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: Pauline Rickard Melody Braxton Alisa Robere	:	CIVIL ACTION NOs.: 1:21-cv-03861-LMM [42, 45] 1:22-cv-00490-LMM [40, 43] 1:22-cv-01583-LMM [50, 53]

ORDER

This multi-district litigation ("MDL") involves the contraceptive Paragard, an intrauterine device ("IUD"), which is regulated as a drug under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et seq., and the federal Food and Drug Administration's ("FDA") implementing regulations in Title 21 of the Code of Federal Regulations. The case is now before the Court on a Motion for Summary Judgment on Federal Preemption of the claims of bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere (collectively, "Plaintiffs"), filed by Defendants Teva Pharmaceuticals USA, Inc., Teva Women's Health, LLC, and Teva Branded Pharmaceutical Products R&D, Inc. (collectively, "Teva") and joined by CooperSurgical, Inc. ("Cooper").[1] The Court held oral

[1] The Court defers ruling on additional arguments raised in Cooper's motion for summary judgment and will address them in a separate Order.

argument on the motion on November 20, 2025. After due consideration, the Court enters the following Order.

I. LEGAL STANDARD

Rule 56 of the Federal Rules of Civil Procedure provides that "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A factual dispute is genuine if the evidence would allow a reasonable jury to find for the nonmoving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A fact is "material" if it is "a legal element of the claim under the applicable substantive law which might affect the outcome of the case." Allen v. Tyson Foods, Inc., 121 F.3d 642, 646 (11th Cir. 1997).

The moving party bears the initial burden of showing the Court, by reference to materials in the record, that there is no genuine dispute as to any material fact that should be decided at trial. Hickson Corp. v. N. Crossarm Co., 357 F.3d 1256, 1260 (11th Cir. 2004) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)). The moving party's burden is discharged merely by " 'showing'—that is, pointing out to the district court—that there is an absence of evidence to support [an essential element of] the nonmoving party's case." Celotex Corp., 477 U.S. at 325. In determining whether the moving party has met this burden, the district court must view the evidence and all factual inferences in the light

most favorable to the party opposing the motion. Johnson v. Clifton, 74 F.3d 1087, 1090 (11th Cir. 1996).

Once the moving party has adequately supported its motion, the non-movant then has the burden of showing that summary judgment is improper by coming forward with specific facts showing a genuine dispute. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.' " Id. "The mere existence of a scintilla of evidence" supporting the non-movant's case is insufficient to defeat a motion for summary judgment. Anderson, 477 U.S. at 252. All reasonable doubts, however, are resolved in favor of the non-movant. Fitzpatrick v. City of Atlanta, 2 F.3d 1112, 1115 (11th Cir. 1993).

II. BACKGROUND

A. Facts

Paragard is an IUD that is implanted into a patient by a healthcare provider. It is a T-shaped device that is made of polyethylene milled with barium sulfate and wrapped in copper. It is indicated for intrauterine contraception for up to 10 years. The T-shape is designed to collapse for insertion and removal. It is supposed to be easy for a healthcare practitioner to remove the Paragard by gently pulling on attached threads.

Paragard has been approved and regulated by the FDA since 1984 without any significant design updates. Teva became the owner of the Paragard NDA in

December 2008. Cooper acquired the Paragard NDA from Teva on November 1, 2017.

Robere underwent placement of a Paragard in June 2011, Rickard had hers placed in May 2012, and Braxton had hers placed in November 2014. At the time Plaintiffs had their Paragards placed, there was nothing in the Warnings, Adverse Reactions, or Patient Information sections of the drug label about breakage, and each plaintiff expected to have a follow-up procedure to have the Paragard removed per the removal instructions on the label. But in each case—when Robere and Braxton had their Paragards removed in or around December 2019 and when Rickard had hers removed in August 2021—the Paragard was broken, and it was necessary for the plaintiff to have surgery to remove fragments of the Paragard.

