IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

TERRY PAULSEN,	)	
	)	
Plaintiff,	)	Case No. 15-cv-4144
	)	
v.	)	Judge Robert M. Dow, Jr.
	)	
ABBOTT LABORATORIES, et al,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiff Terry Paulsen brings this action against Defendants Abbott Laboratories ("Abbott"), AbbVie Inc. ("AbbVie"), Takeda Pharmaceuticals U.S.A. Inc. ("TPUSA"), and TAP Pharmaceutical Products, Inc. ("TAP") (collectively "Defendants") alleging strict products liability, strict products liability-failure to warn, negligence, and negligent misrepresentation. She also asserts fraudulent misrepresentation against Abbott. Currently before the Court are motions by Abbott [144], AbbVie [150], and TPUSA/TAP [147] to dismiss the complaint with prejudice. For the reasons explained below, Defendants' motions [144; 147; 150] are granted in part and denied in part. The motion to dismiss TAP as a Defendant pursuant to Federal Rule of Civil Procedure 12(b)(5) is granted and TAP is dismissed from this action with prejudice. With regard to Defendants' motions under Rule 12(b)(6): all Counts against TPUSA as successor in interest to TAP are dismissed with prejudice; all Counts but Count II against AbbVie are dismissed; and all claims but Counts II & V against Abbott are dismissed. The Court sets this matter for further status on April 8, 2019 at 10:00 a.m. to set a schedule for limited discovery regarding: (1) when Plaintiff's claim accrued; (2) whether the second amended complaint as to AbbVie properly relates back under Rule 15(c)(3); and (3) the roles of the remaining defendants vis-à-vis the manufacturing and development of Lupron. The parties should submit a joint status report and a proposed

schedule for limited discovery no later than April 4, 2019. Finally, as an administrative matter, the motion for Rule 11 Sanctions by AbbVie, Abbott, and TPUSA [153] is stricken without prejudice in light of the notice of withdrawal filed on October 30, 2018 [180].

I. Background[1]

The full background of this case is set forth in the Court's previous opinion, knowledge of which is assumed here. See [111 (*Paulsen v. Abbott Labs.*, 2018 WL 1508532, *1–4 (N.D. Ill. Mar. 27, 2018)]. In brief, Plaintiff alleges that the Lupron injection that she received in 2004 to treat her endometriosis caused permanent damage to her bones and joints leading to her diagnosis of severe joint arthropathy in April 2008 and osteoporosis in May 2010. [143, ¶¶ 21–22.] She also continues to suffer from chronic joint pain, muscle pain, and fatigue. [*Id.* ¶ 22.] Critically, Plaintiff alleges that as early as 1990, Abbott and TAP[2] knew of the continued bone loss incurred by Lupron users and the risk that the medication therefore posed to patient's health, but took no corrective action, provided no additional warnings, and did not take the drug off the market. [*Id.* ¶ 22.] In her second amended complaint, Plaintiff alleges that an Abbott drug detail person explicitly told her physician that Lupron was safe and effective and would not cause any long-term adverse effects. [143, ¶ 50.]

Plaintiff's quest to hold Defendants accountable for the harms allegedly caused by the Lupron that they purportedly designed, manufactured, packaged, marketed, etc. has spawned a veritable odyssey of litigation spanning almost a decade. Although the full saga is more fully laid out in the Court's previous opinion, see [*Paulsen*, 2018 WL 1508532, at *2–4], the Court will

[1] For purposes of the motion to dismiss, the Court accepts as true all of Platinum's well-pleaded factual allegations and draws all reasonable inferences in Platinum's favor. *Killingsworth v. HSBC Bank Nev., N.A.*, 507 F.3d 614, 618 (7th Cir. 2007).

[2] Both TPUSA and AbbVie are sued only as the alleged successors in interest to TAP. [143, ¶¶ 4, 10.]

provide a brief summary here as well. In April 2010, Plaintiff along with several other individuals, filed suit against Abbott, TPNA,[3] TAP, and Takeda Inc. in the Eastern District of New York. [*Id.* at *3.] The case was then transferred to the Southern District of New York, before finally coming to rest in the Northern District of Illinois in July 2011 before Judge Gottschall. [*Id.*] The case proceeded into discovery—after Plaintiff filed an amended complaint in October 2011—until August 2013, when Plaintiff's then-counsel moved to withdraw from the case. [*Id.*] After admonishing Plaintiff that her case would be dismissed for lack of prosecution unless she appeared, Judge Gottschall dismissed the case in October 2013 when Plaintiff failed to appear. [*Id.*] Although the case was briefly reinstated upon the request of Plaintiff's mother, in May 2014 Plaintiff voluntarily dismissed the lawsuit. [*Id.*]

After unsuccessfully attempting to reopen the previous case through newly-acquired counsel in April 2015, Plaintiff filed a new complaint against Abbott, TPNA, Takeda Inc., and TAP in the current action in May 2015. [*Id.*] The complaint [1] asserted seven causes of action against all the defendants including various product liability, negligence, warranty, and misrepresentation claims. See generally [1]. The defendants moved to dismiss the action in July 2015. [*Paulsen*, 2018 WL 1508532, at *3.] The motions were dismissed without prejudice, however, until Judge Gottschall could determine whether the Illinois savings statute or Georgia statute of limitations period applied. [*Id.*] That question turned on whether Abbott was a real party at interest to the litigation. [*Id.*]

After limited discovery, Judge Gottschall determined on a motion for summary judgment that there was a "genuine issue of material fact as to whether Abbott's role in the distribution chain was sufficient to create liability." [*Id.*] The Defendants then refiled their motions to dismiss to

[3] TPNA is the former name of TPUSA. [143, ¶ 4.]

dismiss under Federal Rules of Civil Procedure 12(b)(5) and (b)(6), which this Court resolved in an opinion dated March 27, 2018. See generally [*Paulsen*, 2018 WL 1508532].

The Court granted the motions in part and denied them in part. [*Id.* at *1.] As to the Defendants' motions under Rule 12(b)(6), the Court dismissed all the claims against Takeda Inc. and Takeda Chemical Industries, Ltd. with prejudice, dismissed all the claims against TPNA without prejudice, and dismissed all but the strict liability claims against Abbott without prejudice. [*Id.*] The Court also granted Defendants' motion to dismiss TAP as a defendant pursuant to Rule 12(b)(5) "to the extent that Plaintiff is given until May 22, 2018 to serve an amended complaint upon a proper defendant (whether that is TAP or a proper successor to TAP)." [*Id.*] However, the Court granted Plaintiff leave to file an amended complaint, provided she could do so consistent with the opinion. [*Id.*]

On July 6, 2018, Plaintiff filed her second amended complaint (the "SAC"), after filing a short-lived first amended complaint in April 2018. [143.] The SAC brings four causes of action against all Defendants—strict products liability (Counts I & II), negligence (Count III), and negligent misrepresentation (Count V)—and one cause of action against Abbott alone—fraudulent misrepresentation (Count IV). Defendants have filed three motions to dismiss in response. See generally [144; 147; 150]. First, TAP moves to dismiss the claims against it with prejudice pursuant to Rule 12(b)(5). [147.] The remaining Defendants move to dismiss the claims against them under Rule 12(b)(6). TPUSA asserts that Plaintiff has failed to state a claim against it, because the facts as pled show that TPUSA cannot be held liable as a successor in interest to TAP as Plaintiff claims. [147, at 3–5.] AbbVie, in turn, argues that all the claims against it are barred by the statute of limitations, and that in any case, Plaintiff has failed to state any plausible claims against it under Rule 8. See generally [150]. Finally, Abbott argues that the complaint fails to

state a plausible claim against it under Rule 8 on Counts I–III and V and fails to plead fraudulent misrepresentation in Count IV with the specificity required by Rule 9(b). See generally [144]. Defendants also filed a motion for Rule 11 sanctions [153], which later was withdrawn, see [180].

II. Rule 12(b)(5) Motion to Dismiss

A. Legal Standard

Once a plaintiff files a lawsuit in federal court, the plaintiff must ensure that each defendant receives a summons and a copy of the complaint against it. Fed. R. Civ. P. 4(b), (c)(1). Unless the plaintiff can demonstrate good cause for being unable to do so, she must accomplish this service of process within 90 days of filing to avoid possible dismissal of the suit. Fed. R. Civ. P. 4(m). These service requirements serve several purposes: they "provide notice to parties, encourage parties and their counsel to diligently pursue their cases, and trigger a district court's ability to exercise jurisdiction over a defendant." *Cardenas v. City of Chi.*, 646 F.3d 1001, 1004–05 (7th Cir. 2011) (citing *Henderson v. United States*, 517 U.S. 654, 672 (1996)) (other citations omitted). Generally, "a district court may not exercise personal jurisdiction over a defendant unless the defendant has been properly served with process, and the service requirement is not satisfied merely because the defendant is aware that he has been named in a lawsuit or has received a copy of the summons and the complaint." *United States v. Ligas*, 549 F.3d 497, 500 (7th Cir. 2008).

"A defendant may enforce the service of process requirements through a pretrial motion to dismiss," at which point the plaintiff "bears the burden to demonstrate that the district court has jurisdiction over each defendant through effective service." *Cardenas*, 646 F.3d at 1004–05. (citing Fed. R. Civ. P. 12(b)(5)) (other citation omitted). If the Court determines that the plaintiff has not met that burden and lacks good cause for not perfecting service, the Court must either

dismiss the suit or specify a time within which the plaintiff must serve the defendant. Fed. R. Civ. P. 4(m); *United States v. McLaughlin*, 470 F.3d 698, 700 (7th Cir. 2006). The Court's decision on a Rule 12(b)(5) motion is "inherently discretionary." *Cardenas*, 646 F.3d at 1005 (citing *Ligas*, 549 F.3d at 501). In making its determinations on a Rule 12(b)(5) motion, a court may consider affidavits and other documentary evidence. See *Zausa v. Pellin*, 2017 WL 2311232, at *4 (N.D. Ill. May 26, 2017); *Dumas v. Decker*, 2012 WL 1755674, at *2 (N.D. Ill. May 16, 2012).

