UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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MARIA GIOIA,

Plaintiff,

-against-

JANSSEN PHARMACEUTICALS,

Defendant.
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For Online Publication Only

MEMORANDUM AND ORDER
19-CV-04629 (JMA) (SIL)
19-CV-05377 (JMA)(SIL)

APPEARANCES:

Maria Gioia
Pro se Plaintiff

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AZRACK, United States District Judge:

Plaintiff, Maria Gioia ("plaintiff"), acting pro se, commenced these product liability actions on August 7, 2019 in Supreme Court, County of Nassau (19-CV-04629, "Gioia I"), and August 29, 2019 in Supreme Court, County of Suffolk (19-CV-05377, "Gioia II") against Janssen Pharmaceuticals ("defendant" or "Janssen"), manufacturers of the drug Invega. Defendant removed Gioia I and Gioia II to this Court on the basis of diversity jurisdiction, pursuant to 42 U.S.C. § 1332, on August 12, 2019 and September 20, 2019, respectively. (Gioia I, Notice of Removal, ECF No. 1; Gioia II, Notice of Removal, ECF No. 1.) Plaintiff alleges that she suffered injuries because of side effects she allegedly suffered from taking Invega. (Gioia I Compl., ECF No. 1-1 at 4, Gioia II, Compl., ECF No. 1-1 at 3.) Before the Court is defendant's motion to dismiss the complaints pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. (Gioia

I and II, Def.'s Mot. to Dismiss, ECF No. 20.) For the reasons discussed below, defendant's motion is GRANTED with limited leave to amend.

I. BACKGROUND

A. Factual Background

The following facts are taken from the complaints and the record before the Court, including exhibits which are attached or integral to the complaints. See Sira v. Morton, 380 F.3d 57, 67 (2d Cir. 2004).

Plaintiff's complaints, though bare-boned, appear to allege that defendant's failure to warn about the possible side effects of Invega "led[] to [the] end of [her] career as a primary care physician." (Gioia I, Compl. at 4; see also Gioia II, Compl. at 3 (alleging that defendant is responsible "for loss of career as primary care physician due to no informed consent or warnings of Invega['s] ultimate outcome and side effects").) The Court reads the complaints to assert claims for lack of informed consent and failure to warn. Plaintiff alleges that she suffers from memory loss, hypothyroidism, Horner's syndrome, nerve damage, motor tremors, vocal tics, confusion, loss of taste and sensation, PTSD, and metabolic syndrome, including hypertension, diabetes, and stroke. (Gioia I, Compl. at 9-10.)[1] Plaintiff's complaints both seek over sixteen million dollars in damages. (Id. at 11; Gioia II, Compl. at 3.)

B. Procedural History

Following the defendant's removal of Gioia I and II to this Court on February 12, 2020, plaintiff moved to remand both cases to state court. (Gioia I, ECF No. 16; Gioia II, ECF No. 18.) This Court denied plaintiff's motions on February 19, 2020 and February 20, 2020, respectively. (Gioia I, Docket Entry Order dated February 19, 2020; Gioia II, Docket Entry Order dated

[1] The complaint in Gioia II does not specify Plaintiff's alleged injuries.

February 20, 2020.) On August 20, 2020, plaintiff, again, moved to remand Gioia I and II to state court. (Gioia I, ECF No. 28; Gioia II, ECF No. 25.) On September 28, 2020, this Court denied plaintiff's second motion to remand and warned plaintiff that if she submitted any further frivolous filings concerning remand, the Court may sanction her by dismissing her claims with prejudice. (Gioia I, Electronic Order dated September 28, 2020).

On March 20, 2020, defendant filed its motion to dismiss both Gioia I and II for failure to state a claim. (Gioia I, ECF No. 20; Gioia II, ECF No. 20.) That same day, defendant submitted a letter reply to this Court in further support of its motion to dismiss. (Gioia I, ECF No. 23.) Plaintiff filed an opposition to defendant's motion to dismiss on April 10, 2020. (Gioia I, ECF No. 24.)

