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Attorneys for Defendants Teva Pharmaceuticals USA, Inc., Teva Women's Health, Inc., Teva Women's Health, LLC, The Cooper Companies, Inc., and CooperSurgical, Inc.

EMMA SARMIENTO-TENECELA, Plaintiff, vs. TEVA PHARMACEUTICALS USA, INC., ET AL., Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION ESSEX COUNTY DOCKET NO. ESX-L-002653-20 CIVIL ACTION **ORDER GRANTING TEVA DEFENDANTS' MOTION FOR SUMMARY JUDGMENT**

THIS MATTER, having been brought before the Court on Oral Argument August 28, 2026 by Motion of Greenberg Traurig LLP, attorneys for Defendants Teva Pharmaceuticals USA, Inc., Teva Women's Health, Inc., Teva Women's Health, LLC, seeking an Order on their Motion for Summary Judgment;

AND THE COURT, upon consideration of the Motion, any opposition filed with respect to the Motion, and any arguments of counsel; and for good cause shown,

IT IS HEREBY ORDERED, on this 31st day of August, 2026, that Defendants' Motion for Summary Judgment is hereby **GRANTED**; and for the reasons stated in the attached Statement of Reasons.

IT IS FURTHER ORDERED that judgment is entered in favor of the Teva Defendants and against Plaintiff, dismissing Plaintiff's Complaint with prejudice; and

IT IS FURTHER ORDERED that a copy of this Order shall be served on all counsel within seven (7) days of its receipt by counsel.

/s/ Annette Scoca
HON. ANNETTE SCOCA, J.S.C.

X Opposed / Reply

____ Unopposed

~~The Court's findings of fact and conclusions of law were placed on the record on the 31st day of August, 2026 and were:~~

X Written

____ Oral

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Essex Vicinage

Honorable Avion M. Benjamin
Assignment Judge

Honorable Annette Scoca
Judge

Honorable John Zunic
Presiding Judge

Historic Courthouse, 470 Dr. Martin Luther King, Jr. Blvd.
Newark, New Jersey 07102

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August 31, 2026

ESX-L-2653-20, Sarmiento-Tenecela v. Teva Pharmaceuticals

STATEMENT OF REASONS

1. This matter arises from a product liability action where Plaintiff alleges that she suffered injuries from the Paragard Intrauterine Cooper Contraceptive ("Paragard IUD") that was implanted in Plaintiff in April 2008. On June 6, 2018, Plaintiff went to her medical provider to have the Paragard IUD removed. When Plaintiff's medical providers attempted to remove the Paragard IUD, the arm of the Paragard IUD had broken off. In June 2018, Plaintiff underwent a diagnostic hysteroscopy and a subsequent laparoscopy with hysterosalpingography where Dr. Fuseini informed Plaintiff that the retained IUD fragment was embedded within the myometrial wall and could not be safely removed.
2. Plaintiff filed the Complaint on April 13, 2020. Defendant Teva Pharmaceuticals USA, Inc., Defendant Teva Women's Health, Inc., Defendant Teva Women's Health, LLC, Defendant The Cooper Companies, Inc., and Defendant CooperSurgical, Inc. ("Defendants") filed a Motion to Dismiss for Failure to Make Discovery on June 9, 2026, which was originally returnable on July 17, 2026. The Court adjourned this Motion to August 14, 2026, so Plaintiff could file Opposition. Plaintiff filed Opposition on August 8, 2026. Defendants filed a Reply on August 14, 2026. Defendants Teva Pharmaceuticals USA, Inc., Teva Women's Health, Inc., and Teva Women's Health, LLC ("Defendants Teva") filed a Motion for Summary

Judgment on June 10, 2026, which was originally returnable on July 17, 2026. The Court adjourned this Motion to August 14, 2026, so Plaintiff could file Opposition. Plaintiff filed Opposition on August 8, 2026. Defendants filed a Reply on August 14, 2026. On August 12, 2026, this Court scheduled these Motions for Oral Argument on August 28, 2026. The Court notes that Plaintiff asked this Court to adjourn Oral Argument from August 24, 2026, to September 25, 2026. Defendants objected to this request on August 25, 2026. This Court denied this request, as (1) there has been 2,213 days of discovery; (2) there is a trial date scheduled for October 19, 2026, (3) there have been 3 trial date adjournments, (4) there have been 11 discovery end date extensions, and (5) these Motions were originally returnable on July 17, 2026. The Court notes that this Court does not have the authority to adjourn the trial date, as this request must be made before the Presiding Judge. Plaintiff filed another adjournment request on August 27, 2026, which this Court denied for the same reasons. This Court heard Oral Argument on August 28, 2026. This decision follows.

