UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JAMAL ADEGHE,
Plaintiff,

-against-

JANSSEN PHARMACEUTICALS, INC.,
Defendant.

16 Civ. 2235 (LGS)

OPINION AND ORDER

LORNA G. SCHOFIELD, District Judge:

Plaintiff Jamal Adeghe brings this products liability action under New York law based on his ingestion of Risperdal, a medication manufactured by Defendant Janssen Pharmaceuticals Inc. The Court previously granted summary judgment with respect to Plaintiff's breach of express warranty and failure to warn claims; Defendant now moves for summary judgment with respect to Plaintiff's remaining claims. For the reasons below, Defendant's motion is granted.

I. BACKGROUND

Familiarity with the relevant factual background in this case is assumed based on the previous opinions on the parties' motions for summary judgment and reconsideration. *See Adeghe v. Janssen Pharm., Inc.*, No. 16 Civ. 2235, 2017 WL 3741310 (S.D.N.Y. Aug. 30, 2017); *Adeghe v. Janssen Pharm., Inc.*, No. 16 Civ. 2235, 2017 WL 4839063 (S.D.N.Y. Oct. 24, 2017). The relevant procedural background is as follows.

In August 2014, Plaintiff filed suit in state court against Defendant and other parties. Defendant removed this case to federal court based on diversity jurisdiction. The Second Amended Complaint, the operative complaint, raises eleven causes of action against Defendant under New York law: (1) negligence, (2) strict products liability, (3) manufacturing defect, (4) failure to warn, (5) breach of express warranty, (6) breach of implied warranty, (7) fraudulent

misrepresentation, (8) fraudulent concealment, (9) negligent misrepresentation, (10) fraud and deceit and (11) violation of New York General Business Law §§ 349 and 350.

On March 6, 2017, Defendant moved for summary judgment with respect to all eleven claims, but raised particularized arguments with respect to only three of the claims: breach of implied warranty, breach of express warranty and failure to warn. Summary judgment was granted on Plaintiff's express warranty and failure-to-warn claims, but denied with respect to breach of implied warranty. *Adeghe* 2017 WL 3741310, at *7. In bringing that first summary judgment motion, Defendant made no specific arguments regarding Plaintiff's other eight claims. Instead, Defendant moved to preclude Plaintiff's causation expert, and argued that Defendant was entitled to summary judgment on all claims, because Plaintiff lacked admissible expert testimony on causation. However, the expert's testimony was found to be admissible under Federal Rule of Evidence 702, and accordingly summary judgment was denied with respect to breach of implied warranty and the additional eight claims. *Id.*

On September 11, 2017, Defendant moved for reconsideration of the Court's first summary judgment opinion, raising -- for the first time -- particularized arguments regarding why summary judgment should be awarded on the remainder of Plaintiff's claims. The motion for reconsideration was denied because the new arguments were inappropriate on a motion for reconsideration. However, Defendant was permitted to renew its motion for summary judgment in the interest of judicial economy because the new arguments present serious issues. *Adeghe*, 2017 WL 4839063, at *2.

II. LEGAL STANDARD

Summary judgment is appropriate where the record before the court establishes 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). There is a genuine dispute as to a material fact "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); *accord Nick's Garage, Inc. v. Progressive Cas. Ins. Co.*, 875 F.3d 107, 113 (2d Cir. 2017) (citations omitted). The court must construe the evidence in the light most favorable to the nonmoving party and must draw all reasonable inferences in favor of the nonmoving party. *Liberty Lobby*, 477 U.S. at 255; *accord Soto v. Gaudett*, 862 F.3d 148, 154 (2d Cir. 2017) (citations omitted).

When the movant has properly supported its motion with evidentiary materials, the opposing party must establish a genuine issue of fact by "citing to particular parts of materials in the record." Fed. R. Civ. P. 56(c)(1)(A). "[A] party may not rely on mere speculation or conjecture as to the true nature of the facts to overcome a motion for summary judgment." *Hicks v. Baines*, 593 F.3d 159, 166 (2d Cir. 2010) (alteration in original) (internal quotation marks omitted); *accord Dudley v. New York City Hous. Auth.*, No. 14 Civ. 5116, 2017 WL 4315010, at *14 (S.D.N.Y. Sept. 25, 2017) (citations omitted).

