IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

PATRICIA WEST, as legal guardian of LAQUINTON K. WEST,	)	
Plaintiff,	)	
v.	)	**Case No. 2:15-cv-553-WKW-DAB**
JANSSEN PHARMACEUTICALS, INC.,	)	
Defendant.	)	

REPORT AND RECOMMENDATION

In this pharmaceutical products liability case, Plaintiff Patricia West, as legal guardian of LaQuinton K. West,[1] sues Defendant Janssen Pharmaceuticals, Inc.,[2] alleging her son's ingestion of Risperdal and generic risperidone caused her son to develop gynecomastia, an abnormal development of breasts in males. Pending before the court are the Motion for Summary Judgment by Janssen (Doc. 184), Plaintiff's Motion to Exclude Certain Testimony by Janet Arrowsmith, M.D., (Doc. 175), Plaintiff's Motion to Exclude Certain Testimony by Elias G. Chalhub, M.D. (Doc. 177), Defendant's Motion to Preclude Expert Testimony by Michael D. Freeman, MedDr, MPH, FAAFS (Doc. 186), Defendant's Motion to Preclude Expert Testimony of Elizabeth Z.

[1] The case was initially filed with co-Plaintiff, Teresa Harper, as legal guardian of Clinton Harper, whose claims have since been severed. (Doc. 174).

[2] Plaintiffs' initial complaint sued Janssen Pharmaceuticals, Inc. also known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Ortho-McNeil Pharmaceutical Products, Inc.; Janssen, LP formerly known as Janssen Pharmaceutica Products LP; Johnson & Johnson; Janssen Research and Development, LLC, formerly known as Johnson & Johnson Research and Development, LLC; Dana Michele King; Preston Jerome Byrd; Patty Mims Funkhauser; Mindy L. Basquin; and John Does 1–50. (Doc. 1-13). Janssen Pharmaceuticals, Inc. is the only remaining Defendant in the case.

Naftalis, M.D. (Doc. 188), and Defendant's Motion to Preclude Expert Testimony of Laura M. Plunkett, PhD, DABT (Doc. 190). The parties filed sealed and unsealed joint exhibits in support, *see* Doc. 206, and have had the opportunity to fully brief the motions. *See* Docs. 176, 178, 185, 187, 189, 191, 192–205.[3] The court requested additional briefing on the Eleventh Circuit's recent opinion in *Small v. Amgen, Inc*., et al., No. 17-11440, 2018 WL 501354 (11th Cir. Jan. 22, 2018). (Docs. 207–09). For the reasons that follow, it is recommended that the Motion for Summary Judgment by Janssen (Doc. 184) be **granted** and the *Daubert* motions (Docs. 175, 177, 186, 188, 190) be **denied as moot**.

I. JURISDICTION

Janssen Pharmaceuticals, Inc.[4] ("Janssen") removed the case to this court pursuant to 28 U.S.C. § 1332 on the basis of diversity of citizenship and an amount in controversy in excess of seventy-five thousand dollars.[5] (Doc. 1). Plaintiff dismissed the individual Defendants, some of whom were non-diverse. (Doc. 13). The only remaining Defendant is Janssen Pharmaceuticals, Inc. The parties do not contest personal jurisdiction or venue, and the court finds sufficient information of record to support both. *See* 28 U.S.C. § 1391. On January 5, 2017, the above-styled matter was referred to the undersigned for recommendation on all pretrial matters. (Doc. 62); *see also* 28 U.S.C. § 636(b); Rule 72, Fed. R. Civ. P.; *United States v. Raddatz*, 447 U.S. 667 (1980); *Jeffrey S. v. State Bd. of Educ. of State of Ga.*, 896 F.2d 507 (11th Cir. 1990).

II. LEGAL STANDARD

[3] Additionally, Janssen filed supplemental authority (Doc. 210) in support of its Motion to Preclude Expert Testimony of Laura Plunkett on the preemption issue, but it is not pertinent to the analysis due to the court's recommendation summary judgment be granted on other issues.

[4] Effective December 31, 2007, Janssen Pharmaceutica, Inc. changed its name to Ortho-McNeil-Janssen Pharmaceuticals, Inc. As a result of reorganization, Janssen LP was canceled. On June 22, 2011, Ortho-McNeil-Janssen Pharmaceuticals, Inc. changed its name to Janssen Pharmaceuticals, Inc. (Doc. 1 at 1, n.1).

[5] Defendant acknowledges that Plaintiff meets the jurisdictional amount in controversy for purposes of diversity jurisdiction. (Doc. 1 at 3, n.5).

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In ruling on a motion for summary judgment, the Court construes the facts and all reasonable inferences therefrom in the light most favorable to the nonmoving party. *Reeves v. Sanderson Plumbing Prods., Inc*., 530 U.S. 133, 150 (2000). However, when faced with a "properly supported motion for summary judgment, [the nonmoving party] must come forward with specific factual evidence, presenting more than mere allegations." *Gargiulo v. G.M. Sales, Inc.*, 131 F.3d 995, 999 (11th Cir. 1997).

Summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "Summary judgment may be granted if the non-moving party's evidence is merely colorable or is not significantly probative." *Sawyer v. Southwest Airlines Co*., 243 F. Supp. 2d 1257, 1262 (D. Kan. 2003) (citing *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 250–51 (1986)).

"[A]t the summary judgment stage the judge's function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." *Anderson*, 477 U.S. at 249. "Essentially, the inquiry is 'whether the evidence presents a sufficient disagreement to require submission to the jury or whether it is so one-sided that one party must prevail as a matter of law.'" *Sawyer*, 243 F. Supp. 2d at 1263 (quoting *Anderson*, 477 U.S. at 251–52).

III. BACKGROUND FACTS

Patricia K. West ("Plaintiff") is the mother and legal guardian for her son, LaQuinton K. West ("West"). (Doc. 1-13, ¶ 4). Plaintiff filed this lawsuit against Janssen related to the design, manufacture, sale, marketing, advertising, promotion, and distribution of Risperdal and generic

risperidone.[6] *Id.*, ¶ 1. She alleges that West ingested Risperdal[7] and suffered injuries as a result, including a condition called gynecomastia,[8] abnormal development of breasts in males. *Id.*, ¶ 2–3. Plaintiff asserts claims against Janssen for failure to warn under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") (Count I), negligence (Count II), wanton misconduct (Count III), failure to warn (Count IV), breach of implied warranty of merchantability (Count V), fraud (Count VIII), and negligent misrepresentation (Count IX).[9] (Doc. 1-13). The facts, viewed in a light most favorable to Plaintiff as the non-moving party, are as follows:

A. West's Risperdal and Risperidone Use

West was born January 19, 1983. (Doc. 206-82 at 35:2). He was 32 years old when this lawsuit was filed in 2015. He was diagnosed with autism at an early age. (Doc. 206-82 at 34:18–24).[10] Plaintiff testified her son was first prescribed Risperdal by Dr. Love at the Vaughn Clinic.[11] (Doc. 206-82 at 47:14–48:14). West first saw Dr. Jan Mathisen in 1995 when he was 12 years old; Dr. Mathisen did not prescribe Risperdal at that time. (Doc. 206-83 at 81:7–16). He first prescribed Risperdal for West in October 2000, which was approximately three months prior to West turning 18 years old. *Id.* at 81:7–16; 90:15–92:23. In the October 11, 2000 visit, Plaintiff

[6] The case was filed in state court, but removed to this court by Defendant. (Doc. 1).

