IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

IN RE: Paragard IUD Products Liability Litigation	:	CIVIL ACTION NO. 1:20-md-02974-LMM

ORDER

This multi-district litigation ("MDL") involves the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. Dkt. No. [79] at 1 & ¶¶ 30, 51, 72, 85. The matter is presently before the Court on the Motion to Dismiss Plaintiffs' Second Amended Master Personal Injury Complaint,[1] filed by defendants Teva Pharmaceuticals USA, Inc. ("Teva USA"); Teva Women's Health, LLC; Teva Branded Pharmaceutical Products R&D, Inc.; The Cooper Companies, Inc.; and CooperSurgical, Inc. Dkt. No. [89].

[1] For simplicity's sake, the Court refers to the Second Amended Master Personal Injury Complaint, Dkt. No. [79], as "the complaint."

Defendants filed the motion to dismiss on May 6, 2021. Dkt. No. [89]. Plaintiffs have filed a response brief in opposition to the motion, Dkt. No. [136], and Defendants have filed a reply brief in support of the motion, Dkt. No. [162]. The Court heard oral argument on September 21, 2021. Dkt. No. [218]. After due consideration, the Court enters the following Order.

I. BACKGROUND[2]

Paragard is a non-hormonal, non-surgical IUD that is placed into a woman's uterus by a healthcare provider. Dkt. No. [79] ¶¶ 30-31. It is composed of copper wire wrapped around a T-shaped plastic frame. Id. ¶ 31. The copper is intended to produce an inflammatory reaction that disrupts sperm transport and egg fertilization and prevents a woman from getting pregnant. Id. A thin thread tied through the tip of each Paragard is intended to aid in the easy detection and non-surgical removal of Paragard from a woman's body. Id.

Each Plaintiff in this MDL is a woman who had a Paragard break while it was still inside her body. Id. ¶¶ 11, 14, 148, 150. Plaintiffs allege that Paragard is prone to break inside a woman's body, partly because the product is insufficiently flexible. Id. ¶ 52. Unlike other IUDs, "Paragard's arms have no curvature and are fixed, straight plastic arms bonded to [a] plastic vertical post," which results in a less flexible product. Id. ¶¶ 51, 62. Plaintiffs contend this unique, rigid, T-shaped

[2] For the purposes of this Order, the Court accepts as true the well-pleaded facts alleged in the complaint and construes all reasonable inferences from those facts in favor of Plaintiffs. See infra Part II.

design is prone to snap at the arms, causing Paragard to break more than any other IUD on the market in the United States. Id. ¶¶ 51, 53, 62. Plaintiffs state the inflexibility is also partly caused by the raw plastic not meeting minimum flexibility requirements. Id. ¶¶ 37, 54. Plaintiffs allege that because of these flaws, Paragard breaks in the body before or during removal and has caused their injuries. Id. ¶¶ 62, 148-54.

Plaintiffs further allege that Defendants knew or should have known that Paragard could cause and did cause serious harm to women due to its propensity to break in utero or during removal but that Defendants failed to adequately warn of these risks. Id. ¶¶ 64-69. Specifically, they aver that between 2009 and 2020, Defendants received reports of over 2000 Paragard breaks, which should have put them on notice of disproportionally frequent breakage, but that Defendants failed to properly investigate, record, or submit those reports to the FDA and failed to amend the label to warn (1) that Paragard is prone to break, including during removal, even when it is neither embedded in nor has perforated the uterus; (2) of the frequency with which such breakages occur; and (3) of the severe injuries—including infertility—that can result from such breakages. Id. ¶¶ 6, 7, 68-70, 78-81, 97-102, 120-21. They additionally contend that Paragard undertook a concerted marketing campaign to promote Paragard as a safe, effective, and easily reversible form of non-surgical birth control. Id. ¶¶ 9, 30, 75-77.

Plaintiffs also allege that they suffered injuries from Paragard's manufacturing defects, which resulted from Defendants' failure to comply with Current Good Manufacturing Practices ("CGMPs") and their own Standard Operating Procedures ("SOPs"). Id. ¶¶ 129-47.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 8(a)(2) requires that a pleading contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). While this pleading standard does not require "detailed factual allegations," the Supreme Court has held that "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 Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

To withstand a Rule 12(b)(6) motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Id. (quoting Twombly, 550 U.S. at 570). "Plausibility" requires more than a "sheer possibility that a defendant has acted unlawfully" or the "mere possibility of misconduct," and a complaint that alleges facts that are "merely consistent with" liability "stops short of the line between possibility and plausibility of entitlement to relief." Iqbal, 556 U.S. at 678-79 (quotation marks omitted). A complaint is plausible on its face when the plaintiff pleads factual content necessary for the court to draw the reasonable inference that the defendant is liable for the conduct alleged. Id. (citing Twombly, 550 U.S. at 556).

In other words, the well-pleaded allegations in the complaint must contain factual allegations sufficient to "nudge[] [a party's] claims across the line from conceivable to plausible." Twombly, 550 U.S. at 570.

At the motion-to-dismiss stage, "'all well-pleaded facts are accepted as true, and the reasonable inferences therefrom are construed in the light most favorable to the plaintiff.'" FindWhat Inv'r Grp. v. FindWhat.com, 658 F.3d 1282, 1296 (11th Cir. 2011) (quoting Garfield v. NDC Health Corp., 466 F.3d 1255, 1261 (11th Cir. 2006)). However, this principle does not apply to legal conclusions set forth in the complaint. Iqbal, 556 U.S. at 678.

