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

IN RE: PARAGARD IUD PRODUCTS LIABILITY LITIGATION,	:	**MDL Docket No. 2974**
	:	
	:	**(1:20-md-02974-LMM)**
	:	
	:	**This Document Relates to All Cases**

MEMORANDUM IN SUPPORT OF TEVA PHARMACEUTICALS USA, INC.; TEVA WOMEN'S HEALTH, LLC; TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC.; THE COOPER COMPANIES, INC.; AND COOPERSURGICAL, INC.'S MOTION TO DISMISS PLAINTIFFS' SECOND AMENDED MASTER PERSONAL INJURY COMPLAINT

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Constitutional Provisions

Statutes

Regulations

Rules

Other Authorities

I. INTRODUCTION

This multi-district litigation ("MDL") involves the contraceptive Paragard, a copper "T" shaped intrauterine device ("IUD"), which is a drug regulated 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 ("C.F.R."). Although plaintiffs' Second Amended Master Personal Injury Complaint ("Complaint") includes 16 counts,[1] all plaintiffs' claims are premised on the alleged risk that a Paragard can break upon removal. And, although plaintiffs couch their claims under a variety of headings, when distilled, plaintiffs' claims all allege either a defect in Paragard's design, an alleged failure to warn of the potential for breakage, or an alleged defect in manufacturing. Each claim should be dismissed for several reasons.

First, the Complaint should be dismissed in full because it is a prime example of improper shotgun pleading. Plaintiffs do not distinguish the

[1] (1) Strict Liability – Design Defect; (2) Strict Liability – Failure to Warn; (3) Strict Liability – Manufacturing Defect; (4) Negligence; (5) Negligence – Design & Manufacturing Defect; (6) Negligence – Failure to Warn; (7) Fraud & Deceit; (8) Fraud by Omission; (9) Negligent Misrepresentation; (10) Breach of Express Warranty; (11) Breach of Implied Warranty; (12) Violation of Consumer Protection Laws; (13) Gross Negligence; (14) Unjust Enrichment; (15) Punitive Damages; and (16) Loss of Consortium. (*See generally* Complaint).

various defendants they name, effectively and impossibly alleging that all defendants participated in every act about which plaintiffs complain. Plaintiffs also incorporate by reference 168 paragraphs of purported "factual" allegations, into each successive count, without connecting them to the otherwise generally pled claim in any meaningful way. That type of conclusory, confusing, and fact-deficient shotgun pleading fails to satisfy the federal pleading standard, and the Complaint should be dismissed in its entirety.

Second, plaintiffs do not allege sufficient facts to state a claim upon which relief can be granted. Rather, plaintiffs' allegations are vague, rote, and conclusory statements of the elements of claims or legal conclusions, which otherwise lack facts sufficient to support the claim. That fact-deficient manner of pleading does not satisfy the pleading requirements in the Civil Rules and requires the dismissal of plaintiffs' claims—including plaintiffs' fraud claims, which are subject to an even more rigorous standard.

Finally, all claims asserting a defective design are preempted as explained in *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472 (2013). Failure-to-warn claims also are preempted as explained in *Wyeth v. Levine*, 555 U.S. 555 (2009), *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), *Bartlett*, and *Merck Sharp & Dohme Corp. v. Albrecht*, 587 U.S. ---, 139 S. Ct. 1668 (2019).

Plaintiffs' claims premised on a manufacturing defect similarly are preempted. *Mensing*, 564 U.S. 604 (2011). Paragard is subject to a rigorous regulatory scheme overseen by FDA. The Supreme Court's decisions recognize that state law claims are preempted when it would be impossible for a defendant that sells a highly–regulated product, such as Paragard, to satisfy both its alleged state law duties and comply with federal law.

For these reasons, and others stated below, plaintiffs' Complaint should be dismissed in full

II. STATEMENT OF FACTS

A. PLAINTIFFS' ALLEGATIONS

Plaintiffs in this MDL are women who allegedly "had a Paragard implanted that later broke while still in her body." (Compl., ¶11; *see also id.* ¶14 (identifying plaintiffs as individuals whose Paragard broke while inside their bodies); ¶150 ("Plaintiffs Paragard broke inside their bodies….").) Plaintiffs allege "[u]pon information and belief, [that] the [Paragard] design is flawed because Paragard does not provide sufficient flexibility." (*Id.*, ¶52.) They also allege "upon information and belief," that "sample Paragard raw plastic T units, before having the copper sleeves installed, failed to meet the minimum flexibility requirements with the approved expiration date (i.e., shelf life) of the product." (*Id.*, ¶54.) Thus, according to plaintiffs, the "Paragard

design is [] flawed" because "it does not account for the long expiration date and use of the product to decay and lose flexibility over time on the shelf and in situ." (*Id.*, ¶55.)

Plaintiffs contend that the "Paragard arms" "frequently" "are broken or will break at the joint during removal" resulting in alleged injuries. (*Id.*, ¶62.) They complain that even though defendants allegedly knew of the risk that Paragard might break "in utero and/or upon removal," they did not "adequately warn" of the risk. (*Id.*, ¶¶65-66, 68; 151 (alleging defendants did not warn about "Paragard's propensity to break in the body before or during removal").) They claim that Paragard's warnings "were intentionally vague, confusing, incomplete or otherwise wholly inadequate to alert patients and prescribing physicians to the actual risks associated with Paragard, including, but not limited to, the risk of breakage, the frequency of breakage, and that the risk may result in injury, including surgical intervention and loss of reproductive health and fertility." (*Id.*, ¶69.) According to plaintiffs, the Paragard label, last revised in 2019, remains inadequate. (*Id.*, ¶¶78, 81 (alleging "warnings remain intentionally vague and confusing and fail to adequately warn about the propensity of the product to break" and that "[d]efendants could have but failed to warn of Paragard's risks including, but not limited to, the frequency of breakages, that surgical intervention could be required as a result of a

"difficult" removal, that a non-embedded Paragard could break during removal, or that surgery could prevent a woman from conceiving children").)

Plaintiffs allege they were injured "as a direct and proximate result of using Paragard …." (*Id.*, ¶153.)

B. FEDERAL REGULATION OF PHARMACEUTICAL PRODUCTS

1. New Drug Approval Process

Prescription drugs are regulated under the FDCA, which is implemented and enforced by FDA. *See* 21 U.S.C. §§301 *et seq.*; *id.*, §§371, 393. A drug may not be marketed in interstate commerce unless an application pursuant to 21 U.S.C. §355 is "effective"; i.e., has been approved by FDA. *See* 21 U.S.C. §355(a). Section 355(b) applies to new drugs, like Paragard, and requires submission of a new drug application ("NDA"). In reviewing an NDA, FDA physicians, chemists, statisticians, microbiologists, pharmacologists, and other experts scrutinize all aspects of the drug "from the design of clinical trials to the severity of side effects to the conditions under which the drug is manufactured." *See* FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective.[2] FDA also may consult the sponsor and independent scientific

[2] Available at https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective

experts. *See* 21 U.S.C. §355(n). NDA applicants must demonstrate the new drug is safe and effective for the proposed use before approval is granted. *See* 21 U.S.C. §355(b)(1)(A). Determinations of safety and efficacy are inextricably intertwined with the drug's use under the conditions set forth in the proposed labeling, which "serves as the standard under which FDA determines whether a product is safe and effective." *New Drug and Antibiotic Regulations – Final Rule*, 50 Fed. Reg. 7470 (Feb. 22, 1985); 21 U.S.C. §355(b)(1)(F).

2. Labeling Requirements for New Drugs

"Labeling" includes "all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. §321(m). "Label" is defined as "a display of written, printed, or graphic matter upon the immediate container of any article...." 21 U.S.C. §321(k); *see also* 21 C.F.R. §1.3. FDA's regulations govern the content and format of drug labeling. *See* 21 C.F.R. §§201.56 (general requirements), 201.57 (specific requirements). The title and content of each section required to appear in drug labeling is specified in FDA's regulations.

