ALISON BEAVAN, Plaintiff-Respondent, v. ALLERGAN USA, INC., et al., Defendant-Appellant.	SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO: A-001501-23 Civil Action ON APPEAL FROM SUPERIOR COURT OF NEW JERSEY, LAW DIVISION: MORRIS COUNTY DOCKET NO. MRS-L-151-21 Sat Below: Hon. Louis S. Sceusi, J.S.C.

OPENING BRIEF OF DEFENDANT-APPELLANT ALLERGAN USA, INC.

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PRELIMINARY STATEMENT

This Court should reverse the decision below because it is founded on the erroneous notion that if there has been a product recall—no matter the import, extent, or nature of the recall—a product-liability defendant can never secure summary judgment and the case automatically goes to trial. This violates bedrock principles under the New Jersey Product Liability Act ("PLA") and is exactly the type of dangerous precedent and injustice this Court should immediately correct.

Plaintiff-Appellee Alison Beavan admits she has no direct proof the prescription drug she received was defective. She nonetheless claims it had a manufacturing defect that caused her injuries based solely on the fact the drug was part of a recalled lot. She alleges Defendant-Appellant Allergan USA, Inc. should have recalled the drug sooner. The problem for Plaintiff, however, is that (i) a 'failure-to-timely-recall' claim is both unrecognized by the PLA and preempted by federal law, (ii) her manufacturing-defect claim lacks the required expert (or any other) proof that the specific product at issue had a defect, and (iii) she has no admissible general-causation evidence that the alleged defect was even capable of causing her injuries, and her experts' specific-causation opinions are nothing but speculative, inadmissible "net opinions."

The Parties' briefing on whether the Court should accept this interlocutory appeal reveals that even Plaintiff agrees her 'failure-to-timely-recall' claim is not

actionable. The briefing also demonstrates that Plaintiff cannot overcome a more fundamental deficiency with her case: New Jersey law requires proving defect and causation for complex prescription drugs and medical devices through experts, and ***Plaintiff has no expert opinions on manufacturing defect or general causation***. While her experts offer specific-causation opinions, they are inadmissible "net opinions" that are not based on a reliable methodology or sufficient facts and data.

Under the Trial Court's decision, these fundamental failings can be ignored and summary judgment denied whenever injury is alleged in temporal association with exposure to a product from a recalled lot. But recalls do not abrogate federal or New Jersey law. Recalls do not eliminate a court's gatekeeping duty to exclude unqualified experts who fail to apply reliable methodologies. And recalls cannot be used as a substitute for required evidentiary proof of product defect and causation. This is especially true here, where the undisputed evidence establishes that ***only 2.2%*** of medications from the lot used in Plaintiff's procedure manifested the purported manufacturing defect, and Plaintiff has ***no*** admissible evidence that the specific drug she received was one of those 2.2%.

By denying summary judgment based solely on the existence of a recall, the Trial Court invites plaintiffs from across the country to flock to New Jersey any time a drug is recalled because 'recall-plus-injury' is enough to reach a jury in this State. The ruling eliminates a plaintiff's burden to prove defect and causation in

cases involving a complex product, like a prescription drug, with reliable expert opinions that satisfy NJRE 702 and 703. Allowing a recall to serve as a substitute for this required proof contravenes the purpose and letter of the PLA and presents the precise grave injustice that warrants immediate appellate reversal. The issues on appeal are case dispositive, and, thus, reversing now will avert waste of precious resources on an unnecessary multi-week trial on the Trial Court's already overburdened docket.

STATEMENT OF FACTS AND PROCEDURAL HISTORY

A. Ozurdex® Is an FDA-Approved Eye Injection for Serious Eye Disease.

This products-liability action concerns Ozurdex®, a prescription drug manufactured by Allergan[1] that FDA approved in 2009 to treat certain serious and debilitating eye conditions, including non-infectious uveitis,[2] one of Plaintiff's serious eye diseases. (Da105; Da0224) Ozurdex® is a dexamethasone implant

[1] Other named Defendants were dismissed or never properly served.

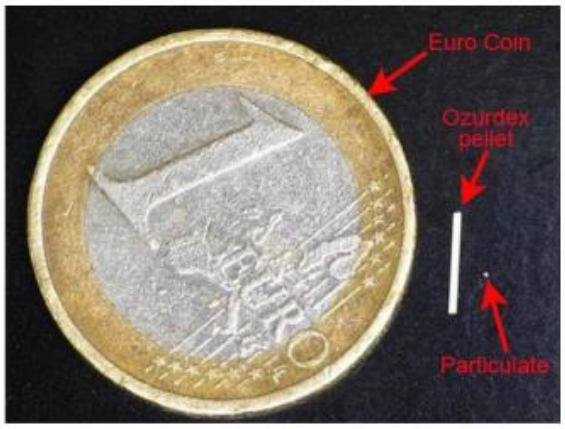
[2] Non-infectious uveitis is inflammation of the eye, which is difficult to treat, can result in macular edema, and is a leading cause of irreversible blindness in the working-age population in the developed world. (Da0047, p. 57); *Uveitis*, National Eye Institute, National Institutes of Health, https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/uveitis; *Macular Edema*, National Eye Institute, National Institutes of Health, https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/macular-edema; *New Pharmacological Strategies for the Treatment of Non-Infectious Uveitis. A Minireview*, Rodrigo A. Valenzuela, Frontiers in Pharmacology (May 7, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7250389/#:~:text=Non%2Dinfectious%20uveitis%20(NIU),population%20in%20the%20developed%20world.

("pellet") preloaded in a single-use applicator and injected by physicians in a surgical procedure into the vitreous of the eye. (Da0105) The applicator's 22-gauge needle is surrounded by silicone to keep the pellet in place and prevent excess needle penetration. (Da0229)

Everyone who testified in this case agrees Ozurdex® is a safe and effective medication. Plaintiff's treating ophthalmologist, William Phillips, M.D., thought so highly of Ozurdex® that he administered it to Plaintiff over ten times. (Da0087) Plaintiff's retained expert, practicing ophthalmologist Maziar Lalezary, M.D., agrees Ozurdex® "works well," having used it "routinely" for over a dozen years. (Da0150, pp. 15-18)

B. Allergan Recalled Certain Ozurdex® Lots, But Not for a Safety Issue.

Following a routine inspection in June 2018, Allergan discovered some Ozurdex® units had a potential for a single 300-micron silicone particulate to sheer off the injector needle sleeve when actuated. (Da0240) The 300-micron silicone particulate is 19 times smaller than the Ozurdex® pellet:



Allergan timely reported this discovery to regulators in countries where affected lots were distributed, including reporting it to FDA in an Initial Field Alert in July 2018. (*Id.*) Allergan kept FDA fully informed of its investigation:

- regularly and timely communicating with FDA personnel, including providing updates on new information revealed by its investigation, submitting multiple Updated Field Alerts, performing and submitting a Benefit-Risk Assessment, and advising of foreign regulatory actions;[3]
- responding on multiple occasions to FDA requests for additional information, including notifying FDA of retained sample testing results and the percentage of affected units within those lots;[4] and
- informing FDA of Allergan's desire to issue a Dear Health Care Provider ("DHCP") letter to U.S. physicians, submitting a draft DHCP letter to FDA for review, and contacting FDA multiple times for feedback on the draft letter and the action FDA believed necessary under the circumstances.

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[3] The different rules, processes, and timelines of foreign regulatory authorities dictated the timing of recalls in their jurisdictions, as the FDA does in the U.S. For example, the Swiss regulatory authority recommended Allergan initiate a recall of certain Ozurdex® lots in September 2018. Allergan initiated recalls in other foreign markets pursuant to their regulatory authority's respective timelines. (Da0258, ¶ 70)

[4] Testing of the lot containing the Ozurdex® unit used in Plaintiff's procedure showed particulate generation in ***only 2.2%*** of units. (Da0229)

(Da0229; Da0258, ¶¶ 49-50, 56, 64-65, 70-71, 74)

By the time Plaintiff received the Ozurdex® injection at issue in this case, Allergan had made ***over 20 attempts*** to obtain authorization from FDA to communicate with U.S. healthcare providers about the silicone particulate issue. (Da0258, ¶ 65) Allergan's regulatory expert, Janet Arrowsmith, M.D., explained why it was necessary for Allergan to wait for FDA's review and clearance: under FDA regulations/guidance, Allergan risked adverse regulatory action for a recall communication (including DHCP letters) inconsistent with FDA's views on recall strategy. (*Id.*, ¶¶ 66, 71-75)

As Dr. Arrowsmith expounded, sending a communication about a recall issue, like the DHCP letter here, is a recall action and thus governed by FDA and its rules and procedures. (Da0452, p. 101) Tracy (Kough) Founds, who was Allergan's Associate Vice President of Post Marketing Quality and Recall Coordinator responsible for U.S. recalls, similarly testified that sending a DHCP letter about the recall issue constitutes a recall action under federal law, and thus first requires authorization by FDA. (Da0577, p. 14; Da0725, p. 46) Plaintiff offered no regulatory expert or other evidence disputing Dr. Arrowsmith's opinion and Ms. Found's testimony.[5]

[5] Plaintiff's retained expert, Dr. Lalezary, admits he is not an expert in the laws and regulations governing communications about drug recalls, and offered no opinion

Although FDA ultimately determined the potential for generation of a silicone particulate was a "product quality" issue, not a "safety concern,"[6] Allergan—in collaboration with FDA—announced on December 20, 2018 a recall of 22 Ozurdex® lots distributed in the U.S. with the ***possibility*** of ***certain*** units generating a silicone particulate. (Da0250; Da0255) In addition, on December 18, 2018, FDA finally responded to Allergan regarding its proposed communication to customers about the recall issue, providing edits/comments to Allergan's draft and directing Allergan to "update accordingly and please issue." (Da0452, pp. 130-31; Da0479)

Allergan complied with FDA's directive and sent an Urgent Drug Recall letter (as edited by FDA) on December 28, 2018 to all customers who received the 22 Ozurdex® lots at issue to inform them of the recall. (Da0255; Da0258, ¶¶ 51-52) The Urgent Drug Recall letter identified the 22 lots recalled, stated the reason for the recall (the possibility of a 300-micron silicone particulate dispensed with certain units), and provided a health hazard assessment that stated "[m]ild transient visual disturbance or intraocular inflammatory reaction in sensitive patients are potential safety risks." (Da0255)

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about when Allergan should have sent notice to U.S. healthcare providers about the potential for generation of a silicone particulate. (Da0150, pp. 52-55, 117)

[6] There were no reports of injury leading to the Ozurdex® recall.

C. Plaintiff's Chronic History of Serious Eye Disease Is an Independent Risk Factor for Blindness.

Plaintiff began treating with Dr. Phillips in 2015 for a long list of eye problems going back years, including inadequately-controlled cystoid macular edema[7] and non-infectious uveitis, all of which independently could lead to blindness. (Da0045; Da0047, pp. 13, 60) In addition to multiple Ozurdex® injections, Plaintiff had numerous eye surgeries and procedures, including:

- an intraocular lens implant;
- trabeculectomy (removing fluid to lower eye pressure);
- two vitrectomies (to remove vitreous fluid in the back of her eye); and
- implantation of a silicone-coated Retisert® tablet (that is 10 times the size of the 300-micron particulate).

