breasts, does that run the risk of causing body image issues that could cause psychiatric problems?

Answer: It does.

Again, she didn't treat him for this

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at all. She's a fact witness, and this is speculative questioning about body image issues that weren't part of the care and treatment of Mr. Yount.

THE COURT: Well, I would sustain the objection as to form because the question should have been rephrased. And there was an objection by Ms. Graff as to form, leading, speculation, and irrelevant. It would be relevant, but the form is incorrect. So I will object and sustain the objection based upon the ground that the form is incorrect and it certainly is leading.

MR. ESSIG: Thank you, Your Honor.

THE COURT: Any other objection?

MR. ESSIG: Not from the defense, Your Honor.

MR. ITKIN: We have some objections, Your Honor. The first objection starts on page 20, lines 9 through 18. This is dealing with specific -- the conduct issues that the Court's already ruled upon, breaking, you know, breaking a chicken's

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back and things like that.

MR. ESSIG: Your Honor, we're willing to take out breaking a chicken's back. Again, I don't mean to beat a dead horse or a dead chicken here, but there is some relevance to the understanding of the aggressive behavior that goes into the prescriber's risk/benefit decision, which, again, is directly relevant to the learned intermediary defense that we have in this case under Tennessee law.

So, Judge, what do you feel about keeping in page 20, lines 14 and 15, which says he had difficulty sitting still, aggressive behavior --

THE COURT: I'm sorry. Which lines?

MR. ESSIG: It's page 20. The answer starts, well, line 14, he had difficulty sitting still. The next line, aggressive behavior with biting, hitting, and we'd strike the rest of that answer.

THE COURT: That's fine. You can take out the rest of lines 15 through 18.

MR. ESSIG: Thank you, Your Honor.

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THE COURT: So we'll keep in he had difficulty sitting still, aggressive behavior with biting and hitting.

MR. ITKIN: That's fine, Your Honor. The next one --

MR. ESSIG: That we'll cut, Jason, 54. That's an error.

MR. ITKIN: Okay. So if we go to 64, lines 11 to 16, this is sort of a relevance objection. It talks about how he has a case manager and things like that. I mean, I don't think we need to be getting into those sort of issues.

THE COURT: That's fine. You can keep that in. He has a case manager and therapist.

MR. ESSIG: I didn't understand that one.

THE COURT: That can remain.

MR. ITKIN: Moving forward, Your Honor, 79-8 through, looks like it goes to 80-17, specific incidents of conduct, hits kids, got cards at school, those sort of issues.

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THE COURT: Okay. Well, one of the issues, of course, is the mother allowed him to take this drug. So I'll keep in part of this answer, and the part that will be stricken is starting at line 12. I'll strike the rest of that.

MR. ESSIG: Where it begins "he has had episodes," 79-12, Your Honor?

THE COURT: Yes. He has episodes hitting the other kids at school and got cards, which I'm thinking that's some sort of disciplinary thing. So all that comes out.

The part where it says the mother reports he, meaning Andrew, has been more difficult to control, he has a temper, refuses to do things, that's been in evidence anyway, so yes.

MR. ESSIG: Thank you, Your Honor.

THE COURT: What is your other objection?

MR. ITKIN: I'm sorry, Your Honor.

Just moving through these, are you all okay designating the completeness clip?

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MR. ESSIG: We'll play the completeness.

THE COURT: Just make sure that clip is out.

MR. ITKIN: Page 100, Your Honor, line 5 to 13, actually, Your Honor, I'm fine with this.

THE COURT: Yes. She's just talking about why she would give the drug, so that's fine. That objection is withdrawn.

What is your next one?

MR. ITKIN: Correct, Your Honor.

So if we move forward to page 111, line 10 to 113-4, two issues with this testimony, Your Honor.

THE COURT: What is your issue?

MR. ITKIN: One, she doesn't treat children or hasn't treated them since 2007, so it's not relevant to what we're dealing with here. And it's kind of misleading in the context talking about today, and we're really looking at risk/benefit analysis back in '03. And she doesn't treat children now. So we're mixing apples and

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oranges.

MR. ESSIG: Your Honor, if I may, the plaintiffs had elicited and they're going to be allowed to play now testimony relating to her saying, if I knew what I've been told now, I wouldn't prescribe it today and I wouldn't prescribe it then.

So I think it's completely relevant for us to have asked her about is she prescribing it today, for what conditions, and what her experience is. And that relates to, you know, the opinions that she's otherwise giving in response.

THE COURT: So the objection is overruled. It stays in.

What else do you have?

MR. ITKIN: Going forward, Your Honor, to page 116, lines 20 through 23, talking about standard of care, prescribe off-label. This isn't a standard-of-care case.

THE COURT: Correct.

MR. ESSIG: This is part of the testimony where she's explaining that she

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does need to prescribe certain medications like Risperdal off-label, and, again, that relates to her understanding of the risk/benefit profile of the drug at the time that she was prescribing.

THE COURT: You object from lines -- which lines? From lines 20 through what?

MR. ITKIN: 20 through 23, Your Honor.

THE COURT: I'll let that question stay in. It's not a standard-of-care case, but her answer goes to off-label usage. That's why I'll let it stay in.

What is your other objection?

MR. ITKIN: We have a counter-designation. We have two on 118. I'm going to withdraw those. We have a counter-designation on 120.

MR. ESSIG: So you're withdrawing the next two objections?

MR. ITKIN: Correct.

THE COURT: Starting which line on page 120?

MR. ITKIN: 120, line 14 to 20, for completeness.

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MR. ESSIG: We'll add that counter in for completeness. That's fine, Your Honor.

THE COURT: Okay. What other ones do you have?

MR. ITKIN: Jump ahead to page 139.

THE COURT: Which lines?

MR. ITKIN: Starting at lines 21 through 140 --

MR. ESSIG: We'll strike those, Your Honor, in line with your prior rulings about specific conduct.

THE COURT: Yes. Okay.

MR. ITKIN: On lines 140, 22 through 3, talking about the mom missing a couple of appointments with the therapist, I don't think that's relevant to the case.

MR. ESSIG: What line are you on?

MR. ITKIN: I'm sorry. Lines 140-22, to 142, line 3.

MR. ESSIG: Well, again, I think it's part of the context of Andrew's condition. And this is testimony where Dr. Eker is explaining that, in addition to the medication, which obviously the plaintiffs

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are taking issue with, he also needed therapy, and she was not regularly making sure that Andrew was receiving therapy.

So I think it relates to the effectiveness of the medication in terms of his overall psychiatric picture, and I think it's relevant to the jury's understanding of what his condition was at that time.

THE COURT: It doesn't go to the heart of the issue in this case, so I'm going to sustain that objection. That comes out.

MR. ITKIN: Your Honor, it's the same objection on 144-3 to 144-19.

THE COURT: Okay. My ruling stands that that does come out.

Up until what page?

MR. ITKIN: 144-3 to 19, Your Honor.

THE COURT: Your next objection?

MR. ITKIN: 149-10 to 16, this is specific instances of conduct, hitting others at home.

THE COURT: You can strike that part, hitting others at home. You can keep he

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was more irritable, he became aggressive.

MR. ITKIN: Similarly, Your Honor, 151-15 to 21.

THE COURT: We'll take out lines 18 through 20. So you can keep he was tending to lose his temper, he wanted his own way.

Do you see that?

MR. ESSIG: Yes, Your Honor.

MR. ITKIN: 159-16 to 22.

THE COURT: Okay.

MR. ITKIN: This is more specific conduct, hit his sister, hurt her eye and head.

THE COURT: Right. That comes out.

MR. ESSIG: Your Honor, just for context here, the start of the answer was he could not sleep. He was oppositional. I think --

THE COURT: Yes.

MR. ESSIG: Temper tantrums.

THE COURT: Yes, that is correct. Line 17, she could -- I'm sorry. He could not sleep. That's what she was trying to say. He was oppositional, having temper

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tantrums three or four times a day. That's it. Everything else comes out.

MR. ESSIG: Can I have the last line that the Seroquel was discontinued by the mother as patient was irritable?

THE COURT: That's fine. That can stay in.

MR. ESSIG: Thank you, Your Honor.

THE COURT: What is your next objection?

MR. ITKIN: Your Honor, kind of going forward, 160, lines 23 to 3, this is more in the context of prejudice. It's talking about he's got the potential to hurt himself and others when he's off the medicine. It makes him look like he's sort of a ticking time bomb.

There's no dispute in the case Andrew needs to be on some medicine. So I think to make it look like, if we have him off Risperdal, which I don't think anyone thinks is the evidence, if we have him off Risperdal and on something else, he's liable to do something awful to himself or

others, it's setting the wrong --

MR. ESSIG: Judge, if I may, this is the first time the jury's heard from a doctor who prescribed medication for treatment of these issues. They already heard about the violence and the self-harm, and this is not a description of a particular incident. It's not prejudicial. It just simply says he gets more aggressive, irritable, has a potential for hurting himself and others. I'm not sure what the prejudice is here, Your Honor.

THE COURT: That objection is overruled. I will keep that in.

MR. ITKIN: The next one is specific instances of conduct. It starts at 163-21 and goes to 164-8, talking about physically restrain him.

THE COURT: Okay.

MR. ITKIN: Broke out a window, et cetera.

THE COURT: Okay. That comes out. What is your next objection?

MR. ITKIN: Your Honor, we're going to

skip ahead. We'll withdraw the next one on 164 and go ahead on 165.

THE COURT: So the one on 164 is withdrawn?

MR. ITKIN: Not the one you just ruled on. There's one after that. We had an objection -- sorry to confuse things.

THE COURT: Go ahead.

MR. ITKIN: Our next objection starts on page 165, line 8 through 12, specific incidents of conduct. This one is probably okay, Your Honor.

THE COURT: Yes, that's fine, temper tantrums, stomping his feet, refusing to do things, not physically aggressive. Yes, that can stay in.

MR. ITKIN: So this is on page 170, lines 2 through 12.

THE COURT: What is your objection?

MR. ITKIN: My objection is they're asking the witness to talk about what's in the social worker's notes. One, I don't think we need to get into there's a social worker, but, more importantly, the doctor

doesn't have personal knowledge of why the social worker -- the doctor is not an expert in the case. The doctor is kind of an expert. It's a doctor. But it's not like a retained expert by one person or the other and did you rely on this in forming your opinions. She's reading the social worker's notes and coming to conclusions about that.

THE COURT: Your response?

MR. ESSIG: Your Honor, it's customary for physicians, in the course of rendering the treatment, for Dr. Eker to have reviewed notes of other providers within the practice who rendered care. So this is relevant to Dr. Eker's understanding of why the Younts discontinued treatment with her at Cherokee.

THE COURT: I otherwise would probably sustain the objection, but I can see, during that time, it wasn't made. Was an objection made at the time of the deposition? I don't see an objection there.

MR. ITKIN: I don't see it in the transcript, Your Honor.

THE COURT: It has to come in.

MR. ITKIN: Your Honor, the next one is lines 170-24 to 171-13, specific incidents of conduct.

MR. ESSIG: Your Honor, I see where we're going here.

Where would you like to stop this cut?

THE COURT: We can allow lines 1, 2, and 3. The rest of that comes out.

MR. ESSIG: Stop after "he had difficulty sitting still"?

THE COURT: Correct.

What is your next objection?

MR. ITKIN: Your Honor, I'm trying to skip some here to speed this up. I think the next one starts on page 175.

THE COURT: Which line?

MR. ITKIN: So this is starting at line 19 going all the way to, I guess, 14. This is asking the doctor to look at a record from a nurse and make an interpretation on it, and this time the

younger Mr. Itkin did make an objection.

THE COURT: I see objection, yes.

MR. ESSIG: There's no objection, and it's relevant to the decision-making that Dr. Eker engaged in in switching medication, based on this information that the nurse provided to her, based on the phone call with Mr. Yount, the plaintiff.

And the fact that Mrs. Yount told the nurse that she was afraid that Zyprexa would cause breast enlargement is obviously directly relevant to their claim that gynecomastia is caused by Risperdal use.

THE COURT: Okay. That stays in. The objection is overruled for that.

MR. ITKIN: Skipping ahead, Your Honor, to page 181.

THE COURT: Which line?

MR. ITKIN: Line 10. This is more of just a relevance objection, Your Honor, 10 to 17.

MR. ESSIG: Your Honor --

MR. ITKIN: They didn't define the potential risk. What risk are we talking

about? Actually, Your Honor, we're going to lose this one, so we'll withdraw it.

THE COURT: Yeah, I'm going to let this stay.

MR. ITKIN: We're going to lose it, so that's okay. I would not -- I do not want to waste the Court's time.

Skipping ahead, Your Honor, this may actually be the last one, you'll be happy to hear. This is 183, lines 12 to 21, and let me put this in context.

I think it's pretty clear from the testimony that Dr. Eker didn't do -- I don't think there's any disagreement amongst plaintiffs and Janssen that Dr. Eker did not do a breast exam. So it's eliciting testimony about was there breast enlargement when she doesn't have the foundation to make that conclusion.

I don't really care about the question about were there incidents of milk coming from his breasts because that's sort of in the records and it didn't happen, but at some point she says breast enlargement. At

one point she looked at him with his shirt off; at another point she didn't.

At this point, where they're asking the question about breast enlargement, it's calling for really some expert testimony where they haven't laid the foundation, you've done the things you need to do to make that determination. So it's misleading, it doesn't have the foundation, and it should be excluded.

THE COURT: There's no objection here anyway. There is further testimony but there's no objection here. You all didn't object to that when the doctor began to testify regarding that. So no objection.

MR. ITKIN: I think the objection is probably preserved as sort of a relevance objection. It's not a form objection. It's more of a substantive objection.

THE COURT: There's an objection before that question, I mean, before the issues before that, but not on this one. That has to come in. I can't see keeping it out. That comes in. That objection is

overruled.

MR. ITKIN: That concludes the plaintiff's objections, Your Honor.

MR. ESSIG: So after Solomon is completed, I think they want to play this next; right?

MR. ITKIN: Correct.

MR. ESSIG: We might need a little break for our techs to tune the clips for some of our cuts.

THE COURT: I'm going to let you do that now before we bring the jury in because, when we're done Dr. Solomon, I'll give them a short break, and then we'll come back and look at that. Make sure those are done in the next 15, 20 minutes. We'll bring the jury in all at once.

You have to finish your cross-examination of the doctor. About how long are we talking about?

MR. ABERNETHY: I think 20 minutes to half an hour, Your Honor.

THE COURT: Then you're going to do redirect, brief redirect maybe?

MR. ITKIN: Maybe. We'll see.

THE COURT: Go ahead.

MR. ITKIN: Is it your practice, one redirect? How often do we ping-pong back and forth?

THE COURT: It depends. I don't interrupt that. If he says things and you want to redirect, and on redirect, he says things he wants to cross, we can go all day. It's limited to what was asked in that specific time, obviously.

So whatever you bring out on redirect, if he wants to recross, he can. Whatever he brings out on recross, if you want to redirect what he said from recross, you can do that. I don't do that. It's going to be contingent upon the testimony anyway. You can't really gauge that.

MR. ESSIG: One other housekeeping matter, based on that time frame, there's, I guess, about an hour and 40 minutes of Dr. Eker, probably.

THE COURT: So during that time, you can probably work.

MR. ESSIG: I'll work on Hughes, which is, I think, the next one they intend to play.

THE COURT: That's going to be about an hour and a half. That should take us to lunchtime, I guess.

MR. ESSIG: Mr. Yount today?

MR. ITKIN: We'll see where the day goes.

THE COURT: You think you're going to do live testimony today?

MR. ITKIN: I think my guess is we'll just have Dr. Solomon as live. If we need to --

THE COURT: Then we'll have the video.

MR. ITKIN: That will take us to the end of the day, probably a little bit more video tomorrow, and then, you know, one, two live witnesses. We'll have our case off tomorrow.

MR. ESSIG: I think it's going to be tough to do more than two videos today given how this went, and we're still working on the other one we got late last

night.

THE COURT: I don't think so. We can move it. If you have issues regarding objections, I can make a ruling. I don't wait all day on those. I can make a decision, and they can do the edits and things. I'll give them time to do the edits, what I just made rulings on, so we can have the video up and going.

And during that video, if you want to look at the objections they sent and vice versa. If you can resolve them, fine. If you can't, I'll make a decision. We're looking at a tight schedule here for next week.

All right. Is there anything else?

MR. ITKIN: Nothing from the plaintiffs, Your Honor.

THE COURT: We'll take about, I guess, 15, 20 minutes. They'll let us know whenever they're done. We'll bring in the jury, put Dr. Solomon back up and get him out of here.

MR. ITKIN: Your Honor, can I ask the

indulgence of the Court? Sometimes these videos, when they get cut, they look a little choppy. I've had juries say, what's going on? Are they hiding stuff?

Sometimes I've had some judges that are willing to say, hey, these are depositions, and we're narrowing it down, something to the effect, so don't think the lawyers are --

THE COURT: Sure. I can say that. That's not a problem.

How many witnesses will you all have?

MR. ABERNETHY: I think we have four live witnesses and a limited amount of video to play.

THE COURT: Are you going to put your witnesses on first, your live witnesses on first, and then videos?

MR. ABERNETHY: We have the potential maybe for a live witness tomorrow, but it's not clear to me we're going to be able to get to that witness. And if we can't, then we may start with some brief video playing.

MR. ITKIN: Do you know who the

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witness would be?

MR. ABERNETHY: I need to check the schedules for tomorrow and Monday and figure out the time frames. So I'll let you know on that.

MR. ITKIN: Okay. I just want to know so we know who to prepare cross-examination for.

THE COURT: All right. Okay. We'll give you about 15, 20 minutes to get that done or however long he needs.

(Whereupon a brief recess is taken.)

THE COURT OFFICER: All rise. This court is now back in session. Please cease all conversations.

(The jury enters the courtroom at 10:12 a.m.)

THE COURT OFFICER: You all may be seated.

THE COURT: Okay. Good morning, ladies and gentlemen. Welcome back. We'll be continuing with the testimony of the cross-examination of Dr. Solomon.

Go ahead.

MR. ABERNETHY: Thank you, Your Honor.

- - -

CROSS-EXAMINATION

- - -

BY MR. ABERNETHY:

Q. Good morning, Dr. Solomon.

A. Good morning, everybody.

Q. Dr. Solomon, would you agree with me that oftentimes fat in the breast region can be confused with gynecomastia?

A. No.

Q. Do you recall testifying to that effect in a prior gynecomastia case in this court?

A. If you would show me that testimony, I'd be happy to comment on it.

Q. I'll be happy to show you the testimony, and then I'll ask you if that's what you said.

Dr. Solomon, this is a transcript of your deposition in a prior case taken on February 8, 2015; correct?

A. Yes.

Q. I think we actually may have looked at this briefly yesterday.

A. Yes.

Q. Would you take a look at page 14 and read lines 20 through page 15, line 8?

A. (Reading.)

So --

Q. Excuse me. There's no question pending.

Have you read the testimony?

A. Yes.

Q. You were asked a question here, are you not, about whether there's a mechanism by which obesity can cause gynecomastia; is that right?

A. That's correct.

Q. And then I think it's fair to say that you begin your answer by saying that there's no definitive evidence for that proposition; correct?

A. Yes, but I'm aware that the Findling revision analysis describes this as well as a possibility.

Q. Okay. I didn't ask you that.

The end of your answer says: And that oftentimes fat in the breast region is confused for gynecomastia.

Was that part of the answer you gave to that question?

A. Partly, but if you go on, the next question is: Are you able to differentiate between fat in the breast versus actually glandular tissue?

And I say: I am.

Q. And you do that, don't you, by the palpation, the physical examination that you described yesterday; correct?

A. Correct.

Q. Okay.

A. Among other things.

Q. Okay. We may come back to that. You can put that transcript aside.

Do you recall being asked some questions yesterday about the initial visit on August 22, 2003, with Dr. Eker, not the first visit with Dr. Eker, but the first time that she prescribed Risperdal? Do you remember generally the questions about that subject?

A. I remember generally the subject. I don't recall the questions.

Q. Okay. I'm going to ask you a few more questions, if I could.

One of the things you read and reviewed in connection with your work as an expert in this case is the deposition of Andrew's mother, Billie Ann

Yount; correct?

A. Yes.

Q. Do you remember reading testimony in Mrs. Yount's deposition indicating that the next appointment after Dr. Eker prescribed Risperdal she talked with Mrs. Yount about breast leakage?

A. I'll happily review the deposition testimony.

Q. I understand there's a lot of testimony, so I'll show it to you. I just wanted to ask if you happened to remember that.

This is the transcript of Mrs. Yount's deposition, which is one of the things that you reviewed as an expert in this case; correct?

A. Yes.

Q. Would you take a look at page 61? I want to ask you about a little bit of the testimony that you reviewed. If you take a look at page 61, line 9, you see there's a question where Mrs. Yount is asked whether at some point Dr. Eker prescribed Risperdal.

Do you see that?

A. That's line 9, as you stated.

Q. And would you read down to line 22, please, to yourself? Actually, to line 1 on the next page.

A. (Reading.)

Q. Have you had a chance to read it, sir?

A. Yes.

Q. And this testimony indicates, doesn't it, that after the first time that Dr. Eker prescribed Risperdal, at the next appointment, when Mrs. Yount went back, Dr. Eker asked if there had been any breast leakage; correct?

A. I'm a little confused. Are we saying that Dr. Eker asked, as proven in her records, or are we saying that that's the recollection of Andrew's mother?

Q. I'm asking whether that's what's indicated in the testimony by Mrs. Yount that you reviewed as part of your work as an expert here.

A. So to the extent that this is a recollection of something that happened 12 years before, I would say to you that, yes, Mrs. Yount stated that.

Q. Do you have any particular reason to doubt Mrs. Yount's recollection of her dealings with Dr. Eker?

A. Not specifically, but the medical records are slightly different in their description of these

events.

Q. Is breast leakage indicative of a condition called galactorrhea?

A. That's correct.

Q. Is that a side effect or a condition that is associated with elevated prolactin?

A. It can be.

Q. Would you agree that if Dr. Eker was, as Mrs. Yount described, discussing breast leakage with her at the time she prescribed Risperdal, then Dr. Eker was looking at side effects associated with elevated prolactin?

MR. ITKIN: Objection, Your Honor.

THE COURT: Objection is sustained.

BY MR. ABERNETHY:

Q. Let me move on.

You were asked some questions yesterday by both the lawyers about a visit on March 22, 2004, with Dr. Phillips, and I'm just going to put the record back up.

We took a look at this yesterday, didn't we?

A. Yes.

Q. This, I think we can agree, is the record

of the March 22, 2004 visit, which is a couple of months after Dr. Eker's first note about gynecomastia; correct?

A. Yes.

Q. And about 11 days after the note that we looked at yesterday that said that Andrew was going to be seen by his primary care physician concerning breast enlargement.

Do you recall that?

A. No. It didn't say he was going to be seen by his primary care physician. She suggested to the mother that she take him to the primary care physician for that.

Q. Well, do you still have the binder that we looked at yesterday?

A. Go ahead.

Q. Take a look at Tab 24, which we looked at yesterday.

A. Yes.

Q. And this is a note from Dr. Eker; correct?

A. Correct.

Q. And the March 11 note, which is 11 days before this March 22 visit, would you agree reads, in part: Patient will see primary care physician for

enlarged breasts?

A. That's exactly what it says. This visit is not for that. This is a sick -- if I can just repeat what I said yesterday on two occasions. Number 1, this is a sick child visit for an ear infection, which you and I can agree is what the record shows.

Number 2, the record, in fact, is incomplete and incorrect because it doesn't mention, under current medications, that he was on Risperdal, and he was.

So this is a really perfunctory note for a short visit for an ear exam, not a breast exam. There's nothing in here about a breast exam. We can agree on that.

MR. ABERNETHY: Move to strike the entire answer as unresponsive, Your Honor. The question was whether this was 11 days after the prior note. None of the rest of the answer had anything to do with what I asked.

THE COURT: All right. Stricken.

BY MR. ABERNETHY:

Q. Do you recall, when you looked at this note with Mr. Itkin yesterday, he asked you some questions

about what Dr. Phillips might have learned if he, Dr. Phillips, had put his stethoscope under Andrew's shirt at this visit?

A. I don't recall that we discussed it in that fashion.

Q. Okay. Do you recall reading Dr. Phillips' deposition testimony about this visit?

A. Again, I know I read it, but, obviously, it's more critical that I read it now.

Q. I understand completely, and I realize there's a lot of deposition testimony here. So let's take a look at it.

Dr. Solomon, is this the transcript of Dr. Phillips, which is one of the deposition transcripts that you reviewed in connection with your work as an expert in this case?

A. Yes.

Q. Would you please turn to page 63, and if you would read -- actually, I'm sorry, if you would start at page 62, line 17.

Could you tell me when you've found that?

A. I have it.

Q. And if you wouldn't mind reading forward to page 65, line 3. Let me know when you finished, and

then I'll ask you a few questions.

A. (Reading.)

Where is the endpoint, sir?

Q. I'm sorry, page 65, line 3.

A. (Reading.)

Okay.

Q. This testimony indicates, doesn't it, that Dr. Phillips looked at Andrew's chest at this visit on March 22, 2004?

A. If I can go to page 64, line 14, where I believe this is Dr. Phillips' answer, he says, quote, probably looking under his shirt but not have his shirt off, probably lifting up his shift -- but I assume that's a typographical for shirt -- and looking under his shirt, unquote.

Q. If you look at line 3 above, it refers to skin inspection palpation.

Do you see that?

A. I do.

Q. And then the answer indicates that no rashes or nodules are noted on the head, neck, trunk, or extremities.

Do you see that?

A. I do.

Q. And if you would now take a look at page 109, would you read -- actually, start at page 108, line 23, and if you wouldn't mind reading through page 110, line 10.

A. (Reading.)

I've read it.

Q. And in this testimony Dr. Phillips indicates, does he not, that his notation that there were no nodules required palpation?

A. Just to clarify to avoid confusion, nodules are not the same as a breast exam. He didn't do a breast exam, and it's clear he didn't do a breast exam. He states that he didn't do a breast exam. He was looking at the integrity of the skin, which is different than looking at the anatomy of the breasts.

And you may say I'm being unresponsive, but, for the jury, you should not confuse my business day-to-day, what I've learned 40 years ago, how to do a physical exam, from what you are trying to force Dr. Phillips to have said or not said.

Q. I'm not forcing anything. I'm asking you what he said.

Sir, did he or did he not testify, in what you just read, that he palpated the skin to look for

nodules? Did he say that or didn't he?

A. He palpated the skin, not the breasts. He's clear about that, the skin not the breasts, and you need to understand that. I'm sure they do.

Q. I'm asking you, Doctor, to stop quarreling and answer my questions.

Did he testify that he did palpation for nodules?

THE COURT: Counsel, he's not quarreling with you. He answered you.

THE WITNESS: Thank you, Your Honor.

BY MR. ABERNETHY:

Q. He also testified, in what you read on page 64 and 65, that if he had noted any unusual breast development, he would have put it in his records.

Didn't he say that?

A. Actually, he backs off on that because on 65, line 2, first he says: I'm sure I would. But as he continues, he goes: I think I would, yes.

So it's not a certainty.

Q. You would agree with me that the record of this visit doesn't contain any notation of unusual breast development; is that correct?

A. Just to be clear, as we talked about yesterday, an ear examination should properly not include a breast examination. You don't go to the cardiologist and get your breasts examined.

Q. Would you agree with me that there is nothing in the record of the visit that makes any reference to unusual breast development? Is there or isn't there?

A. That's correct, for this sick visit, there was no examination of the breast performed.

Q. And there's also no reference in the note to any discussion between Dr. Phillips and Mrs. Yount about breast enlargement or breast issues; correct?

A. Based upon the note, Mrs. Yount did not discuss breast enlargement with the doctor. She apparently discussed ear issues.

Q. You testified yesterday, I believe, that at certain points in time, Andrew was taking generic risperidone.

Do you recall that?

A. I recall we discussed it.

Q. And you told Mr. Itkin, I believe, during his examination, that although the generic product is made by a different company, the active ingredient in

the generic risperidone would be the same as the active ingredient in the branded Risperdal.

Do you recall that?

A. That's my understanding.

Q. And would you agree with me that whatever potential risperidone has to cause gynecomastia, it wouldn't be any different for generic risperidone than it would be for the branded Risperdal?

A. I'm confused by the nature of your question because the issue at hand is the gynecomastia that he got in response to the Risperdal that he took as a small child. So if you're saying did the gynecomastia progress because of the risperidone that he took later, potentially, but that's not what I'm saying.

Q. I didn't ask you that, sir. I'm asking a general question.

Do you believe that generic risperidone would have the same potential to cause gynecomastia as branded Risperdal?

A. Theoretically, that's probably true.

Q. You don't know of any scientific reason or study that would indicate there's any difference between the two in that respect, do you?

A. I have not seen any data regarding that.

Q. Now, it is your opinion, isn't it, that risperidone can cause gynecomastia within a matter of weeks or months after first exposure?

A. If I've said that, I'm happy to review that testimony.

Q. I'm not asking you about your prior testimony.

Is that your opinion, that risperidone can cause gynecomastia within a matter of weeks or months after first exposure to the drug?

A. I believe that my testimony is that the response of the breast tissue occurs at some time after, but I'm not sure I've time-limited it in the past, nor am I time-limiting it at the present.

Q. Doctor, this is a transcript of a deposition that you gave in another gynecomastia case on April 20 of this year, is it not?

A. Correct.

Q. Would you take a look at -- bear with me for just one moment.

Would you take a look first at page 50, lines 1 through 9?

A. (Reading.)

I've read it.

Q. And your testimony here was that, in your opinion, risperidone can cause gynecomastia within a period as short as three months; is that fair?

A. No. May I read the entire response?

Q. Would you read the question and answer?

A. Of course. And, first of all, so we're clear, it's referring to Risperdal. This is the question, line 1, page 50, and I believe it was you who asked me the question: Do you have any opinion, Dr. Solomon, as to how long an individual has to be on Risperdal before it can cause that person to develop gynecomastia?

Answer starting at line 4: I'm aware that, according to data that the Janssen folks have provided, prolactin levels can increase between 8 and 12 weeks after exposure to the Risperdal and that gynecomastia then ensues. So that it would seem to me, given the populations that have been studied, it can be as short as three months.

Q. And you said that your answer referred to Risperdal, which it did, but you just told me a minute ago that you don't know of any data or scientific reason why risperidone would be any

different than Risperdal in causing gynecomastia; isn't that correct?

A. Again, in this particular case of Andrew, since he already had gynecomastia before he was on the generic version, the answer is yes, but it's probably irrelevant to the case at hand.

Q. I'm not asking you about this case. I'm asking you about Risperdal and risperidone, generally.

You don't know of any reason why risperidone generic would be any different than branded Risperdal in causing gynecomastia, do you?

A. Just so we're clear, it's my understanding that I'm here to testify about this case. And as I've said previously, you asked me that question previously, this is the third time I'm answering it, the answer is, no, I'm not aware of any data. I've answered it three times.

Q. Doctor, would you now read page 50, line 22, through page 51, line 19?

A. I'm sorry. Tell me again, please.

Q. 50, line 22, through 51, line 19.

A. (Reading.)

I've read it.

Q. Would you agree with me that your testimony here was that gynecomastia can result from exposure to Risperdal at a later point in time, that is, further down the road than three months?

A. Reading from page 51, line 4, my answer: Again, there are things we don't know because the studies haven't been done longitudinally that follow, for example, the prolactin or other effects that can contribute to gynecomastia that are caused by the drug. So certainly prolonged exposure, in my mind, is associated with a greater likelihood than a short exposure, but, again, the exposure can be as short as 8 to 12 weeks before changes can occur.

Q. But prolonged exposure, in your mind, is associated with a greater likelihood than a short exposure.

That's what you say here; correct?

A. And I think the Etminan paper of 400,000 people with gynecomastia supports the fact that people with gynecomastia, who were exposed to Risperdal, have a five times greater incidence of it than people who don't. So there's data to support my contention.

MR. ABERNETHY: Move to strike as

nonresponsive, Your Honor.

THE COURT: That was responsive.

BY MR. ABERNETHY:

Q. You testified about weight gain.

You would agree with me, wouldn't you, Doctor, that Andrew gained weight both when he was on Risperdal and off Risperdal?

A. There's evidence to that effect.

Q. And your reports in this case -- and you can take a look back at them at Tabs 1 and 2 in the book, if you would like -- they don't analyze or quantify what weight he gained on Risperdal and what he gained off Risperdal, do they?

A. I believe that's correct.

Q. And they don't contain any analysis of his diet or activity or other factors that might have affected weight gain, do they?

A. As opposed to the drug itself? I don't know what the question is.

Q. Your reports do not address in any way, do they, whether diet, activity, or other matters other than drug exposure might have affected his weight gain? You don't talk about that in your reports, do you?

A. Right. The rapid gain he experienced would be unlikely related to diet or exercise, which is why I didn't address it.

Q. They also don't talk anything about family history of obesity, do they?

A. Correct. There's nothing in there about that.

Q. You didn't prepare any growth chart that shows his progression in weight over time or during particular periods of time, did you?

A. Correct.

Q. You described him generally as, I think you used the term a "husky" kid; right?

A. I believe I testified to that yesterday.

Q. And you also told us, didn't you, that he was at a pretty high percentile of weight throughout his growth curve.

Do you recall saying that?

A. We did discuss that.

Q. And, in fact, he was at a pretty high percentile for weight even before he went on Risperdal for the first time, wasn't he?

A. I'd have to see the data, frankly. I don't recall.

Q. You don't recall what his weight was before he started?

A. No, sir.

Q. I want to ask you one or two questions about the photos that you took, and Mr. Itkin showed you the photos in color. He gave me this black-and-white copy, but I think this is actually sufficient for our purpose. So rather than looking for the color copy, maybe you could take a look at the black-and-white copy. Then we'll see if you can answer the question from that.

A. With all due respect, sir, I'd like the color copies projected. They are the photos I took, not these reproductions. And the photos in color are already accurate for the purposes of the court.

MR. ITKIN: Your Honor, we can --

MR. ABERNETHY: Counsel just handed me a color copy. I appreciate it.

BY MR. ABERNETHY:

Q. In this photo and several others, there are some, I would describe them, tell me if you disagree, reddish blotches on Andrew's chest.

A. Why don't you put your finger on one of them so I know exactly what you're talking about.

Q. Here.

A. Yes, I would agree with that.

Q. That doesn't have anything to do with his gynecomastia, does it?

A. I don't believe I've stated that it does at all.

Q. No, I'm just asking you.

It doesn't, does it?

A. Correct.

Q. Thank you.

You testified yesterday, if I understood you correctly, that you can diagnose gynecomastia from a photograph.

Did I get that right?

A. I believe I've testified yesterday and in other cases that I can make that diagnosis.

Q. You don't diagnose patients, who are under your care, who have gynecomastia, you don't diagnose them with gynecomastia solely from photographs and without a physical examination of the breasts, do you?

A. I don't make surgical decisions based solely on photographs, that's correct.

Q. So you wouldn't make a treatment decision

as a plastic surgeon for a patient with gynecomastia based solely on photographs; right?

A. I would not make a treatment plan for surgery based on photographs alone, that's correct.

MR. ABERNETHY: Could I have one moment, Your Honor?

THE COURT: Yes.

MR. ABERNETHY: I don't have anything further. Thank you, Dr. Solomon.

THE WITNESS: Thank you.

THE COURT: Any redirect?

MR. ITKIN: Yes, Your Honor.

- - -

REDIRECT EXAMINATION

- - -

BY MR. ITKIN:

Q. Good morning, Dr. Solomon.

A. Good morning, Mr. Itkin.

Q. Am I picking up?

A. I hear you well.

Q. I've got so many pieces of paper here, so let's see where we begin. But I'll try to be brief. We'll start here. You were -- maybe we ought to just do a little bit of background.