III. DISCUSSION

A. Shotgun Pleading

Defendants first argue that the complaint is an improper shotgun pleading. Dkt. No. [89-1] at 25-28.[3] They contend that the complaint flouts Rule 8's demand to provide a "short and plain statement of the claim" by impermissibly grouping all of the corporate defendants and never attributing any particular alleged act or omission to any particular defendant. Id. They also argue that the complaint is confusing because every count in the complaint incorporates by reference all of the factual allegations appearing in its first 168 paragraphs, many

[3] Where a brief's original page numbering differs from the numbering assigned by the Court's electronic filing system, the Court will use the page numbers assigned by its electronic filing system.

of which Defendants contend are not connected to the pleaded claims in any meaningful way. Id. at 27.

The Court is not persuaded. Defendants' statements of the law are correct. The Eleventh Circuit Court of Appeals condemns the use of shotgun pleadings. See, e.g., Weiland v. Palm Beach County Sheriff's Office, 792 F.3d 1313, 1321-23 (11th Cir. 2015); Magluta v. Samples, 256 F.3d 1282, 1284 (11th Cir. 2001). It has also held that in a case involving multiple defendants, "generalized allegations 'lumping' multiple defendants together are insufficient." W. Coast Roofing & Waterproofing, Inc. v. Johns Manville, Inc., 287 F. App'x 81, 86 (11th Cir. July 24, 2008). A complaint must also connect the causes of action to the alleged facts underlying those causes. Wagner v. First Horizon Pharm. Corp., 464 F.3d 1273, 1279 (11th Cir. 2006); Weiland, 792 F.3d at 1322.

The fact that a complaint raises common allegations against a group of defendants or contains a claim that refers to some factual allegations that may be irrelevant to that particular claim does not necessarily make it a shotgun complaint, however. The characteristic that makes a complaint a shotgun complaint is its "fail[ure] to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests." Weiland, 792 F.3d at 1323.

Here, Defendants have shown themselves perfectly capable of discerning and describing Plaintiffs' claims and factual allegations. See, e.g., Dkt. No. [89-1] at 11-13; Dkt. No. [218] at 18-20. The Court has also found no difficulty in doing

so. Although the complaint has some attributes that have been recognized in shotgun complaints, it provides the detail and the clarity necessary to comply with the applicable pleading standards. The Court is satisfied that Defendants have received fair notice of Plaintiffs' claims and thus that "this is not a situation where a failure to more precisely parcel out and identify the facts relevant to each claim materially increased the burden of understanding the factual allegations underlying each count." Weiland, 792 F.3d at 1324; accord Pinson v. JPMorgan Chase Bank, N.A., 942 F.3d 1200, 1208 (11th Cir. 2019) (declining to dismiss an inelegantly pleaded complaint where the court had no difficulty understanding the allegations and there was "no indication that [the defendant] had difficulty understanding them either"). Accordingly, the Court finds that the complaint in this matter is not an impermissible shotgun complaint.

To Defendants' point, it is not ideal that Defendants are grouped and that the claims presently cross-reference all the paragraphs appearing in the factual-allegations section of the complaint. However, in this particular lawsuit, it would be premature to require Plaintiffs to make a more definite statement, as the Paragard ownership history and Defendants' corporate structures create an unusually complex situation that involves numerous entities with potentially overlapping roles and responsibilities.

The complaint summarizes this history. Plaintiffs allege in the complaint that non-party The Population Council ("TPC") developed Paragard, submitted the new drug application ("NDA") to the FDA, and received the initial approval.

Dkt. No. [79] ¶¶ 32, 33. Several non-party companies subsequently marketed Paragard for distribution. Id. ¶ 34. Later, in or around 2003, non-party FEI Women's Health, LLC ("FEI") acquired the Paragard NDA and the right to market Paragard in the United States, and it thereafter manufactured and sold Paragard in the United States. Id. ¶ 38.

On or around November 9, 2005, Duramed Pharmaceuticals, Inc. ("Duramed"), a subsidiary of Barr Pharmaceuticals, Inc. ("Barr"), acquired FEI, including the Paragard NDA, and began manufacturing and selling Paragard in the United States. Id. ¶ 39. On December 3, 2008, Teva Pharmaceutical Industries Ltd. ("TPI Ltd.") acquired Barr. Id. ¶ 40. As a result of that transaction, Duramed became an indirect, wholly owned subsidiary of Teva USA, and Teva USA became the owner of Paragard. Id. ¶¶ 16, 40. During this transaction, TPI Ltd. and Teva USA also acquired Duramed's manufacturing facilities, sales force, and responsibility for maintaining and updating the labeling for Paragard. Id. ¶ 40.

Teva USA manufactured Paragard through Duramed, which held the Paragard NDA, and designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and sold Paragard through September 2009. Id. ¶ 41. In or around September 2009, Teva USA changed the name of Duramed to Teva Women's Health, Inc., which then continued to operate as a wholly owned subsidiary of Teva USA. Id. ¶ 42. From September 2009 to August 2017, Teva Women's Health, Inc., held the Paragard NDA and designed, developed,

manufactured, tested, labeled, packaged, distributed, marketed, and sold Paragard throughout the United States. Id. ¶ 43. In or around August 11, 2017, Teva Women's Health, Inc., was converted into Teva Woman's Health, LLC. Id. ¶ 44. From August 11, 2017, to November 1, 2017, Teva Women's Health, LLC, held the Paragard NDA and designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and sold Paragard throughout the United States. Id. ¶ 45. On November 1, 2017, The Cooper Companies, Inc., and CooperSurgical, Inc. (collectively, "Cooper Defendants") purchased Teva Women's Health, LLC, including the Paragard asset, from TPI Ltd., and have since held the Paragard NDA and designed, developed, manufactured, tested, labeled, packaged, distributed, marketed, and sold Paragard throughout the United States. Id. ¶¶ 22-24, 47, 48.