3. The Post-Approval Process and Labeling Changes

No provision in the FDCA permits a manufacturer to change an approved drug's labeling without prior FDA approval. *See* 21 U.S.C. §301 *et seq*. The FDCA prohibits introduction into interstate commerce of any drug

not approved under §355. 21 U.S.C. §355(a). Any unapproved label change renders the drug a new, unapproved drug under the FDCA subject to the misbranding provisions. *See id.* Accordingly, under the FDCA, any change to an approved application must be approved by FDA prior to its implementation.

Despite that requirement, FDA issued a notice advising industry that it would exercise its discretion and not take enforcement action if NDA holders instituted labeling changes before approval: (i) to add or strengthen a contraindication, warning, precaution, or adverse reaction; (ii) to add or strengthen a statement about drug abuse, dependence, or overdosage; (iii) to add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product; or (iv) to delete unsupported indications for use or claims of effectiveness. *See* 21 C.F.R. §314.70(c); *Supplemental New-Drug Applications*, 30 Fed. Reg. 993, 993-94 (Jan. 30, 1965). Those changes are made using FDA's "changes being effected" ("CBE") procedure and must be based on "newly discovered safety information" and "sufficient evidence of a causal association with the drug." *See* 21 C.F.R. §314.70(c)(6)(iii)(A); *Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices – Proposed Rule*, 73 Fed. Reg. 2848, 2849 (Jan. 16. 2008). CBE supplements must include the "newly discovered safety information" supporting the change and must be submitted

to FDA for ultimate approval. *See* 21 C.F.R. §314.70(c)(7). FDA can accept, modify, or reject a CBE supplement. *Id*.

FDA proposed what essentially is the current CBE procedure in 1982. *See New Drug and Antibiotic Regulations – Proposed Rule*, 47 Fed. Reg. 46622 (Oct. 19, 1982); *see also* 73 Fed. Reg. 2849. At that time, FDA stated that a CBE is to be used in very limited circumstances; *i.e.*, where the applicant became aware of newly discovered information. 47 Fed. Reg. 46635. The final rule reiterates the narrow exceptions to the general rule of pre-approval:

> Substantive changes in labeling ... are more likely than other changes to affect the agency's previous conclusions about the safety and effectiveness of the drug. Thus, they are appropriately approved by FDA in advance, unless they relate to important safety information, like a new contraindication or warning….

50 Fed. Reg. 7470.

On January 15, 2008, FDA proposed a rule to make "explicit the agency's understanding that a sponsor may utilize the CBE provision only to reflect newly acquired safety information." 73 Fed. Reg. 2850. Current regulations require "a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug." 73 Fed. Reg. 2850; *see also* 21 C.F.R. §201.57(c)(6). Similarly, current regulations require listing adverse reactions that are "reasonably associated with use of a drug." 21 C.F.R. §201.57(c)(7). There must be "some basis to believe there is a causal

relationship between the drug and the occurrence of the adverse event." *Id*. As FDA explained:

> Explicitly requiring that CBE supplements are utilized in a manner proposed by this amendment ensures that only scientifically justified information is provided in the labeling for an approved product. Exaggeration of risk, or inclusion of speculative or hypothetical risks, could discourage appropriate use of a beneficial drug ….

73 Fed. Reg. 2851. Outside the limited enumerated circumstances for which a CBE may be submitted, all other changes must be implemented through a prior approval supplement ("PAS").

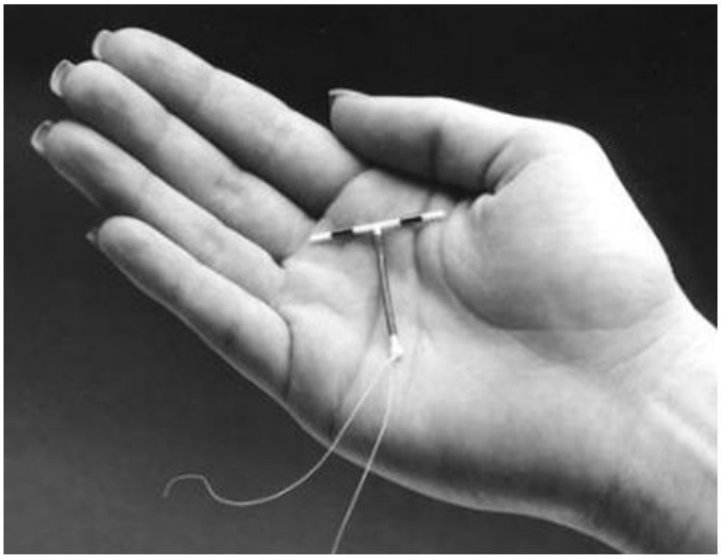
C. PARAGARD, ITS APPROVAL HISTORY, AND WARNINGS

Paragard is placed in the uterus to prevent pregnancy. (Paragard® package insert, available at FDA's website at Drugs@FDA.[3]) The T-frame is made of polyethylene plastic. Approximately 176 mg of copper wire is coiled along the vertical stem and a 68.7 mg collar on each horizontal arm. A Paragard, pictured below, measures 32 mm horizontally and 36 mm vertically.

---

[3] The 2005 and 2013 Paragard package inserts are available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/018680s060lbl.pdf https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/018680s066lbl.pdf The Court may take judicial notice of the package insert as it is a public record. *See Day v. Taylor*, 400 F.3d 1272, 1275-76 (11th Cir. 2005); *see also Eisenberg v. City of Miami Beach*, 54 F. Supp. 3d 1312, 1319 (S.D. Fla. 2014) ("A court may consider documents attached to the complaint or incorporated by reference … if the documents are: (1) central to the complaint, and (2) the documents' authenticity is not in dispute.")(citing *Day*, 400 F.3d at 1275-76).

(*Id.*)



The new drug application ("NDA") for Paragard was filed with the FDA by The Population Council on August 25, 1983. FDA approved the Paragard NDA on November 15, 1984. (*See* Paragard Approval History, available at FDA's website at Drugs@FDA.) Duramed Pharmaceuticals, Inc. (which later changed its name to Teva Women's Health, Inc.), became the holder of the Paragard NDA on November 9, 2005, and held it until August 11, 2017. (Compl., ¶39.) From August 11, 2017, to November 1, 2017, Teva Women's Health, LLC, held the NDA, which later was transferred to CooperSurgical, Inc. (Compl., ¶¶45-46.) CooperSurgical, Inc., currently holds the Paragard NDA. (*See* Paragard Approval History, available at FDA's website at Drugs@FDA.)

On September 1, 2005, FDA approved revised labeling for Paragard. (FDA approval history.[4]) The label was revised again in 2013 when FDA approved a PAS for changes to the Clinical Pharmacology section of the package insert, as well as for changes to the "How does Paragard Work" section in the Patient Package Insert portion. Minor changes also were approved to the Indication and Usage and How Supplied sections. (*See* FDA approval letter, Sept. 11, 2013.[5]) In June 2014, a PAS was submitted to convert the Paragard label to the Physician Labeling Rule ("PLR") format.[6] (*See* FDA's

---

[4] Available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2005/018680s060ltr.pdf

[5] Available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2013/018680Orig1s066ltr.pdf

[6] In 2006, FDA finalized the Physician's Labeling Rule which amended 21 C.F.R. §§201.56, 201.57, and changed the format of prescription drug labels. Implementation of the new format was staggered based on the year a drug originally was approved. *See* 21 C.F.R. §201.56(c). The new label format consists of two parts: "Highlights" and "Full Prescribing Information." The content, including the order in which information appears in both parts, is mandated by FDA regulations. The "Highlights" section must include the product name, any boxed warning (if required by FDA), recent major changes, indications and usage, dosage and administration, dosage forms and strength, contraindications, warnings and precautions, adverse reactions, drug interactions, and use in specific populations—in that order. *See* 21 C.F.R. §201.56(d)(1); §201.57(a)(1). Highlights is intended to spotlight information in the labeling and improve accessibility, readability, and usefulness of information in prescription drug labeling. *See Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics:*

Supplement Approval letter, Sept. 5, 2019.[7]) FDA approved the PAS on September 5, 2019. (*Id.*) The conversion of the Paragard label to the PLR format resulted in a reorganization and reformatting of the label to conform it to the standardized PLR format.

