UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ISABEL L. BECKER, *as Administratrix of the Estate of Deceased*, NORWIN H. BECKER, and ISABEL L. BECKER, *individually*,

Plaintiff,

-against-

CEPHALON, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD.,

Defendants.

14 Civ. 3864 (NSR)

OPINION & ORDER

NELSON S. ROMÁN, United States District Judge:

Plaintiff Isabel L. Becker ("Plaintiff" or "Becker") initiated the instant action as administratrix of the Estate of Norwin H. Becker ("Decedent") and on her own behalf, asserting claims against Cephalon, Inc., and Teva Pharmaceutical Industries, Ltd. (collectively, "Defendants") for failure to warn prospective patients of drug side effects, as well as other related claims. Before the Court is Defendants' motion to dismiss the Complaint, pursuant to Federal Rule of Civil Procedure 12(b)(6), for failure to state a claim upon which relief can be granted. For the following reasons, Defendants' motion is GRANTED.

BACKGROUND

All facts are taken from the Amended Complaint and are accepted as true for the purposes of this motion.

I. Factual Background

This is a personal injury case arising from Decedent's use of the prescription drug TREANDA, the administration of which allegedly "afflicted [D]ecedent with a toxic skin

reaction resulting in horrendous and repeating exfoliative dermatitis such as or similar to Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis ("SJS/TEN")." (Am. Compl. ¶ 1.)

Norwin Becker, the decedent, was diagnosed with chronic lymphocytic leukemia in 2000. (Am. Compl. ¶ 7.) He was a patient of Dr. Matthew Lonberg during all relevant time periods. (*Id*. ¶ 7.) Dr. Lonberg administered allopurinol to Decedent on or about December 8, 2010, and administered TREANDA to Decedent on multiple dates in December 2010 and January 2011. (*Id*. ¶¶ 8-9.)

Plaintiff alleges that Cephalon "has known for many years that intravenous treatment with TREANDA carried grave risks, including that of a patient suffering the skin burning and continual peeling condition known as SJS/TEN and similar toxic skin reactions." (*Id*. ¶ 10.) She further alleges that Cephalon knew of additional grave risks associated specifically with the administration of TREANDA in conjunction with, or shortly after, the administration of allopurinol. (*Id*. ¶ 10.) The Food and Drug Administration ("FDA") has warned Cephalon on more than one occasion cited to by Plaintiff about misleading information contained in dosing cards and sponsored links on internet search engines specifically regarding the risk of SJS/TEN. (*Id*. ¶¶ 12-13.) Cephalon's website for TREANDA has been modified several times, alternately showing a warning that "[a] mild rash or itching may occur during treatment with TREANDA" on some dates and displaying a warning about the more serious risk of SJS/TEN on others. (*Id*. ¶¶ 14-15, 20-24.)

Plaintiff alleges that Dr. Lonberg manifested ignorance of severe skin reactions as risks of the administration of TREANDA and allopurinol, and that he "may have been misled by having read the violative promotional materials for Treanda such as the dosing card, which was the subject of the FDA's letter of December 18, 2009, and further misled by the sanitized

TREANDA.com homepage." (*Id*. ¶ 16.) Had Dr. Lonberg been properly instructed of the risks of severe skin reactions by Cephalon, "he would have advised decedent of the risks, and possibly declined to prescribe TREANDA; in any event decedent would have declined treatment of TREANDA." (*Id*. ¶ 17.) Plaintiff also alleges that Decedent himself relied on these misleading statements on the TREANDA webpage he visited in agreeing to treatment with TREANDA. (*Id*. ¶¶ 22-23.)

II. Procedural History

Plaintiff commenced this action against Defendants in the Supreme Court of the State of New York in the County of Rockland, on January 9, 2014. Pursuant to 28 U.S.C. § 1446, Defendants removed the action to this Court on May 30, 2014. (*See* Not. Removal, ECF No. 1.) Following a pre-motion conference, Defendants moved to dismiss the Complaint on February 27, 2015. (*See* Defs.' Mot. Dismiss, ECF No. 25.)

STANDARD ON A MOTION TO DISMISS

To survive a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted, a complaint must include "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. (citing *Twombly*, 550 U.S. at 556).

