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

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

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

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Plaintiffs submit this memorandum of law in opposition to Defendants' Motion to Dismiss Plaintiffs' Second Amended Master Personal Injury Complaint (MPIC). *See* Dkt. 89-1 (Mot.).

INTRODUCTION

For years, Defendants intentionally marketed Paragard to women—particularly younger women—as quick, easy, and safe to remove. Defendants told women they could use Paragard to effectively prevent pregnancy while the product was in place; but that it could be *quickly* removed "at any time," allowing a woman to "try to get pregnant the same day" when she wanted to conceive. Defendants' representations were false. Paragard poses significant health risks, and the product has subjected untold thousands of women to material injuries.

These injuries stem from the simple fact that Paragard has a propensity to break, especially during removal. That breakage, in turn, often requires a surgical procedure to remove broken pieces from a woman's body. Defendants did not tell Plaintiffs or their healthcare providers how frequently these breakages occur or the severity and permanency of potential injuries (including, but not limited to, rendering women unable to conceive), even though Defendants had received thousands of adverse reports and knew or should have known of Paragard's dangers.

In hundreds of paragraphs of well-pleaded factual allegations, Plaintiffs explain each claim brought against all of the Defendants. Although multiple Defendants manufactured Paragard, each is liable to Plaintiffs for refusing to remedy design and manufacturing defects and/or failing to adequately disclose known risks. Defendants may dispute these well-pleaded allegations, but surely they are on notice of them. Defendants nonetheless maintain that the MPIC (1) has not sufficiently distinguished among the various Defendants or inappropriately incorporates factual allegations into the counts, (2) fails to state a claim for relief, (3) violates Rule 9's pleading standard, and (4) pursues preempted causes of action. Each of the arguments is without merit and Defendants' motion should be denied.

First, the MPIC is not a shotgun pleading. A shotgun pleading is one that "confuse[s] the 'enemy,' and the court," thwarting the defendant's ability to prepare its defense. *Weiland v. Palm Beach Cty. Sheriff's Off.*, 792 F.3d 1313, 1320 (11th Cir. 2015). Here, Defendants are not confused and they do not pretend otherwise. *See* Mot. 17–20. Instead, they simply take issue with Plaintiffs' allegations that "all defendants participated in every act about which plaintiffs complain." *Id.* at 2. But if Defendants dispute the facts, they may answer the MPIC and deny them.

Second, the MPIC states a claim for failure to warn, design defect, and manufacturing defect. Defendants' Motion relies almost entirely on improperly

disputing factual allegations about the defectiveness of Paragard and the adequacy of their warnings. Defendants do not even try to conceal their hostility to the Rule 12(b)(6) standard. They categorize well-pleaded allegations as "factually wrong," Mot. 20, and say the "common thread to all the 'defect' allegations is that they are *contrary to known facts*," *id.* at 25 (emphasis added). Defendants cite only a summary-judgment case, which has no bearing on a motion to dismiss, and they quote selective portions of different warnings they propose are at issue, apparently hoping this Court will deem the warnings adequate as a matter of law in every state. Such questions of fact have no role in a Rule 12 motion, especially where the MPIC pleads ample facts to support the claims.

Third, the fraud claims are pleaded with specificity. The MPIC lists a number of specific misrepresentations—Defendants simply deny they exist, or neglect to cite the relevant portions of the MPIC. Some prongs—such as each plaintiff's reliance—are not in the master pleading, but that sort of plaintiff-specific allegation does not need to be pleaded in a master complaint in an MDL.

Fourth, no claims are preempted. Preemption is an affirmative defense, and a particularly demanding one at that. Yet Defendants argue that *Plaintiffs* needed to plead specific, newly acquired information that Defendants could have used to change their label. That feeble effort at burden shifting would be improper even at

summary judgment or at trial; it certainly cannot succeed on a motion to dismiss. Beyond that fatal problem, new information obviously existed with respect to labels before 2019, as Defendants in fact *changed the label* in 2019. Moreover, Defendants were required to submit adverse event reports, yet failed to do so, which is actionable under state law. Design-defect claims are well pleaded because product warnings are a key aspect of product design under state law, and Defendants could have changed the warnings. Manufacturing defect claims are well pleaded because nothing in federal law barred Defendants from improving their manufacturing process and complying with the processes already in place.

Defendants' full-throated dispute of key allegations in the MPIC makes one point of agreement between the parties clear: this case turns on disputed facts. The Court should deny the Motion so that those facts can be discovered and litigated.

STATEMENT OF FACTS

Paragard is a non-hormonal, non-surgical intrauterine device (IUD) that is placed into a woman's uterus by a healthcare provider. MPIC ¶¶ 30–31. It is composed of copper wire wrapped around a T-shaped plastic frame; the copper is intended to produce an inflammatory reaction that disrupts sperm transport and egg fertilization and prevents a woman from getting pregnant. *Id.* ¶ 31. A thin thread tied through the tip of each Paragard allows the easy detection and non-surgical removal

of Paragard from a woman's body. *Id.* Paragard is supposed to be, and is marketed as, a safe, easy, and fully reversible form of birth control. *Id.* ¶¶ 9, 30.

But Paragard is not safe, easy, or fully reversible. Thousands of women have suffered injuries—including, but not limited to, permanent infertility—from using Paragard. MPIC ¶¶ 148–54. 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 the plastic vertical post" resulting in a less flexible product. *Id.* ¶¶ 51, 62. This unique, rigid T-shaped 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.* ¶ 53. The inflexibility is also partly caused by the raw plastic not meeting minimum flexibility requirements. *Id.* ¶¶ 37, 54. As a result, Paragard breaks during removal and has caused Plaintiffs' injuries. *Id.* ¶ 62, 148–54.

Defendants knew (or should have known) that Paragard could cause and did cause serious harm to women due to its propensity to break, including during removal, but Defendants failed to adequately warn of these risks. MPIC ¶¶ 64–69. Between 2009 and 2020, Defendants received reports of over 2000 Paragard breaks through the FDA Adverse Event Reporting System (FAERS). *Id.* ¶ 121. Defendants received even more adverse event reports, yet failed to properly investigate, record,

or submit those reports to the FDA. *Id.* Complaints of breakage occurred at a disproportionately greater frequency than what would normally be expected, putting Defendants on notice of the issues. *Id.* Yet Defendants failed to act. Specifically, Defendants failed 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. *See id.* ¶¶ 69, 81.

Defendants' labels only warn of breakage as connected to when Paragard is embedded in the uterus or perforates the uterine wall or cervix. MPIC ¶¶ 68–70, 80–81. Such a warning gives the false impression that breakage occurs less frequently than it actually does. Critically, no Paragard label warns that breakage can occur during a routine removal, no label warns about the frequency of breakages, and no label warns that surgical intervention may be required for routine removals. *Id.* Defendants' labels are thus inaccurate and insufficient. The MPIC is a master pleading and does not identify the particular label at issue because different plaintiffs saw different labels. The relevant label will depend on when a specific plaintiff had her Paragard implanted. Some labels were inadequate in other ways, but *all* failed to warn about the risks during routine removal, the frequency of injuries, and the risk of surgical intervention due to breakage.

Despite Defendants' knowledge that Paragard could break during a routine removal and the grave injuries that could ensue, Defendants failed to unilaterally change or supplement the label to adequately warn of these risks. MPIC ¶¶ 6–7, 78–81, 97–102. Defendants could have—and should have—updated the label to reflect additional warnings pursuant to a "changes being effected" (CBE) supplement, 21 C.F.R. § 314.70(c). Notably, the Cooper Defendants ultimately amended the Paragard warning label in September 2019[1] to add some (but not enough) information about breakages, MPIC ¶¶ 78–79, demonstrating that they had enough information to enhance the warning. The Cooper Defendants added a warning that "[b]reakage of an embedded Paragard during non-surgical removal has been reported" but still failed to adequately warn about, for example, "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." *Id.* ¶¶ 80–81. The current warning label thus remains inadequate.

