UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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SAMUEL COLESON, JR.,

Plaintiff,

15 Civ. 4792 (RWS)

- against -

OPINION

JANSSEN PHARMACEUTICAL, INC.,
JOHNSON & JOHNSON SUBSIDES,

Defendants.

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A P P E A R A N C E S:

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Plaintiff, *pro se*
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Sweet, D.J.

Defendants Janssen Pharmaceuticals, Inc. and Johnson & Johnson (collectively, "Janssen" or the "Defendants") have moved pursuant to Fed. R. Civ. P. 56 for summary judgment dismissing the complaint of Plaintiff Samuel Coleson, Jr. ("Coleson" or the "Plaintiff"). As set forth below, the motion is granted.

Prior Proceedings

On April 23, 2015, Coleson filed a *pro se* complaint against Defendants in the Supreme Court, Bronx County, which alleged that he developed gynecomastia as a result of taking Risperdal and generic risperidone. On June 18, 2015, Janssen properly removed the suit to federal district court.

On October 14, 2016, after discovery, Defendants filed the instant motion for summary judgment. The motion was taken on submission and marked fully submitted on November 28, 2016.

Facts

The facts have been set forth in Defendants' Rule 56.1 Statement of Undisputed Material Facts ("Defs.' 56.1"), Plaintiff's Response to Defendants' Statement of Undisputed Material Facts ("Pl.'s 56.1"), and the Declaration of Samuel Coleson, Jr. dated November 18, 2016 ("Coleson Decl."), which are not in dispute except as noted below.

Coleson has a history of substance abuse and psychiatric care for which he has had different mental health providers. One provider was Woodhull Hospital, where Coleson states he was first diagnosed with bipolar schizophrenia around 2009 or 2010. According to Coleson, physicians at Woodhull prescribed him Risperdal and risperidone, which he began taking. Coleson states that the side-effect warning information on the risperidone he received at that time was different than the FDA-approved Risperdal label. Specifically, the label he read did not include language stating that the drug's hormonal side-effects could affect both male and female consumers.

Janssen, a subsidiary of Johnson & Johnson, manufactures Risperdal, a prescription medication intended to treat schizophrenia in adult patients. Risperdal has been approved for

sale by the Food and Drug Administration ("FDA") since 1993. Since at least 1996, Risperdal's FDA-approved disclosures have indicated that Risperdal is associated with endocrine-related side-effects, including gynecomastia, the non-cancerous enlargement of male breasts, and galactorrhea, the production of breast milk independent of childbirth. Janssen lost patent protection over Risperdal in June 2008, after which other manufacturers began producing, marketing, and selling generic versions of Risperdal, known as risperidone.

According to the Defendants, Coleson was first prescribed risperidone by New York City Correctional Health Services following an arrest in July 2010 and that the FDA-approved Risperdal label was used both by brand-name Risperdal and generic risperidone for the entire period that Coleson claims to have taken Risperdal and risperidone.

Medicaid paid for all of Plaintiff's prescriptions. One feature of New York's Medicaid program is that it excludes coverage of brand-name drugs when there is an FDA-approved generic equivalent on the market unless one's healthcare provider specifically requests an exemption for the patient.

Coleson was prescribed risperidone from July 2010 to April 2014. Around late 2013 or early 2014, Coleson switched his antipsychotic medication from risperidone to Seroquel, a drug also linked to gynecomastia. Around this time, Coleson spoke with doctors about his chest pain, his development of a lopsided chest, and discharge from his chest.

On May 30, 2014, Coleson was examined by Dr. Ajay Shah, who did not find gynecomastia. On September 26, 2014, after reviewing an ultrasound taken on September 8, 2014, Dr. Shah confirmed that Coleson did not have gynecomastia.

Around March 2015, Dr. Shah diagnosed Coleson with gynecomastia.