[7] The Complaint uses the term Risperdal to refer both to brand-name Risperdal and generic risperidone. (Doc. 1-13, ¶ 1).

[8] *See* (Doc. 206-5).

[9] Plaintiff had also asserted claims for breach of express warranty (Count VI), breach of implied warranty of fitness for a particular purpose (Count VII), and civil conspiracy (Count X), but the court entered summary judgment in Janssen's favor on those claims based on Plaintiff's concessions. *See* (Doc. 174).

[10] Dr. Mathisen testified West presented at the age of 12 with a history of autism since the age of four that was initially diagnosed at the Vaughn Clinic. (Doc. 206-83 at 81:7–21).

[11] Plaintiff testified her son was prescribed Risperdal by Dr. Love at some time between the ages of six and ten, (Doc. 206-82 at 30:22–31:2), but the first record evidence of Risperdal being prescribed is Dr. Mathisen's testimony that he prescribed Risperdal in October 2000 when West was 17 years old. (Doc. 206-83 at 81:7–16; 90:15–92:23). The earliest pharmacy records show a prescription for Risperdal being filled in June 2002 when he was 19 years old. (Doc. 206-84 at 4). According to Plaintiff, Dr. Love never explained to her why he prescribed Risperdal for West. (Doc. 206-82 at 155).

indicated to Dr. Mathisen that her son's behavior was getting worse and he was not sleeping well. *Id.* at 90:15–91:5. Dr. Mathisen prescribed Risperdal for West's autism and obsessive compulsiveness. *Id.* at 90:15–92:23. West was 17 years old.[12] *Id.* Dr. Mathisen testified that West was physically fully developed, at Tanner Stage V, at that time. (Doc. 206-103 at 367:3–369:9). In West's follow-up visit with Dr. Mathisen on April 26, 2001, it was noted that West had no side effects from the Risperdal and "Mom is very pleased with his progress"; the plan was to continue him on Risperdal and to follow up in six months. (Docs. 206-112 at 2, 206-83 at 94:7–95:2). Dr. Mathisen saw West in October 2001, and he was doing quite well with no reported new problems; Risperdal was continued. *Id.* at 96:12–21. When West was next seen in April 2002, his mother reported concerns with her son's increasing libido. *Id.* at 98:2–10. Because he knew that Risperdal can reduce libido at certain doses, Dr. Mathisen increased West's Risperdal prescription to three milligrams per day. *Id.* at 98:11–100:9. The doctor had a conversation with Plaintiff about alternatively using first-generation antipsychotics, Haldol or Prolixin, but the Plaintiff did not want to pursue those medications because of their side effects. *Id.* at 100:10–20. There are no records of visits with Dr. Mathisen between the April 10, 2002 visit and January 19, 2006. *Id.* at 101. There are pharmacy records of Risperdal prescription refills, however, during this period between visits.[13] *See* (Docs. 206-83 at 106–20, 206-84 at 4). The last time Dr. Mathisen saw West was January 19, 2006. (Doc. 206-83 at 101:19–103:9). At the January 2006 visit, West was 23 years old, and it was reported he wasn't taking his medications and he had an increased libido. *Id.* at 101–02. Dr. Mathisen offered the option of taking intermittent doses of Risperdal in a melt

[12] Citing to 21 C.F.R. § 201.57 (effective until June 29, 2006), Defendant argues that West would be considered an "adult" at all relevant times because FDA regulations during the period of West's use of brand-name Risperdal defined "pediatric" use to include children up to 16 years of age. (Doc. 185 at 4, n.10).

[13] Dr. Mathisen acknowledged it was against his office's general policy to continue to refill prescriptions beyond twelve to eighteen months without a follow-up appointment. (Doc. 206-83 at 104).

version. *Id.* at 102:15–23. Although January 2006 was the last office visit, the last risperidone prescription where Mathisen was the prescribing doctor was filled by West in April 2007. *Id.* at 120:6–11.

Dr. Daniel Mejer first saw West on July 6, 2006. (Doc. 206-86 at 31:20–25). West was present with his parents who expressed concerns of insomnia and exhibitionist behavior. *Id.* at 33. Current medication included Risperdal, but the notes reflect he was non-adherent to his medication. *Id.* at 33–34. Dr. Mejer did not recall West's autism diagnosis. *Id.* at 36. Dr. Mejer next saw West November 16, 2006, and he was doing well behaviorally and denied adverse events. *Id.* at 39:23–40:23. In his next visit of February 1, 2007, West was doing well with no reports of sexually inappropriate behavior. *Id.* at 42:19–20. On May 3, 2007, West was reportedly tired in the mornings and not taking his medication at school. In response, Dr. Mejer changed the time for his medication administration. *Id.* at 43–44. In his next visit of July 5, 2007, his weight was at 176 and he still had some exhibitionist behavior, albeit less frequent. *Id.* at 45. In December 2007, his weight was 174 and in March 2008 his weight was 165. *Id.* at 45–46. Dr. Mejer ordered labs to check for a metabolic issue which is a known side effect of second-generation antipsychotics. *Id.* at 50. In the May 2008 visit, his weight was stable at 165, there was no concern with his medication, but his symptoms worsened with non-adherence. *Id.* at 51:19–52:9. Up to this point in Dr. Mejer's treatment of West, he observed that West did better when compliant with his medication, and that West did not experience side effects from Risperdal. *Id.* at 58:11–23, 60:8–16. Dr. Mejer prescribed Risperdal and generic risperidone for West starting in July 2006 and continuing into October 2015. (Docs. 206-86 at 97:10–16; 206-85 at 6–13). Dr. David Schaffer took over West's care for a period starting in September 2008. *Id.* at 54.

Dr. Shaffer saw West from approximately September 2008 to June 2011. (Doc. 206-87 at 31:21–32:1). West was physiologically an adult the entire time he was treated by Dr. Schaffer.

Id. at 82:9–83:17. Notes from the September 4, 2008 visit, show West's weight was 168 pounds, he was having problems with inappropriate sexual behavior, and part of his problem was due to noncompliance with his medication. *Id.* at 76:12–16. Dr. Schaffer continued West on the Risperdal that he was previously prescribed. *Id.* at 76:17–78:2. He was next seen by Dr. Schaffer on December 4, 2008, his behavior had improved, with room for further improvement, and there were no side effects of the medication. *Id.* at 92:9–15. He was continued on Risperdal. Dr. Schaffer saw West again on March 5 and then June 4, 2009. *Id.* at 95–96. Overall, he was doing well, and he was continued on the Risperdal M. *Id.* West was next seen January 7, 2010. *Id.* at 101. His behavior was stable, and his prescription for Risperdal M was renewed. *Id.* In his July 1, 2010 visit, West reported he was fine. *Id.* at 102. Dr. Schaffer noted a diagnosis of ADHD and prescribed Adderal, in addition to the Risperdal. *Id.* at 102–03. In his January 6, 2011 visit, West's parents requested his Risperdal dosage be increased to help with his walking outside at nighttime. *Id.* at 109. From September 2008 until January 2011, West's weight went from 168 to 164 pounds. *Id.* at 110:6–111:7. During his time treating West, Dr. Schaffer did not note any side effects of the Risperdal, nor did the parents report any. *Id.* at 110—112. It was Dr. Schaffer's opinion that the benefits of Risperdal outweighed any side effects or negative effects. *Id.* at 113:20–22.

