UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

RENNAY MORRISON,	:	
	:	
Plaintiff,	:	
	:	
-against-	:	**OPINION AND ORDER**
	:	14-CV-4476 (DLI)(RML)
HOFFMANN-LA ROCHE, INC., HOFFMANN-LA ROCHE, LTD.,	:	
	:	
Defendants.	:	

DORA L. IRIZARRY, Chief Judge:

Plaintiff Rennay Morrison ("Plaintiff") filed the instant action on May 21, 2014, in New York State Supreme Court, Queens County, alleging that defendants Glaxosmithkline and its corporate affiliates (collectively, "GSK defendants")[1], Hoffmann La-Roche, Inc., and Hoffman La-Roche, Ltd. (collectively, "HLR defendants") defectively designed and manufactured a weight loss drug ingested by Plaintiff that caused her to suffer unspecified medical infirmities. On July 25, 2014, the GSK defendants removed the matter to this Court on the grounds of diversity jurisdiction pursuant to 28 U.S.C. § 1441(b).[2]

Pursuant to a stipulation of dismissal filed on October 29, 2015, Plaintiff settled this action with the GSK defendants and only the HLR defendants remain. (*See generally* Stipulation of Dismissal, Dkt. Entry No. 25.) Accordingly, on October 30, 2015, the Court dismissed the GSK defendants from this action.

[1] The Glaxosmithkline defendants included Glaxosmithkline LLC, Glaxosmithkline PLC, Glaxosmithkline LLC d/b/a Glaxosmithkline Consumer Healthcare, Glaxosmithkline Consumer Healthcare, L.L.C., Glaxosmithkline Consumer Healthcare, L.P., and Smithkline Beecham Corporation. (Complaint ("Compl.") at ¶¶ 2, 7, 9, 14, 19, 24.)

[2] Plaintiff is a resident of New York. (Compl. at ¶ 1.) The HLR defendants are Swiss corporations maintaining their principal place of U.S. business in New Jersey. (Compl. at ¶¶ 29, 31, 34.)

The HLR defendants move to dismiss the complaint for failure to state a claim upon which relief can be granted pursuant to Federal Rules of Civil Procedure 8(a) and 12(b)(6). The HLR defendants contend that Plaintiff: (1) engaged in impermissible group pleading, and (2) failed to surmount the plausibility pleading standard promulgated by the Supreme Court in *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). (*See generally* Defendant's Motion to Dismiss ("Def. Mot."), Dkt. Entry No. 13.) Plaintiff opposes this motion or, in the alternative, requests leave to file an amended complaint pursuant to Federal Rule of Civil Procedure 15(a). (Plaintiff's Memorandum of Law in Opposition to Defendant Hoffmann La-Roche Inc.'s Motion to Dismiss Plaintiff's Complaint Pursuant to Fed. R. Civ. P. 8(a) and 12(b)(6) ("Pl. Opp.") at 1, Dkt. Entry No. 23.) For the reasons set forth below, the HLR defendants' motion to dismiss is granted and Plaintiff's motion for leave to file an amended complaint is denied.

BACKGROUND

The HLR defendants manufacture and sell an anti-obesity prescription medication called Xenical®. (Def. Mot. at 2, 9.) The GSK defendants market and sell an over-the-counter weight-loss drug known by the brand name alli®. (Complaint ("Compl.") at ¶ 37, Dkt. Entry No. 1; Def. Mot. at 2.) Orlistat (also known as tetrahydrolipstatin) is the official name for the weight loss drug sold separately as Xenical® and alli®. (*Id*. at ¶ 37; Pl. Opp. at 8.) The complaint asserts six causes of action against both the GSK defendants and the HLR defendants for: (1) the defective design and manufacturing of alli®; (2) negligence and gross negligence in concealing information about the harmful side effects of alli®; (3) strict liability for placing alli® into the stream of commerce with reckless disregard for public safety; (4) misrepresentation and failure to warn the public about the health hazards and risks associated with alli®; (5) breach of express

and implied warranties regarding alli®'s safety; and (6) violation of New York General Business Law § 349 for engaging in deceptive marketing practices designed to mislead a reasonable consumer. (Compl. at ¶¶ 49-115.) The causes of action did not contain references to Xenical® at all. (*See generally Id*.)

Plaintiff specifically alleges that between March 2011 and June 2011, she purchased and ingested alli®, which caused her to suffer severe and permanent injuries. (*Id*. at ¶¶ 47, 48, 57, 58.) As a result of sustaining these injuries, Plaintiff seeks an unspecified judgment against both the GSK and HLR defendants. (*See generally Id*.)

The HLR defendants contend that, because Plaintiff did not assert any claims relating to her use of Xenical® and that the manufacturing, marketing and selling of alli® is the exclusive province of the GSK defendants, the six causes of action should be dismissed as to the HLR defendants. (Def. Mot. at 2, 3.) The HLR defendants further argue, *inter alia*, that Plaintiff's group pleading fails to distinguish the co-defendants' conduct in contravention of Federal Rule of Civil Procedure 8(a)'s minimum pleading standard. (*Id*. at 3.)

Plaintiff counters that, notwithstanding the HLR defendants' lack of involvement with the design, manufacture or sale of alli® specifically, the HLR defendants' licensing of Xenical® to the GSK defendants in April 2005 implicated them in alli's® design, manufacture and sale. (Pl. Opp. at 8; Pl. Opp. Exhibit 3, Media Release, Dkt. Entry No. 23-2.) Plaintiff further contends that, according to Second Circuit precedent, the district court must "accept as true the factual allegations of the complaint, and construe all reasonable inferences that can be drawn from the complaint in the light most favorable to the plaintiff" when considering a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6). *Roth v. Jennings*, 489 F.3d 499, 510 (2d Cir.

2007); *see also Pension Committee of University of Montreal Pension Plan v. Banc of America Securities LLC*, 568 F.3d 374, 381 (2d Cir. 2009).

However, Plaintiff does not rely simply on the complaint. Plaintiff's opposition memorandum includes more specific information concerning her injuries that were not provided in the complaint. (Pl. Opp. at 1.) Plaintiff claims that, because of her ingestion of alli®, she suffered jaundiced skin and eyes, abdominal pain, nausea, constipation, darkened urine, fatigue and vomiting. (*Id*.) Plaintiff further claims that she was diagnosed with autoimmune hepatitis and underwent two liver biopsies as result of the alli® ingestion. (*Id*. at 1, 2, 3.) The medical records annexed to Plaintiff's opposition memorandum reflect physicians' notes and commentary indicating that the etiology of Plaintiff's hepatitis is unclear and that over-the-counter drugs should be considered a possible inducement for the diagnosis. (Declaration of Brian J. Elbaum[3] ("Elbaum Decl."), Exhibit 1 at 2, Dkt. Entry No. 23-1.)