Applicable Standard

Summary judgment is appropriate only where "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). A dispute is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). The relevant inquiry on application for summary judgment is "whether

the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law." Id. at 251-52. A court is not charged with weighing the evidence and determining its truth, but with determining whether there is a genuine issue for trial. Westinghouse Elec. Corp. v. N.Y. City Transit Auth., 735 F. Supp. 1205, 1212 (S.D.N.Y. 1990) (quoting Anderson, 477 U.S. at 249). "[T]he mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Anderson, 477 U.S. at 247-48 (emphasis in original). Furthermore, "[t]he mere existence of a scintilla of evidence in support of the [non-movant's] position will be insufficient; there must be evidence on which the jury could reasonably find for the [non-movant]." Id. at 252.

When sitting in diversity cases, federal courts are bound to follow the substantive law of the forum state. Travelers Ins. Co. v. 633 Third Assocs., 14 F.3d 114, 119 (2d Cir. 1994) (citing Erie R.R. Co. v. Tompkins, 304 U.S. 64, 58 S.Ct. 817, 82 L.Ed. 1188 (1938)). "To determine the substantive law of the forum, federal courts will look to the decision law of the forum state, as well as to the state's constitution and statutes." Id.

In the Second Circuit, if the substantive law of the forum state is unsettled, the federal court "must carefully review available resources to predict how the New York Court of Appeals would resolve the questions at bar." In re Eastern and Southern Districts Asbestos Litig., 772 F.Supp. 1380, 1389 (E. & S.D.N.Y. 1991), rev'd on other grounds, In re Brooklyn Navy Yard Asbestos Litig., 971 F.2d 831 (2d Cir. 1992). "In making such a determination, a federal court is free to consider all of the resources to which the highest court of the state could look, including decisions in other jurisdictions on the same or analogous issues." Leon's Bakery, Inc. v. Grinnell Corp., 990 F.2d 44, 48 (2d Cir. 1993).

Defendants' Motion For Summary Judgment Is Granted

Reading Plaintiff's complaint in the light most favorable to him as a non-moving *pro se* party, he has brought state law claims of strict products liability and negligence. Defendants have drawn the same conclusion, upon which they have briefed the instant motion (Memo in Supp. at 6 n.2) and the arguments made by Plaintiff in his reply papers accord with this construction, (see Memo in Opp. at 3-6). Based on the following, Defendants' motion for summary judgment is granted.

Plaintiff's complaint can be construed to put forward two different strict products liability claims. Plaintiff asserts that Defendants failed to warn him of the hormonal risks of taking generic risperidone, which requires that he establish: "(1) the manufacturer has a duty to warn; (2) against dangers resulting from foreseeable uses about which it knew or should have known; and (3) that failure to do so was the proximate cause of the harm." Barrett v. Black & Decker (U.S.) Inc., No. 06 Civ. 1970 (SCR)(MDF), 2008 WL 5170200, at *10 (S.D.N.Y. Dec. 9, 2008) (citing Barban v. Rheem Textile Sys., Inc., No. 01 Civ. 8475 (ILG), 2005 WL 387660, at *9 (E.D.N.Y. Feb. 11, 2005), aff'd, 147 F. App'x 222 (2d Cir. 2005)). Plaintiff has also claimed that Risperdal suffered from a design defect and caused him gynecomastia. This requires that Plaintiff establish: "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing the plaintiff's injury." Id. (citing Colon v. Bic USA, Inc., 199 F.Supp.2d 53, 86 (S.D.N.Y. 2001)).

Design defect strict products liability claims differ from negligently designed product claims "in that the plaintiff is not required to prove that the manufacturer acted unreasonably in designing the product." Voss v. Black & Decker Mfg. Co., 59

N.Y.2d 102, 107, 450 N.E.2d 204, 207 (1983). Given this difference, "New York courts generally consider strict products liability and negligence claims to be functionally synonymous" and "analyze both claims under a single test." Barrett, 2008 WL 5170200, at *12 (collecting cases); see also Simon v. Smith & Nephew, Inc., 990 F. Supp. 2d 395, 406 (S.D.N.Y. 2013).