"When there are well-pleaded factual allegations [in the complaint], a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief." *Iqbal*, 556 U.S. at 679. The court must thus "take all well-plead factual allegations as true, and all reasonable inferences are drawn and viewed in a light most favorable to the

plaintiff[ ]." *Leeds v. Meltz*, 85 F.3d 51, 53 (2d Cir. 1996). However, the presumption of truth does not extend to "legal conclusions, and threadbare recitals of the elements of the cause of action." *Harris v. Mills*, 572 F.3d 66, 72 (2d Cir. 2009) (quoting *Iqbal*, 556 U.S. 662) (internal quotation marks omitted). A plaintiff must provide "more than labels and conclusions" to show he is entitled to relief. *Twombly*, 550 U.S. at 555.

The court should read *pro se* complaints "to raise the strongest arguments that they suggest." *Kevilly v. New York*, 410 F. App'x 371, 374 (2d Cir. 2010) (summary order) (quoting *Brownell v. Krom*, 446 F.3d 305, 310 (2d Cir. 2006)). To survive a motion to dismiss, however, even a *pro se* plaintiff must still assert "factual allegations sufficient to raise a 'right to relief above the speculative level.'" *Jackson v. NYS Dep't of Labor*, 709 F. Supp. 2d 218, 224 (S.D.N.Y. 2010) (quoting *Twombly*, 550 U.S. at 555).

DISCUSSION

I. Consideration of Exhibits Submitted by the Parties on the Instant Motion

As an initial matter, the Court must decide whether it can consider and/or take judicial notice of certain documents submitted by the parties. Defendants have submitted the following documents with their motion, all annexed to the Declaration of Devorah Allon, Defendants' counsel: the February 2010 TREANDA label in effect at the time TREANDA was administered to the Decedent (Defense Ex. A[1]); an April 22, 2009 FDA Approval letter to Cephalon (Defense Ex. B); the December 21, 2010 TREANDA label (Defense Ex.C); and a December 18, 2009 FDA letter to Cephalon (Defense Ex. D). Plaintiff has submitted the following with her opposition papers on the instant motion: reports prepared by Dr. Donald Waldorf (Plaintiff's Ex.

[1] Both parties labeled their exhibits using letters. To prevent confusion, all exhibits submitted by Defendants are referred to as "Defense Ex. [Letter]" and all exhibits submitted by Plaintiff are referred to as "Plaintiff's Ex. [Letter]." The Defense Exhibits are appended to the Declaration of Defendants' counsel, Devorah W. Allon (*see* ECF No. 27); the Plaintiff's Exhibits are attached to the Declaration of Jeffrey S. Becker (*see* ECF No. 31).

A); a report and pathologist's report by Dr. Peter Burk (Plaintiff's Ex. B); copies of the Cephalon websites for TREANDA for patients and healthcare professionals, as captured on various dates (Plaintiff's Exs. C - I); and a March 26, 2009 FDA warning letter to Cephalon (Plaintiff's Ex. J).

On a motion to dismiss, "the Court is entitled to consider facts alleged in the complaint and documents attached to it or incorporated in it by reference, documents 'integral' to the complaint and relied upon in it." *Heckman v. Town of Hempstead*, 568 F. App'x 41, 43 (2d Cir. 2014); *see Manley v. Utzinger*, No. 10 Civ. 2210 (LTS)(HBP), 2011 WL 2947008, at *1 n.1 (S.D.N.Y. July 21, 2011) ("The Court may consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, and documents possessed by or known to the plaintiff and upon which the plaintiff relied in bringing the suit."). The Court may also consider "facts of which judicial notice may properly be taken under Rule 201 of the Federal Rules of Evidence." *Heckman*, 568 F. App'x at 43.

Under Federal Rule of Evidence 201, "[t]he court may judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). "If a court takes judicial notice of documents pertinent to a motion to dismiss, it need not convert the motion to dismiss into a motion for summary judgment." *Chapman v. Abbott Labs.*, 930 F. Supp. 2d 1321, 1323 (M.D. Fla. 2013); *see Friedl v. City of New York*, 210 F.3d 79, 83 (2d Cir. 2000); *Fonte v. Bd. of Managers of Cont'l Towers Condo.*, 848 F.2d 24, 25 (2d Cir. 1988). "In the motion to dismiss context, a court should generally take judicial notice to determine what statements the documents contain, not for the truth of the matters asserted." Porrazzo v. Bumble Bee Foods, LLC, 822 F. Supp. 2d 406, 412 (S.D.N.Y. 2011) (internal quotation marks and

alterations omitted). Thus, the Court does not attempt to discern the truth of any statements contained in these exhibits, but rather simply takes judicial notice of the statements they contain.