B. Analysis

1. Defendant TAP

In its previous opinion, the Court granted "Defendants' previous motion to dismiss TAP as a Defendant pursuant to Rule 12(b)(5) * * * to the extent that Plaintiff shall have until May 22, 2018 to serve an amended complaint upon a proper defendant (whether that is TAP, TPNA, Abbott, AbbVie, or some other entity)." [111, at 17.] The Court further warned, that if "Plaintiff fails to serve a proper defendant by this date, TAP will be dismissed from the case." [*Id.* at 17–18.]

In her SAC, Plaintiff states that "all services of processes will be made to all of [TAP's] successor in interest defendants who have been named in this complaint and not to TAP." [143, ¶ 3.] Plaintiff seems to have interpreted the Court's statement above to mean that because Abbott, AbbVie, and TPUSA are successors in interest to TAP, [143, at 1, ¶¶ 2–3], service of those entities suffices to effectuate service on TAP. That is not a correct reading. The Court simply intended to give Plaintiff time to effectuate service on whatever entity currently holds TAP's Lupron liabilities. See [111 at 17 ("Of course it is unclear whether TAP should be served at all. Plaintiff has variously argued that TPNA and Abbott—both properly-served Defendants—currently hold

TAP's Lupron liabilities, and Abbott argues that AbbVie holds these liabilities and would thus be the proper party to sue.").][4]

As to TAP itself, as the Court previously explained, "Plaintiff cannot effectively serve one corporation by serving a completely different corporation." [111, at 14 (citing *Hurtado v. 7-Eleven, Inc.*, 508 F. App'x 564, 565 (7th Cir. 2013)).] Nor has Plaintiff provided any precedent to support the argument that service of a defunct corporation's successor in interest provides this Court with jurisdiction over TAP. Because Plaintiff has not effectuated service on TAP, the Court has no choice but to dismiss TAP from this suit. And, given Plaintiff's representations that she has no intention of serving TAP, that dismissal is with prejudice.

III. Rule 12(b)(6) Motion to Dismiss

A. Legal Standard

To survive a Rule 12(b)(6) motion to dismiss for failure to state a claim upon which relief can be granted, the complaint first must comply with Rule 8(a) by providing "a short and plain statement of the claim showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), such that the defendant is given "fair notice of what the * * * claim is and the grounds upon which it rests." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)) (alteration in original). Second, the factual allegations in the complaint must be sufficient to raise the possibility of relief above the "speculative level." *E.E.O.C. v. Concentra Health Servs., Inc.*, 496 F.3d 773, 776 (7th Cir. 2007) (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.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 555). Dismissal for failure to state a claim under Rule 12(b)(6) is proper "when the allegations

[4] And, as noted above, Plaintiff has now in fact named, and purportedly served, AbbVie as a defendant. See [128].

in a complaint, however true, could not raise a claim of entitlement to relief." *Twombly*, 550 U.S. at 558. In reviewing a motion to dismiss pursuant to Rule 12(b)(6), the Court accepts as true all of Plaintiff's well-pleaded factual allegations and draws all reasonable inferences in Plaintiff's favor. *Killingsworth v. HSBC Bank Nevada, N.A.*, 507 F.3d 614, 618 (7th Cir. 2007). Evaluating whether a "claim is sufficiently plausible to survive a motion to dismiss is 'a context-specific task that requires the reviewing court to draw on its judicial experience and common sense.'" *Id.* (quoting *McCauley v. City of Chicago*, 671 F.3d 611, 616 (7th Cir. 2011)).

B. Analysis[5]

The remaining Defendants—TPUSA, Abbott, and AbbVie—again move to dismiss the SAC in its entirety for failure to plausibly state a claim against each of them under the relevant pleading standards. As it did previously, the Court will address separately the sufficiency of the complaint as to each of these remaining defendants.

1. Defendant TPUSA

In the SAC, Plaintiff again alleges that TPUSA is a wholly-owned subsidiary of Takeda Chemical Industries, Ltd. ("Takeda Ltd.") and now asserts that TPUSA is liable as a successor in interest to TAP. [143, ¶ 4.] She further alleges that when TAP dissolved in 2008, Abbott acquired all the assets, employees, and liabilities related to Lupron.[6] [*Id.* ¶ 7.] In fact, "Abbott exchanged its 50 percent equity interest in TAP for the assets, liabilities and employees related to TAP's Lupron business." [148-2, at 3.][7] Shortly thereafter, in July 2008, TAP's remaining assets were

[5] The Court previously determined that Georgia law governs the substantive issues in this dispute. See *Paulsen v. Abbott Labs.*, 2018 WL 1508532, at *11–13 (N.D. Ill. Mar. 27, 2018). Consequently, the Court will look to Georgia and related federal law for the substantive law in this case.

[6] Plaintiff further alleges that all the Lupron related sales, employees, and liabilities were transferred in December 2012 to AbbVie. [143, ¶ 10.]

[7] Plaintiff does not dispute the accuracy of this statement and actually repeats an almost verbatim version of it in her complaint. See [143, ¶ 7]. The Court therefore takes judicial notice of this document [148-2] for the purpose of

merged into TPUSA after which TAP dissolved as a corporation. [*Id.* ¶ 8.] In light of these transfers, TPUSA argues that it cannot be the successor in interest to Plaintiff's claims against TAP because Abbott, and now AbbVie, received all of TAP's assets, employees, and liabilities related to Lupron. The Court agrees with TPUSA.

Plaintiff argues that TPUSA may be held liable as a successor in interest pursuant to *Perimeter Realty v. GAPI, Inc.*, 533 S.E.2d 136 (Ga. Ct. App. 2000). *Perimeter* provides four circumstances in which a company purchasing another corporation's assets may be considered a successor in interest: "(i) there is an express agreement to assume the liabilities; (ii) the transaction is a fraudulent attempt to avoid liability; (iii) the purchaser is a mere continuation of the predecessor corporation; or (iv) the transaction is, in fact, a merger * * *." See 533 S.E.2d at 145. Here, Plaintiff has alleged that Abbott, and then AbbVie, expressly assumed the liabilities associated with Lupron when it purchased those assets from TAP. Consequently, only AbbVie appears to be the proper successor in interest to TPA. Nonetheless, Plaintiff argues that TPUSA may also be held liable as a successor in interest to TPA given the alleged de facto merger between TPA and TPNA, now TPUSA. However, Plaintiff has provided neither argument nor authority for the notion that a plaintiff may sue both TPUSA and AbbVie as successors in interest when only one of them expressly assumed the liabilities related to the product that allegedly harmed her. Nor does the Court believe she could. Consequently, the Court grants TPUSA's motion to dismiss it from the case because Plaintiff has not pled facts that show TPUSA can be held liable as a success in interest to TPA.

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confirming that Abbott exchanged its stake in TAP for the "assets, liabilities and employees related to TAP's Lupron business." See *Gen. Elec. Capital Corp. v. Lease Resolution Corp.*, 128 F.3d 1074, 1081 (7th Cir. 1997) (a court may take judicial notice of an adjudicative fact that is "not subject to reasonable dispute" and "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned") (quoting Fed. R. Evid. 201(b)). Judge Gottschall also previously found this fact in her opinion denying Abbott's motion for summary judgment as well. [95, at 2.]

2. Defendant AbbVie

AbbVie moves to dismiss every cause of action in Plaintiff's complaint on two grounds: first, on the basis that the complaint is untimely and filed outside the applicable statute of limitations; and second, for failure to state a claim. In support of the latter argument, AbbVie incorporates by reference Section II of Abbott's memorandum of law in support of its motion to dismiss [145] and Sections II & III of TPUSA and TAP's memorandum of law in support of those defendants' motion to dismiss [148].

a. Statute of Limitations[8]

AbbVie asserts that Plaintiff's allegations in the SAC establish that the claim against it falls outside the statute of limitations. Plaintiff retorts that because it timely filed against TAP,[9] and only seeks to proceed against AbbVie as the successor in interest to TAP, its claims are not untimely. The parties' briefing raises two questions: first, does filing a timely suit against a defendant's predecessor in interest toll the statute of limitations such that the otherwise untimely later substitution or addition of the successor in interest should be treated as timely? And, if not, should the Court treat the current complaint as relating back under Rule 15(c)?

Although not cited by the parties,[10] the decision in *Affleck v. Hannah Marine Corp.*, 1986 WL 1419 (N.D. Ill. Jan. 13, 1986), directly contradicts Plaintiff's contention that simply naming a

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[8] The Court assumes that Illinois statute of limitation law applies. See, e.g., *Anabaldi v. Sunbeam Corp.*, 651 F. Supp. 1343, 1345 (N.D. Ill. 1987) ("As a general rule Illinois courts apply Illinois statutes of limitation to common law causes of action arising in other states, even when those causes of action are governed by foreign law."). Neither party has argued or cited any authority to the contrary.

[9] AbbVie and the rest of the Defendants dispute this fact but assert that it is not relevant for the current inquiry. See, e.g., [179, at 3–5].

[10] While Plaintiff has not provided any precedent for her assertion that timely filing suit against a defunct company tolls the statute of limitations indefinitely against any successors in interest—especially where service of process was never properly effectuated on that defunct company—none of the cases cited by AbbVie clearly holds that a plaintiff must name a defendant's successor in interest within the statute of limitations period regardless of whether it has previously named the defendant in a suit. For example, the Court in *Dybala v. Landau & Heyman, Inc.* explicitly found that that there was no successor liability, and thus analyzed the claim against the relevant defendant as if they

party's predecessor in interest is sufficient to toll the statute of limitations as to that party. Indeed, the court in *Affleck* confronted a remarkably similar situation to the case at bar. As that court explained:

> In the two years since this case was originally filed (as Case No. 83 C 9028), the parties and the court have spent most of their efforts trying to unearth the proper defendants. Affleck originally brought this suit against Cities Services Corporation (Cities Services) and Hannah Marine Corporation (Hannah Marine). In his First Amended Complaint, plaintiff added Socony Vacuum Oil Co. (Socony) as a defendant. In the Second Amended Complaint, plaintiff substituted Gulf Oil Corporation (Gulf) for Socony on the basis that Gulf was the successor in interest to Socony. * * * It later became clear that Gulf was not a successor in interest to Socony, and therefore, the court granted Gulf's summary judgment motion and dismissed it from the case. The Third Amended Complaint named Mobil Oil Corporation (Mobil), the true successor in interest to Socony, as a defendant. * * * the court [subsequently] dismissed plaintiff's claim against Mobil for lack of subject matter jurisdiction. * * * Plaintiff then filed a negligence case against Mobil in state court, (*Affleck v. Mobil Oil Corp.*, 85 L 16706). On Mobil's petition the case was removed, and Mobil moves to dismiss plaintiff's complaint for a number of reasons [, including the statute of limitations].