3. "If a party or an officer, director, or managing or authorized agent of a party or a person designated under R. 4:14-2(c) or 4:15-1 to testify on behalf of a party fails to obey an order to provide or permit discovery, including an order made under R. 4:23-1, the court in which the action is pending may make such orders in regard to the failure as are just, and among others the following:

    (1) An order that the matters regarding which the order was made or any other designated facts shall be taken to be established for the purposes of the action in accordance with the claim of the party obtaining the order;

    (2) An order refusing to allow the disobedient party to support or oppose designated claims or defenses, or prohibiting the introduction of designated matters in evidence;

    (3) An order striking out pleadings or parts thereof, or staying further proceedings until the order is obeyed, or dismissing the action or proceeding or any part thereof with or without prejudice, or rendering a judgment by default against the disobedient party;

(4) In lieu of any of the foregoing orders or in addition thereto, an order treating as a contempt of court the failure to obey any orders." R. 4:23-3.

4. The purpose of the summary judgment procedure is to provide a prompt, businesslike, and inexpensive method to resolving a case, but this relief should not be granted at the expense of fairness. Judson v. People's Bank & Trust Co. of Westfield, 17 N.J. 67, 74 (1955). Summary judgment must be granted if "the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." R. 4:46-2.

5. The NJ Supreme Court explained that in determining whether a genuine issue of material fact exists, the question is whether "the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational fact-finder to resolve the alleged disputed issue in favor of the non-moving party" Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 540 (1995). "Credibility determinations will continue to be made by a jury and not the judge," but "when the evidence is so one-sided that one party must prevail as a matter of law, the trial court should not hesitate to grant summary judgment." Id.

6. When deciding a motion for summary judgment, the trial court "must accept as true all the evidence which supports the position of the party defending against the motion and must accord him/her the benefit of all legitimate inferences which can be deduced therefrom, and if reasonable minds could differ, the motion must be denied." Lanzet v. Greenberg, 126 N.J. 168, 174 (1991). However, the non-moving party cannot defeat summary judgment merely by pointing to disputed issues of fact of an insubstantial nature, imaginary, or unreal facts." Brill, 142 N.J. at 529.

7. First, the Court turns to Defendants' Motion to Dismiss for Failure to Make Discovery. On June 2, 2026, this Court entered an Order compelling all experts to be deposed no later than June 30, 2026. Furthermore,

the Order stated "failure to comply with this Order may result in sanctions pursuant to R. 4:23-2(b), including but not limited to preclusion of expert testimony, suppression of proofs, attorney's fees, and such other relief as the Court deems just." Defendants allege that Plaintiff failed to provide deposition dates by the Court-ordered deadline and failed to respond to Defendants' May 29, 2026 request for deposition dates.

8. Defendants believe dismissal is warranted under Rule 4:23-2(b)(3), as the Court has already attempted a lesser remedy by compelling compliance with its discovery order, yet Plaintiff failed to comply. Defendants believe under these circumstances another order compelling compliance would serve no purpose, as Defendants have been prejudiced by Plaintiff's noncompliance with this Court's Order.

9. Alternatively, Defendants argue that the Court should prevent Plaintiff from relying on Dr. Kessler and Dr. Mays, as Defendants are entitled to examine Plaintiff's expert witnesses and whatever opinions they intend to offer. Defendants contend that they should not be forced to defend against expert opinions that Plaintiff has refused to make available for examination despite a direct court order.

10. Lastly, Defendants assert that they are entitled to reasonable attorney's fees and costs under Rule 4:23-2(b) due to Plaintiff's failure to comply with this Court's June 2, 2026 Order, since Defendants have been forced to spend additional time and resources seeking relief that would be unnecessary if Plaintiff complied with the Order.

11. Conversely, Plaintiff alleges that Dr. Kessler and Dr. Mays are general experts involved in the nationwide Paragard litigation, In re Paragard IUD Products Liability Litigation, MDL No. 2974 in the United States District Court for the Northern District of Georgia. Plaintiff continues that the parties in this case have a mutual recognition that developments in the MDL affect the orderly completion of discovery at issue in this case. Plaintiff contends that Plaintiff's counsel does not control the schedules of Dr. Kessler and Dr. Mays and was unable to obtain and coordinate mutually available deposition dates within the abbreviated

period established by this Court's June 2, 2026, Order. Plaintiff claims that Defendant's May 29, 2026, correspondence devoted substantial attention to Dr. Kessler's and Dr. Mays' use of material produced in the MDL and demanded assurances concerning their compliance with the MDL Protective Order. Plaintiff contends that Plaintiff has been unable to coordinate the availability of these experts, as their schedules are affected by the nationwide litigation from which their general opinions arise.