(Da0346, ¶¶ 26, 81 n.3, 91) Plaintiff also continued to smoke, despite consistent warnings over many years from her ophthalmologists that it worsened her chronic eye inflammation. (*Id.*, ¶ 91)

D. Plaintiff Was Warned of the Exact Injuries She Alleges in the Lawsuit, and Consented to Receiving an Ozurdex® Injection.

Plaintiff and her doctor were well aware of the risks of intravitreal injections with Ozurdex®, including the potential for inflammation, retinal detachment, pellet migration, and vision loss—the exact injuries she alleges she incurred. (Da0105;

Da0121) But they decided the benefits outweighed those risks, and on November 6, 2018, Dr. Phillips administered Ozurdex® to Plaintiff's left eye for the ninth time. (Da0087) As before, Plaintiff knew the risks and gave her informed written consent. (Da0089, pp. 73-76; Da0121) Plaintiff alleges she experienced these well-known risks after the November 6 injection. (Da0150, p. 64; Da0204, Nos. 17, 20) Even though these exact injuries can occur after a ***non-defective*** Ozurdex® injection, Plaintiff asserts the injuries were caused by a supposed defect in her Ozurdex® unit. (Da0001)

E. Plaintiff Has No Admissible Proof of Defect and Causation.

Plaintiff does not allege the Ozurdex® pellet itself was defective, but instead alleges that a defect occurred in manufacturing the applicator, which resulted in generation of a silicone particulate. Allergan's testing of retained units from the Ozurdex® lot at issue in this case (lot E82852) showed a silicone particulate generation rate of ***only 2.2%***—*i.e.*, ***97.8% of units in that lot had no risk of generating a silicone particulate***. (Da0237) Plaintiff admits she has no direct evidence the applicator used in her November 6 Ozurdex® injection was one of those very few that generated a silicone particulate. In an attempt to prove her

[7] Cystoid macular edema is when the macula, responsible for central vision, swells and fluid-filled blisters block vision, potentially causing irreversible damage and permanent vision loss. (Da0346, ¶ 91)

Ozurdex® unit nonetheless caused her eye inflammation, retinal detachment, and vision loss, Plaintiff disclosed Drs. Phillips and Lalezary as experts. (Da0329)

1. Plaintiff's Treating Physician Dr. Phillips Speculates a Silicone Particle (He Never Saw) Caused Plaintiff's Eye Inflammation Based Solely on the Recall.

Plaintiff did not disclose her prescriber Dr. Phillips as an expert on product defect, but only on "causation." (Da0329) He testified that he believed the Ozurdex® injected on November 6 caused Plaintiff's eye inflammation. (Da0047, pp. 30-31, 58-60) However, ***he does not believe it caused her retinal detachment***: "[W]e know the detachment can occur spontaneously. It can occur just with the injection. ***I don't think that the silicone particulate would be a cause of the detachment certainly***." (*Id.*, pp. 58-59 (emphasis added))

Dr. Phillips did not offer an independent general-causation opinion that a 300-micron, medical-grade silicone particulate is capable of causing eye inflammation. He is a practicing ophthalmologist with no expertise in biomaterials science or the silicone used in the Ozurdex® needle sleeve, and he admits he is not "aware of any study showing that the silicone particulate causes any injury to patients." (*Id.*, p. 39) He testified he uses "silicone oil in the eye to repair retinal detachments" and agreed it "is inert," depending on its purity. (*Id.*, pp. 54-55) That conclusion is supported by Allergan's expert, Dean Eliott, M.D., a board-certified ophthalmologist and professor at Harvard Medical School, as well as a toxicity

study in which silicone particles greater in size and load than the particulate in the recall were injected into living rabbits' eyes and found to be inert and biocompatible, causing no inflammation. (Da0304; Da0439, p. 38)

When Dr. Phillips was asked why he ignored his experience and the science to assume this silicone could cause inflammation, he answered: "one of the recall notices." (Da0047, p. 54) However, the Urgent Drug Recall letter said only that inflammation was a "potential" risk "in sensitive patients" (Da0255), and Dr. Phillips never opines that Plaintiff qualifies as such a "sensitive patient." Instead, the undisputed evidence reveals this reference was to patients ***sensitive to silicone*** (Da0452, p. 39), and Dr. Phillips does not and cannot opine that Plaintiff is sensitive to silicone.

Dr. Phillips admits no one saw a silicone particulate in Plaintiff's eye and "***there's no way [he] could possibly know whether there was a silicone particulate in [her] eye***." (*Id.*, pp. 50-52 (emphasis added)) He just ***assumed*** it was there solely because the Ozurdex® at issue came from "a recalled lot" and his mistaken belief that 22-25% of units in each recalled lot had the particulate issue. (*Id.*, pp. 47, 50-51) At bottom, Dr. Phillips admits "the only thing" supporting his opinion is the drug Plaintiff received was part of a "recalled lot." (*Id.*, p. 50)

2. Plaintiff's Retained Expert Dr. Lalezary Concedes Her Injury Could Have Occurred Absent the Particulate, and He Is Uncertain a Particulate Ever Existed In Her Eye.

Dr. Lalezary is not an expert in and is not "offering any opinions in this case on the design, the manufacturing, the testing, the development, or the labeling of a prescription drug or medical device"—*i.e.*, he offers no opinion on the issue of product defect. (Da0150, pp. 48-49, 52) He admits there is "no objective evidence" the Ozurdex® at issue generated a silicone particulate, and he "***can't say for certain that [Plaintiff] had the particulate in her eye***." (*Id.*, pp. 15, 100, 106-07, 102, 113 (emphasis added)) Nor could he offer such opinions, as he never examined or tested the subject Ozurdex® applicator or examined, met, or even spoke with Plaintiff. (*Id.*, pp. 15, 19, 106-07) Like Dr. Phillips, Dr. Lalezary's sole basis for saying the Ozurdex® unit at issue generated a silicone particulate: "It was part of the lot that was recalled." (*Id.*, p. 102)

Assuming the Ozurdex® at issue produced a silicone particulate and ***assuming*** that particulate was injected into Plaintiff's eye, Dr. Lalezary offers the opinion that it induced eye inflammation and mechanical traction, which caused a retinal detachment and loss of vision. (*Id.*, pp. 15, 64) Dr. Lalezary provides this specific-causation opinion, however, without an independent general-causation opinion that a 300-micron, medical-grade silicone particulate ***is capable of causing*** inflammation or a tractional retinal detachment. Like Dr. Phillips, he simply

assumes general causation. He further concedes a "retinal detachment is a possible risk following any intraocular procedure" and "any intravitreal injection." (*Id.*, pp. 78, 104, 109-10) But since Plaintiff had not developed problems before, Dr. Lalezary concluded the "temporal relationship" to her injuries indicates a silicone particulate "more likely" than not caused them. (*Id.*, pp. 82-83, 100, 102-04, 109)

3. Plaintiff's Experts Failed to Rule Out the Many Alternative Causes for Her Alleged Injuries.

Everyone—including Plaintiff's experts—agrees her inflammation, retinal detachment, and resulting vision loss could have been caused by many factors ***other than*** a silicone particulate (that no one ever saw in her eye), including her chronic eye inflammation, numerous eye surgeries, procedures, and injections, and the Retisert® implant. (Da0047, pp. 40-41, 58-59; Da0150, pp. 78-80, 112-13; Da0346, ¶¶ 83, 91) The silicone-coated Retisert® is 10 times larger than a 300-micron silicone particulate, and doctors discovered that the Retisert® had dislodged from her retina at the precise location and around the time of her retinal detachment. (Da0150, p. 130; Da0346, ¶ 81 n.3)

Dr. Lalezary testified "we already established that she has multiple risk factors" and admitted "***all of those risk factors…could have led to a retinal detachment…[i]n the absence of a silicone particulate***." (Da0150, pp. 112-13 (emphasis added)) Allergan's expert, Dr. Eliott, agrees, opining that Plaintiff's multiple serious eye conditions, surgeries, and procedures, exacerbated by her long

history of smoking, are the obvious and likely causes of her vision loss. (Da0346, ¶ 94)

Without (i) citing any authoritative literature or studies or performing any analysis or tests demonstrating a silicone particulate ***can cause*** the injuries alleged or (ii) doing any medical or scientific analysis to ***rule out*** the myriad other well-known and obvious alternate causes for Plaintiff's injuries, her experts offer the admittedly-uncertain opinions that a manufacturing defect in the subject Ozurdex® unit caused Plaintiff's injuries ***based exclusively on the recall***. (Da0047, pp. 30-31, 39, 58-60; Da0150, pp. 15, 64, 106-07)

F. Procedural History

Allergan moved for summary judgment on Plaintiff's claim that the specific Ozurdex® unit used in November 6, 2018 procedure had a manufacturing defect that caused her injuries and her claim that Allergan should have recalled the drug sooner. (Da0035)

'Failure-to-timely-recall' claim: Allergan argued this claim is not recognized by the PLA and preempted by federal law. (*Id.*) Plaintiff did not oppose or respond to these arguments, which Allergan asserted was a waiver. In its Order denying Allergan's motion for summary judgment, the Trial Court ignored and never ruled on Allergan's arguments directed at the 'failure-to-timely-recall' claim. (Da0785).

Manufacturing defect: Allergan requested summary judgment because establishing 'defect' in a case involving a complex product like a prescription drug requires expert proof, and Plaintiff offered ***no expert on manufacturing defect***. (Da0035) The Trial Court found Plaintiff presented "sufficient evidence" of defect, but the cited evidence did not come from either of Plaintiff's experts, but instead from Allergan's so-called "expert,"[8] who testified only that ***if*** an Ozurdex® unit generated a silicone particulate, this would be a deviation from Allergan's performance standards. (Da0785, p. 9) The Order did not cite any evidence that the Ozurdex® unit at issue actually generated such a particulate.

Causation: Allergan moved to exclude Plaintiff's experts' unreliable opinions and for summary judgment on Plaintiff's inability to prove general or specific causation. (Da0035; Da0799) The Trial Court refused to exclude Plaintiff's experts, finding they "have a sufficient basis" to opine the particulate "*could have* caused a retinal detachment" and could cause inflammation because "Defendant's own recall contained those very same warnings of intraocular inflammatory reaction" and Plaintiff's other Ozurdex® injections never resulted in injury. (Da0816, pp. 9, 11-12 (emphasis in original)) The Trial Court found the

[8] That testimony was not from an Allergan "expert," but from a corporate representative (Tracy Founds) designated to testify for the company on topics ***other than*** manufacturing standards, which was not her area of responsibility. Nor did Plaintiff make any attempt to qualify Ms. Founds as an "expert" in Ozurdex® manufacturing.

experts' opinions were sufficient to deny summary judgment on causation. (Da0816, p. 9)

Reconsideration: The Trial Court denied Allergan's motion for reconsideration, reaffirming its rulings on defect and admissibility of Plaintiff's experts' opinions on general and specific causation. (Da0830; Da0846, pp. 5, 7-8) It also ruled for the first time that Plaintiff could proceed on her 'failure-to-timely-recall' claim. (*Id.*, pp. 5-8) It misconstrued Allergan's argument that this claim is preempted by ***federal law*** as an argument the claim is "preempted by the PLA," and found no PLA preemption. (*Id.*, pp. 5-7) The Trial Court has never addressed Allergan's ***federal*** preemption argument.