Paragard's labeling includes a package insert with prescribing information for the physician with detailed diagrams on the proper placement of the IUD and a patient package insert. (*See* Paragard package insert available at Drugs@FDA.) In addition to a product description, the prescribing information describes the mechanism of action for contraception, indications and usage, instructions for use, and information for patients. (*Id.*) The prescribing information of the 2005 and 2013 Paragard package insert included warnings, contraindications, precautions, and potential adverse reactions. (*Id.*) In the "Warnings" section, under the headings "embedment"

Requirements for Prescription Drug Product Labels – Proposed Rule, 65 Fed. Reg. 81082 (Dec. 22, 2000).

The "Full Prescribing Information" section includes the same categories of information in greater detail. *See* 21 C.F.R. §201.56(d)(1); §201.57(b). It also includes sections that address drug use and dependence, overdosage, clinical pharmacology, nonclinical toxicology, clinical studies, references, how the product is supplied and stored, as well as handling instructions and patient counseling information. 21 C.F.R. §201.56(d)(1); §201.57(b).

[7]Available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/18680Orig1s069,%2018680Orig1s070ltr.pdf

and "perforation," the prescribing information warned that surgery may be required to remove the IUD:

> 5. **Embedment**
> Partial penetration or embedment of Paragard in the myometrium can make removal difficult. In some cases, surgical removal may be necessary.
>
> 6. **Perforation**
> Partial or total perforation of the uterine wall or cervix may occur rarely during placement, although it may not be detected until later. Spontaneous migration has also been reported. If perforation does occur, remove Paragard promptly, since the copper can lead to intraperitoneal adhesions. Intestinal penetration, intestinal obstruction, and/or damage to adjacent organs may result if an IUD is left in the peritoneal cavity. Pre-operative imaging followed by laparoscopy or laparotomy is often required to remove an IUD from the peritoneal cavity.

(Paragard Package Insert, 2005 & 2013.) "Perforation" and "Embedment" were disclosed among the "most serious adverse events associated with intrauterine contraception" under the Adverse Reactions section of the package insert. (*Id.*)

The package insert also included warnings that the IUD could break. Specifically, under "Continuing Care," the physician was advised that "Paragard can break" and that it can "perforate the uterus." (*Id.*) In the section of the package insert titled "How to Remove Paragard," the physician again was advised of the risks of embedment and/or breakage, and the possibility that surgical removal may be necessary:

> Embedment or breakage of Paragard in the myometrium can make removal difficult. Analgesia, paracervical anesthesia, and cervical dilation may assist in removing an embedded Paragard. An alligator forceps or other grasping instrument may be helpful. Hysteroscopy may also be helpful.

(*Id.*)

Finally, under "Precautions," in a section titled "Information for Patients," the prescribing physician was advised as follows:

> Before inserting Paragard discuss the Patient Package Insert with the patient, give her time to read the information. Discuss any questions she may have concerning Paragard as well as other methods of contraception. Instruct her to promptly report symptoms of infection, pregnancy, or missing strings.

(*Id.*) In turn, the "Information for Patients" portion advises, under a section titled "What side effects can I expect with Paragard," that there can be "[d]ifficult removals" and "[o]ccasionally Paragard may be hard to remove because it is stuck in the uterus. Surgery may sometimes be needed to remove Paragard." (*Id.*) It also advises:

> Perforation: Rarely, Paragard goes through the wall of the uterus, especially during placement. This is called perforation. If Paragard perforates the uterus, it should be removed. Surgery may be needed. Perforation can cause infection, scarring, or damage to other organs. If Paragard perforates the uterus, you are not protected from pregnancy.

(*Id.*)

The labeling after the 2019 change continues to warn that the IUD may become embedded requiring surgical removal. (*See* 9/2019 Label, Highlights & §5.5.[8]) It also warns of the potential for perforation which, again, may require surgery. (*Id.*, §5.6.) And, it warns of the risk of breakage and lists breakage as a reported post-marketing experience. (*Id.*, §§2.5, 2.6, 5.5, 6.2.)

III. LAW AND ARGUMENT

A. STANDARD OF REVIEW

The United States Supreme Court has made clear that a complaint must state "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 545 (2007). Mere "labels and conclusions" are insufficient. *Id.* at 555. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556). "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

[8]Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/018680s069s070lbl.pdf

and plausibility of 'entitlement to relief.'" *Iqbal*, 556 U.S. at 678-79 (citing *Twombly*, 550 U.S. at 557). The well-pled allegations in a complaint must "nudge[] [a party's] claims across the line from conceivable to plausible." *Twombly,* 555 U.S. at 570. *See also Quality Auto Painting Ctr. of Roselle, Inc. v. State Farm Indem. Co.*, 917 F.3d 1249, 1260 (11th Cir. 2019) (stating complaint must contain allegations to "state a claim for relief that is plausible, not merely possible"). Without sufficient factual allegations, a claimant cannot satisfy the requirement that he or she provide not only "fair notice," but also the "grounds" on which the claim rests. *Twombly*, 550 U.S. at 555 n.3; *see also Brown v. Air Line Pilots Ass'n*, 813 F. App'x 353 (11th Cir. 2020).

In *Twombly*, the Supreme Court recognized the liberal minimal standards imposed by Civil Rule 8(a)(2), which requires the plaintiff to state "a short and plain statement of the claim showing that the pleader is entitled to relief," but ruled that a plaintiff's complaint must contain facts with enough specificity "to raise a right to relief above the speculative level." *Id.* at 555. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," will not pass muster. *Iqbal*, 556 U.S. at 678 (*citing Twombly*, 550 U.S. at 555).

While in considering the motion, the court assumes the facts alleged in the complaint are true and construes all reasonable inferences from those facts

in plaintiff's favor, "conclusory allegations, unwarranted deductions of facts or legal conclusions masquerading as facts will not prevent dismissal." *Jackson v. BellSouth Telecomm.*, 372 F.3d 1250, 1262–63 (11th Cir. 2004) (quoting *Oxford Asset Mgmt., Ltd. v. Jaharis*, 297 F.3d 1182, 1188 (11th Cir. 2002)).

Moreover, materials outside the pleadings generally are ignored; however, the court may consider some materials that are part of the public record or do not contradict the complaint, orders, materials embraced by the complaint, and exhibits attached to the complaint. *See Day v. Taylor*, 400 F.3d 1272, 1275-76 (11th Cir 2005).

B. THE COMPLAINT IS AN IMPROPER SHOTGUN PLEADING

Plaintiffs' Complaint flouts Rule 8's demand to provide a "short and plain statement of the claim." *Magluta v. Samples*, 256 F.3d 1282, 1284 (11th Cir. 2001). Throughout, plaintiffs impermissibly group the five corporate defendants named in the Complaint, never attributing any particular alleged act or omission to any particular defendant. The Eleventh Circuit Court of Appeals long has held that "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. 2008).