Pharmacy records show West was prescribed generic risperidone not manufactured by Janssen from October 2012 through October 2015. (Docs. 206-85 at 6–8; 93-2 at 2–11). Dr. Bernard Hale saw West January 15, 2016 for a physical and prescription refill. (Doc. 206-88 at 24:9–13). West weighed 185 pounds on that date. *Id.* at 70. There is no mention of gynecomastia in Dr. Hale's notes. *Id.* at 76. Pharmacy records show West was prescribed risperidone by Dr. Hale and nurse practitioner Jodie Shedd in early 2016 after this lawsuit was filed. (Doc. 206-85 at 13–14). Additionally, Plaintiff testified in July 2016 that West was still taking generic risperidone at that time. (Doc. 206-82 at 78:21–79:1).

Plaintiff testified the first time she observed her son's symptom of swelling of the chest was in July 2013. (Doc. 206-82 at 184:16–20). Dr. Chigozie Obiaka diagnosed West with gynecomastia on September 19, 2013, at the age of thirty.[14] (Docs. 206-93 at 3–4; 206-59). Plaintiff filed a declaration stating she would not have allowed West to take Risperdal if Dr. Mathisen had advised her that Risperdal could cause gynecomastia. (Doc. 206-59). It is undisputed that Risperdal improved West's behavior and provided a benefit. (Doc. 206-82 at 135–36, 151–52, 155–56, 192).

B. 1993 and 2006 Risperdal Labels

The 1993 Risperdal label contained the following information in the "precautions" section:

> Hyperprolactinemia: As with other drugs that antagonize dopamine D_2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. … Although disturbances such as galactorrhea, amenorrhea, gynecomastia, and impotence have been reported with prolactin-elevating compounds, the clinical significance of elevated serum prolactin levels is unknown for most patients.

(Doc. 209-90 at 3). The 1993 label additionally noted that gynecomastia had been reported in pre-marketing clinical trials:

> Other Events Observed During the Pre-marketing Evaluation of RISPERDAL
> …
> *Endocrine Disorders: Rare:*[15] gynecomastia, male breast pain, antidiuretic hormone disorder.

(Doc. 206-90 at 6). The above language from the 1993 Risperdal label continued to be contained in the Risperdal labels until October 2006. *See* Docs. 206-45–206-58, 206-90. During these years,

[14] The records of Montgomery Family Medicine reflect West was seen for "swelling on left anterior upper anterior chest wall around the nipple of 10 months duration progressively increasing in size." (Doc. 206-93 at 3). A diagnosis of gynecomastia secondary to Risperdal was made. *Id.* at 4. Plaintiff denied she told the doctor she first observed it ten months prior which would have been in November 2012; she testified she first noticed her son's condition at a family beach vacation in Myrtle Beach in July 2013. (Doc. 206-82 at 184:16–20).

[15] The Risperdal label defines "rare events" as occurring in fewer than 1 out of 1000 patients. (Doc. 206-90 at 6).

as it relates to pediatric use, the Risperdal label stated that "Safety and effectiveness in children have not been established." *See id.*

In 1996, Janssen added a section to the label concerning adverse events since market introduction which were temporally (but not necessarily causally) related to Risperdal. Up until October 2006, the section never included a reference to gynecomastia being an adverse event. *See* Docs. 206-45–206-5.

The October 2006 Risperdal label added and deleted certain language as it relates to hyperprolactinemia. Specifically, the reference to the "clinical significance of elevated serum prolactin levels is unknown for most patients" was deleted in the October 2006 version. *Compare* Doc. 206-45 at 4 *with* Doc. 206-90 at 3. The revised language contained in the "precautions" section stated:

> Hyperprolactinemia
> As with other drugs that antagonize dopamine D2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents. … Galactorrhea, amenorrhea, gynecomastia and impotence have been reported in patients receiving prolactin-elevating compounds.

(Doc. 206-90 at 4). The October 2006 Risperdal label included the following language regarding pediatric use and the risk of gynecomastia for children/adolescents:

> The efficacy and safety of RISPERDAL in the treatment of irritability associated with autistic disorder were established in two 8-week, placebo-controlled trials in 156 children and adolescent patients, aged 5 to 16 years.
> …
>
> Hyperprolactinemia, Growth, and Sexual Maturation
> Risperidone has been shown to elevate prolactin levels in children and adolescents as well as in adults.
> …
> 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.

(Doc. 206-90 at 5).

C. Janssen Studies and Knowledge of Risks Prior to 2006 Label Change

In December 1994, Janssen conducted a Risperdal taskforce examining the strengths and weaknesses of Risperdal versus competitors' drugs. (Doc. 206-121). High prolactin increase was listed as a Risperdal weakness, *id.* at 8, compared to Sertindole which had a strength of no prolactin increase, *id.* at 6, Seroquel had low prolactin increase, *id.* at 5, and Olanzapine had limited prolactin increase, *id.* at 4. In July 1997, Janssen conducted a "Risperdal National Advisory Board" meeting in which Janssen recognized Ziprasidone's "prolactin increase is less than observed with Risperdal," and "prolactin increase does produce related-side effects regardless of what Integrated Safety Base data shows." (Doc. 206-122 at 3). In August 1997, Janssen prepared a 1998 Business Plan recognizing that Olanzapine, Quetiapine, and Sertindole had "low prolactin," and that "prolactin elevation" was a weakness for Risperdal. (Doc. 206-123 at 3–4). In December 1998, Janssen presented a comparison of risperidone and olanzapine to the American College of Neuropsychopharmacology in which it was acknowledged that gynecomastia is an adverse event "definitely causally related to serum prolactin." (Doc. 206-125 at 2–3). Janssen conducted a study between 1996 and 2000 comparing risperidone and haloperidol in adult patients. (Doc. 206-126). The results of the study issued in a July 2003 report demonstrated prolactin-related adverse events were seen in a higher number of risperidone subjects than haloperidol subjects. *Id.* at 3.

From November 1997 until May 1998, Janssen conducted a study comparing Risperdal and olanzapine in adults aged 18 to 64. (Doc. 206-129). The results of the study published in June 2000 revealed gynecomastia and lactation nonpuerperal were adverse events attributable to prolactin disorder and that prolactin-related adverse events occurred in four risperidone subjects and in two olanzapine subjects. *Id.* at 6. In September 1999, Janssen reported on a study

comparing risperidone and olanzapine which demonstrated a hyperprolactinemia rate of 7.1% for risperidone users compared to 0.0% for olanzapine subjects. (Doc. 206-130 at 7).