It therefore appears that each defendant's liability—to the extent that any of the defendants may be held liable—depends on the timing of their ownership and conduct, the evidence of which is presently under Defendants' exclusive control and therefore is only ascertainable through discovery. Thus, while it is likely that the Court will require Plaintiffs to make a more definite statement prior to summary judgment, it would be premature to do so now.

For these reasons, the Court concludes that the complaint is not an impermissible shotgun pleading and that it is sufficiently specific to enable Defendants to file an answer and allow the parties to proceed to discovery.

B. Failure to State a Plausible Claim for Relief

Second, Defendants argue that the complaint does not allege facts sufficient to state a plausible claim for defective design, failure to warn, or defective manufacturing. Dkt. No. [89-1] at 28-34. They contend that aside from repeated allegations that Paragard may break and that Defendants did not warn of that possibility, the complaint is otherwise "a study in vague, conclusory statements and legal conclusions – none of which state a viable claim sufficient to withstand legal scrutiny." Id.

Again, the Court does not agree. Plaintiffs provide factual underpinnings for the design-defect claims in that they allege that "Paragard is inherently dangerous and defective, unfit and unsafe for its intended and reasonably foreseeable uses, and does not meet or perform to the expectation of patients and/or their healthcare providers" because it "is prone to break while inside a woman's body, including . . . during routine removal during the course of ordinary use." Dkt. No. [79] ¶¶ 172-73. They also set forth reasons why the product has the propensity to break: its lack of flexibility caused by the use of plastic T-shaped units that fall below minimum flexibility standards within the approved expiration date of the product; the lack of any curvature in the arms of the T-shaped units; the product's propensity to decay and lose flexibility over time; the lack of flexibility of the raw plastic used in manufacturing Paragard; and the propensity of the arms to break or break at the joint during removal rather that fold upward to aid in removal. Id. ¶¶ 37, 51, 54, 55, 62. They further allege

that "Paragard breaks more and has more arm breaks than any other IUD on the market in the United States." Id. ¶ 53. They additionally aver that Defendants' failure to provide adequate warnings and instructions for Paragard rendered the device unreasonably dangerous and defective, in that Paragard's warnings do not include warnings of the severity and frequency of the risks associated with Paragard's removal, which include the risk that breakage or removal may require surgical intervention and loss of reproductive health or fertility; Paragard's propensity to break inside the body, including during routine and non-surgical removal, even when non-embedded; and the frequency of the breakages, id. ¶¶ 10, 68-70, 81, and they allege that the warnings that were provided were obscured by misleading marketing messages claiming that Paragard is easily and immediately reversible through non-surgical means, id. ¶¶ 10, 58, 59, 63, 194.[4] These factual allegations are sufficient to state plausible design-defect claims, and the portion of the design-defect allegations pertaining to the lack of warnings are also sufficient to state plausible claims for failure to warn.[5]

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[4] Design-defect claims may turn on the warnings associated with the product as well as the formulation of the product itself. Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 484 (2013).

[5] Defendants additionally argue that Plaintiffs' claims fail because the Paragard labels already provide the necessary warnings. Dkt. No. [89-1] at 29-30, 33. It may indeed have been possible for the Court to consider the labels on a motion to dismiss without converting the motion to a motion for summary judgment. *See* Caver v. Cent. Ala. Elec. Coop., 845 F.3d 1135, 1141 n.4 (11th Cir. 2017) (explaining that a court may consider extrinsic documents on a motion to dismiss without converting the motion to a motion for summary judgment if the documents are central to the plaintiff's claim and their authenticity is not disputed). Such an approach is inappropriate here, however, as Defendants

Contrary to Defendants' argument, Plaintiffs also allege facts sufficient to raise a plausible manufacturing-defect claim. Plaintiffs point to precise manufacturing practices Defendants were required to follow to ensure that Paragard did not deviate from design specifications, id. ¶¶ 129-36, and explain how Paragard nevertheless deviated from design specifications: that the products were prone to breakage because they were produced in violation of federally mandated safety regulations and maintenance, quality control, and cleanliness

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simply provided internet links to the purported documents rather than filing the documents on the record. Dkt. No. [89-1] at 29-30. While this may seem somewhat formalistic in the present digital age, the Local Rules of this Court require that parties file as exhibits to their briefs copies of evidentiary materials that are referenced therein. Cf. LR 56.1(C), NDGa. Moreover, web pages change, and even "accurate citations do not always mean that a future researcher will be able to find the exact same information as the original researcher." Raizel Liebler & June Liebert, Something Rotten in the State of Legal Citation: The Life Span of a U.S. Supreme Ct. Citation Containing an Internet Link (1996-2010), 15 Yale J.L. 273, 275 (2013). The Court also finds it notable that what is purported to be a Paragard label that appeared in the marketplace in 2005 is labeled as "*proposed* prescribing information." See PDF at https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/018680s060lbl.pdf (cited at Dkt. No. [89-1] at 32 n.12) (italics added). Finally, even if the PDFs are accurate copies of at least some of the labels that were distributed in the marketplace during the relevant time period, the Court has no assurance that the links represent all of the labels that were in the marketplace at that time. The Court therefore finds that the issue is not properly before it.