The rule against shotgun pleadings derives from foundational concerns about the administration of justice: "'Experience teaches that, unless cases are

pled clearly and precisely, issues are not joined, discovery is not controlled, the trial court's docket becomes unmanageable, the litigants suffer, and society loses confidence in the court's ability to administer justice.'" *Kareem v. Ocwen Loan Serv., LLC*, 2015 WL 7272765, at *5 (S.D. Fla. Nov. 18, 2015) (quoting *Anderson v. Dist. Bd. of Trustees of Cent. Florida Cmty. Coll.*, 77 F.3d 364, 366–67 (11th Cir. 1996)). For those reasons, the Eleventh Circuit condemns the use of shotgun pleadings in the strongest terms. *See, e.g., Byrne v. Nezhat*, 261 F.3d 1075, 1130 (11th Cir. 2001) (finding shotgun pleadings not only "impede[] the due administration of justice," but also "in a very real sense, amount[] to an obstruction of justice"), *abrogated on other grounds by Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639 (2008); *Jackson v. Bank of Am., N.A.*, 898 F.3d 1348, 1356 (11th Cir. 2018) ("This Court has filled many pages of the Federal Reporter condemning shotgun pleadings and explaining their vices.").

"The Eleventh Circuit has routinely found that a shotgun pleading is the antithesis of the type of pleading required by [the] Federal Rules of Civil Procedure." *Nezbeda v. Liberty Mut. Ins. Corp.*, 306 F. Supp. 3d 1335, 1343–44 (N.D. Ga. 2017). In that "thirty-year salvo of criticism aimed at shotgun pleadings," the Eleventh Circuit has identified four "sins" commonly found in shotgun pleadings, all of which deny "defendants adequate notice of the claims against them and the grounds upon which each claim rests." *Weiland v. Palm*

Beach County Sheriff's Office, 792 F.3d 1313, 1321–23 (11th Cir. 2015). As relevant here, one "sin" is "asserting multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions." *Id.* at 1323. Another "sin" is filing a complaint "replete with conclusory, vague, and immaterial facts not obviously connected to any particular cause of action." *Id.* at 1322.

Plaintiffs commit both sins in their master Complaint. First, the claims are asserted against all defendants, "making no distinction among the … defendants charged, though geographic and temporal realities make plain that all of the defendants could not have participated in every act complained of." *Magluta*, 256 F.3d at 1284. The "generalized allegations 'lumping' multiple defendants together are insufficient." *W. Coast Roofing & Waterproofing*, 287 F. App'x at 86. Second, every count incorporates by reference 168 paragraphs of purported "factual" allegations, many of which are "not connected to the otherwise generally pled claim in any meaningful way." *Wagner v. First Horizon Pharm. Corp.*, 464 F.3d 1273, 1279 (11th Cir. 2006).

As a result, "each count is replete with factual allegations that could not possibly be material to that specific count, and … any allegations that are material are buried beneath innumerable pages of rambling irrelevancies."

Magluta, 256 F.3d at 1284. Those fatal errors warrant dismissal of plaintiffs' Complaint. *Id*.

C. PLAINTIFFS' COMPLAINT DOES NOT ALLEGE FACTS TO STATE A CLAIM FOR RELIEF PLAUSIBLE ON ITS FACE

The crux of the claims in the master Complaint is that Paragards might break.[9] (*See generally* Complaint.) Indeed, plaintiffs' Complaint contains the words "break" and "breakage" 86 times. Yet, aside from repeated allegations that there is a possibility for a Paragard to break and that defendants allegedly did not warn of that possibility (which is factually wrong, *see supra*, pp. 13-14), plaintiffs' Complaint is a study in vague, conclusory statements and legal conclusions – none of which state a viable claim sufficient to withstand scrutiny.

[9]In addition to having no scientific basis, plaintiffs' allegations that Paragard broke "in utero" are inconsistent with the JPML's delineation of the scope of this MDL, which is based on allegations that Paragard units "broke upon removal." (*See, e.g.,* JPML Transfer Order (Doc. No. 60) ("These actions involve common allegations that the ParaGard[s] … break upon removal…."; *see also* JPML Transfer Order in *Sigley* and *Miller* (Doc. No. 188) ("This litigation centers on allegations that the ParaGard intrauterine device (IUD) … break[s] upon removal"; and "All that is needed to fall within the scope of this MDL is that plaintiff allege that the ParaGard IUD broke upon removal"). The allegations also are inconsistent with core biological and physical principles. Specifically, plaintiffs have not, and cannot, plead how an arm that broke while Paragard was "in utero" (and not embedded) would remain in the uterus and would not be discharged as part of menstrual flow.

To be sure, plaintiffs' Complaint includes factual allegations – 33 pages worth – ranging from Paragard's development and ownership of the NDA to FDA's regulations for drug products (including post-marketing obligations and FDA's current good manufacturing practices ("cGMP")). Sprinkled in between are allegations of what defendants knew or should have known regarding the alleged "defect" of breakage and defendants' purported failure to warn of that potential. But plaintiffs' Complaint simply does not plead *facts* to state a claim plausible on its face.

To start, the approved Paragard labeling states, not once, but three separate times, that a Paragard may break. (*See* Label June 2013 ("2013 Label"),[10] p. 14 (stating "Paragard® can break"); p. 15 (advising Paragard® should be removed "[i]f there is evidence of … breakage …." and advising "breakage of Paragard® … can make removal difficult"); Label, Sept. 2005 ("2005" Label"), p. 13 (stating "Paragard® can break" & advising Paragard® should be removed "[i]f there is evidence of … breakage …."); p. 14 (advising "breakage of Paragard® … can make removal difficult").[11] The package insert

[10] Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/018680s066lbl.pdf

[11] Plaintiffs do not identify which Paragard label is relevant to their claims, but, with the exception of one case, to defendants' knowledge, all plaintiffs' Paragards were placed before the 2019 label revision. As such, the relevant labels would be the 2005 and 2013 versions. The 2019 label also

also states twice that surgery may be required to remove the IUD. (*See* 2013 Label, p. 19 ("Surgery may sometimes be needed to remove ParaGard"; "Surgery may be needed"); 2005 Label, p. 19 (same).)

Setting aside that the exact information which plaintiffs contend is absent is, in fact, in the Paragard label, the allegations under each cause of action are merely recitations of the claim's elements. For example, the allegations in the strict liability design defect count state only that:

- Defendants "designed, manufactured, tested, labeled, packaged, distributed, marketed, and/or sold Paragard used by Plaintiffs" (Compl., ¶171);
- "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" (*Id.*, ¶172);
- "Paragard is defective because the product is prone to break …." (*Id.*, ¶173);

---

includes warnings of breakage and surgery. (*See* Paragard Label, Sept. 2019, §2.5 ("Paragard can break"); §2.6 ("Breakage … of Paragard … can make removal difficult"); §5.5 ("Breakage of an embedded Paragard during non-surgical removal has been reported"); §6.2 (listing "device breakage" as adverse reaction identified during post-approval use of Paragard); Highlights portion of label under Warnings and Precautions ("Perforation: May … require surgery"); §5.6 ("Surgery may be required."); Patient Information portion of label, under "What are possible side effects of Paragard" ("Surgery may sometimes be needed to remove Paragard."; "you may need surgery to have Paragard removed"), available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/018680s069s070lbl.pdf

- The product "was not merchantable and/or reasonably suited to its intended use" (*Id.*, ¶174);
- "Defendants' failure to provide adequate warnings and instructions for Paragard renders the device unreasonably dangerous and defective." (*Id.*, ¶175);
- "Plaintiffs were foreseeable users of the Paragard." (*Id.*, ¶176);
- The "product was in a condition that made it unreasonably dangerous" (*Id.*, ¶¶177, 178);
- The product reached plaintiff "without a substantial change in the condition" (*Id.*, ¶179);
- The products were defective in design because they "failed to perform as safely as persons who ordinarily use the products would have expected" and the "foreseeable risks exceeded the alleged benefits associated with its design" (*Id.*, ¶¶180, 181);
- "Defendants knew or had reason to know that Paragard was defective and inherently dangerous and unsafe when used in the manner instructed by Defendants." (*Id.*, ¶182).