12. Plaintiff informs this Court that scheduling difficulties also arose from Plaintiff's counsel's personal issues, as Plaintiff's counsel's mother underwent two significant cardiac procedures requiring hospitalization and counsel's attention and assistance. Plaintiff continues that Plaintiff does not believe that these circumstances relieved Plaintiff of her obligation to comply with the Court's June 2, 2026 Order, but these circumstances demonstrate that the missed deadline was neither willful nor the product of a deliberate disregard of the Court's authority. Plaintiff believes that dismissal with prejudice or preclusion of Dr. Kessler and Dr. Mays would be grossly disproportionate, since any prejudice to Defendants can be fully cured by permitting additional time to coordinate and complete the requested depositions.

13. "The sanction of dismissal should be imposed only sparingly and only when the discovery goes to the very foundation of the cause of action or where the refusal to comply is deliberate and contumacious." Abtrax Pharms. v. Elkins-Sinn, 139 N.J. 499, 502 (1995). "[W]hen the delay has so prejudiced the defendant that his ability to defend his case is seriously impaired, or when other substantial equitable considerations suggest dismissal." Zaccardi v. Becker, 88 N.J. 245, 253 (1982).

14. Defendants claim that Plaintiff is relying on the substance of these experts' opinions to oppose Defendants Teva's Motion for Summary Judgment, yet Defendants have been prevented from deposing these experts. Defendants claim that there are no pending expert-related deadlines or other court-imposed obligations in the MDL case that would have prevented Dr. Kessler or Dr. Mays from being deposed in this case by the timeframe set by this Court. Defendants believe that giving Plaintiff more time for the parties to depose

Dr. Kessler and Dr. Mays is not a sanction contemplated by R. 4:23-2(b), as it is the same discovery obligation that this Court has imposed.

15. Here, the Court finds that Plaintiff has failed to comply with this Court's June 2, 2026 Order compelling all experts to be deposed no later than June 30, 2026. The Court notes this Order stated, "failure to comply with this Order may result in sanctions pursuant to R. 4:23-2(b), including but not limited to preclusion of expert testimony, suppression of proofs, attorney's fees, and such other relief as the Court deems just." Defendants informed this Court that Plaintiff failed to respond to Defendants' May 29, 2026, request for deposition dates, and Defendants once again informed this Court during Oral Argument that they still have not received a response from Plaintiff for deposition dates. While Plaintiff claims that Plaintiff's counsel does not control the schedules of Dr. Kessler and Dr. Mays and was unable to obtain and coordinate mutually available deposition dates within the abbreviated period established by this Court's June 2, 2026, Order, the Court notes that Plaintiff's counsel informed this Court during Oral Argument that their office was unable to contact these experts to schedule the depositions. Furthermore, the Court notes that Defendants informed this Court during Oral Argument that that Defendants never received these expert reports in this case, but Defendant's counsel is aware of the contents of these reports as it was provided to them in the MDL case. The Court believes that barring Dr. Kessler's and Dr. Mays' report is appropriate, as this Court has already attempted a lesser remedy by compelling compliance with its discovery order, yet Plaintiff failed to comply. While the Court understands Plaintiff's counsel's personal issues, the Court finds that Defendants are entitled to depose Dr. Kessler and Dr. Mays if Plaintiff intends on relying on this testimony at trial. Furthermore, the Court notes that this case has a trial date of October 19, 2026, and the discovery end date in this Case was July 31, 2026. While Defendants believe that dismissal is appropriate due to Plaintiff's failure to comply with this Court's June 2, 2026, Order, the Court notes "[t]he sanction of dismissal should be imposed only sparingly and only when the discovery goes to the very foundation of the cause of action or where the refusal to comply is deliberate and contumacious."

Abtrax Pharms. v. Elkins-Sinn, 139 N.J. 499, 502 (1995). Here, the Court does not believe that Plaintiff's refusal to comply with this Court's Order deserves this drastic remedy. Moreover, the Court does not feel that the Teva Defendants are entitled to counsel fees.

16. The Court now turns to Defendants Teva's Motion for Summary Judgment. Defendants Teva argue that (1) Plaintiff's claims are preempted by federal law, (2) alternatively Plaintiff's failure to warn claim fails as Plaintiff cannot show the Paragard Prescribing Information was inadequate of that any alleged defect proximately caused her injuries, (3) Plaintiff is unable to satisfy the elements for a design defect claim, (4) Plaintiff has no evidence supporting her manufacturing defect claim, and (5) New Jersey law does not permit Plaintiff to recover punitive damages, as Paragard is a drug subject to FDA premarket approval. Here, the Court notes Plaintiff does not oppose dismissal of her manufacturing-defect claim, as such the Court will not address that issue since it is not in dispute.