This Court granted Allergan permission to immediately appeal these rulings.

LEGAL ARGUMENT

I. STANDARD OF REVIEW.

A. Summary Judgment.

"A ruling on summary judgment is reviewed de novo." *Davis v. Brickman Landscaping, Ltd.*, 219 N.J. 395, 405 (2014). The Court must determine whether "the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder 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); *accord* Rule 4:46-2(c).

B. Expert Admissibility.

A ruling on admission of expert testimony is reviewed for an abuse of discretion. *In re Accutane Litig.*, 234 N.J. 340, 348 (2018). To offer an admissible opinion on a scientific or specialized topic, an expert must be "qualified," N.J.R.E. 702, and the opinion must be based on sufficient facts or data, N.J.R.E. 703. The expert's proponent has the burden to satisfy three requirements: "(1) the intended testimony must concern a subject matter that is beyond the ken of the average juror; (2) the field testified to must be at a state of the art such that an expert's testimony could be sufficiently reliable; and (3) the witness must have sufficient expertise to offer the intended testimony." *In re Accutane*, 234 N.J. at 348.

When an expert provides a "mere conclusion" that lacks a foundation, a reliable methodology, and the "why and wherefore," it must be excluded as an inadmissible "net opinion." *Davis*, 219 N.J. at 410. The trial court must be "the gatekeeper" and "rigorous[ly]" assess the methodology and data to prevent the jury from hearing unsound science "through the compelling voice of an expert." *In re Accutane*, 234 N.J. at 389-90, 396-97. Not excluding unsupported and unreliable expert opinions is error clearly capable of producing an unjust result. *Lanzo v. Cyprus Amax Minerals Co.*, 467 N.J. Super. 476, 517-18 (App. Div. 2021).

II. THE TRIAL COURT COMMITTED A MISCARRIAGE OF JUSTICE BY PERMITTING A 'FAILURE-TO-TIMELY-RECALL' CLAIM THAT IS NOT RECOGNIZED BY NEW JERSEY LAW AND IS PREEMPTED BY FEDERAL LAW. [(DA0785; DA0816; DA0846); COURT DID NOT ADDRESS PREEMPTION ALTHOUGH IT WAS RAISED IN THE BRIEFING]

A. The PLA Does Not Recognize a 'Failure-to-Timely-Recall' Claim. [ISSUE WAS RAISED (Da0785; Da0816; Da0846)]

Plaintiff's Complaint alleges that Allergan "failed to recall the Subject Product in the United States even after they were certainly aware of the defect." (Da0001, ¶ 48)[9] Such a 'failure-to-timely-recall' claim is not cognizable under the PLA, which recognizes only defective design, manufacturing, or warning claims. N.J.S.A. § 2A:58C-2. A claim that a product should have been recalled sooner is not based on its design, manufacture, or warnings.

The Trial Court's erroneous refusal to grant summary judgment on this non-actionable claim constitutes an unprincipled expansion of the New Jersey PLA—never recognized by the Legislature—that this Court should immediately correct.[10]

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[9] The Complaint does not allege a typical failure-to-warn claim that Allergan did not warn Plaintiff of the injuries she sustained. Nor could Plaintiff allege Allergan's warnings were inadequate, as every injury she alleges is warned of in the Ozurdex® FDA-approved label, which is presumed adequate as a matter of New Jersey law. N.J.S.A. § 2A:58C-4; *In re Accutane*, 235 N.J. at 266. Plaintiff even signed informed consent documents establishing she was warned of those risks. (Da0089, pp. 73-76; Da0121).

[10] In her brief opposing Allergan's motion to permit this interlocutory appeal, Plaintiff did not oppose, and thus conceded, that she cannot proceed on the 'failure-to-timely-recall' claim she pled, pivoting to an ***all-new and different*** claim: that Allergan should have provided a post-sale warning to her doctor about

B. Federal Law Preempts A 'Failure-to-Timely-Recall' Claim. [(Da0785; Da0816; Da0846); COURT DID NOT ADDRESS PREEMPTION ALTHOUGH IT WAS RAISED IN THE BRIEFING]

Preemption is a matter of law for the Court to decide. *Merck, Sharple & Dohme v. Albrecht*, 139 S. Ct. 1668, 1680 (2019).[11] Here, however, both Plaintiff and the Trial Court ignored the dispositive legal issue that a state-law claim for 'failure-to-timely-recall' or 'failure-to-timely-warn-of-a-recall' is impliedly preempted by federal law.

"Where Congress expresses an intent to occupy an entire field, States are foreclosed from adopting any regulation in that area, regardless of whether that action is consistent with federal standards." *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680, 688 (3d Cir. 2016). As relevant here, "Congress vested FDA with the authority to monitor and supervise drug recalls." *Clark v. Actavis Grp. hf*, 567 F. Supp. 2d 711, 717 (D.N.J. 2008). Pursuant to this Congressionally-delegated

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the recall issue. But that claim was neither pled in the Complaint nor argued to the Trial Court. The Court should not allow Plaintiff to raise this new argument and unpled claim for the first time on appeal. Regardless, as explained *infra*, such a 'failure-to-timely-warn-of-a-recall' claim is preempted by federal law. (Da0725, p. 46; Da0258, ¶ 63)

[11] The categories of federal preemption include express preemption, which occurs "when a federal statute includes an express provision for preemption," and implied preemption, which occurs either "when Congress intends federal law to occupy the field in an area of law" or "when a state and federal statute are in conflict." *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)*, 751 F.3d 150, 158 (3d Cir. 2014).

authority under the federal Food, Drug, and Cosmetics Act, FDA has enacted detailed regulations for prescription drug recalls, 21 C.F.R. Part 7 Subpart C, § 7.40 *et seq.*, that are supplemented by FDA's Regulatory Procedures Manual ("RPM"), which provides:

> If a recall is firm-initiated under 21 CFR 7.46, the agency will review the information provided by the recalling firm under 21 CFR 7.46(a). This includes reviewing and suggesting changes to the firm's recall strategy, recall communication, and press release (if necessary)….
>
> The recalling firm should discuss any recall communications and notifications with the FDA Program Office Recall Coordinator before issuance.

RPM at § 7-5-1 & (5). Allergan's unrebutted regulatory expert, Dr. Arrowsmith, who has vast experience working at the FDA, described how these all-encompassing federal regulations and procedures work in practice to require the recalling firm to first communicate with FDA before deciding recall strategy and issuing recall communications. (Da0258, ¶¶ 57-59)

Courts in New Jersey recognize this broad federal law "set[s] forth specific recall procedures whereby the FDA assumes control over monitoring recalls" and, importantly here, "require the FDA to evaluate…the adequacy and extent of recall communications." *In re Hum. Tissue Prod. Liab. Litig.*, 488 F. Supp. 2d 430, 432-33 (D.N.J. 2007). "Congress clearly vested the FDA with the regulatory authority to assess and manage the communications regarding product recalls." *Id.* at 433; *see also Clark*, 567 F. Supp. 2d at 714 ("[T]he FDA 'reviews the adequacy of a

proposed recall strategy developed by a recalling firm and recommends changes as appropriate.'" (citing 21 C.F.R. § 7.42(a)(2))).[12]

FDA's comprehensive recall regulations occupy the entire field, foreclosing any State from using its law to regulate prescription-drug recalls, such as Plaintiff's state-law claim seeking to require an earlier recall or earlier warning to U.S. healthcare providers about the recall issue. Plaintiff's claim frustrates and interferes with the purposes and objectives of FDA's pervasive regulatory scheme governing prescription drug recalls on the U.S. market. *See R.F. v Abbott Labs*., 162 N.J. 596, 618-20 (2000). Here, Allergan worked with FDA for months, making over 20 attempts to obtain authorization to communicate with U.S. healthcare providers, including submitting a draft DHCP letter, prior to Plaintiff's November 6, 2018 Ozurdex® procedure.

If Allergan had recalled sooner or provided an earlier communication, Allergan would have run afoul of FDA's directive to "discuss any recall communications and notifications with the FDA Program Office Recall Coordinator ***before issuance***." RPM at § 7-5-1(5) (emphasis added) (Da0258, ¶¶ 66-75). Hence, Allergan could not, without FDA's authorization, engage in an ***earlier*** U.S. recall or ***earlier*** communication to U.S. healthcare providers.

[12] The federal scheme ensures uniformity when executing a recall. If each State had its own recall process, it would create confusion and inconsistent application,

(Da0258, ¶¶ 66-75) Plaintiff's attempt through this lawsuit to impose state-law duties to recall or communicate with U.S. healthcare providers ***before*** FDA's authorization is therefore impliedly preempted. *See PLIVA v. Mensing*, 564 U.S. 604, 623-24 (2011) ("[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes.").

Critically, Plaintiff never opposed Allergan's preemption argument before the Trial Court. "By not opposing the defense, [Plaintiff] conceded it." *Bell v. Klein*, 2017 WL 2952992, at *7 n.7 (N.J. Super. App. Div. July 11, 2017). And she cannot raise that opposition for the first time on appeal. *Zaman v. Felton*, 219 N.J. 199, 226-27 (2014); *Wein v. Morris*, 194 N.J. 364, 384 (2008). Plaintiff has thus conceded that summary judgment is required on her state-law recall claim based on federal preemption.

To avoid a miscarriage of justice, this Court should reverse the Trial Court's erroneous decision to allow a non-cognizable and federally-preempted 'failure-to-

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leaving prescribing physicians and drug/device manufacturers at a loss for how to proceed.

timely-recall' or 'failure-to-timely-warn-of-a-recall' claim, and remand for entry of summary judgment for Allergan.[13]

III. THE TRIAL COURT COMMITTED A MISCARRIAGE OF JUSTICE IN ALLOWING PLAINTIFF'S MANUFACTURING-DEFECT CLAIM WITHOUT ANY PROOF THAT THE SPECIFIC PRODUCT AT ISSUE HAD THE ALLEGED DEFECT. [ISSUE WAS RAISED (DA0785; DA0816; DA0846)]

"Courts must concern themselves with both weeding out frivolous claims and insuring that cases are sent to a jury where a reasonable man could find that a defect existed while the product was in the control of the manufacturer." *Scanlon v. General Motor Corp.*, 65 N.J. 582, 590 n.1 (1974). Contrary to this Supreme Court directive, the Trial Court is allowing Plaintiff to proceed to trial without evidence that the product had a defect or the purported defect caused her harm. New Jersey law requires expert proof on these essential elements, and Plaintiff's experts wholly fail to supply it. Using "recall" as a substitute for competent evidence of a manufacturing defect in Plaintiff's Ozurdex® unit cannot fill this evidentiary void.