Additionally, the Court's review of the PDFs does not reveal warnings of the strength that Plaintiffs contend was necessary: that breakage or removal may require surgical intervention and cause loss of reproductive health or fertility; Paragard's propensity to break inside the body, including during routine and non-surgical removal, even when non-embedded; and the frequency of the breakages. See PDFs at https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/018680s060lbl.pdf; https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/018680s066lbl.pdf. Thus, even were the issue properly before the Court, the claims would not be subject to dismissal at this time.

standards; were made with plastic material that fell below minimum flexibility requirements; contained copper that corroded or rotted even before shipment; were produced without adequate quality assurance and quality control procedures; and were produced in violation of Defendants' written policies and standard operating procedures, id. ¶¶ 137-47. These allegations also are not vague or general.

The Court therefore finds no basis in Defendants' motion for dismissing the defective design, failure to warn, or defective manufacturing claims for failure to state a plausible claim for relief.

C. Fraud Claims

Third, Defendants contend that Plaintiffs' fraud claims are not pleaded with the required level of particularity. Dkt. No. [89-1] at 34-38. The Federal Rules of Civil Procedure require a party alleging fraud to "state with particularity the circumstances constituting fraud." Fed. R. Civ. P. 9(b). "The purpose of Rule 9(b) is to 'alert[] defendants to the precise misconduct with which they are charged and protect[] defendants against spurious charges.'" U.S. ex rel. Matheny v. Medco Health Sols., Inc., 671 F.3d 1217 (11th Cir. 2012) (quoting Ziemba v. Cascade Int'l, Inc., 256 F.3d 1194, 1202 (11th Cir. 2001)) (modifications in Matheny).

Defendants point out that the Eleventh Circuit Court of Appeals has stated that a plaintiff asserting a fraud claim should allege "(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person

responsible for the statement; (3) the content and manner in which these statements misled the [p]laintiffs; and (4) what the defendants gained by the alleged fraud." Brooks v. Blue Cross & Blue Shield of Fla., Inc., 116 F.3d 1364, 1380-81 (11th Cir. 1997). In other words, the plaintiff must identify the "who, what, where, and how" of the alleged fraud. TechJect, Inc. v. PayPal Holdings, Inc., Civ. Action File No. 1:17-CV-04058-ELR, 2018 WL 9812751, at *6 (N.D. Ga. Aug. 10, 2018) (Ross, J.) (citing Am. Dental Ass'n v. Cigna Corp., 605 F.3d 1283, 1291 (11th Cir. 2010)). While there is no citation in Defendants' brief to any case in which a court strictly applied Rule 9(b) in an MDL, Dkt. No. [89-1] at 34-38, Defendants did at oral argument point to In re Zofran (Ondansetron) Products Liability Litigation, MDL No. 1:15-2657-FDS, 2017 WL 1458193 (D. Mass. Apr. 24, 2017), wherein the court held that broad allegations of statements made in nationwide marketing campaigns are insufficient to pass muster under Rule 9(b). Dkt. No. [218] at 29 (citing In re Zofran, 2017 WL 1458193 at *5-6). Defendants argue that the fraud claims here are likewise deficient because of "[t]he shotgun nature of the Complaint"; because Plaintiffs do not identify a representation of fact that is false; because Plaintiffs do not identify any specific communications where allegedly false statements appeared; and because Plaintiffs have not pleaded facts to support the "reliance" element of the fraud claims.

The Court is not convinced. First, In re Zofran, the only MDL case Defendants rely upon, is an unpublished, out-of-circuit district-court case and

therefore is, at best, of only persuasive value. See Camreta v. Greene, 563 U.S. 692, 709 n.7 (2011) ("A decision of a federal district court judge is not binding precedent in either a different judicial district, the same judicial district, or even upon the same judge in a different case.") (internal quotation marks omitted); United States v. Moore, 541 F.3d 1323, 1328 n.3 (11th Cir. 2008) (explaining that unpublished decisions are not binding but may provide persuasive authority). The Court has examined that case and the cases it relied upon and finds their analyses of the sufficiency of the fraud claims in the respective master complaints too summary to be of much use in its own analysis. See In re Zofran, 2017 WL 1458193 at *5 (reasoning that the creation of an MDL proceeding does not affect the requirements of the Federal Rules of Civil Procedure and that "Rule 9(b) applies to MDL proceedings no less than any other civil proceeding in which fraud is alleged"); In re Gen. Motors Corp. Anti-Lock Brake Prods. Liab. Litig., 966 F. Supp. 1525, 1534-35 (E.D. Mo. 1997) (relying on non-MDL cases for pleading standard); In re Ford Motor Co. Speed Control Deactivation Switch Prods. Liab. Litig., MDL Dkt. No. 1718, 2007 WL 2421480, at *9 (E.D. Mich. Aug. 24, 2007) (same).