Plaintiff alleges he was prescribed and took both name-brand Risperdal and generic risperidone, which caused him to develop gynecomastia. Defendants respond that each of Plaintiff's claims must fail because Plaintiff has put forward no evidence showing that he ingested name-brand Risperdal, only generic risperdone. Consequently, Defendants argue they cannot be held liable for injury resulting from using a product that they did not manufacture, distribute, or sell. Defendants also argue that Plaintiff cannot show medical causation between Risperdal and his gynecomastia.

The New York Court of Appeals has not yet addressed whether a manufacturer of a name-brand prescription drug can be held liable for injuries resulting from another company's generic equivalent. However, Defendants point this Court to two other New York court decisions, both of which have rejected such liability: Goldych v. Eli Lilly & Co., No. 04 Civ. 1477

(GLS)(GJD), 2006 WL 2038436 (N.D.N.Y. July 19, 2006) and Weese v. Pfizer, Inc., 2013 N.Y. Misc. LEXIS 4761, 2013 N.Y. Slip Op. 32563 (Sup. Ct., N.Y. Cty. Oct. 8, 2013). In Goldych, the Northern District of New York rejected a widow's claims against the manufacturer of Prozac, who she blamed for her husband's suicide after he ingested Prozac's generic equivalent. Construing her claims as ones for products liability, the court concluded that the brand-name manufacturer had "no duty to the users of other manufacturers' products" and dismissed her action. Goldych, 2006 WL 2038436, at *6. In Weese, a mother gave birth to a daughter with a serious heart defect after ingesting the generic version of Zoloft and sued the name-brand manufacturer, Pfizer. The court there similarly concluded that Pfizer's "duty should not extend to products and labeling over which it has no control, even if those products and labels mirrors its own, because it has done nothing toward putting them in the hands of consumers." Weese, 2013 N.Y. Misc. LEXIS 4761, at *4-5. These views accord with the majority of courts to consider the topic: fifty-five other state courts across twenty-one states, in addition to all six circuit courts of appeal to have ruled on the question. See In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig., 756 F.3d 917, 938-39 (6th Cir. 2014) (surveying the legal landscape and collecting cases).

A minority of courts have found liability against brand-name drug manufacturers, including one identified by Plaintiff. See Conte v. Wyeth, 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299, 309 (2008); see also In re Darvocet, 756 F.3d at 938-39 (collecting cases to have taken the minority view). These courts have generally found that a duty exists for brand-name manufacturers over the warnings of their generic equivalents because name-brand manufacturers should "reasonably foresee" that patients will be prescribed generic medication in reliance on the brand-name manufacturer's representations. Conte, 168 Cal. App. 4th at 111; see also Wyeth, Inc. v. Weeks, 159 So. 3d 649, 676 (Ala. 2014). At least one court has found a duty for brand-name manufacturers over their generic equivalents with regard to negligent design defects. See Dolin v. SmithKline Beecham Corp., 62 F. Supp. 3d 705, 723 (N.D. Ill. 2014).

Recent New York Court of Appeals case law suggests that New York will side with the majority of courts. Last year, in In re N.Y. City Asbestos Litig., 27 N.Y.3d 765, 59 N.E.3d 458 (2016), the Court of Appeals expanded product manufacturer liability by finding that manufacturers had a duty to warn of potential dangers resulting from their products' use in conjunction with third party products. Id. at 792. To support this expansion, the court noted that the manufacturers had "knowledge and ability to

warn of the dangers" when consumers used the product with a third party's product. The new liability was unlikely to make "the cost of liability and litigation . . . unreasonable," id., and the manufacturers "derive[d] a benefit from the sale of the [other party's] product." Id. at 794. This rationale weighs in the opposite direction here. Defendants had no oversight in the manufacturing of the generic drugs. They earned no profit from the sale of the generic drugs. Given the length of time generic drugs can sell following a patent's expiration, to find a new duty would unforeseeably expand the cost of liability on brand-name drug manufacturers.