[13] Even if this claim was cognizable under the PLA and not preempted by federal law, the claim is still ripe for summary judgment because, as explained below, there is zero proof the product at issue had a defect that was capable of causing Plaintiff's injuries. As a matter of law, Allergan had no duty to recall, recall sooner, or warn about a non-existent defect incapable of causing harm.

A. Plaintiff Has the Burden to Prove Defect and Causation Through Qualified and Reliable Expert Testimony. [ISSUE WAS RAISED (Da0785; Da0816; Da0846)]

To get past summary judgment on her PLA claim, Plaintiff must have evidence to prove (1) the product had a defect that (2) existed when it left the manufacturer's control and (3) caused the plaintiff's injuries. *Myrlak v. Port Auth.*, 157 N.J. 84, 97 (1999). Plaintiff alleges the Ozurdex® administered to her on November 6, 2018 had a manufacturing defect. Accordingly, under the PLA, she must prove that specific Ozurdex® unit deviated "from [its] design specifications, formulae, or performance standards." N.J.S.A. § 2A:58C-2a.

When a PLA claim concerns a complex product beyond jurors' common knowledge, like a prescription drug or medical device, expert testimony is required to establish product defect and causation. *Davis*, 219 N.J. at 407 (explaining that jurors impermissibly speculate without expert testimony where the subject matter is beyond their common knowledge); *Butler v. Acme Markets, Inc.*, 89 N.J. 279, 283 (1982) (stating expert testimony is necessary where the matter "is so esoteric that jurors of common judgment and experience cannot form a valid judgment").[14]

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[14] *See also Schweiger v. Standard Tile Supply, Co.*, 2019 WL 5783478, at *3 (N.J. Super. App. Ct. Nov. 6, 2019) (expert needed to prove complex product (ready-to-use plasma grout) was defective); *In re Phenylpropanolamine (PPA)*, 2003 WL 22417238, at *20 (N.J. Super. Ct. July 21, 2003) (expert required to show chemical ingestion caused harm); *McMillan v. Johnson & Johnson*, 2005 WL 20000203, at *3 (D.N.J. Aug. 19, 2005) (expert required for complex medical device); *In re Mirena IUD Prods. Liab. Litig.*, 202 F. Supp. 3d 304, 311 (S.D.N.Y. 2016)

B. The Trial Court Wrongly Denied Summary Judgment Despite Plaintiff's Complete Lack of Proof of a Manufacturing Defect. [ISSUE WAS RAISED (Da0785; Da0816; Da0846)]

1. Plaintiff Has No Expert Proof of Manufacturing Defect. [ISSUE WAS RAISED (Da0785; Da0816; Da0846)]

Plaintiff's experts—both practicing ophthalmologists—admittedly have no expertise in manufacturing a prescription drug like Ozurdex® and its complex delivery system, and thus ***were not designated to*** and ***do not offer*** any opinion that the subject Ozurdex® unit had a manufacturing defect. Because expert proof is required to prove a defect in a complex prescription drug like Ozurdex®, and Plaintiff has none, the Trial Court committed a miscarriage of justice by not entering summary judgment for Allergan. *Jakubowski v. Minnesota Min. & Mfg.*, 42 N.J. 177, 182 (1964) ("Plaintiff must establish by some proof that weighs heavier than mere surmise or conjecture that his injury resulted from an unreasonably dangerous condition of the [product] for which defendant is responsible."); *McMillan*, 2005 WL 20000203, at *3 (finding that, without expert testimony, the plaintiff had "insufficient proof of product defect to satisfy the *Scanlon* rule as restated in *Myrlak*"); *In re Mirena*, 202 F. Supp. 3d at 312 ("summary judgment is appropriate where required expert testimony is absent").

("[C]ases involving pharmaceuticals, toxins or medical devices involve complex questions of medical causation beyond the understanding of a lay person, and thus expert testimony is required."); *compare Hopkins v. Fox & Lazo Realtors*, 132 N.J. 426, 449-51 (1993) (expert not needed for step color in trip-and-fall case).

Despite Plaintiff lacking the mandatory expert testimony, the Trial Court denied summary judgment because it found that generation of a 300-micron silicone particulate "would deviate" from performance standards. (Da0816, p. 9) But that finding ***assumes*** the subject Ozurdex® unit actually generated a silicone particulate—an assumption for which Plaintiff has ***no admissible evidence***, ***expert or otherwise***.[15] After all, no one ever saw the phantom silicone particulate in Plaintiff's eye, and her experts admit they could not say with any certainty it was there. (Da0047, pp. 50-52; Da0150, pp. 100, 102, 113)

The evidence actually supports the contrary finding: no "reasonable man could find that a defect existed," *Scanlon*, 65 N.J. at 590 n.1, where the unrefuted evidence demonstrates ***only a 2.2% possibility*** that a product from the subject lot had the defect. *Brill*, 142 N.J. at 541 ("To send a case to trial, knowing that a rational jury can reach but one conclusion, is indeed 'worthless' and will 'serve no useful purpose.'"); *Jakubowski*, 42 N.J. at 182 (requiring "proof that weighs

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[15] Though not necessary to decide this appeal, the only witness qualified on the issue of Ozurdex® performance standards, Allergan's Executive Director, Global Regulatory Strategy, Rory Turk, testified that a 300-micron particulate ***would not*** deviate from performance standards. (Da0315, pp. 15-16, 63-64) The Trial Court inexplicably ignored Mr. Turk's on-point testimony and erroneously cited testimony from a ***different*** corporate representative designated to testify on a ***different*** topic (recall coordination and compliance with corresponding FDA regulations and procedures). This error by the Trial Court underscores the complexity of the defect analysis, the Trial Court's unawareness of its nuances, and the need for the legal requirement for expert testimony to explain these multifaceted concepts to lay jurors.

heavier than mere surmise or conjecture" that the plaintiff's injuries resulted from a defect in the product). In fact, a truly rational factfinder could conclude only the opposite.

2. Plaintiff Cannot Backfill Her Lack of Expert Proof on Manufacturing Defect with Circumstantial Evidence. [ISSUE WAS RAISED (Da0785; Da0816; Da0846)]

Without expert testimony, a plaintiff can use circumstantial evidence to establish a product defect only where (a) the case involves ordinary products jurors can understand and (b) the evidence conclusively negates causes of the injury ***other than*** a defect. *Myrlak*, 157 N.J. at 98; *Scanlon*, 65 N.J. at 592-93; *Moraca v. Ford Motor Co.*, 66 N.J. 454, 458-59 (1975). Plaintiff did not and cannot satisfy either requirement.

a. Ozurdex® Is a Complex Product, Requiring Expert Testimony to Prove a Defect. [ISSUE WAS RAISED (Da0785; Da0816; Da0846)]

Manufacturing processes and modes-of-action for prescription drugs and medical devices, like Ozurdex® and its delivery system, are unquestionably outside the ken of average jurors. Such complex products do not qualify for the type of "common sense" inferences of defect from circumstantial evidence allowed for ***simple*** products, like a wheel that stops rotating, a steering column that locks (*Moraca*, 66 N.J. at 459), or a car that "malfunction[s] violently" (*Scanlon*, 65 N.J. at 599).

Importantly, here, New Jersey courts find that expert testimony is required—and circumstantial evidence is insufficient—to prove a defect in a complex product ***even in cases where the product has been recalled***. *E.g.*, *Schweiger*, 2019 WL 5783478, at *4 (finding discontinuation of product did not dispense with need for expert to prove complex product is defective); *Burbank v. BMW of N. Am., LLC*, 2022 WL 833608, at *9 (D.N.J. Mar. 21, 2022) (finding a recall "provides no evidence" that product is defective, as a recall is often "overinclusive" and "does not prove that any individual's [product] actually contained a nonconformity").[16]

An FDA-approved prescription drug injected into the vitreous of the eye with a single-use, silicone-sleeved needle applicator is ***nothing*** like a simple mechanical product with which average jurors have operational familiarity. *E.g.*, *McMillan*, 2005 WL 20000203, at *3 (finding circumstantial evidence not enough to prove defect in medical device; ***expert testimony is required***). No New Jersey appellate court has ever authorized using "circumstantial evidence" to find a

[16] *See also Garcia v. Volkswagen Grp. of Am., Inc.*, 2022 WL 2542291, at *9 (E.D. Va. July 7, 2022) (granting summary judgment, as "[t]hese district court cases make clear that even when a specific defect is alleged in a vehicle or other product, a recall notice is not evidence that demonstrates an individual plaintiff's vehicle or product possesses that defect."); *Bailey v. Monaco Coach Corp.*, 350 F. Supp. 2d 1036, 1045 (N.D. Ga. 2004) (finding "the recall notice is insufficient to create a triable issue regarding the existence of a defect" and granting summary judgment); *Cascio v. Johnson & Johnson*, 2024 WL 693489, at *2 (N.D. Ga. Feb. 20, 2024) ("[A] recall of a product is not evidence of a defect….Defendants' recall notice alone cannot support a plausible inference that the sunscreen Plaintiff Debra Cascio used contained benzene.").

manufacturing defect for a prescription drug or medical device. This Court should not be the first to allow expansion of New Jersey law in such an unprincipled way.[17]

b. Plaintiff Lacks Evidence Negating the Likely Causes of Her Injuries Other Than a Manufacturing Defect. [ISSUE WAS RAISED (Da0785; Da0816; Da0846)]

Plaintiff's evidence falls far short of conclusively negating the many likely causes of her injuries ***other than*** a defect. Plaintiff and her experts did ***nothing*** to negate those other causes, including many they ***concede*** could have ***independently*** caused her inflammation, retinal detachment, and vision loss. The alternate causes Plaintiff's experts do not rule out include: the continued progression of her chronic eye inflammation; increased eye inflammation from continued smoking; the cumulative risk of dozens of intravitreal injections and other eye procedures; and the dislocation of her Retisert® implant. Dispositively, Plaintiff's retained expert Dr. Lalezary agreed these other "risk factors…***could have led to a retinal detachment…[i]n the absence of a silicone particulate***." (Da0150, pp. 112-13 (emphasis added))

[17] Such a holding would be contrary to the PLA, which "evince[es] a legislative policy 'to limit the expansion of products-liability law,'" *Zaza v. Marquess & Nell, Inc.*, 144 N.J. 34, 47 (1996) (quoting *Roberts v. Rich Foods, Inc.*, 139 N.J. 365, 374 (1995)), in part "to reduce the burden on manufacturers of FDA-approved products resulting from products liability litigation," *Kendall v. Hoffman-La Roche, Inc.*, 209 N.J. 173, 194 (2012).