Conversely, the Court is persuaded by the analysis of two cases—In re Zimmer Nexgen Knee Implant Products Liability Litigation, MDL No. 2272, 2012 WL 3582708 (N.D. Ill. Aug. 16, 2012), and In re Trasylol Products Liability Litigation, No. 08-MD-1928, 2009 WL 577726 (S.D. Fla. Mar. 5, 2009)—cited both by Plaintiffs and by the court in In re Zofran for other principles. See

Dkt. No. [136] at 36-37; In re Zofran, 2017 WL 1458193 at *5. In those cases, which both involved the marketing of medical products, the courts recognized that a master complaint is not intended to include each individual plaintiff's unique allegations, but it instead sets forth common claims across an MDL and therefore should not treated like an ordinary complaint. As to fraud claims, in particular, the court in In re Trasylol found that it was necessary to balance the specificity required under Rule 9(b) with the MDL's objective of consolidating discovery proceedings of cases from various states throughout the country, each containing claims under the laws of their home states, "in order to assure an efficient, just and consistent resolution to the issues presented [t]herein." In re Trasylol, 2009 WL 577726 at *8-9 ("The Court cannot envision the task of adequately pleading the consolidated master complaint in a manner which would satisfy Defendants, without completely removing the compromise and attempt at efficiency the Parties and I had in mind in allowing the filing of the Consolidated Master Complaint."). It found that the plaintiffs had minimally stated enough to allow discovery into what information the defendants possessed as compared to information set forth in their packaging inserts and marketing materials, and it recognized that although the fraud claims asserted in the master complaint were "somewhat overly broad" and insufficient themselves to state a plausible fraud claim, the better approach would be to "assess the sufficiency of [the] plaintiffs' [fraud] claims with substantial leniency" in favor of requiring them to be pleaded with particularity in the individual plaintiffs' complaints and "subject to discovery

during the case-specific discovery stage if, and only if, properly alleged." Id. The Court in In re Zimmer expressly found the In re Trasylol analysis persuasive and followed suit. In re Zimmer, 2012 WL 3582708 at *12 (finding "summary judgment upon a more fully developed record the most appropriate time to address the[] [fraud] claims").

The Court likewise concludes that Defendants' position would require a degree of factual detail that is untenable in a master complaint and that at this stage in the case, it is enough for the master complaint to set forth factual allegations concerning the marketing and promotion of Paragard sufficient to put Defendants on notice of the types of representations that form the basis of Plaintiffs' claims. Plaintiffs here have set forth such allegations, as they aver that between 2009 and 2020, Defendants received reports of more than 2000 Paragard breaks; that "limited clinical testing for Paragard revealed a higher risk of adverse events, above and beyond those associated with other products and procedures available for birth control"; that "Defendants deliberately failed to follow up on the adverse results from clinical studies and/or formal and informal reports from physicians and/or other healthcare providers and either ignored, concealed, and/or misrepresented those findings"; and that Defendants therefore knew and failed to disclose in representations to Plaintiffs and their healthcare providers that Paragard was designed and manufactured negligently and defectively, that "Paragard was not as safe as other products and procedures available to aid in the long-term prevention of pregnancy," that "the risk of

adverse events with Paragard was higher than with other products and procedures available for birth control," that "Paragard was not adequately tested," that Paragard had defects that "caused dangerous and adverse side effects, including but not limited to unacceptable incidence of breakage upon removal," and that the Paragard removal procedure "had a very high failure rate." Dkt. No. [79] ¶¶ 121, 311; see also id. ¶¶ 111, 125-27, 309-10, 312-19; compare In re Trasylol, 2009 WL 577726 at *2-5. Plaintiffs further allege that Defendants ignored their duty to disclose the risks and adverse events and instead represented to the public, the medical community, Plaintiffs, and their physicians, through vehicles including "websites, information presented at medical and professional meetings, information disseminated by sales representatives to physicians and other medical care providers, professional literature, reports, press releases, advertising campaigns, television commercials, print advertisements, and other commercial media" that Paragard was safe and effective. Id. ¶¶ 112-20, 292, 300. These pleadings are adequate to allow discovery into what Defendants knew of the safety of Paragard and each defendant's role in the gathering of information and the dissemination of marketing messaging.

It also bears noting that Plaintiffs here have asserted facts pertaining to specific marketing communications. For instance, they have provided a screengrab from the Paragard website that they allege was posted from December 2016 through April 2018, which stated that "PARAGARD is over 99% effective

and 100% hormone free"; that "[i]t helps prevent pregnancy for up to 10 years, but your healthcare professional can remove it at any time"; that "[a]s soon as PARAGARD is removed by your healthcare professional, you can try to get pregnant the same day"; and that Paragard is "FDA approved for over 30 years and used by millions of women." Dkt. No. [79] ¶ 76. A reasonable jury could certainly find that the communication amounted to a representation that Paragard was safe to use and easily removable. The allegations also clearly set forth the "what, where, and how," and set the stage for targeted discovery to glean from information under Defendants' control who it was that was responsible for making the statements. "The heightened pleading standard of Rule 9(b) is relaxed when specific facts are 'peculiarly within the defendant's knowledge or control.'" SEC v. Melvin, Civ. Action No. 1:12-CV-2984-CAP, 2013 WL 12062834, at *4 (N.D. Ga. June 26, 2013) (Pannell, J.) (quoting Hill v. Morehouse Med. Assocs., Inc., No. 02-14429, 2003 WL 22019936, at *3 (11th Cir. Aug. 15, 2003)).

A similar analysis applies to Plaintiffs' allegations regarding the Paragard labeling. Plaintiffs have alleged that Defendants made false statements in the labeling of Paragard by failing at all times to include a warning on the label that users may be injured because Paragard could break before or during removal, failing to include a warning about the frequency of such breakages, and failing to attempt to change the label to delete a false or misleading expiration date or add a proper expiration date to ensure that Paragard would not degrade and thus increase its propensity to break, despite having actual or constructive knowledge

that Paragard could break before or during removal and/or that the expiration date was too long. Dkt. No. [79] ¶¶ 100-02. These pleadings are also sufficient to establish the "what, where, and how," and should likewise set the stage for targeted discovery to determine from information under Defendants' control who it was that was responsible for making the statements.