B. Procedure

The bellwether plaintiffs assert twelve claims against Defendants, all under state[2] law: Strict Liability—Design Defect (Count I); Strict Liability—Failure to Warn (Count II); Negligence (Count IV); Negligence—Design Defect (Count V); Negligence—Failure to Warn (Count VI); Fraud & Deceit (Count VII); Fraud by Omission (Count VIII); Negligent Misrepresentation (Count IX); Breach of Express Warranty (Count X); Breach of Implied Warranty (Count XI); Gross

[2] The parties have determined that Florida law applies to the claims of each of the bellwether plaintiffs, except as to Rickard's claim for punitive damages, which she contends is governed by New York law.

Negligence (Count XIII); and Punitive Damages (Count XV).[3] From 2005 until a label change effected in 2019, the breakage information in the Paragard label stayed substantially the same. Dkt. No. [92-1] ¶ 4.[4] In support of the claims, Plaintiffs allege that by 2010, prior to any of the bellwether plaintiffs having had a Paragard placed, the label should have—but did not—warn that Paragard could break during routine and non-surgical removal, even without embedment; indicate the frequency of the breakages; warn that if Paragard broke, it could cause serious injury, require surgical intervention, or result in loss of reproductive health or fertility; warn of breakage or these injuries in the "Warnings," "Precaution," or "Adverse Reactions" section of the label; and warn of Paragard breakage in the Patient Package Insert. Dkt. No. [67-1] at 11-15; Dkt. No. [92-1] ¶¶ 5-18. They also allege that several design defects—the composition of the materials in the Paragard base, lack of storage controls for the base materials, and the right angles in the base's T-shape—caused the Paragard to break and injure them. Dkt. No. [67-1] at 44-46.

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[3] The master complaint also includes claims of strict liability—Manufacturing Defect (Count III); Negligence—Manufacturing Defect (Count V); Violation of Consumer Protection Laws (Count XII); and Unjust Enrichment (Count XIV). Each of the bellwether plaintiffs agreed to dismiss those claims with prejudice.

[4] Unless otherwise noted, record citations are to the documents filed in Rickard v. Teva Pharms. USA, Inc., Civ. Case No. 1:21-cv-03861-LMM (N.D. Ga.).

Defendants move for summary judgment of the claims on grounds that it was impossible for them to make Plaintiffs' changes without prior approval from the FDA and that the claims are therefore preempted by federal law. Below, the Court first discusses relevant background on preemption in the FDCA drug-approval context. It then addresses the parties' arguments.

III. DISCUSSION

Before a drug manufacturer may market a pharmaceutical drug, it must first submit to the FDA a New Drug Application ("NDA") that contains, among other things, investigation reports showing that the drug is safe and effective; a full list of the articles used as components of the drug; a full statement of the composition of the drug; a full description of the methods used in, the facilities used for, and the controls used for the manufacture, processing, and packing of the drug; and a proposed label. 21 U.S.C. § 355(a)-(b). In general, following NDA approval, a drug manufacturer may only change a drug, Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 477 (2013), or a drug label, Wyeth v. Levine, 555 U.S. 555, 568 (2009), after the FDA approves the change through a supplemental application. Where it is impossible for a manufacturer to comply with both state tort law and federal requirements, this regulatory process may preempt the application of state tort law. Merck Sharp & Dohme Corp. v. Albrecht, 587 U.S. 299, 302-03 (2019); English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990).

The existence of preemption is a question of law for the court to decide. Albrecht, 587 U.S. at 317-18. "[T]wo cornerstones" guide the extent to which federal law preempts state law: "the purpose of Congress" and 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 (cleaned up). Where, as here, no express preemption clause governs, courts will not find implied preemption lightly. Va. Uranium, Inc. v. Warren, 587 U.S. 761, 765 (2019) (plurality opinion) ("[W]e are hardly free to extend a federal statute to a sphere Congress was well aware of but chose to leave alone."); Wyeth, 555 U.S. at 566-67 (explaining that Congress intended from the beginning for federal regulation of food and drugs to supplement the protection afforded consumers by state regulation and common-law liability); see id. at 573 ("Impossibility pre-emption is a demanding defense.").