Defense Exhibits A and C are FDA-approved labels for TREANDA, which are public documents that may be judicially noticed because the labels "can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Chapman, 930 F. Supp. 2d at 1323 (quoting Fed. R. Evid. 201(b)(2)); *see, e.g.*, *Wright v. Medtronic, Inc.*, 81 F. Supp. 3d 600, 606 (W.D. Mich. 2015); *Thorn v. Medtronic Sofamor Danek, USA, Inc.*, 81 F. Supp. 3d 619, 622-23 (W.D. Mich. 2015); *In re Bayer Corp. Combination Aspirin Products Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 367-68 (E.D.N.Y. 2010) (taking judicial notice of portions of FDA website); *In re Epogen & Aranesp Off–Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1286 (C.D. Cal. 2008) ("The Court grants DaVita's request as to Exhibits 1-4, labels for Epogen that are publicly available on the FDA website, finding that the labels are documents not subject to reasonable dispute.")

Defense Exhibits B and D (mistakenly referenced as Exhibit E in counsel's declaration, but labeled as Exhibit D) are letters to Caphalon from the FDA. Both of these letters are publicly available on the FDA website and judicially noticeable for the same reasons as the drug labels themselves are judicially noticeable. Defense Exhibit D is also specifically quoted in Plaintiff's Amended Complaint and therefore is a "document[] 'integral' to the complaint and relied upon in it." Heckman, 568 F. App'x at 43.

As to the documents submitted by Plaintiff, several of these are integral to the complaint and clearly replied upon in it, which means they can be considered on the instant motion to dismiss even though they were not attached to the Amended Complaint. For example, Plaintiff's Exhibit J is another letter to Cephalon from the FDA, quoted in the complaint. (*See* Am. Compl.

¶ 13.) Similarly, Plaintiff's Exhibits C, D, E, and F are copies of the TREANDA website, as depicted on various dates described in the Amended Complaint. The contents of the website on these dates are quoted throughout Plaintiff's allegations. (*See* Am. Compl. ¶¶ 20-23.) "[W]hen a document is referred to in the pleadings and is integral to the claims, it may be considered without converting a motion to dismiss into one for summary judgment." *Commercial Money Ctr., Inc. v. Ill. Union Ins. Co.*, 508 F.3d 327, 335–36 (6th Cir.2007).

Some of the exhibits submitted have not been considered on the instant motion. Plaintiff's Exhibits A and B are medical records cited to support the allegations in the Amended Complaint regarding Decedent's injury. The records (and/or the doctors who created them) are not discussed in the pleadings, and Plaintiff has not addressed whether these can be considered on the instant motion. While Plaintiff alleges that Decedent was afflicted "with a toxic skin reaction resulting in horrendous and repeating exfoliative dermatitis such as or similar to Stevens-Johnson Syndrome/Toxic Epidermal Necrolysis," there is no actual diagnosis for Decedent's health issues alleged in the Amended Complaint. (*See* Am. Compl. ¶ 1.) Plaintiff's Exhibits G, H, and I are copies of the TREANDA website, as accessed on various dates after those described in Plaintiff's Amended Complaint. These iterations of the website are not discussed in the Complaint and were versions of the website that were posted after the events in this case occurred, and therefore their contents could not have been considered by Decedent or his physician when contemplating treatment options. Because these documents do not appear, from the allegations in the pleadings, to be integral to the complaint and are not incorporated into the complaint by reference or attached to it, the Court will not consider the extrinsic evidence contained in these specific exhibits on the instant motion.

II. Strict Liability and Negligence Claims

Plaintiff's first two causes of action are for strict liability and negligence based on Cephalon's alleged "failure, in its marketing and promotion of TREANDA, to warn, and for its misrepresentation of risks of grievous side effects of TREANDA." (Am. Compl. ¶ 29; *see id.* ¶ 30 (replacing "failure" with "negligent failure," and "misrepresentation" with "negligent misrepresentation").) A strict products liability claim arises where "(1) the product is defective, and (2) the defect caused plaintiff's injury." *Lewis v. Abbott Labs.*, No. 08 Civ. 7480 (SCR) (GAY), 2009 WL 2231701, at *4 (S.D.N.Y. July 24, 2009) (citing *Colon ex rel. Molina v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 82 (S.D.N.Y. 2001)). A negligence claim arises where "(1) the manufacturer owed plaintiff a duty to exercise reasonable care; (2) the manufacturer breached that duty by failing to use reasonable care so that the product was rendered defective; (3) the defect was the proximate cause of the plaintiff's injury; and (4) plaintiff suffered loss or damage." *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 611 (S.D.N.Y. 2012) (internal quotations omitted). "Under New York law, '[f]ailure to warn claims are identical under strict liability and negligence theories of recovery.'" *Id.* (quoting Lewis, No. 08 Civ. 7480 (SCR) (GAY), 2009 WL 2231701, at *5).