Plaintiffs have also alleged that on July 25, 2019, Defendant CooperSurgical received a letter from the FDA admonishing Defendants for making a "false or misleading representation[] about the risks associated with Paragard," stating that "[t]he TV ad misbrands Paragard within the meaning of the Federal Food, Drug and Cosmetic Act and makes its distribution violative"; that the "violation is concerning from a public health perspective because it creates a misleading impression about the safety of Paragard"; and that Paragard communications emphasizing that Paragard is "100% hormone free" and contains "1 simple active ingredient" gave the impression to consumers that Paragard was safer than other long-acting reversible contraceptives. Dkt. No. [79] ¶¶ 72, 73. The subject matter and timing of the letter should be sufficient to put Defendants on notice of "who, what, where, and how."

For all of these reasons, the Court concludes that the allegations of fraud are sufficient for the purposes of the master complaint.

D. Preemption

Finally, Defendants move to dismiss Plaintiffs' claims on preemption grounds. Dkt. No. [89-1] at 38-54. Before a drug manufacturer may market a

pharmaceutical drug, it must first submit to the FDA an NDA that contains, among other things, investigation reports showing that the drug is safe and effective; a full list of the articles used as components of the drug; a full statement of the composition of the drug; a full description of the methods used in, the facilities used for, and the controls used for the manufacture, processing, and packing of the drug; and a proposed label. 21 U.S.C. § 355(a)-(b). In general, following NDA approval, a drug manufacturer may only change a drug, Bartlett, 570 U.S. at 477, or a drug label, Wyeth v. Levine, 555 U.S. 555, 568 (2009), after the FDA approves the change through a supplemental application. Defendants argue that it was impossible for them to satisfy both these federal requirements and the state law giving rise to Plaintiffs' claims and thus that Plaintiffs' claims are preempted by the FDCA. Dkt. No. [89-1] at 38-54.

The United States Constitution provides that the laws of the United States "shall be the supreme Law of the Land . . . , any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Congress has not enacted [an express preemption] provision for prescription drugs." Wyeth, 555 U.S. at 574. Where no express preemption clause governs, courts will not find implied preemption lightly. Va. Uranium, Inc. v. Warren, 139 S. Ct. 1894, 1900 (2019) (plurality opinion) ("[W]e are hardly free to extend a federal statute to a sphere Congress was well aware of but chose to leave alone."); see also Wyeth, 555 U.S. at 573 ("Impossibility pre-emption is a demanding defense."). Thus, state law gives way to federal law by implication only "to the extent that it

that it actually conflicts with federal law," or in other words, "where it is impossible for a private party to comply with both state and federal requirements." English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990). The existence of preemption is a question of law for the court to decide. Merck Sharp & Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1672 (2019); id. at 1679 (specifying that the question for the court is "whether the relevant federal and state laws irreconcilably conflict") (punctuation omitted).

1. Pleading Burden

The Court first considers the threshold question of whether Plaintiffs were required to plead facts showing that preemption does not apply. While Defendants concede that preemption is an affirmative defense, they argue that it was necessary for Plaintiffs to plead facts showing that Defendants could have complied with state law without first obtaining FDA approval. Dkt. No. [218] (Oral Arg. Tr.) at 33-34 (citing Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699, 708 (2d Cir. 2019); In re Celexa & Lexapro Mktg. & Sales Practices Litig., 779 F.3d 34, 41 (1st Cir. 2015); Ignacuinos v. Boehringer Ingelheim Pharms. Inc., 490 F. Supp. 3d 533, 541 (D. Conn. 2020); Mitchell v. Boehringer Ingelheim Pharms., Inc., Case No. 1:16-cv-02384-STA-agb, 2017 WL 5617473, at *5 (W.D. Tenn. Nov. 21, 2017); and Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 672-73 (S.D.N.Y. 2017)). However, as Plaintiffs point out, both the Supreme Court and the Eleventh Circuit Court of Appeals have affirmed time and again that a plaintiff does not have a burden to plead around an affirmative defense.

See, e.g., Jones v. Bock, 549 U.S. 199, 211, 216 (2007); Gomez v. Toledo, 446 U.S. 635, 640 (1980); see also Quiller v. Barclays Am./Credit, Inc., 727 F.2d 1067, 1069 (11th Cir. 1984), reinstated on reh'g en banc, 764 F.2d 1400 (11th Cir. 1985) (per curiam). Rather, a Rule 12 motion may be granted on an affirmative defense only in the exceptional circumstance where "the defense clearly appears on the face of the complaint." Quiller, id.