A. Preemption of Warning-Based Claims

Florida state law requires that a drug label carry adequate warnings of the drug's inherent dangers. Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989). Plaintiffs argue that Defendants had the information showing that a breakage warning was necessary well before they had their Paragards placed and that Defendants therefore should be held liable for failing to include the warning on the label via the Changes Being Effected ("CBE") regulation.

The CBE regulation is an exception to the general rule that a manufacturer may change a drug label only with prior FDA approval. Wyeth, 555 U.S. at 568. It allows for a drug manufacturer to unilaterally make changes to a label "to 'reflect newly acquired information' if the changes 'add or strengthen a . . . warning' for which there is 'evidence of a causal association.' " Albrecht, 587 U.S. at 314-15 (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)). The CBE regulation defines "newly acquired information" as:

> [D]ata, analyses, or other information not previously submitted to the Agency, which may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA.

21 C.F.R. § 314.3(b).

Thus, since the CBE regulation permits changes, "a drug manufacturer will not ordinarily be able to show that there is an actual conflict between state and federal law such that it was impossible to comply with both." Albrecht, 587 U.S. at 315. However, the CBE exception will not apply where there is "clear evidence" that the FDA would not have approved the change to the drug's label. Albrecht, 587 U.S. at 302-03 (defining "clear evidence" as "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").

Therefore, to state a non-preempted claim for failure to warn, the plaintiff must plead a labeling deficiency that the defendant could have corrected by using the CBE regulation. Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699, 708 (2d Cir. 2019); Lyons v. Boehringer Ingelheim Pharms., Inc., 491 F. Supp. 3d 1350, 1363 (N.D. Ga. 2020). If the plaintiff does so, the burden shifts to the party asserting a preemption defense to demonstrate that there is clear evidence that the FDA would not have approved the change to the label. Gibbons, 919 F.3d at 708; Lyons, 491 F. Supp. 3d at 1363.

According to Plaintiffs, the "newly acquired information" that would allow for the application of the CBE regulation includes a 2015 FDA submission created by Teva Head of Pharmacovigilance, Dr. Siyu Liu, which identified device breakage as a reportable adverse event. Dkt. No. [67-1] at 8, 15-19, 27-33. Plaintiffs also point to the accumulation of miscoded breakage-related adverse event reports over time, which Plaintiffs argue should have been recognized as newly acquired information much earlier. Id. at 7-8, 19-24, 33-38.

The Court is satisfied that Plaintiffs' evidence identified risks of a different type or greater frequency than previously reported to the FDA and thus revealed labeling deficiencies that Defendants could have corrected by using the CBE regulation. Dr. Liu conducted an analysis of Paragard's post-marketing adverse-event reports in its historical safety database for all events from product launch until January 9, 2015, with at least 300 occurrences and serious adverse events

that had a "reasonably strong causal association" with Paragard. Dkt. No. [92-1] ¶¶ 25, 26, 31; Dkt. No. [59-13] at 11-12. After Dr. Liu reviewed 90 adverse reports for device breakage, he determined that device breakage qualified as a reportable adverse event and was "not already adequately discussed and included under Warnings, Precautions and Adverse Reactions." Dkt. No. [59-16] at 5; Dkt. No. [92-1] ¶¶ 27, 28, 30. Dr. Liu also stated in his report to the FDA that device breakage without embedment was possibly causally associated with use of Paragard, explaining, "Multiple reports demonstrated a possible causal association due to a visualized broken device and lack of additional confounders. Paragard was broken during the removal in some reports, while a breakage can occur without a procedure." Dkt. No. [59-16] at 11. When asked at his deposition why Teva had not made the label-change recommendation earlier, Dr. Liu concluded that Teva had assumed the label it had acquired from the prior NDA holder had been adequate. Dkt. No. [92-1] ¶ 29. This comports with later analysis showing that coding inconsistencies obscured the magnitude of the breakage reports. See Dkt. No. [92-1] ¶¶ 36-38, 44-47. Thus, the Court is persuaded that Dr. Liu's study identified a risk—dating back to the previous NDA holder—of a different type and greater frequency of breakage than previously identified.