Defendants not only failed to warn about the real risks of Paragard, but also undertook a concerted marketing campaign to promote Paragard as a safe, effective,

[1] Although Defendants used the FDA's prior approval process, they could have used the CBE supplement to strengthen the warnings as discussed *infra* § V(C)(2).

and easily reversible form of non-surgical birth control. MPIC ¶¶ 75–77. Plaintiffs relied on Defendants' misrepresentations and had Paragard inserted based on the belief Paragard would be safe and allow them to control their child-bearing timeline. Now, long after some Plaintiffs were injured, Defendants have the audacity to argue not only that Paragard is not defective, but also that Defendants adequately *warned* of material risks. Mot. 21–22. Neither contention is true. The MPIC illustrates that Paragard is a defective product and that Defendants failed to adequately warn about significant health risks despite knowing about them for years.

Plaintiffs also suffered injuries from Paragard's manufacturing defects. Defendants failed to comply with Current Good Manufacturing Practices (CGMPs) and their own Standard Operating Procedures (SOPs) and polices; these violations resulted in the defects that caused Plaintiffs' injuries. MPIC ¶¶ 129–47. Defendants knew of these violations and took no action to correct them. *See, e.g.*, *id.* ¶¶ 139-45.

ARGUMENT

I. Motion to Dismiss Standard

"A 'motion to dismiss for failure to state a claim upon which relief can be granted merely tests the sufficiency of the complaint; it does not decide the merits of the case.'" *Higgins v. Bank of Am., N.A.*, 2015 WL 12086083, at *3 (N.D. Ga. Sept. 22, 2015), *adopted by* 2015 WL 12086093 (N.D. Ga. Oct. 20, 2015). That is

because "Federal Rule of Civil Procedure 8(a)(2) requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the claim is and the grounds upon which it rests.'" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting Fed. R. Civ. P. 8(a)(2), other quotations and citations omitted). A complaint "does not need detailed factual allegations," *id.*; it need only "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Great Am. Assurance Co. v. Goodwin*, 2016 WL 9454434, at *1 (N.D. Ga. Sept. 29, 2016) (May, J.) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). In other words, the plaintiff must "plead[] factual content necessary for the court to draw the reasonable inference that the defendant is liable for the conduct alleged." *Id.* And the Court must take "the factual allegations in the complaint as true and construe them in the light most favorable to the plaintiff." *Pielage v. McConnell*, 516 F.3d 1282, 1284 (11th Cir. 2008). Plaintiffs far exceed this standard.

II. The MPIC Provides Each Defendant Adequate Notice of the Claims.

The MPIC is not a shotgun pleading for the simple reason that Defendants are clearly on notice of the claims against them. The "unifying characteristic" of shotgun pleadings is that they fail "to give the defendants adequate notice of the claims against them and the grounds upon which each claim rests." *Weiland*, 792 F.3d at

1321–23. In a shotgun pleading, "it is *virtually impossible* to know which allegations of fact are intended to support which claim(s) for relief." *Anderson v. Dist. Bd. of Trustees of Cent. Fla. Cmty. Coll.*, 77 F. 3d 364, 366 (11th Cir. 1996) (emphasis added). Each claim in the MPIC is clearly brought against each of the five Defendants. Any Defendant that believes a fact alleged is wrong may deny it; any Defendant that believes a claim has not been adequately pleaded may move (and has moved) to dismiss the claim. But Defendants cannot ignore the well-pleaded allegations in the MPIC and feign *confusion* to dismiss *every claim* on shotgun-pleading grounds.[2]

Defendants argue that the MPIC improperly "lump[s] multiple defendants together" without distinction and "incorporate[es] by reference" too many paragraphs. Mot. 19. Both arguments fail.

A. Plaintiffs Properly Specify Which Claims Apply to Which Defendants.

Plaintiffs plead when each Defendant manufactured and/or was responsible for Paragard, MPIC ¶¶ 38–48, and bring each of their sixteen claims against each of

[2] The proper procedural vehicle to clarify a "shotgun pleading" is a motion for a more definite statement under Rule 12(e)—which requires a defendant to specify which portions are confusing—not a generalized motion to dismiss the entire complaint for failure to state a claim. *See Anderson*, 77 F.3d at 366. Defendants have neither moved for a more definite statement nor identified any allegedly confusing allegations.

the three "Teva Defendants" and two "Cooper Defendants," *id.* ¶¶ 15–24. *Weiland* explains that some complaints commit the "relatively rare sin of asserting multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions," but that plainly did not happen here. 792 F.3d at 1323. This sin is "relatively rare" because employing common allegations to allege common conduct is proper. *See Kyle K. v. Chapman*, 208 F.3d 940, 944 (11th Cir. 2000) (explaining that collective pleading "does not render the complaint deficient" because it "can be fairly read to aver that all defendants are responsible for the alleged conduct").[3] Impropriety arises only if the allegations *cannot* be "fairly read" to apply to each defendant.

For example, Defendants cite *Magluta v. Samples*, in which an inmate was placed in solitary confinement across four prisons over four years and sued fourteen prison officials for purported violations of six constitutional rights. 256 F.3d 1282, 1283 (11th Cir. 2001). Basic "geographic and temporal realities make plain" that the prison officials he dealt with in year four were not responsible for placing him in

[3] *See also Crowe v. Coleman*, 113 F.3d 1536, 1539 (11th Cir. 1997) ("When multiple defendants are named in a complaint, the allegations can be and usually are to be read in such a way that each defendant is having the allegation made about him individually."); *Sprint Sols., Inc. v. Fils-Amie*, 44 F. Supp. 3d 1224, 1227 (S.D. Fla. 2014) ("[A] plaintiff may plead claims against multiple defendants by referring to them collectively, for example by referring to a group of defendants as 'defendants.'").

solitary confinement in year one at a completely different facility. *Id.* at 1284. *That* is a shotgun pleading, because no reader can make sense of what the complaint is alleging. The same cannot be said of the MPIC.[4]

Rather, the MPIC simply alleges conduct each Defendant engaged in; for example, "Defendants failed to undertake any stability testing of Paragard with the copper sleeves on each side of the Paragard arm." MPIC ¶ 37. That means *all five* failed to test, an allegation that is perfectly comprehensible. Requiring a master pleading to allege each fact against each defendant separately would eviscerate the efficiency gains of using a consolidated document. *Any* master pleading in this case would need to put Defendants into logical groups to achieve efficiency.

More practically, Defendants in the same corporate family—such as the Teva Defendants and Cooper Defendants—cannot be confused, since they are the party in the best position to know which entity is responsible for the wrongdoing alleged. *See In re Auto Body Shop Antitrust Litig.*, 2015 WL 4887882, at *6 (M.D. Fla. June 3, 2015).[5] Information about divisions of responsibility among corporate affiliates is

[4] *Magluta* is also inapposite because the court applied a "rule that heightened specificity is required in civil rights actions against public officials who may be entitled to qualified immunity," which does not apply here. 256 F.3d at 1284.

[5] *See also Kruger v. Lely N. Am., Inc.*, 2021 WL 493135, at *7 (D. Minn. Feb. 10, 2021) ("When multiple defendants are members of the same corporate family, are wholly owned subsidiaries, and share counsel, the defendants should be able to sort out amongst themselves who is responsible for the allegedly fraudulent behavior.").

held by each corporate family, and Plaintiffs may only learn of such divisions through the discovery process. *See United States v. Kellogg Brown & Root Servs., Inc.*, 2014 WL 4948136, at *11 (C.D. Ill. Sept. 30, 2014) ("Defendants have the best—and, at this preliminary stage, perhaps only—access to the [necessary] information."). No Defendant actually contends—nor could any credibly do so—that it cannot identify its involvement in the conduct in which its larger corporate family is alleged to have engaged.