III. DISCUSSION

A. Design Defect

Plaintiff's remaining negligence and strict products liability causes of action are both rooted exclusively in a claimed design defect in Risperdal.[1] As explained below, summary judgment is granted to Defendant on both claims, because Plaintiff has not submitted evidence from which a reasonable jury could conclude that Risperdal contains a design defect or that a reasonable alternative design for Risperdal exists.

[1] Summary judgment was previously granted to Defendant with respect to the design defect claim to the extent it was predicated on defects in Risperdal's warning label. *Adeghe*, 2017 WL 3741310, at *7.

"[I]n a design defect case there is almost no difference between a prima facie case in negligence and one in strict liability." *Searle v. Suburban Propane Div. of Quantum Chem. Corp.*, 700 N.Y.S.2d 588, 263 A.D.2d 335, 338 (3d Dep't 2000); *accord Guariglia v. Procter & Gamble Co.*, No. 215 Civ. 04307, 2018 WL 1335356, at *4 (E.D.N.Y. Mar. 14, 2018) (citations omitted) (applying New York law). New York design defect law uses a "risk-utility" approach for determining whether a product is defective. *M.H. v Bed Bath & Beyond Inc.*, 64 N.Y.S.3d 205, 156 A.D.3d 33, 35-36 (1st Dep't 2017) (citing *Voss v Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 109 (1983)). "[I]n order to determine whether a product was designed so that it was not reasonably safe, the risks inherent in the product must be balanced against the product's utility and cost, which requires the consideration of certain factors, including the utility of the product to the public as a whole and to the individual user, the nature of the product -- that is, the likelihood that it will cause injury, the availability of a safer design, the potential for designing and manufacturing the product so that it is safer but remains functional and reasonably priced." *M.H.*, 156 A.D.3d at 35-36 (citations omitted).

Accordingly, under New York law, "[a] defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use, and whose utility does not outweigh the danger inherent in its introduction into the stream of commerce." *Hoover v. New Holland N. Am., Inc.*, 11 N.E.3d 693, 701 (N.Y. 2014) (internal quotation marks omitted). "In order to establish a prima facie case in strict products liability for design defects, the plaintiff must show that the manufacturer breached its duty to market safe products when it marketed a product designed so that it was not reasonably safe and that the defective design was a substantial factor in causing plaintiff's injury." *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d

102, 107 (1983); *accord S.F. v. Archer Daniels Midland Co*., 594 Fed. App'x. 11, 12 (2d Cir. 2014) (citations omitted) (applying New York law) (summary order). "More specifically, the standard is whether, if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner." *Fane v. Zimmer, Inc*., 927 F.2d 124, 128 (2d Cir. 1991) (applying New York law); *accord Greenberg v. Larox, Inc*., 673 F. App'x 66, 69 (2d Cir. 2016) (applying New York law). Accordingly, "[t]he plaintiff bears the burden of presenting evidence that the product, as designed, presented a substantial likelihood of harm and feasibly could have been designed more safely." *Fane*, 927 F.2d at 128.

Plaintiff has not submitted sufficient evidence of a design defect to survive summary judgment. Here, because of the complex chemistry and biology involved in assessing the design of Risperdal and its alternatives, expert testimony is necessary. *See, e.g*., *Fitzpatrick v. Currie*, 861 N.Y.S.2d 431, 52 A.D.3d 1089, 1091 (3d Dep't 2008) ("While the opinion of an expert may not always be necessary in establishing a products liability case, the complex issues involved in the design and operation of an air bag make expert proof imperative . . . .") (citations omitted); *see also Valente v. Textron, Inc*., 931 F. Supp. 2d 409, 437 (E.D.N.Y. 2013), *aff'd*, 559 Fed. App'x 11 (2d Cir 2014) ("A plaintiff is generally required to provide expert testimony in order to establish the feasibility and efficacy of an alternative design, unless a reasonable alternative design is both obvious to, and understandable by, a layperson."). Plaintiff has disclosed only one expert in this case, Dr. Barry B. Bercu. Dr. Bercu's report opined only that Risperdal caused Plaintiff's gynecomastia. The report made no mention of Risperdal's chemical composition and proffered no better alternative design for the drug. The word "design" does not even appear in

Dr. Bercu's report or testimony, and he did not review materials relevant to Risperdal's chemical composition in formulating his report.