With this judicial landscape, it is concluded that the New York authorities are consistent with the majority of other courts around the country in rejecting liability for a company that itself did not manufacture, sell, or distribute generic versions of its name-brand drug. Accord In re Darvocet, 756 F.3d at 949 (predicting that New York would either require product identification for a product liability claim or that name-brand manufacturers did not owe a duty over generically manufactured drugs). Applying this rule to the instant matter, Plaintiff's failure to warn claim must fail because he only alleges a warning defect as to risperdone, over which Defendants had no duty of care.

Plaintiff's design defect and negligence claims also fail because he cannot show by a preponderance of the evidence that he ever ingested name-brand Risperdal. See Anderson, 477 U.S. at 252 ("The judge's inquiry [in civil cases] . . . unavoidably asks whether reasonable jurors could find by a preponderance of the evidence that the plaintiff is entitled to a verdict."). Plaintiff's declaration and deposition states that he was prescribed, amongst other drugs, "Risperdal (risperidone)" and received while at Woodhull Hospital around 2009 or 2010 "Risperdal and/or risperidone." (Coleson Decl. ¶¶ 2, 5; see also Declaration of Thomas P. Kurland dated October 14, 2016 ("Kurland Decl.") Ex. H at 40-41.) Nothing else supports Plaintiff's statements. Plaintiff claims hospital records that prove he actually received Risperdal while at Woodhull were likely destroyed by a fire in January 2015. (Coleson Decl. ¶¶ 2-3; Kurland Decl. Ex. H at 40-41.) It is unfortunate that evidence that might have been valuable to Plaintiff's case was potentially lost due to external forces. In the absence of that evidence, however, the Court is left only with Plaintiff's "mere speculation or conjecture" as to those files' existence and his naked assertion. Fletcher v. Atex, Inc., 68 F.3d 1451, 1456 (2d Cir. 1995) (citation omitted).

A "fair-minded jury" could conclude that Plaintiff received drugs while at Woodhull, and even that Plaintiff was prescribed Risperdal. Anderson, 477 U.S. at 252. However, the following facts remain undisputed. By 2009, risperidone was a widely available generic to Risperdal. (Defs.' 56.1 ¶¶ 6, 9; Pl.'s 56.1 ¶¶ 6, 9.) All of Plaintiff's prescriptions were paid by Medicaid. (Defs.' 56.1 ¶ 29; Pl.'s 56.1 ¶ 29; Coleson Decl. Ex. H at 161.) Aside from exceptional circumstances Plaintiff has not shown, Plaintiff's prescriptions under Medicaid needed to be filled with generic drug equivalents. (Defs.' 56.1 ¶ 8; Pl.'s 56.1 ¶ 8.) From the evidence presented, no jury could draw the "justifiable inference" that Plaintiff received name-brand Risperdal for his prescriptions.[1] Id. at 254. Plaintiff has shown the possibility of injury from his ingestion of risperdone, and were he to pursue claims against the generic drug manufacturers, it might lead to a different outcome. See Guvenoz v. Target Corp., 30 N.E.3d 404, 420 (collecting cases), appeal denied, 39

[1] The fact that Plaintiff's medical records at times recorded his prescription as only for Risperdal do not permit an inference that when filling those prescriptions he received and ingested Risperdal. (See Kurland Decl. Exs. K, M, P (noting that Plaintiff was prescribed "Risperdal," "Respiridol [*sic*]," and "Resperdol [*sic*]").) Generic risperidone is regularly written as "Risperdal (risperidone)," a nomenclature even Plaintiff adopts in his papers. (See Coleson Decl. ¶ 27, Kurland Decl. Exs. G, L.) That a drug is prescribed under its brand-name does not mean that a patient receives that name-brand drug, and is not "justifiable" to infer that it does. Anderson, 477 U.S. at 256; see Goldych, 2006 WL 2038436, at *1 (observing that while a name-brand was prescribed, the pharmacy substituted a generic according to "accepted standards"). (See also Coleson Decl. Exs. A, C (prescription receipts showing Coleson receiving risperdone during the time-frame of being prescribed Risperdal).)