B. Plaintiffs' Incorporation of Factual Allegations Is Not Confusing.

The counts of the MPIC incorporate only the *factual* allegations contained in paragraphs 1 through 168, not the allegations in *all preceding counts*. The mere incorporation of previous factual allegations by reference does not deprive "defendants [of] adequate notice of the claims against them." *Weiland*, 792 F.3d at 1323–24. In *Weiland*, the court denied that a plaintiff's complaint was a shotgun pleading where the counts incorporated the earlier factual allegations because "[t]he allegations of *each count* are not rolled into every successive count on down the line." *Id.* at 1324 (emphasis added). *Contra Magluta*, 256 F.3d at 1284 (granting motion to dismiss and employing a heightened pleading standard where the counts "incorporate[ed] the allegations of any count or counts that precede[d] it"); *Wagner v. First Horizon Pharm. Corp.*, 464 F.3d 1273, 1279 (11th Cir. 2006) (faulting

plaintiffs for adopting all prior allegations and failing to connect facts to claims; faulting district court for dismissing case when repleading was appropriate remedy).

Moreover, incorporating the allegations of prior counts is permissible when the complaint "does so only for convenience, and the Court is able to ascertain which paragraphs are relevant to each of the claims." *Watts v. City of Port St. Lucie, Fla.*, 2015 WL 7736532, at *5 (S.D. Fla. Nov. 30, 2015). The MPIC's incorporation of prior facts does not render it a shotgun pleading.

III. Plaintiffs Have Stated Plausible Claims Against Defendants.

Defendants' Motion improperly seeks summary judgment based on their own submissions. Defendants' grounds for dismissal are uniformly *factual questions*: the existence and extent of the defect and the adequacy of the warning. Amazingly, despite numerous citations to materials outside the pleadings, in their entire argument Defendants cite not a single legal authority that would support dismissal. *See* Mot. 20–26. Apart from general principles from *Twombly* and *Iqbal*, the Motion cites only *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, which is itself a *summary judgment* case. 808 F.3d 281, 287 (6th Cir. 2015). Undeterred by the procedural posture (and absence of any evidentiary record), Defendants simply quote selective portions of different warnings they propose are at issue—which are *not alleged in the pleadings*—then assert that, so long as the Court takes judicial notice of their

submission, under *every state law* the warnings on *every Paragard* are adequate as a matter of law.

The adequacy of each label is a question of fact that will turn on state law, the relevant risks, and the label as a whole, none of which is before the Court. *See Bryant v. Tech. Rsch. Co.*, 654 F.2d 1337, 1345 (9th Cir. 1981) ("The adequacy of a warning under products liability is a question of fact to be left to the jury."); *In re Avandia Mktg., Sales Pracs. & Prods. Liab. Litig.*, 817 F. Supp. 2d 535, 548 (E.D. Pa. 2011) ("[T]he adequacy of a label can rarely be determined based solely on the face of the label."); *In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 266 (E.D.N.Y. 2007) (whether a warning is adequate is "ordinarily determined by a jury"). Defendants rail that the allegations in the MPIC are "factually wrong," Mot. 20; have "no scientific basis"; are "inconsistent with core biological and physical principles," *id.* at 20 n.9; that "the exact information which plaintiffs contend is absent is, in fact, in the Paragard label," *id.* at 22; and that the MPIC shows a "startling lack of understanding of the mechanism of action," *id.* at 24. The Motion sums up its own argument with the bald assertion that the "common thread to all the 'defect' allegations is that they are *contrary to known facts*." *Id.* at 25 (emphasis added). There is a time and place for strenuous denials: an answer. Denial-by-motion is a nullity because "the district court is not allowed to resolve disputes of fact in

adjudicating a motion to dismiss." *Page v. Postmaster Gen. & Chief Exec. Officer of U.S. Postal Serv.*, 493 F. App'x 994, 998 (11th Cir. 2012). Defendants' Motion should be denied both for its failure to conform to the federal rules by reaching beyond the pleadings and the utter lack of any legal authority for its arguments.

Despite Defendants' simplistic mischaracterization, Plaintiffs' claims are more than the mere assertion that "Paragards might break." Mot. 20. In reality, Plaintiffs allege both the precise Paragard defects and the currently known specific design and manufacturing deficiencies that caused those defects. Plaintiffs allege similarly detailed failure-to-warn claims, describing exactly what Defendants failed to warn about—Paragard's propensity to break, including during *routine* removal; the *frequency* of breakages; and the *severity* of resulting injuries—as well as how Defendants' marketing efforts obscured the warnings they did provide and misled Plaintiffs. Taken as true, Plaintiffs have stated facts showing they are entitled to relief, just as Rule 8(a)(2) requires. Defendants can present their alternative version of the facts to a jury. But they cannot obtain dismissal at the pleading phase by loudly proclaiming, "we didn't do it."

A. Plaintiffs State Plausible Design-Defect Claims.

First, Plaintiffs plead a plausible design-defect claim. Plaintiffs allege that Defendants' product 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." MPIC ¶¶ 172–73. Notably, and as Defendants recognize, Plaintiffs allege one of the currently known reasons *why* the product has this propensity to break: "Paragard does not provide sufficient flexibility." Mot. 3 (citing MPIC ¶ 52). Defendants further concede that Plaintiffs allege why Paragard is dangerously inflexible—the overall design and use of raw plastic T units that fall below minimum flexibility standards. *Id.* (citing MPIC ¶ 54).

Plaintiffs allege that (1) unlike other IUDs, "Paragard's arms have no curvature," MPIC ¶ 51; (2) "Paragard breaks more and has more arm breaks than any other IUD on the market in the United States," *id.* ¶ 53; (3) the product decays and loses flexibility over time, *id.* ¶ 55; and, as a consequence, (4) "[t]he Paragard arms are supposed to fold upward to aid in removal, but frequently the arms are broken or will break at the joint during removal," *id.* ¶ 62. And because Defendants failed to adequately warn Plaintiffs about these defects, Paragard was defective and unreasonably dangerous. *Id.* ¶¶ 65, 68–70, 80–81.

Defendants argue that inflexibility is a mere legal conclusion, and so need not be accepted as true, Mot. 24, but that is wrong. Baldly claiming that Paragard is

defectively designed is a legal conclusion; merely asserting that its design was unreasonable is a bare recitation of an element of a design-defect claim. But alleging that Paragard is insufficiently *flexible* is neither of those things. It is an allegation of raw fact: either Paragard is sufficiently flexible—capable of bending without breaking—or it is not. The MPIC's factual allegation is entitled to the presumption of truth. *See Iqbal*, 556 U.S. at 678.

Plaintiffs thus allege not only the specific defects in the product, but also the factual underpinnings that explain that defect and—though not required in every state—the feasible alternative designs available to Defendants. *See, e.g.*, *Banks v. ICI Ams., Inc.*, 450 S.E.2d 671, 673–74 (Ga. 1994) (adopting the risk-utility test for design defect and noting that alternative designs may be considered).[6]

B. Plaintiffs State Plausible Failure to Warn Claims.

Plaintiffs allege that Paragard's warnings were (and remain) inadequate because they fail to warn of (1) "[t]he severity and frequency of the risks associated with Paragard's removal," MPIC ¶ 10, which includes the risk that breakage or removal may require "surgical intervention and loss of reproductive health and fertility," *id.* ¶ 69; (2) "Paragard's propensity to break inside the body," including

[6] Of course, the relevant test for design defect (and required elements) will depend on the state law that applies to a specific plaintiff. Defendants have not moved to dismiss any claims under the law of any specific state.

"during a routine removal procedure and non-surgical removal procedures," *id.* ¶¶ 68, 70; and (3) "the frequency of the breakage." *Id.* ¶¶ 68–69. Plaintiffs also allege that Defendants' labeling continues to omit any warnings of "the frequency of breakages, that surgical intervention could be required as a result of a 'difficult' removal, that a *nonembedded* Paragard could break during removal, or that surgery could prevent a woman from conceiving children." *Id.* ¶ 81 (emphasis added).

Improperly disputing the above allegations, Defendants misrepresent the labeled warnings to argue that they address the defects Plaintiffs identify in the MPIC. Mot. 21. They do not. The three labels Defendants contend warn of "breakage," *id.*, fail to specify, among other things, that Paragard may break during removal, the frequency of breakages, or that the breakage may require surgery to remove the product. Defendants' labeling did not adequately warn of the likelihood of breakages before or during a routine removal (including breakage not associated with embedment or perforation), that surgical intervention could be required for removal, and the long-term effects that could result from such surgical intervention.