According to Dr. Bercu's report, "[t]here are multiple hypotheses for the development of gynecomastia," and "the actual mechanisms of action for the development of gynecomastia is yet unknown." Even accepting Dr. Bercu's opinion that Risperdal caused Plaintiff's gynecomastia, and that the causal mechanisms behind gynecomastia are unknown, Plaintiff has not proffered sufficient expert evidence for a reasonable jury to conclude that Risperdal's chemical composition was unreasonably dangerous -- i.e., that its risk outweighed its utility-- or that there is a better, feasible alternative design for the drug. As a result, summary judgment is granted to Defendant.

Despite not proffering expert testimony on these issues, Plaintiff argues that two citations to the record are sufficient evidence to forestall summary judgment. First, Plaintiff notes that Dr. Bercu's report and deposition reference an FDA study that used the FDA's Adverse Event Reporting System ("AERS") database, and concluded that "Risperdal was attributed to more cases of drug induced gynecomastia than six (6) other antipsychotics that antagonize dopamine D2 receptors." Second, Plaintiff points to the defense expert's testimony that "[Risperal] is associated with higher levels of prolactin elevation than other antipsychotic agents" and that "Prolactin level increase is associated with gynecomastia." Even assuming that Plaintiff's design defect claim could survive summary judgment without relevant expert testimony, the cited evidence is insufficient for a reasonable jury to conclude that Risperdal was unreasonably dangerous or that a better alternative design for Risperdal is possible. That Risperdal may be more likely to cause gynecomastia than six other drugs on the market, or that it is associated with

higher levels of Prolactin, does not necessarily suggest that Risperdal's design was unreasonably dangerous.

The studies cited do not shed light on the relative costs and benefits of Risperdal as compared with other similar drugs on the market. For example, if Risperdal is more effective, either in general or in plaintiff's particular case, or has fewer other dangerous side effects, the risk of gynecomastia may be justified -- "all drugs involve risks of untoward side effects in those who take them." *Zuchowicz v. United States*, 140 F.3d 381, 391 (2d Cir. 1998). Nor do the cited studies suggest that Risperdal's chemical composition could be altered to remain an effective antipsychotic, yet decrease the risk of gynecomastia. In sum, the evidence relevant to the risk-utility analysis or feasibility of alternative designs is insufficient for a reasonable jury to find for Plaintiff.[2] Summary judgment is granted with respect to these claims.

B. Manufacturing Defect

Summary judgment is also granted with respect to Plaintiff's manufacturing defect claim. In order to prove a manufacturing flaw under either negligence or strict liability, a plaintiff must show that their specific unit was defective because of "some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction," and that the defect caused their injury. *Caprara v. Chrysler Corp*., 52 N.Y.2d 114, 129 (1981); *accord Guariglia v. Proctor & Gamble Co.*, No. 215 Civ. 04307, 2018 WL 1335356, at *5

[2] Defendant also argues that summary judgment is appropriate because Plaintiff's design defect claims are preempted by federal law. In light of Plaintiff's failure to establish a prima facie showing of design defect or reasonable alternative design preemption is not addressed. Moreover, courts in this district are split on the issue of preemption. *Compare Utts v. Bristol-Myers Squibb Co*., 226 F. Supp. 3d 166, 178 (S.D.N.Y. 2016) ("this case law, read holistically, indicates that federal law preempts all pre-FDA approval failure to warn and design defect claims for branded prescription medication."), *with Sullivan v. Aventis, Inc.*, No. 14 Civ. 2939, 2015 WL 4879112, at *5 (S.D.N.Y. Aug. 13, 2015) (holding that the FDCA did not preempt design defect claims regarding a brand name drug).

(E.D.N.Y. Mar. 14, 2018) (citations omitted) (applying New York law). Accordingly, in a drug products liability case, a manufacturing defect claim is legally insufficient where the plaintiff does not allege that the pills they ingested are different from all other samples of the drug. *See Caprara*, 52 N.Y.2d at 129; *see, e.g.*, *Morrison v. Hoffmann-La Roche, Inc.*, No. 14 Civ. 4476, 2016 WL 5678546, at *5 (E.D.N.Y. Sept. 29, 2016) (holding that a manufacturing defect claim failed where the "plaintiff has not alleged that the particular drug administered to her had a defect as compared to other samples of that drug") (internal quotation marks and alterations omitted) (applying New York law).

