IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LAMAR A. TROWER,

Plaintiff,

v.

JANSSEN PHARMACEUTICALS, INC.,

Defendant.

Civil Action No. 1:16-cv-00135-RGA

MEMORANDUM OPINION

Kelly E. Farnan, Christine D. Haynes (argued), Sara M. Metzler (argued), and Tyler E. Cragg (argued), RICHARDS, LAYTON & FINGER, P.A., Wilmington, DE.

Attorneys for Plaintiff.

Michael P. Kelly (argued), Daniel J. Brown, and Hayley J. Reese, McCARTER & ENGLISH, LLP, Wilmington, DE; Heather C. Giordanella and Andrew P. Reeve, DRINKER BIDDLE & REATH LLP, Philadelphia, PA.

Attorneys for Defendant.

April 11, 2019

ANDREWS, U.S. DISTRICT JUDGE:

Presently before me are Defendant's Motion for Summary Judgment (D.I. 155), Defendant's Motion to Preclude Expert Testimony of Brendan Carroll, M.D. (D.I. 158), and Defendant's Motion to Exclude Certain Opinion Testimony of Dr. Mahyar Etminan (D.I. 161). The Parties have fully briefed the issues. (D.I. 156, 159, 162, 177, 178, 179, 187, 189, 191). I heard oral argument on March 7, 2019. For the reasons set out below, I will grant Defendant's Motion for Summary Judgment and I will dismiss Defendant's *Daubert* motions as moot.

I. BACKGROUND

Plaintiff suffers from a variety of serious mental illnesses. (D.I. 178 at 2). He has been diagnosed with ADHD, conduct disorder, oppositional defiant disorder, generalized anxiety disorder, major depressive disorder, PTSD, impulse control disorder, antisocial personality disorder, mild mental retardation, bipolar disorder, and schizophrenia. (*Id.*). Doctors have prescribed him Risperdal,[1] Haldol, Doxepin, Prozac, Depakote, Seroquel, Thorazine, Cylert, Clonidine, Elavil, Lexapro, Mellaril, Trazadone and Vistaril to treat these conditions. (*Id.*). Plaintiff was prescribed Risperdal from February 2011 through June 2011; October 2011 through February 2012; and August 2012 through August 2013. (*Id.*). Plaintiff allegedly discontinued use of Risperdal in early 2014. (*Id.* at 3).

Risperdal is FDA-approved for treatment of schizophrenia and bipolar disorder. (D.I. 156 at 5 n.2). Defendant is the manufacturer of brand name Risperdal. (D.I. 178 at 4). Risperidone is the generic name for Risperdal. (D.I. 156 at 5). Other drug manufacturers, such as Zydus Pharmaceuticals (USA), Inc., manufacture risperidone. (*Id.*).

---

[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.

Gynecomastia is a potential side effect of risperidone. (D.I. 178 at 5-7). Increased levels of prolactin may also be a side effect and is allegedly connected to an increased risk of gynecomastia. (D.I. 162 at 8). Gynecomastia is the enlargement of the male breast gland due to 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 March 4, 2016. (D.I. 1). He pled 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. 29 at 4-7). He alleges that because of Defendant's conduct, he developed gynecomastia, breast pain, and discomfort, including hard nipples. (D.I. 156 at 6).

Defendant filed the present motions on October 12, 2018. It sought summary judgment on each count of the second amended complaint. (D.I. 29). In response to Defendant's summary judgment motion, Plaintiff voluntarily withdrew Counts III-VII. (D.I. 178 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. Brand Name Liability for Plaintiff's Use of Generic Risperidone

The Parties do not dispute that Plaintiff's claim is based on his ingestion of generic risperidone. (D.I. 156 at 4-6; D.I. 178 at 12-17). Rather, they dispute whether, under Delaware law, a brand name manufacturer can be held liable, on a negligent failure to warn theory, for a

plaintiff's injuries that result from consumption of a generic drug. (D.I. 156 at 10-11; D.I. 178 at 12-17). That question is an issue of first impression in Delaware.

Under federal law, brand name and generic drug manufacturers are not equally responsible for drug labeling. "A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 613 (2011) (citations omitted). This regulatory reality led the Supreme Court in *PLIVA* to find that federal law preempts state tort liability for a generic drug manufacturer's inadequate label. *Id.* at 623-24.

In her dissent, Justice Sotomayor noted that the *PLIVA* majority opinion "strips generic-drug consumers of compensation when they are injured by inadequate warnings." *Id.* at 643 (Sotomayor, J., dissenting). Plaintiff argues, "The problem is exacerbated because federal law encourages generic drug use and a majority of states have passed law[s] permitting pharmacists to substitute generic drugs without a patient's consent to save costs." (D.I. 178 at 15). Delaware is among the states with such a law. Del. Code Ann. tit. 24, § 2549A.

