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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ALABAMA
NORTHEASTERN DIVISION

KEVIN DRAKE, and DOROTHY DRAKE, as Guardian for Kevin Drake,	)	
Plaintiffs,	)	
v.	)	**Case No.: 5:15-CV-01507-MHH**
ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC., a Pennsylvania Corporation f/k/a JANSSEN PHARMACEUTICA INC.; and JOHNSON & JOHNSON, a New Jersey Corporation,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Kevin Drake and his mother and legal guardian, Dorothy Drake, bring this products liability action based on injuries that Mr. Drake allegedly incurred because he took Risperdal, a prescription drug manufactured by defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutica, Inc. ("Janssen"). The plaintiffs contend that Janssen and its parent company, defendant Johnson & Johnson, knew that Risperdal was unreasonably dangerous and failed to adequately warn about the dangers of the drug. The defendants argue that the plaintiffs' claims fail as a matter of law because the plaintiffs cannot

establish causation. The Court agrees. Because the plaintiffs have not identified a disputed question of material fact regarding causation, the Court finds that the defendants are entitled to judgment as a matter of law and grants the defendants' motion for summary judgment.

I. SUMMARY JUDGMENT STANDARD

"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). To demonstrate that there is a genuine dispute as to a material fact that precludes summary judgment, a party opposing a motion for summary judgment must cite "to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials." Fed. R. Civ. P. 56(c)(1)(A). "The court need consider only the cited materials, but it may consider other materials in the record." Fed. R. Civ. P. 56(c)(3). When considering a summary judgment motion, the Court must view the evidence in the record in the light most favorable to the non-moving party and draw reasonable inferences in favor of the non-moving party. *White v. Beltram Edge Tool Supply, Inc.*, 789 F.3d 1188, 1191 (11th Cir. 2015).

II. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND

A. Risperdal and Gynecomastia

Janssen manufactures and distributes Risperdal, an antipsychotic medication used to treat schizophrenia. (Doc. 40-10, p. 2; Doc. 40-11, p. 2).[1] Risperdal comes in two forms: a Risperdal pill and a long-acting injection called Risperdal Consta. (*See* Doc. 44-3, p. 20). In 1993, the United States Food and Drug Administration, better known as the FDA, approved Risperdal for the treatment of psychosis in adults. (*See* Doc. 40-10, p. 2; Doc. 40-11, p. 2). In 2007, the FDA approved Risperdal for the treatment of schizophrenia in adolescents from ages thirteen to seventeen years old. (Doc. 40-11, p. 2).

Antipsychotic medications like Risperdal have been associated with gynecomastia. (Doc. 40-13, pp. 5, 7, 10-11; Doc. 40-17, p. 2; *see also* Doc. 40-10, p. 9; Doc. 40-11, p. 33; Doc. 40-12, p. 25). Gynecomastia is the benign enlargement of breast tissue in males. (Doc. 40-13, p. 3). Gynecomastia may occur during normal physiological development in puberty, and in some cases, it may persist after puberty. (Doc. 40-13, p. 3). In a study of adult males seeking treatment for gynecomastia, 25% of patients had "persistent gynecomastia due to

[1] The generic form of Risperdal is risperidone. (*See* Doc. 40-10, p. 2). At times, Mr. Drake took risperidone rather than Risperdal. (*See* Doc. 44-6). For purposes of this memorandum opinion, the Court does not distinguish between Risperdal and risperidone.

puberty," another 25% had idiopathic gynecomastia, meaning that no cause for the condition could be identified, 10-20% of patients had gynecomastia "related to drugs or medication," and the remaining patients had gynecomastia caused by various diseases and disorders. (Doc. 40-13, p. 3). Gynecomastia is distinct from pseudo-gynecomastia, which is breast enlargement due to fat deposits in overweight males. The two conditions may be differentiated only with a physical exam. (Doc. 40-13, pp. 4-5; Doc. 44-7, pp. 7, 10; Doc. 44-8, p. 4).

B. Mr. Drake's Risperdal Use

Mr. Drake suffers from schizophrenia. (Doc. 44-2, p. 4; Doc. 44-3, p. 9). Dr. Steven Taylor diagnosed schizophrenia in Mr. Drake in 1999 when Mr. Drake was seventeen years old. (*See* Doc. 44-3, pp. 13, 24). Dr. Taylor prescribed Risperdal in 1999 to treat Mr. Drake's schizophrenia. (Doc. 44-3, p. 24). That same year, Dr. Trevor Lindsay, a psychiatrist in Huntsville, began treating Mr. Drake, and he continued to treat Mr. Drake until 2011. (Doc. 44-3, pp. 4, 11).