We've got a court reporter here; is that correct?

A. Yes, sir.

Q. Court reporter is taking down everything you say; right?

A. Yes, sir.

Q. And when they do, they get printed up into these books like this; right?

A. Yes, sir.

Q. And you were asked about different testimony; right?

A. Yes, sir.

Q. I want to talk a little bit about that for a second.

The last one they asked you was this case Moffatt; is that right?

A. Yes, sir.

Q. And that was a case where a boy, I believe, was claiming he got gynecomastia from Risperdal at age eight; is that right?

A. I believe that's correct.

Q. Mr. Abernethy was asking you questions about it; is that right?

A. That's correct.

Q. It's a case where Janssen was denying that that eight-year-old boy got gynecomastia from Risperdal; is that right?

A. Correct.

Q. The other one they asked you about was a case Pledger; is that right?

A. Correct.

Q. That's the one where you were down in the courthouse testifying; right?

A. And I believe I might have even done a deposition that he asked me about as well. I think we had both documents.

Q. Another case, that boy was eight years old when he was alleging he got his gynecomastia?

A. I believe that's about right.

Q. Another case where the Drinker Biddle firm was the lawyers?

A. Yes, sir.

MR. ABERNETHY: Your Honor, I object to the examination on the specific facts of these cases. This is not going to the specific propositions that I asked him about from his prior testimony. He's just reciting unrelated facts from other cases.

THE COURT: I don't think that's the case. You asked him specifically about what's in these depositions. He's just trying to lay a foundation for the jury as to where these depositions came from, and he's allowed to do that. He hasn't gone into specifics in any of these cases which he mentioned. Objection is overruled.

Go ahead.

THE WITNESS: Thank you, Your Honor.

BY MR. ITKIN:

Q. The Drinker Biddle firm --

A. Yes, sir.

Q. -- was on that case; is that right?

A. Yes, sir.

Q. Janssen was the defendant in that case?

A. Yes, sir.

Q. They were denying their drug caused gynecomastia in that case as well; is that right?

A. Correct.

Q. I believe the third case you were asked about was a case called Stange; is that correct?

A. Yes, sir.

Q. Another case with a boy claiming he got

gynecomastia?

A. Yes.

Q. Another case where Drinker Biddle was the lawyers?

A. Yes.

MR. ABERNETHY: Objection. Relevance.

THE WITNESS: Yes.

THE COURT: Overruled.

Go ahead.

THE WITNESS: Yes.

BY MR. ITKIN:

Q. Another case where Janssen was the defendant?

A. Yes.

Q. Another case involving Risperdal?

A. Yes.

Q. Another case where they denied that it caused the boy gynecomastia?

A. Yes.

Q. Both -- well, I think that point is made. I'm going to move forward for a couple other things.

You were shown some papers, some scientific papers yesterday, and I think what was -- these were questions about this prolactin, can prolactin cause

gynecomastia, and things of that nature.

Do you remember that?

A. I do.

Q. So I want to talk about a couple papers you were not shown. Let me back up.

You're generally familiar with the scientific literature?

A. Yes.

Q. You've reviewed it?

A. Yes.

Q. And like anything, there's parts that are good and parts that are bad.

You kind of consider all that in coming to your opinions; is that right?

A. Exactly, correct.

Q. You don't want to cherry-pick the data; is that right?

A. Correct.

Q. There is a paper by a gentleman named Findling that the jury's heard some about; is that right?

A. Yes, sir.

Q. And I'm going to hand you the Findling article.

THE COURT: Has that been marked as an exhibit?

MR. ITKIN: I don't remember. He didn't mark it yesterday. We'll mark, identify.

THE WITNESS: I have it here as well.

BY MR. ITKIN:

Q. You have it there as well?

A. Yes.

Q. Fantastic.

MR. ITKIN: Your Honor, we would like to publish the Findling article.

THE COURT: We need to have it marked for the record.

Was that a paper he introduced yesterday?

MR. ITKIN: It was in the binder yesterday, but I don't think they put it in.

MR. ABERNETHY: I did not mark it yesterday.

THE COURT: We'll mark this as, what, Plaintiff's Exhibit 2, 3?

MR. ITKIN: We're cleaning up the

record from yesterday, and we will mark it as plaintiff exhibit -- we will get that figured out, Your Honor. I'm sorry about that. Plaintiff's exhibit I don't know, but we'll get it figured out.

THE COURT: But it is the Findling article?

MR. ITKIN: Yes.

BY MR. ITKIN:

Q. And this is the article that Table 21 was not included in this article; is that right?

A. Correct.

Q. I don't want to talk about that right now.

MR. ITKIN: If we can publish it, Your Honor?

THE COURT: Okay.

BY MR. ITKIN:

Q. This is the article. There's a controversy about the Table 21.

This is that article; is that right?

A. Yes, sir.

Q. If we look at the first page of that article down at that bottom on that right-hand column, if we can pull that out, that bottom

paragraph, they've already highlighted it for me. It says: Elevated prolactin has also been associated with gynecomastia, galactorrhea, and menstrual disturbances.

Do you see that?

A. Yes, I do.

Q. That's not a controversial proposition in the medical and scientific community; is that right?

A. That's correct.

Q. I mean, in fact, if we look at the -- I'm going to hand you what has been marked -- actually, it's already in evidence, Plaintiff's Exhibit 3. I'll get you a copy here, Dr. Solomon.

MR. ITKIN: Can we publish Exhibit 3 to the jury? It's the '06 label.

BY MR. ITKIN:

Q. If we look at the label in the top left-hand corner, this is the Risperdal label; right?

A. Yes, sir.

Q. If we go to the very last page of the Risperdal label ending in 264, you can see in the bottom of the page we got the Janssen copyright and the Janssen logo at the bottom; is that right?

A. Yes.

Q. This is the Janssen label; right? This is the Risperdal?

A. Yes. This is what would be the package insert as well.

Q. Okay. If you go to page 259, there's a section called hyperprolactinemia, and we'll blow it up here because I know it's small.

As a reminder, hyperprolactinemia, that just means you've got elevated prolactin; right?

A. That's correct.

Q. And I don't know if we can pull that up any bigger. This is out of the label; right?

A. Right. This is the Janssen label.

Q. It says: As with other drugs that antagonize dopamine D2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration.

This is maybe what I think is the important part, but you tell us: Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents.

I don't know if we can underline that, this last sentence: Risperidone is associated with higher levels of prolactin elevation than other

antipsychotic agents.

Do you see that?

A. I do.

Q. Couple questions about that. Risperidone is the chemical name for Risperdal; right?

A. Yes.

Q. It's a chemical; right?

A. Yes.

Q. And what it does is, according to Janssen's own label, it elevates prolactin levels more than other drugs that would be competitors in the same class; right?

A. That's exactly correct.

Q. Okay. So the next, going down, it says: Hyperprolactinemia may suppress hypothalamic GnRH resulting in pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin elevating compounds.

Do you see that?

A. I do.

Q. I want to focus on that part:

Galactorrhea, amenorrhea -- and most importantly for this case -- gynecomastia, and impotence have been reported in patients receiving prolactin elevating compounds; okay?

A. Yes.

Q. Risperdal is a prolactin elevating compound.

We know that from the sentence above; right?

A. We do, that's correct.

Q. We know from this own Janssen label that, if you have elevated prolactin, gynecomastia has been reported; right?

A. That's correct.

Q. So when you were shown all these snippets from these articles yesterday trying to say prolactin doesn't have anything to do with gynecomastia, I mean, that's not what's even in Janssen's own label, is it?

A. Correct.

MR. ABERNETHY: Objection to the leading, Your Honor.

THE COURT: Objection is overruled.

THE WITNESS: Correct. That's -- it's

contrary to what's in the label.

BY MR. ITKIN:

Q. Their document; right?

A. Yes, sir.

Q. I mean, you mentioned an article by a gentleman named Etminan or a Dr. Etminan, the Etminan article, I think you said.

A. Yes, sir. We've got a copy of it, I think, here.

MR. ITKIN: Your Honor, we'd like to mark, offer, and introduce -- and we'll get the correct exhibit number on a break -- the Etminan article.

THE COURT: That wasn't introduced yesterday.

MR. ITKIN: Correct, Your Honor.

MR. ABERNETHY: I object. It's beyond the scope. It's an epidemiology article. He's not been qualified as an epidemiologist, and it was not marked and he was not asked about it. It's improper use.

THE COURT: Let's see what the question is.

What's your question?

BY MR. ITKIN:

Q. You mentioned this article a moment ago on cross-examination; is that right?

A. Correct.

Q. This is something called an -- what's it called?

A. It's a population study, for lack of a better word, but it's published in a medical journal. And I read and review medical journals as part of my day-to-day life.

Q. Epidemiology, as I understand it, is a branch of science that looks at large populations and studies them to see if there's elevated risks in large groups of people; is that right?

A. Correct. And just to be clear, as part of my medical school curriculum as a medical student, we had a course in public health and epidemiology. So we could interpret papers like this.

Q. You don't do epidemiology studies; correct?

A. I'm not an epidemiologist, correct.

Q. Doctors read this stuff all the time to see if there's some public health concern they should know about; is that right?

A. As a matter or routine. In fact, there's a famous epidemiology study called the Framingham study that gets updated periodically in the New England Journal of Medicine that, as a physician, I think about all the time. It's studies like that that teach us about the risk of smoking, the risk of uncontrolled blood pressure, et cetera, et cetera, et cetera. So these are part and parcel of the practice of medicine, and we, as physicians, rely upon them.

Q. Let's talk about this particular study.

MR. ITKIN: Your Honor, may I publish it to the jury?

MR. ABERNETHY: I object to it, Your Honor.

THE COURT: What is your objection?

MR. ABERNETHY: It's not proper to bolster testimony on direct or redirect with literature that wasn't asked about on cross. It's beyond the scope of cross, and he is not qualified as an expert in this area.

THE COURT: Okay. He is not qualified as an expert in this particular area. His own testimony is clear to that. But he

said he was aware of this article. He's used this article in making decisions and conclusions.

So you're saying that you didn't ask him any questions about this particular article when you asked him questions on cross?

MR. ABERNETHY: I asked no questions about this article, about epidemiology. He can be asked about the literature he was asked about before, but he can't use additional literature to bolster his testimony on direct under the rules of evidence.

THE COURT: Well, he's not using additional literature to bolster the testimony.

Okay. So what is the purpose that you want to show this to the jury?

MR. ITKIN: It's two simple points, Your Honor. First of all, it was brought up on his direct. He mentioned it in direct examination. So let's show the jury what he was talking about.

And the second point is this is something that -- the rules of evidence are not such that you get to show two articles on cross-examination that you think are helpful and you can't come back and show the rest of the literature.

This is something he's reviewed, he's relied upon. It's in the medical science. It goes to the causation opinions in the case. It's not going to take very long, but I think the jury deserves to hear what this 2015 article says.

THE COURT: Did you use this article in making any conclusions in reference to this particular case?

THE WITNESS: Absolutely.

THE COURT: Overruled.

MR. ABERNETHY: This article is not cited or referred to in either of his reports, Your Honor.

THE COURT: Okay. Thank you. It's overruled.

MR. ITKIN: May I proceed, Your Honor?

BY MR. ITKIN:

Q. So let's talk about this article.
This article is entitled "Risperidone and the Risk of Gynecomastia in Young Men."
Do you see that?
A. I do.
Q. And it's got three authors; is that correct?
A. It does.
Q. It was published, it looks like, in the top left, in 2015; is that right?
A. Yes, sir.
Q. So relatively recent article?
A. Correct.
Q. Let's go to the objective, the abstract.
The abstract is kind of the quick summary of what's in the article; is that right?
A. Correct.
Q. The abstract, if we go to the objective section, was: The purpose of this study was to quantify the risk of gynecomastia with risperidone in adolescent and young adult males.
Do you see that?
A. I do.
Q. So trying to figure out what's the risk, if

any, of taking Risperdal and getting gynecomastia; right?
A. Correct.
Q. So then they go down to describe their methods.
Do you see that?
A. Yes.
Q. And they're looking at males age 15 to 25; is that right?
A. Yes.
Q. So these are males that are actually a little older than Andrew; true?
A. Correct.
Q. At least when Andrew got the gynecomastia, by your testimony?
A. Correct.
Q. Okay. If you go down to the results section here, how many men were in the study?
A. So the cohort, meaning the group of records that they reviewed, these are reviews of records, 401,924.
Q. So there were 400,000, roughly, people in the study; is that right?
A. Yes.

Q. Let's go to the analysis here. It says: When the analysis was stratified to children and adolescents younger than 18 years or younger taking risperidone, the risk of gynecomastia was five times higher than for nonusers.
Do you see that?
A. I do.
Q. So men, boys under the age of 18, taking Risperdal had a more than five times higher risk of gynecomastia than boys 18 and younger who were not taking Risperdal; is that right?
A. That's exactly what it says.
Q. Okay. And if we go to the conclusions, it says: Risperidone is associated with an increased risk of gynecomastia in adolescent and young adult males; is that right?
A. That's what it says.
Q. It's the same as your conclusion; right?
A. Exactly.
Q. I mean, if we go to the last page of this study, let's go to the conclusion. Clinical significance. This is fine too.
Our study results suggest an increased risk of gynecomastia in adolescent and young males. Given

that this condition carries a high psychological burden, clinicians might want to consider prescribing antipsychotics with a lower propensity for gynecomastia to young or adolescent males.
Do you see that?
A. I do.
Q. That's what the authors are saying, might consider something else; right?
A. Yes.
Q. And we know from, I don't want to beat a dead horse, but if we go back to Janssen's label, their own label, the 2006 label where the hyperprolactinemia is: Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents; right?
A. Correct.
Q. It raises the prolactin the most?
A. More than the other agents in its class like Abilify and Zyprexa and so forth.
Q. On your cross-examination -- I'm trying not to scratch up the courthouse here -- but on your cross-examination, I was trying to pay close attention.
I didn't hear any questions where it was

challenged that Andrew has gynecomastia, did you?

A. I did not hear any questions to that matter, that's correct. It was not challenged at all, so we agree that he has gynecomastia.

MR. ABERNETHY: Your Honor, I object and move to strike. The witness is not qualified to characterize what I suggested was his suggested cross-examination. He should be answering questions about facts.

THE COURT: Objection is sustained.

THE WITNESS: I'm sorry, Your Honor.

BY MR. ITKIN:

Q. Do you have anything that you were asked on cross-examination that adds any doubt, any question in your mind about whether Andrew has gynecomastia?

A. There was nothing I was asked on cross-examination that creates any doubt in my mind. He has gynecomastia.

Q. Anything you were asked on cross-examination that raises any doubt that he got the gynecomastia, that it began when he was a five-year-old, almost five, four, five-year-old boy when he was taking the Risperdal?

A. There was nothing on cross-examination that

challenged that point that I believe is correct.

Q. I mean, anything that you were asked on cross-examination that raises any doubt in your mind -- because now is the time. Get it out. If there is, I want to know.

Anything that raises any doubt in your mind, any question, anything like, you know, I didn't quite consider that, that the damage was done sometime between August 22, 2003, when he started the Risperdal, and that Christmas 2003 picture, that five-year-old boy when we saw the breasts yesterday?

A. As you know, there are cases I've looked at where I told you there's no connection. This is not that case. This is a case where we absolutely are able to document it from the beginning to the present time. There is no doubt in my mind whatsoever.

MR. ITKIN: Thank you, Your Honor. I'll pass the witness.

THE COURT: Recross.

- - -

RECROSS EXAMINATION

- - -

BY MR. ABERNETHY:

Q. The Etminan paper, do you still have that

in front of you?

A. Yes.

Q. This is a paper on a case-control study; correct?

A. Yes.

Q. Involving the cohort of males 15 to 25 years of age.

That's what the method section says; correct?

A. Correct.

Q. And this is, I think you told us, an epidemiological study; correct?

A. I believe that was your characterization.

Q. Is it an epidemiological study?

A. It's what I would describe as a large-scale case-review study.

Q. It's the kind of study that epidemiologists do, isn't it?

A. It's the kind of study that people who look at populations do. I imagine that's part of what epidemiologists do. I'm not certain. You know, there are two PharmD's and an MD, Ph.D. who did it. I don't know their background.

Q. It's not a kind of study you've ever done;

correct?

A. I have not submitted data recently to large-scale studies. I have in the past.

Q. Do you know Dr. Etminan?

A. I don't.

Q. Did you read the disclosures at the end of the paper?

A. I did.

Q. Which say Dr. Etminan has been a consultant on risperidone and gynecomastia litigation.

Did you see that?

A. It does say that.

Q. Do you know that he's a consultant for plaintiffs who are suing companies in gynecomastia cases?

MR. ITKIN: Objection, Your Honor. I'm not sure that's been -- I don't know Dr. Etminan either.

MR. ABERNETHY: I'm asking him.

BY MR. ABERNETHY:

Q. Do you know that he's a consultant for plaintiffs suing in gynecomastia cases? Do you know that or don't you?

A. I only know that he's a consultant. I

don't know if he's a plaintiff's consultant, a defense consultant, an epidemiology consultant. The other authors have nothing to disclose.

Q. You didn't look into that before you testified about the paper today; correct?

A. Again, I'm aware that the Findling data and the Reyes paper and so forth were all sponsored by your company, by your client. I'm not aware if anybody sponsored this. I'm just aware of what the data says.

Q. I didn't ask you that.

A. I'm telling you that what I know is that your data comes from clients or your client's support of it. This, I don't know who supported it. That's what I'm saying. And I'm not being nonresponsive. You asked me do I know, and the answer is I don't know. Do I do any extra research as to who writes the papers? Is that what you're asking me? No, I do not.

Q. The question was, and I'll put it again, did you look into Dr. Etminan's affiliation as a consultant on gynecomastia litigation before you testified about this paper today? Did you or did you not?

A. So to be clear, just so you folks understand, that's the author's disclosure. He doesn't say what side, and I, frankly, did not. I do know for a fact that he is associated with the Department of Ophthalmology & Visual Sciences at the University of British Columbia in Vancouver. That's the only thing I know about him.

MR. ABERNETHY: Move to strike everything as unresponsive except his response that he didn't look into it, Your Honor.

THE COURT: Okay.

MR. ABERNETHY: That's all. Thank you.

THE COURT: Any redirect?

MR. ITKIN: I don't think so, Your Honor.

THE COURT: Thank you, Doctor.

THE WITNESS: Thank you, Your Honor.

(Witness excused.)

THE COURT: Okay. Who is your next witness?

MR. ITKIN: Oh, sorry, Your Honor. It's our turn still. Dr. Eker, the

prescribing doctor, by videotape.

THE COURT: This is a deposition?

MR. ITKIN: Yes, Your Honor. Our portion is 30 minutes.

THE COURT: Just so you know, I'm going to let you look at their segment of the video that they're presenting. It should take us up to 11:30, 11:45 for lunch.

The video may seem a little choppy, but it was organized so it could flow with all the information that would go to you. Then they'll present their portion probably after lunch; okay?

(The videotaped deposition of Deniz Eker, M.D., is played for the jury.)

THE COURT: Okay. You can be seated.

Ladies and gentlemen of the jury, we're going to now come to the point of a lunch break. All of the instructions I've given you before, there's no communications about this case, reading, or talking about it in any way or in any capacity. We'll be

back here -- it's 11:45 now. We'll be back here at about 12:45. Okay for lunch? Enjoy your lunch. Please stand as the jury exits.

(The jury exits the courtroom at 11:44 a.m.)

THE COURT: Okay. So we're now on lunch break. I guess you all are going to go through the depositions, the objections and so forth.

MR. ESSIG: We'll work on that.

THE COURT: Okay. Enjoy your lunch.

(Whereupon a luncheon recess is taken.)

CERTIFICATE

I, Shannan Gagliardi, Registered Diplomate Reporter in and for the Commonwealth of Pennsylvania, do hereby certify that the foregoing is a true and accurate transcript of the notes of testimony of said witness who was first duly sworn on the date and place hereinbefore set forth.

I further certify that I am neither attorney nor counsel for, nor related to or employed by any of the parties to the action in which this trial was taken, and further, that I am not a relative or employee of any attorney or counsel employed in this action, nor am I financially interested in this case.

SHANNAN GAGLIARDI
Registered Diplomate Reporter
Certified Realtime Reporter

Appendix F

In The Matter Of:

Pledger v.

Janssen

(Jury Trial-AM Session)

XI

February 9, 2015

John J. Kurz, RMR-CRR, Official Court Reporter

City of Philadelphia

First Judicial District Of Pennsylvania

100 South Broad Street, 2nd Floor

Philadelphia, PA 19110

Original File 09FEBRUARY-2015-DJERASSI-PLEDGER-MORNING-FINISHED_AMENDED.txt

Min-U-Script® with Word Index

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

IN RE: RISPERDAL® LITIGATION : March Term, 2010, No. 296

Phillip Pledger, et al., Plaintiffs, : APRIL TERM, 2012
v. : NO. 01997

Janssen Pharmaceuticals, Inc., Johnson & Johnson Company, and Janssen Pharmaceutical Research & Development, L.L.C. Defendants.

- - -

MONDAY, FEBRUARY 9, 2015

- - -

COURTROOM 425
CITY HALL
PHILADELPHIA, PENNSYLVANIA

- - -

B E F O R E: THE HONORABLE RAMY I. DJERASSI, J., and a Jury

- - -

JURY TRIAL - VOLUME XI

- MORNING SESSION - (AMENDED)

REPORTED BY:
JOHN J. KURZ, RMR, CRR
REGISTERED MERIT REPORTER
CERTIFIED REALTIME REPORTER
OFFICIAL COURT REPORTER

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Marianne Mari, Tipstaff
Cory Smith, Video Technician
Ken Reed, Video Technician
Thomas F. Campion, Esquire
Benita Pledger

- I N D E X -

COURT CRIER: All rise.
(Call to order at 9:15 a.m.)
THE COURT: All right. Good morning, everyone. Back to work, at least for me. Plaintiff.
- - -
(The following transpired in open court outside the presence of the jury:)
- - -
THE COURT: We are waiting for one juror, and then we're ready to go.
MR. MURPHY: Your Honor, we do have an issue to raise before the jury comes in.
THE COURT: Pardon me?
MR. MURPHY: We do have an issue to raise with Your Honor before the jury comes in. I have a motion to make. It concerns Dr. Solomon. I think he may be in the courtroom.
MR. KLINE: He is.
THE COURT: Okay.
MR. MURPHY: I would ask that he be excused.
(Dr. Solomon exited the courtroom.)
THE COURT: What is your concern?

MR. MURPHY: The admissibility of his testimony, Your Honor.
THE COURT: We've already been through that.
MR. MURPHY: Pardon me? No.
THE COURT: We've already been through it.
MR. MURPHY: We just --
THE COURT: I'm going to do whatever it takes in front of the jury.
MR. MURPHY: Your Honor, we just had his deposition yesterday.
THE COURT: I know.
MR. MURPHY: And what we've determined --
THE COURT: I didn't get a phone call at all. So as far as I'm concerned, we're not doing it that way. We're going to do it in front of the jury. Whatever has to be done will be done in front of the jury. That's my ruling on this.
MR. MURPHY: You haven't heard the basis for the motion.
THE COURT: I am not interested, honestly. If there's an objection to the

admissibility of his testimony in some way, it will be done in front of the jury.
MR. MURPHY: Understood, Your Honor.
THE COURT: Thank you.
All right. We'll take a recess till we wait for the actual -- until we wait for the actual juror to arrive.
- - -
(Pause.)
- - -
(Whereupon a recess was taken.)
- - -
THE COURT: All right. Please be seated. We do finally have our juror. So I'm now in a better position to hear what the objection is, and then we'll see what the objection is.
MR. MURPHY: Sure, Your Honor. Thank you.
As Your Honor is aware, we deposed Dr. Solomon yesterday.
THE COURT: Yes.
MR. MURPHY: Okay.
THE COURT: What time was that, by the way?

MS. BROWN: 10:00 a.m.
MR. MURPHY: 10:00 a.m.
THE COURT: To what time?
MS. BROWN: 11:30.
MR. MURPHY: 11:30, 11:40.
THE COURT: Okay. For the record, I received no phone call from any of the parties yesterday, though I requested to be informed if there were any objections.
MR. MURPHY: There were no objections in terms of the questions asked. There were no problems with counsel.
THE COURT: Okay.
MR. MURPHY: The issue that I'm raising with Your Honor is the fact that Dr. Solomon's opinions differ dramatically from the opinions that were advanced by Dr. Goldstein.
THE COURT: Okay.
MR. MURPHY: Okay. It's not an issue of the ultimate --
MR. KLINE: Your Honor, Dr. Solomon's in the courtroom.
THE COURT: All right. Just make the record, Mr. Murphy, and then we'll proceed.

MR. MURPHY: Fair enough.
It's not the ultimate conclusion. What really is at issue is the underlying opinions, that is, dates of onset, what mechanism of action the experts identify as suggesting that Risperdal caused the problem in the plaintiff, as well as what things can be ruled in and can be ruled out.
For his part, Dr. Goldstein stated that he had no opinion regarding the date of onset of plaintiff's gynecomastia. What he said, in fact, that it had to be pubertal.
In stark contrast, Dr. Solomon stated that the plaintiff's gynecomastia definitely onset when he was prepubertal. That is a significant departure from what Dr. Goldstein had to say. And it's important because our experts are of the mind and agree with Dr. Goldstein that if there was gynecomastia onset, it was pubertal or beyond.
There was no expert of ours that prepared a report that dealt with the allegation of prepubertal onset. The mechanism of action supporting prepubertal onset is not supported by the literature.

And, quite frankly, I'm sure that is the reason why Dr. Goldstein did not advance it.
The second issue, Dr. Goldstein identifies obesity as a potential cause of the gynecomastia. In fact --
THE COURT: Is that Dr. -- is Dr. Solomon in the room?
COURT CRIER: Dr. Solomon.
MR. KLINE: Yes.
THE COURT: He just walked in. I need him to step out.
COURT CRIER: You need to step out, Doctor, please.
THE COURT: He just walked in.
COURT CRIER: Thank you.
(Dr. Solomon walked in and then walked out of the courtroom.)
THE COURT: Yes, sir.
MR. MURPHY: May I continue?
With regard to obesity, Dr. Goldstein stated that he could not rule out obesity. In fact, he identifies it and rules it in as a potential cause and then acknowledges it -- acknowledges that he cannot rule it out.
Obesity is something that is

identified in Dr. Goldstein's generic report, Your Honor. He dedicates a section to it and explains that children and adolescents who were treated with Risperdal are at a greater risk of developing gynecomastia because of weight gain and obesity associated with the use of the medication.
In stark contrast, Dr. Solomon testified that he can in fact rule out obesity; and further states that he disagrees with Dr. Goldstein on that score -- a dramatic departure. So where we had one expert who was willing to acknowledge that a known and appreciable potential cause of the condition was one that he could not rule out, a second substituted expert comes in and says, "I can rule it out." It's a totally different issue. He's put that back in play when it was never in play.
And, third -- and this is equally significant, Your Honor -- Dr. Solomon offers a mechanism of action with regard to the onset of puberty that is not one advanced by Dr. Goldstein.
Dr. Solomon says that one way in

which the plaintiff here may have developed gynecomastia is through the direct impact of prolactin on breast glands and tissues. That is something that Dr. Goldstein did not advance. Dramatically different. Not an issue that our experts addressed, and we're prejudiced by that, Your Honor.
Under the applicable rule, an expert cannot go beyond the four corners of his report.
What counsel suggested to the Court and to us is that there would be no difference in the opinions expressed by Dr. Goldstein and Dr. Solomon. The ultimate conclusion, that Risperdal is the culprit, yes, they share. But that is not really what's at issue. What's at issue is what mechanism of action they identify, what things they can and cannot rule out. And there is a dramatic departure in that regard.
THE COURT: Mr. Kline.
MR. KLINE: Yes, Your Honor.
THE COURT: Response.
MR. KLINE: Yes, I do have a response.

THE COURT: Okay.

By the way, who were the deposing attorneys yesterday?

MS. BROWN: I was, Your Honor.

THE COURT: Mr. Gomez and Ms. Brown?

MR. GOMEZ: Yes.

MS. BROWN: Yes.

THE COURT: Okay. Go ahead.

MR. KLINE: Your Honor, a number of things.

First of all, we are in this position because of everything that comes before it, which Your Honor is aware of.

THE COURT: So you're saying this whole thing -- situation is not in a void; it's not in a vacuum?

MR. KLINE: Yes.

And, Your Honor, I found something over the weekend, which I must call to the Court's attention, which I put just in the form of a bench memo so it's part of a record.

But in preparing over the weekend, Your Honor will recall that -- am I under the mic? -- in response to the motion, Mr. Murphy

was saying that their experts might hold different opinions. I'll get to that in a moment, I promise.

Over the weekend, in preparing for both this and for their upcoming experts, I compared what was stated to this Court by defense counsel and what was stated by Dr. Vaughan in his sworn testimony. And I want to put it on this record and then answer this motion.

It was stated to this Court -- as officers of the court, I might add -- that -- by defense counsel -- that Dr. Vaughan is local; that we knew we could not send Dr. Braunstein in light of the rules that are in Alabama.

THE COURT: Braunstein? Goldstein.

MR. KLINE: No. Braunstein. They could not bring -- they said that they found out when they went to do an examination -- they hired a California doctor. The California doctor, they told this Court, could not go to Alabama because they knew that it was illegal for him to do that. And that formed the basis of them getting

Dr. Vaughan locally; and then they criticized the plaintiffs, albeit a year later, for committing a felony.

Now, that was what was said.

In the deposition testimony of T. Brooks Vaughan, who is the defense local expert, he was asked the questions as follows: "Besides the attorneys, did you speak with anyone else?"

"Yes. I had a brief conversation with Dr. Braunstein."

"Who called who?"

This is the Alabama doctor.

"I called him. I, Vaughan, Alabama, called Braunstein, California.

"We talked for two minutes, and he simply asked me what I planned to do in my examination."

He then is asked the question: "How did you know to call him?"

And here's the answer under oath, which is the opposite of what this Court was told: "I was asked to call him. It was explained to me that he really couldn't come to the exam himself, and that's why I was to

be involved in the case. Physically, it was difficult for him -- California Braunstein -- to get to Alabama."

So when they represented to the Court -- respectfully, when they represented to the Court that they knew and they hired an Alabama doctor to do this exam because it was illegal for the California doctor to do it, and that tipped them off to the fact that the plaintiffs were acting illegally, the fact of the matter is that this doctor under oath in his deposition, the Alabama doctor, said he was told by the California -- their California doctor nothing about doing an exam for legal purposes or fulfilling a local requirement. It says point-blank here: "I was told by Braunstein that physically it was difficult for him to get to Alabama."

THE COURT: All right.

MR. KLINE: And I'm attaching that.

THE COURT: Do me a favor, Mr. Kline, just for our record, since I understand that all of this is, you know, ripe for a review at some point, can you just -- where is that particular evidence or testimony or whatever?

I'm having a lot of trouble with the jury.

MR. KLINE: Yes.

THE COURT: Because they've been mislead by both counsel here, I believe, in terms of -- maybe not -- I don't know who. I retract that statement.

They are under the belief this is a three-week trial, but now it looks like a five- or six-week trial. So I'm having some difficulty with the jury. We have to get started.

MR. KLINE: Here's the -- that will be submitted to the Court, the bench memo. And we'll have attached to it the two pieces of --

THE COURT: I just need to know with the record --

MR. KLINE: It will reflect --

THE COURT: -- where is that coming from? So that if we have to review the whole circumstance involving this whole situation.

MR. KLINE: So Your Honor has it for the record, it is Mr. Murphy's statement to this Court, February 2, 2015, Page 15, versus Braunstein's deposition testimony --

deposition of Tom B. Vaughan -- deposition of Tom B. Vaughan, June 25, 2014, Pages 25, 26.

THE COURT: All right. Thank you.

MR. KLINE: Now, as to this, briefly, Your Honor. They have an expert who says that it's not pubertal. That won't change. And it wouldn't change because that's his opinion. Opinions don't change because someone else said the opposite. He opines that it's nonpubertal based on his independent opinion.

Point two, Goldstein is saying there's obesity, and Dr. Solomon is saying there's not -- why there's one less issue in the case, and the fact of the matter is, the defense experts themselves rule out obesity.

Three, on mechanism: Dr. Goldstein had said that prolactin was a mechanism; Dr. Solomon says it's a mechanism.

We have opinions which are consistent. We're ready to go. Dr. Solomon, I might add, is prepared to stay here all day, if he has to, but I have a brief examination of him. And he has post-op patients that he hopes to see this afternoon.

I know we were going to get started at 9:00, and I know we had jury problems, but we're ready to go.

THE COURT: Okay. All right. Well, regarding the -- I just want to put a few things on the record.

There's nothing to preclude arguments, if they want, or objections to be made in front of the jury by either party. But just to give you context, I have done my best in order to address a situation that does not appear to have been of the plaintiff's making in this situation involving the Alabama surprise and the late -- the late motion.

So, therefore, we arranged for a deposition to be conducted; an examination took place of the child Wednesday or Thursday of last week. I forget what day that was, and then an expert report was presented, and then a deposition was scheduled.

As I said on the record a few minutes ago, I did not receive a call, as I made myself available in the event there were objections. It now turns out there were no

real objections to the actual content of the -- to the actual conduct of the deposition. I'm very grateful to Ms. Brown and Mr. Gomez for conducting the deposition as professionals.

I'm now told that there's an overall, overarching objection to the admissibility of Dr. Solomon's testimony. And on that regard, I would just note that there does not appear to be surprise. The key element here is "surprise." A deposition has been taken. The defense knows what the testimony is going to be before it actually takes place. They're prepared for cross-examination, as Mr. Murphy has just indicated, as to different causation theories and everything else.

Moreover, their experts on the defense side have at least three or four days to prepare for their rebuttal or contradiction to the testimony proposed by Dr. Solomon or will be testifying. I do not believe that there is unfair prejudice in the manner in which this Court has arranged the situation that has arisen involving

Dr. Goldstein's absence due to cause.
There is also a larger point here: And that is, ultimately, our Forefathers, the Founders of the country, the Constitution, decreed or declared that it is up to a jury, laypeople, to decide issues of fact in these type -- in any type of civil case that was more than $20. And so in the end, different expert opinions are going to be permitted according to their value, and the weight of those opinions are going to be determined by the laypeople who are entrusted by our Constitution to decide this case or any case above $20.
And so, therefore, that's how we're going to proceed. We're going to trust, as we should, in our jury in this case. And I'm asking now for the jury to be brought into the courtroom.
MR. MURPHY: Your Honor, if I may.
THE COURT: Please be seated.
MR. MURPHY: Your Honor, there's --
THE COURT: Please be seated.
MS. SULLIVAN: Judge, we had a request for a jury instruction.

THE COURT: I haven't heard anything about a jury instruction this morning. Everything's going to have to be done in front of the jury from now on as far as this witness is concerned.
MR. KLINE: What time do we begin tomorrow, Your Honor?
THE COURT: I will probably make an accommodation in order to start on time.
COURT CRIER: All rise as the jury enters the courtroom.
- - -
(Whereupon the jury entered the courtroom at 10:06 a.m.)
- - -
(The following transpired in open court in the presence of the jury:)
- - -
THE COURT: All right. Good morning, everybody. Please be seated.
Good morning, everybody.
JURY PANEL: Good morning.
THE COURT: All right. As soon as you're ready, we are ready to proceed now with a new witness on behalf of the

plaintiff.
And as soon as you are ready, Mr. Kline, you may introduce your next witness.
MR. KLINE: Sure, Your Honor.
Official "good morning," members of the jury. Good morning.
JURY PANEL: Good morning.
MR. KLINE: Thank you for being here.
Plaintiff calls Mark Solomon, M.D.
- - -
(Witness took the stand.)
- - -
COURT CRIER: Remain standing, please.
Doctor, please use the microphone. State your name for the record and spell it.
THE WITNESS: Mark P. Solomon. Mark is with a K. Solomon is S-O-L-O-M-O-N, M.D.
COURT CRIER: Raising your right hand.
- - -
... MARK P. SOLOMON, M.D., after having been first duly sworn, was examined and testified as follows:

- - -
VOIR DIRE
- - -
BY MR. KLINE:
Q. Dr. Solomon, good morning.
A. Good morning.
Q. Would you speak into the microphone, as close as you can, even though it's a little uncomfortable, so that everyone can hear.
A. Yes, I'll do that.
Q. Thank you, sir.
You are a physician, correct?
A. I am.
Q. And you are based here in the Philadelphia area, as I understand it?
A. That's correct.
Q. Your office is in Bala Cynwyd?
A. It is.
Q. And your hospital privileges are at Pennsylvania Hospital down the street?
A. Correct. And Shriners Hospital for Children.
Q. And Shriners, yes. I will talk to you about both briefly.
I'd like to qualify you as it pertains to this case.