Plaintiffs further allege that Defendants obscured what warnings they did provide through misleading marketing. For example, Defendants marketed Paragard as "easily reversible," "remov[able] any time before its 10-year expiration if a woman wants to become pregnant and that she 'may become pregnant as soon as

Paragard is removed.'" MPIC ¶ 58. Defendants told women the product's "'contraceptive effect is reversed' as soon as Paragard was removed." *Id.* ¶ 10. Defendants also marketed Paragard as "non-surgical" and removable "'during a routine office visit in just a few minutes.'" *Id.* ¶ 59. As Plaintiffs allege, "[t]he marketing and promotional efforts of Defendants and their advertisers and/or salesforce served to overstate the benefits of Paragard and minimize and downplay the risks." *Id.* ¶¶ 63, 194. These allegations adequately plead a failure-to-warn claim because Defendants' marketing scheme "mitigated or nullified" any warnings that may have been in the label. *See Mendez v. Shah*, 28 F. Supp. 3d 282, 299–300 (D.N.J. 2014) (holding that failure-to-warn claim is plausible based on defendants' marketing scheme that allegedly rendered the label warning inadequate).

C. Plaintiffs State Plausible Manufacturing Defect Claims.

Defendants' attack on Plaintiffs' viable manufacturing-defect claims likewise ignores several pages of allegations on the precise (and currently known) manufacturing practices Defendants were required to follow to ensure their products did not deviate from design specifications, and the specific ways in which those defects manifested and caused Plaintiffs' injuries. *See* MPIC ¶¶ 129–47.

First, Plaintiffs explain why Current Good Manufacturing Practices (CGMPs) are critical to the manufacturing process and required by federal law. MPIC ¶¶ 129–

31. Next, Plaintiffs identify CGMPs Defendants were legally required to follow to manufacture Paragard. *Id.* ¶¶ 132–36. Finally, Plaintiffs catalogue in detail how and why Defendants' products deviated from the design specifications, and why those defective products were nevertheless sold to women: (1) they were produced in violation of federally mandated safety regulations, maintenance, quality control, and cleanliness standards; (2) they were made with plastic material that fell below minimum flexibility requirements; (3) they contained copper that corroded or rotted even before shipment; (4) they were produced without adequate quality assurance and quality control procedures; and (5) they were produced in violation of Defendants own written policies and SOPs. *Id.* ¶¶ 139–47.

Plaintiffs' allegation that Defendants violated CGMPs would alone be sufficient to state a manufacturing-defect claim. *See, e.g.*, *Godelia v. Doe 1*, 881 F.3d 1309, 1318 (11th Cir. 2018) (holding that alleged violations of sections of 21 C.F.R. 820 *et seq.* were sufficient to state a claim for manufacturing defect under Florida law); *Mink v. Smith & Nephew, Inc.*, 860 F.3d 1319, 1331 n.3 (11th Cir. 2017) (concluding manufacturing defect claims based on federal requirements were not preempted and stated valid manufacturing defect theory)[7]; *Bausch v. Stryker Corp.*,

[7] *Mink* also disposes of Defendants' anemic invocation of preemption based on the federal government's exclusive enforcement power. *See* Mot. 44 n.20. In any event,

630 F.3d 546, 559–60 (7th Cir. 2010) (concluding claims were adequately pleaded where the plaintiff alleged violations of federally required manufacturing and inspection processes); *Howard v. Sulzer Orthopedics, Inc.*, 382 F. App'x 436, 440–41 (6th Cir. 2010) (holding a claimed deviation from the FDA-approved manufacturing process and a single CGMP adequately pleaded a manufacturing defect); *Green v. Medtronic, Inc.*, 2020 WL 4577713, at *3 (N.D. Ga. May 1, 2020) (holding that plaintiff "plausibly alleged" manufacturing defect based on alleged violations of CGMPs). Here, Plaintiffs not only identify the alleged CGMPs Defendants violated; they explain the precise manufacturing defects complained of and their causes.

The only case Defendants cite, *Yates*, 808 F.3d 281, is inapposite. In *Yates*, the Sixth Circuit held on *summary judgment* that a warned-of side effect cannot serve as circumstantial evidence of a manufacturing defect. Here, Defendants failed to warn about Paragard's propensity to break, especially during removal, the frequency of such breakages, and the potential resulting injuries. Plaintiffs allege that they have suffered injuries of which they were *not* warned and were caused by the products' manufacturing and design defects. Moreover, *Yates* held that there was no evidence

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that argument is waived, because arguments made "in a footnote only" are waived. *Mock v. Bell Helicopter Textron, Inc.*, 373 F. App'x 989, 992 (11th Cir. 2010).

that the product used by the plaintiff differed from the FDA-approved design, while here the MPIC alleges precisely that fact.

IV. Plaintiffs Pleaded Their Fraud Claims with Specificity and Satisfy the Requirements of Rule 9(b).

Rule 9(b) of the Federal Rules of Civil Procedure requires a party "alleging fraud . . . [to] state with particularity the circumstances constituting fraud." "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, 1222 (11th Cir. 2012); *Zone 4, Inc. v. Brown*, 2019 WL 7833902, at *3 (N.D. Ga. June 12, 2019) (May, J.) (same). The Eleventh Circuit has made clear "[t]he application of the rule, however, must *not* abrogate the concept of notice pleading." *Durham v. Bus. Mgmt. Assocs.*, 847 F.2d 1505, 1511 (11th Cir. 1988) (emphasis added). Moreover, "[t]he heightened pleading standard of Rule 9(b) is relaxed when specific facts are 'peculiarly within the defendant's knowledge or control.'" *SEC v. Melvin*, 2013 WL 12062834, at *4 (N.D. Ga. June 26, 2013) (collecting cases).

Defendants ignore the factual allegations in the MPIC to argue that Plaintiffs fail to "identify a representation of fact that is false" and do not satisfy the pleading requirements of Rule 9(b). Mot. 27. Defendants' contentions are facially incorrect. The MPIC specifies numerous misrepresentations. For example, Plaintiffs detail

specific statements from Defendants' marketing materials that "intentionally convey[ed] to consumers that Paragard removal is easy and safe, with no risk of complication" and failed to "otherwise relay the risks of Paragard." MPIC ¶¶ 56–60; *see, e.g.*, *id.* ¶ 59 ("The relevant Defendants have heavily marketed Paragard as being 'reversible,' 'non-surgical,' and removable by a healthcare provider 'during a routine office visit in just a few minutes.'"); *id.* ¶¶ 106–10.

Critically, Defendants ignore allegations identifying specific marketing material Defendants used on their website from December 2016 through April 2018:

> 75. Defendants intentionally marketed Paragard to women—particularly younger women—as quick and easy to remove without the risk of complications such that a woman could use Paragard and then have it quickly removed when she wanted to conceive. As Defendants told women, "See how Paragard lets you own your story," suggesting that Paragard was risk-free and that by using Paragard, women could decide to get pregnant at any time.
>
> 76. Defendants intentionally downplayed the risks of breakage, including, but not limited to, during removal, and told women they could try to get pregnant the same day they had their Paragard removed. For instance, based on information and belief, from December 2016 through April 2018, Defendants included the excerpt below on the Paragard website:

MPIC ¶¶ 75–76. These allegations clearly set forth the "who, what, where, and how" that Defendants contend is missing from the MPIC. *See* Mot. at 27.