1986 WL 1419, at *1. Addressing Mobil's argument, the court first explained that Illinois's savings statute, 735 ILCS 5/13-217, could not save an action that was barred by the statute of limitations when it was commenced in federal court. *Id.* at *2. Because Affleck had not named Mobil as a defendant until after the expiration of the statute of limitations, the only way he could save his case is if the complaint related back under Rule 15(c) to the complaint in which Socony was named as a defendant. *Id.* at *1–2.

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had been added to the complaint for the first time. 1997 WL 162846, at *5–6 (N.D. Ill. Mar. 27, 1997). And the court in *Russell v. ProMove, LLC* dismissed the defendant because it found the bankruptcy sale from which he had purchased assets explicitly barred any successor liability. 2009 WL 1285885, at *8 (N.D. Ga. May 5, 2009). The third case cited by AbbVie, *Patterson v. Rosser Fabrap Int'l, Inc.*, 379 S.E.2d 787, 788–89 (Ga. Ct. App. 1989), actually lends some credence to Plaintiff's argument. In *Patterson*, the Georgia Appellate Court suggested that the Georgia "renewal" statute could toll the statute of limitations where a plaintiff brought a second suit against the original defendant's successor in interest within the statue's refiling period. See 379 S.E.2d at 789 (explaining that the renewal statute may not be used to suspend the running of the statute of limitation as to defendants different from those originally sued). However, because the "successor in interest" in *Patterson* was not the successor in interest to the original defendant, but the successor in interest of another party who plaintiff had not originally sued, the renewal statute did not save the lawsuit. *Id.*

Although *Affleck* is not controlling, this Court finds it persuasive and is inclined to follow its rationale. Consequently, the Court must determine whether the current complaint relates back to Plaintiff's first complaint in *Cardenas & Paulsen v. Abbott Labs. et al.*, No. 10-cv-1745, ECF No. 1 (E.D.N.Y. April 20, 2010). AbbVie asserts that Plaintiff waived this argument by failing to respond to AbbVie's Rule 15(c) arguments. [179, at 3.] However, the Court concludes that the most logical way to read Plaintiff's argument is that as TAP's successor in interest, claims against AbbVie clearly relate back to the original complaint under Rule 15(c). Plaintiff's assertion that proceeding in this manner would be inappropriate because it "treats the Second Amended Complaint as if it is an independent direct claim against AbbVie, not a claim as a successor in interest" is simply unpersuasive. [163, at 6.] First, Plaintiff has again failed to provide any support whatsoever for this argument, and the argument seems directly contrary to *Affleck* above. But lack of precedent aside, as the Court has already explained, the mere fact that a corporation is sued as a successor in interest does not waive all the normal procedural and substantive requirements of federal litigation. Consequently, the Court will follow *Affleck*'s example and determine whether Plaintiff's complaint relates back under Rule 15(c).

Rule 15(c)(1) provides that "an amendment to a pleading relates back to the date of the original pleading when the amendment changes the party or the naming of the party against whom a claim is asserted, if Rule 15(c)(1)(B) is satisfied and if, within 120 days as provided by Rule 4(m), the party to be brought in by amendment (1) received notice of the action so that it will not be prejudiced in defending on the merits and (2) knew or should have known the action would have been brought against it, but for a mistake concerning the party's identity." Fed. R. Civ. P. 15(c)(1)(C).[11] AbbVie first argues that Plaintiff did not make a mistake in failing to name AbbVie

[11] Rule 15(c)(1)(B) is certainly satisfied here because the amended complaint simply seeks to hold AbbVie liable for the wrongful actions of TAP that she has complained of since first filing the suit in 2010. See Fed. R. Civ. P.

until now, and that as a result the Court should not allow the complaint to relate back. The fact that Plaintiff now claims that Abbott, TPUSA, and AbbVie are each liable as the successor in interest to TAP's liabilities, according to AbbVie, demonstrates that Plaintiff simply does not know which of the three companies she wants to hold liable for alleged injuries, not that she made a "mistake" as contemplated by Rule 15(c)(1)(C).

However, the line of cases cited by AbbVie predates the Supreme Court's decision in *Krupski v. Costa Crociere S.p.A.*, 560 U.S. 538, 550 (2010). For many years, the Seventh Circuit adhered to the "John Doe rule," pursuant to which a plaintiff's lack of knowledge about a defendant's identity was not considered a "mistake" within the meaning of Rule 15(c) such that a plaintiff could amend his complaint and take advantage of the relation-back doctrine. See, e.g., *Hall v. Norfolk S. Ry.*, 469 F.3d 590, 596 (7th Cir. 2006). The question is whether that rule survives *Krupski*.

In *Krupski*, the plaintiff pursued her suit against Costa Cruise Lines N.V.—the North American sales and marketing agent of an Italian cruise ship operator, Costa Crociere S.p.A.—despite multiple filings by Costa Cruise stating that that it was not the proper party in interest. Finally, at summary judgment, the facts presented conclusively demonstrated that Krupski had not sued the right defendant and that the proper defendant was Costa Crociere. 560 U.S. at 542–44. Krupski then dismissed Costa Cruise and named Costa Crociere in an amended complaint. *Id.* at 544. Costa Crociere, represented by the same lawyers as Costa Cruise, subsequently moved to dismiss Krupski's suit on statute of limitations grounds, arguing that Krupski could not save her claim under the relation back provision of Rule 15(c). *Id.* at 544–45. The district court agreed

15(c)(1)(B) ("An amendment to a pleading relates back to the date of the original pleading when: * * * the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out--or attempted to be set out--in the original pleading").

with Costa Crociere, and the Eleventh Circuit affirmed. *Id.* at 544–45. The Supreme Court reversed. *Id.* at 546.

At bottom, the Supreme Court explained, Rule 15(c)(1)(C) is intended to prevent a "windfall for a prospective defendant who understood, or should have understood that he escaped suit during the limitations period only because the plaintiff misunderstood a crucial fact about his identity." *Krupski*, 560 U.S. at 550. Thus, "Rule 15(c)(1)(C)(ii) asks what the prospective defendant knew or should have known during the Rule 4(m) period, not what the plaintiff knew or should have known at the time of filing her original complaint." *Id.* at 548. "Because a plaintiff's knowledge of the existence of a party does not foreclose the possibility that she has made a mistake of identity about which that party should have been aware, such knowledge does not support that party's interest in repose." *Id.* Rather, "information in the plaintiff's possession is relevant only if it bears on the defendant's understanding of whether the plaintiff made a mistake regarding the proper party's identity." *Id.* at 548.

Krupski explicitly rejected the notion that "any time a plaintiff is aware of the existence of two parties and chooses to sue the wrong one, the proper defendant could reasonably believe that the plaintiff made no mistake." *Id.* at 549. The Court distinguished that situation from one in which a plaintiff makes "a deliberate choice to sue one party instead of another while fully understanding the factual and legal differences between the two parties." *Id.* As the Court explained,

> [A] plaintiff might know that the prospective defendant exists but nonetheless harbor a misunderstanding about his status or role in the events giving rise to the claim at issue, and she may mistakenly choose to sue a different defendant based on that misimpression. That kind of deliberate but mistaken choice does not foreclose a finding that Rule 15(c)(1)(C)(ii) has been satisfied.
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> This reading is consistent with the purpose of relation back: to balance the interests of the defendant protected by the statute of limitations with the preference

> expressed in the Federal Rules of Civil Procedure in general, and Rule 15 in particular, for resolving disputes on their merits. [ ]

Id. at 549–50 (citation omitted).

Following *Krupski*, the Seventh Circuit has instructed that,

> [t]he only two inquiries that the district court is now permitted to make in deciding whether an amended complaint relates back to the date of the original one are, first, whether the defendant who is sought to be added by the amendment knew or should have known that the plaintiff, had it not been for a mistake, would have sued him instead or in addition to suing the named defendant; and second, whether, even if so, the delay in the plaintiff's discovering his mistake impaired the new defendant's ability to defend himself.

Joseph v. Elan Motorsports Techs. Racing Corp., 638 F.3d 555, 559–60 (7th Cir. 2011). But, neither *Joseph*, nor any subsequent Seventh Circuit opinions have specifically addressed whether the John Doe rule survived *Krupski*.[12] Nonetheless, multiple courts in this district have concluded that the John Doe rule did not survive *Krupski*. See, e.g., *Clair v. Cook Cnty.*, 2017 WL 1355879, at *3–4 (N.D. Ill. Apr. 13, 2017); *Bagley v. City of Chicago*, 2018 WL 3545450, at *3 (N.D. Ill. July 24, 2018); *Hawks v. Gade*, 2018 WL 2193197, at *4 (N.D. Ill. May 14, 2018); *Haroon v. Talbott*, 2017 WL 4280980, at *6 (N.D. Ill. Sept. 27, 2017). These courts have generally concluded that *Krupski* must have undercut the Seventh Circuit's previous conclusion that naming a fictitious "John Doe" is not a mistake. See, e.g., *White v. City of Chicago*, 2016 WL 4270152, at *16 (N.D. Ill. Aug. 15, 2016) ("While the issue was not before the court in *Joseph, Krupski* also must have "cut the ground out from under" *Hall's* view that the naming of a fictitious "John Doe" defendant was not a "mistake" either, because *Hall* said the two situations are to be treated the same under Rule 15(c)(1)(C) and nothing in *Krupski* undermines that portion of *Hall's* reasoning.).