The HLR defendants contend that "it would be improper for the Court to consider this extraneous material when ruling" on a Rule 12(b)(6) motion to dismiss since this medical information was not attached to the complaint. (Reply in Support of Motion to Dismiss ("HLR Def. Reply") at 2-3, Dkt. Entry No. 16.)

DISCUSSION

I. Motion to Dismiss Standard

Under Rule 8(a) of the Federal Rules of Civil Procedure, pleadings must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Pleadings are to give the defendant "fair notice of what the claim is and the grounds upon which it rests." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 346 (2005) (quoting *Conley v. Gibson*, 355 U.S. 41, 47

[3] Brian J. Elbaum is the attorney for Plaintiff in this matter.

(1957), overruled in part on other grounds by *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007)). "[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 555).

Under Rule 12(b)(6) of the Federal Rules of Civil Procedure, a defendant may move, in lieu of an answer, for dismissal of a complaint for "failure to state a claim upon which relief can be granted." To resolve such a motion, courts "must accept as true all [factual] allegations contained in a complaint," but need not accept "legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). For this reason, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice" to insulate a claim against dismissal. *Id*. "[A] complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Id.* (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Notably, courts only may consider the complaint itself, documents that are attached to or referenced in the complaint, documents that the plaintiff relied on in bringing suit and that are either in the plaintiff's possession or that the plaintiff knew of when bringing suit, and matters of which judicial notice may be taken. *See, e.g.*, *Roth v. Jennings*, 489 F. 3d 499, 509 (2d Cir. 2007). The determination of whether a complaint states a plausible claim for relief signifies a content-specific task requiring the reviewing court to draw on its judicial experience and common sense. *Iqbal*, 556 U.S. at 679.

II. The Complaint Fails to Comply with the Contours of a Rule 12(b)(6) Motion to Dismiss

As noted above, courts restrict the universe of materials that it considers in deciding a Rule 12(b)(6) motion to the complaint, annexed documents, documents incorporated by reference, and matters of which judicial notice may be taken. *See*, *Roth*, 489 F.3d at 509. This restriction applies to new claims and factual assertions set forth for the first time in a plaintiff's opposition papers. *See, e.g., Fonte v. Board of Managers of Continental Towers Condominium*, 848 F.2d 24, 25 (2d Cir. 1988) ("Factual allegations contained in legal briefs or memoranda are also treated as matters outside the pleading for purposes of Rule 12(b).") "Rule 12(b) gives district courts two options when matters outside the pleadings are presented in response to a Rule 12(b)(6) motion: the court may exclude the additional material and decide the motion on the complaint alone or it may convert the motion to one for summary judgment under Fed. R. Civ. P. 56 and afford all parties the opportunity to present supporting material." *Id*. In the instant matter, Plaintiff alleges that the HLR defendants were engaged in the design, manufacture, production, advertising, and sale, *inter alia*, of alli®. (Compl. at ¶¶ 44-45.) However, the HLR defendants contend in their moving papers that they only manufacture and sell Xenical®, which is not at all mentioned in the complaint. (Def. Mot. at 2, 3.) Plaintiff responds in her opposition papers that the HLR defendants' licensing of Xenical® to the GSK defendants implicated them in the design, manufacture, and sale of alli®. (Pl. Opp. at 8; Pl. Opp. Exhibit 3, Media Release.)

Given that the complaint is bereft of any reference to Xenical®, the Court is not obligated to consider Plaintiff's attenuated licensing assertion that appears for the first time in her opposition papers. *See Paul v. Bailey*, 2013 WL 2896990, at *5 (S.D.N.Y. June 13, 2013) ("[A]s a general rule, … courts should not consider factual allegations made for the first time in opposition papers.") However, in connection with a motion to dismiss under Rule 12(b)(6), a

court may also consider documents deemed "integral" to the pleading. *See, e.g., Sira v. Morton*, 380 F.3d 57, 67 (2d Cir. 2004). For a document to be "integral" to the complaint, a plaintiff must "rel[y] on the terms and effect of the document; mere notice and possession is not enough." *Global Network Communications v. City of New York*, 458 F.3d 150, 156 (2d Cir. 2006) (quoting *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002)); *see also International Audiotext Network, Inc. v. American Telephone & Telegraph Company*, 62 F.3d 69, 72 (2d Cir. 1995) (in considering a Rule 12(b)(6) motion to dismiss, the court considered an agreement between the parties to be integral to the complaint notwithstanding its lack of incorporation by reference in the pleadings).

The "integral" exception is most often applied to documents upon which "the plaintiff's complaint stands or falls, but which for some reason – usually because the document, read in its entirety would undermine the legitimacy of the plaintiff's claim – was not attached to the complaint." *Global Network Communications*, 458 F.3d at 157 (citing *Broder v. Cablevision Systems Corporation*, 418 F.3d 187, 196-97 (2d Cir. 2005)). "The exception thus prevents plaintiffs from generating complaints invulnerable to Rule 12(b)(6) simply by clever drafting." *Global Network Communications*, 458 F.3d at 157. Nevertheless, "even if a document is integral to the complaint, it must be clear on the record that no dispute exists regarding the authenticity or accuracy of the document." *Faulkner v. Beer*, 463 F.3d 130, 134 (2d Cir. 2006).

Here, neither Plaintiff nor the HLR defendants appear to dispute the authenticity or accuracy of the exhibits attached to Plaintiff's opposition papers. Plaintiff attached a media release to her opposition papers detailing the HLR defendants' and the GSK defendants' agreement to co-promote Xenical®. (Pl. Opp. Exhibit 3, Media Release.) Plaintiff also attached her medical records chronicling the treatment she received from North Shore University Hospital

("NSUH") in alleged connection with her ingestion of alli®. (Pl. Opp. Exhibit 1, Medical Records, Dkt. Entry No. 23-2.)