Defendants argue that the information should not qualify under the CBE exception because it did not become available at a time when it could have made any difference to Plaintiffs. The Court cannot agree, as the evidence shows that

Defendants themselves caused the delay in discovering the information: that Defendants obscured the breakage reports by miscoding them; that the FDA had ordered a new study of the adverse event reporting to be undertaken years earlier, well before Plaintiffs had their Paragards placed[5]; that Defendants simply failed to do it; and that once Teva did undertake the required analysis, both the breakage risk and the causal relationship became immediately apparent. See id. ¶¶ 19-22, 27, 28, 30, 44-47.

These unique facts—evidence that miscoding caused underappreciation of the breakage risk, that Teva disregarded FDA direction to conduct the retroactive adverse events study years earlier, and that causation is self-evident—distinguish this case from the myriad others relied on by Defendants. See, e.g., Knight v. Boehringer Ingelheim Pharms., Inc., 984 F.3d 329, 338 (4th Cir. 2021) (finding no "newly acquired information" where the FDA was already aware of correlation between drug and risk, and paper did not reveal risk of different type or greater severity or frequency); Hickey v. Hospira, Inc., 102 F.4th 748, 755 (5th Cir. 2024) (vacating preemption order on grounds that the trial court erred by failing to enforce the requirement that newly acquired information reveal risks of a

[5] On January 24, 2006, the FDA published a rule setting out new Physician Labeling Requirements ("PLR") that required adverse reactions identified from post-marketing reports to be listed separately from adverse reactions identified in clinical trials and adding adverse reactions in § 6.2 Postmarketing Experience. Dkt. No. [92-1] ¶¶ 19-22. Manufacturers were to submit a label in the revised PLR format no later than June 30, 2010. Id. ¶ 20.

different type or greater severity or frequency than previously included in submissions to the FDA); Holley v. Gilead Scis., Inc., No. 18-cv-06972, 2023 WL 6390598, at *8 (N.D. Cal. Sept. 28, 2023) (finding no "newly acquired information" where there was no evidence of analyses or other evidence that the manufacturer did not share with the FDA); R.S.B. ex re Hammar v. Merck & Co., No. 20-C-1402, 2021 WL 6128161, at *4 (E.D. Wis. Dec. 28, 2021) (finding no "newly acquired information" where the plaintiffs "ha[d] not pointed to any specific study, data, or any other evidence that Merck allegedly had, or *should have had*" (emphasis added)); Gayle v. Pfizer, Inc., 452 F. Supp. 3d 78, 88 (S.D.N.Y. 2020) (finding no "newly acquired information" where there was no evidence of causation linking the drug to the adverse event); In re Gardasil Prods. Liab. Litig., 770 F. Supp. 3d 893, 908-11, 919 (W.D.N.C. 2025) (same). Moreover, given Congressional intent to maintain state tort law as a means of consumer protection from unsafe drugs, the Court is not at all persuaded that Congress meant to imply preemption where the NDA holder itself manufactured the putative "impossibility." The untimeliness of the study showing the newly acquired information was directly attributable to Teva's failure to comply with the FDA's requirement to conduct the study by a certain date. Thus, the Court concludes that the labeling deficiencies identified by Dr. Liu constitute "newly acquired information" triggering the CBE exception.

Having found that Plaintiffs have pointed out labeling deficiencies that Defendants should have corrected by using the CBE regulation, the Court now turns to the second step of the preemption analysis: whether Defendants have demonstrated that there is clear evidence that the FDA would not have approved corresponding label changes. See Gibbons, 919 F.3d at 708; Lyons, 491 F. Supp. 3d at 1363. Again, in this context, "clear evidence" requires a showing that the drug manufacturer "fully informed the FDA of the justifications for the warning required by state law." Albrecht, 587 U.S. at 302-03.

There is not clear evidence that the drug manufacturer fully informed the FDA of the justifications for Dr. Liu's labeling recommendations. Due to the miscoding, which persisted through August 2013, Dkt. No. [92-1] ¶ 38, and the resulting undercount of breakage reports, which persisted through 2022 and beyond, Dkt. No. [92-1] ¶¶ 36, 37, 41-47; Dkt. No. [89-3] at 127, the Court cannot say that Defendants fully informed the FDA of the justifications for the warnings supported by Dr. Liu's new study. Thus, Defendants have not shown clear evidence that the label reflects all the changes the FDA would have approved had it been fully informed.