Even if the Eleventh Circuit pleading standard was not so well established, the cases Defendants cite do not persuade the Court that it should grant Defendants' motion to dismiss on grounds that Plaintiffs failed to plead facts showing that preemption does not apply. The court in Gibbons grounded its determination that the plaintiff bears the burden of pleading facts showing the absence of preemption based on Wyeth, which was in fact before the court *at the summary judgment stage*, and PLIVA, Inc. v. Mensing, 564 U.S. 604 (2011), and Mutual Pharmaceutical Co. v. Bartlett, 570 U.S. 472 (2013), in which the defendants were generic drug manufacturers and preemption was therefore apparent from the face of the complaint. See Gibbons, 919 F.3d at 708. The court in Ignacuinos relied on Gibbons and ultimately found preemption because the remedial measures demanded on the face of the complaint required changes—a change in the labeled number of doses available in each unit or a change in the dosage strength—that it found were as a matter of law "major" changes that would require a supplemental submission and additional approval by the FDA. Ignacuinos, 490 F. Supp. 3d at 541. In In re Celexa, the court simply assumed

without deciding that it was the plaintiffs' burden to plead facts showing that the impossibility defense did not apply. In re Celexa, 779 F.3d at 40-43. The Court also notes that the Supreme Court has been presented with and has rejected the argument that efficiency considerations warrant placing the burden on the plaintiff to show that an affirmative defense does not apply, contrary to the reasoning stated in Utts, compare Jones, 549 U.S. at 215 with Utts, 251 F. Supp. 3d at 673, and that Mitchell relied on PLIVA, Wyeth, In re Celexa, and Utts, Mitchell, 2017 WL 5617473 at *4-5.

The Court will not depart from this Circuit's well-established pleading requirements as they pertain to the affirmative defense. Accordingly, the Court will consider whether the preemption defense is apparent from the face of the complaint.

2. Design-Defect Claims (Formulation)

Relying primarily on Bartlett, Defendants argue that the design-defect claims based on Paragard's formulation are preempted by federal law because Defendants could not change the Paragard formulation of their own volition: "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application.'" Bartlett, 570 U.S. at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i)) (cited at Dkt. No. [89-1] at 42-44); see also Bartlett, id. at 483 ("In the drug context, either increasing the 'usefulness' of a

product or reducing its 'risk of danger' would require redesigning the drug: A drug's usefulness and its risk of danger are both direct results of its chemical design and, most saliently, its active ingredients.") (cited at Dkt. No. [89-1] at 40-41). In response, Plaintiffs contend that Defendants cannot point to a regulation that prevents them from improving the quality of the materials used to make the product. Dkt. No. [136] at 55-56.

"[C]hanges in the qualitative or quantitative formulation of the drug product, including inactive ingredients," and "[c]hanges in the synthesis or manufacture of the drug substance that may affect the impurity profile and/or the physical, chemical, or biological properties of the drug substance" are considered by the FDA to be the sort of "major changes" with "a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product" that require supplemental submission and FDA approval prior to distribution of the product. 21 C.F.R. § 314.70(b)(1). Improvement in the quality of the materials used to make the product flexible for longer appears likely to fall within these categories. Be that as it may, the need for a supplement applies only to a change in a "condition established in an approved NDA beyond the variations already provided for in the NDA." 21 C.F.R. § 314.70(a)(1)(i). The NDA has not been entered into the record. It is therefore impossible to determine at this juncture whether improving the quality of the materials used to make the product would necessitate a change beyond the

variations already provided for in the NDA. The Court therefore declines to dismiss any formulation-related defective-design claims at this time.

3. Manufacturing-Defect Claims

Defendants argue that Plaintiffs' manufacturing-defect claims are also due to be dismissed. Dkt. No. [89-1] at 51-54. They first note that "a manufacturing defect refers to individual products that are improperly made while a design defect concerns a defect in the entire product line" and contend that Plaintiffs' manufacturing-defect claims must be preempted because they involve the entire product line. Id. at 51-52. They also contend that the plastic in Paragard "is part and parcel of the product design"; that the plastic is therefore an aspect of the NDA that cannot be altered without the FDA's prior approval; and that the claims arising from injuries related to the plastic parts are therefore preempted as design-defect claims. Id. at 52-53. They additionally argue that Plaintiffs have not pleaded facts indicating how any particular Paragard or batch of Paragard units departed from their intended design or how a particular manufacturing process for any Paragard or batch of Paragard units should have been followed but was not. Id. at 53. Finally, they contend that the allegations of defects in the manufacturing process for Paragard amount to allegations that the process should be changed, id. at 54 (citing Compl. ¶¶ 140-41, 143), which is also a "major change" under the regulations and therefore would be preempted, Dkt. No. [89-1] at 54 (citing 21 U.S.C. § 356a(c)(1), (2); 21 C.F.R. § 314.70(b)(1), (2); PLIVA, Inc.,

564 U.S. at 620; In re Zantac (Ranitidine) Prods. Liability Litig., 510 F. Supp. 3d 1141, 1170-71 (S.D. Fla. 2020)).

Again, the Court is not persuaded. Plaintiffs have sufficiently pleaded manufacturing-defect claims based on assertions that some of the units were defectively manufactured: that Defendants failed to follow the FDA's requirements, resulting in the mass production, shipment into circulation, and use of defective and dangerous Paragards, Dkt. No. [79] ¶ 139, and that the Paragards that injured Plaintiffs deviated from Defendants' design or specifications in that, among other things, they were made with unsuitable, insufficiently flexible plastic, were made without adequate quality assurance and control procedures to ensure product conformity, and had experienced copper corrosion or discoloration at the time of final packing, id. ¶¶ 141, 143, 217. This is adequate to put Defendants on notice of the bases for Plaintiffs' manufacturing-defect claims and to allow them to defend against them.

Plaintiffs' argument that claims alleging both manufacturing and design defects should proceed to discovery is also well taken, as it may not be possible to determine without discovery and further investigation whether a product failure is the result of a design problem or a manufacturing problem, particularly in a case involving FDA premarket approval, where "much of the critical information is kept confidential as a matter of federal law." Bausch v. Stryker Corp., 630 F.3d 546, 560 (7th Cir. 2010) (cited in Dkt. No. [136] at 57). Here, Plaintiffs aver, and Defendants have not meaningfully countered, that they cannot allege specifically

which written quality controls were violated without access to documents that are under Defendants' control. Dkt. No. [136] at 58 (citing Dkt. No. [79] ¶ 144).