I understand that you are a plastic surgeon. You're board certified in surgery as well as plastic surgery; is that correct?
A. That's correct.
Q. And as part of that practice of medicine, does that include the treatment of gynecomastia?
A. Absolutely.
Q. Okay. Now, does it also include a lot of other things?
A. Yes. Plastic surgery, if I may, is a specialty unlike almost every other specialty of medicine because most specialties are what we call "anatomically-limited." Neurosurgeons do brain and spinal cord surgery. Heart surgeons do cardiac and chest surgery. Plastic surgery goes from head to toe.
It's a system of thought, actually. And using that system and knowing the anatomy and physiology of the human body, we can do operations all over the body.
Q. Okay. And, in fact, do you do operations head to toe?
A. I do.
Q. Including some operations that include the most sensitive areas of the body?

A. Absolutely.
Q. Okay. Now, do you treat -- have you and do you treat gynecomastia?
A. Yes.
Q. In fact, you have a website, correct?
A. I do.
Q And on your website, if I were searching the web, would I be able to find you, as a procedure doing gynecomastia?
A. You would find descriptive material about gynecomastia and as well as before-and-after photographs of patients that I've operated on. And those are not complete. They're just a few illustrations.
Q. I see. Based on, I'm sure, patient consent?
A. Well, yeah. That's actually the main issue that limits the number of photographs that I put up.
Q. Sure.
And are you someone who has been practicing medicine a long time?
A. I've been practicing medicine since 1978, and I've been in plastic surgery practice since 1985.
Q. Okay. Now, in your plastic surgery practice, you -- I'm sorry -- does that include what some of us might think of as cosmetic surgery? "I want

Botox. I want breast augmentation, breast reduction, for cosmetic reasons."
A. That's correct. That's actually a large part of what I do.
Q. And is some of what you do these very same procedures for medical purposes?
For example, you might do a mastectomy due to -- for medical reasons for a woman.
A. I wouldn't often do the mastectomy. I would do the reconstruction --
Q. The reconstruction.
A. -- after mastectomy, and have done that many, many times.
I also do surgery for birth defects, skin tumors. I used to do hand surgery, but I don't do that any longer.
Q. Okay. I know on your website -- and I'm sure this will get a giggle -- you do penile enlargements, for example, correct?
A. I do.
Q. And are they sometimes because men come to you and that's what they want, and other times it's something that actually is a medical necessity?
A. It falls under both categories. There are

some people who, for a variety of reasons, need it in order to just have, frankly, normal function so they can urinate and have intercourse. And other patients want -- just like breast surgery for women, they want to be better. So that's how I break it down.
Q. Okay. And as far as gynecomastia goes, have you diagnosed patients with drug-induced -- in your practice, with drug-induced gynecomastia?
A. I have.
MS. SULLIVAN: Your Honor, I'm just going to object to hearsay on this issue.
MR. KLINE: Have you yourself --
THE COURT: Overruled. Overruled.
BY MR. KLINE:
Q. Yes. My question was, have you yourself diagnosed patients -- not in this case and not for litigation -- have you diagnosed patients with drug-induced gynecomastia?
A. Absolutely.
Q. Have you operated on -- have you seen children who had gynecomastia?
A. I've seen --
Q. Adolescents, I guess.
A. I've seen adolescents. And some I operate on,

and some I don't.
Q. Okay. Briefly, let's run down your -- oh, and I do want to cover this:
In addition to your plastic surgery practice, are you an active practitioner at the Shriners Hospital, which we all know to be a chartable hospital?
A. That's a part of my practice that takes up roughly 20 percent of my time.
Q. Tell the members of the jury what kinds of things you do there for these children from all over the world.
A. So we have children from all over the world, including this area. I treat patients who have problems related to spinal cord injuries. I treat patients related to what are called "limb deficiency syndromes," where I work with orthopaedic surgeons in order to create a limb that we can then affix a prosthesis to so they can walk, for example.
We are the largest scoliosis center in the Shriners system, which is 22 hospitals. Scoliosis surgery requires the use of metal implants. Often, these children have very thin skin, very thin tissue. So those metal implants can become exposed, which would lead them to be

infected, which would lead to them to be removed, which would cause recurrence of their scoliosis. So my role is to cover the hardware so that they can maintain the scoliosis surgery.
I also see birth defects. I've seen children with soft-tissue tumors of the breast, for example, and a variety of other issues.
Q. And when will you be next at Shriners Hospital?
A. Tomorrow.
Q. And will you be doing complex surgery on children?
A. I have a patient who's got a limb deficiency syndrome who requires coverage to create a way to walk.
Q. Briefly, your -- oh, and as far as being a practicing physician on a daily basis, do you have patients literally later this afternoon?
A. Correct; literally this afternoon.
Q. Post-op patients?
A. Post-op and also preop, new ones; but mostly post-ops.
Q. All right. Let's talk -- because I want to work through this. I want to tick off some things.
You went to Franklin and Marshall

College and graduated in 1974 with a Bachelor's degree, correct?
A. That's correct. In biology.
Q. In biology. Thank you.
And then you went to medical school where?
A. New York University.
Q. That's NYU in New York; graduating in 1978?
A. Correct.
Q. You then did an internship in surgery at the Hospital of the University of Pennsylvania.
A. That's correct.
Q. You did a residency in surgery at Thomas Jefferson University Hospital, correct?
A. That's correct.
Q. And you were the chief resident in surgery from '82 to '83 at Jefferson, correct?
A. That's correct.
Q. So that made you a -- eventually you became a general surgeon, correct?
A. I was qualified to be a general surgeon, and I took what are called board examinations in general surgery.
Q. I see. And a general surgeon? Briefly, two sentences.

A. Gallbladders, appendix, general kinds of hernias, abdominal pain, that kind of stuff. Primary abdomen and breasts, but also chest surgery, vascular surgery, I mean, I went through all the specialties of surgery in that training.
And then as a boarded surgeon, you're boarded to practice general surgery, which is that portion of medicine that does all those things.
Q. As part of that training, sir, do you learn about the breast, which includes the anatomy, the physiology, and the underlying systems that are involved?
A. That's correct.
Q. And as part of your training, would you need to know and understand the endocrine system?
A. Yeah. Actually, endocrine surgery is a separate subset of general surgery because it not only deals with breast disease but also thyroid disease, adrenal disease, the pancreas. Those are all endocrine organs as well as other parts of the body.
Q. And we're talking in this case to some extent about prolactin. And what -- what system and what organ is involved there?
A. So prolactin is a hormone secreted by the

pituitary gland, which is in the brain. And, again, as part of the general surgery rotation or training, you rotate through other specialties, including things like neurosurgery. So I have exposure to neurosurgery where we would resect the pituitary gland for pituitary tumors. But also, the pituitary gland makes prolactin, which the jury may or may not have heard of already, and that's a hormone that acts on the breast --

Q. It's just for qualifications --

A. Right.

Q -- so just tell me if you know.

A. So I know it.

Q. Also, as far as the breast goes, as a general surgeon and then as a plastic surgeon, have you had extensive experience in the treatment of the breast and breast tissue?

A. Absolutely.

Q. In both females, which would be, I'm sure, most of it, as well as males?

A. Correct.

Q. And to treat the breast as a surgeon, would you explain to the jury, two sentences or less, why it is necessary to understand the -- if you understand the underlying endocrine system that's

related to that.

A. Because 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 nonsurgically.

If, for example, I'm going to do an operation and the problem is going to come right back, then I shouldn't do the surgery. So I need to understand the causes of the problem.

Q. Is that part of the evaluation that you make with every patient who you undergo -- who undergoes surgery?

A. That's correct. Every patient is treated start to finish like a patient.

Q. So we know that you saw -- or we're going to learn in this case that you saw Austin Pledger. And we also know that the lawyers sent you for the evaluation. But did you conduct that kind of an evaluation any differently than you'd conduct an evaluation if that same young man showed up with his mother at their own suggestion?

A. It's exactly the same.

MS. SULLIVAN: Your Honor, I'm not sure --

THE COURT: Excuse me. Is there an

objection?

MS. SULLIVAN: No, Your Honor. I'm sorry to interrupt. I wasn't sure when Mr. Kline was going to offer Dr. Solomon as an expert, because I do want to voir dire on qualifications.

THE COURT: Well, you'll have your chance.

BY MR. KLINE:

Q. Now, after your residency in general surgery, you then did a residency in plastic surgery; is that correct?

A. That's correct.

Q. And that was also at the University of Pennsylvania, up at 30 --

A. 34th Street.

Q. -- 34th and Spruce.

A. Yes. That's correct.

Q. Okay. You appear to be Philly-trained once you got back home from New York, through and through.

A. That's true.

Q. Except for you spent in the summer -- you spent '77 through '78 as a craniofacial fellow in Paris.

A. I think it was '87.

Q. I'm sorry if I misspoke. '87 to '88.

A. That's correct.

Q. Okay. And was that at a children's hospital?

A. Yeah. The large children's hospital in Paris. It's called Necker, N-E-C-K-E-R. And I worked there for about six months doing this fellowship in craniofacial surgery.

Q. Okay. And you have had many academic appointments over the years; is that correct?

A. That's correct.

Q. And many affiliations with hospitals in our region from Penn to Drexel; is that correct?

A. That's correct.

Q. Including Hahnemann.

A. That's correct.

Q. Currently you have affiliations at -- what was it? Graduate Hospital as well as Germantown Hospital, correct?

A. Correct.

Q. You've had affiliations at Paoli Hospital and, gee, a number of other hospitals. St. Christopher's Hospital?

A. Correct.

Q. And in all of those times, you were approved

and granted privileges, either courtesy privileges or staff privileges?
A. Correct; to practice the full scope and spectrum of plastic surgery.
Q. You're licensed to practice medicine in the state of Pennsylvania; is that correct?
A. And New York; that's correct.
Q. You're familiar with the -- and you have served on many committees as well, correct?
A. Correct.
Q. You have a Curriculum Vitae, which I've marked as Plaintiff's Exhibit No. 77, for the record, and that would include a number of other -- a number of things, including grants that you've received.

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(Whereupon Exhibit P-77 was marked for identification.)

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BY MR. KLINE:
Q. You've been a participant in and recipient of government grants, correct?
A. Correct.
Q. And that includes a grant from the National Institutes of Health, correct?
A. Correct.

Q. And that actually involved something dealing with the breast, correct?
A. Correct.
Q. We could get into more detail, but it involved -- it involved issues relating to the breast, correct?
A. Correct.
Q. Do you believe, sir, that you're an expert in the physiology and pathology of the breast?
A. I do believe that.
Q. Okay. Have you operated on tens, hundreds, thousands of patients' breasts?
A. Thousands.
Q. And have you examined tens, hundreds, or thousands of breasts?
A. Thousands.
Q. You've written medical -- articles in the medical literature, in published peer journals, correct?
A. And I've also edited peer journals.
Q. And I believe that there is a textbook of yours which deals primarily with cosmetic surgery, but it bears your name, "Male Aesthetic Surgery"; is that correct?
A. That's correct.

Q. And, by the way, while it deals with technique -- because that is what this book's about, technique, correct?
A. Largely. That's correct.
Q. Okay. You have operated on thousands and thousands of individuals; is that correct?
A. Correct.
Q. Is gynecomastia covered in this book?
A. It is.
Q. Okay. And are you able to offer opinions today, sir, on the -- of gynecomastia, its diagnosis, its causes, and its physiology, and its pathology, sir?
A. I am.
Q. Are all of those things, by definition, things that you need to know in order to do what you do every day?
A. Absolutely.
Q. Okay.
MR. KLINE: I offer Dr. Solomon as an expert in surgery, plastic surgery, and as an expert in gynecomastia and the breast.
MS. SULLIVAN: Your Honor, may I?
THE COURT: All right. Questions.
MS. SULLIVAN: Yes, Your Honor.

Thank you.
Mr. Kline, if I could have the microphone.

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CROSS-EXAMINATION ON QUALIFICATIONS

\- - -

BY MS. SULLIVAN:
Q. Good morning, Dr. Solomon.
A. Good morning.
MS. SULLIVAN: Good morning, jurors.
JURY PANEL: Good morning.
BY MS. SULLIVAN:
Q. We haven't met. I'm Diane Sullivan, and I represent the folks at Janssen here. And I'll have a couple questions initially for you, okay, Dr. Solomon?
A. Yes.
Q. Dr. Solomon, the field of endocrinology is a medical specialty that deals with, among other things, hormones like prolactin and hormone-related diseases, right?
A. Correct.
Q. And you're not an endocrinologist?
A. Correct.
Q. You are not board certified in endocrinology?

A. Correct.
Q. And, Dr. Solomon, you know that there are over 200 board-certified endocrinologists in the Philadelphia area, and you're not one of them?
A. I -- that's correct. I don't purport to be.
Q. And you're not a member of any professional organizations in the field of endocrinology?
A. That's correct.
Q And you have acknowledged that you don't regularly review the medical literature in the field of endocrinology?
A. I don't think I've acknowledged it, but I would agree that I don't.
Q. You've never yourself authored an article on gynecomastia or its causes?
A. I've edited the chapter in my book. That's the extent of it.
Q. But the chapter on gynecomastia, you didn't write that chapter; that was somebody else's chapter?
A. That's correct.
Q. And that chapter dealt with primarily surgical technique?
A. That's correct.
Q. In fact, the chapter that you authored dealt

with injectables, including how to get wrinkles out of men's faces, right?
A. That's correct.
Q. And, Doctor, in the past when you've had a patient with a genetic disease called Klinefelter's which can cause gynecomastia, you sent them to an endocrinologist?
A. For confirmation of my diagnosis, but I made the diagnosis clinically first.
Q. And, Dr. Goldstein [sic], you were a substitute expert here, right?
MR. KLINE: Objection.
THE COURT: Sustained.
BY MS. SULLIVAN:
Q. Dr. Solomon, you're aware that the plaintiffs had an expert endocrinologist who --
MR. KLINE: Objection, Your Honor.
THE COURT: That's sustained.
MR. KLINE: And an instruction is requested, Your Honor, it's of no consequence to this jury.
THE COURT: Well, I'm just going to remind the jury at this point that the questions, as we've said a long time ago, are not -- is not evidence. Questions are not

evidence; only answers are.
BY MS. SULLIVAN:
Q. Dr. Solomon, you were called last week by the plaintiffs to get involved in this case after the trial already started?
A. I don't know when the trial started, but I was asked last week to become involved.
Q. You looked at the Pledger case for the first time last week, right?
MR. KLINE: Objection; asked and answered.
THE COURT: Well, I mean --
MR. KLINE: It's the same question.
THE COURT: Sustained.
You know, the fact of the matter is, an examination took place. You know, we're not quite there yet. You're going through qualifications.
MS. SULLIVAN: I'll move on, Your Honor.
BY MS. SULLIVAN:
Q. Doctor, you haven't done any clinical research on prolactin elevation yourself?
A. That's correct.
Q. And you have not performed any clinical trial

on -- clinical trials on medicines?
A. Probably true. That's correct.
Q. And you've acknowledged you're a plastic surgeon and primarily a cosmetic plastic surgeon?
A. That's not correct.
Q. You had -- prior to starting work at Shriners about a year and a half ago. You started working at Shriners Hospital about a year and a half ago?
A. That's correct.
Q. Prior to that, you acknowledge that 90 to 95 percent of your surgeries were elective cosmetic procedures, right?
A. Ah, yes. That's true.
Q. And even now, after starting at Shriners, 80 percent of your surgeries are elective cosmetic procedures?
A. That's true.
Q. And, Doctor, the surgeries you most commonly perform include breast augmentation for women and penis enlargement for men?
A. That's true.
Q. And I want to pull up, if I can, your website, Doctor.
MS. SULLIVAN: Do you have -- we'll mark this -- the next one, Ms. Brown, is?

MS. BROWN: 32.
MS. SULLIVAN: 32. Do you have a copy for Mr. Kline?
(Exhibit D-32 was previously marked for identification purposes.)
MS. SULLIVAN: Any objection to showing the jury his website, Counsel?
MR. KLINE: No.
MS. SULLIVAN: Can you put it up?
THE COURT: May I see this, please?
MS. SULLIVAN: Oh, I'm sorry. Ms. Brown.
MS. BROWN: May I approach, Your Honor?
MS. SULLIVAN: And if you can blow that out a little bit, Ken.
THE COURT: Any objection?
MR. KLINE: No.
THE COURT: Go ahead.
MR. KLINE: None to this page.
THE COURT: This is D-32?
MS. SULLIVAN: Yes.
THE COURT: The first page.
BY MS. SULLIVAN:
Q. And, Dr. Solomon, this is your website.

A. That's correct.
Q. And you advertise the cosmetic and other procedures you offer on your website, right?
A. I'm sorry. I can't hear you.
Q. And you list the kind of procedures you do.
A. Mr. Kline and I discussed that. I said if you go there, you'll see gynecomastia for men.
Q. Yeah. We'll pull it up. If you can pull it up.
You talk about --
MS. SULLIVAN: You know what, Ken, it's easier for me to do it on here.
VIDEO TECHNICIAN: Sure.
BY MS. SULLIVAN:
Q. So, Dr. Solomon, on your website you talk about the fact that you offer some of the most popular surgical and nonsurgical cosmetic enhancements for the face and body, right?
A. That's true.
Q. And you talk about how you offer tummy tucks, liposuction, body tightening, thigh and arm lifts, calf enhancement, something called labioplasty, breast augmentation, breast lifts, breast reduction, facelifts, eyelid surgery, neck/brow lifts, rhinoplasty, Botox, chemical peels, breast reduction

for gynecomastia, and penis enlargement surgery?
A. That's correct.
Q. And, Dr. Solomon, you actually advertise yourself as one of the world's leading surgeons in the area of penis enlargement, right?
A. Yeah. Actually, that's pretty true.
Q. Yes.
And 90 percent of your patients, you've stated, are men who have normal-sized penises but just want to be bigger?
MR. KLINE: Oh, Your Honor, they have nothing else; this is what they do.
THE COURT: Is there an objection?
MR. KLINE: I object. Yes.
THE COURT: All right. Sustained as phrased, "90 percent of your patients." Of which category here?
MS. SULLIVAN: Fair point.
BY MS. SULLIVAN:
Q. Mr. Kline and you discussed the fact that when you do penile enlargements, some people have anatomical problems. But you advertise that 90 percent of your male patients for penile enlargement just want to be bigger, cosmetic enhancement?

MR. KLINE: Your Honor, same objection. He's being asked to be qualified here not as a penile --
THE COURT: I'm going to instruct the jury -- as soon as we get past whether or not there is an objection to the proffer of the fields, I will instruct the jury.
Right now you may proceed on the questions of qualifications, Ms. Sullivan. Please proceed.
THE WITNESS: So if I may clarify, there are three components to that.
I see patients who do electively want larger penises. I see patients who have had surgery by other surgeons that I correct. And the third piece is that I see patients -- and, again, now we're back at Shriners with what's called "buried penis syndrome," because those patients have spina bifida, and I'm the guy who figured out how to give them the ability to function so that they don't pee on themselves and so that they're able to have intercourse.
So that's part of this whole process. So while I know you would think that it's

somewhat prurient, it's got a real medical need, and somebody's got to fulfill that need.

BY MS. SULLIVAN:

Q. Doctor, do you remember giving an interview to "Be Well Philly" entitled, "Philadelphia is the Penis Enlargement Capital of the World"?

MR. KLINE: Your Honor, they want to do it --

THE COURT: No. Is there an objection?

MR. KLINE: No; because she wants to do it.

THE COURT: All right. Then --

MR. KLINE: They have nothing else.

THE COURT: -- are we the capital of penile whatever it is?

MR. KLINE: Yeah. I didn't know that. Wow.

MS. SULLIVAN: Me neither.

(Laughter in the courtroom.)

THE WITNESS: Your Honor, with all due respect, that was Philadelphia Magazine's writer who did that. They interviewed me.

I will go on the record as having

been interviewed by Howard Stern and a number of other people about this topic. It's certainly something that draws attention to Philadelphia and to my practice.

But I'm here to discuss a really serious issue that is also part of my practice, for which I have 30 years of experience. And as far as I know, I'm the only surgeon who manage these patients who's testifying in this matter. So I do think we should move on with my qualifications as a surgeon -- I'm happy to discuss it -- to do surgery on any part of the body.

BY MS. SULLIVAN:

Q. And, Dr. Solomon, I do want to continue to discuss your qualifications.

On average, you do about three or more penis enlargement surgeries a week, right?

A. Not these days. Sometimes yes; sometimes no.

Q. And in this article entitled, "Philadelphia is the Penis Enlargement Capital of the World," you said that, in answer to the question, "How big is the guy that comes in there?" You said, "Answer: Normal."

MR. KLINE: Oh, Your Honor --

THE COURT: That's going to be sustained now. Now we're getting --

MR. KLINE: They are really something.

THE COURT: That's sustained. I'm sorry. We've got to move on to something more contextual to this case.

BY MS. SULLIVAN:

Q. And, Doctor, in fact, in terms of your most widely-advertised specialty, if we go on the Internet and type in penile enlargement surgery.com, your website pops up on the Worldwide Web, right?

A. I'm glad to know that, but I have no way -- frankly, I didn't know that that happened. I think that's what they call search-engine optimalization or organic search. But I don't know anything about that stuff.

MS. SULLIVAN: Ken, you want to show our jurors on the Web?

MR. KLINE: Your Honor, I would object.

Haven't we had enough?

THE COURT: I'm sorry. I just didn't hear the question.

MS. SULLIVAN: I was talking about

his most wildly-advertised specialty and going to type in WWW top doc penile enlargements --

THE COURT: So does this go to his qualifications as a surgeon or plastic surgeon and the disease of gynecomastia?

MS. SULLIVAN: It goes to the fact that he's -- his most widely-advertised qualification is as a penis enhancement --

THE COURT: All right. The objection is sustained, all right? He has that qualification, too. But we're focusing on surgery and plastic surgery and the disease of gynecomastia.

BY MS. SULLIVAN:

Q. And, Dr. Solomon, going back to your website --

MS. SULLIVAN: If we could mark it as Defense Exhibit --

MS. BROWN: The original website?

MS. SULLIVAN: No; the --

MS. BROWN: Okay. 43.

- - -

(Exhibit D-43 marked for identification.)

- - -

THE COURT: Oh, by the way, the last document that had been previously marked as D-32 is P-41 now -- D-41. It had previously been marked as D-32. Now for our records it's D-41.

Okay. So now I'm presented with another document?

MR. KLINE: Yes. More of the same.

THE COURT: D-42 was the one that is from "Be Well Philly," and D-43 is the current exhibit.

You may proceed.

MR. KLINE: I do have an objection, Your Honor.

THE COURT: Basis?

MR. KLINE: The basis is it's a more -- more of the same, and they refuse to talk about the issues --

THE COURT: She can have it marked and even admitted. Though, I'll permit another question or two. But it is kind of defying a court -- you know, we want to know about expertise as to surgery and plastic surgery and the disease of gynecomastia.

This particular document, after I've made that request, has to do with penis enhancement surgery.

BY MS. SULLIVAN:

Q. Well, Dr. Solomon, the truth is, your website has pages and pages and pages of information on penile enlargement surgery and enhancement surgery and not very much on gynecomastia?

A. And pages and pages on breast augmentation and facelift and hair transplants and a variety of other procedures that are of interest to patients. Because the Internet, the Worldwide Web is now the Yellow Pages of the 21st century.

So, admittedly, it is advertising, because I don't need to advertise for patients with reconstructive problems. They show up. But, as you know, it's a very competitive world for aesthetic surgery, so we all have our websites.

MS. SULLIVAN: And if we could put up D-42.

BY MS. SULLIVAN:

Q. And this is part of your website, Dr. Solomon?

A. I think that's what my webmaster calls a minisite, which is sort of a little separate -- I don't know how they structure it. But, yes, you can

click on my website and find that.

Q. "Mark Solomon." That's you, right, on top?

A. Board-certified plastic surgeon; that's me.

Q. And you advertise that most men are good candidates for penis enlargement surgery, right?

A. Again, if that's what it says, I'm not going to dispute it.

Q. And you go on to say that it's not unusual for men to feel disappointed with the size of their penises?

MR. KLINE: Your Honor, when does she stop? Objection.

THE WITNESS: As it's not unusual --

THE COURT: When she decides to stop and I stop her.

MR. KLINE: Objection. Because she has nothing else to talk about in the case.

THE COURT: Counsel, is there an objection?

MR. KLINE: Yes. Objection.

MS. SULLIVAN: It goes to his qualifications, Your Honor.

THE COURT: A few more questions on this line. But I do want you to get back to the qualifications.

Clearly the disease of gynecomastia is what, I think, is the only objection here that is of relevance.

BY MS. SULLIVAN:

Q. And, Dr. Solomon, you also advertise on a site called "The Grip System," right?

A. I do not advertise on that. That's the company's -- that's their own advertising.

But, by the way, women who want larger breasts also come to my website, and they have insecurity about that. So the breast for women and for men, when it's too big, is analogous to the penis issue. We're all sort of hovering around the same issue of things that create anxiety and insecurity for patients.

And, Counselor, I'm not really understanding why you're so, you know, interested in this.

Q. Well, you do a lot more penile enlargement surgery than you do gynecomastia.

THE COURT: All right. I think your point has been made.

By the way, ladies and gentlemen, this particular line of questioning -- I am going to instruct you shortly in a little

more detail -- this goes to the weight of the testimony, whether you believe it or not, not as to his qualifications, unless there's an objection right on what the issues are.

The issues are whether he is an expert in the field of surgery, plastic surgery, or the disease gynecomastia. These questions involving penile enlargement and advertising, they go to whether or not you believe his testimony, the weight of the testimony, not whether he is qualified.

Right now all we're talking about at the moment is whether this doctor's qualified to offer opinions in surgery, plastic surgery, or the disease of gynecomastia.

With that qualification, Ms. Sullivan, I'd ask you, again, to proceed toward the issues at hand.

MS. SULLIVAN: Well, Your Honor, this goes to his qualifications.

THE COURT: All right. Well, then the objection, if there is one, will be sustained.

BY MS. SULLIVAN:

Q. And, Doctor, you also mentioned breast

augmentation.

You actually have a picture of a cheerleader on your Facebook and offered a Super Bowl breast augmentation special, right?

A. Uhmm...

MR. KLINE: Your Honor, objection. What does it have to do with if he has qualifications on gynecomastia?

THE COURT: All right. That's sustained. That is sustained. This, again, goes to the weight.

I'm asking the lawyer to address the issue of actual medical expertise.

BY MS. SULLIVAN:

Q. And, Doctor, you don't advertise yourself as an expert in endocrinology?

A. I think you've already asked me that, and my answer was no.

Q. In fact, you've testified you've never heard of pubertal gynecomastia?

A. I believe I said that in a deposition, but the context is not quite the way you're saying it.

Q. And you've also said that pseudogynecomastia --

MR. KLINE: Your Honor, I object.

BY MS. SULLIVAN:

Q -- gynecomastia from obesity --

THE COURT: All right. Again, this goes to the weight.

This goes to the weight.

Are you objecting to the qualification of -- I'm going to read it in three parts -- of Dr. Solomon as a surgeon?

MS. SULLIVAN: Your Honor --

THE COURT: Are you objecting to his expertise?

MS. SULLIVAN: Not on plastic surgery issues, Your Honor, but on causation.

THE COURT: How about general surgery?

MS. SULLIVAN: On general surgery, Your Honor, I don't have a problem. I have a problem with causation.

THE COURT: All right. So that's what we're focusing on right now, the disease of gynecomastia.

MS. SULLIVAN: Well, that's what I'm asking about, Your Honor.

THE COURT: All right. Well, let's stick with that.

BY MS. SULLIVAN:

Q And, Dr. Solomon, you've also never heard of pseudogynecomastia, gynecomastia from obesity. That was your testimony, right?

A. I think my phrase was, "It's not a term of art," if you read my deposition. But I'm happy -- can I look at that, please?

Q. Sure.

MR. KLINE: Your Honor, I would object. This goes to merits, not qualifications.

THE COURT: No. We might as well get it out now so that the rest of the day goes smoothly.

MS. SULLIVAN: Your Honor, am I not permitted to voir dire on qualifications?

THE COURT: I said you might as well get it out now. Go for it.

MR. KLINE: Your Honor --

BY MS. SULLIVAN:

Q. And, actually, you've testified that the way you diagnose --

MR. KLINE: Your Honor --

THE COURT: Are you going to show him the deposition, Ms. Sullivan?

THE WITNESS: I asked to see the deposition.
MS. SULLIVAN: Yeah.
THE COURT: There has to be some kind of fairness in these proceedings.
THE WITNESS: Thank you, Your Honor.
COURT CRIER: D-44.
- - -
(Whereupon Exhibit D-44, deposition transcript, was marked for identification.)
- - -
COURT CRIER: D-44, Dr. Solomon's deposition transcript.
BY MS. SULLIVAN:
Q. And, Dr. Solomon, on Page 35 of the deposition you were asked --
THE COURT: All right. For the record now -- wait one moment, please. One moment. We do have a record here.
This is a deposition, correct, Wednesday, August 20, 2014, in a different matter?
MS. SULLIVAN: Yes, Your Honor.
THE COURT: Okay. In a different matter. For the record, March Term 2010;

February Term 2013, Nos. 296 and No. 1719.
And what page are you on?
MS. SULLIVAN: I'm on Page 35, Judge.
THE COURT: 35. Okay.
BY MS. SULLIVAN:
Q. And Line 15, Dr. Solomon, do you see where you were asked, "Have you heard the phrase pubertal" -- I'm sorry. This is Page 36.
A. I'm sorry. 35 or 36?
Q. 36. I'm sorry.
A. How about if you look at 35 first, please.
Q. Sure.
A. Because that's where it comes up.
THE COURT: Well, the whole thing is going to be read because we believe in fairness in this courtroom, so everything's going to be in context.
BY MS. SULLIVAN:
Q Well, why don't we read the whole thing, then, Page 35 starting at Line 15 and going to 36, Line 19.
"Question: Have you heard the phrase 'pubertal gynecomastia'?
"Answer: In what context?
"Question: In any context.

"Answer: Not really.
"Question: Have you heard the phrase 'pseudogynecomastia'?
"Answer: I've read the phrase.
"Question: And what is your understanding of that phrase?"
"Answer: It's a poorly-used word that I don't really use, and it's not a surgical word.
"Question: What do you mean by that?
"It's not a word that's in my vocabulary as a surgeon describes any useful information.
"Question: And why is that?
"It just doesn't make any sense to me as a surgeon.
"Question: Why not?
"Answer: Right.
"Question: What about the word 'pseudogynecomastia' -- what about the word 'pseudogynecomastia' does not make sense to you as a surgeon?
"Answer: How would you define pseudogynecomastia?
"Question: That's what I'm asking

you."
And then you go down you say, "Answer: I don't use it. That's why I'm asking you to use it."
That was your testimony.
A. Can I read Line 14, please?
Q. Sure.
A. Which says, "I am asking you to define it because I want to make sure we're talking about the same word."
Q. Right. And then --
A. In other words, what I'm trying to get across is, it's not a term of art to a plastic surgeon who operates on patients with gynecomastia.
Q. Right.
A. It's a word that is loosely used. And if there's any place where language is important, any place, Counselor, as I think you know, it's a courtroom. So I'm not about to use a word that is not a term of art.
And the same goes for what I called "adolescent gynecomastia," that your associate was calling "pubertal gynecomastia," which was not a term that I use.
But I think we need to be very

precise about words. So I'm going to be very precise and be very clear for the jury, for His Honor, and for anybody else who gets my words down in writing.

Q. And I agree with you, Dr. Solomon, we should be precise. And do you know --

MR. KLINE: Objection to the statement.

THE COURT: That's sustained.

I would love to hear what the doctor's definition is because I'm the one in the end who has to make a decision as to whether or not this fella is an expert in this field.

MR. KLINE: It's on page --

THE COURT: If you want to ask him a question. Otherwise, we'll save that for Mr. Kline.

BY MS. SULLIVAN:

Q. Dr. Solomon, you know that your society, the American Society of Plastic Surgeons, actually does use the word "pseudogynecomastia" when talking about gynecomastia, right?

A. Have I seen it in writing from them? No. Might they use it? They might.

But, again, we're here to talk about gynecomastia, which is feminization of the male breasts --

Q And --

A. -- which I've so defined, and every medical source will define.

Q. And the way you diagnose gynecomastia, you said, is like pornography. You know it when you see it, right? That's how you diagnose it, like pornography?

A. I do a physical examination. I take a history, and that's how I make my diagnosis, which is how physicians do what they do.

Q. Sir --

A. And I know gynecomastia when I see it. That's correct.

Q. And, sir, have you not testified you diagnose it like pornography?

MR. KLINE: Your Honor, objection; asked and answered.

THE COURT: That's sustained. That's sustained. It's been asked.

We could go to the part of the deposition, Counselor, if you would, where he describes how these particular examinations

take place, if you wish.

MS. SULLIVAN: Your Honor, I'm voir diring on qualifications.

THE COURT: All right. Then --

MR. KLINE: 59, Line 20 and 64.

THE COURT: -- carry on. Why don't you carry on, then.

But, honestly, Ms. Sullivan, you know --

MS. SULLIVAN: Honestly, Judge.

THE COURT: -- you asked that question before.

MS. SULLIVAN: Honestly, Judge. Honestly.

THE COURT: Honestly, you asked that question before.

BY MS. SULLIVAN:

Q. And, Dr. Solomon, you've acknowledged that you have no idea how Risperdal causes gynecomastia in terms of mechanism, right? That was your testimony.

A. I've since that time done a considerable amount of research to get a much better understanding of that process.

Q Ah. You've figured it out in a week, okay.

MR. KLINE: Your Honor, that snide

comment should be stricken, respectfully. How many does she get for the morning?

THE COURT: Overruled.

We just need to find what the objection is and where it is and then ask questions along those lines.

BY MS. SULLIVAN:

Q. And, Dr. Solomon, prolactin is usually measured with a blood test, right?

A. That's correct.

Q. And you don't do prolactin blood testing?

A. I would send someone to a lab if I ever wanted to get one.

Q. In fact, you don't even know the normal range for prolactin testing in boys or men, right?

A. I would look it up.

Q. But you don't know it.

A. It's not something I need to use on a day-to-day basis.

MS. SULLIVAN: I have nothing further on qualifications, Your Honor.

I would object to this expert talking about causation in endocrinology issues, because he's a plastic surgeon who doesn't have expertise in that area.

THE COURT: All right.

Well, as to the use of the testimony, that's one thing. That's a separate issue, ladies and gentlemen.

I am prepared to qualify Dr. Solomon in the fields of surgery and plastic surgery and the disease of gynecomastia, okay, based on his experience.

Now, I want to tell you a couple things having to do with expert witnesses, and I'm going to do so at this time, all right?