II. DISCUSSION

A. Standard Under Rule 12(b)(6)

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), a plaintiff must allege sufficient facts "to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007). A claim is facially plausible only "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (citing Twombly, 550 U.S. at 556). Mere labels and legal conclusions will not suffice. Twombly, 550 U.S. at 555. In reviewing a motion to dismiss, the Court must accept the factual allegations set forth in the complaint as true and draw all reasonable inferences in favor of the plaintiff. Cleveland v. Caplaw Enters., 448 F.3d 518, 521 (2d Cir. 2006). A court may also consider materials attached to the complaint, materials integral to the complaint, and materials incorporated into the complaint by reference. Sira, 380 F.3d at 67.

While a court is required to read a plaintiff's pro se complaint liberally and interpret it as raising the strongest arguments it suggests, a pro se plaintiff must still plead "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570; see also Harris v. Mills, 572 F.3d 66, 72 (2d Cir. 2009).

B. Jurisdiction

This Court has jurisdiction of plaintiff's state law claims based on diversity, pursuant to 28 U.S.C. § 1332. New York substantive state law applies to this diversity action. Principal Nat'l Life Ins. Co. v. Coassin, 884 F.3d 130, 134 (2d Cir. 2018) ("Federal courts sitting in diversity cases will, of course, apply the substantive law of the forum State on outcome determinative issues.") (citation omitted).

For the foregoing reasons, the complaints fail to plead sufficient claims against defendant. Therefore, defendant's motion to dismiss the complaints is granted.

C. Lack of Informed Consent

Plaintiff claims that defendant failed to "provide proper informed consent about [the] ultimate outcome as well as important side effects from taking their medicine Invega."[2] (Gioia I, ECF No. 24, Pl.'s Opp. to Mot. to Dismiss at 2.) Because the Court finds that plaintiff's lack of informed consent claim is non-cognizable under the law, it is dismissed with prejudice.

"Under New York law, a pharmaceutical manufacturer has a duty 'to warn of all potential dangers in its prescription drugs that it knew, or, in the exercise of reasonable care, should have known to exist.'" DiBartolo v. Abbott Labs., 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2012) (quoting Martin v. Hacker, 83 N.Y.2d 1, 8, 607 N.Y.S.2d 598 (1993)). "Warnings for prescription drugs

[2] For the first time, in plaintiff's opposition papers, she appears to argue that defendant committed fraud by "stealing [her] information [about side effects of the medication] to then update their website." (Pl's Opp.to Motion to Dismiss at 2.) The Court declines to consider plaintiff's futile attempt to raise a fraud claim. See Davila v. Lang, 343 F.Supp.3d 254, 267 (S.D.N.Y. 2018) ("A pro se plaintiff may not raise 'entirely new' causes of action for the first time in his opposition papers.")

are intended for the physician whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects." Id. (quoting Martin, 83 N.Y.2d at 9, 607 N.Y.S.2d 598). "The physician acts as an 'informed intermediary' between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." Id. As such, a failure to obtain informed consent might be a viable theory of liability against the physician who prescribed the medication, see Chandler v. Janssen Pharmaceuticals, Inc., 322 F. Supp. 3d 314, 329 (E.D.N.Y. 2018), however, it is not a sufficient basis to hold a manufacturer liable. Salva v. Blum, 277 A.D.2d 985, 716 N.Y.S.2d 527, 528 (4th Dep't 2000) ("Lack of informed consent is not a theory of liability upon which an injured person may sue the manufacturer of a defective product."); see also Fleming v. Endo Int'l PLC, No. 18-CV-4866, 2019 WL 4378964, at *3 (S.D.N.Y. Aug. 27, 2019) (finding manufacturer had no duty to directly warn plaintiff of the potential side effects or risks of taking Percocet because that was the responsibility of his physicians).