To maintain a claim for an injury that is the side effect of a properly manufactured prescription drug, a plaintiff must show "that the drug caused her injury and that the manufacturer breached a duty to warn of the possibility that the injurious reaction might occur." *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 90-91 (2d Cir. 1980). "The manufacturer's duty is to warn of all potential dangers which it knew, or in the exercise of reasonable care should have known, to exist." *Id.* at 91. The manufacturer owes this duty to the doctor, not the patient, because "[t]he doctor acts as an informed intermediary between the manufacturer and the patient, evaluating the patient's needs, assessing the risks and benefits of available drugs, prescribing

one, and supervising its use." *Id*. (internal quotation marks omitted); *see also Martin v. Hacker*, 83 N.Y.2d 1, 9, 628 N.E.2d 1308, 1311, 607 N.Y.S.2d 598, 601 (N.Y.1993) ("Warnings for prescription drugs 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."). The informed intermediary doctrine ("IID") precludes products liability claims for prescription drugs based solely on a theory that the manufacturer failed to warn the patient, as opposed to the prescribing doctor. *See Figueroa v. Boston Scientific Corp.*, 254 F. Supp. 2d 361, 370 (S.D.N.Y. 2003) ("The manufacturer's duty of adequate warning is therefore fulfilled by providing sufficient information of the product's risk to the treating physician, rather than to the patient directly.").

A prescription medicine warning can be found adequate as a matter of law, *see Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 286-87 (S.D.N.Y. 2009) ("Courts have routinely held as a matter of law that a drug manufacturer will not be liable if there is evidence showing that the warning specifically warned of the side effects which occurred."), and in New York such a warning is adequate when it communicates a warning as to "the precise malady incurred," *Wolfgruber v. Upjohn Co.*, 72 A.D.2d 59, 60 (N.Y. App. Div. 1979); *Fane v. Zimmer*, 927 F.2d 124, 129 (2d Cir. 1991); *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577 (E.D.N.Y. 2012) (dismissing failure-to-warn claim with prejudice because label warned of relevant risks); *Lewis v. Abbott Labs.*, No. 08 Civ. 7480 (SCR) (GAY), 2009 WL 2231701, at *5 (S.D.N.Y. July 24, 2009). In this case, the FDA-approved label for TREANDA is unequivocal in warning about the risk of SJS/TEN and similar serious skin reactions, including a warning about the administration of TREANDA concomitantly with allopurinol. (*See* Defense Ex. A at 3, 4, 8, 13.)

While 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." *Chapman*, 930 F. Supp. 2d at 1323; *see In re Bayer Corp. Combination Aspirin Products Mktg. & Sales Practices Litig.*, 701 F. Supp. 2d 356, 367-68 (E.D.N.Y. 2010) ("Although the purpose of a motion to dismiss is to test the legal sufficiency of a plaintiff's claims, taking all the allegations as true and reading them in the light most favorable to the plaintiff, the court is not required to reason in a vacuum."). Plaintiff's allegations that Cephalon failed to warn of the risk of SJS/TEN when taking TREANDA, particularly in conjunction with allopurinol, are squarely contradicted by the TREANDA label. Section 5.5 of the TREANDA label in effect at the time TREANDA was administered to Decedent reads, in its entirety:

> **5.5 Skin Reactions**
>
> A number of skin reactions have been reported in clinical trials and post-marketing safety reports. These events have included rash, toxic skin reactions and bullous exanthema. Some events occurred when TREANDA was given in combination with other anticancer agents, so the precise relationship to TREANDA is uncertain.
>
> In a study of TREANDA (90 mg/m2) in combination with rituximab, one case of toxic epidermal necrolysis (TEN) occurred. TEN has been reported for rituximab (see rituximab package insert). Cases of Stevens-Johnson syndrome (SJS) and TEN, some fatal, have been reported when TREANDA was administered concomitantly with allopurinol and other medications known to cause these syndroms. The relationship to TREANDA cannot be determined.
>
> Where skin reactions occur, they may be progressive and increase in severity with further treatment. Therefore, patients with skin reactions should be monitored closely. If skin reactions are severe or progressive, TREANDA should be withheld or discontinued.