Dr. Lindsay confirmed Mr. Drake's diagnosis of schizophrenia, but switched Mr. Drake's medication from Risperdal to Clozaril in September 1999. (Doc. 44-3, pp. 13, 24-25, 27).[2] Weight gain and hyperprolactinemia are known side effects of Clozaril. (Doc. 44-3, p. 24). Dr. Lindsay also prescribed Haldol and Zyprexa to

[2] Dr. Lindsay switched Mr. Drake's medication in September 1999 because the Risperdal "didn't seem to be working right . . . ." (Doc. 44-3, p. 27).

treat Mr. Drake's schizophrenia. (Doc. 44-3, p. 27). Weight gain and hyperprolactinemia are known side effects of Zyprexa. (Doc. 44-3, p. 28). In 2001, when Mr. Drake was nineteen years old, Dr. Lindsay switched Mr. Drake's medication back to Risperdal. (Doc. 44-3, p. 30). When Dr. Lindsay prescribed Risperdal for Mr. Drake, Dr. Lindsay took into account the fact that Risperdal may elevate prolactin levels. (Doc. 44-3, p. 18). Prolactin is a hormone that induces lactation, but it "does not have a direct growth-stimulating effect on the breast glandular tissue." (Doc. 40-13, pp. 7-8). "Adult men with high levels of prolactin [] may exhibit gynecomastia," (Doc. 40-13, p. 8), but elevated prolactin levels do not necessarily lead to gynecomastia, and there are multiple potential causes for prolactin elevation. (Doc. 44-8, p. 5). Dr. Lindsay maintained Mr. Drake's treatment with Risperdal through 2011. (Doc. 44-3, p. 41).[3]

Mr. Drake changed psychiatrists in 2011 and began seeing Dr. Rachel Pope. (*See* Doc. 44-3, p. 11; Doc. 44-5, pp. 20-26). Mr. Drake continued taking Risperdal through September 2014. (*See* Doc. 44-5, pp. 20-26). Sometime between September and December 2014, Dr. Pope discontinued Mr. Drake's Risperdal prescription and instead prescribed Abilify and Zyprexa to treat Mr. Drake's schizophrenia. (*See* Doc. 44-5, pp. 16-26; Doc. 44-2, p. 34).

[3] At times, Mr. Drake refused to take medication by mouth. (Doc. 44-2, p. 15). When that happened, Dr. Lindsay would prescribe Risperdal Consta, the injectable form of Risperdal. (Doc. 44-3, p. 38; *see also* Doc. 44-2, p. 15).

Ms. Drake does not remember Dr. Lindsay discussing the risks and benefits of Risperdal, but she relied on Dr. Lindsay and other psychiatrists to prescribe the medication that would provide the best treatment for Mr. Drake's symptoms. (Doc. 44-2, pp. 23-24). Ms. Drake testified that her son's behavior improved when he was on Risperdal, and the medication helped control his symptoms of schizophrenia. (Doc. 44-2, pp. 27, 30).

C. Mr. Drake's Injuries

According to the plaintiffs, because Mr. Drake took Risperdal, he developed enlarged breasts and experienced excessive weight gain. (Doc. 44-1, p. 9).[4] In August 2006, more than five years after he first prescribed Risperdal for Mr. Drake, Dr. Lindsay noted in Mr. Drake's records that Mr. Drake had "large breasts." (Doc. 53-6). Still, Dr. Lindsay did not diagnose Mr. Drake with gynecomastia, and no other physician has formally diagnosed him with the condition. (Doc. 44-1, p. 10; Doc. 44-2, p. 12; Doc. 44-3, pp. 24, 39). Ms. Drake has acknowledged that she "is unaware of a physician who has diagnosed Kevin Drake with gynecomastia." (Doc. 44-1, p. 10, #12). No doctor and no other health

[4] The plaintiffs also contend that Risperdal caused Mr. Drake to suffer urinary incontinence and fecal incontinence. (Doc. 44-1, p. 9). In response to the defendants' motion for summary judgment, the plaintiffs did not raise arguments or cite evidence regarding those alleged injuries. (*See* Doc. 49; Doc. 53-9). Accordingly, the plaintiffs have abandoned their claims based on Mr. Drake's alleged urinary and fecal incontinence, and the defendants are entitled to summary judgment as to those claims. *See Resolution Trust Corp. v. Dunmar Corp.*, 43 F.3d 587, 599 (11th Cir. 1995), *cert denied*, 516 U.S. 817 (1995) ("[G]rounds alleged in the complaint but not relied upon in summary judgment are deemed abandoned.").

care provider has told Ms. Drake that Risperdal caused Mr. Drake to experience excessive weight gain. (Doc. 44-2, p. 14).