From May 1997 until October 1998, Janssen conducted a study of risperidone use in children aged 5 to 12 years. (Doc. 206-127). The November 2000 report on the study showed a 12.7% rate for hyperprolactinemia in the children treated with risperidone. *Id.* at 3. In a risperidone study conducted September 18, 1997 until July 1, 1999 in children aged 5 to 12 years, Janssen reported in November 2000 that the study revealed an 11.3% rate for hyperprolactinemia in the children and adolescents treated with risperidone.[16] (Doc. 206-128 at 2–5). In a September 2003 report, Janssen admitted that "[e]levated prolactin plasma levels can directly induce galactorrhea and gynecomastia," and in long-term phase III trials, 3.7 % of males reported gynecomastia. (Doc. 206-131 at 3).

In a 2003 article titled *Prolactin Levels During Long-Term Risperidone Treatment in Children and Adolescents*, *see* Doc. 206-133, the authors noted "[n]o correlation was found between SHAP [side effects hypothetically attributable to prolactin] and prolactin levels, even when male gynecomastia during puberty was included." *Id.* at 8. Plaintiff has proffered communications between the authors and Janssen representatives, prior trial testimony of the authors, and drafts of the manuscript to demonstrate Janssen was aware of a statistically significant relationship at usage for 8 to 12 weeks between SHAP and prolactin levels, which directly contradicts the article's statement of no correlation. (Doc. 199 at 21–22). A white paper from Janssen Medical Affairs, LLC, dated August 2004 and titled Prolactin: From Mechanisms to Sequelae, stated: "Current evidence suggests that risperidone leads increases in prolactin levels when other atypicals have comparative weak to neutral effects on prolactin." (Doc. 206-83 at 183).

[16] No subject in the risperidone group and one subject in the placebo group reported prolactin-related adverse events (dysmenorrhea). (Doc. 206-128 at 4).

D. Knowledge of Prescribing Physicians

1. Dr. Mathisen

Dr. Mathisen started prescribing antipsychotics early in his practice in approximately 1988. (Doc. 206-83 at 66:5–15). He prescribed first-generation antipsychotics such as Haldol and Mellaril. *Id.* In the 1996-1997 time frame, he began prescribing Risperdal, a second-generation antipsychotic, to his patients. *Id.* at 68. This was considered an off-label[17] use because an indication for Risperdal in autistic children and adolescents was not approved until 2006. *Id.* at 69:7–12. He was aware that hyperprolactinemia was a side effect of the first-generation antipsychotics and because Risperdal was a drug that similarly blocked the dopamine receptor, "it made sense that it would have a similar response, that it would cause some elevation of prolactin." *Id.* at 72:17–73:7. His understanding, however, was that there were no specific long-term issues. *Id.* at 73:7–10. He was aware that prolactin elevation can cause side effects of galactorhhea, breast enlargement, and osteoporosis. *Id.*

As of October 2006, Dr. Mathisen had treated over one thousand patients with Risperdal without any patient experiencing gynecomastia as a side effect. (Doc. 206-103 at 517:18–518:7). If he had seen something unusual, he would have spent more time looking at the package insert regarding it. *Id.* at 518:7–13. Dr. Mathisen was aware that gynecomastia was a potential side effect of prolactin-elevating compounds independent of what was contained in the label.

> Q. And with respect to the information in the label, without a doubt it was there; and had you read it, you would have seen it, and you could have taken it into account in your prescribing decisions, correct?
> …

[17] An off-label use can include "prescriptions of the drug for a condition not indicated on the label, treating an indicated condition at a different dose or frequency than specified on the label, or treating a different patient population than approved by the FDA." *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1356 n.4 (11th Cir. 2011). Off-label use of a prescription medicine is lawful. "Once a drug has been approved by the FDA and placed on the market, physicians may prescribe it for *any* purpose. The use of a drug 'off-label' is therefore common in and accepted as beneficial by the health care community." *Id.* (emphasis in original).

A. That's true.

Id. at 518:18–519:3

Q. And then the second paragraph under Hyperprolactinemia, compare those in the 2014 and October 2006 labels. Are those the same as well?
…
A. It does appear to be word-for-word the same.
Q. Okay. In the second paragraph, in both of these labels, the October 2006 and the 2014 label, it says that, Gynecomastia has been reported in patients receiving prolactin-elevating compounds, correct?
…
Q. Is that right?
A. Yes.
Q. And that's something you knew even before it was put in the label, right?
…
A. Yes. Uh-huh.
Q. And that's something that you generally knew through your medical education and experience, correct?
A. Correct.
Q. And that's true of all antipsychotic agents or any prolactin-elevating compound, that there had been reports of gynecomastia in some of those people, correct?
A. Yes.
…
Q. And would that have been something that you took into account in prescribing Risperdal over the years?
…
A. Well, over the years, we always had the issue of prolactin elevation as part of our discussion. Early in the course, we felt that it was just part of the potential risk of all the medicines that we were using. As this labeling would show that in 2006, it obviously focused more that Risperdal had that effect more than some of the other medications.

Id. at 423:2–425:4.

Dr. Mathisen testified that if he had known that Risperdal elevated prolactin levels more than any other second-generation antipsychotic, he would have factored that into his analysis and discussed with his patient's parents. (Doc. 206-83 at 252:21–253:12). He acknowledged that the description of the incidence of gynecomastia being rare in adults referenced in the Risperdal label was accurate. (Doc. 206-103 at 425:15–427:7). And before October 2006, the Risperdal label did not say anything about the risk of gynecomastia in children because it had not been proven as safe and effective in children yet. *Id.* at 427:8–16. He knew that the label before 2006 was never

intended as a risk profile for Risperdal in children and adolescents, and he took that into account in making his prescribing decisions. *Id.* at 428:3–11.

> Q. Okay. And so as you sit here today, isn't it true that your prescribing decision for Mr. West wouldn't have been changed because -- by the addition of the language in October 2006 relating to hyperprolactinemia, because with respect to Mr. West as an adult, the label always accurately described the risk as rare?
> …
> A. Yes.
> …
> Q. And just so it's clear, you wouldn't have changed your decision to prescribe Risperdal for Mr. West at any time that he was considered to be an adult, would you?
> A. No.

Id. at 447:15–450:11.

2. Dr. Mejer

Dr. Mejer saw West beginning in July 2006 and continued to see him off and on up until at least March 2016. (Doc. 206-86 at 105:1–6, 126:2–8). Dr. Mejer completed his fellowship in child and adolescent psychiatry in 1995 and would have learned about first and second-generation antipsychotics during his medical training. *Id.* at 110:15–111:9. He became aware in October 2006 that Risperdal received an indication for pediatric use in patients with behavioral problems associated with autism. *Id.* at 117:7–25. From the time he first started prescribing Risperdal, Dr. Mejer was familiar with the medication's side effects of weight gain; development of hyperprolactinemia and potentially conditions associated with hyperprolactinemia, such as gynecomastia; and metabolic disorders including diabetes. *Id.* at 118:24–119:18. He would have taken knowledge of those side effects into account when prescribing Risperdal. *Id.* at 120:2–7. He decided to prescribe Risperdal to West because he believed it would provide a therapeutic benefit, and that benefit outweighed any risk of an adverse event based on his assessment at the time. *Id.* at 122:8–123:1.