Plaintiff's experts' failure to rule out the impact of the Retisert® implant and its dislocation is alone sufficient to warrant summary judgment. To the extent Plaintiff blames her injuries on the fact the particulate was composed of silicone, the Retisert® tablet in her eye ***for nearly a decade*** was not only ***encased in silicone***, but was ***10 times larger*** than the alleged 300-micron particulate. And to the extent Plaintiff blames her retinal detachment on mechanical traction from a purported microscopic particulate, the 10-times larger Retisert® was found dislodged from her retina around the ***same time*** and at the ***precise location*** of her retinal detachment.

Plaintiff's inability to negate all of the likely alternate causes for her injuries prohibits her from using circumstantial evidence to prove a manufacturing defect. *Scanlon*, 65 N.J. at 600 (directing defense judgment for "fail[ure] to prove the defendants' responsibility for the defect by the negation of the other most likely probable causes").

3. Plaintiff's Experts Fail to Offer Independent—Much Less, Reliable—Opinions that the Ozurdex® Unit at Issue Had a Defect. [ISSUE WAS RAISED (Da0785; Da0816; Da0846)]

All of Plaintiff's experts' causation opinions ***assume*** the subject Ozurdex® unit was defective. That assumption is not based on an accepted and reliable methodology, or any facts and data. Instead, Plaintiff's experts infer the unit must

have had a defect because it came from a recalled lot and she had not suffered injuries after injections of Ozurdex® from non-recalled lots.

But such a 'this-time-is-different' methodology is neither reliable nor generally accepted. It is nothing more than inferring defect based on fact of injury and temporal proximity, which New Jersey law rejects. *Myrlak*, 157 N.J. at 98 ("The mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect."); *Zaza*, 144 N.J. at 49 ("An inference of defectiveness may not be drawn from the mere fact that someone was injured."); *Lauder v. Teaneck Volunteer Ambulance Corps.*, 386 N.J. Super. 320, 332 (App. Div. 2004) ("[T]he fact that someone was injured [is] not sufficient to demonstrate a defect."); *Nicholson v. Bloomin Brands, Inc.*, 2018 WL 3614355, at *5-6 (N.J. Super. App. Div. July 30, 2018) (affirming that temporal association between product exposure and injury is insufficient to survive summary judgment). The fact that Plaintiff alleges injury in temporal association with use of Ozurdex® from a recalled lot does not excuse her failure to meet her burden of proof.

Because Plaintiff cannot cite anything—no treatise or peer-reviewed publication—demonstrating that her experts' 'this-time-is-different' testimony is a reliable and accepted method to establish a manufacturing defect, it amounts to an inadmissible 'net opinion' insufficient for Plaintiff to meet her burden to prove product defect. *Pomerantz Paper Corp. v. New Cmty. Corp.*, 207 N.J. 344, 372

(2011) (experts offer inadmissible net opinions if they "cannot offer objective support…but testif[y] only to a view about a standard that is 'personal'"); *Kemp ex rel. Wright v. State*, 174 N.J. 412, 427 (2002) (explaining New Jersey courts must disallow experts' "unsubstantiated personal beliefs"); *Vinci v. Clifton Bd. of Educ.*, 2012 WL 5869576, at *5 (N.J. Super. App. Div. Nov. 21, 2012) (affirming exclusion of expert's "personal opinion" without "any source or authority for that conclusion"); *see also Moody v. Gen. Mills, Inc.*, 2006 WL 6872309, at *1 (D.N.J. Feb. 9, 2006) ("various courts have noted that reliance on a temporal relationship in the absence of scientific studies, authoritative research or peer review is insufficient to constitute a reliable opinion") (collecting cases).

Regardless, the evidence does not support the experts' assumption that the only difference in the November 6, 2018 Ozurdex® treatment was that it came from a recalled lot. *E.g.*, *Townsend v. Pierre*, 221 N.J. 36, 57-58 (2015) (affirming exclusion of opinion not supported by evidence); *Vuocolo v. Diamond Shamrock Chemicals Co.*, 240 N.J. Super. 289, 299 (Ct. App. 1990) ("Historically, courts have refused to admit expert medical testimony…unsupported by the evidence."). As just discussed (*see* Section III(B)(2)(b)), the record reveals numerous material differences between this and Plaintiff's prior Ozurdex® injections that likely could have caused Plaintiff's injuries, with which Plaintiff's own experts agree. Her experts' "net opinions" that "fail to negative [those] other possible causes"—like

the Retisert® implant, the continued progression of her chronic eye disease, and her refusal to stop smoking—are thus insufficient to prove a manufacturing defect. *Vuocolo*, 240 N.J. Super. at 300; *see also Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 610 (D.N.J. 2002) (excluding opinion chemical caused cancer, where expert acknowledged smoking could also be a cause of the cancer but could not explain how he ruled it out).

Allowing Plaintiff's untenable manufacturing defect claim to proceed to trial ***without any proof***—direct, expert, or circumstantial—of a defect in the specific product used in Plaintiff's procedure constitutes a manifest injustice this Court should immediately correct. *E.g.*, *Davis*, 219 N.J. at 401 (directing defense judgment because expert had ***no objective evidence*** to support his standard, ***only his personal opinion***); *Germann v. Matriss*, 55 N.J. 193, 208-09 (1970).

IV. DENYING SUMMARY JUDGMENT WAS A MISCARRIAGE OF JUSTICE BECAUSE PLAINTIFF'S EXPERTS FAILED TO OFFER ANY GENERAL-CAUSATION OPINIONS AND THEIR SPECIFIC-CAUSATION OPINIONS ARE INADMISSIBLE "NET OPINIONS." [ISSUE WAS RAISED (DA0785; DA0816; DA0846)]

Plaintiff's inability to prove defect is alone fatal to her case, but her problems do not stop there. As noted above, Plaintiff must also provide "expert testimony to satisfy [her] burden with respect to both general causation and specific causation." *In re Phenylpropanolamine (PPA)*, 2003 WL 22417238, at *20. "A mere possibility of such causation is not enough; and when…***the***

probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant." *Townsend*, 221 N.J. at 60-61 (emphasis added) (quoting *Davidson v. Slater*, 189 N.J. 166, 185 (2007)).

That is the case here. Plaintiff has ***no evidence*** to prove general causation, without which Plaintiff cannot make a submissible case. *Scott v. Eli Lilly & Co.*, 2016 WL 1741241, at *2 (N.J. Super. Ct. App. Div. May 3, 2016) (affirming summary judgment where the plaintiff had no expert proof of general causation); *Rutigliana v. Valley Bus. Forms*, 929 F. Supp. 779, 783 (D.N.J. 1996) (stating the plaintiff's expert must first prove general causation). And while Plaintiff tries to prove specific causation through her experts, neither did the work necessary to offer a ***reliable*** specific-causation opinion. They do not provide the why and wherefore to support their inadmissible net opinions. They performed no tests, conducted no research, and engaged in no scientific or medical analysis, instead offering personal opinions based solely on temporal association of Plaintiff's alleged injuries to use of a product from a recalled lot.

The Trial Court failed to properly perform its gatekeeping role, once again, allowing "recall" and temporal association to substitute for qualified expert opinion derived from application of reliable methodology to the facts. Given Plaintiff's failure to marshal the evidence required to meet her burden to prove

causation, allowing this case to proceed past summary judgment constitutes a manifest injustice.

A. Plaintiff's Experts Do Not Offer Independent General-Causation Opinions, and Lack the Qualifications and Factual Basis to Do So. [ISSUE WAS RAISED (Da0785; Da0816; Da0846)]

Neither Dr. Phillips nor Dr. Lalezary offers an independent general-causation opinion that a 300-micron, medical-grade silicone particulate ***is capable of causing*** eye inflammation, a tractional retinal detachment, or vision loss. Plaintiff's inability to prove general causation dooms her case.

That Plaintiff's experts do not offer independent general-causation opinions is not surprising given they both lack the necessary qualifications to offer such an opinion. Neither has any education, training, experience, or skill in biomaterials science, biocompatibility and biomechanics of a microscopic silicone particulate, and whether it ***is capable of causing*** inflammation or a tractional retinal detachment. Neither has ever published on the silicone used in the Ozurdex® needle sleeve or held himself out as an expert in the field of biomaterials, biomechanics, and biocompatibility of silicone used in ocular procedures. And neither expert explains how his experience as a practicing ophthalmologist qualifies him to opine on the composition, character, and size of the purported silicone particulate, its propensity (or not) to induce an inflammatory response, or

whether it is capable of causing a tractional retinal detachment—which Dr. Lalezary speculates happened, ***but Dr. Phillips wholly rejects***.

Since Plaintiff's experts have zero qualifications to address this complex subject matter, any possible general-causation opinion they could offer is inadmissible under N.J.R.E 702. The Court cannot allow Plaintiff to proceed with her claims without this required proof. *E.g.*, *Agha v. Feiner*, 198 N.J. 50, 54 (2009) (directing defense judgment for lack of expert qualified to offer needed opinion).

Compounding Plaintiff's problems, her experts do not have the facts and data required by N.J.R.E. 703 to offer a reliable opinion that this medical-grade silicone can cause eye inflammation. To the contrary, Plaintiff's experts testified silicone is used ***all the time*** in the eye for medical treatments (Da0047, pp. 54-55), and neither expert performed or relied on any testing differentiating his experience successfully using silicone from the supposedly-harmful silicone at issue here. *E.g.*, *Rutigliana*, 929 F. Supp. at 784-86 (excluding general-causation opinion not supported by facts or data); *Townsend*, 221 N.J. at 53 (noting that expert opinion must be grounded in facts or data); *Roening v. City of Atl. City*, 2022 WL 151940, at *4 (N.J. Super. Ct. App. Div. Jan. 18, 2022) (holding expert's opinion inadmissible because he failed to "support his opinion with facts, scientific data, or an accepted standard"), *cert denied*, 251 N.J. 16 (2022).

The sole and undisputed record evidence on biocompatibility of the silicone used in the Ozurdex® needle sleeve—a rabbit-eye toxicity study—establishes conclusively that it does ***not*** cause inflammation. (Da0304) While Plaintiff's retained expert Dr. Lalezary criticizes this study, he offers no contrary analysis, test, study, or peer-reviewed published literature. Courts across the country have rightly held that such "mere criticism" of opposing scientific evidence "cannot establish causation." *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 886 (10th Cir. 2005); *see also Caraker v. Sandoz Pharms. Corp.*, 188 F. Supp. 2d 1026, 1034 (S.D. Ill. 2001) (finding expert's "broad criticisms" of existing evidence did not help plaintiffs meet their burden; "[p]laintiffs' burden is an affirmative one, not served by such attacks").