The integrality of the aforementioned documents cannot be disputed because they relate directly to the gravamen of the complaint with respect to the HLR defendants' involvement with the production, marketing, and sale of alli® and its physiological effects on Plaintiff. Therefore, the media release and the medical records may be considered on this motion to dismiss. *See Chambers*, 282 F.3d at 153 ("a plaintiff's reliance on the terms and effect of a document in drafting the complaint is a necessary prerequisite to the court's consideration of the document on a dismissal motion"); *Hova v. Royal Caribbean Cruises Ltd*, 2013 WL 1820914, at *2 (E.D.N.Y. Apr. 30, 2013) (holding that a district court "'is not obliged to convert a 12(b)(6) motion to one for summary judgment in every case in which a defendant seeks to rely on matters outside the complaint in support of a 12(b)(6) motion.'"). Although the complaint ultimately fails to satisfy the Rule 12(b)(6) standard of review notwithstanding consideration of these attachments, the Court addresses each allegation in turn.

III. The Complaint Fails to Meet *Twombly/Iqbal* Plausibility Standard

A. Plaintiff's Use of Group Pleading Was Impermissible

The group pleading doctrine provides that a complaint alleging fraud against multiple defendants "should inform each defendant of the nature of his alleged participation in the fraud." *Yung v. Lee*, 160 F. App'x 37, 42 (2d Cir. 2005) (internal quotation marks omitted). "Although Fed. R. Civ. P. 8 does not demand that a complaint be a model of clarity or exhaustively present the facts alleged, it requires, at a minimum, that a complaint give each defendant 'fair notice of what the plaintiff's claim is and the ground upon which it rests.'" *Atuahene v. City of Hartford*, 10 F. App'x 33 (2d Cir. 2001) (quoting *Ferro v. Ry. Express Agency, Inc.*, 296 F.2d 847, 851 (2d

Cir. 1961)). *Atuahene* rejected the plaintiff's complaint because it failed to satisfy this minimum standard by amalgamating all the defendants together in each claim without providing any factual distinctions. *Id*.

Here, in each of the six causes of action, Plaintiff alleges that the GSK and HLR defendants collectively designed, manufactured, labeled, marketed, promoted, advertised and sold a defective pharmaceutical product, causing Plaintiff to suffer severe and permanent injuries. (*See generally* Compl.) Missing from each cause of action are specific statements from Plaintiff as to which defendant is responsible for particular conduct. The grounds upon which Plaintiff's claims rest do not appear in the Complaint and, therefore, neither the GSK nor HLR defendants have been provided with fair notice of what offenses are attributable to them. Accordingly, the motion to dismiss is granted on this ground. Moreover, because the complaint fails to satisfy the elements necessary to state a claim for the various causes of action brought by Plaintiff, as detailed below, Plaintiff's request for leave to amend the complaint is denied. Notably, none of the causes of action in the Complaint has any mention of Xenical®. The Complaint refers only to alli®, as discussed in Section II.A. *supra*, Plaintiff improperly lumped both defendants and products together and alleges no facts as to Xenical®.

B. Plaintiff's Defective Design and Manufacturing Claim Fails

1) Defective Design Claim

Plaintiff's first asserted cause of action is for defective design and manufacturing of alli®. (Compl. at ¶¶ 49-64.) To state a cause of action for a design defect in a pharmaceutical product such as alli®, a plaintiff must allege that the drug was unreasonably dangerous for its intended use. *McCarthy v. Olin Corp.*, 119 F.3d 148, 155 (2d Cir. 1997). "'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.'" *Id.* (quoting *Robinson v. Reed-Prentice Division of Package Mach. Co.*, 49 N.Y.2d 471, 479 (1980)). Moreover, "[a]s a matter of law, a product's defect is related to its condition, not its intrinsic function." *Id.* (internal quotation marks omitted). Plaintiff bears the burden of presenting evidence that the product at issue, as designed, presents a substantial likelihood of harm and feasibly could have been designed more safely. *Fane v. Zimmer, Inc.*, 927 F.2d 124, 128 (2d Cir. 1991). Mere inadequate warnings alone are insufficient to render a product unsafe. *Id.*

More specifically, in order to establish a prima facie case in products liability for defective design, 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 the plaintiff's injury. *Caronia v. Philip Morris USA, Inc.*, 715 F.3d 417, 428 (2d Cir. 2013). Under New York's strict product liability law, the manufacturer of a defective product is liable to an injured or damaged person if:

> (1) the product is defective because it is not reasonably safe as marketed; (2) the product was used for a normal purpose; (3) the defect was a substantial factor in causing the plaintiff's injuries; (4) the plaintiff [sic] by the exercise of reasonable care [sic] would not have both discovered the defect and apprehended its danger; (5) the plaintiff would not have otherwise avoided the injury by the exercise of ordinary care.

Urena v. Biro Mfg. Co., 114 F.3d 359, 363 (2d Cir. 1997).

Here, Plaintiff fails to state the manner in which alli® was defectively designed and manufactured. Merely alleging that alli® is defective in its design and manufacture because "it is not reasonably fit, suitable or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and manufacturing" lacks the specificity required to meet the *Twombly*/*Iqbal* plausibility standards. (Compl. at ¶ 50.) Such insufficient pleadings are inherently subject to dismissal. *Reed v. Pfizer, Inc.*, 839 F. Supp.2d 571, 578 (E.D.N.Y. 2012).

Plaintiff's design defect claim also fails because Plaintiff does not plead facts alleging the existence of an alternative design that would make alli® safer, as is required to establish a design defect under New York law. *Id*. As a result of these failures, the design defect claim is dismissed as to the HLR defendants pursuant to Rule 12(b)(6).

2) Defective Manufacturing Claim

A manufacturing defect claim under New York law is premised upon the relevant product being defective because it was not manufactured as intentionally designed. *Reed*, 839 F. Supp.2d at 577. Such a claim is "properly dismissed if a plaintiff has not alleged that the particular [drug] administered to her had a defect as compared to other samples of that drug." *Id*. (internal quotation marks omitted).

Here, Plaintiff fails to plead any facts making such an allegation. Rather, Plaintiff merely pleads the legal conclusions that alli® is "defective in its design and manufacturing in that it is not reasonably fit, suitable or safe for sale for its intended purpose" and "it lacks efficacy and/or poses a great likelihood of injury that other similar medicines and similar drugs on the market and is more dangerous than ordinary customers . . . can reasonably foresee." (Compl. at ¶ 50.) By not pleading facts indicating how or why the alli® ingested by Plaintiff differed from its design, Plaintiff has not enabled the Court "to draw the reasonable inference that the defendant[s are] liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Furthermore, the Complaint fails to provide comparisons between the alli® that Plaintiff ingested and other samples of the drug. Therefore, the manufacturing defect claim is dismissed as to the HLR defendants pursuant to Rule 12(b)(6).