First of all, the test to be applied when qualifying an expert witness is whether the witness has any reasonable pretension to specialized knowledge on the subject under investigation. If he does, he may testify, and the weight to be given to such testimony is for the trier of fact, you, to determine. That's the law, all right?

So when you're looking at an expert witness who's been qualified, your job is to determine whether or not you accept or not accept any expert opinion he may give. And in doing so, you can accept it or not accept

it. That's up to you. But an expert witness is like any other witness, like a fact witness, in the sense that you are also not expected to forget the situation involving credibility, whether you believe somebody based on whatever might affect his truthfulness. And an expert witness is to be evaluated also on those grounds. That's called evaluating on the weight of the testimony, all right?

So I want you to be clear. Right now he's been qualified as an expert in the fields of surgery, plastic surgery, and the disease of gynecomastia. And now it's up to you to determine the weight you wish to give to his opinion, whatever it is.

You may proceed.

MR. KLINE: Your Honor, thank you.

\- - -

DIRECT EXAMINATION

\- - -

BY MR. KLINE:

Q. Okay. He looks real happy (indicating).

A. It's a model. And it says so, by the way.

Q. I want to talk to you about serious things here, sir. I want to talk to you about your examination of this young man.

Did you, at our request, see a young man, 20 years old, whose name is Austin Pledger?

A. I did.

Q. And are you prepared to discuss your examination of him with this jury today, sir?

A. I am.

Q. Have you brought -- did you bring to that examination 30 years' experience as a surgeon?

A. Yes.

Q. Okay. And would that include 30 years of experience in examining the breasts, knowing the pathology and the physiology and the anatomy of the breast?

A. That's correct.

Q. Did it have a darn thing to do with anything else that you happen to do in your medical practice?

A. No. And when I was with him, I was focused on him.

Q. When you get a -- when you send someone out for any laboratory test, do you have to -- do you memorize the high and the low values, or do you look at the lab slip, sir?

A. One gets a result back with a lab slip. And

the reason is, there's what's called a "reference range." And there's several reasons for that.

First of all, every laboratory may have a slightly different reference range. And, second of all, from time to time, the units of measurement will change for a given study. So the lab will send back a slip saying, "This is the normal value range, and here's the result for your patient." And then some labs now, by the way, will flag it with an "H" or an "L" to tell you if it's high or it's low.

And what that does, as a practicing physician, makes it easier for me to look at, evaluate, and make a determination as to what I want to do with that result.

MR. KLINE: Whoever changes the tablet, eventually, could we get a tablet change at some point soon? Both Ms. Sullivan and I would appreciate it, I bet.

BY MR. KLINE:

Q. Been here for two weeks of testimony, sir. Take apart the word for us, "gynecomastia." G-Y-N-E -- did I spell it right?

A. You did.

Q. G-Y-N-E-C-O. Derivation is?

A. It's a Greek derivation meaning "woman."
Q. Like as in gynecologist?
A. That's correct. The woman's doctor.
Q. Female.
A. Correct.
Q. Mastia.
A. Mastia is, I believe, a Latin root referring to breast.
Q. "Gynecologist," female doctor. "Gynecomastia," female breast. Correct?
A. Correct.
Q. Did you examine Austin Pledger?
A. I did.
Q. Did he have female breasts?
A. Absolutely.
Q. Any doubt about it?
A. No.
Q. The breast, sir, the breast is made up of breast tissue. Well, why don't you tell us, what's the breast made up of?
A. So breasts, both in men and women, have three components: Skin overlying it, breast tissue, and fat that's interspersed through that breast tissue. And there are varying ratios of fat-to-breast tissue.

Q. We heard the Judge talk about experts with pretension of knowledge. You or an endocrinologist, who examines breasts for a living and reconstructs breasts for a living?
A. Plastic --
MS. SULLIVAN: Objection.
THE COURT: Overruled.
THE WITNESS: Plastic surgeons, all the time, every day. Myself absolutely included.
BY MR. KLINE:
Q. Now, are you prepared to give the jury just a little lesson in what constitutes the breast?
A. Absolutely.
Q. You told us skin, fat, breast tissue, correct?
A. Correct.
Q. Okay. And is there a textbook called "The Breast"?
A. There is.
Q. Has it been around forever?
A. Forever being 30-plus years, I imagine, yes.
Q. Is it a standard text?
A. Yes.
Q. Do you have a picture that we -- under a microscope of the breast?

A. I believe I gave one to you.
Q. You did. You pointed it out to me, not vice versa.
Let me show you Exhibit 79.
(Exhibit P-79 marked for identification.)
MS. SULLIVAN: Can I have it, Counsel?
BY MR. KLINE:
Q. I have figures 7.2, 3, 4, 5, 6, 7, 8. I don't want to display them all. It would take forever. I'm going to hand them to you as one exhibit marked as P-79.
MS. SULLIVAN: What are they, Counsel?
MR. KLINE: They are the photographs that we dropped off at his deposition, which are -- which show the pathology of the breast, the basic pathology of the breast, fat and skin -- fat and breast tissue.
MS. SULLIVAN: So these aren't of Mr. Pledger; this is just from a --
MR. KLINE: I already said -- I already said that they were from a textbook.
THE COURT: May I see them, please?

I've never seen them.
COURT CRIER: Going to be 79 A through E, Your Honor.
THE COURT: So there's one document here?
MR. KLINE: Yes. They're a series of pathology slides.
THE COURT: Okay. Is there an objection?
MS. SULLIVAN: No, Your Honor.
THE COURT: All right. No objection.
MR. KLINE: Okay.
BY MR. KLINE:
Q. Let me hand them to you.
Tell me the one or two which would be best for the jury to understand the breast as seen under a microscope.
A. So that in fact is the point I want to make; that we all have an image of the breast to the naked eye. But way back in medical school we get -- we dive deep. We get microscopic pieces under -- we look under a microscope at tissue that is taken to look at these different body parts.
So when you look at the breast under a microscope, if I look at Figure 7.8 here, this is

what's called "breast tissue." It's this dense material that has a number of structures within it that I'll show you in a second. And it's surrounded by and infiltrated with these -- these are actually individual cells. Those are fat cells.

MR. KLINE: Can everyone see?

THE WITNESS: Can everybody see on the jury?

So you've got a breast that's breast tissue and fat.

MR. KLINE: Okay.

THE WITNESS: If I may. And then if you dive down -- and this is an example. If you go into that area where the breast tissue was --

BY MR. KLINE:

Q. These are pictures of breasts under a microscope?

A. These are all under a microscope. And, remember, under a microscope, you can raise the magnification. So you look at this magnification and you get a higher picture which enlarges the small parts. Make sense?

Q. Go ahead. I just want to do this in a mini form.

A. Right. So if you go in this area of the breast tissue -- not the fatty tissue -- you start to see these things, which are ducts. And this is how the milk gets from the breast tissue out through the nipple to the end point, which is the child.

Men have ducts, too. They just don't ever have big glands that make milk. And we don't really have any good pictures of glands. But there are collections of cells that are little nests that go into a tube, and that's the gland going to the duct which becomes how the milk gets from the inside to the outside. And that's the histology of the breast.

Q. Okay. So there is something that's distinguished between -- I'm holding Figure 7.8 in front of me, of Exhibit No. 79, and I'm displaying it to the jury as you and I talk. There's this breast tissue and then there is some fat tissue, too?

A. Correct.

Q. If someone loses weight, can the fat tissue go away?

A. So those cells, fat cells have a unique property which is -- and we all know this -- as we eat more they get bigger and as we lose weight they get smaller.

Q. But the breast tissue --

A. Remains. Breast tissue does not respond to weight. Fat responds to weight.

Q. So in the female breast, if there are -- if someone has large breasts and then they appear to be larger because that person has gained weight and then lose the weight, what do they lose?

A. The fat shrinks, the breast tissue starts to sag and the skin which follows along with this stretching and shrinking starts to sag and it looks, in a not pleasant way to say it, but it's a way to think about it, a rock in a sock. Just this tissue hanging at the bottom of a skin envelope.

Q. Okay. And are you as a surgeon someone who can actually -- actually routinely evaluates this kind of condition?

A. I do it every working day of every week for 30 years.

Q. Okay. Now, let's look at one of those days. Austin Pledger came to your office, correct?

A. Correct.

Q. You got to know Austin just a little bit, I'm sure, correct?

A. Correct.

Q. And he was there with his mom, correct?

A. And his dad, I recollect, I think.

Q. Okay. And mom I believe you might recognize in the courtroom.

A. That's correct.

Q. Okay. I'm going to mark, by the way, for the record, not to examine him on, but for the record, P-80, which is Dr. Solomon's report, just so the Court has a copy.

THE COURT: All right.

(Exhibits P-80 and P-81 were marked for identification.)

BY MR. KLINE:

Q. And when you saw the mom, you took a history; is that correct?

A. That's correct.

Q. And I'm going to mark the notes of your history as Exhibit P-81.

Do you routinely take a history when you see a patient?

A. Absolutely.

Q. And I'm marking as P-82 a Patient Registration Form.

You have patients fill out a registration form?

A. That's correct.
Q. Routinely in your practice; is that correct, sir?
A. Yes, that's correct.
Q. Okay. Now, you took photographs, correct?
A. That's correct.
Q. And you also have reviewed other photographs; is that correct?
A. That's correct.
Q. Okay. Mr. Gomez is working very quickly here. I need the photographs.
Okay. Now, in addition -- and I want to mark it as an exhibit. It's something the jury has seen before, but I'm going to mark it as P-83 in a glossy form. We handed one of these to counsel yesterday.
MR. KLINE: And, Your Honor, we're now going to be dealing with a whole series of photographs which I believe the Court's instructions would be they're under seal and to be displayed only to the jury, not publicly in the courtroom.
THE COURT: All right. Let me just see the series and we'll see what we're talking about here.

MR. KLINE: Okay. They're the series --
THE COURT: Do you have P-83; is that a series?
MR. KLINE: No. P-83 is a glossy of the picture.
THE COURT: Right. That's not under seal.
MR. KLINE: Okay. And for purposes of this examination, there are five photographs in standard positions taken by Dr. Solomon.
One of which has -- I think they all were marked previously, but we should mark them for this purpose.
THE COURT: If you're marking them now, yes.
MR. KLINE: Yes. We should mark them as P exhibits. And we're going to mark them as P-84-A, P-84-B, P-84-C, and P-84-D and P-84-E.
COURT CRIER: Let me show them to the Judge.
P-84-A is the photo which was denominated PHO13.

84-B is PH0015.
84-C is PH0016.
84-D is PH0014.
And 84-E is PH0017.
Those are that series, Your Honor.
THE COURT: Okay.
MR. KLINE: And in addition, so I have everything marked and right out in front of us, we can give it a P number.
In addition, there is a series which I would mark as 85-A, B and C.
THE COURT: Can I see those, please?
MR. KLINE: Yes.
THE COURT: The 85 series.
COURT CRIER: These are photos as well.
MR. KLINE: Your Honor, you've seen one of these three before. They're part of a series of when Austin was heavier.
I'm handing them to the Court.
COURT CRIER: Thank you.
THE COURT: Okay.
BY MR. KLINE:
Q. Now, you reviewed certain materials in connection with your evaluation of Austin; is that

correct?
A. That's correct.
Q. And you took a history from mom; is that correct?
A. Yes.
Q. You reviewed -- had available to you medical records, correct?
A. That's correct.
Q. And those included the medical records of Dr. Mathisen as well as some other medical records, correct?
A. Yes.
Q. Okay.
MR. KLINE: May I approach?
THE COURT: Yes.
BY MR. KLINE:
Q. Before we display these to the jury --
THE COURT: Well, first of all, why don't -- a lot of these -- these documents have already been displayed, correct?
MR. KLINE: Only one.
THE COURT: Only one.
MR. KLINE: But they are part of his physical examination.
THE COURT: Okay.

MR. KLINE: And his comparison and his opinions.

THE COURT: Okay.

MR. KLINE: So we have to do them.

What I would propose to the Court -- and maybe I should have done this earlier -- what I propose to the Court is that Dr. Solomon has certain things to point out and that he and I simply stand in front of the jury.

THE COURT: Well, I want to be very clear about what the ruling is as far as the sealed. This is not to -- to not permit members of the group in this courtroom from seeing these documents. My concern is having them published outside of this courtroom. Just so anybody who wants to see these documents, they will be made available through Marianne for an inspection.

MR. KLINE: Okay.

THE COURT: All right. You may proceed.

MR. KLINE: Yes. And we have no objection.

THE COURT: All right.

MR. KLINE: With the Court's permission, may I have Dr. Solomon step down?

THE COURT: Absolutely.

MR. KLINE: Okay. Thank you.

BY MR. KLINE:

Q. Dr. Solomon, first of all, and I'll try to do very little examination here, but a few questions. Did you take a history from mom?

A. I did.

Q. And did the history include when the breasts -- when she first saw breast development?

A. It did.

Q. And when did you learn that that was?

A. My notes reflect it was around two to three months after he started taking Risperdal.

Q. Okay. And did you also have available to you a photograph of him described as about when he was eleven years old, around 2005?

A. I did.

Q. Okay. And did you -- as I understand it, you also do photography yourself?

A. Well, only to the extent that it's medical. It's very standardized. It's not fancy. Plastic surgeons use photographs the way orthopaedic surgeons use X-rays. We take standard views so that

we have a consistent and, in my case, consistent lighting and projection. I have a photo studio. Patients stand at different places. The camera is at a certain distance, because I want to have consistency of photography so I can evaluate my results and I can evaluate, more importantly, the problem at hand. Because it's one thing to see the patient, but I also use the photograph to help formulate my plan of care.

Q. For comparative purposes, did you actually, at your suggestion, take the photo which we've now marked as P-83, which the jury has previously seen, the photo of the pool, and turn it into a glossy for comparative purposes?

A. I did.

Q. Okay. And would you show that to the members of the jury.

A. (Witness complies.)

Q. And would you tell the members of the jury what you see.

And, by the way, are you able in a case like this, having seen the boy's breasts here, to determine whether there's gynecomastia on that photograph?

A. I am.

Q. And tell us how, and how you did it, and what you find. And if I can, maybe I can be the holder and you can be the pointer.

A. So there are several things about this photograph that tell me that he has gynecomastia in the photograph. But I need to digress slightly because when I examine patients, I will sometimes have them lift their arms up or you'll read in the literature sometimes they say patients should lay down; or the other thing I'll have patients do is press their hips if I have any questions or concerns. Why do I do that? It takes the soft tissue away and essentially it's the breast tissue.

He's doing that right here. His arm is out. So while this breast is sagging, look at the shape of this right breast. It's projected. It's tight (indicating).

If you take this face away where you don't know it's a boy, you wouldn't know whether it's a boy or a girl. It's female breast appearance. That's gynecomastia.

Q. Okay. Now, there are some photographs -- in addition to the photos you took, in addition to the photos you took, the jury has seen photos. They know that from mom, from Mrs. Pledger, that Austin

has lost something like 70 pounds. So there are photos taken a few years ago when he was very much heavier than he is today.

Did you look at those photos?

A. I did.

Q. Okay. And I want to show a couple of them to you.

First of all, 85, I'll be the holder, you be the 'splainer.

A. Okay.

Q. What does the jury see there?

A. So the jury sees breasts which look female. They're very full. The fullness is because of the fat that's so intimately related to the breast tissue that I showed you on the microscopic picture. And so that gives those breasts that appearance.

Q. Okay. And the jury has now seen 85-A.

I'm displaying it also to His Honor so he follows us.

THE COURT: All right.

MR. KLINE: And knows what we have.

BY MR. KLINE:

Q. Now, there's 85-B, keeping in mind, is this the boy that you saw the other day? Was he this heavy? Did he look anything like this?

A. No. He's not that heavy at this point in time.

Q. Okay.

A. Again, it's a similar photo with sagging breasts, female breasts.

Q. Okay. And here's from the side, just so we get everything out on the table, when he was heavy.

A. So, again, what's impressive about this is two things. Your eye is drawn to this -- this is the left breast. And you can see that tightly defined crease. That's called the inframammary fold, the inframammary crease. That's an important anatomic landmark that, again, if you look under the microscope looks different than the surrounding skin in all of us. And then on the right breast you can see that hang. We call that ptosis, that sagging of the breast.

Q. Here, you're pointing here (indicating)?

A. Yes. You can see the right breast. And you'll see it better in the photographs in a minute, but in the three-quarter view, that's what shows that sagging really well.

Q. Okay. Now, his breasts back then when he had all this excessive weight, he doesn't have this girth anymore, correct?

A. Correct.

Q. When we see him way back when he had this, were his breasts fuller?

A. Yes.

Q. And why -- you might have implied that earlier, but tell us why.

A. So remember we talked about those fat cells, they get bigger. If they get bigger, everything gets bigger. So it almost sort of lifts things up. And then as one loses weight, the fat cells don't go away, they just shrink.

Q. Okay.

A. So things hang.

Q. So when we're back to 85-A, 85-A, on those breasts, are those larger and fuller when these photos were taken when he was much heavier?

A. That's correct.

Q. But you had an opportunity to see him right during this trial, so we don't have to rely on older photos, correct?

A. Correct.

Q. And I'd like you to spend some time with the jury talking about his -- about his breasts.

Exhibit 84-A, is this the condition -- is this the current condition of a

young man named Austin Pledger?

A. That's his appearance in my office. I believe it was last Tuesday.

Q. And does he have gynecomastia?

A. Absolutely.

Q. And looking at the gynecomastia -- looking at the photo, sir, if I may, does he also have all of the indicia of maleness? Is that the right word?

A. Yeah.

Q. Of being a male?

A. He's got chest hair.

Q. Other than this?

A. He's, you know, a little bit -- you can see some of the acne there. He's got some fine hairs around his nipples. He's a man.

Q. Does he have facial hair, too?

A. He has a beard, as I recollect.

Q. Okay. By the way, does he have Klinefelter's disease, as been thrown out here?

A. No. And I know that from the rest of my physical examination, by the way.

Q. And what is that briefly?

A. I examined his genitals, because I certainly have experience examining male's genitals, as counsel was kind enough to point out, and he has

normal testicles, no hernias, and a normal what we call a pubic escutcheon, meaning he's got normal pubic hair.

Klinefelter's have what's known as a hypogonadism. That's a fancy word for saying small testicles. He doesn't have any.

Q. And do they have hair and they develop like males?

A. They actually have delayed puberty or no puberty. They don't get facial hair. And those are -- and they also have a disproportion in their body where their legs will be relatively longer than their trunk. This is sort of about the halfway point in terms of our height. And he's normal in that regard.

Q. Let's go back to his breasts. He has gynecomastia, correct?

And why don't you rather than me explain to the jury what we see here. Let me hand you something to point with.

84-A is in front of the jury.

A. So looking at his breasts, first of all, he has differing amounts of breast tissue in each breast, which is not abnormal. It's pretty common. Women, many women, most women have breast

asymmetries. He's got a little asymmetry, too. This nipple is lower than that one. There's more breast tissue here than there is in this breast. He's got a stretched skin envelope, because we saw in those earlier photos it was all filled up. And skin doesn't necessarily shrink. And, again, I'm sure women know because that's a big thing they come to see me for, they want to get rid of that extra skin. Men don't shrink either.

So this is breast tissue. This is skin. There's that inframammary crease, which is a portion of the skin that holds the breast level, and his breast has fallen below that.

Q. When you say "there is," for the record, you're talking about the right breast on him, right breast facing the jury?

A. This is his right; this is his left.

Q. Yes.

A. And the crease is what -- you can't see it. It's hidden underneath the breast.

Q. Okay.

A. It looks like a woman's breast.

Q. And is it a woman's breast?

A. Correct. That's gynecomastia, by definition.

Q. Can you feel the breast and feel breast tissue

as distinguished from fatty tissue?

A. That's another point that's a good one to make, which is that if you -- if one examines breasts that are like the breasts in the previous picture, there's this buttery, fatty feeling. Breast tissue, if you recall that microscopic picture, is denser. So this is firm, not rubbery, compared to fat which is, for lack of a better word, buttery or fat. I mean, I don't know how else to describe it.

So which is why I say I know gynecomastia when I see it and when I feel it. Breast tissue is breast tissue; and once you've examined enough breasts, which you learn in medical school and you do in residency all the time and certainly I do in practice every day, I know what I'm feeling.

Q. Okay. And also, Dr. Solomon, if I could have that pool picture back.

Now, I'd like to talk to you a little bit about the structure, the middle of the breast which is the areola. Do I have the word right?

A. That's correct.

Q. And talk to the jury a minute about his areola, both in the photo as a youngster, P-83, and

his current condition.

A. So, actually, part of what a doctor does is paint a picture of what's going on with the patient. That's the history, and then combine it with the physical examine. So I actually have to go back to what his mother said to me as part of the history, when she said that his breasts started to develop. And I said how? And she said, he had bigger nipples. And that's exactly how breasts grow.

And, again, the women in the jury will understand this and in the audience better than anybody else, because breast development starts in the center and starts to push out. You can think of it like a skyscraper getting built from the ground up. So it just constantly projects.

So, first of all, this is 2005, I think we said, and he started the drug in 2002. You don't get -- you don't go from zero to 60 like that. It takes time for cells to divide and grow and divide and grow and divide and grow. So this right breast has the -- it's got a big areola for a boy. That areola is bigger in diameter. The breast tissue is well-defined, okay. And this one where he's sort of -- he's incorporated the fat because his muscle is not pulling the fat out of the way,

this one is sagging. And, again, the nipple areola complex is big.
Q. And today?
A. So that fat is gone. The areolas are big. The skin envelope is big, and the breast tissue remains. And you can feel it with your hand.
Q. Okay. Thank you. If you would return.
THE COURT: I'm going to -- I just want to take a recess right here for about five, ten minutes, all right. Just one second.
You can have a seat, sir.
All right. Ladies and gentlemen, we'll take a recess for about ten minutes. Same old rules, and we'll see you in about ten minutes.
COURT CRIER: All rise as the jury exits the courtroom.
- - -
(Whereupon the jury exited the courtroom at 11:21 a.m.)
- - -
THE COURT: All right. We're in recess for about ten minutes. Please do not discuss the matter with the attorneys.

THE WITNESS: Sure.
- - -
(Whereupon a recess was taken.)
- - -
THE COURT: You can be seated, everybody.
COURT CRIER: All rise as the jury enters the courtroom.
- - -
(Whereupon the jury reentered the courtroom at 11:40 a.m.)
- - -
THE COURT: All right. You may be seated.
All right. You may proceed.
MR. KLINE: Your Honor, thank you.
BY MR. KLINE:
Q. You can remain there, Dr. Solomon.
With the Court's permission, I'm going to lean over your shoulder a little bit.
We have 84-B here.
A. Yes.
Q. You take five photos. Would you explain just briefly to the jury, one or two sentences, why you take five photos.

A. It shows the breasts in all projections, front, three quarters, side, for both sides.
Q. Okay. And the photo that we have, you're mentioning male -- a male thing. I'm just pointing out the obvious, that he has hair under his arms, of course?
A. Correct.
Q. Okay. To briefly run through them, 84-B, is that another photo in -- another of your five standard shots?
A. That's correct.
Q. And what view is this?
A. That's the left three-quarter view.
Q. And anything special here when I display it to the jury?
A. The three-quarter view nicely demonstrates the shape and hang of the right breast because you're looking at it from that projection, that's all. You can also see the hair on his chest.
Q. Right. But in terms of the breasts.
A. In terms of the breasts, it highlights that. It highlights the crease here very well. All those anatomic landmarks that are hallmarks of the feminized male breasts.
Q. What kind of volume are in these breasts?

A. So when I did my exam, I made measurements of his chest circumference at that inframammary crease and then at the mid-nipple.
Q. Inframammary crease being this crease here?
A. Yes. It's the point where the breast hits the chest wall.
Q. Okay.
A. Okay. That's the strap number for a bra.
And then the mid-nipple is another landmark. And the difference between those two is the cup size.
Q. Okay. So --
A. So I measured in centimeters, but when you convert it to inches, he's a 46 double D.
Q. Okay. And then this is another photo, 84-C. Just tell us a view of this. I just wanted to comprehend.
A. It's the right three-quarter.
Q. And from the side, 84-D, is that a side-view?
A. Left profile.
Q. And the next one is right profile?
A. Right profile.
Q. Left and right profile for 84-D. 84-D is left. 84-E is right, correct, right and left profile, correct?

A. Correct.
Q. Okay. Sir, today have you and will you continue to express all opinions to a reasonable degree of medical certainty?
A. I have and will do so.
Q. Sir, do you have a way with patients, not only this one, but with others to form what is called a differential diagnosis?
A. That's part and parcel of taking a history, doing a physical.
Q. Is that part and parcel of practicing medicine?
A. It's the essence of the practice of medicine.
Q. If you show up either in an emergency room or a plastic surgeon's office, does the doctor do a differential diagnosis?
A. Absolutely.
Q. Would you tell us briefly, a sentence or two, what is a differential diagnosis?
A. It's basically what are all the possibilities, what's the patient have. So you have this big laundry list, you narrow it down.
Q. And is that part and parcel of doing a clinical diagnosis?
A. Correct.

Q. Okay. And is this, sir, a clinical, what you've done here, a clinical differential diagnosis?
A. That's correct.
Q. Seeing the patient, getting a history, knowing and understanding the pathology, physiology, anatomy behind it?
A. That's correct.
Q. And I assume also ruling out other causes?
A. Correct.
Q. Ruling out causes?
A. Again, a differential, you outline all the potential things that it could be and then you say, well, it's not this for these reasons and it's not that for those reasons.
Q. Okay. Did you reach an opinion in this case with reasonable medical certainty as to whether Risperdal causes gynecomastia and whether it caused it in this child on your evaluation of him, as well as your knowledge, background and experience with patients and with everything else that you would know?
A. I did make that decision and did reach that conclusion.
Q. Okay. And would you explain to the members of the jury what you concluded as to whether Risperdal causes gynecomastia and whether it caused it in this patient.

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

A. That's correct.
Q. And are you aware of the fact that he was on Risperdal at the time that the mother indicates that he developed the breast buds -- the breast development?
A. Correct.
Q. Would you tell the members of the jury, as you understand it, whether this all happened before or after he was in puberty, the development of the breast buds?
A. So in 2002 he was 8. So by definition, that's before puberty.
Q. Okay. To a reasonable degree of medical certainty, will you tell the jury briefly how and why you understand Risperdal causes gynecomastia, then we'll get to this boy.
A. So, briefly, Risperdal is a drug that among its side effects, it's a stimulant -- or it's a potent stimulant of elevations of prolactin which is this hormone that we talked about briefly that's secreted by the pituitary gland and acts on the breast tissue.
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 till 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.

Q. There's no prolactin level that was taken during this period of time. And I would simply ask you from your knowledge, did prolactin levels in patients like Austin rise during administration of this drug?

A. My understanding of the drug and its side effects, that's more than 80 percent -- I think 87 percent in some cases of the time the prolactin will go up.

Q. Did you also take into account -- and we don't want to go over it laboriously. The jury knows the things that are said in the 2006 label, like the

incident rate is 2.3 percent at least. Are you familiar with all of those -- all of that?

A. I am; and some other literature that actually sets it closer to 5 percent.

Q. Okay. And in this patient, in a boy who had not yet hit puberty who develops breasts, what is the, as you understand it, background rate, that is to say, boys who are 8 years old who develop breasts who are not pubertal?

A. Absent another cause, another drug, another tumor, another kind of anything, a normal 8-year-old boy has a zero incidence of gynecomastia.

Q. Are you familiar with the medical literature which shows that there is an increase of gynecomastia rates in children who are prepubertal who are on Risperdal?

A. That's correct, I am aware of that.

Q. And did you take that into account in reaching your opinion?

A. I did.

Q. Okay. Does he have true, real gynecomastia, sir?

A. Yes.

Q. Gynecomastia meaning female breasts?

A. He has female breasts, without any doubt.

Q. And do you see anything else logically that would be the cause of it?

A. There's nothing else. And, again, a big part of practicing medicine which I've, you've heard, done for a long time is that logic is important. That's the whole basis of how we do what we do.

Q. Do you have the expertise, training and background to make this kind of diagnosis, sir, and to reach this kind of conclusion?

A. Absolutely.

Q. In fact, something that was not pointed out earlier is that if you go to your website, sir -- if we go to your website, sir, and we would simply go to just for men and hit breast reduction for gynecomastia, you're familiar with your own website, right?

A. Somewhat. That's correct.

Q. And I touch it, and it says male breast reduction, and you talk about it. And it says "causes of gynecomastia." Causes of gynecomastia include medications -- something that you actually do ordinarily in your medical practice, correct?

A. Absolutely.

Q. And in this case, when you saw this young man, did you determine that he has Risperdal-induced

gynecomastia?

A. I did.

Q. And in fact, sir, was this -- this was not the first time that you made that kind of diagnosis, Risperdal-induced gynecomastia, correct?

A. That's correct.

Q. And the other time that you made it had nothing to do with litigation, nothing to do with a lawyer sending someone to you, correct?

A. That's correct.

MR. KLINE: I was not going to actually mark it. I just had a discussion with him about it.

THE COURT: Anything else?

MR. KLINE: Bear with me.

COURT CRIER: Do you want that marked, the web page?

THE COURT: The second page. If you wish him to do something, you may. If not --

MR. KLINE: No. I just want to have a discussion with him about it.

Bear with me one second, Your Honor.

(Pause.)

MR. KLINE: Mr. Gomez was my checklist.

No further questions. Cross-examine.
THE COURT: All right. Thank you.
All right. Cross.
MS. SULLIVAN: Thank you, Your Honor.

- - -

CROSS-EXAMINATION

- - -

BY MS. SULLIVAN:
Q. All right. Good morning again, Dr. Solomon.
Mr. Kline left off talking about your website. And I want to put up and mark the piece of your website that discusses gynecomastia that you guys were talking about, okay?
MS. SULLIVAN: And, Ms. Brown, you'll tell me the new exhibit number.
MS. BROWN: Forty-five.
MS. SULLIVAN: Forty-five.
(Exhibit D-45 marked for identification.)
MS. SULLIVAN: Okay, Counsel?
No objection, Counsel?
MR. KLINE: I'm sorry, where are you; back to his website?
THE COURT: D-45.
MS. SULLIVAN: Yes. It was the

section you --
THE COURT: Let me see that.
MS. SULLIVAN: It was the section you were talking to him about and didn't put up.
MR. KLINE: No; no objection.
(Displaying D-45 on the screen.)
MS. SULLIVAN: Can you guys see that up there?
BY MS. SULLIVAN:
Q. And, Dr. Solomon, your website talks about causes of gynecomastia, right?
A. Correct.
Q. And it says in many cases of gynecomastia, the cause is unknown, right?
A. That's correct.
Q. And you guys didn't put that up, but that's true, right?
MR. KLINE: Your Honor, can we stop the snide "you guys didn't put that up?"
I could have put up four hours of testimony and I didn't.
MS. SULLIVAN: I'll withdraw the question, Your Honor.
BY MS. SULLIVAN:
Q. Your website says in many cases of

gynecomastia, the cause is unknown, right?
A. Correct.
Q. And it goes on to say it is thought that it is genetic in many cases; some men get the condition during puberty and then as they age it goes away. Some other causes of gynecomastia include androgen resistance, steroids, medications, alcohol. And it goes on to say in men with gynecomastia, the condition persists well into adulthood, right?
A. That's what it says.
Q. And that's true, right, in men with gynecomastia, the condition persists well into adulthood?
A. Correct.
Q. And, Dr. Solomon, I want to talk a little bit about your testifying experience.
This is not the first time you've served as an expert witness?
A. That's correct.
Q. In fact, you've done it 50, 60 or more times in the past?
A. Uhmm, I think I'm on the record for something like that, but I don't recall the -- can you show me the testimony? And I'm happy to review it.
Q. Yeah. But does that sound right, about 50 or

60 times?
A. I really don't want to guess, if I've spoken before --
Q. Sure.
A. -- and you've got it written down, I'd really appreciate the opportunity to evaluate it.
Q. Can we show Dr. Solomon his Goldenberg deposition on Page 4, 4 to 12.
MS. BROWN: You've already marked it as 44.
MS. SULLIVAN: Lines 4 to 12.
COURT CRIER: D-44 to the witness.
THE WITNESS: Counsel, do you have a page and line?
MS. SULLIVAN: Yes. It's Page 4, Lines 4 to 12.
THE COURT: Wait a minute. Can I see which document this is?
MS. BROWN: Your Honor, it was marked as 44.
THE COURT: D-44. And what page is this?
MS. BROWN: Page 4.
THE COURT: Okay. Thank you.
THE WITNESS: May I respond to your

question, Counsel?
THE COURT: Yes.
Now, you hold on to D-44, okay. And why don't you review it and see if that refreshes your memory.
THE WITNESS: The question was --
THE COURT: And I'm talking about Page 4.
THE WITNESS: Page 4.
THE COURT: And then we'll have our court reporter reread the question. I'm going to direct you, Doctor, to just answer the questions as asked.
So why don't you refresh your memory by reading Page 4 and then we'll have the question asked again.
MS. SULLIVAN: Great.
BY MS. SULLIVAN:
Q. And, Dr. Solomon, do you see your testimony?
A. I do.
Q. And you've testified in 40 to 50 depositions as an expert, the vast majority have been expert depositions, right?
A. So what I said was I've testified in probably 40 -- I've been deposed probably 40 to 50 times, and

the majority was as an expert.
Q. The vast majority?
A. The vast majority was as an expert, that's correct.
Q. Yeah. I don't mean to quibble, but you've done this a fair amount of times?
A. That's a subjective statement. I'm only reading what I read here.
Q. You've served as an expert in litigation a fair amount of times?
A. I have been an expert in litigation. I've been in practice for 30 years, and I've been doing this as part of practice because doctors get called to testify for any number of things. And I've had to testify, by the way, on my own behalf from time to time. So all of those are depositions that I've given.
Q. And actually, you've served as an expert for the Sheller firm, one of the plaintiff's law firms involved in this lawsuit here, right?
A. On one occasion that I can recall.
Q. And actually, Dr. Solomon, it was more than once, right?
A. I -- can you show me where I said that it was more than once?

Q. Sure.
You won't agree that you've reviewed cases for Mr. Sheller's firm?
A. That's not the question you asked me.
Q. Ah, fair point.
So let's start with that. You've reviewed other cases for the plaintiff's law firm in this litigation, right?
A. I believe I stated that I might have reviewed them or I've probably seen one or two over the years. But I can only recall testifying in one matter.
Q. And going back to the 1990s, you reviewed med mal cases; you've reviewed some accident reconstruction cases and things like that for the Sheller law firm?
A. I don't have a specific recollection of those. I've stated that I reviewed cases.
Q. For the Sheller law firm?
A. For a lot of law firms.
Q. But including for the law firm that brought suit in this case?
A. And Post & Schell and Harvey Pennington and Marshall Dennehey --
Q. Yeah.

A. -- and Michael Barrett's firm.
Q. And you've testified as an expert enough times that you actually have a "fees for legal expert services" sheet that you give out to lawyers who use you, right?
A. I don't give it out. They request it and then they decide if they want to retain my services because I'm compensated for the time away from my practice, which, as you can see, is considerable.
Q. And we can mark this, Ms. Brown, as...
MS. BROWN: Forty-six.
MS. SULLIVAN: D-46.
(Exhibit D-46 marked for identification.)
MS. SULLIVAN: Any objection, Counsel?
MR. KLINE: No.
Bring Dr. Arrowsmith's when he comes.
THE COURT: D-46. Do you have a copy of that?
THE WITNESS: I see it on the screen, Your Honor.
THE COURT: Here, you want a hard copy?
THE WITNESS: That would be good.