Accordingly, the Court concludes that the labeling deficiencies identified by Dr. Liu are not preempted. Because Plaintiffs' failure-to-warn claims track those identified labeling deficiencies, it follows that the claims are not preempted.

B. Preemption of Design-Defect Claims

Similar to the label restrictions, a manufacturer generally cannot change the design of a drug without prior FDA approval. 21 C.F.R. § 314.70(b)(2)(i) (requiring prior approval in order to make "changes in the qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved NDA"); id. § 314.70(b)(2)(iv) (requiring prior approval for "[c]hanges in the . . . manufacture of the drug substance that may affect . . . the physical, chemical, or biological properties of the drug substance"). This regulatory framework ensures that modifications do not compromise the drug's safety or effectiveness without FDA oversight.

Nevertheless, Plaintiffs argue that the Paragard design is defective under Florida's "consumer expectations" test and that Defendants could have made the Paragard safer while still complying with both federal and state law either by designing a safer Paragard from the start or by making several changes to the design that were either expressly permitted by the NDA or not specified at all.[6]

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[6] "The consumer expectations test . . . 'considers whether a product is unreasonably dangerous because it failed to perform as safely as an ordinary consumer would expect when used as intended or in a reasonably foreseeable manner.' " Cates v. Zeltiq Aesthetics, Inc., 73 F.4th 1342, 1351 (11th Cir. 2023) (quoting Aubin v. Union Carbide Corp., 177 So. 3d 489, 503 (Fla. 2015)). "Even so, 'a manufacturer is not under a duty in strict liability to design a product which is totally incapable of injuring' consumers." Cates, 73 F.4th at 1352-53 (quoting Grieco v. Daiho Sangyo, Inc., 344 So. 3d 11, 19 (Fla. Ct. App. 2022)). "Whether a product is 'unreasonabl[y] dangerous' is 'based on an objective standard and not the viewpoint of any particular customer.' " Cates, 73 F.4th at 1352-53 (quoting Liggett Grp. v. Davis, 973 So. 2d 467, 475 (Fla. Ct. App. 2007)).

Dkt. No. [67-1] at 23-27, 43-46. Specifically, Plaintiffs contend that Defendants could have and should have stayed with Dupont 2005 for the Paragard base material rather than switching to Dupont 20 in or around 2007; applied a surface treatment to the barium sulfate to minimize clusters in the base material; manufactured the base material in the bottom range of the amount of barium sulfate allowed by the NDA rather than the top of the range; softened the T-shape of the Paragard base to eliminate right angles; and implemented warehouse storage controls to maximize the stability of the base material such that it would not degrade and become increasingly prone to breakage. Id. at 23-27, 44-46. Defendants, in turn, contend that they are entitled to summary judgment of the design-defect claims because they did not own the NDA until decades after it was designed; because several of the changes advocated by Plaintiffs sound in manufacturing defect rather than design defect; and because the changes Plaintiffs suggest to cure the perceived defects "are precisely the kind of major changes that must be approved by the FDA" and therefore would have been impossible to effect unilaterally without violating federal law. Dkt. No. [42] at 8, 25-28; Dkt. No. [92] at 23-25.

The Court has already granted summary judgment to Cooper on the design-defect claims, as nothing in the record suggests that Cooper could have altered the Paragard design at any time material to Plaintiffs' claims. Dkt. No. [116] at 4. Likewise, Plaintiffs' argument that Teva could have or should have

designed a safer Paragard from the start makes no sense, since Teva did not own the Paragard NDA until December 2008. Thus, the Court limits its analysis to whether Teva was preempted from making changes to remedy design defects after it acquired the Paragard NDA.