In the summer of 2014, a social worker noticed that Mr. Drake had large breasts and told Ms. Drake that her son should be tested for gynecomastia. (*See* Doc. 44-1, p. 9; Doc. 44-2, pp. 8-9). The social worker stated that Risperdal could be the cause of Mr. Drake's large breasts. (*See* Doc. 44-1, p. 9). Medical staff at Wellstone Behavioral Care and Dr. Chimata, Mr. Drake's family care doctor, ordered lab work to test Mr. Drake's hormone levels. (Doc. 44-2, pp. 8-9, 11, 20). The lab results showed that Mr. Drake had three times the normal level of the hormone prolactin in his blood. (Doc. 44-2, pp. 9, 11).[5] After receiving the results, a nurse from Wellstone told Ms. Drake that Dr. Pope said: "We've got to stop this. The drug is what's causing that." (Doc. 44-2, p. 11). Dr. Pope then took Mr. Drake off of Risperdal. (*See* Doc. 44-2, p. 11; *see also* Doc. 44-5, pp. 16-26).[6] Wellstone tested Mr. Drake's hormone level again six to seven months after he stopped taking Risperdal, and his prolactin levels were lower. (Doc. 44-2, p. 11).

[5] Ms. Drake did not identify the hormone tested in Mr. Drake's blood, (*see* Doc. 44-2, pp. 9, 11), and the plaintiffs did not cite medical records showing the results of Mr. Drake's blood tests. (*See* Doc. 49; Doc. 53-9). Viewing the evidence in the light most favorable to the plaintiffs, the Court infers that the hormone that Ms. Drake described is prolactin, a hormone that may become elevated with Risperdal use and that has been associated with gynecomastia. (*See* Doc. 40-13, p. 8).

[6] Mr. Drake currently takes Abilify to treat his schizophrenia. (Doc. 44-2, p. 4).

Ms. Drake testified that she noticed that her son had developed larger breasts several years before the social worker raised a concern, but Ms. Drake attributed Mr. Drake's enlarged breasts to "weight gain." (Doc. 44-2, p. 9). The plaintiffs attribute Mr. Drake's weight gain to his Risperdal use, (*see* Doc. 44-1, p. 9), but no physician has told Ms. Drake that her son gained weight because he took Risperdal, (Doc. 44-2, p. 14). Ms. Drake testified that she can't say that Risperdal "was the sole reason that [Mr. Drake] gained weight." (Doc. 44-2, p. 31).

Mr. Drake was overweight before Dr. Lindsay prescribed Risperdal to treat Mr. Drake's schizophrenia. (Doc. 44-3, p. 28, 30). Mr. Drake gained weight between August and December 2000 while he was taking Zyprexa. (Doc. 44-3, p. 29). Accordingly, Dr. Lindsay encouraged him to eat less and lose weight. (Doc. 44-3, p. 29).

Mr. Drake continued to gain weight after Dr. Lindsay prescribed Risperdal for him in 2001. Between August 22, 2001 and March 27, 2002, Mr. Drake's weight increased from 260 to 300 pounds. (Doc. 44-3, p. 30, 32). Mr. Drake then lost weight between 2002 and 2006 while taking Risperdal, and he weighed 270 pounds on August 23, 2005, and 264 pounds on May 9, 2006. (Doc. 44-3, p. 34). Mr. Drake gained weight again after 2006 while still on Risperdal, and he weighed 286 pounds on August 12, 2013. (Doc. 44-7, p. 9). Mr. Drake gained weight after

he stopped taking Risperdal in 2014. On December 30, 2014, Dr. Pope noted that Mr. Drake had gained significant weight. (Doc. 44-5, p. 18).

D. Risperdal's Label

Risperdal's and Risperdal Consta's FDA-approved labels warn that the drug "elevates prolactin levels," that "the elevation persists during chronic administration," and that gynecomastia has "been reported in patients receiving prolactin-elevating compounds." (Doc. 40-10, p. 4; Doc. 40-11, p. 12; Doc. 40-12, pp. 13, 68). Risperdal's label also states that "the clinical significance of elevated serum prolactin levels is unknown for most patients." (Doc. 40-10, p. 4). The labels identify gynecomastia as a rare adverse event associated with the drug. (Doc. 40-10, p. 9; Doc. 40-11, p. 24; Doc. 40-12, pp. 25, 80). Risperdal's 2007 label states that in clinical trials involving 1,885 children and adolescents, "gynecomastia was reported in 2.3% of Risperdal-treated patients." (Doc. 40-11, p. 33). The 2007 label warns that "Risperdal is associated with higher levels of prolactin elevation that other antipsychotic agents." (Doc. 40-11, p. 12). Risperdal's and Risperdal Consta's labels identify weight gain and increased appetite as commonly observed adverse events in clinical trials of the drug. (Doc. 40-20, p. 6; Doc. 40-11, pp. 2, 18, 21, 27; Doc. 40-12, pp. 2, 28, 51, 73, 81).