During the time Dr. Mejer treated West, West's parents did not report any ill effect or injury from the medicine. *Id.* at 125:14–19. West's medical records reflect a 30-pound weight

gain. *Id.* at 129:1–14. There are no notes in West's medical records that Dr. Mejer had a conversation with the parents about side effects, but West came to him already being prescribed Risperdal so the assumption was those conversations already occurred. *Id.* at 132:9–25, 138:9–22. Given that gynecomastia was listed as "rare" in terms of likelihood, he probably would not have gone over it with his patients in any event. *Id.* at 144:16–145:1. Dr. Mejer knew that second-generation antipsychotics can cause elevated prolactin levels and that elevated prolactin levels are associated with certain events including gynecomastia. *Id.* at 160:7–19.

3. Dr. Schaffer

Dr. Schaffer was well aware that one potential side effect of Risperdal is hyperprolactinemia, or elevated prolactin levels, and that hyperprolactinemia has been associated with certain other conditions, including gynecomastia. He was aware of the different potential side effects at the time he prescribed Risperdal to West, took them into account when making his prescribing decision, and determined the benefits of Risperdal outweighed the potential side effects. (Doc. 206-87 at 93:9–95:15).

4. Dr. Hale and Nurse Practitioner Shedd

Dr. Hale saw West on only one occasion in January 2016. (Doc. 208-88 at 58:5–8). Dr. Hale was aware of the side effects of prolactin-elevating compounds and took that into account when prescribing Risperdal to West. *Id.* at 39. Shedd saw West in February 2016; he was 33 years old at the time and his weight was 189 pounds. (Doc. 208-89 at 65, 97). She similarly testified that she was familiar with the side effects of Risperdal and weighed those risks against the benefits prior to refilling his Risperdal prescription. *Id.* 45:5–46:2, 105:1–106:4. In renewing West's Risperdal prescription, Shedd allowed for a one-year's supply of refills. *Id.* at 92. She did not diagnose gynecomastia and there is no mention of it in West's chart. *Id.* at 82–83.

IV. DAUBERT MOTIONS

Plaintiff challenges defense experts, Janet Arrowsmith, M.D., and Elias G. Chalhub, M.D. (Docs. 175, 177). Dr. Arrowsmith is being offered by the defense as a regulatory expert regarding matters related to the Food and Drug Administration (FDA) and labeling of medications. Plaintiff argues that Dr. Arrowsmith's opinions about what the FDA would have done had it been provided additional information are speculative and conjecture, and her opinions regarding what the FDA did in 2014 and 2015 are irrelevant to West's use of brand-name Risperdal in 2000 through 2009. (Doc. 176 at 5–7).

Dr. Chalhub opines on pediatric neurology matters and drug labeling. Plaintiff contends Dr. Chalhub's opinions should be excluded because they rely solely on his personal experiences, and not on any of the peer-reviewed literature he cites, which document that Risperdal causes significantly higher levels of prolactin, especially in children and adolescents, than other second-generation atypical antipsychotics. (Doc. 178 at 5–11). Plaintiff impugns Dr. Chalhub's qualifications to testify as to the adequacy of the Risperdal label and challenges his opinion that gynecomastia is "rare" as being contradictory to the facts and the medication label. *Id.* at 12–15. Lastly, Plaintiff contends Dr. Chalhub's opinion that the medication is "safe and effective" is argument and not expert testimony, and therefore should be excluded under Fed. R. Evid. 702 and *Daubert*. *Id.* at 15.

Defendant challenges Plaintiffs' experts, Dr. Michael Freeman, Dr. Elizabeth Naftalis, and Dr. Laura Plunkett. (Docs. 186, 188, 190). Defendant seeks to exclude the specific and general causation opinions of Drs. Freeman and Naftalis. (Docs. 187, 189). Regarding Dr. Plunkett, Defendant challenges Dr. Plunkett's opinions regarding Risperdal label adequacy for the period of 1994 through October 2006 and any general causation opinions. (Doc. 191).

V. DISCUSSION

To a significant degree, this case epitomizes the limitations of medical science, the law, and their interaction. The course of human history has seen profound improvements in our understanding of health, disease, and other afflictions. Recent advances in diagnosis and treatment of medical conditions, both physical and mental, are often little short of miraculous. Despite these advances, our understanding of maladies and their safe and effective treatment remains incomplete and imperfect. This is especially and poignantly true with respect to the broad category of mental health conditions. Doctors and the pharmaceutical industry have developed any number of powerful medicines for treatment of many of those conditions, with varying levels of effectiveness. All these medicines carry the burden of potential side effects for some or all users. Determining the origin of adverse conditions associated with certain drugs is often difficult.

Measuring the breadth and fixing the limits of legal liability for adverse drug reaction requires development and application of legal principles in an area of great medical uncertainty and conflicting economic and societal goals. Through federal and state legislation, administrative regulation and approvals, and the common law, we establish standards for patients, doctors, and pharmaceutical companies to govern their affairs. Legal concepts of proof and causation are often not readily applied where scientific knowledge is incomplete and uncertain. The twin aims of providing appropriate compensation to individuals injured by others while encouraging doctors and drug companies to advance the field of medicine frequently conflict, as in this case.

Here, Janssen argues its Risperdal label provided adequate warnings to West's medical providers, which it urges is all that is required to support summary judgment in its favor. Specifically, Janssen initially argues that Plaintiff has offered no expert evidence that any label for Risperdal or generic risperidone after October 2006 was inadequate or misleading. Second, Janssen submits that Plaintiff lacks evidence of the essential elements of reliance and causation,

including the inability to satisfy Alabama's learned intermediary doctrine. Third, Janssen argues that Plaintiff lacks sufficient evidence to show Risperdal caused West's claimed gynecomastia. Finally, Janssen contends that Plaintiff is unable to establish separate claims for wanton misconduct, breach of the implied warranty of merchantability, fraud, negligent misrepresentation or punitive damages. (Doc. 185).

A. West's Generic Risperidone Use

According to Plaintiff's filings, West used the generic version of risperidone since 2009. *See* Doc. 176 at 6. Thus, on the failure to warn claims, Janssen submits that Plaintiff's only potential theory of liability available under Alabama law is the narrow one articulated in *Wyeth, Inc. v. Weeks*, 159 So. 3d 649 (Ala. 2014).[18] In *Weeks*, the Alabama Supreme Court held a brand-name drug manufacturer liable for fraud or misrepresentation, based on statements it made in connection with the manufacture of the drug, in an action brought by a consumer who was allegedly injured by long-term use of the generic version of the brand-name drug manufactured by a different company. *Id.* at 676. Janssen contends that Plaintiff's gynecomastia could only have been caused by generic risperidone.