Plaintiff proposes that the appropriate solution is to allow plaintiffs to maintain claims against brand name manufacturers for failure to warn, even when the plaintiffs ingested only the generic manufacturers' products. (D.I. 178 at 13). He argues this solution is desirable for two policy reasons: (1) "it ensures drug labels are consistent and consumers adequately warned, regardless of whether a generic or brand name drug is dispensed by a pharmacist," and (2) "imposing liability on brand name manufacturers better reflects what is actually at issue in failure to warn claims." (*Id.* at 15).

Beyond his policy-based argument, Plaintiff notes that some courts have allowed claims against brand name drug manufacturers in these circumstances. In 2014, the Alabama Supreme Court held that brand name manufacturers may be liable for harm caused by a generic manufacturer's product due to the brand name manufacturer's unique regulatory position. *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 676-77 (Ala. 2014), *superseded by statute*, Ala. Code § 6-5-530(a) ("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."). Additionally, in 2010, a district court sitting in diversity held, "There is no reason, under Vermont law, to limit [a defendant's] duty of care to physicians by the pharmacist's choice of a generic bioequivalent drug to fill the physician's prescription." *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708-09 (D. Vt. 2010).

Defendant responds that Delaware law does not support imposing liability on defendants that did not make the allegedly harmful product. To state a claim in a products liability case, a plaintiff must plead facts that identify the allegedly defective product and the manufacturer of that product. *In re Benzene Litig.*, 2007 WL 625054, at *6 (Del. Super. Ct. Feb. 26, 2007). "[G]eneric identification of a product is not enough to establish liability absent some other evidence that that generic product was the specific product of a defendant." *Lee v. A.C.& S., Inc.*, 1986 WL 15421, at *2 (Del. Super. Ct. Dec. 15, 1986). Moreover, at least one Delaware court has expressed hesitation when pressed to make changes to traditional tort law in the product liability space. *Nutt v. A.C. & S. Co.*, 517 A.2d 690, 694 (Del. Super. Ct. 1986) (choosing to defer to the legislature rather than judicially expand the scope of liability).

In response, Plaintiff cites to just one Delaware case, *Wilkerson v. Am. Honda Motor Co.*, 2008 WL 162522, at *2 (Del. Super. Ct. Jan. 17, 2008). In *Wilkerson*, the Superior Court held that a defendant may be liable for a plaintiff's asbestos exposure from a third-party product if it was reasonably foreseeable that use of defendant's product would result in use of the third-party product that would result in exposure to asbestos. *Id.* at *2. The court also held, "Any necessary warning must be tailored to the risks associated with the reasonably-anticipated use of the manufacturer's own product." *Id.* I understand *Wilkerson* to allow liability for a reasonably foreseeable harm that stems from use of a manufacturer's product, even when the actual vessel for the harm-causing agent was manufactured by a third party. I do not, however, agree with Plaintiff's conclusion that *Wilkerson* stands for the proposition that the question of liability starts and ends with whether a defendant owed a duty to a plaintiff. (D.I. 178 at 12 ("[T]he appropriate initial question is not whether Plaintiff ingested a drug manufactured by Defendant, but whether Defendant owed a duty to Plaintiff.")). Consistent with other Delaware cases, *Wilkerson* requires that defendant produced the product at the center of the dispute.

Defendant further argues that the Third Circuit disfavors district courts creating new state law while sitting in diversity. When faced with "two competing yet sensible interpretations" of state law, the Third Circuit instructs that district courts should "opt for the interpretation that restricts liability, rather than expands it, until the [state's supreme court] decides differently." *Werwinski v. Ford Motor Co.*, 286 F.3d 661, 680 (3d Cir. 2002); *see also Bruffett v. Warner Commc'ns, Inc.*, 692 F.2d 910, 920 (3d Cir. 1982) ("One of the authentic obligations of federalism at the judicial level requires that we permit the state courts to decide whether and to what extent they will follow the emerging law.").

I agree with Defendant. Delaware law does not support imposing liability on a brand name defendant for a generic manufacturer's product. I further agree with Defendant that, even if Delaware law provided some basis for imposing liability for failure to warn on brand name manufacturers, it would be imprudent for me to extend Delaware's law to that point while sitting in diversity. Accordingly, as it is undisputed that Defendant did not manufacture the pills that Plaintiff ingested, I will grant Defendant's motion for summary judgment.

B. 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. 156 at 12-13). 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. 156 at 12-13). 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

Delaware law does not support Plaintiff's claim against Defendant, a brand name manufacturer that did not produce the product that Plaintiff ingested. Plaintiff is also unable to establish that an additional warning would have impacted his prescribing physician's decision to prescribe Risperdal. Thus, I will grant Defendant's Motion for Summary Judgment and enter judgment in Defendant's favor. As no claims remain pending in the case, I will also dismiss Defendant's *Daubert* motions as moot.