When asked, the only facts or data Dr. Lalezary could identify as support for his assumption of general causation is Allergan's Urgent Drug Recall letter stating inflammation is a "potential" risk in "sensitive patients." (Da0255) But such equivocal statements in a recall document cannot be a reliable basis upon which to establish causation because there are "myriad reasons, including an abundance of caution or the avoidance of lawsuits, why a manufacturer may warn of a possible phenomenon without being convinced that it is a genuine risk." *In re Mirena*, 202 F. Supp. 3d at 323. Moreover, public policy principles prohibit elevating statements in such recall documents to the status of evidentiary admissions because

that "would chill free and frank discussion by manufacturers of drugs or devices." *Id.* at 320. That is why "no court has held that admissions [in recall documents] can substitute for required expert testimony, and this Court [should] not be the first." *Id.*[18]

In any event, Dr. Lalezary misinterprets the recall document. He thinks "sensitive patients" refers to patients with eye problems, when it actually refers to patients with ***sensitivity to silicone***. (Da0452, p. 39) Dr. Lalezary does not say Plaintiff is sensitive to silicone—nor could he given her experience for more than a decade with the silicone-coated Retisert® implant 10-times larger than a 300-micron particulate. Because Dr. Lalezary misconstrued the sole foundation for his assumption that the phantom silicone particulate is capable of causing inflammation, his opinion is untethered to the facts, unreliable, and should have been excluded. *E.g.*, *Townsend*, 221 N.J. at 57-58 (affirming exclusion of expert opinion that ***diverged*** from the evidence); *Vuocolo*, 240 N.J. Super. at 299 ("It seems universally agreed that an expert medical opinion as to the cause…is inadmissible if it is solely an unsupported conclusion of the witness, since…an opinion must have reference to the material facts of the case as reflected by the

[18] *Accord Lowery v. Sanofi-Aventis LLC*, 535 F. Supp. 3d 1157, 1172 n.12 (N.D. Ala. 2021); *Beyer v. Anchor Insulation Co.*, 238 F. Supp. 3d 270, 283 (D. Conn. 2017).

evidence.") (quoting *Opinion Evidence—Disease or Injury*, 66 A.L.R.2d 1082, 1086 (1959)).

Dr. Lalezary also has no basis to opine a 300-micron silicone particulate is capable of causing mechanical traction that can result in a retinal detachment. On this point, Plaintiff's experts are at odds. Dr. Phillips ***rejects*** Dr. Lalezary's theory: "I don't think that the silicone particulate would be a cause of the detachment." (Da0047, pp. 58-59) For his contrary opinion, Dr. Lalezary points to ***nothing***—not even the recall document, which never discusses retinal detachment. This is the epitome of an inadmissible "net opinion." *Lanzo*, 467 N.J. Super. at 508-11 (holding it an abuse of discretion to admit opinion where expert had no studies supporting general causation, had not published his opinion for peer review, and cited no authorities in support); *In re Accutane*, 234 N.J. at 396 (finding that absent reliable scientific methodology, expert's opinion on general causation cannot be admissible).[19]

Looking to the *Daubert* factors now part of New Jersey law, *In re Accutane*, 234 N.J. at 398, confirms Plaintiff's experts could not offer a reliable and

[19] *See also Vuocolo*, 240 N.J. Super. at 299-300 ("Expert medical opinion evidence as to causation between an event and…a physical condition is inadmissible if it would amount to the expression of a pure conclusion, without reference to factual causative antecedents….") (quoting 66 A.L.R.2d at 1116-17); *Townsend*, 221 N.J. at 55 (proper to exclude expert opinion "based merely on unfounded speculation and unquantified possibilities.").

admissible opinion on general causation—even if either was qualified to offer such an opinion, which they are not. Neither Dr. Lalezary nor Dr. Phillips has:

1. tested the theories that a 300-micron particulate of the medical-grade silicone used in the Ozurdex® needle sleeve (a) is capable of causing eye inflammation or (b) is capable of causing a retinal detachment;

2. published either theory or otherwise subjected it to peer review;

3. determined if either theory has any known or potential rate of error and if there exist any standards for maintaining or controlling application of either theory to avoid that error; or

4. cited any evidence that either theory has been generally accepted by the relevant scientific community.

Id. Because Plaintiff did not and cannot establish that the "the scientific community would accept the methodology employed by [her] experts and would use the underlying facts and data as did [her] experts," the Trial Court failed to perform its gatekeeping function to exclude the experts' unreliable opinions. *Id.* at 400.

The Trial Court nonetheless found the ***recall*** provided a sufficient basis for Plaintiff's experts to opine on general causation based on their testimony that 'this time is different.' As with the issue of product defect, no New Jersey court has held 'this time is different' is a reliable and accepted methodology to establish general causation, and the 'fact of a recall' does not excuse this methodologic failure. As the judge overseeing the federal Zantac MDL recently observed, the fact that a drug has been recalled is not proof that the drug is capable of causing harm and

cannot be used as a substitute for the required expert proof on causation. *In re: Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1094, 1285 (S.D. Fla. 2022) (excluding the plaintiffs' experts' unreliable and unsupported general-causation opinions). As in *Zantac*, it is telling that "there was no scientist outside this litigation who" holds the general-causation opinions that Plaintiff asserts in this case. *Id.* at 1094.

This Court should immediately correct the manifest denial of justice in rejecting summary judgment, where Plaintiff has no proof of general causation, her experts are not qualified to offer general-causation opinions, and any opinions they do offer are not grounded in reliable methods or sufficient facts and data. *E.g.*, *Lanzo*, 467 N.J. Super. 504-18.

B. Plaintiff's Experts Did No Work to Offer Reliable and Factually-Supported Specific-Causation Opinions. [ISSUE WAS RAISED (Da0785; Da0816; Da0846)]

When an expert wants to offer an opinion that one of a number of potential causes of an injury is the actual cause, the expert must have a reliable basis to both 'rule in' each potential cause and 'rule out' everything other than what the expert opines is the actual cause. Such a differential diagnosis, if properly performed, can be an accepted method to establish specific causation. *Magistrini*, 180 F. Supp. 2d at 609.

Here, however, Plaintiff's experts did ***nothing***—no testing, research, or scientific or medical analysis—to 'rule in' the purported silicone-particulate defect as a potential cause of Plaintiff's eye inflammation, tractional retinal detachment, and vision loss. They also did ***nothing***—no testing, research, or scientific or medical analysis—to 'rule out' the many alternatives they agree are likely causes of Plaintiff's eye inflammation and retinal detachment ***absent a silicone particulate***, including: her chronic eye disease; her frequent intravitreal injections, eye surgeries, and intraocular procedures; ***dislocation of the Retisert®***; and her continued smoking that exacerbated her uveitis (chronic eye inflammation).

Instead, Plaintiff's experts merely ***assumed*** specific causation based on temporal proximity of her injuries to exposure to a product from a recalled lot. But, as explained, the law rejects the assumption of causation based only on temporal proximity and the fact of a recall—particularly where, as here, the record evidence reveals a host of material differences between this Ozurdex® treatment and Plaintiff's prior treatments that could have caused her injuries independent of any purported silicone particulate.

The Supreme Court rejects claims like these, where Plaintiff's experts fail to reliably apply a methodology to rule out alternate causes, leaving nothing but speculation and guesswork as a basis for their specific-causation opinions. *E.g.*, *Davis*, 219 N.J. at 401; *Germann*, 55 N.J. at 208 (where evidence "shows a number

of possible causes, only one of which" makes defendant liable, "the issue of the [defendant's] responsibility cannot be submitted to the jury for determination. To do so would be to authorize a decision on the basis of conjecture and speculation."); *Jakubowski*, 42 N.J. at 183 (insufficient evidence of causation where expert "failed to exclude other possible causes"); *see also Nicholson*, 2018 WL 3614355, at *5 ("[C]ourts should not send a case to the jury if the nature of the evidence would not allow them to determine the probable cause of the plaintiff's injury without guess or speculation.").

Left only with bare conclusions unsupported by any reliable methodology applied to the facts in the case, Plaintiff's experts' specific-causation opinions are subject to the 'net opinion' rule and are inadmissible. *E.g.*, *Murray v. Consolidated Rail Corp.*, 2023 WL 2193825, at *5-6 (N.J. Super. Ct. App. Div. Feb. 24, 2023) (holding expert's specific-causation opinion was inadmissible "net opinion," where opinion was based on assumptions and speculation and expert could not explain why he attributed the cause to one of many potential causes); *In re Phenylpropanolamine (PPA)*, 2003 WL 22417238, at *25 ("[A]n expert opinion...based on the expert's bare conclusions which are unsupported by factual evidence, are subject to the net opinion rule.").

CONCLUSION

Allergan respectfully requests that this Court reverse and remand with directions to (i) exclude the unqualified and unreliable opinions of Plaintiff's experts and (ii) enter summary final judgment for Allergan.

Respectfully submitted,

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ALISON BEAVAN, Plaintiff-Respondent, vs. ALLERGAN USA, INC., et al., Defendant-Appellant.	SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO.: A-1501-23T2 Civil Action ON APPEAL FROM SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MORRIS COUNTY DOCKET NO. MRS-L-151-21 Sat Below: Hon. Louis S. Sceusi, J.S.C.

OPPOSITION BRIEF OF PLAINTIFF-RESPONDENT ALISON BEAVAN TO DEFENDANT-APPELLANT ALLERGAN USA INC.'S OPENING BRIEF

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PRELIMINARY STATEMENT

Alison Beavan was blinded by an intravitreal injection of Ozurdex when a silicone particulate broke off from a defective Ozurdex applicator (also called an "actuator") and was injected along with the Ozurdex steroid pellet into Ms. Beavan's left eye. Ms. Beavan's injury was entirely preventable. Ms. Beavan received her Ozurdex injection on November 6, 2018, but Allergan had knowledge of the manufacturing defects associated with these actuators since June 21, 2018. In fact, Allergan had issued Recalls, Rapid Alerts and Warning letters to physicians in forty (40) countries around the world, yet knowingly continued to distribute defective lots of Ozurdex in the United States ("U.S.") without any warning to physicians or patients until finally issuing an Urgent Drug Recall in the U.S. on December 28, 2018.

Allergan inexplicably maintains that there is no evidence of a manufacturing defect related to these applicators, despite the fact that Allergan's U.S. recall specifically states that the applicators contain a defect. Furthermore, Allergan's October 25, 2018 Root Cause Analysis Report specifically identified the manufacturing defect that caused the silicone particulate to be injected from the defective Ozurdex applicator, as well as the changes made in the manufacturing process to prevent this from occurring in the future. **Notably, Allergan has admitted that the specific lot from which Ms. Beavan's**

November 6, 2018 Ozurdex injection originated, contained 145 of these defective Ozurdex applicators. Allergan's own corporate representatives testified that any actuator that dispensed a silicone particulate deviated from the product's performance standards and that the Ozurdex actuator was not designed to release a silicone particulate. Under the New Jersey Product Liability Act ("PLA"), N.J.S.A. sec. 2A:58C-2, a manufacturer of a product shall be held liable if the claimant proves that the product causing harm deviated from the design specifications or the performance standards of the manufacturer.

Plaintiff's two (2), board-certified ophthalmology experts, Dr. Lalezary and Ms. Beavan's treating ophthalmologist, Dr. Phillips, after a complete and thorough review, each testified to a reasonable degree of medical probability that the defective Ozurdex caused a silicone particulate to be injected into Ms. Beavan's left eye ultimately resulting in blindness. Additionally, Dr. Lalezary testified that the silicone particulate caused a tractional retinal detachment that required surgical repair. As a result of the retinal detachment surgery necessitated by the silicone particulate insult, an opening was created that caused the Ozurdex steroid to migrate into Ms. Beavan's left anterior chamber, resulting in her blindness. Moreover, Dr. Phillips testified that the silicone particulate caused excessive ocular inflammation and corneal edema in Ms.