The rote conclusory allegations continue and the pattern repeats through each count. Noticeably absent from plaintiffs' allegations are *facts* of any defect, either in the design, warnings, or manufacture. To state a "product can break" is not a *fact* that alleges a defect in the product's design – any product "can break," but that does not demonstrate a defect exists. Nor does plaintiffs' assertion that "[u]nlike other intrauterine ("IUDs"), Paragard's arms have no curvature and are fixed, straight plastic arms bonded to the plastic vertical post and cooper sleeves are slid on each arm" (*id.*, ¶51) identify any defect. It

describes the product, no more. Further, the mere fact one product is not like another, similar product does not demonstrate any defect in either product. Like a ladder, stating the fact that one is made of wood, while another is made of aluminum does not translate to an allegation that either is defective.

Plaintiffs' allegations tied to the expiration date and the speculative "decay" or loss of "flexibility" over time do not add the substance necessary to state a plausible design defect claim. Plaintiffs plead no facts supporting the conclusory allegation that there is a loss of "flexibility," and they plead no facts that the alleged loss of flexibility causes breakage upon removal. Similarly, their allegations that Paragard "decay[s]" not only lacks facts, but also exhibits a startling lack of understanding of the mechanism of action of Paragard.[12] Furthermore, expiration dating deals with the status of the Paragard before placement, whereas plaintiffs' claims are based on a unit that has been placed. Plaintiffs also do not plead facts as to an expiration date that should have been used. And, finally, plaintiffs do not plead facts showing an expiration date would have made a difference with respect to the vague general design defect allegations they have made.

---

[12] *See, e.g.*, 2005 ParaGard label at CLINICAL PHARMACOLOGY: "The contraceptive effectiveness of ParaGard® is enhanced by copper continuously released into the uterine cavity." Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2005/018680s060lbl.pdf

Similarly, alluding "upon information and belief," that the plastic material did not have "sufficient flexibility to satisfy flexibility specifications" does not allege a manufacturing defect, and, on its face, appears to conflict with plaintiffs' general, vague design defect allegations. Allegations that a Paragard broke or surgical removal was required are not sufficient to plead a manufacturing defect. Those possible risks are and have been disclosed in the Paragard labeling. Accordingly, even if proven, those allegations would not support a manufacturing defect claim. *See, e.g., Yates v. Ortho-McNeil-Janssen Pharm., Inc.,* 808 F.3d 281, 301-02 (6th Cir. 2015) (holding manufacturing defect claim cannot be based on plaintiff experiencing known and warned-of possible side effect while using product noting that "[i]f evidence of a known and warned-of side effect could be used as sufficient circumstantial evidence of a manufacturing defect, then every drug-user who suffered a known and warned-of side effect could state a claim for a manufacturing defect").

Moreover, merely saying there was "no warning," when, in fact, there was a repeated warning, does not state a defect in the product's warnings. The common thread to all the "defect" allegations is that they are contrary to known facts or are vague generalizations that are insufficient to state a claim plausible on its face.

As the Supreme Court stated in *Iqbal*, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. Here, plaintiffs' Complaint lacks "factual content." Basically, plaintiffs allege they had a Paragard placed and it broke either at the time of removal or before.

But, the Supreme Court was clear in *Iqbal* and *Twombly* that more than "unadorned, the defendant-unlawfully-harmed me accusation[s]" are required to state a viable, plausible claim. *Iqbal*, 556 U.S. at 678. Instead, plaintiffs must make a "showing" rather than a blanket assertion that they are entitled to relief from defendants. *Twombly*, 550 U.S. at 444, n.3. Because plaintiffs' allegations are merely conclusory, they are not entitled to a presumption of truth and judgment should be entered for defendants on each and every cause of action. *See Iqbal*, 556 U.S. at 678.

D. PLAINTIFFS' FRAUD-BASED CLAIMS ARE NOT PLED WITH THE REQUISITE SPECIFICITY

Plaintiffs' fraud-based claims are subject to Federal Rule of Civil Procedure 9(b)'s heightened pleadings standards, and must specifically 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 mislead the Plaintiffs'; and (4) what the defendants gained by the alleged fraud." *Brooks v. Blue Cross and Blue Shield of Fla., Inc.*, 116 F.3d 1364, 1380-81 (11th Cir. 1997); *see also U.S. ex rel., Joshi v. St. Luke's Hosp., Inc.*, 441 F.3d 552 (8th Cir. 2006) (stating fraud-based claim must allege "such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result"). Stated differently, plaintiff must identify the "who, what, where, and how" of the alleged fraud as to each defendant. *Techject, Inc. v. Paypal Holdings, Inc.*, 2018 WL 9812751, *6 (N.D. Ga. Aug. 10, 2018) (citing *In American Dental Assn. v. Cigna Corp.*, 605 F.3d 1283, 1291 (11th Cir. 2010)).

Plaintiffs' claims fail on several grounds. The shotgun pleading nature of the Complaint alone renders the allegations far short of the specificity required. Moreover and fundamentally, nowhere in the Complaint do plaintiffs identify a representation of fact that is false. Under the "Fraud & Deceit" count, plaintiffs play games with the Paragard label, making up language that is nowhere in the label and inferring statements that simply do not exist. (Compl. ¶¶ 289-307.) For example, a statement that Paragard is "safe" (*see id.*, ¶290) appears nowhere in the Paragard label – and plaintiffs point to no such language in the label (nor can they). Plaintiffs' naked assertion

that defendants claimed Paragard was safe in the label is fundamentally flawed for a product that carries a warning about risks of such things as pelvic inflammatory disease, ectopic pregnancy, and the possibility of surgery. Plaintiffs also point to no advertisements or other promotional items where any defendant represented that Paragard was "safe." Although it is true that FDA's approval of Paragard is a determination that "this drug is safe and effective for use as recommended in the submitted labeling,"[13] plaintiffs set forth no facts in their Complaint identifying any place in the Paragard label or any Paragard advertisements where the statement "Paragard had been appropriately tested and was found to be safe and effective" appears, as plaintiffs allege in paragraph 293 of the Complaint. Also absent is any identification of a source for each defendant's purported statements that Paragard "was as safe or safer than other products and/or procedures available and/or on the market," as plaintiffs allege in paragraph 298. In fact, plaintiffs can point to nothing in the Paragard label or promotional items issued by "Defendants" in which it is stated that Paragard is "safe" or "safer than other products." To the contrary, the Paragard label warned of various risks,

[13] *See* https://www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/018680_original_approval.pdf

including perforation, embedment, breakage, and surgery. Plaintiffs' vague allegations regarding information on websites, meetings, literature, press releases, etc. (Compl., ¶300), do not add any specificity to their fraud allegations.[14] As with the other allegations, there is no who, what, or where, which are essential to proper pleading of a fraud claim. *Techject, Inc.,* 2018 WL 9812751, at *6; *Moore v. Mylan, Inc.*, 840 F. Supp. 2d 1337, 1350-51 (N.D. Ga. 2012).[15] Instead, plaintiffs apply their improper shotgun pleading strategy to the fraud and misrepresentation counts, alleging all defendants made the "representations" to the plaintiffs. None of plaintiffs' allegations that defendants made a false representation regarding Paragard is entitled to deference or presumption of truth, and do not satisfy the plausibility mandate set forth in *Twombly* and *Iqbal*, or the heightened Rule 9 pleading standards.

Also, plaintiffs fail to sufficiently plead the "reliance" element of their fraud claims. Plaintiffs claim they and their physicians relied on the "false

---

[14] None of the individual complaints filed to date and pending in this MDL include sufficient allegations to sustain a fraud claim. Those complaints suffer from the same insufficient allegations as appear the master Complaint. In the master Complaint, in addition to alleging the "who, when, where, and how" of the alleged fraud, plaintiffs should, at the very least, allege specific statements or representations (the "what").