Defendants next improperly dispute not the *specificity* of the allegations, but their *veracity*, accusing plaintiffs of "making up language" and suing based on "statements that simply do not exist," in particular that Paragard was "safe." Mot. 27. The argument borders on the absurd. Defendants' marketing materials conveyed that Paragard was safe in that it was easily removable with no complications such that woman could "try to get pregnant the same day" and that Paragard would enable women to "own [their] story." MPIC ¶¶ 58–60, 75–76. Defendants also stated that "Paragard is 99% effective and 100% hormone free," further promoting Paragard as a safe and effective contraceptive. Notably, *the FDA* found Defendants' statement that Paragard is "100% HORMONE FREE" to be misleading because it "gave the impression to consumers that Paragard was safer than other long-acting reversible

contraceptives."[8] *Id.* ¶ 73. The other statements set forth in the above promotional material similarly give the impression that Paragard is safe and effective even if the materials do not use the term "safe."

Furthermore, Defendants failed to include accurate labeling to make Paragard safe and effective. Specifically, Defendants failed to include a warning that Paragard could break during removal and cause injury, failed to include information about the frequency of breakages, and failed to include a proper expiration date to ensure Paragard would not degrade and be subject to breakage. MPIC ¶¶ 100–02. Plaintiffs further allege that Defendants knew or should have known about these issues but failed to include appropriate warnings about these risks and failed to provide a proper expiration date. *Id.* ¶ 102. These false statements bear on Defendants' representation regarding the safety of the product in its labeling, and Defendants' attempts to argue otherwise fail.

Plaintiffs also sufficiently pleaded the "reliance" element of their fraud claims. The MPIC expressly alleges that Plaintiffs had Paragard inserted after

[8] Defendants even argue that the statements the FDA found misleading "still fall short" because the MPIC supposedly lacks any indication of what the "representation" entailed. Mot. 29 n.15. The simplest refutation of this pants-on-fire argument is paragraph 73, which *quotes* the representations, including "100% HORMONE FREE," which is the same statement Defendants made in the marketing material set forth in the MPIC ¶ 76.

relying on Defendants' misrepresentations that it would be "safe, effective, and reversible." MPIC ¶¶ 77, 296–297.

Regardless, the MPIC is a master pleading and is not intended to include each individual plaintiff's unique allegations (as reliance must be); rather, it sets forth claims common across the MDL. *See In re: Allergan Biocell Textured Breast Implant Prods. Liab. Litig.*, 2021 WL 1050910, at *19 (D.N.J. Mar. 19, 2021). As a general matter, a master complaint "should not be given the same effect as an ordinary complaint." *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 141–42 (E.D. La. 2002); *see In re Zimmer Nexgen Knee Implant Prods. Liab. Litig.*, 2012 WL 3582708, at *3 (N.D. Ill. Aug. 16, 2012) ("[M]aster or consolidated complaints must be interpreted in light of the primary purpose of multidistrict litigation: to promote efficiency through the coordination of discovery.") (internal citations and quotation omitted); *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 454 (E.D. La. 2006). With this "further overlay" of a master complaint to the deferential 12(b)(6) standard, courts review master complaints in MDLs and corresponding motions to dismiss "in light of [the master complaint's] procedural purpose." *In re Digitek Prods. Liab. Litig.*, 2009 WL 2433468, at *8 (S.D. W.Va. Aug. 3, 2009).

For instance, in *In re: Allergan*, the court assessed common facts across the MDL according to the typical motion to dismiss standard but would "review[] with

substantial leniency[] the facts that may be specific to each individual [p]laintiff or largely within the control of [defendant].” 2021 WL 1050910 at *19. Similarly, in *In re Trasylol Prods. Liab. Litig.*, the court refused to dismiss plaintiffs’ fraud claims because the allegations defendants demanded would “completely remov[e] the compromise and attempt at efficiency” intended by filing a master complaint. 2009 WL 577726, at *8 (S.D. Fla. Mar. 5, 2009). Similarly, here, individual plaintiffs should identify the respective statements upon which they or their physicians relied in an individual pleading or fact sheet. *See id.* (“[F]or the most part, the information missing from the plaintiffs’ complaints in this case . . . is outweighed by the sufficiency of the description of the claims against the defendants.”) (citation omitted).

V. Defendants Cannot Demonstrate Federal Preemption.

A. Regulatory Background

Before marketing a pharmaceutical drug, drug manufacturers must submit a New Drug Application (NDA) that contains a proposed label and investigation reports showing that the drug is safe and effective. *See* 21 U.S.C. § 355(a)–(b). The Food, Drug, and Cosmetics Act (FDCA), however, recognizes that drug-safety information may change over time, and that this new information may require changes to the label. 21 C.F.R. §§ 314.80(c), 314.81(b)(2)(i). Manufacturers also

must "promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers," and submit such adverse event information to FDA. *Id.* § 314.80(b)–(c).[9]

Additionally, the FDCA deems a drug misbranded "[i]f it is dangerous to health when used in the dosage, or manner or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof," or "[i]f its labeling is false or misleading in any particular." 21 U.S.C. § 352(j), (a)(1). It is unlawful to misbrand a drug, to sell a misbranded drug, or to receive or deliver a misbranded drug into interstate commerce. *Id.* § 331(a)–(c).

These provisions squarely place responsibility for a drug's labeling on a manufacturer, but do not impose any particular method for changing a drug's label. Defendants' contrary assertion that "under the FDCA, any change to an approved application must be approved by FDA prior to its implementation" cites no authority and is false. Mot. 7; *see Wyeth v. Levine*, 555 U.S. 555, 568 (2009) (noting that FDA

[9] If adverse event information is forwarded to the manufacturer from the FDA, the manufacturer "must submit all followup information on such reports to the FDA." § 314.80(b).

regulations, consistent with the FDCA "permits a manufacturer to make certain changes to its label before receiving the agency's approval").

The FDA has promulgated relevant regulations for changes through what it calls "supplemental" applications. The intent and text of these regulations require FDA pre-approval for changes that may pose a risk to the public, but only notice to the Agency for changes that *enhance* warnings or *reduce* ineffectiveness. A "major change"—which must be approved before implementation—is defined as "any change in the drug substance, drug product, production process, quality controls, equipment, or facilities that has a **substantial** 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(b)(1) (emphasis added). A "moderate change"—which can be implemented either immediately or after 30 days' notice—is defined the same way, with the word "substantial potential" changed to "moderate potential." *Id.* § 314.70(c)(1). A "minor change"—which can be implemented immediately and disclosed in an annual report—is one with a "minimal potential." *Id.* § 314.70(d)(1). Beyond these overall definitions, the regulation has specific examples of changes that fit within each category.

Certain changes that manufacturers may make immediately as moderate changes "include, but are not limited to":

> (iii) Changes in the labeling to reflect newly acquired information . . . to accomplish any of the following:
> (A) To add or strengthen 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;
> (B) To add or strengthen a statement about drug abuse, dependence, psychological effect, or overdosage;
> (C) To add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product;
> (D) To delete false, misleading, or unsupported indications for use or claims for effectiveness . . . .

21 C.F.R. § 314.70(c)(6). The text and its underlying logic are clear: no pre-approval is needed for *enhancing* warnings, *deleting* false information, *removing* an unsupported indication, or *strengthening* an instruction, because none of these has the substantial potential to have an *adverse* effect on safety or effectiveness.

B. Preemption Law

Federal preemption follows from the Supremacy Clause of the Constitution, which renders "Laws of the United States . . . 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, because "it is [a court's] duty to respect not only what Congress wrote but, as importantly, what it didn't write." *Va. Uranium, Inc. v. Warren*, 139 S. Ct. 1894, 1900 (2019) (plurality opinion). As relevant here, state law gives way to federal law by implication only "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 Supreme Court's leading case addressing impossibility preemption for pharmaceuticals is *Wyeth v. Levine*, which held that a failure-to-warn claim against the brand-name manufacturer of Phenergan was not preempted. The Court began by observing that "[i]n all preemption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied,' . . . we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Wyeth*, 555 U.S. at 565 (quoting *Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996)). The Court then reviewed "the history of federal regulation of drugs and drug labeling," explaining that the law has become more protective over time, and that Congress has consistently preserved state remedies. *Id.* at 566–68. Through numerous enhancements to the FDCA, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label

at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 570–71. The duty to ensure drug safety rests squarely with the manufacturer. The *Wyeth* Court set out the applicable test: "absent clear evidence that the FDA would not have approved a change to [a drug's] label, we will not conclude that it was impossible for [a Defendant] to comply with both federal and state requirements." *Id.* at 571.