[12] Of the two cases since *Krupski* that have applied the John Doe rule, one, *Flournoy v. Schomig*, 418 F. App'x. 528, 532 (7th Cir. 2011), is unpublished, and another, *Gomez v. Randle*, 680 F.3d 859, 864 n.1 (7th Cir. 2012), cites to the John Doe rule in dictum. Moreover, neither of the cases addressed whether *Krupski* abrogated the rule.

As AbbVie correctly notes, some courts have refused to allow a complaint to relate back where a plaintiff makes a deliberate choice not to discover the identity of the new defendant, appearing to conflate "deliberate choice" with "lack of diligence." See *White*, 2016 WL 4270152, at *18 (collecting cases); *Fleece v. Volvo Constr. Equip. Korea, Ltd.*, 2012 WL 171329, at *4 (N.D. Ill. 2012). In *Fleece*, for example, the defendant manufacturers argued that Fleece had affirmatively and deliberately chosen not to name them before the limitations period ran. *Fleece*, 2012 WL 171329 at *4. However, because the materials upon which the defendants relied were outside the pleadings, the district court denied that motion with leave to refile the motion as a motion for summary judgment. *Id.* The Court questions the propriety of such an analysis given the admonition by *Krupski* and *Joseph* that district courts must limit their inquiry under Rule 15(c)(1)(C)(ii) to what the newly named defendants knew or should have known. See, e.g., *Clair*, 2017 WL 1355879, at *4 (citing *Krupski*, 560 U.S. at 553–54 and *Joseph*, 638 F.3d at 559–60, and deferring the question of whether Rule 15(c) applied given "the complaint did not speak to what the newly added defendants knew or should have about this lawsuit").

Apparently aware of that admonition, AbbVie argues that there is simply no way—eight years since the original lawsuit was filed, and more than five years since AbbVie assumed Lupron's liabilities—that AbbVie knew or should have known that, absent some mistake, this action would have been brought against it. [151, at 13.] It is true that the other defendants in this case have argued in previous motions that Plaintiff should be pursuing AbbVie rather than them. See, e.g., [26, at 4 ("The pharmaceutical products business, including Lupron, went to AbbVie Inc. * * * Today, as Abbott's counsel has already explained to plaintiff's counsel, Abbott has no relationship to Lupron whatsoever.")]. However, the same was true in *Krupski*. See 560 U.S. at 543–44 (listing the numerous filings in which Costa Cruises alerted Krupski to the existence of

Costa Crociere). Courts faced with similar arguments and circumstances have deferred the question to the summary judgment stage. See *Clair*, 2017 WL 1355879, at *4 ("Because the complaint does not speak to what the newly added defendants knew or should have known about this lawsuit, the court cannot resolve the Rule 15(c)(1)(C)(ii) issue in their favor on a motion to dismiss.") (collecting cases); *Fleece*, 2012 WL 171329 at *4 (deferring consideration of the defendants' arguments regarding a deliberate failure to discover the correct plaintiff to a limited motion for summary judgment).

In light of this precedent and AbbVie's arguments, the Court concludes that the correct course of action in this case is to defer the question of whether the SAC properly relates back and to permit AbbVie to raise the question in a motion for summary judgment. This course will permit the parties to develop the factual record regarding any prejudice that AbbVie may have incurred as a result of the delay in being added as a defendant in this case and its assertion that the entire case was untimely when Plaintiff first filed her suit in 2010.

b. Failure to Plead Each Defendant's Actions Independently

Incorporating the argument by reference, AbbVie next asserts that Plaintiff has failed to state a claim because she has not pled facts to show exactly what each defendant did to harm her. Instead, AbbVie explains, the SAC lumps Defendants together and alleges that "All Defendants" were involved in some undefined way in each of the tortious actions alleged in the SAC, except for her fraudulent misrepresentation claim that she asserts against Abbott alone.

Both Seventh Circuit and Georgia law require that a plaintiff structure her complaint such that each individual defendant knows what it did that allegedly harmed the plaintiff. See, e.g., *Bank of Am., N.A. v. Knight*, 725 F.3d 815, 818 (7th Cir. 2013) ("The Rules of Civil Procedure set up a system of notice pleading. Each defendant is entitled to know what he or she did that is

asserted to be wrongful. A complaint based on a theory of collective responsibility must be dismissed."); *Brazil v. Janssen Research & Dev. LLC*, 249 F. Supp. 3d 1321, 1337 (N.D. Ga. 2016) (*Brazil I)* (dismissing product liability claim, in part, because "Plaintiff does not allege that any of the Defendants were the manufacturer. Instead, the Complaint generically states that "Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently acquired the Defendants who have designed, researched, manufactured, tested, advertised, promoted, marketed sold, and distributed Invokana." * * * The Complaint provides no notice of what role any of the Defendants played.").

Here, Plaintiff's complaint largely mirrors the one dismissed in *Brazil I*. She alleges that,

> At all times herein mentioned, the Defendant[s] Abbott and TAP, jointly, severally, acting in concert, with or through others, their partners, agents, servants and/or employees, the companies they own, control, or for whose actions they are responsible, manufactured, compounded, tested, distributed, recommended, marketed, labeled and packaged, merchandized, advertised, promoted, sold, purchased, prescribed, and administered the Lupron and the Plaintiff used, took, or injected with.

[143, at ¶ 25.] Georgia courts faced with "lump" allegations generally dismiss the allegations without prejudice and/or order repleading. See, e.g., *F.D.I.C. v. Briscoe*, 2012 WL 8302215, at *7–8 (N.D. Ga. Aug. 14, 2012) (collecting cases and noting that "'[a]lthough a complaint against multiple defendants is usually read as making the same allegation against each defendant individually, factual allegations must give each defendant 'fair notice' of the nature of the claim and the 'grounds' on which the claim rests. Accordingly, at times, a plaintiff's 'grouping' of defendants in a complaint may require a more definite statement.'") (citation omitted). However, because Plaintiff did name Abbott and TAP in each of her allegations, rather than simply using "Defendants," and asserts that both were involved in the actions she alleges, the Court will assess whether Plaintiff has adequately alleged facts to support her claims. See, e.g., *Barnes v. AstraZeneca Pharm. LP*, 253 F. Supp. 3d 1168, 1172 (N.D. Ga. 2017) (concluding that plaintiff's

allegations were insufficient to put the various defendants on notice to her claims but proceeding to examine each of the claims in turn).

c. Count I (Strict Liability – Design Defect)

Because Plaintiff has sued AbbVie as the successor interest to TAP, if Plaintiff has stated a claim against TAP, she has stated a claim against AbbVie. The Court therefore analyzes whether Plaintiff has stated a claim against TAP in the SAC.

To state a claim for strict products liability under Georgia law, a plaintiff must allege that "(1) the defendant manufactured the allegedly defective product; (2) the allegedly defective product was not merchantable and reasonably suited for its intended use when the defendant sold it; and (3) the allegedly defective product proximately caused the plaintiff's injuries." *Edwards v. Wis. Pharmacal Co., LLC*, 987 F. Supp. 2d 1340, 1345 (N.D. Ga. 2013) (citing *Chi. Hardware & Fixture Co. v. Letterman*, 510 S.E.2d 875, 877–78 (Ga. Ct. App. 1999)); *Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1334 (N.D. Ga. 2012) (applying Georgia law). In other words, Plaintiff must establish "that the product or products that allegedly caused [the injury] were, in fact, manufactured or supplied by the defendants in this case." *Swicegood v. Pliva, Inc.*, 543 F. Supp. 2d 1351, 1355 (N.D. Ga. 2008) (quoting *Hoffman v. AC&S, Inc.*, 548 S.E.2d 379, 382 (Ga. Ct. App. 2001)). A defendant that is not the manufacturer of an allegedly defective product cannot be held strictly liable under a theory of strict liability. See *Vax v. Albany Lawn & Garden Ctr.*, 433 S.E.2d 364, 366 n.7 (Ga. Ct. App. 1993) (citing *Ellis v. Rich's, Inc.*, 212 S.E.2d 373, 376 (Ga. 1975)). But, any entity which actively participated in the conception, design, or specification of a product may be treated as the manufacturer. See *Davenport v. Cummins Alabama, Inc.*, 644 S.E.2d 503, 508 (Ga. Ct. App. 2007).

The Court's previous decision recognized that there is some doubt as to whether Abbott, TAP, or Takeda Ltd. manufactured the Lupron at issue in this case.

> The Court concludes that it is only appropriate on this motion to dismiss to consider the allegations that are set out in Plaintiff's complaint in analyzing whether Plaintiff has adequately stated a claim for each cause of action. Judge Gottschall assumed in her opinion that the parties agreed that Takeda Ltd. was the manufacturer, but Judge Gottschall did not specifically rule on summary judgment that Takeda Ltd. (and only Takeda Ltd.) was the manufacturer of Lupron.

See *Paulsen*, 2018 WL 1508532, at *14. AbbVie now argues that the court should dismiss Plaintiff's claims because she does not specifically allege whether Abbott or TAP was the manufacturer or designer of the product. Plaintiff responds by pointing to her allegations in Paragraph 25 of the SAC, set forth in the previous section.

Georgia courts have repeatedly explained that alleging that a group of defendants engaged in a laundry list of actions is not sufficient to state a claim that a particular defendant "is a manufacturer, distributor, supplier, or seller of the product at issue." See, e.g., *Brazil I*, 249 F. Supp. at 1337–38 (citing *Henderson v. Sun Pharm. Indus., Ltd.*, 2011 WL 4024656, at *5 (N.D. Ga. June 9, 2011)). In *Brazil I*, for example, the plaintiff simply referred to all defendants as "Defendants," *id.*, rather than identifying them by name as Plaintiff did here, see [143, ¶¶ 6, 25]. Additionally, Plaintiff has alleged that "TAP's purpose, pursuant to the joint venture agreement, was to develop, manufacture, market and sell human pharmaceutical products * * * including Lupron * * *." [143, ¶ 6.] Thus, the Court concludes that Plaintiff has alleged facts to show that TAP actively participated in the conception, design, or specification of Lupron.

Under Georgia law, "[t]there are three general categories of product defects: manufacturing defects, design defects, and marketing/packaging defects." *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 672 (Ga. 1994). The parties treat Count I as a design defect claim, and the court will do the same.