For these reasons, the Court is persuaded that the manufacturing-defect claims are sufficiently pleaded and that there has been no showing thus far that they are subject to preemption.

4. Design-Defect Claims (Failure to Warn)

Defendants concede that despite the general prohibition against label changes, in certain circumstances, a manufacturer may make certain "moderate" changes to the labeling of a drug product prior to receiving FDA approval by proceeding under the "changes being effected" or "CBE" regulation, 21 C.F.R. § 314.70(c)(6)(iii). Dkt. No. [89-1] at 46-51. Moderate labeling changes are those changes defined as having a "moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." 21 C.F.R. § 314.70(c)(1), (6)(iii). The regulation permits a manufacturer to change the labeling "to reflect newly acquired information" by "add[ing] or strengthen[ing] a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfies the standard for inclusion in the labeling under § 201.57(c) of this chapter"; "add[ing] or strengthen[ing] an instruction about dosage and administration that is intended to increase the safe use of the drug product"; or "delet[ing] false, misleading, or unsupported indications for use or claims for effectiveness." 21 C.F.R. § 314.70(c)(6)(iii); accord Albrecht, 139 S. Ct.

at 1673 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)); Wyeth, 555 U.S. at 568. Nevertheless, the FDA ultimately must approve a change effected under the CBE regulation, and claims against an NDA holder are preempted where "clear evidence" shows that the FDA would not have approved a change to the drug's label. Wyeth, 555 U.S. at 571-72.

Defendants argue that Plaintiffs' failure-to-warn claims are preempted because the label changes they seek cannot be effected through submission of a CBE. Dkt. No. [89-1] at 46-51. First, they contend that Paragard labeling already adequately warns of the potential for breakage and surgery; that the label changes Plaintiffs request would therefore amount to "wordsmithing"; and that "wordsmithing" does not satisfy the standard for use of a CBE. Id. at 46-48. Second, they argue that Plaintiffs cannot show that Defendants should have changed the label under the CBE regulation because they have not pleaded that "newly acquired information" existed that constituted reasonable evidence of a causal association supporting a new or strengthened warning that would have supported the submission of a CBE. Dkt. No. [89-1] at 39-41, 47-51 (citing 21 C.F.R. § 314.701(c)(6); Albrecht, 139 S. Ct. at 1679). Defendants additionally aver that the expiration date is part of the "indications and usage" section of the label and that they therefore could not have made a change to the expiration date under the CBE regulation. Dkt. No. [89-1] at 50-51 (citing 21 C.F.R. § 314.70(c)(6)).

On these claims as well, Plaintiffs have the better end of the argument. First, as previously discussed, no Paragard label—in any of its iterations—is in the record, and thus arguments about the sufficiency of the warnings allegedly contained therein and arguments pertaining to the location of the expiration date on the label are not properly before the Court. See supra n.5. As also discussed, even if the PDFs appearing at the links are accurate copies of the labels at issue in this matter, they do not contain warnings of the strength urged by Plaintiffs. Id. Additionally, Defendants' general citation to 21 C.F.R. § 314.70(c)(6) does not make clear why Paragard's shelf-life could not have been shortened without prior FDA approval. See Dkt. No. [89-1] at 50-51. The Court cannot and will not supply an argument on a party's behalf. See NLRB v. McClain of Ga., Inc., 138 F.3d 1418, 1422 (11th Cir. 1998) ("Issues raised in a perfunctory manner, without supporting arguments and citation to authorities, are generally deemed to be waived.").

The argument regarding "newly acquired information" is also unavailing. As set out above, Plaintiffs were not required to plead facts establishing the absence of an affirmative defense. See supra Part III.D.1. And even if they were required to make such a showing, they have alleged in the complaint that more than 2000 Paragard breaks were documented by the FDA Adverse Event Reporting System database between 2009 and 2020, Dkt. No. [79] ¶ 121, far greater than the number of adverse incidents found sufficient in Wyeth, see Wyeth, 555 U.S. at 569-70 (finding that 20 incidents over four decades was sufficient to trigger the CBE regulation because the manufacturer "could have

analyzed the . . . data"), and they have further alleged that Defendants deliberately ignored, concealed, and/or failed to follow up on results from clinical studies and physicians' reports of adverse events, Dkt. No. [79] ¶ 311. "'[N]ewly acquired information' is not limited to new data, but also encompasses 'new analyses of previously submitted data.'" Wyeth, 555 U.S. at 569 (quoting 73 Fed. Reg. 49603, 49604 (2008)); see also Wyeth, id. (explaining that the rule "accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments"). Plaintiffs therefore have asserted in the complaint that newly acquired information exists that constitutes reasonable evidence of a causal association supporting a new or strengthened warning.

For these reasons, the undersigned concludes that there is no basis in Defendants' arguments for a determination that any claims arising from their alleged failure to warn are preempted by federal law.

IV. CONCLUSION

In accordance with the foregoing, the Motion to Dismiss Plaintiffs' Second Amended Master Personal Injury Complaint, Dkt. No. [89], is **DENIED**. The discovery stay is lifted, and discovery may commence consistent with the other orders that have been entered in this case.

IT IS SO ORDERED this 16th day of November, 2021.

Leigh Martin May
United States District Judge