C. Plaintiff's Negligence and Gross Negligence Claim Fails

Plaintiff's second asserted cause of action is for negligence and gross negligence in that the GSK and HLR defendants concealed information about the harmful side effects associated with ingestion of alli® and failed to warn the medical profession and the consuming public of these dangers. (Compl. at ¶¶ 65-84.) Under New York law, a claim for gross negligence will survive a motion to dismiss only if the plaintiff alleges facts plausibly suggesting that the defendant's conduct evinces a reckless disregard for the rights of others or implies intentional wrongdoing. *Bayerische Landesbank, New York Branch v. Aladdin Capital Management LLC*, 692 F.3d 42, 61 (2d Cir. 2012). "Recklessness in the context of a gross negligence claim means 'an extreme departure from the standards of ordinary care,' such that 'the danger was either known to the defendant or so obvious that the defendant must have been aware of it.'" *Id*. at 61-62 (quoting *AMW Materials Testing, Inc. v. Town of Babylon*, 584 F.3d 436, 454 (2d Cir. 2009)).

To state a cause of action for negligence, Plaintiff must demonstrate: (1) that the GSK and HLR defendants owed her a duty or obligation, recognized by law; (2) a breach of duty; (3) a reasonably close causal connection between the GSK and HLR defendants' conduct and the resulting injury; and (4) loss or damage resulting from the breach. *McCarthy*, 119 F.3d at 156. "In the absence of duty, as a matter of law, no liability can ensue." *Id*. (internal quotation marks omitted). However, "[a] claim of gross negligence requires a plaintiff to prove that the defendant failed to exercise even slight care, scant care, or slight diligence, or that the defendant's actions evinced a reckless disregard for the rights of others." *Baidu, Inc. v. Register.com, Inc.*, 760 F. Supp.2d 312, 318 (S.D.N.Y. 2010) (internal quotation marks and citations omitted).

"'New York courts generally consider strict products liability and negligence claims to be functionally synonymous.'" *S.F. Archer Daniels Midland Co.*, 594 F. App'x 11, 12 (2d Cir.

2014) (summary order) (quoting *Goldin v. Smith & Nephew, Inc.*, 2013 WL 1759575, at *6 (S.D.N.Y. Apr. 24, 2013)). Under both types of claims, the consumer assumes the burden in demonstrating that a defect in the product was a substantial factor in causing the injury. *Kosmynka v. Polaris Industries, Inc.*, 462 F.3d 74, 86 (2d Cir. 2006). However, "to show negligence, the plaintiff must also prove that the injury caused by the defect could have been reasonably foreseen by the manufacturer." *Id*.

The crux of Plaintiff's negligence theory is that the GSK and HLR defendants negligently marketed alli® for sale to the general public without making proper safety disclosures. Plaintiff contends that because of the various medical infirmities associated with the ingestion of alli®, the GSK and HLR defendants should have known that a large swath of their consumer base would be subject to a significant and increased risk of side effects, including hepatitis and liver damage. (Compl. at ¶ 76.) Plaintiff further argues that the defendants' reckless disregard for public safety manifested itself in their minimization of and otherwise failure to warn of the harmful and deadly side effects of alli®. (*Id*. at ¶ 78.) However, aside from these conclusory allegations, Plaintiff does not plead facts demonstrating that the GSK and HLR defendants owed Plaintiff a cognizable duty of care. Plaintiff's failure to indicate the origins of the purported duty in the complaint renders the negligence and gross negligence cause of action insufficient. Accordingly, the negligence and gross negligence claims are dismissed as to the HLR defendants pursuant to Rule 12(b)(6).

D. Plaintiff's Strict Liability Claim Fails

Plaintiff's third asserted cause of action is for strict liability for placing alli® into the stream of commerce with reckless disregard for public safety in that the drug was not adequately tested. (Compl. at ¶¶ 85-89.) Under New York law, "a plaintiff in a products liability action is

not required to prove a specific defect when a defect may be inferred from proof that the product did not perform as intended by the manufacturer." *Jarvis v. Ford Motor Co.*, 283 F.3d 33, 44 (2d Cir. 2002). However, strict liability may apply to a manufacturer who places a defective product into the stream of commerce that causes injury. *McCarthy*, 119 F.3d at 154.

> In New York, there are three distinct claims for strict products liability: (1) a manufacturing defect, which results when a mistake in manufacturing renders a product that is ordinarily safe dangerous so that it causes harm; (2) a warning defect, which occurs when the inadequacy or failure to warn of a reasonably foreseeable risk accompanying a product causes harm; and (3) a design defect, which results when the product as designed is unreasonably dangerous for its intended use.
> *Id*. at 154-55.

Strict products liability claims under New York law ultimately require proof that: "(1) the product is defective because it is not reasonably safe as marketed; (2) the product was used for a normal purpose; (3) the defect was a substantial factor in causing the plaintiff's injuries; (4) the plaintiff, by exercise of reasonable care, would not have both discovered the defect and apprehended its danger; and (5) the plaintiff would not have otherwise avoided the injury by the exercise of ordinary care." *Humphrey v. Diamant Boart, Inc.*, 556 F. Supp.2d 167, 172 (E.D.N.Y. 2008) (internal quotation marks omitted).

In the instant matter, Plaintiff fails to provide evidence that alli® did not perform as intended by the GSK and HLR defendants. There is no defect that is reasonably inferable from the pleadings as they fail to inform beyond a threadbare recitation of the elements of this cause of action. Accordingly, the strict liability claim is dismissed pursuant to Rule 12(b)(6).

E. Plaintiff's Failure to Warn Claim Fails

The first prong of Plaintiff's fourth asserted cause of action is for failure to warn the public about the harms associated with alli® while aggressively marketing the product as safe for potential users. (Compl. at ¶¶ 91-104.) In order to establish a prima facie case for failure to

warn under New York law, a plaintiff must demonstrate the following: (1) the manufacturer had a duty to warn; (2) the manufacturer breached the duty to warn in a manner that rendered the product defective such that the product was reasonably certain to be dangerous; (3) the defect was the proximate cause of the plaintiff's injury; and (4) the plaintiff suffered loss or damage. *Bee v. Novartis Pharmaceuticals Corp.*, 18 F. Supp.3d 268, 282-83 (E.D.N.Y. 2014); *see also McCarthy v. Olin Corp.*, 119 F.3d 148, 156 (2d Cir. 1997); *Becker v. Schwartz*, 46 N.Y.2d 401, 410 (1978). "These prima facie elements of a failure to warn claim remain the same under New York law regardless of whether they sound in negligence or strict liability." *Bee*, 18 F. Supp.3d at 283; *see Martin v. Hacker*, 83 N.Y.2d 1, 8 n. 1 (1993).