Beavan's left eye, both of which outcomes were adverse effects as identified in Allergan's Ozurdex Urgent Drug Recall.

Regarding Ms. Beavan's failure to warn claim under the PLA, Allergan disingenuously attempts to characterize it repeatedly as a claim for "failure-to-timely-recall" or a "failure-to-timely-warn-of-recall." Casting aside Allergan's subterfuge, Ms. Beavan's failure to warn claim is predicated upon Allergan's abrogation of its post-sale duty to warn of the dangerous defects it discovered after the Ozurdex left its custody pursuant to N.J.S.A. §2A:58C-4.

Clearly, Allergan's post-sale duty to warn began on June 21, 2018, when it first discovered the existence of these manufacturing defects. Moreover, on September 17, 2018, Allergan discovered that the manufacturing defects were present within the specific lot [E82852] that was eventually injected into Ms. Beavan's eye on November 6, 2018. In other words, although Allergan knew of specific, product-related issues precisely 138 days prior to Ms. Beavan's fateful injection, and then discovered 88 days prior to said injection the presence of the associated manufacturing defects within lot E82852, Allergan said nothing. Allergan did nothing. This is undisputed. Had Allergan simply done the right thing, Ms. Beavan's blindness would have been prevented.

STATEMENT OF FACTS AND PROCEDURAL HISTORY

STATEMENT OF FACTS

Tracy Founds was Allergan's Associate Vice President of Post Marketing Quality in 2018. (Da0579) Ms. Founds was designated by Allergan to testify on its behalf regarding a number of matters of inquiry, including when Allergan first became aware that a silicone particulate was being dispensed in Ozurdex implants. (Pa107) On June 21, 2018, she testified that Allergan became aware that "During a routine manufacturing inspection, a silicone particulate, approximately 300 microns in diameter, was observed in dispensed Ozurdex implants." (Da0581-0582)

Allergan admits that any Ozurdex applicator that dispensed a silicone particulate deviated from its own performance standards. (Pa108-Pa109) Because of this deviation from its own performance standards, Allergan ceased production of Ozurdex. (Pa108-Pa109)

In 2018, Rory Turk was Allergan's Director of Global Regulatory Affairs. (Pa168-Pa169) Mr. Turk was designated by Allergan to testify on its behalf regarding the issues of design and manufacture relating to the recall of Ozurdex. (Pa168-Pa169) Allergan admits that the Ozurdex actuator was not designed to release a silicone particulate. (Da720-Da721) By September 26, 2018, Allergan

was additionally aware that there was an adverse risk to patients of suffering a corneal reaction if injected with the silicone particulate. (Da586)

Incredibly, Allergan knew that the defect existed in specific Ozurdex Lot number E82852 by September 27, 2018. (Da602, Da607) However, prior to Ms. Beavan's fateful injection on November 6, 2018, Allergan did not make any attempt to warn any physician or healthcare providers in the U.S. of the defect and associated risks of Ozurdex. (Da586)

Of course, nothing prevented Allergan from ceasing to distribute the Ozurdex applicators from Lot #E82852 within the United States. (Pa110) Further, Allergan did not need FDA approval to issue a simple warning to physicians and health care providers in the United States about the defective Ozurdex applicators with the silicone particulate defect, or otherwise issue a product recall. 21 C.F.R. Secs 7.46(a) and 7.46(b). In support of her opinions, Allergan's expert, Janet B. Arrowsmith, MD, cites in her report the FDA publication **"Guidance for Industry and FDA Staff, Dear Health Care Provider letters: Improving Communication of Important Safety Information.**" (Da0258, ¶ 67.) The FDA makes clear in the publication that: "FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities….The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required." (Da0619,

Da0623) **"Guidance for Industry and FDA Staff, Dear Health Care Provider letters: Improving Communication of Important Safety Information**" at page 1. The phrase ***"Contains Nonbinding Recommendations"*** is printed at the top of every page of the FDA Guidance. (Da0619-Da0639; Emphasis in original.)

Allergan's expert, Dr. Arrowsmith, never claimed in her report, or at deposition, that FDA approval was necessary in order for Allergan to notify health care providers in the United States about the defective Ozurdex applicators. (Da0259-Da0303) By October 3, 2018, Allergan had prepared a Dear Health Care Provider ("DHCP") letter to send to health care providers in the United States regarding the defective Ozurdex applicators with the silicone particulates. (Pa111-Pa112) However, Allergan never set the warning letter.

The DHCP letter would have served to warn physicians that "During a routine manufacturing inspection, a single silicone particle, approximately 300 microns in diameter, was observed in dispensed Ozurdex implants. The silicone particle has been confirmed to originate from the needle sleeve." "A number of Ozurdex batches already distributed may contain a silicone particle." The DHCP letter further would have warned physicians of the risk of "Obscuration of vision by particle, Intraocular inflammation and Corneal adverse reaction." (Da0649-Da0650)

By October 25, 2018, Allergan's Root Cause Analysis had identified the manufacturing defect and its cause, which was improper assembly technique. "Based on the investigation performed at both the Allegan Westport & TSK, Japan manufacturing sites the most likely cause is retention of the silicone sleeve in the needle slot. This is based on the following: During sleeve assembly at TSK, operators push the sleeve section of the sleeve into the needle slot. By performing this action, the silicone sleeve can become jammed against the front edge of the needle slot. When the implant is pushed into position during Ozurdex assembly, the sleeve cannot freely move laterally to accommodate the implant as a result of the sleeve being packed into the needle slot. This results in the formation of the particulate. The depth of the sleeve in the needle lumen in this respect is also important. If there is more present, then it provides a greater obstacle to the implant during implant assembly if the sleeve cannot move freely. The corrective action implemented in Allergan Westport requires repositioning of the sleeve such that the leading edge of the slot is visible, returning the sleeve to a position where it can accommodate the implant, and this prevents the generation of the particulate." (Da0229, Da0237)

Allergan then tested ninety (90) such Ozurdex applicators from the subject Lot #E82852 and found a defect rate of 2.2% dispensing the silicone particulate. (Da0229, Da0237) In other words, Ozurdex Lot #E82852 contained 6,553

applicators that Allergan knowingly, and without warning, distributed, which contained a staggering 145 (2.2% of 6,553) defective applicators, including the defective Ozurdex applicator that blinded Ms. Beavan. Allergan knowingly distributed this defective lot without any warning to physicians or healthcare providers in the U.S. (Da0346, Da0373)

On November 6, 2018, Ms. Beavan was injected with defective Ozurdex from Lot number E82852. (Da0087) On November 6, 2018, when Dr. Phillips injected Ms. Beavan's left eye with Ozurdex he had not heard of any defects with Ozurdex, nor of any risk of a silicone particulate being dispensed with Ozurdex, nor had Allergan bothered to inform physicians similarly situated to Dr. Phillips that there was a risk of a silicone particulate being injected into a patient's eye during the administration of Ozurdex. (Pa129-Pa130) Dr. Phillips testified that he would have expected Allergan to notify him of the silicone particulate defect as soon as Allergan had become aware of the problem. (Pa132-Pa133) Had Dr. Phillips been aware that there was a risk of injecting a silicone particulate during the administration of Ozurdex, he would not have administered the Ozurdex to Ms. Beavan on November 6, 2018. (Pa130-Pa131)

On November 13, 2018**,** Ms. Beavan returned to Dr. Phillips with severe left eye blurred vision, decreased vision and blind spot. Dr. Phillips diagnosed a retinal detachment. (Da0664) On November 14, 2018, Dr. Phillips performed

a Pars Para Vitrectomy on Ms. Beavan's left eye to treat the retinal detachment. Ms. Beavan returned to Dr. Phillips on November 15, 2018 for a follow up visit. Dr. Phillips appropriately instructed her to lie flat and face down following surgery. (Da0670) Ms. Beavan returned to Dr. Phillips on November 26, 2018. Dr. Phillips documented that the Ozurdex steroid pellet had migrated to Ms. Beavan's anterior chamber. (Da0674)

Finally, on December 28, 2018, Allergan issued an URGENT DRUG RECALL in the United States for twenty-two (22) lots of Ozurdex. (Da0256-Da0257) The Urgent Drug Recall included Lot #E82852, the same defective lot from which Ms. Beavan had received the November 6, 2018, Ozurdex injection that blinded her left eye. (Da0256-Da0257)

Allergan's failure to warn of the dangers of its product cost Ms. Beavan her vision. Almost two months after Ms. Beavan's fateful Ozurdex injection, Allergan finally decided to warn health care providers in the United States that: **"During a routine manufacturing inspection, a single silicone particle, approximately 300 microns in diameter, was observed in dispensed Ozurdex implants. The silicone particle has been confirmed to originate from the needle sleeve. Retain sample testing has determined that the above-mentioned lots are affected by this defect."** [(Da0256-Da0257). Emphasis added.]

Allergan further admitted in the Health Hazard Assessment that: **"Mild transient visual disturbance or intraocular inflammatory reaction in sensitive patients are potential safety risks. There is also a remote possibility of corneal reaction if the particulate migrates to the anterior chamber."** [(Da0256-Da0257). Emphasis added.]

Dr. Phillips first became aware of the Ozurdex recall in early 2019 and realized that the Ozurdex injection that Ms. Beavan received on November 6, 2018 was from one of the recalled lots which caused her injury. Dr. Phillips spoke with Ms. Beavan on January 15, 2019 and documented: "I spoke with Mrs. Beavan today to discuss the Ozurdex recall involving the lot that she received and injection of in November 2018. The recall was secondary to inflammation and a possible corneal reaction of which she has developed both." (Da0680)

By February 1, 2019 Ms. Beavan was almost completely blind in her left eye. Ms. Beavan was evaluated by Dr. Phillips who determined that Ms. Beavan could only see hand motion with her left eye, whereas her vision on November 6, 2018, just before the Ozurdex injection was 20/100. (Da0682; Da0651) On February 1, 2019, Dr. Phillips referred Ms. Beavan to corneal specialist, Dr. Jonathan Solomon. In his referral, Dr. Phillips documented that Ms. Beavan "now has significant corneal edema in the left eye and was a patient who has

received numerous Ozurdex implant[s] in the past, but most recently for her left eye, received an implant from the lot that was subsequently recalled and found to have a silicone oil particle that had caused significant inflammation and sometimes corneal edema. She does have persistent corneal edema but the inflammation is slowly resolving…." (Da0148)

On February 6, 2019, Ms. Beavan was seen by cornea specialist, Jonathan Solomon, M.D. After performing a detailed evaluation, Dr. Solomon determined that Ms. Beavan had suffered "corneal degeneration, 2nd [secondary] to contaminated injection OS [left eye]." (Da0686)