Dr. Lindsay reviewed the information in Risperdal's label before prescribing the medication. (Doc. 44-3, p. 16). Dr. Lindsay was familiar with and relied upon

the information contained in the label when he prescribed Risperdal for Mr. Drake. (Doc. 44-3, pp. 16, 18-19). Considering the information available to him, Dr. Lindsay prescribed Risperdal for Mr. Drake because he believed that the drug's benefits outweighed the risks for Mr. Drake. (Doc. 44-3, pp. 16, 17, 19).

III. ANALYSIS

The plaintiffs assert claims against the defendants under Alabama law for negligence, breach of express warranty, strict product liability, fraudulent concealment, failure to warn, and negligent misrepresentation. (Doc. 1). To prevail on each of those claims, the plaintiffs must prove that Risperdal caused Mr. Drake's injuries. *See Univ. of Texas Southwestern Med. Ctr. v. Nassar*, 570 U.S. 338, 346 (2013) ("Causation . . . is a standard requirement of any tort claim. . . .") (citations omitted); *Lemley v. Wilson*, 178 So. 3d 834, 842 (Ala. 2015) ("'Proximate cause is an essential element of [] negligence claims . . . .'") (quotation omitted); *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 656 (Ala. 2014) (identifying causation as an element of fraudulent misrepresentation and products liability claims); Ala. Pattern Jury Instr. Civ. §§ 18.05, 28.00, 32.06-07, 32.15, 32.17-18 (3d ed. 2017) (identifying causation as an element of negligence, breach

of express warranty, products liability, failure to warn, fraudulent concealment, and fraudulent misrepresentation claims).[7]

In a pharmaceutical products liability case such as this one, a plaintiff must prove both general and specific causation. *See Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1334 n.4 (11th Cir. 2010); *see also McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1237 (11th Cir. 2005) ("Plaintiffs must prove the toxicity of the ephedrine/caffeine combination and that it had a toxic effect on them causing the injuries that they suffered . . . .") (applying Alabama law). General causation requires proof that the drug at issue is capable of causing the type of injuries the plaintiff suffered. *Chapman v. Procter & Gamble Distributing, LLC*, 766 F.3d 1296, 1303 (11th Cir. 2014); *McClain*, 401 F.3d at 1239. Specific causation requires proof that the drug caused the plaintiff's specific injuries. *Chapman*, 766 F.3d at 1303; *McClain*, 401 F.3d at 1239.

Due to the complex nature of the claims, expert testimony generally is required to establish general and specific causation in product liability cases. *McClain*, 401 F.3d at 1237 ("This type of proof requires expert testimony . . . ."); *see also Garrison v. Novartis Pharma. Corp*, 30 F. Supp. 3d 1325, 1339 (M.D. Ala. 2014) (granting summary judgment in favor of the defendant in an AEMLD

[7] Because this action is before the Court on the basis of diversity jurisdiction, (*see* 28 U.S.C. § 1332; *see also* Doc. 1, p. 3), Alabama substantive law applies. *See, e.g., Erie Railroad Co. v. Tompkins*, 304 U.S. 64 (1938).

case because the plaintiff "lacks admissible expert testimony to show specific causation"); *Sutherland v. Matrixx Initiatives, Inc.*, 2006 WL 6617000, * 14 (N.D. Ala. 2006) ("[W]ithout an expert to connect a toxin to an injury, there is no toxic tort.").

To support their claims, the plaintiffs rely on expert reports by and testimony from Dr. David A. Kessler, the former commissioner of the FDA, who has testified in other cases involving Risperdal. (*See* Docs. 49 & 53-9). In those cases, Dr. Kessler opined that the defendants misrepresented the risk of gynecomastia for children and adolescents taking Risperdal. (Doc. 44-3, p. 39).[8] Dr. Kessler's report and deposition testimony from other cases might be sufficient to raise a question of fact regarding general causation, (*see* Doc. 53-3, p. 7, ¶ 17), but his report and testimony contain no evidence regarding the cause of Mr. Drake's alleged injuries. Dr. Kessler has not examined Mr. Drake.