Under New York law, a plaintiff is required to prove that the product did not contain adequate warnings. *Reed*, 839 F. Supp.2d at 575; *see Mulhall v. Hannafin*, 45 A.D.3d 55, 58 (1st Dep't 2007). Various federal district and appellate courts have dismissed failure to warn claims when the plaintiff does not plead facts specifically indicating how the provided warnings were inadequate. *Reed*, 839 F. Supp.2d at 575; *see Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 608-09 (11th Cir. 2008) (affirming the dismissal of a failure to warn cause of action when the complaint "only assert[ed] that the warning was insufficient because it failed to warn of various dangers of the use of [the drug], without explaining either the information available to [the] physician at the time of the administration of the drug or how the contents of the label were inadequate"); *Wendell v. Johnson & Johnson*, 2010 WL 271423, at *4 (N.D. Cal. Jan 20, 2010) (dismissing a failure to warn claim because the plaintiffs "fail[ed] to allege how [the] warnings about [the drug] were inadequate").

Notwithstanding Plaintiff's enumeration of injuries (*i.e.*, jaundiced skin and eyes, nausea, abdominal pain, constipation, liver disease, *inter alia*) in her opposition papers that are

commonly associated with the ingestion of alli®, the complaint is devoid of any description of Plaintiff's actual injuries.[4] (Pl. Opp. at 2; *see generally* Compl.) Additionally, the Complaint is silent about the content of alli's® warnings and does not allege that the alli® label specifically failed to warn of these injury risks. (*See* Compl.) The courts of the Second Circuit consistently have held that mere assertions that warnings on product labels are inadequate constitute conclusory statements lacking in empirical support. *See Reed*, 839 F. Supp.2d at 576; *Cavanaugh v. Ford Motor Co.*, 2014 WL 2048571, at *4 (E.D.N.Y. May 19, 2014); *Henson v. Wright Medical Technology, Inc.*, 2013 WL 1296388, at *2 (N.D.N.Y. March 28, 2013); *Pelman v. McDonald's Corp.*, 237 F. Supp.2d 512, 540 (S.D.N.Y. 2003) (holding that "[t]he standard for evaluating failure to warn liability is 'intensely fact-specific, including but not limited to such issues as feasibility and difficulty of issuing warnings in the circumstances …; obviousness of the risk from actual use of the product; knowledge of the particular product user; and proximate cause." (quoting *Liriano v. Hobart Corp*., 92 N.Y.2d 232, 243 (1998)). Accordingly, Plaintiff's failure to warn claim is dismissed.

F. Plaintiff's Misrepresentation Claim Fails

The second prong of Plaintiff's fourth asserted cause of action is for misrepresentation of the safety and dangers associated with use of alli®. (Compl. at ¶¶ 91-104.) Although Plaintiff failed to specify whether her misrepresentation claim sounds in strict liability, fraud or negligence, the Court will address this cause of action under all three theories.

1) Strict Liability Misrepresentation

Section 402B of the Restatement (Second) of Torts defines strict liability misrepresentation as:

[4] Plaintiff enumerated many of these same injuries as risks commonly associated with the ingestion of alli®. However, Plaintiff failed to make clear that Plaintiff actually sustained any of those injuries. (Compl. at ¶ 61.)

> One engaged in the business of selling chattels who, by advertising, labels, or otherwise, makes to the public a misrepresentation of a material fact concerning the character or quality of a chattel sold by him is subject to liability for physical harm to a consumer of the chattel caused by justifiable reliance upon the misrepresentation, even though
> (a) it is not made fraudulently or negligently, and
> (b) the consumer has not bought the chattel from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402B (1965). "However, New York has never adopted the strict liability approach set forth in Section 402B of the Restatement." *DiBartolo v. Abbott Laboratories*, 914 F. Supp.2d 601, 623 (S.D.N.Y. 2012) (internal quotation marks and citation omitted). Accordingly, to the extent that Plaintiff asserted a cause of action for strict liability misrepresentation, such claim is dismissed as it is inapplicable in New York State.

2) Fraudulent Misrepresentation

To state a claim for fraudulent misrepresentation in New York, a plaintiff must allege: "(1) a material misrepresentation or omission of fact; (2) which the defendant knew to be false; (3) which the defendant made with the intent to defraud; (4) upon which the plaintiff reasonably relied; and (5) which caused injury to the plaintiff." *Financial Guaranty Ins. Co. v. Putnam Advisory Co., LLC*, 783 F.3d 395, 402 (2d Cir. 2015).

Plaintiff claims that, "[b]y use of affirmative misrepresentations and omissions, the Defendants engaged in promotion or advertising programs that falsely and fraudulently sought to create the image and/or impression that the use of [alli®] was safe or had minimal risks to the public and the Plaintiff in particular." (Compl. at ¶ 92.) Plaintiff further alleges that the GSK and HLR defendants "were in possession of information demonstrating serious side effects evidencing the increased risk [alli®] posed to patients, or clearly should have been in possession of such information yet continued to market [alli®] by providing false and misleading information with regard to safety as [sic] aforesaid drug(s)." (*Id.* at ¶ 101.)

Federal Rule of Civil Procedure 9(b) provides that "in alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "A plaintiff bringing a fraud claim must allege 'the time, place, speaker, and sometimes even the content of the alleged misrepresentation.'" *Bertini v. Smith & Nephew, Inc.*, 8 F. Supp.3d 246, 259 (E.D.N.Y. 2014) (quoting *Bangkok Crafts Corp. v. Capitolo Di San Pietro in Vaticano*, 2006 WL 1997628, at *5 (S.D.N.Y. July 18, 2006)). Here, Plaintiff does not allege any misrepresentations or omissions with the degree of particularity required by Fed. R. Civ. P. 9(b). As set forth below, Plaintiff failed to allege any reliance on any specific misrepresentations made by the GSK and/or HLR defendants. Therefore, to the extent that Plaintiff's cause of action for misrepresentation sounds in fraud, such claim is also dismissed.