Dr. Freeman testified the half-life of Risperdal or risperidone was a few days, and agreed that if the last time West took the branded medication was in 2008, then the branded medication could not have caused gynecomastia developing in late 2012 or in 2013. (Doc. 206-96 at 29, 62). Dr. Naftalis testified that given the half-life of Risperdal or risperidone that it would be out of a patient's system within one to two weeks. (Doc. 206-95 at 144–45). Based on the testimony of

[18] Janssen's pleadings note the limited theory of recovery established in *Weeks* subsequently was abrogated by the Alabama legislature. *See* ALA. CODE § 6-5-530 ("In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product.") (Doc. 185 at 18 n.63).

Plaintiff's experts regarding a medication's half-life and the fact that Plaintiff did not develop gynecomastia until allegedly 2013, Janssen submits that the only potential source of causation could be the generic risperidone used by West since 2009.[19] (Doc. 185 at 16–17). Be that as it may, the *Weeks* opinion supports a finding that Janssen may be held liable for West's ingestion of generic risperidone even if not manufactured by Janssen.

B. Failure to Warn/AEMLD Claims and the Learned Intermediary Doctrine

The gravamen of Plaintiff's claims is that Janssen failed to provide accurate or complete information about the risk of gynecomastia from Risperdal use. Plaintiff points to numerous pre-2006 Janssen studies and internal documents to support her argument that Janssen knew the risks associated with Risperdal use were significantly different from the risks outlined in the Risperdal label prior to 2006 and Janssen was negligent or fraudulent in failing to warn consumers of those risks.

Plaintiff has sued Janssen under Alabama's Extended Manufacturer's Liability Doctrine (AEMLD). Under the AEMLD, "a manufacturer, or supplier, or seller, who markets a product not reasonably safe when applied to its intended use in the usual and customary manner, constitutes negligence as a [m]atter of law." *Casrell v. Alltec Indus., Inc.*, 335 So. 2d 128, 132 (Ala. 1976). In the context of prescription medication, the adequacy of the warning issued by a drug manufacturer bears on whether a plaintiff has proven a prima facie case under the AEMLD. *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304 (Ala. 1984). Consequently, "in the case of an 'unavoidably unsafe' yet properly prepared prescription drug, the adequacy of the accompanying warning determines whether the drug, as marketed, is defective, or unreasonably

[19] Dr. Freeman testified the half-life of Risperdal or risperidone was a few days, and agreed that if the last time West took the branded medication was in 2008, then the branded medication could not have caused gynecomastia developing in late 2012 or in 2013. (Doc. 206-96 at 29, 62). Dr. Naftalis testified that given the half-life of Risperdal or risperidone that it would be out of a patient's system within one to two weeks. (Doc. 206-95 at 144–45).

dangerous." *Id.* (citations omitted). To prevail on an inadequate warning claim under Alabama law, Plaintiff must establish that Janssen breached a duty which proximately caused Plaintiff's injury. *E.R. Squibb & Sons, Inc. v. Cox*, 477 So. 2d 963, 969 (Ala. 1985).

"A prescription-drug manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug. Once that duty is fulfilled, the manufacturer has no further duty to warn the patient directly." *Weeks*, 159 So. 2d at 673. Alabama has adopted the learned-intermediary doctrine. *See Stone*, 447 So.2d at 1304–05 (adopting the learned-intermediary doctrine in pharmaceutical products liability cases). Alabama's learned-intermediary doctrine "creates an exception to the general rule that one who markets goods must warn foreseeable ultimate users about the inherent risks of his products." *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 519 (11th Cir. 2007). The doctrine imposes on a pharmaceutical company, such as Janssen, a duty to provide warnings solely to the prescribing physician rather than to the patient directly. *Stone*, 447 So. 2d at 1304. The Alabama Supreme Court explained:

> The principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer of a drug and the consumer/patient and that, therefore, the physician stands in the best position to evaluate a patient's needs and to assess the risks and benefits of a particular course of treatment for the patient.

Weeks, 159 So. 3d at 672–73. The doctrine exists because consumers can obtain prescription drugs only through a physician or other qualified healthcare provider, and physicians are trained to understand the highly technical warnings required by the FDA in drug labeling. *Id.* at 673 (citing 21 U.S.C. § 353(b)(1); 21 C.F.R. § 201.56). The doctrine "recognizes the role of the physician as a learned intermediary between a drug manufacturer and a patient." *Id.*

While the adequacy of a drug manufacturer's warning is measured by its effect on the physician, and not by its effect on the consumer, "if the warning to the learned intermediary is

inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient." *Id*. For the doctrine to apply, a plaintiff must make a specific showing: "that the manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury." *Id.* at 673–74.

Alabama's learned-intermediary doctrine applies both to actions brought pursuant to the AEMLD, *see Morguson v. 3M Co*., 857 So.2d 796, 802–03 (Ala. 2003), and to those based on a negligent failure to warn theory. *See Stone*, 447 So.2d at 1304–05. The learned-intermediary doctrine can be an absolute defense to a failure to warn claim. *Weeks*, 159 So. 3d at 673 (citing Mitesh Bansilal Shah, Commentary, *As a Matter of Fact or a Matter of Law: The Learned Intermediary Doctrine in Alabama*, 53 Ala. L. Rev. 1299, 1301 (2002)). Viewing the facts in a light most favorable to Plaintiff, Janssen knew prior to the 2006 label change that Risperdal caused potentially greater risk of increased prolactin levels than competing second-generation antipsychotics, but failed to warn consumers of that risk prior to October 2006. That said, the record evidence establishes that the pre-2006 label was not intended to be a risk profile for adolescents, and the precaution section of the label specifically advised that risperidone can increase prolactin levels and gynecomastia has been reported in patients taking prolactin-elevating compounds. West was physiologically an adult at all times that he took Risperdal and risperidone.

Of significance, West's treating physicians testified they knew that gynecomastia was a potential side effect of prolactin-elevating compounds such as Risperdal or risperidone, separate from what was contained in the manufacturer's label, and chose to prescribe the medication notwithstanding those risks. Although Dr. Mathisen stated he would have factored the pre-marketing studies into his risk-benefit analysis and his discussion with patients (had Janssen shared that information with him), he nevertheless testified that his prescribing decision would not have

changed.[20] Plaintiff has declared that she would not have allowed her son to take Risperdal if Dr. Mathisen had advised her that Risperdal could cause gynecomastia, *see* (Doc. 206-59), but this testimony contradicts the fact that she continued to refill his Risperdal prescriptions at least up until 2016 despite West's diagnosis of gynecomastia in 2013.