The plaintiffs' evidence concerning specific causation is threadbare. There is no evidence that Mr. Drake has been diagnosed with gynecomastia. Ms. Drake admits that she is not aware of such a diagnosis. (Doc. 44-1, p. 10, #12). Dr. Lindsay testified that he did not make such a diagnosis. (Doc. 44-3, p. 39).

The plaintiffs' evidence that Mr. Drake had three-times the normal level of the hormone prolactin in his blood is a start, but the association between elevated

[8] The defendants object to the plaintiffs' reliance on Dr. Kessler's reports and testimony. (Doc. 56, pp. 8-12). These objections are moot.

levels of prolactin and gynecomastia falls short of proof of specific causation. (*See* Doc. 44-2, pp. 9, 11). Association does not establish causation. (Doc. 40-13, p. 5); *see also Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1338 (11th Cir. 2010) ("'Showing an association is far removed from proving causation.'") (quotation, alteration, and emphasis in original omitted). The plaintiffs have not introduced evidence that contradicts the defendants' expert's testimony that elevated prolactin levels do not necessarily lead to gynecomastia. (Doc. 44-8, p. 5; *see also* Doc. 49; Doc. 53-9). Rather, the plaintiffs argue that if Mr. Drake's elevated prolactin level caused "testosterone level drops leading to estrogen expression[, then] the drug could *theoretically* cause gynecomastia." (Doc. 49, p. 26) (citing 44-8, p. 9) (emphasis added). But there is no evidence in the record regarding Mr. Drake's testosterone or estrogen levels, and evidence that Risperdal could theoretically cause gynecomastia is not sufficient to raise a disputed question of material fact concerning specific causation. *See Tidwell v. Upjohn Co.*, 626 So. 2d 1297, 1301 (Ala. 1993) ("On issues of medical causation a showing of probably cause, rather than possible cause, must be made."). In the absence of medical or expert evidence, a fact finder must speculate about the cause of Mr. Drake's enlarged breasts, and a verdict may not rest on speculation.

The plaintiffs argue that they can carry their burden of proof because they can establish that Risperdal may cause weight gain, which can lead to pseudo-

gynecomastia. (Doc. 49, p. 2). The argument is unavailing for a number of reasons. First, evidence indicates that Mr. Drake was overweight before Dr. Lindsay prescribed Risperdal in February 2001, and there is no medical or expert evidence to suggest that Risperdal caused Mr. Drake's weight gain. (*See* Doc. 44-3, pp. 28, 30). In fact, evidence in the record suggests that other medications potentially could have caused Mr. Drake's weight gain: Dr. Lindsay testified that Mr. Drake gained excessive weight while taking Zyprexa in 2000, and Mr. Drake gained weight in 2014 after he stopped taking Risperdal. (Doc. 44-3, p. 29; Doc. 44-5, p. 18). Besides, proof that a drug may cause weight gain still is proof of general causation; the evidence does not bridge the specific causation gap.

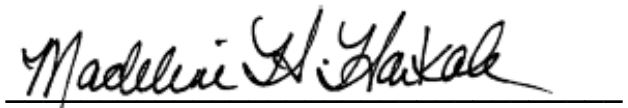
Ms. Drake's testimony that a nurse at Wellstone told her that Dr. Pope said Risperdal "is what's causing that" does not allow her to avoid summary judgment. (*See* Doc. 44-2, p. 11). Dr. Pope's alleged statement, which is hearsay within hearsay, is ambiguous. It is not clear from Ms. Drake's testimony whether Dr. Pope's purported statement means that Dr. Pope believed that the drug was causing Mr. Drake's enlarged breasts or his elevated prolactin levels. Because Dr. Pope allegedly made the statement after receiving the results of the lab tests on Mr. Drake's hormone levels, the Court cannot infer from the hearsay statement that Dr. Pope believed that Risperdal caused Mr. Drake's enlarged breasts as opposed to his elevated prolactin levels.

Based on the record before the Court, there is no evidence from which a factfinder could reasonably infer that Mr. Drake's use of Risperdal caused his enlarged breasts or weight gain. Because the plaintiffs have not identified sufficient evidence to raise a genuine issue of material fact regarding specific causation, the Court will grant the defendants' motion for summary judgment.

IV. CONCLUSION

For the reasons discussed above, the Court **GRANTS** the defendants' motion for summary judgment. (Doc. 38). The plaintiffs' claims against the defendants are **DISMISSED WITH PREJUDICE**.

DONE and **ORDERED** this March 22, 2018.



MADELINE HUGHES HAIKALA
UNITED STATES DISTRICT JUDGE