[15] The references in paragraphs 72 and 73 of plaintiffs' Complaint regarding a letter from FDA to CooperSurgical in 2019 still fall short. There is no indication of what the "representation" entailed, much less that it involved the issues in this litigation; *i.e.*, embedment, breakage or surgery.

representations" (Compl., ¶296), but never allege any plaintiff or any plaintiff's physician saw or read the Paragard label, or the specific time at which any plaintiff or plaintiff's physician allegedly saw or read it, or the manner in which the statements in the Paragard label misled them at the time. Because plaintiffs do not allege that any plaintiff or plaintiff's physician ever saw or read the Paragard label or any other "representations," the allegation that they reasonably relied on any purported misrepresentation is no more than a conclusory allegation that merely (and impermissibly) parrots the elements of fraud. *See Twombly*, 550 U.S. at 555, 557; *see also Wilding v. DNC Services Corp.*, 941 F.3d 1116, 1128 (11th Cir, 2019) ("A bare allegation of reliance on alleged misrepresentations, bereft of any additional detail, will not suffice under Rule 9(b)."

E. DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS DIRECTED AT PHARMACEUTICAL PRODUCTS ARE PREEMPTED BY FEDERAL LAW

Aside from the fact that plaintiffs do not state actionable claims, plaintiffs' claims are preempted by the FDCA which governs pharmaceutical products.

1. The Supremacy Clause, *Wyeth v. Levine*, *PLIVA, Inc. v. Mensing*, *Mutual Pharm. Co., Inc. v. Bartlett*, and *Merck Sharp & Dohme Corp. v. Albrecht*

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. It has been well-settled since *M'Culloch v. Maryland*, 17 U.S. (4 Wheat) 316 (1819), that state law that conflicts with federal law is "without effect." *See Maryland v. Louisiana*, 451 U.S. 725, 746 (1981).

In recent years, the United States Supreme Court addressed preemption in lawsuits aimed at pharmaceutical products on four occasions. The first, *Wyeth v. Levine*, 555 U.S. 555 (2009), involved preemption of state-law claims involving pharmaceutical products approved through an NDA, like Paragard. The Court, pointing to FDA's CBE process, held it was not impossible for Wyeth to satisfy both its state law duty to provide adequate warnings and federal law requirements. It did so, however, only because information existed that would have supported the submission of a CBE; *i.e.*, newly acquired information existed that warranted a change to one or more of the label sections specified in 21 C.F.R. §314.70(c)(6). The Court acknowledged, however, that ultimately FDA must approve the change and FDA retains authority to reject the change. *Id.* Although the Court held that the plaintiff's

claims in *Levine* were not preempted, it ruled that claims against an NDA holder are preempted where "clear evidence" shows FDA would not have approved a change to the drug's label, rendering it impossible for the manufacturer to comply with both state and federal law. *Id.* at 571-72.

Two years later, the Supreme Court again addressed preemption of claims against pharmaceutical manufacturers in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), a case involving generic drugs approved under an abbreviated new drug application ("ANDA"). While the *Mensing* Court acknowledged that the federal requirements applicable to NDA drugs differ from those applicable to an ANDA, the Court was clear that the "question for 'impossibility' preemption is whether the private party could *independently* do under federal law what state law requires of it." *Id.* at 620 (emphasis added) (*citing Levine*, 555 U.S. at 573). If not, the state-law is preempted.

Two years after *Mensing*, the Supreme Court decided *Mutual Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472 (2013). In *Bartlett*, the Court reiterated its holding in *Mensing* and also held that state-law design defect claims aimed at pharmaceutical products are preempted. With respect to the design defect claim, the Court found that "[i]n the drug context, either increasing the 'usefulness' of a product or reducing its 'risk of danger' would require redesigning the drug." *Id.* at 483. It held design defect claims are preempted

because legally a drug may not be changed without FDA's prior approval. *Id.* at 483-84. Like *Mensing*, *Bartlett* involved a generic drug, but the holdings in both cases apply equally to drugs approved under an ANDA or an NDA.

Then two years ago, the Court decided *Merck Sharp & Dohme Corp. v. Albrecht*, 586 U.S. ---, 139 S. Ct. 1668 (2019). In *Albrecht*, the Court ruled that the preemption question is one of law for the court to decide. *Id.* at 1672. It also discussed the "clear evidence" language used in its *Levine* decision. The Court stated that "clear evidence" is evidence that shows FDA was fully informed of "the justifications for the warning required by state law" and "FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug's label to include that warning." *Id.* at 1672. During the course of its discussion, however, the Court acknowledged that FDA's CBE regulation "permits drug manufacturers to change a label [only] to 'reflect newly acquired information' if the changes 'add or strengthen a ... warning' for which there is 'evidence of a causal association.'" *Id.* at 1679 (citing 21 C.F.R. §314.70(c)(6)(iii)(A)). And, the Court recognized that "manufacturers cannot propose a change that is not based on reasonable evidence." *Id.*[16]

[16] In an amicus brief submitted in *Albrecht*, the Solicitor General described what qualifies as "newly acquired information" sufficient to support a label change using the CBE:

Applying *Levine*, *Mensing*, *Bartlett*, and *Albrecht*, it is clear that "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Mensing*, 465 U.S. at 623-24. And, FDA's regulation informs manufacturers that FDA will not permit a change to drug labeling, through use of a CBE, unless "newly acquired information" exists that constitutes reasonable evidence of a causal association supporting a new or strengthened warning.

2. Design Defect Claims Directed at Pharmaceutical Products Are Preempted By Federal Law

Plaintiffs' design defect claims are preempted by federal law. "Once a drug—whether generic or brand-name—is approved, the manufacturer is

---

> Information—including "new analyses of previously submitted data"—will qualify as "[n]ewly acquired information" only if it "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. 314.3(b). Accordingly, nominally "new" information concerning risks of a materially similar type, severity, and frequency as those revealed in information previously evaluated by FDA is cumulative and not "newly acquired information" that could justify a CBE supplement. If for instance, FDA previously determined that that evidence of X was insufficient to warrant a warning about risk Y, the existence of additional but similar information about X would be insufficient to justify a warning.

Albrecht, Amicus Brief, p. 28, n.11, available at 20180920182839284_17-290tsacUnitedStates.pdf (supremecourt.gov).

prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active 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)). A design defect theory would require that Paragard be redesigned. That is precisely the kind of impossibility that led the Supreme Court to find preemption. As the Supreme Court definitively stated in *Bartlett*, "we hold that state-law design-defect claims like New Hampshire's that place a duty on manufacturers to render a drug safer by either altering its composition or altering its labeling are in conflict with federal laws that prohibit manufacturers from unilaterally altering drug composition or labeling." *Id*. at 490. Importantly, a hypothetical supposition that the "FDA may approve an alteration does not negate the present impossibility." *Barcal v. EMD Serono, Inc.*, 2016 WL 1086028, at *4 (N.D. Ala. 2016).

In *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139-1140 (8th Cir. 2014), the Eighth Circuit Court of Appeals applied *Bartlett* and held the plaintiff's claims were preempted. In *Brinkley*, the plaintiff alleged she developed a neurological disorder as a result of taking defendant's product long-term. *Id.* at 1136. In affirming the district court's dismissal of the plaintiff's design defect claim, the Eighth Circuit held that federal law preempts state law claims that would require the manufacturer to redesign its drug. *Id.* at 1139-40. The court noted

that "[s]ince *Bartlett*, there is a growing consensus in the federal circuit courts that the preemption analysis in *Mensing* and *Bartlett* proves fatal to state law claims like [the plaintiff's]." *Id.* (citations omitted).