(Handing document to the witness.)
BY MS. SULLIVAN:
Q. And, Dr. Solomon, this is your fees for legal expert services, right?
A. That's correct.
Q. And you charge for in-court testimony $20,000 a day, right?
A. That's compensation for time away from my practice.
For example, if I may, this morning I could have or would have done two breast augmentations. That's $5,000 apiece. There's $10,000 for a half day. So it's just I have expenses and overhead, staff, insurance, taxes. And I just need to be compensated at the same rate for being here as I'm compensated for my patients, to whom I'm eternally grateful, by the way, but I'm trying to run a business.
Q. Do you remember my question?
A. You asked me if that was the rate at which I'm compensated and I said yes and I explained why.
Q. Yes.
You charge $20,000 a day and plus first-class air travel if it's out of town, plus expenses to testify for plaintiffs' lawyers, right?

A. And defense, by the way.
MR. KLINE: Your Honor --
THE WITNESS: Much more for defense.
MR. KLINE: I missed the last part.
MS. SULLIVAN: $20,000 a day.
THE COURT: Is there an objection?
THE WITNESS: I testify more for defense than plaintiffs.
THE COURT: Do you have an objection?
MR. KLINE: I didn't hear.
THE COURT: Oh.
Doctor, why don't you speak into the microphone.
THE WITNESS: I'm trying, Your Honor. I'm sorry.
BY MS. SULLIVAN:
Q. And, Doctor, you also have a policy about scheduling?
A. Correct.
Q. That if there's a schedule change, you get the full 20,000 even if you don't show up?
MR. KLINE: Oh, Your Honor, objection. None of that plays in here.
MS. SULLIVAN: Oh, it goes to bias, Your Honor.

THE COURT: Well, you'll have a chance to redirect on this.
MR. KLINE: They have a witness who was paid $700,000, and this goes to bias?
THE COURT: Have a seat.
MS. SULLIVAN: We don't have any --
THE COURT: Have a seat.
MR. KLINE: $700,000 --
MS. SULLIVAN: That's improper, Your Honor.
MR. KLINE: -- he was paid.
MS. SULLIVAN: That's improper.
THE COURT: Well, what I do know at this moment is that the objection is overruled.
THE WITNESS: Your Honor, if I may answer that question.
MS. SULLIVAN: He already --
THE COURT: No. Objection overruled means please answer the question.
MS. SULLIVAN: And, Doctor --
THE WITNESS: My answer is as follows, Counselor: Once a plane takes off, I can't get on it. If I don't schedule surgery, I still have rent to pay. I still

have salaries to pay. If I've been compensated for my time, which is just like you, I'm a professional, I'm compensated for my time. I'm not sure why that's an issue. The jury knows all the experts are paid. So I'm not sure why you're making such an event of this.
BY MS. SULLIVAN:
Q. Do you remember my question, Dr. Solomon?
A. I answered it.
Q. My question was if -- even if you don't show up, you get $20,000?
A. No; I show up.
Q. If there's a scheduling change and you don't show up, you still get the $20,000?
A. Because I can't schedule surgery at the last minute.
Q. And have you calculated how much that is an hour? It's like 3- or $4,000 an hour, isn't it?
A. So I went to college. I went to medical school. I did seven years of residency, six months of fellowship. I am at an age that I don't want to discuss how old I am. I'm an accomplished individual; and, frankly, compared to an NFL quarterback or a basketball player who may have less

experience and education, it's a pittance. And I hold people's lives in my hand every day. What do you think that's worth, Counselor? I think it's worth a lot of money because I make a lot of hard decisions about taking young, healthy people and operating on them. And that's a real issue that people always forget and I never forget. My job's a sacred trust; and if you think I take that lightly, I don't.

And, by the way, I certainly give away enough care when I feel like it, don't I? So I think you're totally out of line questioning how I make a living, because I take care of my family and my patients, and that's my job.

Q. Do you remember my question, Dr. Solomon?

A. I answered your question. Please ask the next question.

Q. Do you remember --

THE COURT: You know, Doctor, and Counsel, but for you, Doctor, it's really going to be beneficial for the jury for answers that respond to the questions and allow the jury to determine what's going on or what's not going on. Otherwise, I'm afraid you are going to miss the rest of the

day and all the income that you say you have.

THE WITNESS: I understand that, Your Honor.

THE COURT: Thank you.

THE WITNESS: Thank you, Your Honor.

BY MS. SULLIVAN:

Q. And, Dr. Solomon, you said $20,000 is a pittance to you?

MR. KLINE: Your Honor --

THE WITNESS: No.

THE COURT: Objection sustained. Is that an objection?

MR. KLINE: Yes.

THE COURT: That's sustained. We're not going to characterize now. The jury has heard an answer.

And you may proceed, Ms. Sullivan.

BY MS. SULLIVAN:

Q. And, Dr. Solomon, I also note you have a no-refund policy, right?

MR. KLINE: Oh, Your Honor, when does it end?

THE COURT: Well, it's not going to end until we get through this document, so that's overruled.

BY MS. SULLIVAN:

Q. This is your fee schedule for litigation like this?

A. That's what it says.

Q. And you say no refunds, twenty grand?

A. I also have no refunds for surgery, but that's a different schedule.

MR. KLINE: It's everything.

COURT REPORTER: I'm sorry, Counsel.

BY MS. SULLIVAN:

Q. And you have a minimum, a full-day minimum, right? Twenty grand no matter what, even if you only show up for an hour?

MR. KLINE: Oh, Your Honor, objection. How many times can she badger him?

THE COURT: Sustained.

MS. SULLIVAN: This is his schedule for his --

THE COURT: Well, we understand that. If you're creating a new point, that's one thing. But if you are badgering somebody, that's another thing.

MR. KLINE: Your Honor, respectfully, does it open up, so I know, a comparison

between what the lawyers make for Johnson & Johnson?

THE COURT: No, I don't think so.

MS. SULLIVAN: I wish, Judge. I wish.

THE COURT: I don't think so. I was thinking the same thing, Mr. Kline. But we're not going there at all, hopefully.

MS. SULLIVAN: I wish.

BY MS. SULLIVAN:

Q. Okay. Dr. Solomon, on the money point, Doctor, for cosmetic surgery, you actually have, in terms of charges, you have a YouTube video talking to customers about how they can pay for your services, and you have a surgical table full of money on the video, right, sir?

A. No. I -- I defy you to show me that, that I produced it and I put it up there.

Q. Okay. Let's take a look.

A. With me in it?

MR. KLINE: Your Honor, may we see you first?

MS. SULLIVAN: Let's take a look. Can we have this marked as Defense Exhibit 47?

MS. BROWN: Forty-seven.
MS. SULLIVAN: Forty-seven.
MR. KLINE: Is it a video?
THE COURT: Just make sure at the moment nothing goes up on the screen. I really need to see what this is.
MR. KLINE: Your Honor, we need to see it in camera maybe over the lunch hour, because I have not seen it and we need to know.
MS. SULLIVAN: Well, Your Honor, I could play the video or I could just show the screen shots with the table.
MR. KLINE: I would like to see the video, Your Honor.
THE COURT: Well, do you have the entire document here?
MS. SULLIVAN: I have the video -- it's from a video he has on YouTube.
THE COURT: Do you have -- I don't know. Have you seen the video?
MR. KLINE: No.
THE COURT: All right. That's sustained for right now.
THE WITNESS: Your Honor, I haven't

seen the video, so I have no idea what she's talking about.
THE COURT: All right. Well, then that's sustained.
THE WITNESS: I'm not sure if it's --
BY MS. SULLIVAN:
Q. Dr. Solomon, that's you, right?
A. I don't know.
MR. KLINE: Your Honor, see, she's told she can't show a document and she does it.
THE WITNESS: May I see it?
MR. KLINE: That's --
MS. SULLIVAN: I didn't put it up.
MR. KLINE: -- that's what you're dealing with in the courtroom, respectfully.
THE COURT: I know what I'm dealing with is two attorneys who are right now in front of the bar of the court.
MR. KLINE: You should know.
THE COURT: May I have that document, please?
THE WITNESS: Yes.
And, Your Honor, it's not my document.

THE COURT: Ms. Sullivan, can you step back?
MS. SULLIVAN: Sure.
THE COURT: At the moment, this is sustained, D-47 is sustained. There is no prior notice involved here.
I certainly would be happy to have it examined by counsel and then properly submitted. But this sounds to me like no one has seen this document before. I haven't seen it.
MR. KLINE: My objection is when she's told something, she doesn't obey.
THE COURT: Well, that's --
MR. KLINE: That's my problem.
THE COURT: That's not --
MS. SULLIVAN: Your Honor --
THE COURT: You know, Mr. Kline, let me run the courtroom. And as far as I'm concerned, so far everything is hunky-dory with Ms. Sullivan.
MS. SULLIVAN: Thank you, Your Honor.
BY MS. SULLIVAN:
Q. And, Dr. Solomon, let's talk about Mr. Pledger and your exam of Mr. Pledger.

You were called just last week for the first time related to this case by the plaintiff's lawyers?
A. That's correct.
Q. And before that time you had not reviewed any medical records concerning this plaintiff, right?
A. That's correct.
Q. You had not talked to any of his treating physicians, right?
A. That's correct.
Q. You still haven't talked to any of Mr. Pledger's treating doctors in Alabama, right?
MR. KLINE: Objection. She knows that's not part of the process.
THE COURT: Again, this is cross-examination. She can ask the questions and you can do a redirect.
MR. KLINE: She absolutely knows that, just like her doctor. Holy moley.
MS. SULLIVAN: Your Honor, that's improper.
THE COURT: Counsel --
MS. SULLIVAN: He certainly could talk to the plaintiff's treating doctors if he wanted to.

THE COURT: Mr. Kline's objection is overruled. You may proceed.
BY MS. SULLIVAN:
Q. And prior to last week, you had never spoken to Mrs. Pledger or Mr. Pledger or anyone in the Pledger family?
A. That's correct.
Q. And the plaintiff's lawyers flew Mr. Pledger up from Alabama so you could examine him here in Philadelphia?
A. I would suggest you ask Mr. Kline about how that happened.
Q. He was here in Philadelphia, Mr. Pledger?
MR. KLINE: Your Honor, is it -- I would object to relevance.
THE COURT: All right. That's sustained, unless --
MR. KLINE: And they didn't fly first-class.
THE COURT: That is sustained at this point.
We may take a lunch break then right here, if you wish, Ms. Sullivan.
MS. SULLIVAN: That's fine.
THE COURT: To go over the parameters

of this whole discussion.
So, ladies and gentlemen, we're going to recess right here for lunch break till about 1 o'clock, till about 1 o'clock, okay? Same rules apply. Please wear your yellow badges. Do not discuss this matter with each other. Keep an open mind, and that's it. Well, the investigation part, too, all right? See you at 1 o'clock.
COURT CRIER: All rise as the jury exits.
- - -
(Whereupon the jury exited the courtroom at 12:11 p.m.)
- - -
(The following transpired in open court outside the presence of the jury:)
- - -
THE COURT: All right. I think that, Doctor, you are excused for the moment. We're in a lunch break. And I think that we're going to try to get back at 1 o'clock.
THE WITNESS: Your Honor, may I be heard about that video, because I --
THE COURT: Well, you need to speak

to your attorney, then.
THE WITNESS: Well, then, I'll be allowed to speak to Mr. Kline; that's fine.
THE COURT: Pardon me?
THE WITNESS: I'm allowed to speak to Mr. Kline about it?
THE COURT: About the video? No. You know what, let me hear what the objection is in the witness's presence.
MR. KLINE: I'd like to see it.
THE COURT: All right. Let's run it.
MS. SULLIVAN: Can we run it?
THE WITNESS: Is it made by a third party?
THE COURT: Well, again, I understand.
THE WITNESS: Because they co-opted my images and put them on the Internet without my permission.
MR. KLINE: Well, let's see what it is.
THE COURT: Well, let's see it and then you may respond to it.
But I'm also more concerned about a different issue which is how far is the

defense willing to go before opening the door to its perceived -- well, what this Court has already ruled on is a cause that created this situation. How far do you want to go, Ms. Sullivan, in terms of opening the door to that whole line of circumstance?
MS. SULLIVAN: Well, Your Honor, so it's an issue for -- the prejudice is an issue for us in terms of the jury not knowing what happened since we opened on Dr. Goldstein.
THE COURT: Well, I understand that. So I'm willing to hear some kind of proposal before we go headlong into it. Because, frankly, I'd like to have that thought out before we go forward. That is really not Dr. Solomon's domain or a responsibility on that front. So let's address the issue, the video first, and then we'll excuse Dr. Solomon to address the other issue.
MS. SULLIVAN: And, Your Honor, the video, I mean, if it's going to cause a lot of -- I think it's proper and I should be able to use it because it's him. But if it's going to save time, I can move on.

THE COURT: Well, I don't know whether it's going to save time or not. I don't really care about the time part. What I care about is whether or not there's a fraud that's been perpetrated on Dr. Solomon which could place him in a bad light in a trial in open court when he hasn't actually had the opportunity to see this video. So why don't we run it and let's see what this is all about, unless you wish to withdraw the whole thing.

MS. SULLIVAN: Your Honor, this video was pulled from the public domain. It's been running. He's on it, but I'm happy to move on.

THE COURT: So you're willing to move on without it?

MS. SULLIVAN: I'm happy to move on.

THE COURT: All right, fine. So then, Doctor, it's not coming into evidence here, so now you're excused.

THE WITNESS: Thank you, Your Honor.

THE COURT: Please do not discuss this matter with your attorneys.

And I do want to get into how to

handle at this point the circumstances involving this matter as to what the jury should know and should not know, and I think that for that purpose, we will see you at sidebar.

- - -

(The following discussion transpired in the Judge's robing room, out of the hearing of the jury:)

- - -

(Mr. Kline, Mr. Sheller, Mr. Gomez, Ms. Brown, Mr. Murphy present; then Ms. Sullivan entered the robing room.)

- - -

THE COURT: Okay. Back in here again.

You know, I was on the phone this morning already with a juror's -- we're waiting for Ms. Sullivan -- with the employer of one of our jurors here, McDonald's. I've even spoken so far now to Mr. Tucker over at Pepper Hamilton. Still no decision.

MR. KLINE: On?

THE COURT: So I would let them know that as far as I'm concerned, McDonald's may

not be the same -- it's a question of who's the employer. And so I've advised him that as far as I'm concerned, McDonald's should step up as a corporate citizen. But they haven't promised yet that they would do so. So, meanwhile, Dayana Williams has not been excused.

MR. KLINE: Can I ask you a question? McDonald's hired the Pepper firm to determine --

THE COURT: No. McDonald's has a regional office. And so I was in contact with their legal counsel who then had their legal counsel from Pepper on the phone.

MR. KLINE: So rather than pay a juror, they're paying Pepper rates.

THE COURT: Something like that.

MR. KLINE: To get --

THE COURT: Something like that.

MR. KLINE: Holy moley.

THE COURT: I'd like to know that -- you know, if I'm forced to excuse somebody for a hardship and that causes a mistrial here, McDonald's will not be forgotten.

MR. GOMEZ: My older brother actually

works for McDonald's corporate. Maybe I'll give him a call and tell him what transpired here.

THE COURT: Maybe you can call him up.

MR. GOMEZ: Get it done.

THE COURT: So anyway, I'd like to know how we're going to handle this situation involving -- I do agree since it's on the record that, you know, he was just called in in the middle of trial, that any juror would probably wonder why that was, what should -- how -- what's the best way for the Court to handle this.

MR. KLINE: I have a proposal.

MS. SULLIVAN: We had a instruction --

THE COURT: All right. And then I'll hear from Ms. Sullivan.

MR. KLINE: My proposal, since he was my expert and since I was put to this, is that the jurors simply be told that, members of the jury, it is of no consequence when the examination or the opinions were formed by Dr. Solomon.

MS. SULLIVAN: No.

MR. KLINE: And anything short of that or any inference that's drawn when they created this mess -- by the way, this prejudicial mess to us, to the plaintiff, would be -- would be horribly prejudicial.

There is good case law, although I haven't looked at it, I should say I believe there's good case law for the proposition that it is of no consequence when an expert forms his opinion or her opinion, whether it be two years ago or two minutes ago. And to the extent that they think that they should benefit by cross-examination of a witness as to when he formed or didn't form his opinion would be horribly prejudicial.

I might add that while all of the focus and all of the yelling -- and it was yelling -- by Ms. -- by the defense about the horrible prejudice that they have incurred, the fact of the matter is that the post-trial motion that Your Honor would see if the plaintiff lost would be how horribly prejudiced we were.

And the fact of the matter is that

the only way to fairly balance this is to simply tell the jury it is of no consequence to you one way or the other when either an examination took place or when -- by the way, I would give them this: Either where or when, because they have theirs down in Alabama, by the way, now we know, under false pretenses.

But it's of no consequence as to when or where the examination took place in terms of the formation of the opinions. You must determine the competing opinions in this case based upon the evidence that you've heard and the instructions which I shall give you.

THE COURT: All right.

MR. KLINE: Something like that should be said to this jury.

MS. SULLIVAN: And, Your Honor, from our standpoint, that would compound the prejudice because it certainly goes to credibility and reliability of the opinion; that he came to it in a day or two. And that goes squarely to how reliable it is and how credible it is.

And so we had a -- we have a proposed instruction for Your Honor to take a look at and for counsel to take a look at.

(Handing document to the Court.)

MS. SULLIVAN: The other issue is, he says in his report that he relies on Dr. Goldstein's opinions, and so Dr. Goldstein is part of the case and will be part of the cross-examination, since he says he relies on him. He's reviewed Dr. Goldstein's reports and relies on his opinions.

MR. KLINE: And, Your Honor, as to that part of his report, that was simply --

THE COURT: I'm sorry, I really am. I was reading the proposed instruction.

MR. KLINE: He --

THE COURT: What is the last thing you said?

MS. SULLIVAN: Sure. So they gave him a bunch of stuff to enable him to review the case. And one of the things that they gave him were Dr. Goldstein's opinions and report. And he makes reference to it in his opinions, and so it's fair

cross-examination -- it's one of the key things he reviewed -- to cross-examine him on Dr. Goldstein's report.

MR. KLINE: No. And here's why, Your Honor: The reason why is because he doesn't say in his report that he, quote, relies on the opinion.

One more thing that's not represented accurately. What he said -- what he says is he recites the fact that his opinions agree with Dr. Goldstein.

Do you know why he says that? He says that because I wanted to assure the Court -- that is information for the Court -- I wanted to assure the Court that the opinions, that the core opinions are essentially the same.

He doesn't touch any other part of Dr. Goldstein's report. This jury if they --

THE COURT: I understand it's well-crafted. It says after forming my opinions. I see that, okay.

MR. KLINE: Yes. And the point is, we should be entitled, given what they created here, the situation they created, we

should be entitled to nothing less than a fair trial, which means that this --

THE COURT: Well, let me --

MR. KLINE: Which means that the jury is told that this opinion stands for whatever it is, good, bad or indifferent; that it stands on its merits.

The problem with the defense, honestly, in this case -- I've never seen anything like it in 37 years -- is that nothing ever reaches the merits. It always reaches some collateral bull...

That's what it hits.

And the fact of the matter is that it should be of no consequence to him. He should be examined on his opinion, the opinion he reached, the conclusions he reached.

And, my word, she's going after him hammer and tong. It's going to be interesting to watch this afternoon. But it should not be Dr. Goldstein on the stand. He's not on the stand. His opinions aren't on the stand, whether this guy agrees or disagrees with some phantom expert. There's

case law on that. Again, I didn't bring it. But there's case law on examining against an expert whose report is not -- who is not in the courtroom.

So it should just be a fair playing field.

THE COURT: All right.

MS. SULLIVAN: Your Honor --

MR. KLINE: That's my view.

MS. SULLIVAN: Your Honor, first we dispute the -- we vigorously disagree that we caused this. We submit they caused it.

THE COURT: Well, the Court's already made a finding on that. That's the difficulty the defense has.

MS. SULLIVAN: We respectfully disagree.

THE COURT: I know that.

But I have made a finding on that, otherwise we wouldn't even be here, that upon cause shown, we permitted this discovery.

MS. SULLIVAN: And it --

THE COURT: And so, you know, I don't know who's going to appeal the most here, but that has already been decided. I have

already decided as a matter of the law in this case that the cause for this situation is on the defense, otherwise I would not have permitted further discovery.

So having said that, the question now becomes whether or not I need to have the jury understand the whole situation that led to the cause.

I think that would be prejudicial actually to both parties. So I'm inclined to go with an instruction that, fundamentally, you know, it is of no consequence when the opinion was made and how it was made, as long as you understand the opinion and can decide on it any way you wish. Because other than that, we would have to get into a phantom document. We don't need Goldstein's expert opinion whatsoever in this case.

If you want me to give an instruction that relates to your -- so that the defense is not prejudiced having mentioned in about two pages the Dr. Goldstein reference, I can and will address that.

But I see that anything short of that, to really bring into the jury's

attention everything that we've kept away from the jury up till now would be prejudicial, not only to -- it would be prejudicial to this trial. And I am committed to navigating this thing to a safe landing.

MS. SULLIVAN: And, Your Honor, they shouldn't be able to have it both ways. They've given Goldstein's report. He says he agrees with it and then we can't cross-examine on it.

THE COURT: Well, he does not --

MS. SULLIVAN: That's prejudicial.

THE COURT: Only if you bring it up. The way this is phrased here is "After" -- I'm going to read it now -- "After forming my opinions, I also reviewed the report of Dr. David E. Goldstein, M.D., that relates to Austin Pledger. I agree with the opinions in that report."

He does not need to explain or refer to Dr. Goldstein because he already formed his opinions absent Dr. Goldstein's opinion.

If you wish to cross-examine him on that, on some of the points that Mr. Murphy

raised this morning in his motion, go for it. Then we'll take it as it is.

But I will not get into this is somebody who the plaintiff decided not to bring here after cause was shown. That's what I would tell the jury; that the plaintiff has decided, within their rights, not to present this particular witness after a situation where I ruled there was cause for them to be permitted not to produce that witness.

If you want to go that route involving Dr. Goldstein, that's where it's going to end up.

MS. SULLIVAN: Well, Your Honor, it's prejudicial. And we don't agree with the Court's instruction.

THE COURT: As far as prejudicial is concerned, I haven't heard a mistrial motion from the plaintiff. So right now they don't have a post-trial motion that's going to be sustained.

MS. SULLIVAN: Your Honor --

MR. KLINE: You have not heard one.

THE COURT: No. So your post-trial

motion at the moment is --

MR. KLINE: I made a comment.

THE COURT: I understand.

MR. KLINE: And --

THE COURT: I have heard repeated post-trial motions from the defense. And I'm willing to, as I said, to explain this to a higher court, as we need to, if we need to. But, again, the question of introducing Dr. Goldstein and the mess that surrounded the cause that I found is really up to the defense at this point, if you want to cross-examine -- if you want to compare Goldstein's report to this one.

I certainly will not prohibit whatsoever the defense from cross-examining as a matter of medical knowledge the questions that Mr. Murphy raised this morning involving prolactin and the increase in levels, and all of those issues certainly is permissible. It need not, however, be made in reference to Dr. Goldstein.

But if you want to go that route, I will tell them that there was a permission by this Court to excuse this witness for cause

shown.

MR. KLINE: Your Honor, I would -- I would simply -- I just don't want to be silent. I would respectfully object only to this extent; that to get into Dr. Goldstein in any way, shape or form is highly prejudicial. This witness did not form his opinions based on Dr. Goldstein.

THE COURT: Well, that's what I said.

MR. KLINE: But if they -- but this is: Give a millimeter, take ten miles over here. And what you're going to have -- what you're going to have, respectfully -- it's true -- and what you're going to have is a situation where she's going to blurt out Dr. Goldstein was hired by the plaintiff's lawyer, plaintiff's lawyers, and the plaintiff's lawyers hired him down there and he said this and you say that. That's not the basis of this -- that should not be fairly the basis of a cross-examination.

THE COURT: Well, what is it that you want to try to get through Goldstein?

MS. SULLIVAN: He was given -- it's fair cross --

THE COURT: I understand there's some legitimate issues, but I also do understand the potential for prejudice to this trial and the jury. So what is it exactly that you want out of Goldstein?

MS. SULLIVAN: And, Your Honor, I would submit that it's fair cross-examination, a report that they chose to give him, I mean, as part of his reliance materials, it's fair cross to say the endocrinologist who they hired as an expert disagrees with your opinion on X, Y and Z, and point to Dr. Goldstein's report.

MR. KLINE: Highly prejudicial.

THE COURT: No, I can't permit that. The reason I can't permit it is that Goldstein himself is not here to explain that report. Just like we don't have the expert report itself read to the jury. We have actual witness testimony. We can't do that here, and have testimony on one side and the report on the other without having Goldstein present. Since Goldstein is not present for cause shown, I can't permit that that way.

MS. SULLIVAN: We have testimony from

Goldstein as well, Your Honor.

THE COURT: Pardon me?

MS. SULLIVAN: We have deposition testimony from Goldstein, Your Honor.

MR. KLINE: Same thing.

THE COURT: Well, frankly, you're going to have to show me how that's admissible here.

MS. SULLIVAN: And, Your Honor, we have testimony from Solomon who says he disagrees with Goldstein.

THE COURT: Well, you can do anything from Solomon --

MS. SULLIVAN: Okay. I'll do it that way, Judge.

THE COURT: -- as far as Goldstein is concerned. I'm not making a ruling in advance on that.

But I really think that the answer is, I will couch the Goldstein situation then in my own language to minimize any prejudice to either party in this case, if that comes up.

MR. KLINE: I would respectfully request that the jury not be told at all that

in any way, shape or form because it would be -- it would be -- it would be gravely prejudicial.

THE COURT: But, Counsel, how do you deal with the fact that Ms. Sullivan did in fact refer to your witness, Dr. Goldstein, in her opening argument? What do you -- what should be said about that?

MR. KLINE: That's a simple thing, too. That's actually pretty simple, okay? If I may be heard uninterrupted for less than two minutes.

MS. SULLIVAN: I haven't interrupted you at all.

THE COURT: Go ahead. I've been interrupting him.

MR. KLINE: The answer -- the answer is simple. Witnesses for many reasons in cases become unavailable. My word, witnesses have heart attacks during cases. Witnesses die during cases. Witnesses have accidents during cases. Witnesses have -- witnesses refuse to come to court in cases. I've been involved in various scenarios. Under those circumstances, substitute witnesses are

allowed. The jury needs and should know nothing, nothing, about the prior witness who the Court, for good cause shown, allowed us to substitute.

Now, we were allowed to substitute an expert witness. We substituted that expert witness. We have that expert witness in play.

Imagine this scenario, Your Honor, Dr. Goldstein who's actually -- I hate to use elderly, so I won't. He's a man of 72 years old. What if he had -- what if he had developed some disease? Why, the Court would have allowed me to substitute.

MS. SULLIVAN: No. We'd have a mistrial.

MR. KLINE: Not necessarily.

And there are all kinds of circumstances. And under these circumstances, the only fair -- there's no prejudice created at all to defend and to be able to wale -- this is the word I'd like to use -- and whack -- I'd like to use that word, too -- away at Dr. Solomon. They're allowed to do that so long as they conform to

the rules.

But what would be enormously prejudicial is to tell this jury that for good cause shown Mr. Kline was allowed to get an expert. That raises more questions than it -- than it -- than it stops. And you can't, without prejudicing the plaintiff, you absolutely, in my view, cannot mention Dr. Goldstein, Dr. Goldstein's opinions, Dr. Goldstein's anything. They knocked him out. They filed a motion that said he was disqualified and the Court allowed -- granted their wish.

MS. SULLIVAN: No.

MR. KLINE: Their wish. They can't -- you promised not to.

You cannot have them be the beneficiary of having the jury know that I had some expert and some late expert in the case.

The only way to handle it, and I consider -- I suggest that the Court might want to think about it over the lunch hour without us here -- the only fair way to handle it is to tell the jury to consider the

experts straight up on who they are and what they've said. That's a fair trial. Anything short of it would be unfair.

THE COURT: So did Dr. Goldstein -- did his name come up in the deposition on Sunday?

MS. SULLIVAN: Yes.

MS. BROWN: Yes, repeatedly.

THE COURT: And what was --

MS. SULLIVAN: And how he disagreed with -- we're trying a whole new case, Judge, than the one that they opened on.

THE COURT: Well, that's the part that I don't really buy. I just don't buy that, in the sense that if I felt there was undue surprise involved here, I would not allow it to continue. There just isn't. There's no undue surprise. You've taken his deposition, of Solomon, many times. You've probably taken Goldstein's deposition, you just said. There is no surprise here.

It may be that they're proving causation in a different manner, but it's not a manner unknown to you. So I don't go for that, that there's a whole new trial going on

here.

It's sort of like if you had a trial and then all of a sudden, they changed their strategy in the middle of trial, going back to homicide, and it's a different theory now. Instead of third degree, you know, they're trying to prove something else. I don't buy that.

The only question I have is whether or not a reference to Dr. Goldstein has been shown to me to be probative in any meaningful way against the prejudice that would exist here. And I don't need any lunch break for that.

I do know that the references to Dr. Goldstein opens up a can of worms in this case that exposes the jury to prejudice to both sides and to this Court and to them and raises the risk of an unfair trial. Therefore, there will be no reference to Dr. Goldstein in this case, and that is an order of this Court, all right?

MR. KLINE: All right. Thank you, Your Honor.

MS. SULLIVAN: We move again for a

mistrial, Your Honor.

THE COURT: I understand you're moving for a mistrial. That's denied.

MS. SULLIVAN: Thank you, Your Honor.

Your Honor, can we mark this as a court exhibit, the proposed jury instruction?

THE COURT: About the jury instruction, you can mark that as well.

I would note for the record, I will read the jury instruction for the record to explain my -- further explain -- we have the one matter here involving the proposed jury instruction, which I think I will read into the record. I also believe that it illustrates the reason for my previous decision.

This says, "Dear Judge Djerassi, given the introduction of a new expert witness, Janssen respectfully requests that the Court issue the following jury instruction as follows: 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 now not going to appear at this trial. Plaintiff has substituted a new expert, Dr. Mark Solomon, in place of Dr. Goldstein."

This is denied.

I also do believe that that illustrates the Court's concern about going into inadmissible evidence in this trial that is prejudicial; for example, in the very jury instruction proposed, it had to do with plaintiff -- examining plaintiff in a hotel room in a Alabama. Completely irrelevant --

MS. SULLIVAN: That was part of the opening statements.

THE COURT: -- completely irrelevant to a fact finding of opinion evidence in this case. It may be relevance for the purposes of the review as to whether a cause was shown or not. It's part of the trial record. But certainly that is the concern that this Court would have; that there would be inability of this Court to contain prejudicial evidence in this case when probatively it hasn't been shown as to outweigh the prejudice. That is

the ruling of this Court, okay?
So see you guys after lunch.
MR. KLINE: What time are we back, Your Honor?
THE COURT: I'd like to be back here at 1:15.
MR. KLINE: 1:15?
THE COURT: 1:30, all right. Okay. 1:30.
(Sidebar discussion concluded.)
- - -
(Whereupon a luncheon recess was taken.)
- - -
(Whereupon the Afternoon Session was reported and transcribed by Judith Ann Romano, CRR, Official Court Reporter.)
- - -

C E R T I F I C A T I O N

I hereby certify that the proceedings and evidence are contained fully and accurately in the notes taken by me on the trial of the above cause, and that this copy is a correct transcript of the same.
I further certify that I am not a relative or employee of any attorney or counsel employed in this case.

_____
John J. Kurz, RMR, CRR
Registered Merit Reporter
Certified Realtime Reporter
Official Court Reporter

(The foregoing Certification of this transcript does not apply to any reproduction of the same by any means unless under the direct control and/or supervision of the certifying reporter.)

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IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
CIVIL TRIAL DIVISION

IN RE: RISPERDAL® LITIGATION March Term, 2010, No. 296	:	
PHILLIP PLEDGER, by BENITA PLEDGER, as Guardian of his Person and Conservator of his Estate, Plaintiffs,	:	APRIL TERM 2012
v.	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, and Janssen Pharmaceutical Research and Development, L.L.C. Defendants	:	NO. 01997

- - -

MONDAY, FEBRUARY 9, 2015

VOLUME XI
AFTERNOON SESSION

- - -

COURTROOM 425
CITY HALL
PHILADELPHIA, PENNSYLVANIA

- - -

B E F O R E: THE HONORABLE RAMI I. DJERASSI, J.,
and a Jury

- - -

REPORTED BY:
JUDITH ANN ROMANO, CRR
CERTIFIED REALTIME REPORTER
OFFICIAL COURT REPORTER

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(Hearing is reconvened at 1:45 p.m. and the following transpired in open court out of the hearing of the jury:)

MR. MURPHY: Your Honor, if I may before the jury comes in, before we broke there were a number of inappropriate comments made regarding a witness who has not appeared and who may yet not appear on behalf of the defense, comments made by Mr. Kline. Also commentary made about the salaries of the lawyers who represent J&J, and the ongoing, unchecked tirade against Ms. Sullivan, all prejudicial, Your Honor, and for the record we move for a mistrial on this basis.

THE COURT: Do you wish a cautionary of any sort?

MR. MURPHY: I would.

THE COURT: Draft one and we will look at it.

MR. MURPHY: But you deny my motion, I take it.

THE COURT: I haven't denied anything. I need to see a cautionary. What I am saying to you is, as far as I can tell, it's

certainly within the possibility of an instruction if requested that could be made, for me to repeat to the jury that the commentary by both counsel in this case is really not helpful to a resolution of the facts that the jury has been charged with. I see it as a back-and-forth between counsel that has been not helpful. It's not just one attorney to the other.

I understand that this case has some issues involving an expert witness that has been discussed at sidebar on the record, and frankly, I do wish that counsel would manage to try this case without all the bickering.

MR. MURPHY: I understand that, but I have made a motion and I --

THE COURT: That's denied. I will certainly reserve the right to give a cautionary, as I said. Go ahead.

(At this time the jury enters the courtroom.)

THE COURT: All right, members of the jury, we are going to resume the examination of Dr. Solomon. Let me just remind you again,

and I think we have done it before, but we are being plagued a little bit, I think, by back-and-forth commentary between the attorneys, the lead trial attorneys. I have told them, and I am going to tell you what I have told them, which is it's not helpful to your job, because your job is to listen to the evidence, which is the answers that come from the witnesses and not the personality contest between any lawyers.

And so from that point of view, I am cautioning you again to just to follow the trend of the answers to the questions. I am doing my best to get the lawyers to be more humble toward each other. We are working on it.

So with that, Mr. Kline, you may proceed on the examination of Dr. Solomon.

MS. SULLIVAN: It's my cross, Your Honor.

THE COURT: I am sorry, cross examination by Ms. Sullivan is where we left off.

MS. SULLIVAN: Thank you, Your Honor.

(MARK P. SOLOMON, MD, having been previously sworn, resumes the witness stand.)

- - -

CROSS-EXAMINATION (Continuing)

- - -

BY MS. SULLIVAN:

Q Good afternoon, everyone, thank for coming back. Good afternoon, Dr. Solomon, thank you for coming back. Dr. Solomon, we left off talking about your examination of Mr. Pledger and I want to go back to that if I could.

So you examined Mr. Pledger last week in your office?

A Correct.

Q And when you examined Mr. Pledger he had not been on Risperdal for about eight years, correct?

A Correct.

Q In fact, he had been on another antipsychotic, Geodon, for most of those eight years, correct?

A Correct.

Q And you know, Dr. Solomon -- or do you, do you know that antipsychotics generally can elevate prolactin and have reports of gynecomastia?

A Not to the extent of Risperdal, but I am aware

that they do it, that's correct.
Q Do you know that Geodon has a label that says that it elevates prolactin and gynecomastia has been reported?
MR. KLINE: Objection.
THE COURT: Overruled.
A As I stated, I am aware that that class of drugs has a history of elevating prolactin, but not to the extent of Risperdal.
Q But when you examined Mr. Pledger he had not been on Risperdal for eight years, he had been on Geodon for most of those eight years?
MR. KLINE: Objection, asked and answered.
THE COURT: That is sustained.
Q And, Doctor, you will agree that you cannot determine based on physical examination how long somebody has been -- let me rephrase that. You will agree, Doctor, you cannot tell based on physical examination alone for how long someone has had gynecomastia?
A That's not true.
Q Can I show you, Doctor, your deposition in the Goldenberg matter, on page 111, 24.