17. Defendants Teva assert that Plaintiff's failure-to-warn claim is preempted, as Defendants Teva could not have added Plaintiff's proposed warning due to the changes being affected by regulation.

18. "[D]rug manufacturers are limited in their ability to unilaterally change the labels on their products. Specifically, to make a change on their own, a manufacturer must comply with the 'changes being effected' ('CBE') regulation, set forth at 21 C.F.R. § 314.70(c)(6)(iii)." Gibbons v. Bristol-Myers Squibb Co., 919 F.3d 699, 707 (2d Cir. 2019).

19. "Newly acquired information is data, 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.

20. "Post-FDA approval preemption analysis proceeds in two stages. First, the plaintiff must show that there existed 'newly acquired information' such that the defendants could unilaterally change the label pursuant to the CBE regulation without FDA approval. But, the mere availability of a CBE label amendment does not necessarily defeat a manufacturer's preemption defense. Because the FDA 'retains the authority to reject labeling changes,' a manufacturer

> may still -- even after the plaintiff has identified 'newly acquired information' establish an impossibility preemption defense through 'clear evidence that the FDA would not have approved a change' to the label."

Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 661 (S.D.N.Y. 2017) (citations omitted).

21. Defendants Teva believe that Plaintiff is unable to satisfy the burden to identify newly acquired information, as Plaintiff has failed to identify any information Defendants possessed prior to her Paragard placement in 2018 that would qualify as newly acquired information under the CBE. Defendants Teva continue that while Plaintiff alleges that Teva Defendants came into possession of newly acquired evidence between 2005 and 2015, Plaintiff only alleges that "the FDA received over 1600 reports of Paragard IUD breakage, with over 700 classified as serious." Compl. ¶ 53. Defendants Teva contend that adverse event reports about Paragard being embedded and/or breaking is not newly acquired information, as those risks were included in the FDA approved Paragard labeling before the insertion of Plaintiff's Paragard in 2008. Defendants Teva claim that the adverse event reports could not have supported a CBE label change, as these adverse event reports do not "reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3.

22. Furthermore, Defendants Teva argue that Plaintiff has not identified a new analysis of previously submitted data that satisfies the CBE regulation, as the FDA was aware of the risks of embedment and breakage and the adverse event reports when the Paragard label was approved by the FDA. Defendants Teva contend that the Federal District Court presiding over the Paragard MDL ruled that some of plaintiffs' claims in the MDL were not preempted, and the Court relied on a 2015 submission to the FDA by a Teva pharmacovigilance employee named Dr. Siu Liu. In re Paragard IUD Prods. Liab. Litig., 1:20-md-02974-LMM, 2026 WL 252761, at *4–5 (N.D. Ga. Jan. 16, 2026). Plaintiff's Exhibit A. Defendants Teva allege that Plaintiff has not identified Dr. Lui's submissions as newly acquired information relevant to her claims. Furthermore, the plaintiffs in MDL alleged that by 2010, the Paragard label should have been changed via the CBE regulation, but Plaintiff received her Paragard in 2008. Thus, Defendants Teva

believe that Plaintiff is unable to meet her burden to identify newly acquired information that would have supported a unilateral CBE update adding Plaintiff's proposed warnings prior to her Paragard placement in April 2008.

23. Defendants Teva also assert that evidence shows that the FDA would not have approved the change to the warnings section of the Paragard label for which Plaintiff seeks changes in, as the FDA did not recommend any further changes or additions to the Warnings section of the label beyond the language already incorporated there in 2019. Defendants' Exhibit 11.

24. Defendants Teva contend that any warning-based claim on a failure to report adverse events to the FDA is preempted. "[P]laintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by federal law." Buckman v. Plaintiffs' Legal Committee, 531 U.S. 341, 348 (2001). Thus, Defendants Teva claim that any warnings-based claim based on an alleged failure to report adverse events to the FDA is impliedly preempted under Buckman and 21 U.S.C. § 337(a).

25. Defendants Teva argue that Plaintiff's design defect claim is preempted, as Defendants Teva were unable to make a change to Paragard's approved design and the materials from which Paragard is made without obtaining FDA's prior approval for such changes. "Once a drug — whether generic or brand-name — is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application.'" Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 480 (2013) (quoting 21 CFR §314.70(b)(2)(i)). "Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly pre-empted where it is impossible for a private party to comply with both state and federal requirements." Id. 570 U.S. at 480 (citations omitted). Defendants Teva allege that it was unable to comply with state law (allegedly requiring a change to the design of the product), as federal law requires FDA approval prior to any major changes.