Similarly, in *Yates*, the United States Court of Appeals for the Sixth Circuit, applying *Bartlett*, found the plaintiff's design defect claim preempted. The plaintiff in *Yates* had a stroke after using a birth control patch and sued the brand-name manufacturers for various claims under New York law, including defective design. *Yates,* 808 F.3d at 287-88. The plaintiff contended, even after the FDA approved the medication, that the defendant manufacturers had a duty to change the design of the medication once they discovered that it was unreasonably dangerous. *Id*. at 297-98. As framed by the Sixth Circuit, the issue in *Yates* was whether the defendants could have complied with their alleged duty under New York law to change the product design post-approval, while simultaneously complying with federal law." *Id*. at 294. After careful analysis, the Sixth Circuit rejected the plaintiff's arguments and held that federal law expressly prohibited the defendants from complying with New York's design defect law. *Id*. at 297-300.

The Sixth Circuit held that the plaintiff's "design defect claim is clearly preempted by federal law." *Id*. at 298. The court reasoned that "FDA regulations provide that once 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.'" *Id.* (quoting 21 C.F.R. § 314.70(b)(2)(i)). The court was "convinced" and thought that it was "clear" that the plaintiff's suggested design change—reducing the dosage of estrogen in the medication—amounted to a "major change" in the medication. *Id.* The court thus concluded that "to the extent [plaintiff] argues that defendants should have altered the formulation of [the medication] after the FDA had approved the patch," the claim clearly was preempted as "federal law prohibited defendants from decreasing the dosage of estrogen post-approval." *Id.* at 298-99.

Other courts agree. For example, in *Barcal*, the plaintiff alleged that her mother's use of the fertility medication Serophene caused her to be born with a severe cardiac birth defect. *Barcal*, 2016 WL 1086028, at *1. The court held that the plaintiff's design defect claim under state law was preempted by federal law. *Id.* at *3. The court reasoned that the state law claim "would essentially require [the defendant] to redesign Serophene." *Id.* at *4. "This is precisely the kind of impossibility in which the Supreme Court has found preemption." *Id.* FDA-approved medicines "cannot be altered without the FDA's prior permission, rendering compliance with both state and federal law

impossible." *Id.*; *see also Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 184-185 (S.D.N.Y. 2016) (dismissing design defect claim as preempted); *Fleming v. Janssen Pharm., Inc.*, 2016 WL 3180299, *4-5 (W.D. Tenn. 2016) (same); *Rheinfrank v. Abbott Labs., Inc.*, 137 F. Supp. 3d 1035, 1040-41 (S.D. Ohio 2015) (same); *Shah v. Forest Laboratories, Inc.*, 2015 WL 3396813 (N.D. Ill. May 26, 2015)(same); *Booker v. Johnson & Johnson*, 2014 WL 5113305 (N.D. Ohio Oct. 10, 2014) (same); *Amos v. Biogen IDEC, Inc.*, 2014 WL 2882104, *3 (W.D.N.Y. Oct. 10, 2014) (same).

As in those cases, a design change to Paragard would require FDA-approval. Thus, it is impossible to redesign the product without violating federal law. Accordingly, any design defect claim is preempted by federal law, and that conclusion is not altered by plaintiffs' allegations that Paragard's "design is [] flawed" because "it does not account for the long expiration date and use of the product to decay and lose flexibility over time on the shelf and in situ." (Compl., ¶55.)

3. Plaintiffs' Failure-to-Warn Claims Are Preempted as Plaintiffs Do Not Identify any "Newly Acquired Information" that Would Warrant or Support a Label Change

Like the design defect claims, plaintiffs' failure-to-warn claims are

preempted.[17] The first step in analyzing plaintiffs' warnings-based claims, is to unwind exactly what plaintiffs allege. In a nutshell, plaintiffs complain that defendants did not adequately warn of the potential for breakage and surgery. Plaintiffs clearly cannot dispute, however, that the Paragard labeling includes warnings as to both (three times as to breakage and twice as to surgery). Nor can they dispute that FDA's CBE regulation permits changes to warnings only to "add or strengthen" a warning. *See* 21 C.F.R. §314.70(c)(6)(iii)(A). Breakage and surgery already are included in the labeling and obviously cannot be "added" through submission of a CBE.[18] As for "strengthening," plaintiffs seemingly are alleging that defendants should have wordsmithed the existing language in some fashion (yet, plaintiffs never say what exactly that warning

---

[17] Plaintiffs' Tenth Count is titled "Breach of Express Warranty." (*See* Compl., p. 81.) In reality, although plaintiffs include the necessary express warranty buzz words, that cause of action is no more than a differently-titled failure-to-warn claim as evidenced by plaintiffs' allegation that defendants did not "accurately warn." (*Id.*, ¶346.) As such, the preemption analysis applies equally to that cause of action. The same is true of plaintiffs' negligent misrepresentation count. (*See, e.g.*, *id.*, ¶323 (alleging defendants failed to disclose material information); ¶331 (alleging defendants "misrepresented Paragard's high risk of unreasonable and dangerous side effects"). The substitution of the buzz word "misrepresentation" for "inadequate warning" in the misrepresentation count is a distinction without a difference. The gravamen of the claim remains one of purportedly failing to warn.

[18] Nor could defendants change the labeling by adding a boxed warning to emphasize the potential for breakage and surgery as only FDA may require boxed warnings. *See* 21 C.F.R. §201.80(e) (only FDA may require boxed warnings).

should be). There are two problems though.

First, the CBE regulation is not, and never was, intended to be used to "wordsmith" label language.[19] Moreover, "wordsmithing" does not satisfy the standard required for use of a CBE. As the *Albrecht* Court explained, submission of a CBE requires "newly acquired information" that "evidences [] a causal association." *Albrecht* at 1679 (citing 21 C.F.R. §314.70(c)(6)(iii)(A)). And, "manufacturers cannot propose a change that is not based on reasonable evidence." *Id.*

That leads to the second problem: The non-existence of "newly acquired information." As the *Albrecht* Court and the First Circuit Court of Appeals in *In re: Celexa and Lexapro Marketing and Sales Practices Litig.*, 779 F.3d 34, 37 (1st Cir. 2015), recognized, an NDA holder can use FDA's CBE supplement process to change product labeling only where "newly acquired information" becomes available supporting certain changes to certain sections of product labeling. *See also* 21 C.F.R. §314.70(c)(6). As a result, plaintiffs must allege, in the first instance, what "newly acquired information" warrants the label change they advocate. Where the plaintiffs do not allege the "newly acquired

[19] One can only imagine the burden on FDA if manufacturers continually, and repeatedly, submitted CBEs to wordsmith label language like plaintiffs suggest.

information" that would have supported an independent label change the company could have made, they do not overcome the preemptive effect of federal law. *Id*. at 42-43. *See also Utts v. Bristol-Myers Squibb Co*., 251 F. Supp. 3d 644, 673 (S.D.N.Y. 2017); *Mitchell v. Boehringer Ingelheim Pharms*., 2017 WL 5617473 (W.D. Tenn. Nov. 21, 2017).

Changes using a CBE supplement are limited to those based on "newly acquired information" that supports a change to add or strengthen a contraindication, warning, precaution, adverse reaction; a statement about drug abuse, dependence, or overdosage; an instruction about dosage and administration that is intended to increase the safe use of the drug product; or that would delete false, misleading, or unsupported indications for use or claims for effectiveness. *See* 21 C.F.R. §314.70(c)(6)(iii); *see also Seufert v. Merck Sharp & Dohme Corp*., 187 F. Supp. 3d 1163, 1176 (S.D. Cal. 2016) (acknowledging CBE can be used to make label change "only when submission is supported by sufficient scientific data"). Without any "newly acquired information" to support submission of a CBE, any change to a pharmaceutical product's label must be accomplished through FDA's prior approval process (unless the change falls within the categories FDA delineated as reportable in the company's annual report).