Doctor, do you see starting on line 24, you were asked the question, "Can you make that determination solely by looking at the individual's body without other information?
"A The diagnosis of" --
And then there was an objection, "What determination, that he has gynecomastia or how long the gynecomastia has been there?
"Q How long it's been there."
And then you answered: "Oh, how long the gynecomastia has been there is not something you can determine solely on physical examination. That's correct."
I have read that correctly?
A But your question was something different, so that we are clear. You need the physical and the history to make the diagnosis of the duration. So you can diagnose the condition, but the duration requires the historical question, which Mrs. Pledger assured me it started two to three months after he started taking the drug, then we know he had established gynecomastia in 2005 on the picture we discussed earlier.
So we know that from at least 2005 on

photographic evidence he had gynecomastia and he was not on Geodon or any of the other antipsychotics in 2005. We can agree on that.
Q Dr. Solomon, do you remember my question? It was pretty simple: Can you diagnose how long gynecomastia existed based on physical exam alone?
A And I said in line 12, It's not something you can determine solely on physical examination, you need a history. That's what I am trying to make sure you understand. I know the jury understands that.
Q In your testimony you didn't say you need a history, you said you can't diagnose gynecomastia solely on physical exam alone.
MR. KLINE: Objection.
THE COURT: Sustained.
Q Doctor, when you examined Mr. Pledger just last week you didn't do any testing at all, did you, sir?
A I am not sure what you mean by "testing".
Q You didn't run any blood work?
A That's correct.
Q You didn't see if his prolactin was elevated while he was on Geodon?

A I would need to do blood work. I already answered I didn't do any blood work.
Q And you didn't do any X-rays or ultrasound to confirm the diagnosis of gynecomastia?
A I don't typically do that.
Q And in fact, you didn't do any testing at all?
A I did a physical exam. That's a test.
Q You didn't --
A No laboratory test or ancillary test, but it is a test.
Q You didn't do any diagnostic testing at all, sir?
MR. KLINE: Objection. Asked and answered.
A Physical --
THE COURT: Hold on. If there is an objection from an attorney, don't answer until we make a ruling. The objection is sustained.
Q Doctor, I think you told the jury that on your physical exam you confirmed that some of Mr. Pledger's enlarged breasts was due to fatty deposits?
A I don't believe that's my testimony.
Q Can we take a look at your -- you gave a

deposition yesterday?

THE COURT: You said the testimony. Are you talking about deposition?

MS. SULLIVAN: Yes, sir.

A I am happy to review the deposition if you have it.

Q Doctor --

THE COURT: One minute. It's the first I have seen this document. All right, it's now D-48.

(D-48 is marked for identification.)

Q Doctor, on page --

A I don't have it. May I have a copy of it?

Q I am sorry, I thought you had it, sir.

THE COURT: What page?

MS. SULLIVAN: Sixteen, line 23.

THE COURT: So, Doctor, why don't you review the overall context of this and then answer the question.

Q Dr. Goldstein, you were asked on line 23 --

THE COURT: Dr. Solomon.

Q I am sorry, Dr. Solomon, you were asked on line 23: "In your opinion did Mr. Pledger have some fatty tissue in his breasts, is that right?"

And you answered, "Some."

A That's correct.

Q And, Doctor, you were not able or you didn't do anything to quantify how much fatty tissue Mr. Pledger had in his breasts during your physical exam?

A I believe I stated so in the deposition yesterday, that's correct.

Q That you weren't able -- you didn't do anything to quantify how much fat?

A I believe I stated that.

Q And so you didn't do anything to determine the degree that his breast volume was due to obesity versus due to glandular tissue?

A That's a different question.

Q Doctor, how much of his breast volume was due to obesity?

A Not much.

Q Did you do anything to quantify it?

A I examined him.

Q How much?

A His breast tissue occupies probably 70 to 80 percent of his breast. You may recall, as I showed earlier, there is fat intimately associated

with the breast and also there is fat under the skin. So you can't separate out all the fat. But in terms of what I felt, there is breast tissue. There is no doubt in my mind about that.

Q But you weren't able to quantify the amount of fatty tissue in his breast?

MR. KLINE: Objection. Asked and answered.

THE COURT: I thought I heard an answer to that question. Sustained.

Q Dr. Solomon, you issued an expert report in this case?

A I did.

Q And you list the things that you reviewed on the first page of your report. Do you have it, sir?

A I do.

Q And the report, if you take out the list of things you reviewed, is just a page and a half, right?

A The list is not -- the list is a page.

Q Your report on this exam and your opinions in this case, it's just a page and a half, right?

A It is a page and a half.

Q Yeah. In your expert report you don't cite a

single medical article at all, right?

A In 30 years I don't think I have ever cited a medical journal article in an expert report.

Q So you gave your expert opinions and you didn't cite to any medical literature or medical article in support of those opinions in your report, correct?

A I am happy to discuss if you ask me.

Q My question is, Doctor, you gave your opinions in this case in a page and a half and in support of your opinions up didn't cite a single medical article or a textbook, right?

MR. KLINE: Objection, asked and answered. Objection, the deposition was given yesterday.

THE COURT: I believe that's sustained because I think we have the answer already to that question. It's not in his expert report. Now what that means I have no idea, and we are waiting.

Q Did you see the reports of other experts in this case?

MR. KLINE: Objection.

THE COURT: That's sustained.

(Solomon - Cross)

Q Did you see the reports of defense experts in this case?

MR. KLINE: Objection.

Q In fact, you were sent them by Plaintiff's counsel, right?

THE COURT: Objection is sustained. I think there is a list of one through 22, with the exception of one of those, is all admissible.

Q Yeah, and so, Doctor --

THE COURT: Anyone you want to ask him of those documents except for one of those --

MS. SULLIVAN: Understood, Your Honor.

THE COURT: -- is fair game.

MS. SULLIVAN: Yeah.

Q Doctor, did you review any of the expert reports in this case?

A It so states in the report that I reviewed them. They are listed as line items. You should be able to see them.

Q And you actually reviewed them?

A Absolutely.

Q And did you notice that, for example, the defense expert report from Dr. Braunstein and Dr.

(Solomon - Cross)

Vaughan, they cited a whole bunch of medical articles and textbooks in support of their opinions?

A They are not surgeons, they don't really do this kind of stuff all the time. That's exactly why they need to do that.

Q They are actually endocrinologists, right?

A That's my point.

Q But it's your position because you are you, you don't have to cite any medical support for your opinions?

MR. KLINE: Objection.

THE COURT: Sustained. Argumentative.

Q And, Doctor, you actually said in relation to your diagnosis of Mr. Pledger that you can diagnose gynecomastia because, "If it walks like a duck, talks like a duck, quacks like a duck, it must be a duck." Right?

A Actually, in the context, I think that's in my deposition from yesterday, is that correct?

Q Yes, sir.

A Can we have the line and page in context for the jury?

Q Sure. It's on page 112 to 113.

A Which deposition, I am sorry?

(Solomon - Cross)

Q Your deposition from yesterday.

THE COURT: One second. Marianne --

A Oh, yes, I am sorry, the bottom of 113.

Q Yeah, and you say, There is an expression that I learned in medical school which is, "If it looks like a duck, it walks like a duck, it's a duck." And if you are exposed to a drug that's known to elevate prolactin, which according to the package insert causes 2 percent incidence of pubertal -- gynecomastia, and that pubertal gynecomastia is zero, this boy has gynecomastia and I think it's caused by that agent. Right?

A Can I read the entire paragraph? You missed some key words there.

Q Go ahead, doctor?

MR. KLINE: It was prepubertal, Your Honor.

THE COURT: Wait a minute. This is a conversation that's happening without -- where is this?

MS. SULLIVAN: Your Honor, this is his deposition from yesterday, on page 112 and 113.

THE WITNESS: It's page 113, line 19 is

(Solomon - Cross)

where it starts, Your Honor.

THE COURT: So I really need some clarification. What was the question that brought us to this deposition?

MS. SULLIVAN: My question was that he said, in part, that he diagnosed gynecomastia in Mr. Pledger because, "If it looks like a duck, it walks like a duck, it's a duck."

THE COURT: So the point is, is there a question that's associated with that statement in yesterday's deposition?

MS. SULLIVAN: Yeah, did he say that?

THE COURT: Did you say that?

MR. KLINE: Your Honor, objection. There is nothing inconsistent. That would be the basis for the use of the deposition.

THE COURT: Is there an objection to whether he said that or not?

MR. KLINE: No, it's an objection to it not being contrary to anything he said in the deposition.

THE COURT: I will permit if he said it. Did you say that yesterday?

THE WITNESS: Not in that context, Your

Honor. I think context is important.

THE COURT: Then you may answer.

A The context in which I was asked had to do with causation, meaning that I had eliminated all of the other possibilities that would cause gynecomastia, and the only one left, without any doubt, in Austin Pledger is his exposure to Risperdal in 2002 to 2007, which caused prepubertal, that means before puberty, gynecomastia, where I went on to say in this testimony that the incidence of gynecomastia before puberty in a boy is zero.

So that the only cause is Risperdal. That's the context in which I said if it walks like a duck and it looks like a duck, it's a duck. And I did learn that in medical school and that's why I said it.

Q Did you also learn in medical school, Doctor, that gynecomastia, you know it when you see it, like pornography?

A I actually learned that reading some Supreme Court literature, but it's a similar kind of concept.

Q And that's also something that you concluded, that you can tell, like when you see pornography, if

somebody has got gynecomastia, you know it when you see it?

MR. KLINE: Objection.

THE COURT: Sustained. I think we have been over that more than once.

Q I want to talk about Mr. Pledger's -- you agree, Dr. Solomon, that Mr. Pledger suffered from obesity throughout most of his life?

A I would not say it quite that way.

Q Well, let's pull out the records then, sir. You reviewed his medical records, right?

A I have.

Q And do you know, sir, that before he started taking Risperdal he was obese?

A I think he was overweight, I wouldn't describe him as obese.

Q And do you know that his treating doctor described him as obese, before taking Risperdal?

A If you show me that sentence I am happy to review it. I don't recollect it from the record.

Q And do you know, sir, that he was -- when he was seven, 4 feet 4 inches tall and 96 pounds?

A I am sorry, I didn't follow what you just said.

Q Do you know how tall or how heavy he was before he started taking Risperdal?

A Again, if you show me the medical record I will know it instantly, but I am not going to guess here.

Q So you don't know?

A I don't think that's what I said.

Q Well, do you know?

THE COURT: Do you remember?

THE WITNESS: I don't remember.

THE COURT: Do you have the document to refresh his memory?

Q I will show you a weight chart from Dr. Dy. Do you know who Dr. Dy is, Dr. Solomon?

A I believe it's his pediatrician.

MS. SULLIVAN: We will mark this as Defense Exhibit 49.

Any objection?

MR. KLINE: I didn't see it.

THE COURT: What document is this now?

MS. SULLIVAN: It's part of his pediatrician's medical records.

THE COURT: Has this been admitted so far in this case?

MS. SULLIVAN: No, sir.

THE COURT: Why don't we do that, unless there is an objection.

MR. KLINE: I don't believe it's the right timeframe she is talking about. It's 2007-2008. If that's what she wants to put in front of him, I agree it's the medical record.

MS. SULLIVAN: While we are pulling the timeframe --

THE COURT: Whatever you wish, Ms. Sullivan, I just need to know that D-49 is a document that has not been introduced before, so I want to know if you want to have the witness look at it, then let's either have an objection or not an objection to this document. Whatever it stands for is what it stands for. I don't really care.

MS. SULLIVAN: Is there any objection? It's his medical record.

MR. KLINE: No.

(D-49 is marked for identification.)

THE COURT: No objection, all right.

Q And if we look, Dr. Solomon, do you recall, sir, that he stopped taking Risperdal in mid to late

April of 2007?
A Around that time period. He has been exposed to it now for five years at that point.
Q So in April of 2007, Mr. Pledger is 194 pounds, right? According to his family doctor or pediatrician, right?
A Correct.
Q And after he stops taking Risperdal, he actually gains about 126 pounds off of Risperdal, right, if we look over the next four years, if we look at the October 25, 2011 entry, do you see that?
A So that's a four and a half year period where he went from being about, I think 13 to, what's that 18, maybe, 19? So he grew, so it's partly that, and it's partly his exposure to the other drugs of the same class that are all known to cause weight gain. He absolutely gained weight, no one has denied that.
Q So he gained, according to Dr. Dy's chart, about 126 pounds after he stopped taking Risperdal?
A My math is 125, but --
Q Okay, I will take it. 125 pounds in the years after Risperdal. And 321 pounds for a man of his height puts him in the morbidly obese category, correct?

A I have not done a BMI calculation, Body Mass Index, but I would think that's it, yes, that's correct.
Q And to his credit, Dr. Solomon, Mr. Pledger by 2012 and by the time you saw him, had lost some weight?
A About 70 pounds, thereabouts.
Q But the 264-265, and the weight that you recorded would still put him in the obese category, correct?
A He is overweight, as I described.
Q He is actually clinically obese, correct?
MR. KLINE: Objection. Asked and answered.
THE COURT: That's overruled. However, Ms. Sullivan, as I recall, weren't we asking about what his obesity was at the time that he first took Risperdal?
MS. SULLIVAN: We are asking that while Ms. Brown --
THE COURT: Where is that document? That's the one I thought was relevant here. I am not sure how this is relevant to the line of question you had earlier.

MS. SULLIVAN: This is relevant to the case, Your Honor, I am trying to save time.
THE COURT: I understand. Let's be straightforward here for our jurors.
Q Did you read Dr. Mathisen's testimony in this case?
A I reviewed Dr. Mathisen's records. I did not, according to my report, I did not review his testimony.
Q And if we look at Dr. Mathisen's records, do you have -- we don't have a copy in evidence.
MS. BROWN: It's already in evidence, P-1, Dr. Mathisen's chart.
Q Dr. Solomon, do you dispute that he was obese before he started Risperdal?
A Before he started Risperdal?
Q Yes, sir.
A I requested that you show me his records so that I can make that determination because I don't want to guess and I don't have a recollection.
Q You don't know, okay.
A So I don't think it's fair to the jury or the Court for me to guess.
THE COURT CRIER: Showing P-1 to the

witness.
Q Doctor, if you turn to page, on the bottom right-hand corner, 446 of the records. Do you see that, sir?
A Yes.
Q And do you see he records the weight of 44 kilograms, right?
A That's correct.
Q And do you know that that put him in the obese category?
A Well, you are not showing me a curve that would do that. It is 44 kilograms. It is what it is I think is the way I would answer that.
Q And that's over 90 pounds?
A I don't think it's over. I think it's about.
Q About 90 pounds, okay, and he is seven years old. And then there is a weight chart where Dr. Mathisen -- and this is on page 472 -- where Dr. Mathisen records where he is in terms of his height and all of the weight measurements are in the obese category. Right, Dr. Solomon?
A Show me where you are pointing to that? Because my copy is a little fuzzy here.
I don't believe it says obese here.

(Solomon - Cross)

Q You are referring to his treating doctor who actually saw him?
A But I don't see any statement --
MR. KLINE: Objection to it not having the dates on the chart.
THE COURT: Objection is sustained. If the doctor is able to answer the question, great, if not, I am sure you will have your expert to explain that document.
MS. SULLIVAN: I will move on, Your Honor.
Q Doctor, going back to Dr. Dy's chart, we know that Mr. Pledger gained a significant amount of weight in the years after Risperdal?
A I believe I even discussed that in my report, that's correct.
Q And you saw from his medical records that he did not have the healthiest of diets as it relates to his autism? Did you see notations about the kinds of food he ate?
A I did.
Q And you will agree that he ate a lot of fatty food?
A He ate food common to the diet that children

(Solomon - Cross)

eat in America in the 21st century.
Q Do you know, sir, or did Mrs. Pledger tell you that children with autism have fixations on certain foods, in particular fatty foods?
A And in fact, she told me they worked very hard to move those fixations away and put him on a treadmill so he would lose 70 pounds, which he did.
Q And in fact, Dr. Solomon, Mr. Pledger gained a lot more weight off of Risperdal than he ever gained on Risperdal?
A He also grew over the intervening, how many years is that, seven years?
Q Yes.
A So he went through adolescence. Remember, he was preadolescent when he started the drug, and it's my understanding that that's the focus of our discussion, his preadolescence.
Q He also grew in the five years he was on Risperdal?
A That's true.
Q And he gained a lot more weight off of Risperdal than he did on Risperdal?
A If you say.
Q Well, you read his records?

(Solomon - Cross)

A Again, I agree with this chart. I think that will make this all a lot easier for us.
Q And even after losing some weight, Mr. Pledger is obese today?
A I would describe in the overweight category.
Q He has a BMI, according to your -- you weighed him at 257 pounds?
A I believe that's what I said.
Q And if we do a BMI, that would put him at 33, and that's in the obese category?
A Okay.
Q Did you not do a BMI?
A That's correct, I did not calculate his BMI.
Q And, Doctor, I think you told our jurors when he lost weight from when he was morbidly obese, 321, until the time you saw him, he lost some fatty volume in his breasts?
A I think my exact words were he lost the fat in his breasts, and the only thing remains is breast tissue.
Q But he is still obese today?
A You just asked me about his breasts.
Q Right.
A He has breast tissue.

(Solomon - Cross)

Q And you also stated he has some fatty tissue as well?
A In his body, that's correct.
Q And in his breasts?
A Again, you are mischaracterizing my testimony, but he had some fat in his breasts, that is correct.
Q And, Doctor, looking at your notes from the medical exam, I am pulling out your expert report.
By the way, these pictures that you showed our jurors of slides, these aren't Mr. Pledger, right?
A That's correct. They are from a textbook.
Q You didn't do anything to look at his -- on the cellular level at Mr. Pledger?
A That's correct.
Q And if we look, Dr. Solomon, at your notes from the exam?
THE COURT: Has that been marked now in this courtroom?
MS. SULLIVAN: Yes, Mr. Kline used them, Your Honor, and it is Plaintiff's Exhibit 81.
Q Dr. Solomon, these are your notes from your exam of Mr. Pledger last week?

A Yes.

THE COURT: Do you have a hard copy?

THE WITNESS: I actually do.

MR. KLINE: Your Honor, may we see you at sidebar for something I believe is important enough to ask?

THE COURT: All right.

(The following transpired at sidebar out of the hearing of the jury:)

MR. KLINE: Your Honor, you can see from here she is examining him in an unorthodox way. She has her books opened to the jury and they are all looking over to it. I wouldn't bring it to the Court's attention but she has her, essentially, the jury looking into counsel table with documents, some of which are admissible, some of which aren't, and her notes, which are right now open and exposed to the jury.

THE COURT: We will take a recess right here for a minute.

(The following transpired in open court:)

THE COURT: Ladies and gentlemen, we

will take our recess right here for about five minutes.

(The jury exits the courtroom and the following transpired in open court:)

THE COURT: We are on the record here. There is a concern by counsel that some of the materials -- it reminds me of in a criminal case where you had the gun on the table right next to the jury box.

MS. SULLIVAN: Oh, come on, Judge.

THE COURT: Some judges permit that, some don't. This Court does not permit that. So therefore, any non-admissible documents that may be observed by the jury should be placed on a podium or something out of the presence of the jury, just as a precaution. That can go either way. But I do know that in criminal cases that was a favorite of prosecutors, and on the defense side they had their own tactics.

MS. SULLIVAN: Just for the record, Your Honor, the documents that are on this table are all Plaintiff's exhibits except for Dr. Dy's weight chart which the Court has

admitted.

THE COURT: I understand. It's difficult to -- remember, counsel, you are using the courtroom in a way that I am permitting, but normally, counsel asks their questions from the bar, from where you are seated. And if there is a complaint here that jurors who are 3 feet away from you are looking at your notes and your documents which are not admissible, that's a fair concern.

So if there is some way of keeping your notes protected from the jury then stay where you are. If not, come back to the table and ask the questions from here. All right.

MR. KLINE: What I specifically object to is her with her back -- with her books open to the jury to look into them. That's exactly what's going on. I have never seen that. And I would just ask that she be straight on to the witness.

THE COURT: You must not have practiced criminal law. That was routine.

MS. SULLIVAN: I will move here, Mr. Kline, will that make you happy?

THE COURT: That might be a little better, Ms. Sullivan.

THE COURT: That was routine, where the ammunition, the gun, the bloody shirt was all on the table right in front of the jury. Some courts would permit that, by the way, because it's not reversible, and some would not.

It just so happens this Court will not permit that. We want as unbiased a case as it can possibly be.

MS. SULLIVAN: Does that go the same for counsel? The jury is right here looking at his stuff, Judge.

THE COURT: I am aware of that. I don't think you have any open books, do you?

MR. KLINE: No, of course not.

MS. SULLIVAN: He has a bunch of documents there.

MR. KLINE: In fact, my notes are actually down. And I look at a witness.

THE COURT: Both counsel, be aware of these type of extraneous issues, but anyway, we are going to take a five-minute recess and resume.

(A brief recess is taken at 2:22 p.m.)

(The following transpired in open court out of the hearing of the jury:)

THE COURT: I really can't do much about the schedules of professionals in this courtroom. We are all professionals and we have all kind of timing issues ourselves. Please be seated. If you need to make a call to your office, you may do so, but I can't reschedule it until tomorrow morning. We have a live jury here.

THE WITNESS: Your Honor, I do understand. I have live patients who rely on me as well.

THE COURT: Unfortunately, the live jury takes precedence.

THE WITNESS: I understand. My concern is that, looking at the way things are moving --

THE COURT: You will be finished by 5 o'clock today guaranteed. You might want to postpone your patients today until tomorrow morning, but you are guaranteed to be done here by 5 o'clock.

MR. KLINE: Dr. Solomon, there you have it. Please, Dr. Solomon.

THE WITNESS: May I make a phone call for a minute then?

THE COURT: Sure.

(Pause.)

(The jury enters the courtroom at 2:45 p.m.)

THE COURT: All right, counsel, you may proceed.

MS. SULLIVAN: Thank you, Your Honor.

BY MS. SULLIVAN:

Q Dr. Solomon, before the break we were looking at your exam notes from Mr. Pledger's exam that you did last Tuesday evening, right? And this is the exhibit we were talking about. And so Mrs. Pledger gave you a history on Tuesday evening when you examined her son, right?

A That's correct.

Q And she told you that he had started gaining weight right away, right, in terms of when he was on Risperdal?

A That's correct.

Q And she said the breast development began

immediately, right?

A That's correct.

Q And then, as I read your deposition, you probed her further to see what she meant by "immediately", right?

A That's correct.

Q So you got her to say within two months?

MR. KLINE: Objection.

A I didn't -- that mischaracterizes --

THE COURT: Well, sustained as far as the phrasing of that question.

Q Mrs. Pledger told you that the breast growth happened immediately, and then you asked her some more questions, and you concluded within two months?

A That mischaracterizes my deposition testimony and the facts. The facts are that, as I stated in my deposition, patients say things, I write them down, I ask further questions to get a better time course.

So she used the word "immediately" and I said please tell me what that means to you. And as we explored it, she said within two months.

Q But her first comment to you was that it happened immediately, and you wrote that down?

MR. KLINE: Objection.

THE COURT: Sustained.

Q And, Doctor, when we look at your report, the two months grew to two to three months, right?

A When I dictate the report that's my recollection of the notation.

Q So she told you immediately, you wrote two months, and then when you did your report you moved it to two to three?

MR. KLINE: Objection, Your Honor.

THE COURT: Sustained.

Q Nothing in your notes in terms of your history from Mrs. Pledger talks about three months, right, Doctor?

A Correct. Two months makes sense given the facts we know about the drug.

Q Yeah, but in your report you stretched it out to two to three months?

MR. KLINE: Objection.

THE COURT: Sustained.

Q Mrs. Pledger never said three months?

MR. KLINE: Objection.

THE COURT: I don't know. Overruled.

A I don't recall.

Q And Mrs. Pledger told you that she thought the breast growth was consistent with his weight gain? Right?
A I did not use the word "consistent", I said "due to".
Q She told you, I thought it was due to weight gain, the breast enlargement?
A That's correct.
Q And you wrote that down?
A That's correct.
Q And incidentally, Doctor, she told you that he lost about 30 pounds, he was able to lose about 30 pounds while he was on Risperdal, right?
A My note says approximately between 2004 and 2005.
Q Yeah, which would have been when he was on Risperdal?
A That's correct. In fact, that's consistent with the pictures of the gynecomastia in 2005. So he had lost some weight even before that picture was taken, I presume.
Q So Mrs. Pledger tells you that he starts gaining weight immediately, that she thought the breast growth was due to weight gain, but you

believe it was gynecomastia based on your review of this swimming pool picture, right?
MR. KLINE: Objection. Three questions in one.
THE COURT: Sustained.
Q Doctor -- I will reask it. Doctor, Mrs. Pledger told you that he started gaining weight in his breasts immediately?
A Within two months, as we noted.
Q Right, she said immediately and then you probed further?
MR. KLINE: Objection.
THE COURT: Sustained. Sustained, unless you are going to backtrack.
Q But notwithstanding what she told you, you said, it's not weight gain, I am looking at this pool picture, it's gynecomastia, right?
MR. KLINE: Objection.
THE COURT: Overruled. Overruled. You can answer that if you understand it.
A To the extent that I understand it, which isn't great, it mischaracterizes my testimony.
Q Well, Doctor, your diagnosis of gynecomastia in this case is based on this swimming pool picture,

in terms of him having it on Risperdal?
A My diagnosis of gynecomastia is based on my history, my physical examination, my 30 years of experience as a plastic surgeon treating patients with gynecomastia. That's how I make a diagnosis.
Q Well, do you think you can diagnose gynecomastia based on a photograph?
A There are many things as a plastic surgeon that I can diagnose based on a photograph.
Q So you, Doctor, believe that you, Dr. Solomon, can diagnose gynecomastia based solely on a photograph?
MR. KLINE: Objection.
THE COURT: Overruled.
A Solely? It depends on the photograph, the circumstances, but I think if you review what I said earlier today, we use photographs the way orthopods use X-rays. So orthopods can diagnose a fracture on an X-ray. It's helpful to talk to a patient and take a history and do an exam, but the X-ray is certainly diagnostic.
I can look at somebody, because of my training and experience, and diagnose things. I can see somebody from across the room and diagnose

things. That doesn't mean I get the whole picture, but I certainly get a large part of it.
Q And, Doctor, you said in your direct exam with Mr. Kline that Mrs. Pledger told you that her son developed enlarged nipples while he was on Risperdal. Do you remember that testimony this morning?
A I don't think I used the word "nipple", but that's somewhat consistent with what I said.
Q That's not reflected in your notes in terms of the history you got from her, though, right?
A Did I write it down? No. Did she tell that to me? Absolutely.
Q But you wrote down the key parts of the history and that doesn't appear anywhere in your notes?
MR. KLINE: Objection, asked and answered.
THE COURT: Sustained. How long was this history, by the way, Doctor, when you took it?
THE WITNESS: Talking to them?
THE COURT: Yes.
THE WITNESS: Half hour, 45 minutes.

THE COURT: So if I read this, it would take how long to read that?

THE WITNESS: How long would it take you to read my medical shorthand?

THE COURT: Yes.

THE WITNESS: It's two pages.

THE COURT: So the jury can understand what we are talking about, we are talking about notes? Are these your notes?

THE WITNESS: These are notes that I take when I am talking to people.

THE COURT: You may move on, Mrs. Sullivan, please.

Q It's not in your notes?

MR. KLINE: Objection.

THE COURT: It's not in his notes. We understand the notes speak for themselves. You have a full deposition, however, correct?

MS. SULLIVAN: From yesterday.

THE COURT: I permitted you to have a deposition in this case, right?

MS. SULLIVAN: Yes, but that's different from what Mrs. Pledger told him, Your Honor.

THE COURT: Then let's look at the deposition, not these notes.

MS. SULLIVAN: These are the notes of his examination.

THE COURT: But they are notes, they are not the entire history.

MS. SULLIVAN: Isn't that for the jury to decide, Judge?

THE COURT: If you show them in the deposition notes, yes, absolutely.

Q Dr. Solomon, this book that you and Mr. Kline talked about, the Male Aesthetic Surgery book, where you were an editor, right?

A Is there a question?

Q Yeah. You were the editor of this book?

A That's correct, one of them.

Q But you didn't write the chapter on gynecomastia, right?

A I believe you asked me that earlier.

Q And it's true you didn't?

MR. KLINE: Objection, asked, answered, asked, answered.

Q I am going to put up Chapter 16 from your book, Doctor. And the chapter on gynecomastia in your book was written by Dr. Rosenberg and Dr. Colon?

A Colon.

Q And the chapter in your book says that, "Physical exam confirms the presence of gynecomastia." Right?

A That's what it says.

Q So the chapter in the book you edited says, "physical exam" is what confirms the diagnosis -- I am sorry, the jury can't see. Is that better?

Your book chapter says, "Physical exam confirms the presence of gynecomastia." Do you see that, sir?

A Correct.

Q But you just told our jury that you, Dr. Solomon, don't need a physical exam, you can diagnose it based on a photograph?

A That's not what I said. That mischaracterizes my testimony completely. I said given the history along with the physical exam that I did in my office, I am able to confirm that Mr. Pledger has gynecomastia, that it started within months, weeks to months after taking the drug, and that in the picture of 2005, his photograph is absolutely

consistent with the presence of gynecomastia. And I explained why in my direct testimony.

Q I thought you told our jurors, sir, that you, Dr. Solomon, can look at this and say that's gynecomastia?

MR. KLINE: Objection.

THE COURT: Overruled. Let's clear it up.

A Again, to be clear, in the context of the overall picture, not just the photograph but the picture of Mr. Pledger, and I so stated based on my findings about the fact that, yes, by lifting up his arm he is in essence being maneuvered that one can do to remove the fatty tissue leaving the breast tissue.

I am not sure that's such a hard concept to understand, because as a plastic surgeon, for example, in my board examinations we are shown pictures, that is part and parcel of what we do to confirm we know what we are talking about. If I see someone with a droopy eyelid, I can diagnose ptosis of the eyelid, and then I have to figure out why it occurs, but I can do that from across the room.

So in order to answer your question,

(Solomon - Cross)

yes, that's gynecomastia, given the history of the patient that is absolutely gynecomastia, and everything is consistent, so the jury understands it's gynecomastia.

Q So even though, Dr. Solomon, your book says you need a physical exam you say, no, you, Dr. Solomon can do it based on a photo?

MR. KLINE: Objection.

THE COURT: That's sustained.

Q Okay, and looking further, Dr. Solomon, this book has examples of people with gynecomastia, right?

MR. KLINE: Objection, as to the photos, and we are going to have this as an ongoing issue, Your Honor, other than of Austin.

MS. SULLIVAN: It's his book.

MR. KLINE: Understand.

THE COURT: Overruled.

Q Doctor, this book talks about several patients including this one who has gynecomastia, and they show it pre- and post-surgery, right?

A Much like Mr. Pledger, that picture it shows ptosis of the breast and severe gynecomastia.

(Solomon - Cross)

Q And this is a patient who never took an antipsychotic, right?

MR. KLINE: Objection.

THE COURT: Overruled.

A I have no way of knowing.

Q Did you review this chapter before you came in?

A Not in the past day or so.

Q Do you know it discusses pubertal gynecomastia and gynecomastia from obesity?

A It discusses gynecomastia from several viewpoints, but it doesn't tell the specific history of that patient.

Q And in fact, the chapter in your book, Doctor, talks about the fact that there is a 65 percent incident of gynecomastia in pubertal males, right?

A Well, Mr. Pledger was prepubertal at the time of the events we are discussing, so you are now comparing apples and oranges, which again for the jury I think is a mischaracterization of my testimony. I said he had prepubertal gynecomastia. That's pubertal gynecomastia, in pubertal males as we talked about. I agree that puberty can be associated with gynecomastia. Prepuberty, before

(Solomon - Cross)

puberty, there is no incidence of gynecomastia, and nothing in my chapter or Dr. Rosenberg's chapter or Dr. Colon's chapter says that. There are no prepubescent photographs.

Q Doctor, do you remember my question?

THE COURT: Counsel, why don't you rephrase the question rather than posing it to him.

MS. SULLIVAN: I just asked him if that's what his book says.

THE COURT: Again, he is answering your questions.

Q Doctor, your book says that gynecomastia is a familiar entity to many males and that in a study by Nydick, there is an incidence of 65 percent in pubertal males, correct?

A That's what it says.

Q And it also says that liposuction has transformed the surgical treatment for gynecomastia, right?

A That's what Dr. Marchac wrote, that's correct.

Q And your book goes on to talk about why physical exam is so important in diagnosing gynecomastia. It talks about the pinch test? Do

(Solomon - Cross)

you see that?

A Yes.

Q And the reason it talks about physical exam being important is because that's how you can tell the difference between fatty tissue and glandular tissue, right?

A Absolutely, and if you read, the patient is asked to raise his arms while the examiner is still pinching, and that's exactly what that photograph from 2005 demonstrates. He is raising his arm. We are just not pinching, I can see it, but it's the same exact -- I am really glad you brought that up, it's the same principle.

Q And there was no -- it talks about the pinch test telling what you need to do to tell the difference between fat and glands, right?

A I didn't hear the question, I am sorry.

Q Your book talks about physical exam and this pinch test to tell the difference between fatty tissue and glandular tissue?

A Correct.

Q Dr. Solomon, all men have prolactin in their bodies, right?

A At some level, that's correct.

(Solomon - Cross)

Q And all men have breasts?
A I have testified to that.
Q And all men have glandular tissue in their breasts?
A That's what breasts are.
Q And all men have fatty tissue in their breasts?
A As we showed pictures to the jury this morning.
Q And the chapter in your book goes on to talk about the fact that gynecomastia is a benign condition, right?
A Correct.
Q And that it occurs mostly in postpubertal young adults and in males secondary to obesity, right?
A In elderly males and postpuberty. Again, it's not really relevant to this discussion because Austin was prepubertal.
Q Well, you have seen the literature and there is discussion in your book about even younger males who have gynecomastia from obesity?
A I am happy to review any literature you would show me, but you are not showing me any literature,

(Solomon - Cross)

are you?
Q We will look at some, but have you seen that literature, that talks about gynecomastia or pseudogynecomastia from obesity?
A I am happy to review anything you put in front of me.
Q Can you answer my question, sir?
A I have read literally thousands of pages of literature since 1978, so I can't recall every page I have read. So my answer is I don't remember everything but if you have something you want me to read I will be happy to read it.
Q Do you know there is medical literature that talks about the fact that obesity can cause gynecomastia?
A I want to make sure we are clear, are you talking about as a causation factor?
Q Yes, sir.
A I am aware that some people think that may be the case, but it's speculative at best.
Q But you have seen that literature or some of it?
A I have.
Q And I want to show you -- by the way, can you

(Solomon - Cross)

cite us to any medical textbook or peer-reviewed medical article that talks about Risperdal causing gynecomastia in prepubertal boys?
A I believe there is a study that I have seen in which prepubertal boys, there were five of them, they all had elevated prolactin and they all had gynecomastia.
Q Do you have the name of the study or did you bring it here, sir?
A I think it's Findling.
Q Findling?
A Is what it's called. But I have also seen some internal documents that have that exact same data.
Q So, Doctor, just so we are clear, the sole basis of your testimony in terms of medical literature support that prepubertal boys can get gynecomastia from Risperdal is the Findling article?
MR. KLINE: Objection. That's not what he said.
THE COURT: Sustained as to how that question is phrased. You asked a sole question. He already answered two or several.
Q Is there any medical literature in the

(Solomon - Cross)

peer-reviewed journals other than Findling that you relied on for the proposition that boys before puberty can get gynecomastia?
A You asked me what I can recall out of the many documents that I read in my life; that's one that comes to mind as I sit here. Obviously, I am sure the company, Johnson & Johnson and Janssen, have lots of them and I am happy to review everyone in front of jury with you.
Q Doctor, we are hear to talk about what your opinions are and what the basis is.
MR. KLINE: Objection.
THE COURT: Sustained.
Q And, Doctor, the Findling article, do you know how the doses of the patients in the Findling article compare with the doses that Mr. Pledger was on of Risperdal?
A Again, if we are going to talk about a specific article, may I see it, please?
Q I am just going to ask you first, do you know whether Mr. Pledger had substantially lower doses than people in the Findling article?
A We all due respect, counsel, I don't remember the dosing in the Findling article specifically. I

remember that Austin's dosing was adjusted throughout his five years of -- was it five years, seven years, I have to do the math -- five years of exposure to it.