It first bears distinguishing the design-defect claims from manufacturing-defect claims, which the bellwether plaintiffs have dismissed. See supra note 3. A design defect occurs where a product is "produced as designed[,] but the design itself is defective," as opposed to a manufacturing defect, which occurs when specific units of the product "do not conform to planned specifications due to manufacturing error." Ford Motor Co. v. Hill, 404 So. 2d 1049, 1051 (Fla. 1981). Plaintiffs point to manufacturer error in exposing the base material to sunlight, heat, and oxygen. Dkt. No. [67-1] at 46. Thus, the allegations regarding storage controls go to manufacturing, not design. Accordingly, those claims are no longer in the case.

Defendants argue federal law prevented them from making the remaining design changes Plaintiffs suggest. This is incorrect as to Plaintiffs' allegations that Defendants could have and should have stayed with Dupont 2005 for the Paragard base material rather than switching to Dupont 20 and should have adhered to the bottom boundary of the allowable content of barium sulfate, as the Paragard NDA allows for the use of either Dupont 2005 or Dupont 20 in the base material and for the percentage of barium sulfate Plaintiffs contend that

Defendants should have used in manufacturing the Paragard base. Thus, those claims are not preempted.

As to the suggestion that Defendants should have softened the T-shape of the Paragard base to eliminate right angles or should have applied a surface treatment to the barium sulfate used in the base, the Court agrees with Defendants that these would have been major changes requiring prior approval. Although a rounded T-shape is still, generally speaking, a T-shape and therefore arguably consistent with the NDA, see Dkt. No. [42-24] at 9, the regulatory ban covers not only changes in the specifications provided in the approved NDA, but also "changes in the *qualitative or quantitative* formulation of the drug product, including inactive ingredients," 21 C.F.R. § 314.70(b)(2)(i) (emphasis added), and changes that may affect "the *physical* . . . properties of the drug substance," id. § 314.70(b)(2)(iv) (emphasis added). One can readily see that softening the T-shape, as Plaintiffs propose, would have affected these properties of the drug in violation of 21 C.F.R. § 314.70(b)(2)(i) and (iv):

Dkt. No. [56-5] at 86; Dkt. No. [67-1] at 46. Likewise, it is axiomatic that applying a surface treatment to the barium sulfate would have changed its physical properties and thus violated 21 C.F.R. § 314.70(b)(2)(iv).

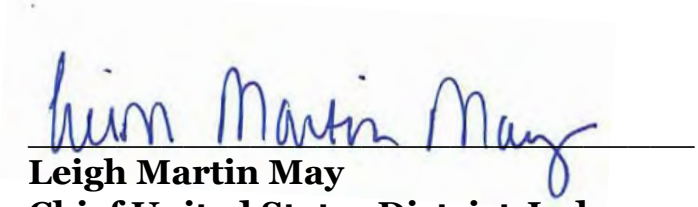
Plaintiffs have not cited any cases holding that a manufacturer would be allowed to make such design changes without prior FDA approval, nor has the Court's own research revealed any. Instead, these are major changes that would have had to be approved by the FDA. Consequently, the Court concludes that Defendants could not have made the suggested modifications to the shape of the Paragard base or the surface of the barium sulfate without prior approval of the FDA, and those claims are therefore preempted.

IV. CONCLUSION

In accordance with the foregoing, Teva's Motion for Summary Judgment on Federal Preemption of the claims of bellwether plaintiffs Pauline Rickard, Melody Braxton, and Alisa Robere, joined by Cooper, is **GRANTED IN PART AND DENIED IN PART**. The motion is **DENIED** as to the failure-to-warn claims; **DENIED** as to the design-defect claims arising from the use of Dupont 20 rather than Dupont 2005 and the incorporation of up to 24% barium sulfate in the Paragard base materials; and **GRANTED** as to the other claims for design defect. The Court **DEFERS** ruling on the remaining portion of Cooper's motion for summary judgment of Plaintiffs' failure-to-warn claims and shall address it in a separate Order. The Clerk is **DIRECTED** to terminate submission

of Teva's Motion for Summary Judgment on Federal Preemption in each of the bellwether cases.

IT IS SO ORDERED this 19th day of December, 2025.



Leigh Martin May
Chief United States District Judge