26. Alternatively, Defendants Teva assert that Plaintiff's failure to warn claim fails under New Jersey law, as Plaintiff is unable to show that the Paragard prescribing information was inadequate or that any alleged defect proximately caused her injuries. "In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction." N.J.S.A. 2A:58C-4.

27. "An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician."

N.J.S.A. 2A:58C-4.

28. Defendants Teva claim that the Paragard label was approved by the FDA on September 1, 2005, thus there is a rebuttable presumption that Paragard's warnings regarding embedment and breakage were adequate as a matter of New Jersey law. Defendants' Exhibit 8.

29. "Three pathways are available to overcome the presumption of adequacy [of an FDA-approved label warning]. The first pathway is if a plaintiff can establish 'deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects.' Perez, 161 N.J. at 25, 734 A.2d 1245. The second is if a plaintiff can demonstrate 'economically-driven manipulation of the post-market regulatory process.' McDarby, 401 N.J. Super. at 63, 949 A.2d 223. The third is if a plaintiff can prove by clear and convincing evidence that a manufacturer knew or should have known in the postmarketing phase that the drug warnings were inadequate based on the label warning updating requirements in 21 C.F.R. § 201.57(c), 21 C.F.R. § 314.70(c), or any other pertinent federal regulation."

In re Accutane, 235 N.J. 229, 277 (2018).

30. Defendants Teva allege that Plaintiff has presented no evidence that support any of these pathways. Defendants Teva continue that the Paragard Prescribing Information warned of embedment, breakage, and need for surgical removal in its WARNINGS and ADVERSE REACTIONS sections of the labeling. Defendants' Exhibit 3.

31. Defendants Teva argue that there is no dispute of material fact as to causation for Plaintiff's failure-to-warn claim, as NP Banks, Plaintiff's prescribing healthcare provider, was aware of the risks of the Paragard when prescribing the product to Plaintiff.

32. "In the case of prescription drugs, the PLA codifies what is commonly referred to as the learned intermediary doctrine — a doctrine that acknowledges that 'the physician acts as the intermediary between the manufacturer and the [patient].'" In re Accutane Litig., 235 N.J. at 265 (quoting Niemiera v. Schneider, 114 N.J. 550, 559 (1989)). "Under the learned intermediary doctrine, a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." Id. at 266 (citations omitted). Defendants Teva believe that Plaintiff lacks evidence to prove proximate causation, as NP Banks' testimony shows that she was aware of the risks of the Paragard at issue here before prescribing the product for Plaintiff. Defendants' Exhibit 12, T32:11-33:16. Defendants Teva continue that Plaintiff never elicited any testimony from NP Banks demonstrating that a defect in the Paragard warnings proximately caused her injuries.

33. Furthermore, Defendants Teva argue that Plaintiff's design defect fails, as Plaintiff lacks expert testimony to satisfy the safer alternative design requirement.

34. "[I]n a design defect products liability case, plaintiff must prove, not only that the alternative design is feasible and practical, but that it is also safer than the manufacturer's design. Since plaintiff failed to meet that burden, defendant was entitled to judgment as a matter of law." Diluzio-Gulino v. Daimler Chrysler Corp., 385 N.J. Super. 434, 439 (App. Div. 2006). "Expert testimony in conclusionary terms is insufficient to meet that burden." Id. at 438. Defendants Teva allege that Plaintiff has no competent evidence to establish any alternative design for Paragard that would have reduced or prevented the risks of Plaintiff's

claimed injuries. Defendants contend that Dr. Luciani fails to offer any opinions on this issue. Thus, Defendants believe that Plaintiff's design defect claim fails as a matter of law.

35. Defendants Teva also assert that Plaintiff lacks any expert testimony establishing that Paragard was defective or that a defect in Paragard's design caused her injuries. Dr. Luciani's report lacks any opinions on whether the design of Paragard is defective, as Dr. Luciani testified that "that's beyond the scope of my expertise." Defendant's Exhibit 34, T149:22-150:1.

36. Lastly, Defendants Teva argue that Plaintiff is unable to recover punitive damages under N.J. Stat. Ann. § 2A:58C-5(c), as Paragard is a drug subject to FDA premarket approval.

37. "Punitive damages shall not be awarded if a drug or device or food or food additive which caused the claimant's harm was subject to premarket approval or licensure by the federal Food and Drug Administration under the 'Federal Food, Drug, and Cosmetic Act,' 52 Stat.1040, 21 U.S.C. s.301 et seq. or the 'Public Health Service Act,' 58 Stat. 682, 42 U.S.C. s.201 et seq. and was approved or licensed; or is generally recognized as safe and effective pursuant to conditions established by the federal Food and Drug Administration and applicable regulations, including packaging and labeling regulations. However, where the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's regulations, which information was material and relevant to the harm in question, punitive damages may be awarded. For purposes of this subsection, the terms 'drug,' 'device,' 'food,' and 'food additive' have the meanings defined in the 'Federal Food, Drug, and Cosmetic Act.'"