Thus, here, as the drug's manufacturer, Janssen had no duty to warn plaintiff directly of the potential side effects or risks of taking Invega—that was the responsibility of plaintiff's physician. Accordingly, because plaintiff's lack of informed consent claim is not plausible against defendant as the drug manufacturer, plaintiff's claim for lack of informed consent is DISMISSED with prejudice.

D. Failure to Warn

Pursuant to New York law, "a plaintiff may assert that a product is defective because the manufacturer failed to provide adequate warnings regarding the risks and dangers associated with the use, or foreseeable misuse, of its product." Oden v. Bos. Sci. Corp., 330 F. Supp. 3d 877, 891

(E.D.N.Y. 2018) (citation omitted). To state a prima facie claim for failure to warn, "[a] plaintiff must demonstrate [1] that the warning was inadequate and [2] that the failure to adequately warn of the dangers of the drug was a proximate cause of his or her injuries." DiBartolo, 914 F. Supp. 2d at 611-12 (quoting Glucksman v. Halsey Drug Co., 160 A.D.2d 305, 307 (N.Y. App. Div. 1st Dep't 1990)).

In the context of a motion under Rule 12(b)(6), "a failure to warn cause of action is appropriately dismissed if a plaintiff does not plead facts indicting how the provided warnings were inadequate." Reed v. Pfizer, Inc., 839 F. Supp. 2d 571, 576 (E.D.N.Y. 2012) (finding failure to warn allegations that failed to identify how the provided warnings were inadequate were not "enough to raise a right to relief above the speculative level") (citing Twombly, 127 S. Ct. at 1965.); see Oden, 330 F. Supp. 3d at 885-91 ("Without facts setting forth what the warnings stated and how and/or why the warnings were inadequate, Plaintiff's failure to warn claim is insufficiently pleaded.")

Here, plaintiff's complaints provide only conclusory allegations that are insufficient to properly plead a failure to warn claim. Plaintiff fails to allege any facts to suggest that her treating physician was not informed of the risks associated with Invega.[3] See Trisvan v. Heyman, 305 F. Supp. 3d 381, 399 (E.D.N.Y. 2018) (dismissing failure to warn claim where plaintiff failed to allege any facts that his psychiatrists or any other treating physicians were not informed of the risks associated with Risperdal and Wellbutrin.) Instead, Plaintiff merely alleges that she suffered a number of side effects from taking Invega, including, for example, nerve damage, memory loss, hypertension, diabetes, vocal tics, and motor tremors. (Gioia I, Compl. at 4, 9-10.) Wholly lacking

[3] As discussed supra, pursuant to the "informed intermediary" doctrine, "the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient." Martin, 83 N.Y.2d at 9.

from plaintiff's complaints are any allegations as to the contents of Invega's warnings, and, specifically, whether or not plaintiff's physician was warned of the side effects plaintiff allegedly suffered. See Reed, 839 F. Supp 2d at 576 (finding allegations that plaintiff "suffered from certain conditions" and "assertions that warnings were not 'adequate' or 'sufficient' are nothing more than legal conclusions unsupported by factual content"); Parillo v. Stryker Corp., No. 15-CV-155, 2015 WL 12748006, at *7 (N.D.N.Y. Sept. 29, 2015) ("Plaintiff fails to state a plausible failure to warn claim because he does not allege any facts whatsoever as to what the warning was, or how it was inadequate.") For this reason alone, plaintiff's conclusory allegations are insufficient to state a plausible failure to warn claim.

Notably, in support of its motion to dismiss, defendant offered Invega's FDA-approved package insert as evidence of Invega's warnings of possible side effects including, among others, hyperglycemia, diabetes, hypertension, stroke and tardive dyskinesia. (See Gioia I and II, Russo Decl., ECF No. 22, Ex. E at 1-27.) Despite having the opportunity to do so, plaintiff has not contested the authenticity of these FDA warnings.[4] "[T]he fact that [plaintiff] suffered from certain conditions that were also identified risks of ingesting [Invega] is tragic, but cannot alone make plausible a claim that defendant misrepresented or hid those risks in some way." Reed, 839 F. Supp. 2d at 576-77 (emphasis in original) (dismissing failure to warn claim where the "FDA-approved warning labels warn of the very injuries plaintiffs have pled.")[5] Therefore, plaintiff's