According to Plaintiffs, the GSK and HLR defendants "deceived the medical community and public at large [sic] including all potential users [sic] including the Plaintiff [sic] of the products by promoting [alli®] as safe and effective." (*Id*. at ¶ 102.) However, the mere fact that Plaintiff purchased alli®, without more, does not demonstrate that Plaintiff relied on the GSK or HLR defendants' alleged misrepresentations and omissions when deciding whether to ingest the weight loss drug. *See Pacs Industries, Inc. v. Cutler-Hammer, Inc.*, 103 F. Supp.2d 570, 572 (E.D.N.Y. 2000) (dismissing claim of fraud where only reliance shown was purchase of defendant's product). The complaint is devoid of any assertion of reliance by Plaintiff on the GSK and HLR defendants' alleged misrepresentations and omissions. Absent allegations of fact demonstrating Plaintiff's reliance on the alleged misrepresentations, Plaintiff's fraudulent misrepresentation claim cannot stand. *See Premium Mortgage Corp. v. Equifax, Inc.*, 583 F.3d 103, 108 (2d Cir. 2009); *Vermeer Owners, Inc. v. Guterman*, 78 N.Y.2d 1114, 1116 (1991)

(affirming dismissal of fraud claim, noting that "[n]othing in this record establishes that plaintiffs in fact relied on any misrepresentation by defendants to their detriment.").

3) Negligent Misrepresentation

Under New York law, the elements necessary to prevail on a negligent misrepresentation claim include proof that: "(1) the defendant had a duty, as a result of a special relationship, to give correct information; (2) the defendant made a false representation that he or she should have known was incorrect; (3) the information supplied in the representation was known by the defendant to be desired by the plaintiff for a serious purpose; (4) the plaintiff intended to rely and act upon it; and (5) the plaintiff reasonably relied on it to his or her detriment." *Hydro Investors, Inc. v. Trafalgar Power Inc.*, 227 F.3d 8, 20 (2d Cir. 2000). Furthermore, "liability for negligent misrepresentation has been imposed only on those persons who possess unique or specialized expertise, or who are in a special position of confidence and trust with the injured party." *Dallas Aerospace, Inc. v. CIS Air Corp.*, 352 F.3d 775, 788 (2d Cir. 2003).

New York law also holds that a pharmaceutical manufacturer cannot be held liable on a consumer's negligent misrepresentation claim regarding advertising for its drug where the consumer was not in privity of contract with the manufacturer. *DiBartolo* at 914 F. Supp.2d at 623-24. In the absence of privity of contract, a plaintiff must demonstrate: "'(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.'" *Id*. at 624 (quoting *Marcellus Construction Co., Inc. v. Village of Broadalbin*, 302 A.D.2d 640, 640 (3d Dep't 2003)). Plaintiff also must prove that the statement contained a falsity, omission or material misrepresentation. *Id*.

Plaintiff fails to demonstrate that she and the GSK and HLR defendants have a special relationship such that privity of contract, or something approaching it, existed between them. Although the complaint includes numerous allegations that alli's® advertising was misleading, Plaintiff is unable to satisfy the elements of a claim for negligent misrepresentation. (Compl. at ¶¶ 91-105.) Plaintiff has not alleged that she was a known party to the GSK or HLR defendants or that either undertook specific conduct linking them to her and evincing their understanding of her alleged reliance on their ads. Accordingly, Plaintiffs negligent misrepresentation claim is dismissed in its entirety.

G. Plaintiff's Breach of Express and Implied Warranties Claim Fails

Plaintiff's fifth asserted cause of action is for breach of express and implied warranties that alli® is safe for use by patients. (Compl. ¶¶ 107-109.) Each prong of the breach of warranty claim is addressed separately below.

1) Express Warranty of Merchantability

Under New York law, a successful claim of a breach of express warranty requires proof that an express warranty existed, was breached, and that the plaintiff relied upon that warranty. *Reed*, 839 F. Supp.2d at 578. Furthermore, a successful breach of warranty claim requires that the product at issue be defective. *Id*. Indeed, New York's Uniform Commercial Code holds that any "affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." N.Y.U.C.C. § 2-313(1)(a). Proof of this promise or representation is required to support an action for breach of express warranty under New York law. *Horowitz v. Stryker Corp.*, 613 F. Supp.2d 271, 286 (E.D.N.Y. 2009).

Plaintiff fails to state an express warranty claim because the allegations are insufficient to draw a reasonable inference that: (1) alli® was defective or (2) what the GSK and HLR defendants promised was different than what they provided. *Reed*, 839 F. Supp.2d at 579. The complaint only broadly alleges that "the manufacturing Defendants expressly and implicitly warranted that the products were safe when used by patients for whom they were not otherwise contraindicated." (Compl. at ¶ 107.) However, the complaint does not contain any allegations that Plaintiff relied on the GSK and HLR defendants' alleged representations that alli® was safe. Plaintiff does not even describe how these alleged representations were made beyond the all-encompassing bald assertion that the GSK and HLR defendants expressly and implicitly warranted product safety. (*Id*.) This lack of specificity renders Plaintiff's allegations insufficient to support an express warranty claim. *See DiBartolo*, 914 F. Supp.2d at 627 (dismissing plaintiff's breach of express warranty claim for failure to allege a specific "affirmation of fact or promise that is false or misleading"); *Fisher v. APP Pharmaceuticals, LLC*, 783 F. Supp.2d 424, 431-32 (S.D.N.Y. 2011) (dismissing plaintiff's breach of express warranty claim for failure to allege "any specific words, promises or statements" made by defendants that would create an express warranty). Accordingly, Plaintiff's breach of express warranty claim is dismissed.

2) Implied Warranty of Merchantability

Under New York law, implied warranty of merchantability is a guarantee by the seller that its goods are fit for the intended purpose for which they are used and that they will pass in the trade without objection. *Caronia v. Philip Morris USA, Inc.*, 715 F.3d 417, 433 (2d Cir. 2013). "This standard does not require that the goods be perfect, or that they fulfill [a] buyer's every expectation; it requires only that the goods sold be of a minimal level of quality." *Id*. at 433-34 (internal quotation marks omitted). The inquiry:

> focuses on the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners. The cause of action is one involving true strict liability, since recovery may be had upon a showing that the product was not minimally safe for its expected purpose—without regard to the feasibility of alternative designs or the manufacturer's reasonableness in marketing it in that unsafe condition.

Id. at 434 (internal quotation marks and italics omitted). Upon a showing that a product is not minimally safe for its expected purpose, a plaintiff may recover under New York law for a breach of implied warranty. *Porrazzo v. Bumble Bee Foods, LLC*, 822 F. Supp.2d 406, 417 (S.D.N.Y. 2011).

To the extent that Plaintiff's breach of implied warranty claim is based on design defect, under New York law such a claim "requires proof of the following three elements: (1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident." *Simon v. Smith & Nephew, Inc.*, 990 F. Supp.2d 395, 407 (S.D.N.Y. 2013) (internal quotation marks omitted).