N.J. Stat. Ann. § 2A:58C-5(c).

38. Conversely, Plaintiff argues that federal law permitted Defendants to strengthen Paragard's warnings, as CBE regulation permits manufacturers to strengthen warnings without prior FDA approval under qualifying circumstances. Plaintiff continues that the MDL court held that evidence developed from Paragard's historical adverse-event data constituted "newly acquired information" permitting a labeling change through the CBE regulation and defendants failed to establish "clear evidence" that FDA would have rejected an appropriate warning. The MDL plaintiffs alleged that the Paragard label should have: (1) warned that the device could break during routine, nonsurgical removal even without embedment; (2) indicated the frequency of breakages, (3) warn that if Paragard broke it could cause serious injury, require surgical intervention, or result in loss of reproductive health or fertility, (4) warn of breakage or these injuries in the "Warnings," "Precaution," or "Adverse Reactions" section of the label, and (5) warn of Paragard breakage in the Patient Package Insert. Plaintiff's Exhibit A, pg 5. Plaintiff contends that the evidence identified by the MDL court remains highly relevant, as Dr. Liu, analyzed Paragard's historical safety database and concluded that device breakage was not already adequately discussed and included under Warnings, Precautions and Adverse Reactions. Plaintiff does not believe that the difference between Plaintiff's April 2008 implantation and the later implantation dates of the MDL Bellwether plaintiffs does not reflect a material difference in the breakage warning they received, as the MDL court found "[f]rom

2005 until a label change effected in 2019, the breakage information in the Paragard label stayed substantially the same."

Id. at pg. 5.

39. Plaintiff continues that Dr. Liu analyzed Paragard's historical safety database from product launch through January 2015, thus Plaintiff claims that the MDL Order establishes that the historical database ultimately revealed a materially different and more frequent breakage risk dating back to the prior NDA holder and that the delayed recognition of that risk resulted, at least in part, from the manner in which breakage events had been coded and analyzed. The MDL Court held:

> "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"

Id., pg 10.

40. "[T]he 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."

Id., pg 12.

41. Plaintiff asserts that Defendants Teva have failed to provide this Court with "clear evidence" that the FDA would have rejected an adequate removal-related breakage warning. The MDL Court held "[t]here is not clear evidence that the drug manufacturer fully informed the FDA of the justifications for Dr. Liu's labeling recommendations. … the Court cannot say that Defendants fully informed the FDA of the justifications for the warnings supported by Dr. Liu's new study." Id., pg 13. Plaintiff alleges that according to Defendants Teva the investigation reviewed information including adverse-event reports and manufacturer responses containing data extending back to 2011. Plaintiff contends that even if Plaintiff must establish qualifying newly acquired information by April 2008, Defendants separately bear the

burden at the second stage of the preemption analysis to establish that FDA would have rejected the corresponding warning. Furthermore, Plaintiff believes that the fact that the FDA did not affirmatively require Defendants to adopt Plaintiff's proposed warning years later does not establish as a matter of law that FDA, if timely and fully informed, would have rejected an appropriate manufacturer-initiated CBE warning concerning removal related fracture in the relevant period.

42. Plaintiff argues that the general statement that "Paragard can break" does not establish that the label adequately warned of the risk that caused injury to Plaintiff, as Plaintiff's claim concerns the risk that Paragard can fracture during routine removal, including without preexisting embedment, leaving a retained fragment. Plaintiff claims that the MDL court recognized precisely the warning deficiencies relevant here, including failure to warn that Paragard could break during routine nonsurgical removal without embedment and failure to adequately disclose the frequency and potential consequences of such breakage.

43. Plaintiff asserts that Defendants have not established absence of causation under the learned-intermediary doctrine, as the relevant inquiry is whether NP Banks independently possessed the specific information allegedly omitted from Paragard's labeling concerning the nature and magnitude of the removal-related fracture risk, including the risk that Paragard could fracture during routine removal even without preexisting embedment, the frequency of such fractures, and the potential for retained fragments necessitating additional invasive procedures.

44. "Where a failure-to-warn case involves something advised by a physician, such as a prescription drug or a medical device, the issue is whether the warning should have been given to the prescribing physician." Hrymoc v. Ethicon, Inc., 467 N.J. Super. 42, 85 (App. Div. 2021) (citations omitted). "A plaintiff must prove that the lack of a warning was a proximate cause of the harm." Id. at 85-85 (citations omitted).