The prescribing decisions of West's health care providers were made after weighing the risks of gynecomastia from Risperdal use. Critical to a plaintiff avoiding the learned-intermediary doctrine is a demonstration "that the manufacturer failed to warn the physician of a risk *not otherwise known to the physician*." *Weeks*, 159 So. 3d at 673 (emphasis added). Dr. Mathisen testified he was aware that gynecomastia has been reported in patients receiving prolactin-elevating compounds even before the information was printed on the Risperdal label and would have factored that into his prescribing decision. (Doc. 206-103 at 423:2–425:4). From the time Dr. Mejer first started prescribing Risperdal, he was familiar with Risperdal's side effects of weight gain, hyperprolactinemia (elevated prolactin levels), and conditions potentially associated with hyperprolactinemia, such as gynecomastia. (Doc. 206-86 at 118–19). Dr. Schaffer was well aware that a potential side effect of Risperdal is hyperprolactinemia, or elevated prolactin levels, and that hyperprolactinemia has been associated with certain other conditions, including gynecomastia. (Doc. 206-87 at 94). Dr. Hale testified that he was aware of Risperdal's side effects, including hyperprolactinemia, and that gynecomastia has been reported in patients taking prolactin-elevating compounds. (Doc. 206-88 at 33–39). When nurse Shedd prescribed Risperdal to West, she was aware gynecomastia was a potential side effect of the medication. (Doc. 206-89 at 45–46). Drs. Mathisen, Schaffer, Mejer, Hale, and nurse practitioner Shedd testified they made

[20] Additionally, as Janssen points out, Dr. Mathisen acknowledged that until a study is completed and the data analyzed, it is not available for him to rely upon in making his prescribing decision. (Doc. 206-103 at 485–86).

their prescribing decisions after weighing the risk of Risperdal's side effects with the benefits West received from being on the medication.

Applying Alabama's learned-intermediary doctrine to the facts here, the court finds that Janssen provided adequate warnings to West's prescribing physicians and health care providers such that Plaintiff's claims against Janssen under the AEMLD and for failure to warn are barred. The prescribing physicians were aware of the risks when making their prescribing decisions, and thus, the doctrine still applies to bar Plaintiff's AEMLD and failure to warn claims.[21] *See Ellis v. C.R. Bard, Inc*., 311 F.3d 1272, 1283 n.8 (11th Cir. 2002) ("Where a learned intermediary has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided, courts typically conclude that the learned intermediary doctrine applies or that the causal link is broken and the plaintiff cannot recover.") (citation omitted). In this Circuit, summary judgment is appropriate when a Plaintiff's claims against a drug manufacturer are barred by the learned-intermediary doctrine. *See, e.g.*, *Small v. Amgen, Inc.*, No. 17-11440, 2018 WL 501354 (11th Cir. Jan. 22, 2018), *Bodie*, 236 F. App'x at 522. For the reasons set forth above, summary judgment is due to be granted in Janssen's favor on Plaintiff's AEMLD and failure to warn claims on the basis of the learned-intermediary doctrine.

C. Wantonness Claim

In Alabama, the term "wantonness" is statutorily defined as "[c]onduct which is carried on with a reckless or conscious disregard of the rights or safety of others." ALA. CODE § 6–11–20(b)(3). To state a common law claim for wantonness, a plaintiff must show defendant engaged in "the conscious doing of some act or the omission of some duty while knowing of the existing

[21] Additionally, given the experts' testimony regarding the half-life of the medication, Plaintiff would be unable to establish West's Risperdal ingestion as a 17-year old in 2000 caused his gynecomastia diagnosed in 2013.

conditions and being conscious that, from doing or omitting to do an act, injury will likely or probably result." *Ex parte Essary*, 992 So.2d 5, 9 (Ala. 2007) (citing *Bozeman v. Central Bank of the South*, 646 So.2d 601 (Ala. 1994)). Although Janssen's internal studies showed that gynecomastia was a potential side effect of Risperdal use, Plaintiff can point to no evidence that supports Janssen knew that gynecomastia was a *likely or probable* result of Risperdal usage.

Alabama courts have recognized that wantonness requires an "act done or omitted with knowledge of the probable consequence and with reckless disregard of such consequence." *Scharff v. Wyeth*, No. 2:10-CV-220-WKW, 2012 WL 3149248, at *3 (M.D. Ala. Aug. 1, 2012) (citation omitted). Plaintiff argues Janssen acted wantonly in actively marketing Risperdal to child physicians prior to Risperdal having an approved indication for use by children and adolescents. (Doc. 199 at 50–52). Dr. Mathisen testified, however, that he knew that Risperdal had not yet been approved for use by children when he prescribed it prior to October 2006 and that the label was not intended to be a risk profile for children and adolescents. Moreover, the pre- and post-2006 Risperdal labels specifically warned of the possibility of gynecomastia. The fact that the warnings could have been broader or stronger does not equate to reckless disregard or an indifference toward safety. *See Scharff* at *9 ("Even accepting [plaintiff's] argument and evidence that Wyeth engaged in an extreme disinformation campaign, which challenged the studies, muddied the waters with less reliable industry-funded studies, underplayed the risks with dear doctor letters, and engaged in suspicious attacks on the outside studies, these acts are not sufficient to overcome the warning requirement for wanton conduct [where it was] undisputed that Wyeth [warned] … the risk of breast cancer is unknown, although a moderately increased risk [of breast cancer] in those taking combination estrogen/progestin therapy has been reported."). Even if Janssen prior to 2006 could or should have included a warning that Risperdal leads to greater increases in prolactin levels than other second-generation antipsychotics, this fact does not negate

that the 1993 through 2006 labels contained a precaution specifically stating that "risperidone elevates prolactin levels and the elevation persists during chronic administration." *See, e.g.*, (Doc. 209-90 at 3). The same section identified that "disturbances such as … gynecomastia … have been reported with prolactin-elevating compounds, [although] the clinical significance of elevated serum prolactin levels is unknown for most patients." *Id.* Perhaps the warning could have been worded clearer and without qualifications, but it cannot be said that it evidences an indifference toward safety. Accordingly, Janssen's motion is due to be granted on Plaintiff's wantonness claim.

D. Breach of Implied Warranty of Merchantability

Under Alabama law, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." ALA. CODE § 7–2–314 (1975). "Merchantability" refers to a product's being, in part, "fit for the ordinary purpose for which such goods are used." *Id.* These provisions in the Alabama Code mirror the Uniform Commercial Code's ("U.C.C.") provisions on the implied warranty of merchantability. *See* U.C.C. § 2–314. A plaintiff can establish a prima facie case for breach of the implied warranty of merchantability if the plaintiff can prove the existence of the warranty; a breach of that warranty; and damages proximately resulting from that breach. *Bodie*, 236 F. App'x at 522.