As discussed above, Plaintiff's defective design claim fails and, thus, the breach of implied warranty claim fails as well. *See Lewis v. Abbott Laboratories*, 2009 WL 2231701, at *6 (S.D.N.Y. July 24, 2009) (holding that where "plaintiff has not pleaded necessary elements to support a design … defect claim," "plaintiff has failed to plead an essential element of her breach of implied warranty claim"). The HLR defendants contend that Plaintiff's allegations concerning a breach of implied warranty are ambiguous and lack the necessary facts to explain why the alli® that Plaintiff ingested was not of merchantable quality. (Def. Mot. at 12.) Indeed, the complaint avers generically that the GSK and HLR defendants "implicitly warranted that the products were safe when used by patients for whom there were not otherwise contraindicated." (Compl. at ¶ 107.) The complaint continues by asserting that the GSK and HLR defendants

"breached such warranty in that said drugs are not safe for the purpose for which they were intended." (*Id*. at ¶ 108.) This threadbare allegation is conclusory because there are no concrete factual allegations to support the claim that alli® was defectively designed. Ultimately, Plaintiff has not sufficiently pled facts making it plausible that alli® was not fit for its intended purposes. Accordingly, Plaintiff's claim for breach of implied warranty is dismissed.

H. Plaintiff's Violation of New York General Business Law § 349 Claim Fails

Plaintiff's sixth asserted cause of action is for violation of New York General Business Law § 349 ("NYGBL § 349") insofar as the GSK and HLR defendants' marketing practices allegedly deceptively induced consumers to purchase and ingest alli® thereby causing injury. (Compl. at ¶¶ 112-115.) Section 349 proscribes "deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service" in New York State. N.Y. Gen. Bus. L. § 349(a). To assert a claim under NYGBL § 349, "a Plaintiff must show: (1) acts or practices that are consumer oriented; (2) that such acts or practices are deceptive or misleading in a material way; and (3) that plaintiff has been injured by reason of those acts." *Statler v. Dell, Inc.*, 775 F. Supp.2d 474, 483 (E.D.N.Y. 2011) (internal quotation marks omitted).

"A 'deceptive act or practice' has been defined as a representation or omission 'likely to mislead a reasonable consumer acting reasonably under the circumstances.'" *Shapiro v. Berkshire Life Ins. Co.*, 212 F.3d 121, 126 (2d Cir. 2000) (quoting *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 26 (1995)). The "consumer oriented" element of NYGBL § 349 requires a plaintiff to demonstrate that the business practices at issue have a "'broad impact on consumers at large; private contract disputes unique to the parties … would not fall within the ambit of the statute.'" *Statler*, 775 F. Supp.2d at 483-84 (quoting *New*

York University v. Continental Insurance Co., 87 N.Y.2d 308, 320 (1995) (internal quotation marks omitted)).

Plaintiff fails to make any reference to the specific acts or practices that she claims are deceptive or misleading nor does Plaintiff allege why these acts are deceptive or misleading. A cause of action under NYGBL § 349 cannot be maintained where a plaintiff fails "to identify any 'material' 'deceptive acts' engaged in by the defendant." *Horowitz*, 613 F. Supp.2d at 287 (quoting *Benjaminov v. Republic Insurance Group*, 241 A.D.2d 473, 474 (2d Dep't 1997)). Even if the deceptive or misleading conduct referenced in Plaintiff's opposition memorandum relates to the findings of the Food and Drug Administration's ("FDA") alli® advisory committee and the GSK and HLR defendants' failure to reveal such information to Plaintiff, Plaintiff provides no connection between the GSK and HLR defendants' deceptive conduct and a specific injury that she suffered as a result of that activity. (Pl. Opp. at 4.); *see Bogosian v. All American Concessions*, 2008 WL 4534036, at *4 (E.D.N.Y. Sept. 30, 2008) ("[d]efendants should not be required to infer from the pleadings the critical facts and the operative legal standard underlying a claim [under General Business Law Section 349]."). Accordingly, Plaintiff's claim for a violation of NYGBL § 349 is dismissed.

IV. Denial of Leave to Amend

Plaintiff, in her opposition memorandum, informally requests leave to amend the complaint in the event the Court dismisses her causes of action in their entirety. (Pl. Opp. at 1, 9-12.) As an initial matter, Plaintiff's argument is procedurally improper, as Plaintiff has failed to make a proper motion to amend her complaint. *See In re Tamoxifen Citrate Antitrust Litigation*, 466 F.3d 187, 220 (2d Cir. 2006) ("It is within the court's discretion to deny leave to amend implicitly by not addressing the request when leave is requested informally in a brief filed

in opposition to a motion to dismiss."). However, even construing Plaintiff's argument as a motion to amend the complaint, the motion is denied pursuant to Federal Rule of Civil Procedure 15(a).

Federal Rule of Civil Procedure 15(a) requires that leave to amend a complaint "shall be freely given when justice so requires." Fed. R. Civ. P. 15(a)(2). Leave to amend a pleading may be denied properly if amendment would be futile, as when the proposed new pleading fails to state a claim on which relief can be granted. *Anderson News, L.L.C. v. American Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012). When determining whether to grant leave to amend, district courts are to consider the following elements: (1) whether the party seeking the amendment has unduly delayed the proceedings; (2) whether that party is acting in good faith; (3) whether the opposing party will be prejudiced; and (4) whether the amendment will be futile. *Eskenazi-McGibney v. Connetquot Central School District*, 84 F. Supp.3d 221, 225 (E.D.N.Y. 2015). When there is evidence of undue delay, bad faith or a dilatory motive on the movant's part, repeated failures to cure deficiencies by amendments previously allowed, undue prejudice, or futility of amendment, leave to amend properly may be denied. *Ruotolo v. City of New York*, 514 F.3d 184, 191 (2d Cir. 2008). Moreover, a plaintiff need not be given leave to amend a pleading if it fails to specify to the district court how amendment would cure the pleading deficiencies in its complaint. *TechnoMarine SA v. Giftports, Inc.*, 758 F.3d 493, 505 (2d Cir. 2014); *see also City of Pontiac Policemen's & Firemen's Retirement System v. UBS AG*, 752 F.3d 173, 188 n. 71 (2d Cir. 2014) (denying leave to amend where "plaintiffs have identified no additional facts or legal theories—either on appeal or to the District Court—they might assert if given leave to amend").