"However, our case law also instructs that in order for dismissal of the lawsuit to be warranted on this basis, the evidence must be clear and unequivocal." Id. at 89.

45. Plaintiff claims that Defendants Teva have not produced evidence that a stronger warning would not have altered the prescribing decision. Plaintiff continues at minimum, a materially stronger warning may affect the information the provider communicates to the patient so that the patient can make an informed decision concerning whether to accept the product's risks.

46. Plaintiff argues that Defendants Teva's preemption argument also fails as to Plaintiff's design-defect claim, as the MDL Court denied Teva's Motion for summary judgment "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." Plaintiff's Exhibit A, pg. 19. Plaintiff believes that this refutes Defendants Teva's assertion that any design-defect theory would have required Defendants Teva to violate federal law. The plaintiffs in the MDL case claimed that "Defendants could have and should have stayed with Dupont 2005 for the Paragard material rather than switching to Dupont 20 in or around 2007", which was prior to Plaintiff's Paragard placement in 2008. Id. at pg. 15.

47. Plaintiff asserts that Defendants Teva's attack on the sufficiency of Plaintiff's design-defect proof does not warrant summary judgment without consideration of the MDL's general causation evidence, as the Court must evaluate Plaintiff's general expert evidence as a whole rather than treating Dr. Luciani's appropriate limitation of his case-specific opinions as an abandonment of the design-defect claim. As discussed above, the MDL court considered alternative designs, and Plaintiff's general expert opinions encompass those design issues.

48. In their Reply, Defendants Teva argue that Plaintiff has not presented the Court with any competent evidence to support any of the factual assertions in her summary-judgment opposition, as Plaintiff relies on a January 2026 Order from the Paragard MDL addressing Teva's preemption-based summary judgment

motion in the MDL Bellwether cases. Defendants Teva claim that the MDL Court's preemption ruling was based on its analysis of the developed evidentiary record in the three cases before it.

49. Defendants Teva claim that the 2015 Dr. Liu submission did not reveal that Teva "inadequately disclosed removal-related breakage risk", but it confirmed that device breakage met the company's criteria for inclusion in an entirely new adverse reactions section of the labeling because reports demonstrated a possible causal association between Paragard and device breakage. Here, the Court notes the MDL plaintiff 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." Plaintiff's Exhibit A, pg 5. Furthermore, the MDL noted that "[m]anufacturers were to submit a label in the revised PLR format no later than June 30, 2010." Id. at pg 11. Defendants Teva continue that the MDL Court later certified this issue for appeal to the Eleventh Circuit, concluding that "the issue here creates substantial grounds for difference of opinion." Defendants' Exhibit 21. Defendants Teva argue that Plaintiff concedes that "[t]he MDL order does not resolve that question [whether the historical safety information had developed sufficiently by April 2008 to support a CBE warning change], but it establishes that the historical database ultimately revealed an inadequately appreciated removal-related breakage risk dating back to the prior NDA holder and that miscoding and delayed analysis contributed to FDA's incomplete understanding of that risk." Plaintiff's Opp., pg. 16. Defendants Teva argue that Plaintiff points to nothing in the Liu submission that was available to Teva prior to her Paragard placement that showed any new risk or breakage with any greater frequency or severity.

50. Defendants Teva assert that the two design changes that made it past preemption in the MDL case are inapplicable, as Plaintiff cites no evidence showing that her Paragard was made with DuPont 20 rather than DuPont 2005. Defendants Teva continue that Plaintiff fails to cite any expert testimony suggesting that a lower concentration of barium sulfate would have prevented Plaintiff's Paragard from breaking.

51. Summary Judgment is warranted if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show there is no genuine issue as to any material fact challenged. Here, the record does not demonstrate a genuine issue of material fact as to whether Plaintiff's claims are preempted.

52. "Newly acquired information is data, 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.

53. "Post-FDA approval preemption analysis proceeds in two stages. First, the plaintiff must show that there existed 'newly acquired information' such that the defendants could unilaterally change the label pursuant to the CBE regulation without FDA approval. But, the mere availability of a CBE label amendment does not necessarily defeat a manufacturer's preemption defense. Because the FDA 'retains the authority to reject labeling changes,' a manufacturer may still -- even after the plaintiff has identified 'newly acquired information' establish an impossibility preemption defense through 'clear evidence that the FDA would not have approved a change' to the label."

Utts v. Bristol-Myers Squibb Co., 251 F. Supp. 3d 644, 661 (S.D.N.Y. 2017) (citations omitted).