Before examining whether Plaintiff has adequately pled a design defect claim, the Court must consider Defendants' argument that conflict preemption bars design defect claims such as Plaintiff's. First, the Court agrees that any claims by Plaintiff that TAP should have changed the formulation of Lupron is preempted by FDA regulations that prohibit a change in the formulation of a drug once it has been approved. See *Brazil v. Janssen Research & Dev. LLC*, 196 F. Supp. 3d 1351, 1363 (N.D. Ga. 2016) (*Brazil II*) ("Any claim by Plaintiff that Defendants should change the formulation of Invokana is preempted by FDA regulations."). But, contrary to Defendants' argument, district courts in Georgia have allowed design defect claims to proceed where the argument is that a defendant "should be liable because a stronger warning would have changed [the drug's] risk-utility to make it not unreasonably dangerous."[13] *Id.* The Court agrees with this approach.

The question of whether the Supreme Court's decision in *Mutual Pharmaceutical Co., Inc. v. Bartlett*, 570 U.S. 472 (2013), preempts all state law design defect claims has divided federal courts across the country. See *Brazil I,* 249 F. Supp. 3d at 1341–48 (analyzing a preemption argument and collecting cases). However, the court's prior decision in the very case cited by AbbVie for the proposition that Count I is preempted, see [145, at 11 (citing *Brazil II*, 196 F. Supp. 3d at 1363)], concluded that some design defect claims are not preempted. *Brazil I*, 249 F. Supp. 3d at 1348. As *Brazil I* noted, *Bartlett*'s conclusion relied on the fact that FDA regulations prohibit generic drug manufacturers from making unilateral changes to their labels. *Id.* at 1347; see also *Bartlett*, 570 U.S. at 486–88. By contrast, FDA regulations allow drug manufactures some leeway to make changes unilaterally to the warning labels of brand name drugs like the ones at issue in

[13] Given that a failure to warn claim appears to be the only kind of design defect claim allowed in light of FDA regulations, it is not readily apparent to the Court how the design defect claim in Count I differs in any material way from Count II's failure to warn claim. However, at least one other court considering such claims have treated them separately, see e.g., *Brazil II,* 196 F. Supp. 3d at 1358–60. The Court will therefore do the same.

Brazil I and here. *Brazil I*, 249 F. Supp. 3d at 1342 (citing *Wyeth v. Levine*, 555 U.S. 555 (2009)). That difference is crucial because "[a] design defect claim under Georgia law [ ] allows a drug manufacturer to ameliorate the risks of danger of the drug and thus to fulfill its legal duty by improving the warnings attached to the product." *Brazil I*, 249 F. Supp. 3d at 1346. In *Bartlett*, preemption applied because federal law—which forbade any change to the generic drug's warning label—and state law—which required a change to the label—directly conflicted. 570 U.S. at 486–47. As *Brazil I* illustrates, in a situation involving a brand name drug, that is not the case and therefore a plaintiff may state a design defect claim.[14]

However, *Brazil I* also noted that a plaintiff must plead facts that establish there is in fact a design defect. *Id.* at 1337–38. In *Brazil I*, the plaintiff failed to allege such a defect given that she merely alleged that the drug could cause diabetic ketoacidosis, without providing any facts that tied that harm to a design or manufacturing defect. *Id.* at 1338. Referencing *Bailey v. Janssen Pharmaceutica, Inc.*, 288 Fed. App'x. 597, 607 (11th Cir. 2008), as persuasive authority, the court explained that the plaintiff should have provided at least some possible mechanisms for how the drug caused her injury. *Id.* at 1338 n.5.

Here, Plaintiff has simply alleged that "as a direct and proximate result of the defective and unsafe condition of Lupron, Plaintiff * * * [suffered] negative effects on bone mineral density, osteoporosis, and/or osteopenia." [143, ¶ 31.] As explained by *Brazil I*, simply alleging the harm that resulted from the use of drug is not sufficient to establish a design or manufacturing defect under Georgia law. The Court must therefore dismiss this claim against TAP and AbbVie as the alleged successor in interest to TAP.

[14] However, if discovery shows TAP did not, or its successor does not, in fact hold the New Drug Application ("NDA") from the FDA, then the claim would be preempted. See *Brazil II*, 196 F. Supp. 3d at 1364–65 ("When a company does not have the NDA, it has 'no more power to change the label' of a drug than a generic manufacturer.") (citation omitted).

d. Count II (Strict Liability – Failure to Warn)[15]

With regard to Count II, AbbVie again argues that the claim must be dismissed because Plaintiff has failed to allege which of the Defendants, specifically, was responsible for the manufacturing, designing, etc. of the Lupron in question. However, as noted above, Plaintiff's complaint specifically alleges that "TAP's purpose, pursuant to the joint venture agreement, was to *develop*, manufacture, market and sell human pharmaceutical products * * * including Lupron * * *." [143, ¶ 6.] Consequently, the Court looks to see if Plaintiff has sufficiently alleged facts to state a failure to warn claim against TAP.

Even if a product is not defective, a manufacturer of a product may still be liable under a strict liability failure to warn theory. *Brazil II*, 196 F.Supp.3d at 1359–60 (citing *Battersby v. Boyer*, 526 S.E.2d 159, 162 (Ga. Ct. App. 1999)). To plead such an action, a plaintiff must allege facts to show that "(1) the defendant knew, or had reason to know, that the product is likely to be dangerous for the intended use; (2) the defendant had no reason to believe that the user would realize the danger; and (3) the defendant failed to exercise reasonable care to inform the user about the danger." *Id.* at 1360 (quoting *Carmical v. Bell Helicopter Textron, Inc.*, 117 F.3d 490, 494–95 (11th Cir. 1997) (applying Georgia law)). In *Brazil II* for example, the court found the

[15] There seems to be a difference of opinion in Georgia courts whether to treat "failure to warn" claims as a strict liability or negligence-based tort. Compare *Schmidt v. C.R. Bard, Inc.*, 2014 WL 5149175, at *5 n.1 (S.D. Ga. Oct. 14, 2014) (Although Plaintiff styles his failure to warn claim as a strict liability claim, failure to warn under Georgia law is "based on a negligence theory of product liability.") (citation omitted), and *Henderson*, 2011 WL 4024656, at *4 (N.D. Ga. June 9, 2011) ("The Court construes Plaintiff's failure to warn claim as a claim for negligent failure to warn, not strict liability."), with *Brazil II*, 196 F.Supp.3d at 1360 ("[T]he Court rejects Defendant's contention that Plaintiff's strict liability failure to warn claim is based on a risk of an injury that she did not suffer."), and *Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1343 (N.D. Ga. 2012) ("[T]he Court dismisses plaintiff's claim for strict liability for failure to warn against Pfizer except as to the failure to warn the decedent's prescribing physician."). Still other courts treat them as two separate theories but analyze them together. See, e.g., *In re Cook Med., Inc. IVC Filters Mktg., Sales Practices & Prod. Liab. Litig.*, 2018 WL 6415585, at *2 n.1 (S.D. Ind. Dec. 5, 2018) (noting that under Georgia law failure to warn claims may proceed under either a strict liability or a negligence theory and collecting cases). Based on these cases, the Court concludes that such claims may proceed under either theory and will analyze them separately.

complaint sufficient where plaintiff had alleged some facts showing that shortly after the drug was released, numerous reports of adverse reactions were announced and that the defendants had actually warned against using the drug in question in certain patients, possibly showing they were aware of the adverse relationship. [*Id.* at 1360.]

Here, Plaintiff alleges on information and belief that as early as October 22, 1990, TAP and Abbott were aware of the continued bone loss incurred by users of Lupron. [143, ¶ 15.] Plaintiff also points to an April 1998 report that TAP submitted to the FDA in which researchers disclosed that more than a third of the women in their study who had taken Lupron "did not 'demonstrate either partial reversibility' or 'a trend toward return' of bone mass in the six months after they stopped taking the drug." [*Id.* ¶ 14.] Finally, Plaintiff points to the fact that in 2001 the FDA approved a "Lupron 'add-back therapy,' designed to counteract the harmful bone-depleting effects of Lupron." [*Id.* ¶ 15]. Although, as in *Brazil II*, the question is close, the Court concludes that these facts are sufficient to show that TAP/Abbott knew that there was a substantial risk of bone depletion with Lupron.

With regard to the latter two elements, Plaintiff has alleged that "the warnings and information which were given to the medical community and women consumers did not accurately reflect the severity and permanence of symptoms, duration, scope, or severity of the potential side effects, health concerns, and risks of Lupron." [143, ¶ 35.] "Had adequate warnings or instructions regarding permanent bone loss side effects been provided, Plaintiff would not have used, taken, or received administration of Lupron, and would not have suffered the harmful side effects, other injuries and damages described herein." [*Id.* ¶ 38.] Plaintiff further alleges that an "Abbott detail person, who visited [Plaintiff's physician's] office, characterized Lupron as appropriate, safe and effective for patients with her medical condition [(endometriosis)]." [*Id.* ¶ 21.] According to

Plaintiff, "neither she nor her physician were made aware, by Abbott or TAP, of the serious threat to her bone health posed by the use of Lupron for her endometriosis."[16] [*Id.*] Plaintiff concludes that she would have never taken Lupron if she had been apprised of the risks involved. [*Id.* ¶ 38.] The allegations suffice to plead a failure to warn claim. Compare [143, ¶¶ 21, 35, 38, 39] with *Brazil II*, 196 F. Supp. 3d at 1360–61 (allowing claim to proceed where plaintiff alleged that (1) defendants had made the warning stronger since plaintiff took the drug; (2) defendants failed to warn plaintiff's physicians of the risks posed by the drug; (3) safer alternatives were available; (4) plaintiff was not warned of the benefits and risks of the drug; and (5) plaintiff would not have taken the drug if she had been fully informed). Consequently, the motion to dismiss Count II is denied as to AbbVie as successor in interest to TAP.

e. Count III (Negligence)

AbbVie next argues that Plaintiff's complaint is too vague and conclusory to plead any of the elements of a negligence claim under governing law. In Georgia, to state a claim for negligence, a Plaintiff must allege: (1) "a legal duty to conform to a standard of conduct raised by the law for the protection of others against unreasonable risks of harm;" (2) "a breach of this standard;" (3) "a legally attributable causal connection between the conduct and the resulting injury;" and (4) "some loss or damage flowing to the plaintiff's legally protected interest as a result of the alleged breach of the legal duty." *Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337, 1351 (N.D. Ga. 2012) (quoting *Dixie Grp., Inc. v. Shaw Indus. Grp.*, 693 S.E.2d 888, 895 (Ga. Ct. App. 2010)). Georgia law recognizes two negligence-based causes of action in the products liability context:

[16] Importantly, to state a claim—and eventually succeed on her claim—Plaintiff must show that her physician was inadequately informed given Georgia adheres to the learned intermediary doctrine in failure to warn cases. *Frazier v. Mylan Inc.*, 911 F. Supp. 2d 1285, 1290 (N.D. Ga. 2012) ("Third, the learned intermediary doctrine would still bar plaintiff's claim because it only requires a duty to warn the physician."); see also *Bartlett v. Mut. Pharm. Co., Inc.*, 2010 WL 3659789, at *6 (D.N.H. Sept. 14, 2010) (rejecting the plaintiff's failure to warn claim based on not issuing a medication guide because there was no support that medication guides warrant a special exception to the learned intermediary doctrine). Whether or not Plaintiff received the information is therefore immaterial.