A. Undue Delay in the Proceedings

Here, the timeline of this litigation suggests an unnecessary delay in the proceedings. Plaintiff commenced this action on May 21, 2014, in New York State Supreme Court, Queens County against the GSK and HLR defendants. (*See generally* Compl.) However, the HLR defendants contend that Plaintiff never served them within the 120-day period after the filing of the complaint as is required pursuant to Federal Rule of Civil Procedure 4(m). (HLR Defendants' Memorandum of Law in Support of Motion to Dismiss the Complaint Pursuant to Fed. R. Civ. P. 4(M) ("Mot. to Dismiss Pursuant to Rule 4(M)") at 2, Dkt. Entry No. 7-1.) On January 21, 2015, Plaintiff conceded that it had not served the HLR defendants with the complaint. (Case Management Statement Initial Conference Questionnaire ("Initial Conf. Questionnaire") at ¶ 19, Dkt. Entry No. 11.) On January 22, 2015, the Honorable Robert M. Levy, U.S.M.J., granted Plaintiff a 30-day extension of time to serve the HLR defendants.

On February 3, 2015, Plaintiff served the HLR defendants with the complaint. (HLR Def. Reply at 1.) On February 23, 2015, rather than interposing an answer to the complaint, the HLR defendants filed the instant motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (*See generally* Mot. to Dismiss.) On May 13, 2015, Plaintiff belatedly filed a letter motion requesting a 30-day extension to file a response to the HLR defendants' motion to dismiss citing preoccupation with the collection and exchange of discovery as reasons for her failure to timely request an adjournment. (Letter Motion for Extension of Time to File Response/Reply to Motion to Dismiss at 1, Dkt. Entry No. 19.) In that same letter motion, Plaintiff requested leave to amend the complaint and, in the alternative, an opportunity to respond to the HLR defendants' motion to dismiss. (*Id*. at 2.) On June 26, 2015, this Court reluctantly granted Plaintiff's request for an extension and took umbrage with Plaintiff's

purported focus on discovery when the only discovery from any defendants in this matter was served over two weeks after Plaintiff's original deadline to file opposition papers had passed. In accordance with the granted extension, Plaintiff filed her opposition to the motion to dismiss on July 10, 2015, and did not move to amend the complaint.

Based on this timeline, it would appear that Plaintiff has caused substantial delay in these proceedings. However, "[m]ere delay … absent a showing of bad faith or undue prejudice, does not provide a basis for the district court to deny the right to amend." *Ruotolo*, 514 F.3d at 191 (internal quotation marks omitted).

B. Bad Faith

There is no evidence of bad faith on Plaintiff's part. The Court moves to the remaining two prongs of the analysis.

C. Prejudice to the Opposing Party

In determining whether granting leave to amend would impose undue prejudice upon the opposing party, the district court must consider, *inter alia*, whether an amendment would "'require the opponent to expend significant additional resources to conduct discovery and prepare for trial' or 'significantly delay the resolution of the dispute.'" *Ruotolo*, 514 F.3d at 192 (quoting *Block v. First Blood Associates*, 988 F.2d 344, 350 (2d Cir. 1993)).

Here, Plaintiff already has settled this matter with the GSK defendants, who were the actual manufacturers and purveyors of alli®. (*See generally* Stipulation of Dismissal.) There is limited utility in continuing this action against the HLR defendants when their only alleged connection to the production of alli® is a 2005 orlistat licensing agreement between the two companies. (Pl. Opp. Exhibit 3, Media Release.) Given that Plaintiff has conceded that the HLR defendants do not manufacture alli®, and the HLR defendants' highly attenuated connection to

this litigation, Plaintiff should not be permitted to amend the Complaint against the HLR defendants. (Pl. Opp. at 3.)

Because the GSK defendants are the manufacturers of the weight loss drug that Plaintiff ingested, the GSK defendants ostensibly would be in possession of most of the relevant discovery. This would require the HLR defendants to expend significant additional resources in producing discovery that was not originally in their possession. The gravamen of Plaintiff's complaint against the HLR defendants is that, as the designer and developer of orlistat, the HLR defendants are liable for all defects associated with the over-the-counter strength version of Xenical® that had been licensed to the GSK defendants. (*Id*.) The recent removal of the GSK defendants from this litigation by settlement renders a conceivable hardship on the HLR defendants, who are not the makers of the weight loss drug at issue, in requiring them to exchange discovery.

D. Futility

Futility is a determination, as a matter of law, that proposed amendments would fail to cure prior deficiencies in the complaint or to state a claim under Rule 12(b)(6). *Panther Partners Inc. v. Ikanos Communications, Inc.*, 681 F.3d 114, 119 (2d Cir. 2012). Here, Plaintiff does not present the Court with a specific proposed set of amended pleadings, but rather seeks to amend the complaint pursuant to Rule 15(a) in the event the Court dismisses her causes of action. (Pl. Opp. at 1, 9-12.)

Notwithstanding Plaintiff's enumeration of injuries allegedly suffered as a result of her alli® ingestion, her opposition memorandum and annexed medical records fail to identify any new plausible allegations that might remedy the numerous deficiencies identified in this Memorandum and Order. Rule 15(a) does not serve as "a shield against dismissal to be invoked

as either a makeweight or a fallback position in response to a dispositive motion." *Gutkowski v. Steinbrenner*, 680 F. Supp.2d 602, 616 (S.D.N.Y. 2010) (internal quotation marks and citation omitted). "At the very least, a party seeking leave to amend must provide some indication of the substance of the contemplated amendment in order to allow the Court to apply the standards governing Rule 15(a)." *Id*. (internal quotation marks and citation omitted).

Plaintiff's assertion that the physicians treating her at NSUH suspected that her autoimmune hepatitis diagnosis resulted from "'hypertoxicity from OTC Alli vs. underlying genetic-liver disease'" does not cure the deficiencies in the complaint as it pertains the HLR defendants. (Pl. Opp. at 2 (quoting Pl. Opp., Exhibit 1, Medical Records at 4, Dkt. Entry No. 23-1).) Ultimately, Plaintiff's ingestion of alli®, and not Xenical®, forestalls an action in tort against the HLR defendants.

For these reasons, Plaintiff's request for leave to amend the complaint is denied.

CONCLUSION

For the foregoing reasons, the HLR defendants' motion to dismiss this action is granted, with prejudice, and Plaintiff's request for leave to amend the complaint is denied.

SO ORDERED.

Dated: Brooklyn, New York
September 29, 2016

/s/
DORA L. IRIZARRY
Chief Judge