Q You know, Dr. Solomon, that the Findling study was not a placebo-controlled study, do you know that?

A I am not sure what you mean by that. Are you talking about a double-blind controlled prospective study?

Q Yeah.

A I don't believe that it was. But again, Your Honor, with all due respect, if I am going to be asked about a study can I have it in front of me, please?

THE COURT: I don't know. First of all, is there an objection here or not? It doesn't matter to me but is there an objection?

MR. KLINE: Yes.

THE COURT: I think the first thing to establish is whether this Findling article was even relied upon in this particular expert opinion. And if it was, it was. If it

wasn't, then you need to show it to him so he can comment on it.

Q Dr. Solomon, you didn't cite the Findling article in your expert report here?

A Correct.

Q And, Doctor, do you know, sir, that there were at least nine randomized controlled clinical trials on Risperdal?

A To look for gynecomastia?

Q That recorded incidence of gynecomastia in the control group and in the Risperdal group?

A Again, I have seen a number of articles, and I am happy to review any of them you put in front of me. I am relatively sure I have read them already, but I think to be fair to the jury I should look at them before I comment on them.

Q My question was do you know that there were nine placebo-controlled studies on Risperdal, in kids?

A Again, do I know as a fact? I don't know as a fact off the top of my head, that's correct.

Q Did you look at any of them?

A Again, I stated to you that I have looked at any number of them. If you have a specific one that

you have in mind, as I asked the Court, I would love to see it. But you would agree with me that I should not be guessing in front of these fine citizens, guessing anything. It's too important here. You have to put things in front of me so I can read them and opine on them. That's what I am here to do.

Q Doctor, I am here to ask you what you relied on, and my question is first, you didn't cite anything in your report, we have already established?

MR. KLINE: Objection. We brought a stack --

THE COURT: Overruled, as phrased, you didn't cite anything. I am looking at 21 documents here. So again, when you say "anything" you are talking about treatises or something?

Q Yes. You cited medical records but you didn't the cite any medical literature in your report?

A Again, as a practicing physician, I walk around with a fund of knowledge as to causative agents, for example, in a given patient. And as I stated to the jury, the incidence of prepubertal

gynecomastia is zero. It should never occur. If it occurs, a practicing physician has to ask why.

So what I relied upon was my knowledge as a practicing physician, that among the agents that can cause gynecomastia are drugs and that among the drugs is Risperdal. And it really comes down to that fact. So that's what I have done, counsel.

Q And, Doctor, I am going to show you an article that we will mark as defense exhibit -- this is the article by Dr. Bachar, Dr. Phillip, and Dr. Klippert and Dr. Lazar from *Clinical Endocrinology,* dated 2004, talking about prepubertal gynecomastia.

(D-51 is marked for identification.)?

MR. KLINE: Your Honor --

THE COURT: Is this a document in the record right now?

MS. SULLIVAN: No, Your Honor.

THE COURT: That's sustained. Are you objecting?

MR. KLINE: Yes.

THE COURT: Sustained. If it's in the record, so be it. But a document that is -- it's not admissible. It's just not admissible.

(Solomon - Cross)

MS. SULLIVAN: Your Honor, this is a learned treatise from a respected journal. I would like to cross-examine the witness on it.

THE COURT: You can ask him questions about it, but it's not going to be read to the jury. That's not the way we do things under the rules of evidence in Pennsylvania, counsel.

MR. KLINE: He needs to agree it's authoritative.

MS. SULLIVAN: I can authoritate it with our experts, Your Honor.

THE COURT: Absolutely, please do, with your experts.

MS. SULLIVAN: But that means I should be able to cross-examine him on it.

THE COURT: I am not even sure I would permit that then, because there are rules of evidence that go to this. Otherwise we would have a trial just by documents, by books. But we have a live witness here.

Q Doctor, are you familiar with literature that talks about the fact that 5 percent of boys prepuberty develop gynecomastia?

(Solomon - Cross)

MR. KLINE: Objection, based on the Court's prior ruling.

THE COURT: Are you aware of it?

THE WITNESS: Again, I have not read this article.

THE COURT: Sustained then. He says he is not aware of it.

Q Have you heard of something called idiopathic gynecomastia in prepubertal boys?

THE WITNESS: Your Honor, she is reading from an article I haven't read so --

MS. SULLIVAN: I am happy to give him a copy and talk to him about it.

MR. KLINE: Objection.

THE COURT: Sustained.

Q And are you familiar with the fact that in studies in prepubertal boys they found 31 percent of boys prepubertal had gynecomastia from obesity?

MR. KLINE: Objection.

THE COURT: Sustained. You don't have to answer.

MR. KLINE: She is reading from a document she was told she couldn't use.

THE COURT: You will have an expert,

(Solomon - Cross)

you can ask them, if it's admissible.

Q Would you agree that oftentimes fat in the breast region is confused with gynecomastia?

A I think that inexperienced clinicians, as well as average citizens, can look at a breast and would think that a fatty breast may be gynecomastia. I don't know what other people think, but I guess that there is an opportunity for people to have that mistake.

Q And, Doctor, you have actually operated on obese men with enlarged chests or breasts from obesity to reduce their chest size, right?

A I am not sure that's a good characterization.

Q Have you performed breast reduction surgery on obese men?

A I have removed breast tissue on obese men, that's correct. And obese women, by the way.

Q By the way, Mrs. Pledger told us at her deposition the other day that you didn't ask any questions about when Mr. Pledger went through puberty.

MR. KLINE: Objection, as to rather than questioning him, using the deposition which -- there is nothing to contradict.

(Solomon - Cross)

THE COURT: Why don't you rephrase the question as to when was he told or whatever, rather than referring to the deposition.

Q So, Dr. Solomon, you have said and acknowledged that a lot of boys get gynecomastia going through puberty?

A You made a statement, I didn't hear a question.

Q I said you acknowledged that a lot of boys, and we looked at your book, 65 percent, can get gynecomastia going through puberty, right?

A I so stated, that's correct.

Q But one thing you didn't do when you took a history of Mr. Pledger is ask Mrs. Pledger any questions about when her son was going through puberty?

A I believe that's correct.

Q You didn't probe that subject at all in your exam?

A No, but fortunately, I had medical records that I received after that that I reviewed that told me about that.

Q When did the medical records tell you that he was in puberty?

A I believe I saw things in the records referring to Tanner staging.
Q My question was when?
A I read them Tuesday night.
Q No, sir, what year in your view did Mr. Pledger go through puberty?
A I read, I don't know, six or ten different records, I don't have them all committed to memory.
Q But you didn't ask Mrs. Pledger any questions about when he started developing hair on his chest, change in voice, that kind of thing, right?
A I did not ask those questions, that's correct.
Q And you ruled out puberty as a cause of Mr. Pledger's gynecomastia based on that picture we looked at, the pool picture, right?
A I didn't rule out puberty. He went through puberty. We agreed just now he went through puberty.
Q You ruled out puberty, as I understand your testimony, you said puberty didn't cause his gynecomastia because I can tell he had it based on this swimming pool picture?
A So in that photograph, which was taken in 2005, he was 11 years old and he had a large amount

of breast tissue. So pubertal gynecomastia, if I may go back to -- I am sorry to repeat myself, folks, but remember we talked about that skyscraper concept -- pubertal gynecomastia in boys is similar to pubertal growth of breasts in girls. They get an outpouching of the nipple and it continues and continues.

What's demonstrated in that picture in 2005 is end stage breast growth. That's a full breast. That's not a little nipple out pouch. 2005, he was 11, that would have been the beginning of the puberty. So if it were pubertal in its origin, you would see a little out pouch of a nipple, not an outline of a breast.

Q Do you remember my question, sir?
A I just answered it quite thoroughly.
Q You based your opinion that it wasn't pubertal on the swimming pool photograph?

MR. KLINE: Objection. Asked and answered.

THE COURT: Sustained.

Q And, Doctor, you agree that higher prolactin levels are not predictive of gynecomastia, right?
A Are you reading from my deposition?

Q I am asking you a question.
A Did I say that in a deposition?
Q Yes, sir?
A May I have the line and page so we can read?
Q Sure, it's page 169, line 20?
A From which?
Q The Goldenberg deposition.
A I don't know if I have that -- no, I don't have that, I am sorry.

THE COURT: All right, to be very clear about this for the jury, this is not the deposition of yesterday. Correct, counsel?

MS. SULLIVAN: Yes, but this is asking about his --

THE COURT: I understand. I just want to make sure, there are different depositions involved here and memories may not be as good one day as they are for another day.

Q Doctor, you were asked on line 20, "Does this not demonstrate, though, that higher prolactin levels were not predictive of the development of gynecomastia?

"A I don't believe I ever said that they were."

That was your testimony, correct?
A That's my testimony.
Q And, in this case, Doctor, we actually have a prolactin measurement for Mr. Pledger while he was on Risperdal, right?
A In 2007, at the end of his exposure to it, when we know that the levels go up in the first two to three months, according to the corporate data.
Q And, Doctor, there is no evidence in terms of any blood work that Mr. Pledger ever had elevated prolactin levels on Risperdal?
A I believe the label says no prolactin levels needed to be drawn, so nobody drew them.
Q Can you answer my question, sir?
A I just said nobody drew them.
Q The one time that they did draw it, when he was -- after he was taking Risperdal for five years and while he was still on it, his prolactin levels were absolutely normal, right?

MR. KLINE: Objection. Asked and answered.

THE COURT: Overruled. You can ask again. Answer it.

A I did answer that it was normal. When he was

on the drug it was never drawn. The label said it wasn't necessary, nobody drew it, nobody would have thought about it.

Q Well, it was drawn when he was on the drug, at least once, right?

A We have established that, haven't we?

Q Okay. And when it was drawn, let's mark this as Defense Exhibit 52.

(D-52 is marked for identification.)?

THE COURT: What's this?

MS. SULLIVAN: It's a medical record, Your Honor, from Dr. Dy.

MR. KLINE: May I see it?

THE COURT: Any objection?

MR. KLINE: This was taken, I believe, when he changed to Dr. Paoletti, who took him off the drug.

THE COURT: I understand. That's up to the jury to decide, by the way, whether he was on the drug at that time. But right now D-52 is admissible.

Q Doctor, you know from your review of the record that he is still on Risperdal in early April 2007 when this blood is drawn, right?

A I believe it was being tapered according to the record.

Q Yeah, he is still on it?

A Yeah, and as I said, according to published literature, your own corporate documents, the levels go up early on and then come back down. He had already had gynecomastia by 2007 because we demonstrated he had it in 2005. So I am not sure this is helpful in any way as a clinician.

Q Do you remember my question, sir?

A You asked me if he had a level in 2007, and here it is.

Q And it's completely normal?

A It says it's normal.

Q Not elevated in any way?

A No surprise.

Q Still on Risperdal, five years of taking Risperdal, completely normal prolactin level?

MR. KLINE: Objection, asked and answered.

THE COURT: Sustained.

Q Doctor, I think you told the jury that 87 percent of patients who receive Risperdal had elevated prolactins. Do you remember that

testimony?

A I believe I did.

Q And you based that on the Risperdal label, right?

A That's the source that I recollected off the top of my head.

Q But you didn't read the label right, did you, sir?

A I have been reading for a very long time.

Q Okay, well, let's take a look at what the label actually --

A May I have it, please.

THE COURT: Doctor, let's just be patient. You will get out of here by five.

MS. SULLIVAN: Almost done, Doctor. Can you give Dr. Solomon a copy of the -- Ms. Brown, what exhibit do we have?

MS. BROWN: D-53.

(D-53 is marked for identification.)

THE COURT: What year is this document?

MS. SULLIVAN: This is the 2007 label that Dr. Solomon told us yesterday that he relies on for his opinion that 87 percent of children like Mr. Pledger have elevated

prolactin.

MR. KLINE: That's not what he said.

THE COURT: I don't know what he relied on yesterday, we haven't heard that. Members of the jury, remember, questions and statements by attorneys, either one, is not evidence.

Q Dr. Solomon, you told us that you rely on the Risperdal label for your position that 87 percent of kids on Risperdal have elevated prolactin, right?

MR. KLINE: Objection, mischaracterizes --

THE COURT: Sustained. Let's see the evidence.

Q Doctor, turning to page 32, first of all, this is the 2007 Risperdal label, right? And if you turn to page 32, Doctor, that's where you get your 82 to 87 percent, right?

A 82 to 87 percent of patients who received Risperdal had elevated levels of prolactin compared to 3 to 7 percent of patients on placebo.

Q Yeah, and that's where you get your opinion that 87 percent of kids have elevated prolactin, right?

(Solomon - Cross)

A It's a fact.
Q But you are not looking at the part of the label that actually applies to Mr. Pledger, are you, sir? He was under 13 when he was taking Risperdal, right?
A Correct.
Q And he was not a schizophrenic or bipolar, right?
A Correct.
Q And you know that schizophrenia and bipolar disease have been associated themselves, whether or not you are on an antipsychotic, if you have schizophrenia you have a higher chance of having elevated prolactin, right?
A That's your statement. I don't have any proof of that.
Q You don't know that?
A I just stated I don't have proof of it.
Q But for kids like Mr. Pledger in this age group who have autism, it's actually 49 percent. Right?
A Again, A, it says it's 49 percent in that group, and B, I said that patients -- I didn't limit it to Mr. Pledger -- patients exposed to Risperdal

(Solomon - Cross)

has an incidence as high as 87 percent, was my statement.
Q But this case --
A If you want to parse the language, then yes, one out of two patients exposed to Risperdal have an elevation in their prolactin.
Q Dr. Solomon, this case is about Mr. Pledger and you came in here to talk about Mr. Pledger, right?
MR. KLINE: Objection, argumentative. It's not even a question.
THE COURT: Sustained.
Q And in kids like Mr. Pledger, five to 17, only 49 percent had elevated prolactin, right?
MR. KLINE: Objection, asked and answered.
THE COURT: The document speaks for itself. I mean if you are trying to impeach him let's see the deposition. Otherwise, move on, counsel.
MR. KLINE: Your Honor, it's misleading. It says 49 to two --
THE COURT: Whatever, it speaks for itself. The entire document is admissible at

(Solomon - Cross)

this point. The jury can read it for themselves. Move on, unless you are impeaching him on something that is inconsistent with what he said yesterday. Then all pleasure to it, go for it. But otherwise, we got to move on.
MS. SULLIVAN: Well, Your Honor, he is saying 87 percent, but in this case Mr. Pledger --
THE COURT: We understand that, counsel.
BY MS. SULLIVAN:
Q Doctor, in fact, people like Mr. Pledger, 51 percent of them don't have elevated prolactin at all?
MR. KLINE: Objection.
THE COURT: Sustained. You are being rhetorical now, between 49 and 51.
Q And, Doctor, you know that the incidence rates in children and adolescents from the clinical trials is 2.3 percent, not 87 percent, right?
MR. KLINE: Objection. Also asked and answered.
THE COURT: I don't know whether it was

(Solomon - Cross)

asked and answered, but whatever is speaking for itself is speaking for itself, unless there is something you are impeaching.
Q Doctor, you will agree that the data shows that about 98 percent of the kids on Risperdal never get gynecomastia?
A The label says 2.3 percent. There is literature that talks about as high as 5 percent. And again, to review, so the jury understands, that's not distinguishing prepubertal from pubertal. And in a prepubertal patient, even at a rate of 2 percent is 200 times higher than expected.
Q Dr. Solomon, the 2.3 percent includes the 65 percent of patients who might have gotten it from puberty? That's the total incidence, right?
A I am not sure where you are getting that concept from.
Q Well, if it includes all people in the clinical trials, it also includes people who got it from puberty?
A We would have to read the source data to understand whether that's a true statement or not, so I don't think you can say that.
Q You don't know?

(Solomon - Cross)

MR. KLINE: That's objected to.

THE COURT: Sustained. By the way, counsel, this is -- this particular study is something for your own experts to determine. This is from Dr. Kessler's testimony?

MS. SULLIVAN: That's his expert Your Honor.

THE COURT: Have you read Dr. Kessler's testimony?

THE WITNESS: I haven't.

THE COURT: Move on.

MS. SULLIVAN: Doctor, in the direct testimony he relied on --

THE COURT: Move on.

BY MS. SULLIVAN:

Q And, by the way, Dr. Solomon, it's your opinion that the dose Mr. Pledger took doesn't matter on the issue of whether Risperdal caused gynecomastia, right?

A I am not sure I am on the record as having said that.

Q Let's look at your testimony from yesterday, page 73, line nine. And you were asked, sir, "My question for you is simply, did it affect your

(Solomon - Cross)

opinion, is the dose he took at all relevant to your opinion that Risperdal causes his gynecomastia?"

And your answer was No. Dose didn't matter. Right?

A So for completeness, there is an objection stated prior to my answer, first of all. Second of all, if you go back up I was talking about his total exposure to the drug, not the actual dose.

So I think what happened was we started talking about total exposure and it was narrowed down to a specific dose, whereupon I said, I am aware that his dose changed on several occasions.

So I would say to you his dose on a given day? I am talking about total exposure is what counts as having stimulated the problem here.

Q You were asked, doctor, "Is the dose he took relevant to your opinion that Risperdal caused gynecomastia?" And you said No.

MR. KLINE: Objection. Asked and answered. And asked and answered. Then, yesterday, and today.

THE COURT: I didn't hear a question there so that's sustained. May I have the document, please, whatever it was.

(Solomon - Cross)

Q And, Doctor --

THE COURT: One second. I need a copy of it. Where is that, the deposition? Do we have another copy of that?

MS. SULLIVAN: You can have my copy, Your Honor.

THE COURT: Unless you are moving on, I think I need it.

MS. SULLIVAN: I am moving on, Judge.

Q One last thing, Dr. Solomon. I want to go back to your website. Incidentally, did you measure with a tape measure or a ruler Mr. Pledger's breasts, in terms of the size of the fatty tissue versus the glandular tissue?

A No, I measured the circumference of your chest.

Q And you do have tape measures and rulers around, because I have seen your website with all the naked men and measuring them?

MR. KLINE: Your Honor, really, objection. The best she can do.

THE COURT: Do I really have to rule on this? Sustained. Go ahead.

Q Dr. Solomon, you have a bunch of naked men on

(Solomon - Cross)

your website, right?

A And naked women.

Q And you have rulers to show that you added 2 inches to the length on volumes and volumes --

THE COURT: Counsel, is there a question related to the observation of Mr. Pledger, in all seriousness?

Q Dr. Solomon, you didn't use those tape measures to measure Mr. Pledger's breasts in terms of fatty tissue versus gland tissue?

A As a practical matter, as a plastic surgeon who measures breasts in men and women every day, there are certain tools that I use to measure breasts, and I measure certain dimensions, and depending on what procedure I am contemplating, I will measure different dimensions.

So in the case of Mr. Pledger, I measured, as I stated before, the circumference of his aereola and the circumference of the inframammary crease. I did not measure a diameter that I saw, I think it was Dr. Vaughan measured, because there is no way to tell by putting a calibers on the breast the difference between the fat and the tissue, that's something you feel.

That's what I know as a surgeon. And also as a surgeon, remember, I have seen breast tissue in the operating room. It looks different, I felt it without the skin and fat around it. I know it. And by the way, it even smells different in the operating room. Breast tissue is breast tissue is breast tissue. You can take that one to the bank with me.

Q Doctor, the fact is you didn't measure how much Mr. Pledger's breast was fat versus gland tissue, you didn't do that?

MR. KLINE: Objection. Asked and answered.

THE COURT: Sustained.

Q Doctor, Mr. Pledger is a good candidate in your view for gynecomastia reduction surgery?

A I don't believe I ever said that.

Q Well, in your website you say that after this breast reduction surgery, "most men are extremely happy with their results and many remark that they wish they had known that their gynecomastia could be corrected so quickly and easily." Right?

A That's what the website says, that's correct.

Q And did you and Mrs. Pledger discuss surgical

correction with Mr. Pledger?

A We did not.

Q She didn't ask you about it and you didn't raise it?

A Correct.

Q But you operated on men with gynecomastia and had extremely good results, according to your website?

A I have.

MS. SULLIVAN: No further questions, thanks.

THE COURT: Do you wish redirect?

MR. KLINE: Yes.

THE COURT: Fifteen minutes on redirect, 15 minutes on recross, and that's it.

MR. KLINE: I only have a few discreet areas, Your Honor.

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REDIRECT EXAMINATION

- - -

BY MR. KLINE:

Q A few questions in a few areas. One, I am not coming for a consultation, that's number one.

Number two, Ms. Sullivan just asked you whether he is a candidate for gynecomastia reduction surgery. In follow-up to her question, would you tell the members of the jury, since it's been asked, what would be involved in the removal of these breasts and what would be the results, sir, based on your experience?

A I need to break that down, if I may, into two components. One is the surgery and one is what's called the perioperative or the medical care related to the surgery.

Q Yes.

A The surgery, the surgery would involve removal of skin and breast tissue. Any time you remove skin you create scars. The scars would be similar to those that some of you may have seen when a woman gets a breast reduction. It looks like the letter T upside down, with a circle around the areola. The name of that is called a Wise pattern.

So the scars would be around the nipple, down the chest wall, into that crease region, and all that in a man, the hanging tissue gets removed. So you get a scar going across the chest on each side, one going up and down in the

middle of the breast and one around the areola.

Q Would this be simply liposuction, or would this be an operation known as a masectomy?

A Actually, it would be known as a reduction mammaplasty. It's a more complex procedure than, frankly, either of those because the challenge is to maintain blood flow to the nipple so that it doesn't die.

Q Would it undoubtedly cause significant scarring and therefore deformity?

A Yes. And then, if I may, because we talked about the -- there is the carrying out of the procedure and then his particular needs. With his level of autism he would require inpatient hospital care, even though the vast majority of patients treated for gynecomastia are treated on an outpatient basis. But in his particular circumstance, given his level of autism, for his own safety and well-being, I have testified that he would need to be placed in a hospital for at least one night.

Q Would it be major surgery, yes or no?

A Yes.

Q And would it be significant scarring when all

was said and done?
A Significant permanent scarring, yes.
Q On the label that was being discussed, I would like to put back up, that was Defense Exhibit Number -- the 2007 label?
MS. BROWN: Fifty-three.
Q D-53, and they were on page D205.32. You understand this to be the Defendant Janssen Pharmaceutical Company's own information contained in their own prescribing information, correct?
A Correct. The information we rely upon.
Q And it says here, if I may read the entire sentences, let's go down to the kids with schizophrenia:
It says, "Similarly" -- our eyes will get there, Dr. Solomon, one moment. We are used to this in this courtroom.
"Similarly, in placebo-controlled trials in children and adolescents aged ten to 17 with bipolar disorder or adolescents aged 13 to 17 with schizophrenia, 82 to 87 percent of patients who received Risperdal had elevated levels of prolactin compared to 3 to 7 percent of patients on a placebo."

Do you see that?
A I do.
Q So for this group of children who were schizophrenic, when they compared the kids taking Risperdal and whether they had elevated prolactin, in the schizophrenic kids, 87 percent who were on the Risperdal got elevated prolactin, correct?
A Correct.
Q And if they were on a sugar pill, that would be a placebo, also called a placebo, 7 percent. The low end numbers are 82, and the low end number is 3 here.
So it's either 82 compared to 3 percent or 87 compared to 7 percent. Is that what it says there?
A That's correct.
Q So for a schizophrenic child who was on the drug, this drug Risperdal, when you reviewed this label did you see that the chances were 87 percent for a child who was on Risperdal who was a schizophrenic to have an increased prolactin level versus a 3 to 7 percent of a child on the placebo, meaning the sugar pill, when they did a test. Is that correct?

A That's correct.
Q And Ms. Sullivan, the company lawyer, called your attention to this: "With autistic disorder" -- children with autistic disorder, it would be right up here -- "in the double-blind placebo-controlled studies of up to eight weeks duration." Do you see that?
A Yes.
Q And by the way, eight weeks, like two months?
A Right.
Q Like when breast buds form?
A Correct.
Q In the autistic kids it says here it was shown -- "Risperdal has been shown to elevate prolactin levels in children and adolescents as well as adults in double-blind placebo-controlled studies of up to eight weeks duration in children and adolescents age five to 17." That obviously includes prepubertal and postpubertal, correct?
A Correct.
Q "With autistic disorders or psychiatric disorders other than autistic disorder, schizophrenia or bipolar." This now about autistic kids. The full story there is autistic, if you were

autistic, 49 percent of the patients who got the Risperdal got the elevated prolactin level, correct?
A Correct.
Q Basically, one out of two. We could nickel and dime or penny over whether it's 51 or 49, but roughly one out of two?
A Correct. And it stopped at eight weeks and we know from other data that it actually increases for up to 12 weeks.
Q Let's just stick with this.
A Okay.
Q And if they got a sugar pill, they had a -- 2 percent of them had an elevated prolactin. Do you see that?
A I do.
Q So the chances of having, for an autistic child, chances of an autistic child having an increased prolactin level, and by the way, it's right in there, five to 17 includes five to ten, correct?
A Correct.
Q Because five to ten is less inclusive than five to 17, correct?
A Yes.

(Solomon - Recross)

Q So look with me here and I can be done with this in a moment.

As to autistic kids, which is what Janssen's lawyer showed you, the chances of having an increased prolactin level at eight weeks is 25 times. Correct?

A Correct.

Q 49, Risperdal. Two on the sugar pill. Correct?

A Correct.

MR. KLINE: Those are the only two areas that I wish to examine on for redirect, Your Honor.

THE COURT: Thank you.

MR. KLINE: I would assume that would be similar on recross.

MS. SULLIVAN: Just on those two points, Judge.

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RECROSS-EXAMINATION

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BY MS. SULLIVAN:

Q Going back, Dr. Solomon, to this chart, Mr. Pledger is not the 87 percent schizophrenic, he

(Solomon - Recross)

is the autistic children who are 7 and 13, right, the 49 percent?

A Right, he is only 25 times more likely to have it happen.

Q So 51 percent of kids like Mr. Pledger didn't have elevated prolactin at all in the studies?

A At eight weeks. We don't know what happened beyond that.

Q Well, you are claiming it happened in eight weeks, right?

MR. KLINE: Objection to "claiming". He was answering my question.

THE COURT: Sustained.

Q That's your opinion here, that it happened in eight weeks, right?

MR. KLINE: Same objection.

THE COURT: I don't know, what is your opinion?

A My opinion is that somewhere between eight and 12 weeks it happened, and that's what I testified to before, consistent with the history and consistent with the knowledge that the levels go up over eight to 12 weeks. I mean, it looks to me that you cut off the data at eight weeks and who knows where it

(Solomon - Recross)

would have gone at 12, frankly, in that labeling issue.

Q Have you looked at the Government-funded study by Anderson to see whether prolactin levels have anything to do with gynecomastia?

MR. KLINE: Objection. Beyond the scope.

THE COURT: Sustained on the beyond the scope aspect. I don't know, though, are you asking about this -- overruled.

Q Yeah. So, Dr. Solomon, you will agree just because you have elevated prolactin doesn't mean you develop gynecomastia? In fact, an overwhelming majority of people with elevated prolactin have no problems in the studies, right?

A We know that at least 2 percent and as many as 5 percent in studies have gynecomastia.

Q But 90-plus percent have no problems, right?

A Right, but in Austin Pledger's case it's an obvious call.

Q But even if you have elevated prolactin 90-plus percent of the time --

MR. KLINE: Objection, Your Honor.

THE COURT: That's sustained at this

(Solomon - Recross)

point.

MR. KLINE: And beyond the scope.

Q Doctor, would you use the schizophrenia number when Mr. Pledger is autistic?

MR. KLINE: Asked and answered.

THE COURT: The question is why? That has not been answered. Go ahead.

A That's interesting, because with schizophrenia you are only 12 times more likely to get it, whereas with autism you are 25 times more likely to get it. So maybe I was somehow trying to be unbiased towards the data.

Q But this is Mr. Pledger.

A Right, so he is 25 times more likely to have had it.

Q In terms of gynecomastia, he is 98 percent less likely to develop it --

MR. KLINE: Objection.

THE COURT: That has been asked and answered. When you say 45 percent you are talking about elevated prolactin levels?

THE WITNESS: Right. We are now focused on prolactin is my understanding.

Q There is a difference between elevated

prolactin and a side effect?
A No, elevated prolactin is a side effect. It's called an adverse event, as I recollect the labeling.
Q There is a difference between elevated prolactin and any symptoms, any clinical problems?
A That's a different discussion that we haven't talked about, frankly.
Q And, doctor, you will agree that the overwhelming majority of the people in the studies who have elevated prolactin levels have no clinical symptoms?

MR. KLINE: Objection.

THE COURT: That's sustained. That gets back into Dr. Kessler Land.

Q And, Doctor, are you familiar with the Government study that showed no relationship in autistic kids between prolactin levels on Risperdal and gynecomastia?

MR. KLINE: Objection.

THE COURT: Sustained.

MS. SULLIVAN: Your Honor, there is a learned treatise rule in Pennsylvania that you can cross-examine experts with medical

articles.

THE COURT: You can cross-examine on them, I will allow a question based on that, you can't use that for the same reason I explained before. In Pennsylvania we don't try a case by books, we try them by live witnesses.

MR. KLINE: Your Honor, I only examined on the label, one paragraph of the label.

Q Doctor, didn't you cite in your deposition yesterday the Anderson Study?

MR. KLINE: Objection, beyond the scope.

THE COURT: What does that have to do with -- maybe, I don't know.

MS. SULLIVAN: It goes to the prolactin level side --

THE COURT: There is no controversy here, as I understand, this is not about prolactin levels, right?

MR. KLINE: It's about the label and what the label showed, and it was redirect examination to a very narrow point, limited to less than five minutes.

THE COURT: Whatever. You know what, go ahead.

Q And, Doctor, you cited in your deposition yesterday to this Anderson study. That was not done by Janssen, right? You read it?
A You know I don't believe if I cited it or if it was asked as a supplement. I am not sure if there was a question asked of me about Anderson.

THE COURT: Counsel, let me understand this. Is there a question as to contradicting something using this article? Again, we are not going to get into broadcasting the contents of an outside treatise. That is against the Pennsylvania Rules of Evidence, unless there is -- this document itself is admissible here. Let's take that down now.

MR. KLINE: It's the Aldridge case.

Q Are you aware, Dr. Solomon, that Government studies have shown no relationship between prolactin elevation and side effects like gynecomastia?

MR. KLINE: Objection. Same thing.

THE COURT: I think it has been answered. Do you want to explain again the relationship between these two, if there is

one.
A Frankly, the only Government study I know talks about elevated prolactin in pituitary tumors at an increased rate in humans, but we haven't talked about pituitary tumors. But that's consistent with the animal data, which again, this stuff is making pituitary tumors in animals and humans and elevated prolactin and gynecomastia.

As I stated many times, I just stated I am familiar with that particular study, but if you want to show me something I suppose you could, but since it wasn't within the scope of Mr. Kline's questions to me, that's your call.

THE COURT: That's my call, Doctor. All I am asking, if you have an opinion on this subject that you haven't already answered, tell us. If not, say I have already answered.

THE WITNESS: I have already answered.

THE COURT: Fine.

Q Doctor, going on the surgery issue that you and Mr. Kline talked about, I am going back to your website that was put up as Defense Exhibit 45, part of your website. You talk about the fact that you

make a small incision at the edge -- as part of this breast reduction surgery, you make the smallest possible incisions and it results in minimal scarring, right?

A I make the smallest possible incision. In Mr. Pledger's case, the smallest possible incision is to remove skin. Because a small incision only using liposuction, for example, or a small incision removes a small amount of breast tissue, for example, would be insufficient for his particular needs.

While that is an advertisement on a website, the book chapter we cited talked about a number of different methods that are used, and that's in fact the reason I wrote the chapter was to talk about all those different methods.

So that's not medical literature, that's marketing literature for the consumption of the public. And I must tell you that I see patients all the time when I have discussions about, here is what I can do, here is what I can't based on your individual needs. I have individualized surgical care.

Q And your book chapter talks about liposuction

as a procedure for breast reduction?

A So to put it in historical context, that chapter was written in the mid-'90s when liposuction was evolving as the method for removing some breast tissue because there was some controversy. So Dr. Rosenberg was a proponent of that, and Dr. Colon was not a proponent of that. Hence, a discussion in the chapter of the various techniques, and hence Dr. Marchac's comment that liposuction has been shown to be a useful adjunct in the treatment of gynecomastia. All of those are true statements.

MS. SULLIVAN: I have nothing further, thank you, Your Honor.

THE COURT: All right. And if there are no further questions, Dr. Solomon, you are use excused, sir.

THE WITNESS: Thank you very much.

(The witness is excused.)

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THE COURT: Let me see counsel here at sidebar.

(The following transpired at sidebar out of the hearing of the jury:)

THE COURT: At this time, are there

anymore Plaintiff witnesses?

MR. KLINE: No.

THE COURT: So you want to rest and do the motions outside their hearing?

MR. KLINE: Absolutely.

THE COURT: As far as the plan, what is the plan?

MS. SULLIVAN: We will have a live witness after our motions.

THE COURT: Today?

MS. SULLIVAN: Tomorrow.

THE COURT: What is your plan for tomorrow? I do have a meeting tomorrow with about 30 people from around the City. But I really want to move this case along, so I am more than happy to just greet the people when they arrive at 11 o'clock, take a half hour break, come back here and resume. I just want to know if I did that, is it going to be rewarded with continuous testimony? In other words, are you going to have more than one witness tomorrow?

MS. SULLIVAN: The witness we have will probably take up to a full day or maybe more.

THE COURT: So we will resume tomorrow. We will start in the morning tomorrow, with the idea that probably around 10:30 we will take a one-hour break.

MR. KLINE: So tomorrow we would have a break and we of course would have a lunch break, too.

THE COURT: Yes, we are, that's what we are going to do. I can't afford the whole morning.

MS. SULLIVAN: Does it make sense, Your Honor, to do the motions in the morning?

THE COURT: I would rather do that now. If you have legal argument to make we will do that now.

MS. SULLIVAN: We were going to take -- part of the motion would involve Dr. Solomon's testimony and we wanted to take a look at it. We can file it first thing in the morning.

THE COURT: I don't want to delay -- then what you are telling me -- no. Put everything on the record and I will give you leave to file it. But I am not going to delay the start of the case. I mean if I grant a

directed verdict then any testimony that has been taken will be moot. But I really need to get moving on the defense case, testimony wise. So you can put whatever you want on the record --

MS. SULLIVAN: So your plan is to have them come in for a half hour, and then break until lunch?

THE COURT: No, the plan tomorrow would be to start at 930, to break at 10:45 come back 11:30, continue until 12:45, then to take a break from 12:45 until two and then continue. That's the plan for tomorrow. I have got to get this case moving. So we will address any motions you have, and if you want to supplement it with whatever, we can do that, too.

So you are going to rest?

MR. KLINE: I will rest subject to the moving of exhibits, those will be my words.

MR. MURPHY: Your Honor, would it work if we got here early tomorrow morning and you entertained our motion?