(Def. Ex. A at 3.) Section 6, "Adverse Reactions," also includes a note that skin reactions are one form of serious adverse reaction associated with TREANDA in clinical trials, and refers physicians to Section 5.5 for further detail. (Defense Ex. A at 4.) Section 6.3 specifically warns

of the risks of SJS and TEN when TREANDA is administered concomitantly with allopurinol and other medications. (Defense Ex. A at 8.) "Because all of the alleged side effects described by [Plaintiff] are specifically indicated as potential side effects in [the drug's] package insert, the warning is adequate as a matter of law." *Alston*, 670 F. Supp. 2d at 287. Thus, Plaintiff's strict liability and negligence products liability claims based on a failure to warn theory are foreclosed and must be dismissed.

Plaintiff attempts to circumvent the IID by alleging that her products liability claims are based not only on a failure-to-warn theory, but also on Cephalon's affirmatively misleading statements to both the Decedent and his doctor regarding the risk of a mild rash versus more serious skin conditions like SJS/TEN. (*See* Pl.'s Opp'n at 17-18.) The statements in question include Section 17 of the TREANDA label, which states:

> **17 PATIENT COUNSELING INFORMATION**
>
> * * *
>
> Rash
> Advise patients that a mild rash or itching may occur during treatment with TREANDA. Advise patients to immediately report severe or worsening rash or itching.

(Defense Ex. A at 13). Plaintiff avers that Section 17 "renders the warning ineffective." (Pl.'s Opp'n at 9). This is illogical and contradicted by the label, however, as not only do several sections of the TREANDA label explicitly warn of the risk of SJS/TEN and other severe skin reactions, but Section 17 itself tells doctors to advise their patients that they should report "severe or worsening rash or itching." (*See* Defense Ex. A at 3, 4, 8, 13.) Further, the statement regarding a risk of mild rash is not false. (*See* Defense Ex. A at 5, 7 (reporting "rash" as adverse reaction in clinical studies). Therefore, it must be that the statement is misleading, if at all, because it fails to emphasize the more serious risks—making Plaintiff's claim, in essence, simply a failure-to-warn claim, not a distinct type of claim or theory as Plaintiff asserts. As discussed

above, any products liability claim based on a failure-to-warn theory cannot survive in this case because the TREANDA label warns of the very malady allegedly suffered by Decedent. Further, Plaintiff's policy-based arguments are unsupported by citations to any cases actually finding that the IID should not apply where there are allegations of misleading statements to consumers, not just a failure to warn.

As unfortunate as the circumstances of Decedent's illness are, a products liability claim simply cannot lie against Cephalon based on the facts of this case because the TREANDA label clearly and adequately warns of the very side effects suffered by the Decedent.

III. Breach of Warranty Claim(s)

Plaintiff alleges that "Decedent relied . . . on the reputation and representations of Cephalon in its promotion of TREANDA, which misled decedent to conclude that the potential side effects of TREANDA were less severe than they truly were, and did not include the risk of severe exfoliative skin reactions," and that "Decedent had the right to expect that Cephalon would stand behind its product and bear the burden for any injuries that [D]ecedent sustained as a result of his use of TREANDA in reliance on Cephalon's representations." (Am. Compl. ¶ 31.) Plaintiff does not specify in the Amended Complaint whether she asserts a claim for breach of express warranty or breach of the implied warranty of merchantability, so both causes of action are addressed here.

A. Breach of Express Warranty

To state a claim for breach of express warranty, a plaintiff must allege that "there was an affirmation of fact or promise by the seller, the natural tendency of which was to induce to buyer to purchase and that the warranty was relied upon to the plaintiff's detriment." *DiBartolo v. Abbott Labs.*, 914 F. Supp. 2d 601, 625 (S.D.N.Y. 2012). "To plead a cause of action for breach of express warranty, Plaintiff must allege: (1) the exact terms of the warranty; (2) that the

warranty formed part of the basis of the bargain; (3) the warranty was breached and (4) the breach caused injury to the plaintiff." *In re Hydroxycut Mktg. & Sales Practices Litig.*, No. 09MD2087-BTM (AJB), 2010 WL 2839480, at *2-3 (S.D. Cal. July 20, 2010) (applying New York law) (citing *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 286 (E.D.N.Y. 2009); *Fagan v. AmerisourceBergen Corp.*, 356 F. Supp. 2d 198, 217 (E.D.N.Y. 2004)).