The most recent case in this area reaffirmed *Wyeth*. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1678 (2019). *Albrecht* set out a two-part test for impossibility preemption: the drug manufacturer must show that (1) "it fully informed the FDA of the justifications for the warning required by state law" and (2) "the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning." *Id.* To prove the second prong, defendants must provide "clear evidence" that the FDA would reject a label change by pointing to "the only agency actions that can determine the answer to the pre-emption question," which are those actions "taken pursuant to the FDA's congressionally delegated authority,"—*i.e.*, only "agency actions carrying the force of law" can preempt state laws. *Id.* at 1679. Mere predictions based on agency preferences, letters, or draft materials would not suffice, because such agency actions lack the "force of law," and show only the "possibility of impossibility." *Id.* at 1678.

As both *Wyeth* and *Albrecht* explain, even where a defendant has submitted similar warnings to the FDA *and had those warnings rejected*, preemption does not follow without "evidence that shows the court that the drug manufacturer *fully informed the FDA* of the justifications for the warning required by state law and that the 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 (emphasis added). All told, in the drug labeling context the burden on defendants and fact-intensive nature of preemption means "[i]mpossibility preemption is a demanding defense." *Id.* at 1678 (quoting *Wyeth*, 555 U.S. at 573).

C. Each Claim Survives Federal Preemption.

To carry their demanding burden on impossibility preemption, Defendants would need to persuade the Court that it presented adequate warnings to the FDA and that the FDA rejected those warnings with full information and in a formal act carrying the force of law. To carry that burden on a motion to dismiss, Defendants must meet their burden armed only with the well-pleaded allegations in the MPIC. Defendants do not merely fail to *carry* their burden—they fail to pick it up. That is not surprising, because accepting the MPIC's allegations as true, federal law *encouraged* or *even required* Defendants to meet their state-law duties. Conflict preemption cannot exist where state and federal law are in perfect harmony.

1. *Defendants Failed to Carry Their Burden to Show Impossibility on Any Claim.*

Preemption is an affirmative defense. Despite that black letter law, Defendants complain that *Plaintiffs* did not "allege, in the first instance, what 'newly acquired information' warrants the label change they advocate." Mot. 40. Defendants' upside-down preemption argument is that any label change *must be* impossible because Plaintiffs did not allege specific facts showing why it *was possible*. The Motion must be denied because nothing in the federal rules required Plaintiffs to do so.[10] *See* Fed. R. Civ. P. 8(a)(2).

The Supreme Court has affirmed this principle time and again. For instance, in *Jones v. Bock*, the Court held that even though "exhaustion is mandatory under the PLRA," because exhaustion was an affirmative defense, "inmates are not

[10] A minority of cases place the burden on plaintiff to plead with specificity what newly acquired information was available. Those authorities are not binding and are not correct. *See* Mot. 40–41 (citing, *e.g.*, *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34 (1st Cir. 2015), which was decided before *Albrecht*). As *Albrecht* makes clear, "impossibility pre-emption is a demanding defense" and ***Defendants*** must show that they fully informed the FDA of the need for the warning and that the FDA would not approve the change. 139 S. Ct. at 1678; *see also In re Avandia Mktg., Sales & Prods. Liab. Litig.*, 945 F.3d 749, 758–59 (3d Cir. 2019) (placing burden of proof on defendant). None of the cases Defendants cite considered the argument that plaintiffs have no burden to plead around affirmative defenses; in following those cases this Court "would risk error [by] rel[ying] on assumptions that have gone unstated and unexamined." *Ariz. Christian Sch. Tuition Org. v. Winn*, 563 U.S. 125, 145 (2011).

required to specially plead or demonstrate exhaustion in their complaints." 549 U.S. 199, 211, 216 (2007). This was so even though the obvious consequence is that inmates could simply allege nothing about exhaustion and proceed to the next stage of litigation. "[C]ourts should generally not depart from the usual practice under the Federal Rules on the basis of perceived policy concerns." *Id.* at 212. Similarly, in *Gomez v. Toledo*, the Supreme Court held that because "qualified immunity is a defense, the burden of pleading it rests with the defendant" and so "[i]t is for the official to claim that his conduct was justified by an objectively reasonable belief that it was lawful. *We see no basis for imposing on the plaintiff an obligation to anticipate such a defense by stating in his complaint that the defendant acted in bad faith.*" 446 U.S. 635, 640 (1980) (emphasis added).

Following this reasoning, the Eleventh Circuit has long held that "[g]enerally, the existence of an affirmative defense will not support a motion to dismiss." *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). A Rule 12 motion may be granted only in the exceptional circumstance "when [the complaint's] own allegations indicate the existence of an affirmative defense, so long as the defense clearly appears on the face of the complaint." *Id.* This Court has time-and-again held that defendants cannot prevail on an affirmative defense unless each element of the

defense appears on the face of the complaint. *See*, *e.g.*, *King v. Nat'l Union Fire Ins. Co. of Pittsburg, Pa.*, 2018 WL 8929811, at *3 (N.D. Ga. July 6, 2018) ("[A]n affirmative defense must be clearly established *on the face of the complaint*. . . ."); *Weed v. SunTrust Bank*, 2018 WL 2100590, at *3 (N.D. Ga. May 7, 2018) (noting express consent defense is "simply premature" because it "does not clearly appear on the face of the Amended Complaint").

Defendants do not even purport to argue that Plaintiffs here "plead[ed] itself out of court by pleading facts that establish an impenetrable defense to its claims." *Tamayo v. Blagojevich*, 526 F.3d 1074, 1086 (7th Cir. 2008). Nowhere in the pleadings do Plaintiffs allege that Defendants *could not* have changed their design or label or that they *lacked* new information. The MPIC says the opposite. MPIC ¶ 79 ("Defendants could have updated the warning label based on 'newly acquired information' but chose not to"); *id.* ¶¶ 120–21 (Defendants failed "to adequately communicate and submit adverse event reports or new information gleaned from adverse event reports about Paragard breakages and associated injuries" and alleging that "breakage occurred at a disproportionately greater frequency than what would normally be anticipated"); *id.* ¶ 126. Defendants' only play is to imply that preemption is *presumed*, and dismissal must follow because they believe the MPIC did not "overcome preemption." Mot. 42. This Court should decline that gambit, and

instead follow the bedrock law that preemption is an affirmative defense that *Defendants* must establish, and the only relevant *presumption* is the one courts must employ *against* preemption. *Wyeth*, 555 U.S. at 565; *see also id.* at 572 (rejecting preemption argument because defendant "offered no such evidence" that the FDA would have rejected a label change).

Imposing a heightened pleading requirement would be especially inappropriate given that defendants often have most of the relevant information. *Cf. Gomez*, 446 U.S. at 640–41 ("[T]he allocation of the burden of pleading is supported by the nature of the qualified immunity defense . . . [which] depends on facts peculiarly within the knowledge and control of the defendant."). Defendants' own records show what it told the FDA, what analyses it performed on its data, and how the FDA responded. Many of those records are confidential. All are unavailable to Plaintiffs before discovery, and none of those preemption-determinative facts are before this Court. For precisely that reason, courts that have considered this question have held that a motion to dismiss cannot be granted merely because the plaintiffs did not plead facts to defeat an impossibility preemption defense. *See Gremo v. Bayer Corp.*, 469 F. Supp. 3d 240, 253–54 (D.N.J. 2020) ("[A]s the Supreme Court has reiterated, impossibility pre-emption is 'a demanding defense' rather than a pleading requirement. Moreover, the impossibility pre-emption defense places the

burden on Defendants—and not Plaintiff—to support that defense with 'clear evidence[.]'");[11] *Evans v. Gilead Scis., Inc.*, 2020 WL 5189995, at *10–11 (D. Haw. Aug. 31, 2020) ("Evans is not required to plead the existence of 'newly acquired information.' 'FDCA preemption, like all federal preemption, is an affirmative defense. . . .' As such, whether 'newly acquired information' existed prior to when [plaintiff] was prescribed [the drug], is an issue for post-discovery motion practice."). The alternative would require a plaintiff to include in her complaint studies, new analyses, and adverse events not fully considered by the FDA in its review of "'thousands of pages and . . . clinical trials conducted over several years,' . . . [which] would give new meaning to the phrase 'short and plain' under Rule 8(a)(2)." *Evans*, 2020 WL 5189995, at *10 n.17.