[4] The Court takes judicial notice of the FDA-approved package insert. See Becker v. Cephalon, Inc., No. 14-CV-3864, 2015 WL 5472311, at *3 (S.D.N.Y. Sept. 15, 2015) (taking judicial notice of FDA-approved labels in assessing failure to warn claim "because the labels can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.") (internal quotation marks omitted); Trisvan, 305 F. Supp. 3d at 400 (noting that "[w]hile a court must generally accept a plaintiff's factual allegations as true in evaluating a motion to dismiss, it 'need not accept as true allegations in a complaint that contradict or are inconsistent with judicially-noticed facts.'") (quoting Becker, 2015 WL 5472311, at *5.

[5] In fact, pursuant to New York law, "prescription medicine warnings are adequate when [as occurred here] information regarding 'the precise malady incurred' was communicated in the prescribing information." Alston v. Caraco Pharm., Inc., 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009) (quoting Wolfgruber v. Upjohn Co., 72 A.D.2d 59,

conclusory allegations coupled with plaintiff's allegations of suffering from the very side effects of which defendant warns, require dismissal of plaintiff's claim. Accordingly, plaintiff's failure to warn claim is DISMISSED without prejudice.

E. Leave to Amend

A pro se plaintiff should ordinarily be given the opportunity "to amend at least once when a liberal reading of the complaint gives any indication that a valid claim might be stated." Shomo v. City of New York, 579 F.3d 176 (2d Cir. 2009) (quoting Gomez v. USAA Fed. Sav. Bank, 171 F.3d 794, 795 (2d Cir. 1999) (internal quotation marks omitted)). Yet while "pro se plaintiffs are generally given leave to amend a deficient complaint, a district court may deny leave to amend when amendment would be futile." Id. (citations omitted). Here, because the deficiencies in plaintiff's lack of informed consent claim are substantive and would not be cured with better pleading, leave to amend that claim is denied.

However, the Court grants plaintiff an opportunity to amend her failure to warn claim in accordance with this Order. In amending her failure to warn claim, plaintiff must provide non-conclusory allegations as to why defendant failed to provide adequate warnings to her physician. Plaintiff's amended complaint must be labeled as an "amended complaint," bear the same docket number as this Order, 19–CV–04629, 19-CV-05377 (JMA)(SIL), and shall be filed within thirty (30) days from the date of this Order. Plaintiff is advised that an amended complaint completely replaces the original complaints, so plaintiff must include any allegations she wishes to pursue against the defendant in the amended complaint. Further, if plaintiff does not file an amended complaint within the time allowed, her cases shall be closed.

60, 423 N.Y.S.2d 95 (4th Dep't 1979). See also Trisvan, 2018 WL 6573434, at *4-5 (dismissing failure to warn claim where manufacturer warned of the alleged side-effects suffered by plaintiff.)

III. CONCLUSION

For the reasons stated above, the Court grants Janssen's motion to dismiss. Plaintiff's lack of informed consent claim is dismissed with prejudice, and plaintiff's failure to warn claim is dismissed without prejudice. The Court grants plaintiff thirty (30) days to amend the complaint to allege a failure to warn claim, consistent with the instructions provided in this Memorandum and Order.

The Court certifies pursuant to 28 U.S.C. § 1915(a)(3) that, should she seek in forma pauperis status for the purpose of an appeal, any appeal from this order would not be taken in good faith and therefore in forma pauperis status is denied. See Coppedge v. United States, 369 U.S. 438, 444-45 (1962).

The Clerk of the Court is directed to send a copy of this Order to the pro se plaintiff.

SO ORDERED.

Dated: February 16, 2021
Central Islip, New York

/s/ (JMA)
JOAN M. AZRACK
UNITED STATES DISTRICT JUDGE