A breach of express warranty claim "require[s] a plaintiff to plead some affirmative statement of fact that forms the basis of the warranty. The statement must be definite enough so that its 'natural tendency [is] . . . to induce the buyer to purchase.'" *Elkind v. Revlon Consumer Products Corp.*, No. 14-CV-2484 (JS)(AKT), 2015 WL 2344134, at *13 (E.D.N.Y. May 14, 2015) (quoting *Weiner v. Snapple Beverage Corp.*, No. 07 Civ. 8742 (DLC), 2011 WL 196930, at *5 (S.D.N.Y. Jan. 21, 2011)). Plaintiff alleges that the affirmative statement of fact that forms the basis of the warranty is the "mild rash or itching" warning contained in Section 17 of the TREANDA label and also found on Cephalon's website for TREANDA and other marketing materials. (Pl.'s Opp'n at 17.) As discussed in Section I, *supra*, this statement is not false. (*See* Defense Ex. A at 5, 7). Therefore, if the statement is misleading at all, it is only because it fails to emphasize more serious side effects, not because it makes an affirmative statement that is itself problematic. Thus, Plaintiff's claim, even if couched in the language of a breach of express warranty, is fundamentally a failure-to-warn claim, and is defeated by the adequacy of Cephalon's TREANDA label. *See McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 410 (S.D.N.Y. 2014) ("Relating a warning theory in terms of 'warranty' or 'fraud' does not avoid the implications of an adequate warning.").

B. Breach of Implied Warranty

To state a claim for breach of the implied warranty of merchantability, a plaintiff must allege that "a defect in the product was a substantial factor in causing the injury and . . . the

defect complained of existed at the time the product left the manufacturer or entity in the line of distribution being sued." *DiBartolo*, 914 F. Supp. 2d at 627. The alleged defect may arise from "a manufacturing flaw, improper design, or a failure to provide adequate warnings regarding use of the product." *Adesina v. Aladan Corp.*, 438 F. Supp. 2d 329, 345 (S.D.N.Y. 2006).

Similarly to the claim for breach of express warranty, Plaintiff's claim for breach of implied warranty fails. Plaintiff has not alleged a manufacturing flaw or improper design, and thus only a failure to provide adequate warnings regarding use of the product remains as a potential ground for a breach of implied warranty claim. But as noted in earlier sections, the IID bars such a claim where, as here, the prescription drug's label is adequate as a matter of law because it clearly and adequately warns the prescribing physician of the very malady suffered by Decedent. *See McDowell*, 58 F. Supp. 3d at 410.

IV. False Advertising Claim

New York General Business Law § 350 states: "[f]alse advertising in the conduct of any business, trade or commerce or in the furnishing of any service in this state is hereby declared unlawful." N.Y. Gen. Bus. Law § 350. To state a claim for a § 350 violation, a plaintiff must allege "(1) that the act, practice or advertisement was consumer-oriented; (2) that the act, practice or advertisement was misleading in a material respect, and (3) that the plaintiff was injured as a result of the deceptive practice, act or advertisement." *Pelman v. McDonald's Corp.*, 237 F. Supp. 2d 512, 525 (S.D.N.Y. 2003). To determine whether the advertisement is false within the statute's meaning, "the test is whether the advertisement is likely to mislead a reasonable consumer acting reasonably under the circumstances." *Andre Strishak & Assocs., P.C. v. Hewlett Packard Co.*, 300 A.D.2d 608, 609 (N.Y. App. Div. 2002). In addition, a plaintiff must also "plead reliance on the misleading advertising at the time of purchase." *Elkind*, No. 14-CV-2484 (JS)(AKT), 2015 WL 2344134, at *11; *see Horowitz*, 613 F. Supp. 2d 271, 288

(E.D.N.Y. 2009) ("In order to make a claim under NYGBL Section 350, a plaintiff must plead reliance on a false advertisement at the time the product was purchased.").