[11] *Gremo* also emphasized the stark difference between the fact-intensive inquiry contemplated by *Wyeth* and the analysis possible on a Rule 12 motion: "Even though 'a judge, not the jury, must decide the pre-emption question,' that question is not properly before the Court to answer at this time. *See*, *e.g.*, *Wyeth*, 555 U.S. at 572–73 (finding that after the completion of discovery and at the trial-ready stage of the case Wyeth's evidence for its pre-emption defense failed for two reasons: (1) the record did not show that Wyeth supplied the FDA with an evaluation or analysis concerning the specific dangers that would have merited the warning, and (2) the record did not show that Wyeth attempted to give the kind of warning required by state law but was prohibited from doing so by the FDA)." 469 F. Supp. 3d at 254.

2. *Plaintiffs' Failure-to-Warn Claims Survive Preemption.*

Even apart from Defendants' burden, Plaintiffs' claims easily survive preemption. First, Defendants misstate the standard for "newly acquired information" by overstating both how new it must be and how substantial it must be. Second, Defendants misapply that standard to the MPIC.

The test for "new" information is quite low: Under FDA regulations, most every sort of information not previously submitted to the Agency qualifies as "new." As the Supreme Court explained,

> '[N]ewly acquired information' is not limited to new data, but also encompasses 'new analyses of previously submitted data.' The [FDA's] 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: '[I]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'

Wyeth, 555 U.S. at 569 (quoting 73 Fed. Reg. 49603 (2008)).

The supposed limitation to "evidence of a causal association" is no impediment to Plaintiffs' claims. Mot. 33. Section 314.70(c)(6)(iii)(A) simply requires "evidence of a causal association"—the language Defendants repeatedly quote—that "satisfies the standard for inclusion in the labeling under § 201.57(c)."

And § 201.57(c)—which Defendants deemphasize—sets out two of those standards for inclusion, one for warnings and one for adverse events. "[L]abeling must be revised to include a *warning* about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; ***a causal relationship need not have been definitely established***." 21 C.F.R. § 201.57(c)(6)(i) (emphasis added); 73 Fed. Reg. 49603, 49604 (Aug. 22, 2008) (interpreting the standard to be *less than* preponderance of the evidence). The standard is even lower for adverse events, which should be included if "there is *some basis to believe* there is a causal relationship between the drug and the occurrence of the adverse event." § 201.57(c)(7) (emphasis added).

The Supreme Court applied these prongs in *Wyeth*. It first noted as a strike against Wyeth—who bore the burden on preemption—that the "record is limited concerning what newly acquired information Wyeth had *or should have had*." *Wyeth*, 555 U.S. at 569 (emphasis added). Here, of course, there is *no* record, but beyond that, this shows that information Defendants *should have had* is sufficient. The Court continued:

> Levine did, however, present evidence of at least 20 incidents prior to her injury in which a Phenergan injection resulted in gangrene and an amputation. After the first such incident came to Wyeth's attention in 1967, it notified the FDA and worked with the agency to change Phenergan's label. In later years, as amputations continued

> to occur, Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug.

Id. at 569–70. The analysis is worth restating: 20 incidents over four decades was sufficient to trigger the CBE regulation in *Wyeth* because the manufacturer "could have analyzed" the data. If *that* was enough for the Supreme Court reviewing a jury verdict, surely alleging more than **two thousand** Paragard breaks over a ten-year stretch is enough on a motion to dismiss. MPIC ¶ 121.

Defendants' preemption argument collapses even on its own terms, since Defendants *changed the label* in 2019, and a substantial majority of Plaintiffs in this action used Paragard with the pre-2019 label. As the MPIC alleges, Defendants plainly had new information for that labeling change, MPIC ¶¶ 78–79, which means none of the claims based on the pre-2019 label can be preempted. Defendants' argument that they already warned of Paragard's propensity to break upon removal is simply false. Mot. 39. Although the label vaguely referenced breakage in relation to embedment, it never warned that a non-embedded Paragard could break upon removal and cause significant injuries, as Plaintiffs allege. MPIC ¶¶ 69–71, 76, 78–81. And the post-2019 label is still inadequate because it fails to warn about the *propensity* and *frequency* of Paragard breaking during routine removal and the serious consequences that could result. *Id.* ¶ 81.

Separately, multiple federal courts have held that another variant of failure to warn—failing to submit adverse event reports to the FDA—survives preemption and is available to injured persons. *See, e.g.*, *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (en banc); *Hughes v. Bos. Sci. Corp.*, 631 F.3d 762, 769 (5th Cir. 2011). In some states, a manufacturer's duty to warn consumers includes "a duty to convey warnings to a third party that can reasonably be expected to warn the consumer." *Coleman v. Medtronic, Inc.*, 223 Cal. App. 4th 413, 429 (2014); *see also, e.g.*, *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 185 (N.D.N.Y. 2014); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 837–38 (E.D. Pa. 2016). More specifically, this duty to warn includes "a requirement to file adverse event reports with the FDA if that is the only available method to warn doctors and consumers." *Coleman*, 223 Cal. App. 4th at 429. This state-law duty to warn the FDA does not conflict with any requirement of federal law—in fact, it is required by both federal and state law—and thus is not preempted. *See Stengel*, 704 F.3d at 1233–34.

Here, Plaintiffs allege that "Defendants systematically failed to properly monitor and handle complaints . . . and fail[ed] to adequately communicate and submit adverse event reports" to the FDA. MPIC ¶¶ 111–28, 230, 275–76. The MPIC also alleges that had Plaintiffs received proper or adequate warnings and instructions, Plaintiffs would have heard about and heeded those warnings. *Id.* ¶ 286.

Defendants' Motion wholly ignores this theory, providing no argument that it is preempted (which of course it is not), or that it was insufficiently pleaded.

3. *Plaintiffs' Design-Defect Claims Survive Preemption.*

The standard for a design defect differs across states, but the Supreme Court has recognized that many states' design-defect claims turn on the warnings associated with the product, which are part of the product itself: "New Hampshire's design-defect cause of action imposed a duty on Mutual to strengthen sulindac's warnings." *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 484 (2013); *see also Chellman v. Saab-Scania AB*, 637 A.2d 148, 150 (N.H. 1993) ("The duty to warn is part of the general duty to design . . . . If the design of a product makes a warning necessary to avoid an unreasonable risk of harm from a foreseeable use, the lack of warning or an ineffective warning causes the product to be defective and unreasonably dangerous."). Other states similarly consider the label in assessing design defects. *E.g.*, *Freund v. Cellofilm Props., Inc.*, 432 A.2d 925, 929–32 (N.J. 1981) (discussing cases in which "the design defect consists of an inadequate warning involving safety of the product"); *Mohr v. St. Paul Fire & Marine Ins. Co.*, 674 N.W.2d 576, 589 (Wis. Ct. App. 2003) ("An inadequate warning on a product can, by itself, render the design defective.").