Plaintiffs' Complaint lacks allegations that new safety information existed to support a change to Paragard's label. Plaintiffs must, but have not and cannot, plead "newly acquired information" received by defendants that would have supported a CBE to change the Paragard label. And, plaintiffs' cannot merely allege that defendants had "newly acquired information," without identifying the information. That thread-bare allegation does not overcome preemption. *See Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708-09 (2d Cir. 2019) (holding "conclusory and vague" allegations that a manufacturer became aware of newly acquired information do not meet the Rule 8 standard); *see also In re: Celexa and Lexapro*, 779 F.3d at 41-42; *Utts*, 251 F. Supp. 3d at 673 (dismissing inadequate-warning claims where plaintiffs identified specific information but none of it actually qualified under the CBE regulation as "newly acquired information"). Without newly acquired information that scientifically supports a change, the Paragard label could be changed only with "[FDA's] special permission and assistance," i.e., through submission of a PAS. As a result, plaintiffs' warning claims are preempted.

Plaintiffs' "expiration date" allegations do not help them escape preemption. According to plaintiffs, defendants knew or should have known that the "expiration date was too long." (Compl., ¶102.) They allege defendants should have changed "its label to delete a false and misleading

expiration date, or to add a proper expiration date to ensure that the Paragard would not degrade, causing the product to be more susceptible to breakage once inside a woman's body." (*Id.*, ¶101.) But, what plaintiffs really are asserting is that the indication for use should have been changed. Paragard is "indicated for intrauterine contraception for up to 10 years." (2005 Label, p. 4; 2013 Label, p. 4.) Plaintiffs contend that is "too long" and assert defendants could have changed the "expiration date" without FDA's prior approval. Yet, because the expiration date is tied to the indicated use, plaintiffs are mistaken. The "indications and usage" section of a drug label cannot be changed using the CBE. *See* 21 C.F.R. §314.70(c)(6). In short, plaintiffs' "expiration date" theory is a red herring that does not change the preemption analysis.

4. Plaintiffs' Manufacturing Defect Claims Are Preempted

Preemption bars with equal force plaintiffs' purported manufacturing defect claims. Generally speaking, a manufacturing defect refers to individual products that are improperly made while a design defect concerns a defect in the entire product line. *See, e.g. May v. Ethicon, Inc.*, 2020 WL 674357, *3 (N.D. Ga. Feb 11, 2020) ("Generally, a manufacturing defect results from an error specifically in the fabrication process, as distinct from an error in the design process" and "[w]hen a plaintiff calls into question the safety of an entire

product line ... the claim is one for a design defect and not for a manufacturing defect." (citing *Fletcher v. Water Applications Dist. Grp., Inc.*, 333 Ga. App. 693, 773 S.E.2d 859 (2015), *aff'd in part, rev'd in part on other grounds sub nom, Certainteed Corp. v. Fletcher*, 300 Ga. 327, 794 S.E.2d 641 (2016))). Plaintiffs have alleged that "at all times" Paragard was inherently dangerous as designed, manufactured or sold. (Compl., ¶393; *see also id.*, ¶¶172, 182, and 317.)

Additionally, some allegations, although titled "manufacturing defect," are framed in terms of a design defect affecting every Paragard. (*See, e.g.*, Compl., ¶220 (alleging "Paragard" risks "are far more significant and devastating than the risks posed by other products" and that the risks "far outweigh the utility of Paragard."[20]); *see also* ¶217.) That Paragards are made of "plastic," is part and parcel of the product design, and that aspect of the NDA

[20] Plaintiffs' allegations that defendants failed to follow cGMPs is preempted for the additional reason that only the federal government is empowered to enforce federal regulations, and a private cause of action based upon cGMPs is preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *see also Frere v. Medtronic, Inc.*, 2016 WL 1533524, at *7 (C.D. Cal. 2016) ("Plaintiff[ ]s manufacturing defect claim is impliedly preempted under *Buckman*, because Plaintiff's entire claim rests on conduct Plaintiff claim [sic] that Defendants violated the FDA's CGMP's."); *Burkett v. Smith & Nephew GmbH*, 2014 WL 1315315, at *5 (E.D. N.Y. 2014) ("Because Burkett's manufacturing defect claim is based on violation of generally applicable cGMP's, as opposed to federal requirements specific to the R3 liner, preemption bars the claim.").

is an integral part of FDA's approval, which could not be altered without FDA's prior approval. Plaintiffs' attempt to caption them as manufacturing defect allegations notwithstanding, those allegations and claims based on them are preempted design defect claims.

As best they can be understood, plaintiffs' other allegations are vague, general, and conclusory "manufacturing defect" allegations that are directed at the Paragard manufacturing process. (*See, e.g.*, Compl., ¶¶139, 140-141; 142.) Plaintiffs have not pled any specific facts such as the identification of 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, but was not followed. *See Iqbal,* 556 U.S. at 678 (complaint must offer more than labels, conclusory statements and naked assertions devoid of factual enhancement to plead a claim upon which relief can be granted). The Southern District of Florida recently dismissed manufacturing defect claims lacking those allegations as not plausibly pled. *In re Zantac (Ranitidine) Products Liability Litigation*, --- F. Supp. 3d ---, 2020 WL 7864213, *21 (S.D. Fla. Dec. 31, 2020).[21]

[21] In *In re Zantac*, the dismissed claims, similar to those here, included allegations of manufacturing defects due to "failure to follow Current Good Manufacturing Practices" and to "implement procedures that would reduce or eliminate" the purported defect. *Id.* (*Compare* Compl., ¶¶220 (a) and (c).)

The allegations of defects in the manufacturing process for Paragard are allegations that the process should be changed. (*See* Compl., ¶¶140-141; 143.) A "'major manufacturing change' is a manufacturing change that has 'substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug.'" 21 U.S.C. §356a(c)(2); *see also* 21 C.F.R. §314.70(b)(1). Included are changes "in the qualitative or quantitative formulation" of the drug product or a change in the "manufacture of the drug substance that may affect the impurity profile and/or the physical, chemical or biological properties of the drug substance." 21 U.S.C. §356a(c)(2)(A); 21 C.F.R.§314.70(b)(2)(i), (iv). A drug product that is made with a major manufacturing change may be distributed only after the submission of a PAS to the FDA and FDA approval of that PAS. *See* 21 U.S.C. §356a(c)(1); *see also* 21 C.F.R.§314.70(b). The manufacturing process changes plaintiffs assert are changes to physical, chemical and/or biological properties of Paragard that could not be made independently without FDA pre-approval. Consequently, plaintiffs' manufacturing defect claims are preempted. *Mensing*, 564 U.S. at 620; *In re Zantac,* 2020 WL 7864213, *21.

IV. CONCLUSION

Plaintiffs' claims are inadequately pled. Further, their claims are preempted by federal law. Accordingly, defendants' motion to dismiss should be granted.

Respectfully submitted,

/s/ Frederick M. Erny
Frederick M. Erny, Esq.
Gina M. Saelinger, Esq.
Ulmer & Berne LLP
600 Vine Street, Suite 2800
Cincinnati, OH 45202
Telephone: 513.698.5144
ferny@ulmer.com
gsaelinger@ulmer.com

Co-Lead Counsel for Defendants

/s/ Lori G. Cohen
Lori G. Cohen, Esq.
Allison Ng, Esq.
Greenberg Traurig, LLP
Terminus 200
3333 Piedmont Road NE, Suite 2500
Atlanta, GA 30305
Telephone: 678.553.2385
CohenL@gtlaw.com
nga@gtlaw.com

Co-Liaison Counsel for Defendants

LOCAL RULE 7.1 CERTIFICATE

This brief has been prepared in accordance with Local Rule 5.1 in Century Schoolbook, 13 point font.

/s/ Lori G. Cohen
Lori G. Cohen

CERTIFICATE OF SERVICE

I certify that on this 6th day of May, 2021, I electronically filed a copy of the foregoing Memorandum in Support of Motion to Dismiss Plaintiffs' Second Amended Master Personal Injury Complaint with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

By: */s/ Lori G. Cohen*
Lori G. Cohen, Esq.