"In general, Alabama law does not recognize a cause of action for breach of implied warranty of merchantability for inherently dangerous products." *Barnhill v. Teva Pharm. USA*, Inc., 819 F. Supp. 2d 1254, 1263 (S.D. Ala. 2011). As the Eleventh Circuit has noted "courts applying Alabama law have seen fit to subsume U.C.C.-based breach of implied warranty claims into tort and product liability claims, where the product is fit for its intended use and there is no evidence of 'non-merchantability' other than a general allegation that the product contains inherent dangers." *Bodie*, 236 F. App'x at 524. Here, Plaintiff lacks evidence that Risperdal was not fit for its intended purpose as a mental health medicine. "[I]f the product does what it is supposed to,

that product is presumed merchantable even if there are also substantial risks connected with the use of that product." *Collins v. Novartis Pharm. Corp.*, No. 2:08-CV-438-MHT-PWG, 2015 WL 178157, at *7 (M.D. Ala. Jan. 14, 2015), *report and recommendation adopted in part*, No. 2:08CV438-MHT, 2015 WL 2183700 (M.D. Ala. May 11, 2015); *see also Shell v. Union Oil Co.*, 489 So. 2d 569, 572 (Ala. 1986) ("U.C.C. does not impose upon the seller the broader obligation to warrant against health hazards inherent in the use of the product when the warranty of commercial fitness has been complied with"). The mere presence of harmful consequences which may result from appropriate use will not render a product unfit for purposes of a claim for breach of implied warranty of merchantability. Summary judgment in favor of Janssen is therefore appropriate on this claim.

E. Fraud and Negligent Misrepresentation

A review of Plaintiff's fraud and negligent misrepresentation claims reveal the causes of action are primarily based on allegations of Janssen's failure to disclose or warn of known risks of Risperdal. *See* (Doc. 1-13, ¶¶ 167–94). To the extent these counts are repetitive of Plaintiff's failure to warn claims, they would be barred for the reasons set forth above.

The Alabama Supreme Court has recognized, however, that plaintiffs can pursue claims for fraud and negligent misrepresentation against drug manufacturers independent of an AEMLD claim. *See Weeks*, 159 So. 3d at 656. To state a claim for fraud under Alabama law, a plaintiff must establish "(1) a false representation (2) concerning a material fact (3) relied upon by the plaintiff (4) who was damaged as a proximate result." *Id.* The elements of a claim for negligent misrepresentation are "(1) a misrepresentation of material fact, (2) made willfully to deceive, recklessly, without knowledge, or mistakenly, (3) which was justifiably relied on by the plaintiff under the circumstances, and (4) which caused damage as a proximate consequence." *Foremost Ins. Co. v. Parham*, 693 So. 2d 409, 422 (Ala. 1997).

In a light favorable to Plaintiff, the Janssen studies revealed that the occurrence of gynecomastia could be considered "frequent" and not "rare" as was referenced in the Janssen Risperdal label.[22] Additionally, Plaintiff claims Janssen misrepresented that prolactin elevation was a class effect when it knew, but failed to disclose, that Risperdal resulted in greater levels of prolactin compared to other second-generation antipsychotics. Even if Plaintiff can establish these facts were false or misleading, Plaintiff has failed to come forward with evidence establishing that these statements or omissions were relied upon by West's prescribing physicians or that they caused West's gynecomastia in 2013 when his prescribing doctors testified they were independently aware of the risks of gynecomastia and elevated prolactin levels, weighed those risks, and stand by their prescribing decisions. Because Plaintiff is unable to establish reliance or causation, Janssen's motion for summary judgment is due to be granted on Plaintiff's fraud and negligent misrepresentation claims.

F. Punitive Damages

In order to recover punitive damages, a plaintiff must prove "by clear and convincing evidence that the defendant consciously or deliberately engaged in oppression, fraud, wantonness, or malice with regard to the plaintiff." ALA. CODE § 6-11-20.

As used in this provision, "fraud," "malice," "wantonness," "clear and convincing evidence," and "oppression" are defined as follows:

> (1) Fraud. An intentional misrepresentation, deceit, or concealment of a material fact the concealing party had a duty to disclose, which was gross, oppressive, or malicious and committed with the intention on the part of the defendant of thereby depriving a person or entity of property or legal rights or otherwise causing injury.
> (2) Malice. The intentional doing of a wrongful act without just cause or excuse, either:
> a. With an intent to injure the person or property of another person or entity, or
> b. Under such circumstances that the law will imply an evil intent.

[22] Janssen disagrees, arguing that the frequency of gynecomastia is not referenced in the precautions section of the label, and the reference to the condition being "rare" is only made with regard to a particular pre-marketing study result.

> (3) Wantonness. Conduct which is carried on with a reckless or conscious disregard of the rights or safety of others.
> (4) Clear and convincing evidence. Evidence that, when weighed against evidence in opposition, will produce in the mind of the trier of fact a firm conviction as to each essential element of the claim and a high probability as to the correctness of the conclusion. Proof by clear and convincing evidence requires a level of proof greater than a preponderance of the evidence or the substantial weight of the evidence, but less than beyond a reasonable doubt.
> (5) Oppression. Subjecting a person to cruel and unjust hardship in conscious disregard of that person's rights.

ALA. CODE § 6-11-20. For the reasons discussed above as to why the court finds no claim for fraud or wantonness, the court similarly finds that Plaintiff is unable to satisfy the steep burden of establishing entitlement to punitive damages.

VI. CONCLUSION AND RECOMMENDATION

When a patient who is treated with a course of medication develops other medical problems, issues of causation and responsibility can arise. Was the second condition a result of the drug treatment or merely correlated or coincidental? Even if deleterious, is the second condition a proper trade-off for relief from the first condition? Though our scientific knowledge has advanced considerably, medicine cannot fully address these questions.

Not all medical issues have cures or effective treatments. Not all injuries have legal remedies. In this case, sadly, West suffers from life-long medical conditions that are difficult to treat and probably impossible to cure. It may well be that treatment of his underlying condition caused or contributed to his gynecomastia. Whether or not that is so (and we may never know) the law applicable to his circumstances affords no remedy against the manufacturer of the drug prescribed for his underlying condition. The court concludes the laws and regulations direct a finding in favor of Janssen. Accordingly, for the reasons set forth above, it is the **RECOMMENDATION** of the Magistrate Judge that Defendant's Motion for Summary Judgment (Doc. 184) be **granted**.

It is further **RECOMMENDED**, if this Report and Recommendation is adopted, that the Plaintiff's Motion to Exclude Certain Testimony by Janet Arrowsmith, M.D., (Doc. 175), Plaintiff's Motion to Exclude Certain Testimony by Elias G. Chalhub, M.D. (Doc. 177), Defendant's Motion to Preclude Expert Testimony by Michael D. Freeman, MedDr, MPH, FAAFS (Doc. 186), Defendant's Motion to Preclude Expert Testimony of Elizabeth Z. Naftalis, M.D. (Doc. 188), and Defendant's Motion to Preclude Expert Testimony of Laura M. Plunkett, PhD, DABT (Doc. 190) be **denied as moot**.

VII. NOTICE TO PARTIES

A party has fourteen days from this date to file written objections to the Report and Recommendation's factual findings and legal conclusions. Accordingly, it is hereby **ORDERED** that any objections to the Report and Recommendation shall be filed on or before **April 18, 2018**. A party's failure to file written objections waives that party's right to challenge on appeal any unobjected-to factual finding or legal conclusion the district judge adopts from the Report and Recommendation. See 11th Cir. R. 3-1; see also 28 U.S.C. § 636(b)(1).

Respectfully recommended this 4th day of April, 2018.

DAVID A. BAKER
UNITED STATES MAGISTRATE JUDGE