Defendants recognize this, since they too quote *Bartlett*'s holding 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." Mot. 35 (quoting *Bartlett*, 570 U.S. at 490 (emphasis added)). But, critically, the product in *Bartlett* was a generic, and so the manufacturer was required by federal law to match the brand-name *label* and *formulation* in virtually every respect—this duty of sameness is what produced preemption. Here, by contrast, Defendants, like those in *Wyeth*, could have modified their label, making *Bartlett* inapposite.[12] A valid design-defect claim predicated on an inadequate label

[12] Defendants' other cases either involve only generic drugs, *e.g.*, *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1135 (8th Cir. 2014), or expressly reject the simplistic reasoning they propose: "[T]he *Bartlett* Court did not reach the sweeping conclusion that all design defect claims are preempted by federal law, but rather applied the impossibility preemption analysis to the plaintiff's design defect claim regarding a **generic** drug, and clarified that preemption cannot be avoided if the only way a manufacturer can comply with both federal and state law is to exit the market." *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 296 (6th Cir. 2015) (emphasis added). Notably, *Yates* rejected Defendants' reading of *Bartlett* to extend impossibility preemption to all design-defect claims for both generic and brand-name manufacturers, noting that that portion of *Bartlett* "is dicta, written in a section explaining the general approval process that manufacturers must go through to gain approval from the FDA before marketing any drug in interstate commerce." *Id.* at 296. *Yates* held that the label was adequate, *id.* at 292, and to the extent any non-label theory of design defect existed, it would require a change to the chemical composition of the drug, which the court determined for that drug would be a major change, *id.* at 299–300.

is not defeated simply because Plaintiffs have also pleaded, for instance, negligent failure to warn. Rule 12 authorizes a motion to dismiss for "failure to state a claim." Fed. R. Civ. P. 12(b)(6). Rule 12(b)(6) is not a vehicle to foreclose a movants' preferred arguments, theories, or approaches. If any theory can support a recovery, a motion to dismiss must be denied. *See BBL, Inc. v. City of Angola*, 809 F.3d 317, 325 (7th Cir. 2015) ("A motion to dismiss under Rule 12(b)(6) doesn't permit piecemeal dismissals of parts of claims; the question at this stage is simply whether the complaint includes factual allegations that state a plausible claim for relief.").

The defendant cannot select a plaintiff's theory for her. Here, Plaintiffs' design-defect theory is based on the *combined* effect of the product itself and its warnings. For example, the product loses flexibility over time, and even if the structural features causing that decay could not be changed, the number of years listed on the label could be.[13] Similarly, Defendants can point to no regulation

[13] Defendants' attempt to deny this finds no support in FDA regulations. They argue—based on their own materials, not the pleading—that 10 years is an "indication for use," not an "expiration date." Mot. 43. In the first place, it is simply false that "The 'indications and usage' section of a drug label cannot be changed using the CBE." *Id.* Nothing in the "major change" regulation suggests indications for use require pre-approval. And while Defendants cite 21 C.F.R. § 314.70(c)(6), which concerns "moderate changes," it appears they looked only at subsection (c)(6)(iii)(A), addressing warnings, precautions, or adverse reactions, and overlooked the other subsections, including (C) (dosage and administration) and—crucially—(D) which empowers a manufacturer to "delete false, misleading, or unsupported *indications for use* or claims for effectiveness." This of course makes

preventing them from improving the quality of the materials used to make the product flexible for longer. Neither changes to the label nor improvements to the materials or manufacturing would have "a substantial potential to have an adverse effect on the…safety or effectiveness of the drug product." 21 C.F.R. § 314.70(b)(1).

4. *Plaintiffs' Manufacturing Defect Claims Survive Preemption.*

Defendants correctly identify that "a manufacturing defect refers to individual products that are improperly made while a design defect concerns a defect in the entire product line," Mot. 43, but then pretend the manufacturing defect claims must be preempted because they involve the entire product line.[14] Plaintiffs in this case used different products over different time periods, and there is nothing contradictory about saying that Paragard itself had a defective label, a defective

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sense and is consistent with FDA's approach to warnings and the label generally: while *adding* or *enhancing* an indication for use could not be done unilaterally, correcting an overstated indication can be. Second, the label includes both an indications-for-use and a separate expiration date by which the product must be placed in a woman. MPIC ¶¶ 33–36. There is no reason Defendants could not have retained the indication while reducing the expiration date or adding a warning for anyone who exceeds some lower number of years.

[14] Curiously, Defendants cite as support the allegation that Paragard was inherently dangerous "at all times," but—apart from this allegation being consistent with a manufacturing defect that rendered it *more* dangerous—this allegation is made in the *Design Defect* Count, not the *Manufacturing Defect* Count, nor is it incorporated into the Manufacturing Defect Count by reference. *Compare* Mot. 44 (citing MPIC ¶¶ 172, 182, 317, 393), *with id.* ¶ 214 (the Manufacturing Defect Count, not incorporating any of those paragraphs).

design, and *some of the units* were also defectively manufactured (namely, the ones used by injured plaintiffs alleging this claim).[15]

Courts routinely allow claims alleging both manufacturing and design defects to proceed to discovery, and for good reason. As the Seventh Circuit has explained:

> [T]he victim of a genuinely defective product—for example, an air bag that fails to inflate in a serious automobile collision, or an implantable cardiac defibrillator that delivers powerful electric shocks to a heart that is functioning normally—may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem. It is common, for example, for injured plaintiffs to plead both defective manufacture and defective design and to pursue discovery on both theories, as occurred in *Riegel* itself, for example.

Bausch, 630 F.3d at 560 (citing cases). In FDA cases, "much of the critical information is kept confidential as a matter of federal law. The specifications of the FDA's premarket approval documents, for example, are confidential, and there is no public access to complete versions of these documents. An injured patient cannot gain access to that information without discovery." *Id.* If after discovery "the problem turns out to be a design feature that the FDA approved" Plaintiffs' manufacturing defect claim may fail, but "if the problem turns out to be a failure to

[15] In a master complaint there may be different causes of action that apply to different plaintiffs. If Defendants' position is correct, they would win dismissal unless all claims are for design defect or all claims are for manufacturing defect.

comply with the FDA's legally enforceable conditions" then preemption is unavailable. *Id.*

Plaintiffs allege that Defendants failed to follow the FDA's requirements and best practices, and instead sold a product with inconsistent quality in which certain units were defectively manufactured and those defects caused Plaintiffs' injuries. MPIC ¶ 139. For example, contrary to Paragard's design, the plastic on the units some Plaintiffs used was made with "insufficient flexibility" and "the Paragard copper had experienced corrosion or discoloration *at the time of final packing*." *Id.* ¶ 217 (emphasis added). The plastic should have met the design specifications but did not because "sourcing suitable plastic with sufficient flexibility has been an ongoing problem." *Id.* ¶ 141. And *obviously* the copper should not have been corroded and discolored when packaged for sale. *See also id.* ¶ 143 (alleging the copper inside some Paragard units was "rotting"). The MPIC alleges that these issues violated "Defendants' written quality controls," but of course Plaintiffs have no access to those documents, and so cannot allege specifically which policies or practices were violated and by how much. *Id.* ¶ 144.[16]

[16] Defendants cite *In re Zantac (Ranitidine) Prods. Liab. Litig.*, but that case is distinguishable. 2020 WL 7864213 (S.D. Fla. Dec. 31, 2020). There, Plaintiffs alleged "within a manufacturing-defect count itself that" the drug did not deviate from its "design." *Id.* at 21. The theory there was that ranitidine inherently degrades

Defendants claim any effort to prevent manufacturing defects would be a preempted "major change," but provide no explanation of how a process *improvement* that *reduces* manufacturing problems (for example, more careful testing, better plastic sourcing, or inspection of the copper before packaging) could be "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.'" Mot. 46 (quoting 21 U.S.C. § 356a(c)(2) and 21 C.F.R. § 314.70(b)(1)) (emphasis added). Additional testing has *no* potential to *adversely* affect the safety or effectiveness of Paragard, and the FDA has never prevented manufacturers from improving safety. *Cf.* 21 C.F.R. § 314.70(c)(6)(i) (deeming a "moderate change" "changes in the methods or controls to provide **increased** assurance that the drug substance or drug product will have the characteristics of identity, strength, quality, purity, or potency that it purports or is represented to possess" (emphasis added)).

CONCLUSION

Defendants' Motion to Dismiss should be denied.

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into a carcinogen, not that flaws in the manufacturing process caused any problem. *Id.* Even so, the court allowed plaintiffs to replead. *Id.*

Dated: June 21, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 21, 2021, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

/s/ *Erin K. Copeland*
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