Plaintiff alleges that Cephalon falsely advertised that the side effects of TREANDA would be limited to those of which it was aware and which it disclosed in its marketing and presentation to physicians and patients. Plaintiff also alleges reliance on the reputation and representations of Cephalon, and that its representations regarding the side effects of TREANDA misled Decedent. Plaintiff's claim, however, still bumps up against the IID. While Plaintiff asserts that her claim is based on affirmatively misleading statements, it is clear from the underlying allegations and the contents of the label that her claim is merely based on a failure-to-warn theory. Though the New York state courts do not appear to have confronted the issue directly, other courts, in applying New York law or similar laws of other states, have found that the IID bars claims arising under consumer protection laws that are based on a failure-to-warn theory where the label has been found adequate. *See, e.g., Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 552 (E.D. Pa. 2006) *aff'd*, 521 F.3d 253 (3d Cir. 2008) *cert. granted, judgment vacated on other grounds*, 556 U.S. 1101 (2009) (applying New York law and holding IID precludes consumer protection claim "because the consumer protection statute forbids deceptive acts or practices likely to mislead a reasonable *consumer*, specifically requiring proof that the defendant's acts are directed at consumers, . . . while the [I]ID dictates that all pharmaceutical information is directed at *physicians, not consumer-patients*. . . . Further, . . . prescription drugs are not available in the same manner as usual consumer products." (emphasis in original)); *Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364, 384 (D.N.J. 2004) (applying PA law, concluding that IID bars consumer protection claim).

V. Misrepresentation Claim

Plaintiff also sets forth a claim for misrepresentation, alleging that "Cephalon, by its communications directed to physicians such as Dr. Lonberg, falsely represented that the side effects of TREANDA would be limited to those of which Cephalon was aware and which it disclosed in its marketing and presentation to physicians and patients," and that Cephalon's representations "may have misled Dr. Lonberg to conclude that the potential side effects of TREANDA were less severe than they truly were, and did not include the risk of severe exfoliative skin reactions." (Am. Compl. ¶ 33.) Therefore, Plaintiff alleges, "Cephalon must bear the burden for any injuries that [D]ecedent sustained as a result of Dr. Lonberg's prescription of, and failure to warn [D]ecedent of the risks of, TRENDA, in reliance on Cephalon's false representation." (*Id*. ¶ 33.)

Defendant's proffered basis for dismissal of the negligent misrepresentation claim is that Decedent was not in privity, or any relationship approaching privity, with Defendant, and that the Amended Complaint does not allege that Decedent was a "known party" to Defendant or that Defendant undertook conduct linking it to him. *See DiBartolo*, 914 F. Supp. 2d at 624 (explaining that absent privity, a negligent misrepresentation claimant must allege "(1) an awareness by the maker of the statement that it is to be used for a particular purpose; (2) reliance by a known party on the statement in furtherance of that purpose; and (3) some conduct by the maker of the statement linking it to the relying party and evincing its understanding of that reliance"); *see also Sullivan v. Aventis, Inc.*, No. 14-cv-2939-NSR, 2015 WL 4879112, at *9 (S.D.N.Y. Aug. 13, 2015) (same).

Similarly to the plaintiff in *DiBartolo*, Plaintiff cannot satisfy the elements of a claim for negligent misrepresentation because she and/or the Decedent were not in privity of contract with Cephalon, and there are no allegations that Plaintiff or Decedent was a "known party" to

Cephalon or that Cephalon undertook special conduct linking it to them. The Amended Complaint sets forth no allegations regarding any communication between Cephalon and Plaintiff or Decedent. Plaintiff's only proffered basis for the existence of privity is that Decedent's insurance company purchased TREANDA from Cephalon on his behalf, acting as his agent. (Pl.'s Opp'n at 24; Decl. of Jeffrey S. Baker ¶ 4.) But this is not alleged in the Amended Complaint and Plaintiff cites to no authority for the proposition that this form of transaction or relationship establishes privity of contract. Instead, generally "privity does not exist between manufacturers and patients when the medication is only available by prescription." *Dimieri v. Medicis Pharm. Corp.*, No. 2:14-CV-176-FTM-38, 2014 WL 3417364, at *6 (M.D. Fla. July 14, 2014); *see also DiBartolo*, 914 F. Supp. 2d at 624 (dismissing negligent misrepresentation claim because plaintiff was not in privity of contract with prescription drug manufacturer).

CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss is granted. The Court respectfully directs the Clerk to terminate the motion at ECF No. 25 and to terminate the case in accordance with this Opinion.

Dated: September 15, 2015
White Plains, New York

SO ORDERED:

NELSON S. ROMÁN
United States District Judge