(1) the sale of a defective product and (2) failure to warn of the product's dangers. *Edwards*, 987 F. Supp. 2d at 1344. These causes of action implicate separate duties on the part of the product manufacturer—the duty to exercise reasonable care in manufacturing products so that they are reasonably safe for intended and foreseeable uses, and the duty to warn the public of those damages arising from their products' use about which they know or reasonably should know. *Id.* Otherwise, these causes have the same elements, see *id.* (citing *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994)), although failure-to-warn negligence claims in the context of pharmaceuticals are constrained by the learned intermediary doctrine. See *Frazier v. Mylan Inc.,* 911 F. Supp. 2d 1285, 1289 (N.D. Ga. 2012). Negligence-based products liability claims differ from those that sound in strict liability because negligence-based claims focus on the actions of the defendant, while strict liability claims focus on the product itself. *Butts v. Stryker Corp.*, 2014 WL 12772370, at *3 n.5 (S.D. Ga. June 30, 2014) (applying Georgia law).

Plaintiff's allegations are once again insufficient to state a claim for negligence. Plaintiff again lists various acts that purportedly constitute negligence by TAP and Abbott, including negligently (1) "formulating, analyzing, designing, fabricating manufacturing, supplying, distributing, advertising, promoting, packaging, marketing, selling and recommending Lupron in its defective condition, Defendant Abbott and TAP knew or should have known;" (2) "failing to identify, eliminate, and/or reduce the risks and hazards associated with the intended and foreseeable use of the Lupron;" and (3) "failing to advise Plaintiff and her physician the dangers associated with the use of Lupron." [143, ¶¶ 45(a)–(c).] While Plaintiff has now alleged various specific duties that those negligent acts allegedly breached, see [*id.* ¶¶ 42–43], as the Court noted in its analysis of Count I above, Plaintiff has still not pled any facts to show how exactly Abbott or TAP were negligent as it pertains to any manufacturing or design errors.

By contrast, the specific risks allegedly posed by Lupron laid out in the SAC, see [*id.* ¶¶ 44(a)–(c)], do support the conclusion that Abbott/TAP had a duty to warn Plaintiff's physician of those risks.[17] However, Plaintiff's allegation that Abbott/TAP failed to advise her physician of the dangers associated with the use of Lupron is simply too conclusory to state a claim.[18] *Cf. Henderson*, 2011 WL 4024656, at *4 (allowing a negligent failure to warn claim where plaintiff alleged (1) defendants knew or should have known of the risks of a drug based on the specific studies and data available; (2) defendants failed to provide adequate warnings that the use of the drug could increase the risk of the specific side effects plaintiff suffered; (3) defendants failed to add information or warnings regarding the particular danger of those side effects to members of certain racial groups to which plaintiff belonged; and (4) "[Plaintiff] and his prescribing physician" relied on the incomplete 'representations made on the product labels and other promotional and sales materials.'").

Plaintiff has not provided any factual detail about what the warning label did or not did not state, and the Court simply cannot infer negligence where a plaintiff has not provided any factual details about either a defendant's action(s)—*i.e.* what they or their agents said or failed to say—and how those actions influenced Plaintiff's *physician's* decision to inject her with Lupron. The Court will therefore grant the motion to dismiss as to Count III.

[17] As already noted above, under Georgia law, pharmaceutical manufactures have no duty to inform individual plaintiffs themselves. Rather, they only have a duty to inform plaintiffs' physicians under the learned intermediary doctrine. See *Frazier*, 911 F. Supp. 2d at 1290; *Bartlett*, 2010 WL 3659789, at *6. Thus, to the extent Plaintiff's complaint suggests otherwise, those allegations are stricken.

[18] Moreover, Plaintiff does not even raise the conversation during which she alleges an Abbott detail person had with her physician a prior to her injection in which the detail person "characterized Lupron as appropriate, safe and effective for patients with her medical condition." [143, ¶ 21.] Even if she had, the allegation does not change the Court's conclusion. The Court cannot impute the actions of one defendant's agent to its codefendant without some plausible basis for doing so and Plaintiff has not provided such a basis.

f. Count V (Negligent Misrepresentation)

Finally, AbbVie argues that Plaintiff has still failed to state a claim for negligent misrepresentation against TAP, and therefore it. To state a claim for negligent misrepresentation, Plaintiff must show "'(1) the defendant's negligent supply of false information to foreseeable persons, known or unknown; (2) such persons' reasonable reliance upon that false information; and (3) economic injury proximately resulting from such reliance.'" *Marquis Towers, Inc. v. Highland Grp.*, 593 S.E.2d 903, 906 (Ga. Ct. App. 2004) (quoting *Hardaway Co. v. Parsons, Brinckerhoff, Quade & Douglas, Inc.*, 479 S.E.2d 727, 729 (Ga. 1997)). This type of claim "stems from the policy that '[o]ne who supplies information during the course of his business, profession, employment, or in any transaction in which he has a pecuniary interest has a duty of reasonable care and competence to parties who rely upon the information in circumstances in which the maker was manifestly aware of the use to which the information was to be put and intended that it be so used.'" *Swicegood v. Pliva, Inc.,* 543 F. Supp. 2d 1351, 1356 (N.D. Ga. 2008) (quoting *Benefit Support, Inc. v. Hall Cty.*, 637 S.E.2d 763, 773 (Ga. Ct. App. 2006)). In Georgia, "a negligent misrepresentation claim is viable only when a plaintiff can allege and prove direct communication with a defendant and specific reliance on that defendant's communication." *Patel v. Patel*, 761 F. Supp. 2d 1375, 1382 (N.D. Ga. 2011) (citing *Holmes v. Grubman*, 691 S.E.2d 196, 200 (Ga. 2010)).

The Court previously dismissed this claim because Plaintiff had not identified any specific misrepresentations by Abbott or TAP on which Plaintiff relied. See *Paulsen*, 2018 WL 1508532, at *18. Plaintiff asserts that the claim should now survive the claim because she now pled that

> [A] few days before her injection with Lupron, an Abbott drug detail person personally contact Plaintiff's physician, Dr. Perry[,] at his office * * * and expressly represented the safety and effectiveness of Lupron[,] that [it] would effectively treat

> Plaintiff's reproductive tract ailment, [and] that there is [sic] no long term adverse effect.

[143, ¶ 50.] As AbbVie correctly points out, however, this allegation was not included in her negligent misrepresentation count, except by a reference to all the other allegations in her complaint. That is a dangerous way to proceed, for it is neither this Court's, nor the Defendants', duty to "piece together allegations and construct a claim it suspects a plaintiff might have intended to bring." *Intellicig USA LLC v. CN Creative Ltd.*, 2016 WL 5402242, at *10 (N.D. Ga. July 13, 2016). Nonetheless, the Court will consider this allegation in its determination of the sufficiency of plaintiff's complaint of negligent misrepresentation. Having done so, the Court concludes plaintiff has still failed to state a claim.

First, multiple district courts, applying Georgia law, have held that "Georgia does not recognize a claim for misrepresentation apart from a failure to warn claim in products liability cases." *In re Bard IVC Filters Prod. Liab. Litig.*, 2018 WL 1256768, at *7 (D. Ariz. Mar. 12, 2018) (citing *Brazil I*, 249 F. Supp. 3d at 1340 and *Swicegood*, 543 F. Supp. 2d at 1357 ("In the absence of clear precedent, I am not prepared to recognize the viability of misrepresentation claims distinct from products liability or failure to warn claims. In my view, misrepresentation claims against a manufacturer properly collapse into the failure to warn claims.")); but see *Lee v. Mylan Inc.*, 806 F. Supp. 2d 1320, 1325 (M.D. Ga. 2011) ("the Defendants' motion and the Parties' briefs do not address whether the Plaintiff can state a claim based upon negligent misrepresentations to others, [ ] and the Court declines to go down that path on its own.") (footnote omitted). However, given (1) the split of Georgia authority cited above and (2) the fact that Defendants did not raise this argument until a footnote in their reply brief. [177, at 13 n.6.], the Court will not dismiss the claim on this ground despite its skepticism that Plaintiff may actually pursue such a claim.

Instead, the Court will dismiss the claim against AbbVie because Plaintiff has still not identified any specific misrepresentations by TAP on which Plaintiff's physician relied.[19] Plaintiff again generally alleges that her physicians "detrimentally relied on Defendants' misrepresentations in treating Plaintiff with Lupron," but only identifies one specific misrepresentation. And, that single misrepresentation was purportedly made by an agent of Abbott, not TAP. Although Plaintiff need not plead these claims with specificity, she must still meet the plausibility standard of Rule 8. *Paulsen*, 2018 WL 1508532, at *18. Without allegations pointing to statements by TAP on which Plaintiff's physician relied before injecting Plaintiff with Lupron, Plaintiff's complaint does not provide AbbVie with notice of the basis for the negligent misrepresentation claims against it under Rule 8's pleading standard.