In this case, summary judgment is appropriate because there is no evidence in the record that the Risperdal tablets that Plaintiff ingested deviated from Defendant's intended design for the drug and from other Risperdal tablets Defendant produced. Plaintiff's opposition brief makes no argument defending the manufacturing defect claim, apparently conceding this point. Summary judgment for Defendant is granted with respect to the manufacturing defect claim.

C. Fraud and Misrepresentation Claims

Plaintiff also asserts claims for breach of implied warranty; fraudulent misrepresentation; fraudulent concealment; negligent misrepresentation; fraud and deceit and violation of NYGBL §§ 349 and 350. Each of these claims requires proof that Plaintiff's reliance on Defendant's deceptive conduct caused Plaintiff's injuries. *See TVT Records v. Island Def Jam Music Grp.*, 412 F.3d 82, 90-91 (2d Cir. 2005) (stating the elements of fraudulent concealment under New York law); *Dallas Aerospace, Inc. v. CIS Air Corp.*, 352 F.3d 775, 784 (2d Cir. 2003) (stating the elements of fraudulent misrepresentation under New York law); *Wynn v. AC Rochester*, 273 F.3d 153, 156 (2d Cir. 2001) (stating the elements of fraud under New York law); *Hydro Inv'rs, Inc. v. Trafalgar Power Inc.*, 227 F.3d 8, 20 (2d Cir. 2000) (stating the elements of negligent

misrepresentation under New York law); *Maurizio v. Goldsmith*, 230 F.3d 518, 521 (2d Cir. 2000) (stating the elements of NYGBL §§ 349 and 350); *Ainger v. Michigan Gen. Corp*., 632 F.2d 1025, 1026 (2d Cir. 1980) (stating the elements of breach of implied warranty under New York law); *accord In re Kind LLC "Healthy & All Natural" Litig*., No. 15 Civ. 2645, 2018 WL 1156009, at *7 (S.D.N.Y. Mar. 2, 2018) (breach of implied warranty and negligent misrepresentation); *First Solar, Inc. v. Absolute Process Instruments, Inc.*, No. 17 Civ. 8518, 2018 WL 1166632, at *2 (S.D.N.Y. Feb. 8, 2018) (fraud and deceit); *Elavon, Inc. v. Ne. Advance Techs., Inc.*, No. 15 Civ. 7985, 2017 WL 4876300, at *9 (S.D.N.Y. Oct. 27, 2017) (fraudulent misrepresentation); *VR Optics, LLC v. Peloton Interactive, Inc*., No. 16 Civ. 6392 , 2017 WL 3600427, at *4 (S.D.N.Y. Aug. 18, 2017) (fraudulent concealment); *Kurtz v. Kimberly-Clark Corp*., 321 F.R.D. 482, 525 (E.D.N.Y. 2017) (NYGBL §§ 349 and 350).

Summary judgment is granted with respect to each of these claims, because Plaintiff has not adduced evidence from which a reasonable jury could find that Plaintiff relied on any misrepresentation by Defendant, or that he was injured as a result. As noted in the first summary judgment opinion, "Plaintiff fails to identify any misleading affirmation of fact or promise from Defendant that induced Plaintiff's Risperdal use." *Adeghe*, 2017 WL 3741310, at *7. When Plaintiff and his mother were asked at their depositions if they remembered ever reading the warning information that accompanied Risperdal, both acknowledged that they had no recollection of doing so. As a result, even if the Risperdal warning labels were misleading, Plaintiff has not adduced evidence that he or his physician actually read the misstatement and relied upon it.

IV. CONCLUSION

For the foregoing reasons, Defendant's motion for summary judgment is GRANTED as to all remaining claims. The pending motions in limine and motion to strike are DENIED as moot. The Clerk of Court is respectfully directed to close all open motions and to close the case.

Dated: August 29, 2018
New York, New York

LORNA G. SCHOFIELD
UNITED STATES DISTRICT JUDGE