THE COURT: I will entertain the motion

now. I am not saying I have to rule on it, but all I am telling you is, frankly, if you are going to make a record you got to make a record, and you have the luxury of realtime transcripts, I just heard the testimony as you have.

(The following transpired in open court:)

THE COURT: Mr. Kline, any further witnesses?

MR. KLINE: Subject to the moving of exhibits, Plaintiff rests.

THE COURT: Well, we finally made it to one part of the case that has been completed, which is the Plaintiff's direct testimony in this case.

So what we are going to do now is we are going to recess until tomorrow at 9:15. I really understand, I had ice this morning myself in my driveway. So try to be here at 9:15 so we can get going. The game plan tomorrow is as follows:

I have a meeting, however, I am going to make an appearance at the meeting and go to

the lunch. So we will start at 9:30, go until 10:45, take about 45 minutes off so I can at least say Hello and then come back. That's the plan. We got to get moving. That's what I intend to do.

So again, please wear those yellow badges, please do not discuss this matter with anyone at all, please keep an open mind, we have not heard the defense case, remember that, and also, please do not read, pay attention to, find, do anything having to do with the media, social media, radio, television, magazines, you name it, ignore. It's our case right here.

All right, so we will see you tomorrow around 9:15.

(The jury is excused at 3:55 p.m. and the following transpired in open court:)

THE COURT: Let's take a recess for about ten minutes and then we will start.)

(A brief recess is taken.)

THE COURT: All right, Plaintiff has rested. How many Plaintiffs' documents are there? Are there objections to the

admissibility of any of these documents?

MS. SULLIVAN: Yes, Your Honor.

THE COURT: We will have a list of those and I will review those and I am not sure I am going to address them now. I will see what the arguments are.

THE COURT CRIER: Plaintiffs' Exhibits 1 through 86.

THE COURT: That doesn't help me, we have to do them one by one. If we are going to do these one by one we will do them at another time. The admissibility of these documents are subject to further review at the time of closing argument.

MS. SULLIVAN: Your Honor, we will --

THE COURT: I do need a memo from the defense as to the specifics for each one, give us a heads-up, and we will examine it accordingly.

MR. KLINE: And, Your Honor, there is one exhibit which we are not sure if it was marked, it's P-70(C), and I am handing it to Marianne.

THE COURT: Which was it?

MR. KLINE: It was a call out.

MR. GOMEZ: During Mr. Gilbreath's testimony.

MR. KLINE: It was on the screen and we snapshot it. We are not exactly sure.

THE COURT: Put it in the there, the last one P-70(C).

(P-70(C) is marked for identification.)

THE COURT: I would rather have this in writing so the record is clear as to what is objected to, I mean the reasons for the objections, and that will enable us to hopefully make a correct ruling.

Now are there any motions at all?

MS. SULLIVAN: Yes, Your Honor, at this time with the Court's permission Janssen would like to move for a compulsory nonsuit on a couple of grounds, and I will state them briefly. There is also a brief with supporting law coming to the Court.

First, Janssen submits that the label, the 2002 label was adequate as a matter of law. This is not a case where the label was devoid of risk information. Elevated

prolactin and reports of gynecomastia were in the Precautions section of the label. Even their prescriber acknowledged that's a significant and important section. He acknowledged, Dr. Mathisen, in his testimony that he was well aware of the risk of elevated prolactin and that Risperdal had the potential risk of gynecomastia.

He further acknowledged that the risk in children could be greater than what was reported in the adult label. And there is also clearly demarcated in the 2002 label, the legend, safety and efficacy has not been established in children. I submit, Your Honor, that's a stronger warning than any prolactin information we could have provided. It says we are not proven safe for children, clearly, in the label.

Second, Your Honor, Dr. Mathisen testified that he was aware of the risk of gynecomastia when he prescribed it to Mr. Pledger. Mrs. Pledger testified that Dr. Mathisen did not advise her even though the record is clear that Dr. Mathisen knew of that

risk.

In addition, Your Honor, a different warning would not have mattered to Dr. Mathisen, this was a prescriber who had in his hand the 2006 label and continued to prescribe to Mr. Pledger, a label that Plaintiff's counsel and Judge New has held up as adequate as a matter of law in terms of alerting people to the potential risk of gynecomastia. Dr. Mathisen had that label in his hands by his testimony and continued to prescribe.

So a different warning, the warning that they and Judge New hold up as adequate, would not have made a difference on the decision to prescribe, Your Honor, and I think that is clear from the record. And Dr. Mathisen continued to prescribe Risperdal to children to this day.

So those are our learned intermediary warnings ground. In addition, Your Honor, we move on pre-emption grounds. Dr. Mathisen's testimony that Risperdal and the risk of gynecomastia and risk in children required a warning is preempted by Federal law. The law

is clear that serious adverse events are those that trigger the CBE provision, the voluntary labeling provision in the Regulations. It's also clear from the Regulations that Janssen could not warn about off-label risks, which this was, and so it's preempted on two grounds. One, it's not a serious adverse event that triggers the CBE provision of the Regulations, and two, that Janssen under Federal regulatory scheme could not warn.

THE COURT: Is there any case law right now on the off-label issue?

MS. SULLIVAN: Your Honor, we have the Regulations and the FDA's conclusion on the serious adverse event issue, and we will submit that to you. There may be law in addition. But the FDA and the serious adverse event issue has specifically weighed in and said that this is not what triggers a CBE in terms of warning in a label. So that's one basis for our pre-emption argument. And evidence of the fact that pre-emption applies here was Janssen's effort to get safety information in terms of pediatric dosing in

the label, and the FDA said, no, we don't want you to do that because you could use it to market the medicine off-label.

Finally, Your Honor, we move on causation grounds that Plaintiff can't under applicable law satisfy the Frye standard here. Dr. Solomon, both on qualifications and on substance was woefully inadequate to satisfy the burden. He did nothing in terms of a comprehensive differential diagnosis to rule out other causes. He did no testing, he did nothing but look at a photograph which his own textbook said is not sufficient for the diagnosis of gynecomastia. He also did nothing to rule out the high background rate of gynecomastia in the general population. And we submit, both on qualifications, a cosmetic surgeon who cited no literature in his report and cited no controlled studies whatsoever was inadequate both on qualifications and on Frye substance in terms of his causation opinion.

Thank you, Your Honor.

THE COURT: All right, before we hear

any response at this time, what is your plan on getting me your brief on this issue?

MS. BROWN: Tomorrow morning, Your Honor.

THE COURT: Again, we are under tremendous strain as far as this jury is concerned and I don't think that I really have the ability to decide the directed verdicts with a full memorandum of law on my part by tomorrow morning at 10 o'clock if we are going to start at 9:30 for the trial. So some of this has to do with whether or not the defense is willing to go forward now with their case in chief as we review these matters for directed verdict.

MS. SULLIVAN: Subject to Your Honor's review, I think that's fair, Your Honor.

THE COURT: Okay, thank you. All right, counsel, let me hear your argument.

MR. KLINE: Briefly, Your Honor. The nonsuit must be denied. As to the 2002 Warning label, it was not adequate, as a matter of fact or matter of law. The whole point here is that Janssen misled the entire

medical community by saying that it had increased prolactin in gynecomastia but failed to disclose what they knew in their own files back in 2000 and 2001, namely, that this drug had as high as a five and maybe as high as a 12 percent gynecomastia rate in children and adolescents, that they eventually admitted to a negotiated 2.3 rate information that they had substantially in their files at the time back in 2000 and 2002.

They never reported, to this day, Table 21, the full SHAP data. That was the subject of a request for admission, actually, generally in this litigation, and they gave us an answer which was frankly, BS, and they haven't said anything to the contrary this entire case.

So as to the adequacy of the label as a matter of law, that clearly fails.

Also, it clearly fails that they failed, as Dr. Kessler, the former Commissioner of the FDA said, to do a number of things, including Dear Doctor letters, warning doctors of innocent, vulnerable

children, the most vulnerable in society, as to these terrible safety problems that they saw in their own drug.

As to point number two, Dr. Mathisen knowing of gynecomastia, the evidence is actually to the contrary in this case. He didn't know the real risk. He said it. He came up from Alabama to tell this jury exactly that, that he didn't know the real risk and had he known the real risk he wouldn't have prescribed the drug.

The thought that he knew or that any physician knew that gynecomastia was associated with the drug Risperdal or that increased prolactin levels were associated with this class of drug is exactly, exactly how Janssen Pharmaceuticals malignantly misled physicians, parents of autistic children, children with ADHD and other maladies. I would submit to the Court that Janssen Pharmaceuticals preyed on the most vulnerable in our society. That was the subject of other litigation in other places.

Three, as to the 2006 label, Dr.

Mathisen had no recollection of whether he received the label, as I recall his testimony. I can tell the Court that we had extensive examination of the sales representative Mr. Gilbreath, which was stunning, in that the sales representative dropped off a document which said the exact opposite from the label. Buried on page six of the label was a 2.3 percent rate of gynecomastia, buried in the label is that it's worse than any other drug in the category as to prolactin levels. And then he has a leave-behind, what is called a "leave-behind", which says the exact opposite and reassures the doctor --

THE COURT: Let me focus for a moment just on that point. I mean on that point, isn't it true that the FDA label was what it was in 2007 and --

MR. KLINE: No. Actually not, and we plan to go back to Judge New, who never knew this fact, that the training manual, which this jury and Your Honor saw for the first time saw the light of day in this courtroom and now which the American press knows as

well, is the sales reps were trained to say the exact opposite to the doctors. And we had a document in this courtroom that said tell them, while they handed out the label with one hand --

THE COURT: Your point is that the existence of the 2007 label is not dispositive of your claim of failure to warn even at that time.

MR. KLINE: Not only is it not dispositive but it has actually, it proves the opposite, and it would do no good for Austin Pledger or his physician Dr. Mathisen because the whole sorry incident here took place between June of 2002 and October of 2006.

THE COURT: There is another question on the facts that I just had to be clear about it, there was no evidence presented here that the existence of the 2007 label had anything to do with the change of the medication in the Spring of 2007 by the new doctor. I heard nothing about that.

MR. KLINE: That evidence, I believe -- there was no direct evidence on it. There was

inferential evidence on it, and the Court saw a deposition transcript of the doctor and precluded evidence where Dr. Paoletti said that he recognized that it was gynecomastia. I think it would be fair --

THE COURT: All right.

MR. KLINE: I think it would be fair to say that there is no direct evidence to the point Your Honor asked.

THE COURT: Okay. That's fine.

MR. KLINE: But on pre-emption grounds, I just want to make sure I have a record as well here and also a road map, on pre-emption grounds, there is no basis for pre-emption. Counsel for Janssen makes two points here, one, that it wasn't a serious adverse event. That is a down-right false. The fact of the matter is we saw in this courtroom another drug which had a gynecomastia label, so that drug, which name is Striant, must have met the criteria for the Warning.

In any event on point two, point one (A) for me on not a serious adverse event, in this particular instance, the literature

created by Janssen Pharmaceuticals themselves, which the jury saw, the so-called Findling article, described it as a "distressing symptom."

THE COURT: Here is the issue on that. I mean why should this Court even get involved with this whole pre-emption issue in the first place? I mean isn't it pretty settled at this point that the state cause of action and failure to warn is in fact a state action that is not preempted under Wyeth and the other cases. It's pretty clear from the Supreme Court of the United States that they are not going to interfere with a state action as long as there are separate cause of actions. Why would this Court get involved with this, I am talking about the Common Pleas Court, has addressed the issue repeatedly. I don't need a brief on this.

MS. SULLIVAN: The exception is when the FDA has specifically weighed in on a topic, and we can give you case law on that score, Your Honor, when the FDA has specifically weighed in, as here where they

said recently this is not a serious adverse event, and also, with the pediatric dosing, saying you can't warn of an off-label risk that satisfies --

THE COURT: We will get to that in a moment. The problem that I have is I don't agree with that in the context of failure to warn in this case, but more importantly, the decision about what is serious adverse event is really up to the jury in this case. Because if we give them the CFR, a reasonable jury can infer that this gynecomastia is in fact a serious adverse event.

So I am just not persuaded on the pre-emption argument, so that one is stricken already. Discharged. Denied.

MR. KLINE: The last point on causation, Your Honor, it's all fresh in our minds. Dr. Solomon gave an opinion to a reasonable degree of medical certainty, based on his review of literature, based as a clinician, it's a clinical diagnosis, he made the diagnosis, he ruled out other things, and he clearly is qualified. I would respectfully

suggest to the Court that as to breast matters, while he was maligned and, at least to these old eyes, in this courtroom mistreated today by the questioner, I believe that he is eminently qualified and I believe more so qualified than some endocrinologist who will come in here, who doesn't routinely examine breasts, who doesn't know the pathology of the breast. So he gave a qualified opinion and he gave a sound opinion which met all of the criteria under Pennsylvania law.

THE COURT: All right, well, let me narrow the focus of what I would need to the following:

Regarding the 2002 label, point number one raised by Ms. Sullivan, that motion is denied. The question as a matter of law, it is a matter for the jury to decide whether or not the Warning was adequate. It's a factual matter based on the evidence in this case, and I see no reason to deviate from the overall framework of this case after hearing the evidence here so far on the Plaintiff's side.

As to whether Dr. Mathisen was aware of the risk of gynecomastia, that motion is denied. That is a factual question. We had testimony from him on that question, and the issue is for the jury as to whether they believe him or not, and that is denied. So that's a factual issue. A threshold has been made on that point, where Dr. Mathisen said that had he had the adequate Warning, what his view was he would have told his client, his patient's mother of the risk of this particular side effect. And if you give the inference to believability of the mother, she testified that she never heard that term gynecomastia until a commercial on TV many years later. So you have to give the inferences to the non-moving party in such a motion, so that motion is denied.

Regarding the next one -- what was your number three, Ms. Sullivan?

MS. SULLIVAN: It was based on the fact that a different Warning would not have mattered to Dr. Mathisen's decision to prescribe because he had what both Plaintiffs

and Judge New have determined is the adequate label and he continued to prescribe.

THE COURT: Right. That is a purely factual question, as far as I see it, so that is denied, also. That really has to do with what went on at the time of the change, the change of doctors. There is some evidence presented from the Plaintiff's mother on these issues. That is a factual issue that needs to be determined in the end by the jury.

Pre-emption grounds I have already denied as well.

Now I am interested in the issue of, what you phrase, Mrs. Sullivan, as the issue of whether or not Janssen could have done anything about the off-label. I mean doesn't that come to the crux of this whole case? There is powerful evidence in this case that Janssen essentially marketed this drug to pediatric neurologists, and I don't remember the exact details of how many doses were provided as samples. Are you telling me that in your view Janssen was handcuffed in terms of making some kind of Warning in conjunction

with its kind of behind-the-scenes promotion of this drug for children?

MS. SULLIVAN: Yes, Your Honor, and I respectfully disagree with Your Honor's characterization of the evidence, but on the question the Court cites, there are two reasons why we were "handcuffed."

One, there is specific evidence that when we tried to add pediatric safety data to prevent overdoses in children or infants, the FDA said no, we don't want you to use it to market it off-label.

And second, Your Honor, The regulation is clear that only the FDA -- in other words, the CBE provision that provides that pharmaceutical companies can voluntarily change their label for known risks if they are serious, relates to on-label uses. And then --

THE COURT: I will allow you to brief that, that one is the one I would hold. But the reality of the matter is, based on other experience and my own previous research is that unless you can tell me that there was an

inability to warn people based on adverse effects or on some kind of registry or some kind of letter to doctors, I don't see that as a basis for a directed verdict. But I will be willing to hear what your position is so that we can be sure about that, whether the same type of issues apply that have been seen in other pharmaceutical liability cases where the same argument has been made, that FDA simply does not allow safety, particularly, I am inclined to deny it right here, now that I am remembering Dr. Kessler's actual testimony which was -- he said it three times -- there is nothing out there that precludes a pharmaceutical company from issuing a warning, or from issuing a Dear Doctor letter. I remember him saying it over and over.

But I am still willing to look at the case law for us to be sure about, and certainly for jury instructions.

MS. SULLIVAN: Thank you, Your Honor.

THE COURT: And finally, on the issue of causation, it was indicated to me that you may want to pursue a little more carefully

Dr. Solomon's testimony today. I will give you leave to do that in order to focus in on what you think the gap may be in terms of causation. I can understand the issue. I think, just again, without having seen any brief from counsel about this, this gets into an interesting question of whether a particular discipline is required in terms of a medical expert opinion. And unless I have seen otherwise, it seems to me, to this Court, that a question of causation can be approached from different medical angles or different fields. And that may be the situation we have in this case.

So that's kind of where we are on that point. But I certainly would give you the opportunity to take a look at what the actual testimony was and where you think the gap was, that would be, certainly before I make a formal ruling I would like to see that.

MS. SULLIVAN: Thank you, Your Honor.

THE COURT: So where we are going to leave this for right now, we are going to resume tomorrow at 9:30 with your witness

tomorrow. Those two issues are on hold and we will look at them. So that's it, and we will continue tomorrow.

MS. SULLIVAN: Thank you, Your Honor.

THE COURT: Good night, counsel.

- - -

(Hearing is adjourned at 4:36 p.m.)

- - -

(Pledger v Janssen, et al.)

I HEREBY CERTIFY THAT THE PROCEEDINGS AND EVIDENCE ARE CONTAINED FULLY AND ACCURATELY IN THE NOTES TAKEN BY ME ON THE TRIAL OF THE ABOVE CAUSE, AND THAT THIS COPY IS A CORRECT TRANSCRIPT OF THE SAME.

JUDITH ANN ROMANO, RPR-CM-CRR
OFFICIAL COURT REPORTER
COURT OF COMMON PLEAS
PHILADELPHIA COUNTY

THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY ANY MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR DIRECTION OF THE CERTIFYING COURT REPORTER.

Appendix G

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IN RE RISPERDAL® LITIGATION

T.M. et al.,

Plaintiffs,

v.

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

Defendants.

PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION

MAY TERM 2013
NO. 1076

MOTION *IN LIMINE* OF DEFENDANTS JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, AND JANSSEN RESEARCH & DEVELOPMENT, LLC, TO PRECLUDE ANY EXPERT OPINION BY MARK P. SOLOMON, MD, OUTSIDE THE SCOPE OF HIS EXPERT REPORT

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Filing Date: October 24, 2016
Response Date: November 7, 2016
Reply Date: November 14, 2016
Control Number:

IN RE RISPERDAL® LITIGATION	PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION
T.M.. et al., Plaintiffs, v. Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Research & Development, LLC, Excerpta Medica, Inc., and Elsevier, Inc., Defendants.	**MAY TERM 2013** **NO. 1076** **CONTROL NO.**

ORDER

AND NOW, this _____ day of _____ 2016, upon consideration of the Motion *in Limine* of Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC, to preclude any expert opinion by Mark P. Solomon, MD, outside the scope of his expert report, and the response of Plaintiffs, if any, it is ORDERED that the motion is GRANTED.

By the Court:

_____

J.

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October 24, 2016

VIA ELECTRONIC FILING AND HAND DELIVERY

The Honorable Arnold L. New
Court of Common Pleas of
Philadelphia County
Complex Litigation Center
City Hall, Room 622
Philadelphia, PA 19107

Re: *In re Risperdal® Litigation*, March Term 2010, No. 296
***T.M. v. Janssen Pharmaceuticals, Inc.*, May Term 2013, No. 1076**

Dear Judge New:

In accordance with the Case Management Orders governing all Risperdal®/Risperidone Cases and mass tort motion procedure, Defendants Janssen Pharmaceuticals, Inc. ("Janssen"), Johnson & Johnson, and Janssen Research & Development, LLC, submit this motion *in limine* to preclude any expert opinion by Mark P. Solomon, MD, outside the scope of his expert report.

EXECUTIVE SUMMARY[1]

The crux of this action is the claim of Plaintiffs Brenda Tinkham and T.M. that Janssen failed to provide adequate warnings about the potential side effect of gynecomastia that is purportedly connected with the use of Risperdal. As reflected in

[1] All exhibits cited herein are attached to the Compendium of Exhibits filed with Motion *in Limine* of Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC, to Exclude any Evidence that Information Relevant to Risks Associated with Risperdal (Including "TABLE 21" and Related Information) Should Have Been Submitted to the US Food and Drug Administration.

their opposition to Defendants' motion for summary judgment, Plaintiffs allege that T.M. developed gynecomastia by 2012, after stopping Risperdal in 2008.[2]

In this case, Plaintiffs have designated a single expert, Dr. Solomon, as to the issue of specific causation.[3] In his report, however, Dr. Solomon (1) *never* opines as to *when* T.M. developed actual gynecomastia and (2) never opines as to the theory that allegedly ties T.M.'s alleged gynecomastia to his use of Risperdal from 2004–2008. Plaintiffs should be precluded from offering any testimony from Dr. Solomon as to any of these issues at trial.

ARGUMENT

Under Pennsylvania law, Plaintiffs are bound by the content of Dr. Solomon's expert report. Accordingly, at trial, Dr. Solomon cannot offer additional opinions that are not set forth in his report. Pa.R.C.P. No. 4003.5(c) ("[T]he direct testimony of the expert at the trial may not be inconsistent with or go beyond the fair scope of his or her testimony in the discovery proceedings as set forth in the deposition, answer to an interrogatory, separate report, or supplement thereto."); *see also Woodard v. Chatterjee*, 827 A.2d 433, 441 (Pa. Super. Ct. 2003) ("The fair scope rule, addressed specifically in Pa.R.C.P. 4003.5(c), 'provides that an expert witness may not testify on direct examination concerning matters [that] are either inconsistent with or go beyond the fair scope of matters testified to in discovery proceedings or included in a separate report.'" (citation omitted)); *Jones v. Constantino*, 631 A.2d 1289, 1294 (Pa. Super. Ct. 1993) ("We believe that Dr. Hughes' testimony was certainly not within the letter or spirit of Pa.R.Civ.P. 4003.5."). Testimony about opinions concerning when T.M. first developed

[2] Ex. S, Pls.' Resp. in Opp'n to Defs.' Mot. for Summ. J. at 25.

[3] *See* Ex. R, Expert Report of Mark P. Solomon, MD, dated June 1, 2016.

gynecomastia and whether his alleged gynecomastia developed two years after T.M. stopped taking Risperdal, none of which appear anywhere in Dr. Solomon's expert report, are not within the "fair scope" of the report.

Defendants obviously will be prejudiced if Plaintiffs are permitted to introduce expert testimony at trial beyond that set forth in Dr. Solomon's written report. *Woodard*, 827 A.2d at 441 ("The purpose of this rule [4003.5] is '[t]o prevent incomplete or 'fudging' of reports [that] would fail to reveal fully the facts and opinions of the expert or his grounds therefor.' Pa.R.C.P. 4003.5(c), cmt. In other words, the fair scope rule 'favors the liberal discovery of expert witnesses and disfavors unfair and prejudicial surprise.'" (citation omitted)).

To ensure compliance with Pennsylvania law, as well as to prevent prejudice to Defendants, Plaintiffs should be precluded from offering at trial any expert opinion by Dr. Solomon that is outside the scope of his expert report.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their motion *in limine*.

Respectfully submitted,

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IN RE RISPERDAL® LITIGATION	PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION
T.M. et al., Plaintiffs, v. Janssen Pharmaceuticals, Inc., Johnson & Johnson, Janssen Research & Development, LLC, Excerpta Medica, Inc., and Elsevier, Inc., Defendants.	MAY TERM 2013 NO. 1706

ATTORNEY CERTIFICATION OF GOOD FAITH

The undersigned counsel for movant hereby certifies and attests that:

☑ She has had the contacts described below with opposing counsel regarding the foregoing motion in an effort to resolve the specific disputes at issue and, further, that despite all counsel's good faith attempts to resolve the disputes, counsel have been unable to do so.

On October 24, 2016, I contacted counsel for Plaintiffs, Christopher Gomez. As of the filing of this Motion, the parties have been unable to reach an agreement to resolve any of the disputes at issue.

CERTIFIED TO THE COURT BY:

Dated: October 24, 2016

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Johnson & Johnson, and
Janssen Research & Development, LLC

CERTIFICATE OF SERVICE

I hereby certify that, on October 24, 2016, I caused a true and correct copy of the Motion *in Limine* of Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC, to Preclude Any Expert Opinion by Mark P. Solomon, MD, Outside the Scope of His Expert Report to be served via electronic mail on counsel of record as follows:

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Appendix H

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Attorneys for Plaintiffs

IN RE: RISPERDAL® LITIGATION	:	
		PHILADELPHIA COUNTY
T.M., et al.,	:	**COURT OF COMMON PLEAS**
		TRIAL DIVISION
Plaintiffs,	:	
		MAY TERM, 2013
v.	:	
		No. 1076
Janssen Pharmaceutical, Inc., et al.	:	
Defendants.	:	

PLAINTIFFS T.M., ET AL'S RESPONSE TO DEFENDANTS JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, AND JANSSEN RESEARCH & DEVELOPMENT, LLC'S MOTION *IN LIMINE* TO PRECLUDE ANY EXPERT OPINION BY MARK P. SOLOMON, MD, OUTSIDE THE SCOPE OF HIS EXPERT REPORT

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Control No. 16102831
Motion filed: October 24, 2016
Response date: November 7, 2016
Reply date: November 14, 2016

IN RE: RISPERDAL® LITIGATION	:	**PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION**
T.M., et al.,	:	
Plaintiffs,	:	**MAY TERM, 2013**
v.	:	**No. 1076**
Janssen Pharmaceutical, Inc., et al.	:	
Defendants.	:	

O R D E R

AND NOW, this _____ day of _____, 2016, upon consideration of Defendants' Motion *in Limine* to Preclude any Expert Opinion by Mark P. Solomon, Outside the Scope of his Expert Report, and any response thereto, it is hereby **ORDERED, ADJUDGED and DECREED** that Defendants' Motion is **DENIED**.

BY THE COURT:

_____

J.

Arnold & Itkin LLP
TRIAL LAWYERS

November 7, 2016

VIA ELECTRONIC FILING
The Honorable Arnold L. New
Coordinating Judge,
Complex Litigation Center
622 City Hall
Philadelphia, PA 19107

Re: ***In re: Risperdal Litigation*, March Term 2010, No. 0296**
***T.M., et al v. Janssen Pharmaceuticals Inc., et al.*, May Term 2013, No. 1076**

PLAINTIFFS T.M., ET AL'S RESPONSE TO DEFENDANTS JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, AND JANSSEN RESEARCH & DEVELOPMENT, LLC'S MOTION *IN LIMINE* TO PRECLUDE ANY EXPERT OPINION BY MARK P. SOLOMON, MD, OUTSIDE THE SCOPE OF HIS EXPERT REPORT

Dear Judge New:

In accordance with Case Management Orders governing this mass tort proceeding and mass tort motion procedure, please accept the following Response in Opposition to Defendants' Motion *in Limine* to Preclude Any Expert Opinion by Mark P. Solomon, MD, Outside the Scope of His Expert Report.

I. SUMMARY

If Defendants simply asked this Court to enforce Rule 4003.5, Plaintiffs would have no issue with this motion. However, Defendants ask this Court to go beyond that rule and exclude testimony that is within the fair scope of Dr. Solomon's report. As indicated by both the letter of the Rule itself, as well as the related case law, Dr. Solomon may flesh out his opinions at trial and testify on any matter in which he was never questioned during discovery proceedings. Dr.

Solomon explained in his report that, after reviewing medical records, depositions, and photographs, he ruled out other causes for T.M.'s gynecomastia. To the extent Defendants wanted to have Dr. Solomon flesh out his opinions in greater detail, they had ample opportunity to take Dr. Solomon's deposition.

Dr. Solomon's opinions will be within the fair scope of his report. Defendants do not, and cannot, argue that any testimony of the nature they seek to exclude would come as a surprise to them or put them in a position where they are unable to respond.

II. LEGAL ARGUMENT

The rule Defendants rely on to try to exclude key evidence in Plaintiffs' case reads as follows:

> (c) To the extent that the facts known or opinions held by an expert have been developed in discovery proceedings under subdivision (a)(1) or (2) of this rule, the direct testimony of the expert at the trial may not be inconsistent with or go beyond the fair scope of his or her testimony in the discovery proceedings as set forth in the deposition, answer to an interrogatory, separate report, or supplement thereto. However, the expert shall not be prevented from testifying as to facts or opinions on matters on which the expert has not been interrogated in the discovery proceedings.

Pa.R.C.P. No. 4003.5(c)

Defendants claim that Dr. Solomon cannot testify as to when T.M. developed gynecomastia, and how T.M.'s use of Risperdal was a substantial factor in bringing about his gynecomastia. All of these issues are well within the scope of his report.

Dr. Mark P. Solomon is a board certified plastic surgeon who has testified in previous Risperdal cases.[1] He attended medical school at NYU and completed his plastic surgery training and the University of Pennsylvania.[2] Dr. Solomon reviewed T.M's medical records, and the

[1] *See* Ex. A, M. Solomon Expert Report
[2] *Id.*

depositions taken in this matter, in addition to performing a medical examination of T.M.[3] Dr. Solomon utilized his training, education, extensive experience, and review of the materials mentioned above in formulating his expert opinions on causation in this matter.[4] Ultimately, Dr. Solomon concluded, to a reasonable degree of medical certainty, that the "only cause" of T.M.'s persistent gynecomastia, "is his prolonged exposure to Risperdal."[5] Reviewing all of the medical records and finding no other potential causes for the adverse effect of gynecomastia known to be related to Risperdal, Dr. Solomon opined that T.M.'s gynecomastia is due to his ingestion of Risperdal.[6] In fact, Dr. Solomon reports that he considered other possibilities for T.M.'s gynecomastia and, finding none, determined that Risperdal to be the cause. Excluding specific possibilities, like generic risperidone, which Defendants raised in their motion for summary judgment, is just fleshing out the opinions he rendered in his report. If Defendants wanted to discuss specifics they were interested in, they could have done so through additional discovery. With regard to when gynecomastia developed, contrary to Defendants' position, Dr. Solomon also takes into account, in connection with reaching his opinion, that the gynecomastia was first noticed when T.M. was 12 to 13 years of age, in 2009.[7]

"No hard and fast rule exists for determining when a particular expert's testimony exceeds the fair scope of his or her pre-trial report, and [a court] must examine the facts and circumstances of each case." *Woodard v. Chatterjee*, 2003 PA Super 207, ¶ 19, 827 A.2d 433, 442 (Pa. Super. Ct. 2003).

> In deciding whether an expert's trial testimony is within the fair scope of his report, the accent is on the word 'fair.' The question to be answered is whether, under the circumstances of the case, the discrepancy between the expert's pre-trial report and his trial testimony is of a nature which would prevent the adversary from preparing a

[3] *Id.*
[4] *See Id.*
[5] *Id.* at 2
[6] *Id.*
[7] *See Id.*

> meaningful response, or which would mislead the adversary as to the nature of the appropriate response.

Bainhauer v. Lehigh Valley Hosp., 2003 PA Super 338, ¶ 21, 834 A.2d 1146, 1151 (Pa. Super. Ct. 2003).

Defendants certainly cannot say that anything in Dr. Solomon's report is misleading, so they must be arguing that they cannot provide a meaningful response to the issues they seek to exclude. However, Defendants can absolutely provide a meaningful response. Indeed, the issue of Risperdal causing T.M.'s gynecomastia was raised *by Defendants* in their motion for summary judgment, so they cannot say that having Dr. Solomon address it would come as any type of surprise. *Tiburzio-Kelly v. Montgomery*, 452 Pa.Super. 158, 172-73, 681 A.2d 757, 764 (1996) (the determination of whether expert testimony must be made with reference to the facts and circumstances of each case and the controlling principle must be the purpose of the rule which is to avoid unfair surprise); *Daddona v. Thind*, 891 A.2d 786, 808 (Pa.Cmwlth. 2006) (although words "diffuse axonal injury" were not used in expert report, report discussed nature of the injuries and addressed nature of opposing expert's rebuttal allegations, no surprise.) Because Risperdal causing T.M.'s gynecomastia is one of the issues raised by Defendants, it's shocking that they have told this Court they are surprised to hear that Dr. Solomon will address it in connection with his opinions that Risperdal was the only cause T.M.'s gynecomastia. Again, Dr. Solomon states in his report that he reached this opinion *after considering other causes*. The issue of when the gynecomastia began (which *is* discussed in Dr. Solomon's report) is related to addressing the issue of Risperdal as the cause of T.M.'s gynecomastia raised by Defendants. Indeed, the effect of Risperdal on prolactin levels during the initial 8-12 weeks (from Defendants own documents) has been a major focus of this litigation and can hardly come as a surprise.

Courts have repeatedly held that experts are allowed to flesh-out their opinions at trial, and in fact, have reversed lower courts for limiting testimony that was fairly within the scope of

the broader opinions set forth in expert reports. *See e.g. Schaaf v. Kaufman*, 2004 PA Super 129, ¶ 50, 850 A.2d 655, 667 (Pa. Super. Ct. 2004) (expert's report stating "other possible causes" for injury was sufficient to allow him to discuss the specifics of the other medical causes at trial; an expert is entitled to expect that the report will be read by qualified experts on the other side so that there will be no surprise); *Bainhauer*, 2003 PA Super 338, ¶ 21, 834 A.2d at 1151 (expert asked about whether a drug given at a specific time contributed to injury, court excluded testimony as outside of report and appellate court reversed because it was within scope of general opinions); *Andaloro v. Armstrong World Indus., Inc.*, 2002 PA Super 112, ¶ 30, 799 A.2d 71, 85 (Pa. Super. Ct. 2002) (Testimony by experts that every exposure of workers to asbestos was a substantial contributing factor to workers' development of disease was not outside the fair scope of their reports, though reports did not impose any specific limit on the quantity or frequency of exposure necessary to develop disease.).

As indicated by the letter of the statute and the accompanying case law, Defendants' Motion *In Limine* NO. 7 to Preclude Dr. Solomon from addressing the topics they list in their motion should be denied.

II. CONCLUSION

For all the foregoing reasons, Plaintiffs respectfully request that this Court DENY Defendants' *Motion in Limine* to Preclude Any Expert Opinion by Mark P. Solomon, MD, Outside the Scope of His Expert Report. Alternatively, this Court should RESERVE RULING on Defendants' Motion until trial to assess the evidence as it develops.

Respectfully submitted,

ARNOLD & ITKIN LLP

Date: November 7, 2016

/s/ Jason A. Itkin

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CERTIFICATE OF SERVICE

The undersigned certifies that a true and correct copy of the foregoing Plaintiffs T.M., et. al.'s Response to Defendants Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Janssen Research & Development, LLC's Motion *in Limine* to Preclude Any Expert Opinion by Mark P. Solomon, MD, Outside the Scope of His Expert Report, has been served via first-class mail and electronic mail on the following counsel of record:

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Counsel for the Janssen Defendants

Date: November 7, 2016

Arnold & Itkin LLP

/s/ Jason A. Itkin
Jason A. Itkin, Esquire

Appendix I

IN RE: RISPERDAL® LITIGATION	:	**PHILADELPHIA COUNTY COURT OF COMMON PLEAS TRIAL DIVISION**
T.M., et al.,	:	
Plaintiffs,	:	**MAY TERM, 2013**
v.	:	**No. 1076**
Janssen Pharmaceutical, Inc., et al.	:	
Defendants.	:	

ORDER

AND NOW, this 29 day of NOVEMBER, 2016, upon consideration of Defendants' Motion *in Limine* to Preclude any Expert Opinion by Mark P. Solomon, Outside the Scope of his Expert Report, and any response thereto, it is hereby **ORDERED, ADJUDGED and DECREED** that Defendants' Motion is **DENIED**. WITHOUT PREJUDICE.

BY THE COURT:

J.

Tm Etal Vs Janssen Phar-ORDER

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DOCKETED
COMPLEX LIT CENTER
NOV 29 2016
J. STEWART