3. Defendant Abbott

Abbott moves to dismiss every cause of action in Plaintiff's complaint on two grounds: first, that it cannot be held liable as the successor in interest to AbbVie; and second, for failure to state a claim.

a. Liability as Successor in Interest and Failure to Plead Each Defendant's Actions Independently

First, Abbott moves to dismiss all the claims against it to the extent Plaintiff asserts that Abbott is liable as the successor in interest to TAP. As explained above, based on Plaintiff's amended complaint, the Court can only conclude that AbbVie is the proper successor in interest to TAP. Thus, Plaintiff may not state a claim against Abbott as the successor in interest to TAP.

Additionally, like AbbVie, Abbott moves to dismiss all the claims against it because Plaintiff has not sufficiently pled what each defendant allegedly did to harm her. But Plaintiff

[19] Again, assuming that negligent misrepresentation is a viable claim under Georgia law, Georgia adheres to the learned intermediary doctrine which "clearly eliminates any duty to warn patients," *Lee*, 806 F. Supp. 2d at 1324, thus Plaintiff must allege a negligent misrepresentation to her physician to state a claim.

named both Abbott and TAP in nearly every one of her allegations of wrongdoing. Moreover, as explained above, even if the Court were inclined to dismiss the claims against Abbott on that ground, it would be with leave to replead. Rather than simply have Plaintiff duplicate each paragraph as to each defendant, the Court will look to see if Plaintiff has adequately pled facts that state a claim against Abbott.

b. Counts I & III (Strict Liability – Design Defect & Negligence)

Counts I and III fail against Abbott for the same reasons they failed against TAP (AbbVie). In Count I, Plaintiff has simply not alleged any facts to show a design defect. Likewise, in Count III, Plaintiff has not provided any more factual basis for the Court to conclude that Abbott acted negligently than she did with regard to TAP.[20] Consequently, both Counts I & III are dismissed as to Abbott as well.

c. Count II (Strict Liability – Failure to Warn)

Although the Court has concluded that Plaintiff may proceed on Count II against AbbVie, whether she may proceed against Abbott is a much more difficult question. The question is whether Plaintiff has properly alleged facts such that the Court may treat Abbott as the manufacturer of Lupron. Unlike TAP—whose purpose under the joint venture agreement between Takeda Ltd. and Abbott was allegedly to develop, manufacture, market and sell products, including

[20] Plaintiff did not include the allegation regarding the alleged misrepresentation by an Abbott drug detail person, see [143, ¶ 50], in the section of her complaint regarding Abbott's alleged negligence, see [*id.* ¶¶ 41–47]. Nor did she raise this allegation in her response to Defendant's motion to dismiss. Consequently, she has waived any argument that that allegation should preclude the dismissal of her negligence claim. *Lane v. Money Masters, Inc.*, 2015 WL 225427, at *12 (N.D. Ill. Jan. 15, 2015) ("A party waives an argument against dismissal by failing to make it."); *Intellicig USA LLC v. CN Creative Ltd.*, 2016 WL 5402242, at *10 (N.D. Ga. July 13, 2016) ("It is not the Court's duty to piece together allegations and construct a claim it suspects a plaintiff might have intended to bring."); see also *G & S Holdings LLC v. Cont'l Cas. Co.*, 697 F.3d 534, 538 (7th Cir. 2012) ("The obligation to raise the relevant arguments rests squarely with the parties, because * * * [o]ur system of justice is adversarial, and our judges are busy people. If they are given plausible reasons for dismissing a complaint, they are not going to do the plaintiff's research and try to discover whether there might be something to say against the defendants' reasoning."). And, the allegation that was included by reference in Count III, that an Abbott detail person's representation that Lupron was "appropriate, safe and effective" for Plaintiff's condition, [143, ¶ 21], is simply too vague to state a claim for negligence. See *Twombly*, 550 U.S. at 555.

Lupron, [143, ¶ 6]—Plaintiff merely alleges that Abbott and TAP, "jointly, severally, acting in concert * * * manufactured, compounded, tested, distributed, recommended, marketed, labeled and packaged, merchandised, advertised, promoted, [and] sold" the Lupron she was injected with, [*id.* ¶ 25]. The question is whether the Court must, or may, take notice of additional information put forward by the parties in the previous motion for summary judgment, and in support and defense of the now withdrawn motion for sanctions.

First, Judge Gottschall concluded on a motion for summary judgment that there was a genuine issue of material fact whether Abbott was a proper party at interest in this lawsuit. See [95, at 12 ("the court finds that genuine issues of material fact exist as to whether Abbott's involvement Abbott's involvement in Lupron's distribution was sufficient" for a finding of liability)]. However, that ruling assumed Illinois strict liability law applied, and as this Court subsequently determined, Georgia law applies to the substantive claims in this case. *Paulsen*, 2018 WL 1508532, at *11–13. Unlike Illinois, which holds all "'all persons in the distributive chain are liable for injuries resulting from a defective product, including suppliers, distributors, wholesalers[,] and retailers,'" [95, at 7 (quoting *Smith v. Phoenix Seating Sys., LLC,* 894 F. Supp. 2d 1088, 1093 (S.D. Ill. 2012))], Georgia law only allows strict liability claims against those who manufactured the product or who actively participated in the conception, design, or specification of the product, see *Vax*, 433 S.E.2d at 366 n.7; *Davenport*, 644 S.E.2d at 508. The Georgia strict liability law explicitly excepts "those who package, label, or market the product." *In re Stand "N Seal, Prod. Liab. Litig.*, 2009 WL 2145911, at *3 (N.D. Ga. July 15, 2009). While Judge Gottschall previously determined that Abbott had a role in the distribution of TAP's product line and was thus subject to liability under Illinois law, she did not determine whether it could liable as a non-

manufacturer under Georgia law. Thus, that decision does not provide the law of the case regarding the propriety of holding Abbott strictly liable as a manufacturer.

The more difficult question is whether the Court should, or even may, take judicial notice of all the documents that Plaintiff submitted in response to Defendants' motion for sanctions. Unlike a motion for sanctions in which a court may consider materials outside the pleadings, see *Triad Assocs., Inc. v. Chicago Hous. Auth.*, 892 F.2d 583, 596 n.10 (7th Cir. 1989), abrogated on other grounds by *Bd. of Cty. Comm'rs, Wabaunsee Cty., Kan. v. Umbehr*, 518 U.S. 668 (1996), a motion under Rule 12(b)(6) can only be based on "the complaint itself, documents attached to the complaint, documents that are critical to the complaint and referred to in it, and information that is subject to proper judicial notice," *Geinosky v. City of Chicago*, 675 F.3d 743, 745 n.1 (7th Cir. 2012). As the Seventh Circuit in *Geinoksy* went on to explain, however, "a plaintiff * * * has much more flexibility in opposing a Rule 12(b)(6) motion and in appealing a dismissal." *Id.* Indeed, "a party opposing a Rule 12(b)(6) motion may submit materials outside the pleadings to illustrate the facts the party expects to be able to prove." *Id.* However, the miscellaneous documents providing insight into the various Defendants' roles in the design, manufacturing, marketing, distribution, etc. of Lupron were not attached to any of Plaintiff's responses to the Defendants' motions to dismiss, but rather to her response to the motion for sanctions. If Plaintiff had attached the documents to her responses to the Defendants' motions to dismiss, the Court could easily consider them. However, the parties have not briefed the issue of whether documents submitted in response to a motion for sanctions may be considered by the Court in its resolution of the motion to dismiss without converting the instant motion into a motion for summary judgment. See *Geinosky*, 675 F.3d at 745 n.1.

Additionally, none of the cases cited by Defendants stand for the proposition that where a plaintiff has explicitly named a Defendant and alleged that they had some role in a laundry list of actions without providing any more specific details, the Court should dismiss the case as a matter of law. For example, *Quashie v. Olympus Am., Inc.* the court explained that

> Although Plaintiff insisted at the hearing that all Defendants here are somehow involved in the manufacturing, production, and sale of the Q180V, the Amended Complaint contains no specific facts to support this assertion.[ ] This general pleading prevents the Defendants from knowing which one or which ones Plaintiff alleges to have manufactured a defective product.

315 F. Supp. 3d 1329, 1341–42 (N.D. Ga. 2018). Although Abbott asserts that this holding stands for the proposition outlined above, the Court concludes that the *Quashie* court's real concern was with Quashie's "group pleading" given its prior comment that "[b]ecause Plaintiff refers only to Defendants as a group, it is impossible to discern from the face of the Amended Complaint which Defendant allegedly breached what duty or committed what tortious act." *Id.* at 1341; see also *Brazil I*, 249 F. Supp. 3d at 1337 ("the Complaint generically states '[d]efendants * * *'"); *Barnes*, 253 F. Supp. 3d at 1171–72 (noting that plaintiff had failed to properly give the defendants notice of their alleged wrongdoing, but examining the substance of the claims nonetheless). Here by contrast, there are only two defendants and Plaintiff alleges that they both can be treated as a manufacturer for purposes of strict product liability.

In sum, for the reasons explained above, the Court declines to dismiss Count II against Abbott at this time.

d. Count V (Negligent Misrepresentation)

Unlike AbbVie, as to which Plaintiff has not provided any specific representations, Plaintiff alleges that an Abbott drug detail person contacted her physician at his office in Athens Georgia and "expressly represented the safety and effectiveness of Lupron[,] that [it] would effectively treat Plaintiff's reproductive tract ailment, [and] that there [would be] no long term

adverse effect." [143, ¶ 50.][21] Abbott asserts that even with this allegation, Plaintiff's complaint still fails to state a claim.[22]

As the Court has previously explained, all of Plaintiff's claims are constrained by the learned intermediary doctrine. See, e.g., *Catlett v. Wyeth, Inc.,* 379 F.Supp.2d 1374, 1381 (M.D. Ga. 2004) ("It is clear that Georgia courts would find the 'learned intermediary rule' encompasses any fraud, fraudulent concealment, misrepresentation, failure to warn or breach of warranty claims related to the sale and use of prescription drugs."). Thus, Plaintiff may only state a claim, if any, for negligent misrepresentation if (1) Abbott or its agents negligently supplied false information to Plaintiff's physician, (2) the physician reasonably relied on that representation when deciding whether to administer Lupron to Plaintiff, and (3) Plaintiff suffered an economic harm as a result of that reliance. See *Marquis Towers, Inc.*, 593 S.E.2d at 906 (providing the elements of negligent misrepresentation under Georgia law).

