IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

DONTE L. HOPKINS,

Plaintiff,

v.

Civil Action No. 1:14-cv-01366-RGA

JANSSEN PHARMACEUTICALS, INC.,

Defendant.

MEMORANDUM OPINION

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Attorneys for Plaintiff.

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Attorneys for Defendant.



Presently before me are Defendant's Motion for Summary Judgment (D.I. 143) and Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan. (D.I. 146). The Parties have fully briefed the issues. (D.I. 144, 147, 160, 161, 168, 170). I heard oral argument on March 7, 2019. For the reasons set out below, I will grant Defendant's Motion for Summary Judgment and dismiss as moot Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan.

I. BACKGROUND

Plaintiff suffered a traumatic brain injury at age five and has since suffered from serious mental illness. (D.I. 160 at 5). He has been diagnosed with suicidal ideation, schizophrenia, and bipolar disorder. (*Id.* at 6). Doctors have prescribed him Risperdal, Haldol, Geodon, Prozac, and Zyprexa to treat those conditions. (*Id.*). Plaintiff was first prescribed Risperdal in June 2008 and remained on the drug until June 2010. (*Id.*). Plaintiff also took the drug for two months in early 2011 and from July 2012 to September 2014. (*Id.*).

Risperdal is FDA-approved for treatment of schizophrenia and bipolar disorder. (D.I. 144 at 5). Defendant is the manufacturer of brand name Risperdal. (D.I. 160 at 2). Risperidone is the generic name for Risperdal. (D.I. 144 at 2). Other drug manufacturers, such as Zydus Pharmaceuticals (USA), Inc. or Torren Pharmaceuticals Ltd., manufacture and sell risperidone. (*Id.* at 5).

Gynecomastia is a potential side effect of Risperdal. (D.I. 160 at 3-4). Increased levels of prolactin may also be a side effect and is allegedly connected to an increased risk of gynecomastia. (D.I. 147 at 8). Gynecomastia is the enlargement of the male breast gland due to

¹ I use the brand name "Risperdal" to refer to the drug Plaintiff took. This is not meant to indicate whether Plaintiff took the brand name or a generic drug at any given time.

a hormonal imbalance. Prolactin is a hormone which enhances breast development and initiates lactation in the human (typically female) body.

Plaintiff filed this lawsuit on November 3, 2014. (D.I. 3). He asserted seven claims against Defendant based on its marketing and sale of Risperdal: negligence (Count I), negligent misrepresentation (Count II), breach of warranty (Count III), breach of the implied warranty of merchantability (Count IV), breach of the implied warranty of fitness for a particular purpose (Count V), breach of express warranty (Count VI), and fraud by concealment (Count VII). (D.I. 39 at 3-7). He alleges that because of Defendant's conduct, he developed gynecomastia and pus bumps. (D.I. 144 at 6).

Defendant filed the present motions on October 12, 2018. It sought summary judgment on each count of the first amended complaint. (D.I. 39). In response to Defendant's summary judgment motion, Plaintiff voluntarily withdrew Counts III-VII. (D.I. 160 at 1 n.1). Thus, the only Counts remaining are negligence and negligent misrepresentation.

II. LEGAL 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). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex*, 477 U.S. at 323.

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586-87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute" Fed. R. Civ. P. 56(c)(1).

When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). A dispute is "genuine" only if the evidence is such that a reasonable jury could return a verdict for the non-moving party. *Anderson*, 477 U.S. at 247-49. If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

III. DISCUSSION

A. Proximate Cause

To prove his remaining negligence claims, Plaintiff must prove that Risperdal proximately caused him harm. *Culver v. Bennett*, 588 A.2d 1094, 1097-98 (Del. 1991) (discussing Delaware's "but for" rule of proximate cause in negligence cases). A determination of the proximate cause of a specific instance of a disease or medical condition must "rest upon the individualized findings and opinion of a trained physician." *Money v. Manville Corp.*

Asbestos Disease Comp. Tr. Fund, 596 A.2d 1372, 1376 (Del. 1991). A plaintiff's bald assertion that he has a condition and that the condition was caused by a certain drug are insufficient.

Defendant argues that Plaintiff cannot establish proximate cause, as a matter of law, because he "has not produced an expert report addressing specific causation—i.e., that his use of generic risperidone caused his alleged gynecomastia or pus bumps." (D.I. 144 at 9). I agree. Plaintiff's claim is not supported by expert testimony that Risperdal proximately caused his condition. (D.I. 160 at 13 (arguing Plaintiff's proof is adequate based on expert testimony of general causation)). Evidence of only "general causation" is insufficient to establish a negligence claim under Delaware law. Thus, I will grant Defendant's motion for summary judgment.

B. Brand Name Liability for Plaintiff's Use of Generic Risperidone

Defendant also argues that it is entitled to summary judgment because Plaintiff never took the brand name drug that it manufactures, Risperdal. (D.I. 144 at 7-8). Rather, it is undisputed that Plaintiff took only generic risperidone. (*Id.* at 4-5). As I explain more fully in my simultaneously-entered summary judgment opinion in a related case, *Trower v. Janssen Pharms.*, *Inc.*, Case No. 16-135-RGA (D. Del.), Delaware law does not support a claim against a brand name drug manufacturer for a plaintiff's use of a generic drug. I will grant Defendant's summary judgment motion for this additional reason.

² Plaintiff also does not have a diagnosis from a medical professional confirming that he does, in fact, have gynecomastia. (D.I. 160 at 6-7).

³ "General causation" addresses the question of whether a particular substance is capable of causing a particular harm. "Specific causation" addresses the related question of whether a particular substance caused a particular harm to a particular person.

C. Learned Intermediary Doctrine

Defendant also argues that it is entitled to summary judgment because Plaintiff cannot establish that an additional warning would have changed Plaintiff's physician's decision to prescribe Risperdal. (D.I. 144 at 9). Plaintiff's evidence of the inadequacy of the Risperdal label is identical to the evidence presented in a related case, *Green v. Janssen Pharms., Inc.*, Case No. 15-401-RGA (D. Del.), and is similarly insufficient to establish the Risperdal label was inadequate as a matter of law. Moreover, it is undisputed that none of Plaintiff's physicians were deposed for this litigation. (D.I. 144 at 9). Thus, as I explain more fully in my simultaneously-entered summary judgment opinion in the *Green* case, Plaintiff cannot overcome Delaware's learned intermediary doctrine. I will grant Defendant's summary judgment motion for this additional reason.

IV. CONCLUSION

Plaintiff cannot establish a negligence cause of action under Delaware law because he has no evidence of proximate causation, did not consume Defendant's product, and cannot overcome Delaware's learned intermediary doctrine. Thus, I will grant Defendant's motion for summary judgment and enter judgment for Defendant. I will also dismiss Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan as moot. A separate order will be entered.

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ORDER

For the reasons set forth in the accompanying Memorandum Opinion, IT IS HEREBY

ORDERED that Defendant's Motion for Summary Judgment (D.I. 143) is GRANTED and

Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan (D.I. 146) is

DISMISSED as MOOT.

Entered this <u>|</u> day of April, 2019.

United States District Judge