54. While Plaintiff believes that the MDL Order demonstrates that Defendants cannot establish preemption merely by pointing to the general breakage language contained in the 2008 label or by asserting that FDA necessarily possessed all information relevant to the removal-related fracture risk, here the Court notes that the MDL Court held that the MDL plaintiffs' claims were not preempted 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; 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."

Plaintiff's Exhibit A.

55. Here, the Court finds that the MDL Court held that the MDL plaintiff's claims were not preempted as the FDA published a rule requiring manufacturers "were to submit a label in the revised PLR format no later than June 30, 2010", and that Defendants failed to order this study by 2010. Plaintiff's Exhibit A.

Furthermore, the plaintiffs in the MDL case received their IUDs in 2011, 2012, and 2014, which was before manufacturers were required to submit a label in the revised PLR format. Furthermore, the Court notes that the MDL Court's preemption ruling was based on its analysis of the developed evidentiary record in the three cases before it.

56. In this case, Plaintiff received her MDL in 2008, and Plaintiff has failed to provide this Court with any evidence to substantiate her claim in this case that she has viable claims that are not preempted by federal law. Specifically, Plaintiff has failed to provide this Court with any newly acquired information available to Defendants before Plaintiff's Paragard was installed in 2008. Furthermore, the Court notes that the Court does not know what Dr. Kessler would opine about newly acquired information available to Defendants in 2008, as Dr. Kessler did not focus on that issue in the report that was before the MDL report. Moreover, Plaintiff failed to inform this Court of any evidence establishing that the findings in Dr. Lui's 2015 should have been discovered by Defendants prior to Plaintiff's installation of her IUD in 2008. As such, the Court finds that Plaintiff's failure-to-warn claims are preempted, against Defendants Teva.

57. Furthermore, the Court notes that Plaintiff's design-defect theories are preempted by federal law, as Plaintiff cites no expert opinions supporting those theories, but rather relies upon the theories asserted by the plaintiffs in the MDL case. In the MDL case the Court held that the MDL's "plaintiff's 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" were not preempted. Furthermore, the MDL holding was based on Florida Law, which is a state that does not have a safer alternative design requirement. In this case, the Court notes that Plaintiff cites no evidence showing that her Paragard was made with DuPont 20 rather than DuPont 2005, and Plaintiff cites no expert testimony suggesting that a lower concentration of barium sulfate would have prevented Plaintiff's Paragard from breaking. Furthermore, Plaintiff has failed to provide this court with any evidence satisfying the safer alternative design requirement. As such, the Court finds that Plaintiff's information defect and design defect claims are preempted under federal law.

58. Furthermore, the Court finds that even if Plaintiff's claims were not preempted, Plaintiff's failure-to-warn claim independently fails under New Jersey law. Plaintiff believes that the language "Paragard can break" are inadequate because the label did not specifically describe fracture "during routine removal . . . without preexisting embedment" or disclose its frequency, but the Court notes that Dr. Luciani, testified that the Paragard was embedded at the time of removal. Luciani Dep. at 104:16-23. Furthermore, Plaintiff has not identified information revealing "risks of a different type or greater severity or frequency than previously included in submissions to FDA." 21 C.F.R. § 314.3(b). Lastly, the Court notes that in Plaintiff's Opposition to Defendant's Motion to Bar, Plaintiff informed this Court that Plaintiff informed this Court that "Plaintiff does not oppose Defendants' request to preclude Richard Luciani, M.D. from offering opinions at trial concerning the adequacy of the Paragard labeling or warning. Dr. Luciani was retained as a case-specific medical expert, not as a regulatory or labeling expert, and Plaintiff does not intend to offer him for the purpose of establishing that the Paragard label was inadequate." Pl's Opp. Pg 1. As such, the Court notes that Plaintiff has no expert in this case to touch on the adequacy of the Paragard label.

59. For these reasons, Defendant Teva Pharmaceuticals USA, Inc.'s, Defendant Teva Women's Health, Inc.'s, Defendant Teva Women's Health, LLC's, Defendant The Cooper Companies, Inc.'s, and Defendant CooperSurgical, Inc.'s Motion to Dismiss is **granted in part as the Court did not dismiss the Complaint based upon the failure to present Dr. Kessler and Dr. Mays for deposition, but ordered that their testimony was barred at trial and did not allow for Counsel Fees.**

60. For these reasons, Defendant Teva Pharmaceuticals USA, Inc.'s, Defendant Teva Women's Health, Inc.'s, and Defendant Teva Women's Health, LLC's Motion for Summary Judgment is **granted.**

/s/ Annette Scoca

8/31/2026 **HON. ANNETTE SCOCA, J.S.C.**