Abbott asserts that the claim fails because Plaintiff has pled no facts to show that her prescribing physician would have made a different decision if he had received different information. [177, at 13.] Abbott has not, however, provided any case law to support that proposition. Thus, the Court must simply look to the allegations on their own merits.

First, although the question is an extremely close one, the Court concludes that the Abbott agent's alleged representation that Lupron had no long-term adverse effects when as discussed

[21] While Abbott asserts that Plaintiff has not properly integrated this allegation into her claim, she affirmatively incorporated this allegation from her fraudulent misrepresentation claim into her negligent misrepresentation claim. See [143, ¶ 58 (incorporating by reference paragraphs 1–57).] Moreover, Plaintiff expressly raised this allegation in her opposition to Abbott's motion to dismiss, see [162, at 13], and using a response to call attention to a fact already incorporated by reference in one's complaint cannot be construed as amending the complaint.

[22] As previously explained, several courts have concluded that a plaintiff cannot state a misrepresentation claim in the pharmaceutical products liability context. See *supra* Section III(B)(2)(f). However, given the issue is not properly before it, the Court cannot dismiss the claim on that ground. See *id*. Defendants are not, however, foreclosed from raising this argument in a subsequent motion for summary judgement.

above, Defendants knew or should have known of a significant risk of long-term, permanent bone depletion constitutes the negligent supply of false information. Plaintiff has also alleged that Plaintiff's physicians relied on that representation, among others, when deciding to treat Plaintiff with Lupron. [143, ¶ 61.] And, finally Plaintiff has certainly alleged that she suffered an economic injury. In light of these allegations, the Court concludes that Plaintiff has alleged sufficient facts to survive a motion to dismiss.

e. Count IV (Fraudulent Misrepresentation)

Abbott asserts that Plaintiff's allegations to support her claim of fraudulent misrepresentation sill do not meet the heightened pleading standards of Rule 9 to state a claim. Specifically, Abbott asserts, among other things, that Plaintiff has failed to adequately plead scienter.

To state a claim for fraud under Georgia law, Plaintiff must allege "(1) a false representation by the defendant; (2) scienter; (3) intention to induce the plaintiff to act or refrain from acting; (4) justifiable reliance by the plaintiff[;] and (5) damage to the plaintiff." *Barnes*, 253 F. Supp. 3d at 1175 (citation omitted). Furthermore, when alleging fraud, a plaintiff must satisfy the pleading standard of Rule 9(b), which requires a party to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "To satisfy the heightened pleading standard of Rule 9(b), the circumstances [of the alleged misrepresentation] must be pleaded in detail. The who, what, when, where, and how: the first paragraph of any newspaper story." *Blankenship v. Pushpin Holdings*, LLC, 2015 WL 5895416, at *7 (N.D. Ill. Oct. 6, 2015) (internal quotation marks omitted; citing *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)). Rule 9(b) specifically requires alleging with particularity: "the identity of the person making the misrepresentation, the time, place, and content of the misrepresentation, and the

method by which the misrepresentation was communicated to the plaintiff." *Id.* (quoting *U.S. ex rel. Grenadyor v. Ukranian Vill. Pharmacy, Inc.*, 772 F.3d 1102, 1106 (7th Cir. 2014)).

Under Georgia law, an allegation that defendants knew or should have known that their statements were false asserts constructive knowledge, not the scienter required for fraud. *WESI, LLC v. Compass Envtl., Inc.*, 509 F. Supp. 2d 1353, 1359 (N.D. Ga. 2007) (citing *Hertz Corp. v. Cox,* 430 F.2d 1365, 1375 (5th Cir. 1970)). An allegation that a defendant knew or should have known something is "lacking at least in the essential averment that the defendants had actual knowledge" of the falsity. *Hertz Corp.*, 430 F.2d at 1375. For example, in *WESI, LLC*, the counter-plaintiffs alleged that that the counter-defendant knew or should have known whether certain developments had made the completion of the project in question impossible. 509 F. Supp. 2d at 1359. However, the specific fraud allegations acknowledged that the counter-plaintiffs were uncertain whether the counter-defendants actually knew or merely should have known the facts at issue. *Id.*

As in *WESI, LLC*, Plaintiff's allegations are insufficient to state a claim for fraudulent misrepresentation. Plaintiff first alleges that Abbott "knew or should have known * * * the specific representation to Plaintiff's physician * * * was false." [143, ¶ 51.] She then alleges that Abbott knew or should have known "that serious long-term health problems are associated with Lupron." [*Id.* ¶ 51.] In fact, nowhere in her entire complaint does Plaintiff ever specifically allege that Abbott or any other defendant knew of the harmful side effects of Lupron that could possibly affect women and did affect Plaintiff. Rather, at every point in the SAC, Plaintiff has alleged that the Defendants knew or should have known of these dangers. These are exactly the kind of allegations that *Hertz Corp.*, *WESI, LLC*, and other courts have specifically found insufficient to state a claim for fraud under Georgia law. *Hertz Corp.*, 430 F.2d at 1375; *WESI*, *LLC*, 509 F. Supp. 2d at 1359;

see also *Edelen v. Campbell Soup Co.*, 2008 WL 11324064, at *10 (N.D. Ga. Sept. 25, 2008), report and recommendation adopted, 2008 WL 11337304 (N.D. Ga. Dec. 10, 2008); *CAR Transportation Brokerage Co., Inc. v. John Bleakley R.V. Ctr., Inc.*, 2008 WL 11416958, at *5 (N.D. Ga. Sept. 25, 2008), aff'd sub nom. *Car Transp. Brokerage Co. v. Blue Bird Body Co.*, 322 F. App'x 891 (11th Cir. 2009). Consequently, the Court will grant Abbott's motion as to Count IV.

4. Fraud on the FDA Allegations

In paragraphs 20 and 54 of her complaint, Plaintiff alleges that TAP/Abbott made affirmative and/or negligent misrepresentations to the FDA regarding Lupron. [143, ¶¶ 20, 54.] Any claims based on those allegations are preempted by the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, which held that "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." 531 U.S. 341, 348 (2001). The Court therefore strikes those allegations from the complaint to the extent they allege TAP/Abbott made misrepresentations to the FDA.

5. Leave to Amend

Finally, Defendants request that any and all dismissals be with prejudice. In deciding whether to dismiss with prejudice (and foreclose any attempts to amend the complaint) this Court is mindful that the Court should "freely give leave [to amend] when justice so requires." Fed. R. Civ. P. 15(a)(3). However, leave is not to be automatically granted. *Johnson v. Cypress Hill,* 641 F.3d 867, 871 (7th Cir. 2011). Courts have broad discretion to deny amendment where there is undue delay, bad faith, dilatory motive, repeated failure to cure deficiencies, undue prejudice to the defendants, or where the amendment would be futile. *Id.* at 871–72.

Here, Plaintiff has now had three attempts to plead in this case, multiple opportunities in the previous case, and the opportunity to conduct at least some discovery in the prosecution of the previous motion to dismiss. The Court has now twice concluded that she has alleged sufficient facts to proceed on at least some of her claims. At this point, the Court is convinced that any further repleading as to TPUSA would be futile, given that Plaintiff's allegations clearly show AbbVie to be TAP's only possible successor in interest.

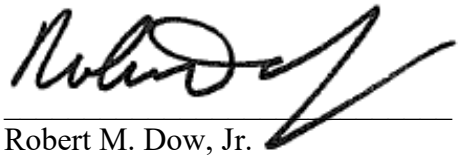
With regard to Abbott and AbbVie, after three complaints the Court is convinced that another complaint and a further round of motions to dismiss would be a waste of judicial resources. The events at issue in this case occurred in 2004, were discovered in 2008, were first subject to suit in 2010, reasserted in a refiled suit in 2015, addressed in motion for summary judgment in 2017, a motion to dismiss in 2018, and now, finally, a second motion to dismiss in 2019. It is time to move this case forward. Consequently, the Court will not consider any motion for leave to file an amended complaint until the parties resolve the issues flagged by Defendants in this latest round of briefing that go to the heart of this action's viability, namely: (1) whether the entire suit is untimely; (2) whether the complaint as to AbbVie may relate back; and (3) the actual roles played by Abbott and TAP vis-à-vis the manufacturing, packaging, and distribution of Lupron. However, at the end of that discovery and the resolution of any motions for summary judgement, should Plaintiff discover facts that lead her to conclude that she should amend her complaint, she may file a motion seeking leave to file an amended complaint.

IV. Conclusion

For the reasons explained above, Defendants' motions [144; 147; 150] are granted in part and denied in part. Pursuant to Federal Rule of Civil Procedure 12(b)(5), TAP is dismissed from this action with prejudice. With regard to Defendants' motions under Rule 12(b)(6), all Counts

against TPUSA as successor in interest to TAP are dismissed with prejudice; all claims but Count II against AbbVie are dismissed; and all claims but Counts II & V against Abbott are dismissed. The Court sets this matter for further status on April 8, 2019 at 10:00 a.m. to set a schedule for limited discovery regarding: (1) when Plaintiff's claim accrued; (2) whether the second amended complaint as to AbbVie properly relates back under Rule 15(c)(3); and (3) the roles of the remaining defendants vis-à-vis the manufacturing and development of Lupron. The parties should submit a joint status report and a proposed schedule for limited discovery no later than April 4, 2019. Finally, as an administrative matter, the motion for Rule 11 Sanctions by AbbVie, Abbott, and TPUSA [153] is stricken without prejudice in light of the notice of withdrawal filed on October 30, 2018 [180].

Dated: March 19, 2019



Robert M. Dow, Jr.
United States District Judge