N.E.3d 1002 (Ill. 2015), cert. denied, 136 S. Ct. 2409 (2016). Here, though, it cannot "serve as a basis for liability" against Risperdal's manufacturer. In re Darvocet, 756 F.3d at 938.

Even assuming that Plaintiff had ingested Risperdal, his design defect and negligence claims against Defendants would still fail because he cannot establish that Risperdal caused his gynecomastia. "[I]n any products liability or personal injury action, Plaintiffs must prove causation—that the Defendants' conduct . . . was the proximate cause of Plaintiff's injuries." In re Mirena IUD Prods. Liab. Litig., 202 F. Supp. 3d 304, 310 (S.D.N.Y. 2016) (citations omitted) (finding summary judgment for defendants for strict product liability and negligence claims). "Generally, in products liability cases, to establish causation, [plaintiffs] must offer admissible expert testimony regarding both general . . . and specific causation," particularly "where a causal link is beyond the knowledge or expertise of a lay jury." Id. (quoting Amorgianos v. Nat'l R.R. Passenger Corp., 303 F.3d 256, 268 (2d Cir. 2002)) (quotation marks omitted).

Plaintiff argues that he has sufficient evidence for a jury to find causation. He points to Risperdal's warning label, which discusses gynecomastia, to prove general causation and a July

2015 medical report, which concludes that Plaintiff's gynecomastia "is related to phychiatric [*sic*] medical ingestion," to prove specific causation. (Coleson Decl. Ex. F; Memo in Opp. at 5.)

Risperdal's warning label cannot establish general causation. Product warning labels can have over-inclusive information on them, often out of "an abundance of causation or the avoidance of lawsuits." In re Mirena, 202 F. Supp. 3d at 323. Unless a warning label specifically indicates that an alleged injury can be caused by a drug, courts have found that a drug's product warning label alone cannot "raise a genuine issue of material fact with respect to general causation." Id. Risperdal's label states it "elevates prolactin levels" and that "gynecomastia . . . ha[s] been reported in patients receiving prolactin elevating compounds." (Kurland Decl. Ex. C.) This is not the same as an admission of "a genuine phenomenon" creating a "material fact with respect to general causation." In re Mirena, 202 F. Supp. 3d at 323.

Plaintiff's July 2015 medical report does not establish proximate cause. Plaintiff claims to have taken Risperdal only around either 2009 or 2010. Throughout 2010 to 2014, Plaintiff took risperidone. In early 2014, Plaintiff switched to a

different antipsychotic, Seroquel, which is undisputedly associated with cases of gynecomastia. Plaintiff was diagnosed with gynecomastia only in early 2015, and the medical report to which Plaintiff points indicates Plaintiff had taken both Seroquel and risperidone. (See Coleson Decl. Ex. F.) This report does not state which, if any, of these complicated drugs is responsible for Plaintiff's injury. Without "competent medical expert testimony on the issue of causation," a jury would be left only to "theorize" as to how Plaintiff came to suffer from gynecomastia. Fane v. Zimmer, Inc., 927 F.2d 124, 131 (2d Cir. 1991) (rejecting a showing of causation without expert testimony as to the relationship between the alleged defective product and a broken bone).

Conclusion

For the foregoing reasons, Defendants' motion for summary judgment is granted.

It is so ordered.

New York, NY
May 3, 2017

ROBERT W. SWEET
U.S.D.J.