PROCEDURAL HISTORY

On February 17, 2023, Allergan filed a motion for summary judgment as to manufacturing defect and a motion for summary judgment on causation to exclude Plaintiff's expert witnesses. (Da0035; Da0799) On March 7, 2023, Ms. Beavan filed oppositions to the summary judgment motions, both of which included Statements of Additional Facts in support of Plaintiff's Opposition. (Pa001; Pa037) Plaintiff also filed separate Responsive Statements of Undisputed Material Facts. (Pa029; Pa066) May 26, 2023 the Trial Court denied both of Allergan's motions for summary judgment. (Da0785 and Da0816) The Trial Court held:

> "Defendant's motion to exclude expert testimony and motion for summary judgment must be denied because a dispute of material

fact exists since Plaintiff's experts have opined that the Ozurdex was defective with a silicone particulate that proximately caused Plaintiff's injuries. While Defendant argues that such expert testimony should [be] excluded, the court disagrees and finds that Plaintiff's experts have sufficiently based their opinions in facts and evidence to be admissible under N.J.R.E. 703. Therefore, since a dispute of material fact exists, it would be improper for this court to decide the issue as a matter of law." (Da0785; Da0792; Da0816; Da0823)

The Court further held:

"Turning to the facts of this case, the court finds that Plaintiff presents sufficient evidence to create a dispute of material fact as to whether a product defect caused Plaintiff's injuries. First, the court finds that Plaintiff has presented sufficient evidence that the Ozurdex applicator was defective to survive a motion for summary judgment. Despite Defendant's argument that the Ozurdex applicator did not deviate from the allowable "manufacturing specifications," Plaintiff presents testimony Defendant's own expert that the disbursement of a silicone particulate would deviate from Allergan's own **performance standards** for the product, and that the Ozurdex applicator was **not designed to dispense a silicone particulate** with the Ozurdex steroid medication. *See* Plaintiff. Opp. Ex. 1, Founds Dep., at 39:14-40:1. Under the PLA, N.J. Stat. Sec. 2A:58C-2, a manufacturer of a product shall be held liable if the claimant proves that the product causing harm deviated from the "**design specifications…or the performance standards of the manufacturer."** N.J.S.A. Sec. 2A:58C-2 (emphasis added). Therefore, the court finds that there is sufficient evidence that the subject Ozurdex applicator was defective under the PLA." (Da0816, Da0825)

"Second, the court finds that Plaintiff provided sufficient expert testimony to create a dispute of material fact as to whether the alleged defect (i.e., the silicone particulate) proximately caused Plaintiff's injuries." (Da0816; Da0825) "From Dr. Lalezary's deposition excerpt, it is clear that his opinion is that the silicone particulate proximately caused Plaintiff's injuries by causing

inflammation and traction that induced a retinal detachment in Plaintiff's eye." (Da0816; Da0826)

"Similarly, the court finds that Dr. Phillips has also provided sufficient expert testimony to show that the silicone particulate proximately caused Plaintiff's injuries…Dr. Phillips clearly opined that the alleged silicone particulate created persistent inflammation in Plaintiff's eye that proximately caused her injuries." (Da0816; Da0826.)

"Third, the court finds that Dr. Lalezary's and Dr. Phillip's opinions are sufficiently based in fact to be admissible under N.J.R.E. 703." (Da0816; Da0827)

"Finally, the court finds that Plaintiff's experts have a sufficient basis for their opinion that a microscopic particulate of silicone *could have* caused a retinal detachment in a human eye…Therefore, the court does not find it reasonable to conclude that Plaintiff's experts lacked a sufficient basis to opine that the silicone particulate could cause inflammation and corneal reaction when Defendant's own recall contained those very same warnings of intraocular inflammatory reaction and corneal reaction as potential safety risks. Under New Jersey law, Plaintiff is only required to show that the alleged product defect proximately caused or was a substantial factor in causing her injuries, and it is clear to the court that Plaintiff's experts have based their opinions on facts and data sufficient to be admissible under N.J.R.E. 703." (Da0816; Da0828)

"Consequently, the court finds Plaintiff has presented sufficient evidence of a manufacturing defect and admissible expert opinion that such defect proximately caused Plaintiff's injuries to create a dispute of material fact. Accordingly, since a dispute of material fact exists, it would be improper for the court to decide the issue as a matter of law. Thus, Defendant's motion to exclude expert opinions and motion for summary judgment are denied." (Da0816; Da0829)

On June 15, 2023, Allergan filed a Motion for Reconsideration of the Trial Court's rulings on the two motions for summary judgment. (Da0830) On July

13, 2023, Ms. Beavan filed her opposition to Allergan's Motion for Reconsideration. (Pa076) On November 13, 2023, the Trial Court denied Allergan's motion for reconsideration. (Da0846) Pursuant to the November 13, 2023 Statement of Reasons, the Trial Court indicated:

> "The Court was within its discretion in finding that Plaintiff had presented sufficient evidence that the Ozurdex applicator was defective to survive a motion for summary judgment, that Plaintiff provided sufficient expert testimony to create a dispute of material fact as to whether the alleged defect (i.e., the silicone particulate) proximately caused Plaintiff's injuries, and other inconsistencies of fact best reserved for a jury to contemplate. The finding of any one of these material facts justified the Court's decision to deny Defendant's Motion for Summary Judgment. Therefore, the Motion for Reconsideration on this argument fails." (Da0846; Da0851)

The Trial Court also denied Allergan's argument "seeking dismissal of Count Two under the PLA for alleged failure to warn." (Da0846; Da0853)

On the issue of the admissibility of Plaintiff's expert witness opinions in its November 13, 2023 Statement of Reasons, the trial court restated certain portions from the Orders denying the motions for summary judgment. The Trial Court further stated that it had "previously found that the weight of Plaintiff's expert testimony should be considered by a jury, not by the Court. Sufficient expert testimony has been shown to create an issue of material fact as to whether the defective Ozurdex applicator proximately caused Plaintiff's injuries. A Motion for Reconsideration is not the opportunity to get a second bite of the

apple. Therefore, Defendant's Motion for Reconsideration is DENIED." (Da0846; Da0853-0854)

LEGAL ARGUMENT

I. THE TRIAL COURT PROPERLY DENIED ALLERGAN'S MOTIONS FOR SUMMARY JUDGMENT AND ITS SUBSEQUENT MOTION FOR RECONSIDERATION GIVEN THAT NUMEROUS QUESTIONS OF MATERIAL FACT ON LIABILITY AND CAUSATION EXIST. [ISSUE RAISED AND DECIDED (Da0785; Da0816; Da0846)]

Appellate courts apply a deferential standard in reviewing factual findings by a judge. Balducci v. Cige, 240 N.J. 574, 594-595 (2020); State v. McNeil-Thomas, 238 N.J. 256, 271 (2019) "To decide whether a genuine issue of material fact exists, the trial court must draw all legitimate inferences from the facts in favor of the non-moving party. Friedman v. Martinez, 242 N.J. 450, 472 (2020) (quoting Globe Motor Co. v. Igdalev, 225 N.J. 1, 13 (2021) Brill v. Guardian Life Ins. Co. of America, 142 N.J. 520, 540 (1995)

Under the Brill standard, if the competent evidential materials and the reasonable inferences to be drawn therefrom, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational factfinder to resolve the alleged dispute in favor of the non-moving party, then there is a genuine issue for trial and a motion for Summary Judgment must be denied. See Brill v. Guardian Life Ins. Co. of America, 142 N.J. 520, 523 (1995); see also Norman v. Selective Ins. Co., 249 N.J. Super. 104, 109, HN5 (App. Div.

1997)("[I]f the fact finder can reasonably draw or reject an inference or if conflicting inferences can be drawn from a given set of facts, the issue is one of fact, and summary judgment is inappropriate.").

The function of a summary judgment motion is not to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial. Id at 540; Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986) A factual dispute resolution should be up to a jury. Suarez v. E. Intern. College, 428 N.J. Super. 10, 27 (App.Div. 2012); Mangual v. Berezinsky, 428 N.J. Super. 299, 308 (App.Div.2012). The slightest doubt as to an issue of material fact must be reserved for the fact finder and precludes a grant of judgment as a matter of law. Akhtar v. JDN Props at Florham Park, LLC, 439 N.J. Super. 391, 399 (App. Div. 2015).

As set forth in the Court's May 26, 2023 Orders denying Allergan's motions for summary judgment and based upon the evidence presented by Ms. Beavan and Allergan, Ms. Beavan has clearly presented "sufficient evidence to create a dispute of material fact as to whether a product defect caused Plaintiff's injuries" (Da816; Da0825)

II. TRIABLE ISSUES OF MATERIAL FACT EXIST AS TO THE PRESENCE OF A MANUFACTURING DEFECT IN THE OZURDEX APPLICATOR [ISSUE RAISED AND DECIDED (Pa001; Pa003-Pa007; Pa009-Pa011; Pa023; Da0791-Da0794; Da0798; Da0850-Da0853)]

The New Jersey Product Liability Act, N.J.S.A. Sec 2A:58C-2 - Liability of manufacturer or seller in product liability action - sets forth the three theories of liability, i.e., manufacturing defect, design defect or defective warning, under which a manufacturer or seller may be strictly liable for harm caused by a product. Roberts v. Rich Foods, Inc., 139 N.J. 365, 375; See also Dewey v. R.J. Reynolds Tobacco Co., 121 N.J. 69, 94-95; See also N.J.S.A. 2A:58C-2.

A plaintiff may establish the existence of a manufacturing defect "through circumstantial evidence…which would permit an inference that a dangerous condition existed prior to sale." Scanlon v. Gen. Motors Corp., Chevrolet Motor Div., 65 N.J. 582, 592-93 (1974). As set forth by the Trial Court in its Orders denying Allergan's motions for summary judgment, "…direct evidence of a product defect is *not* required under the PLA to show a product defect existed." *See* Scanlon, 65 N.J. 582 at 592-93 (1974). Instead, as the Trial Court noted, a product defect can be demonstrated through 'circumstantial evidence and the facts shown,' which is the case here." (Da0815: Da0827) In Ms. Beavan's case, a factfinder may clearly infer that there was a manufacturing defect in the Ozurdex applicator based on Plaintiff's Undisputed Facts 1-71 as set forth in Ms. Beavan's opposition to Allergan's motions for summary judgment. (Pa066)

As provided in N.J. Model Jury Charge 5.40B for Manufacturing Defect and in supporting case law, whether there was a manufacturing defect in the

subject product, may be shown by the plaintiff in one of three ways. First, it may be demonstrated by direct evidence, such as a defective part. Second, a defect may be inferred by circumstantial evidence. Scanlon v. General Motors Corp., 65 N.J. 582, 592-593 (1974); Moraca v. Ford Motor Co., 66 N.J. 454 (1975); Consalo v. General Motors, 258 N.J. Super. 60 (App. Div. 1992) 582, 592-593 (1974); Sabloff v. Yamaha Motor Co., 113 N.J. Super. 279 (App. Div. 1970), aff'd, 59 N.J. 365 (1971); Jakubowski v. Minnesota Mining & Manufacturing, 42 N.J. 177, 184 (1964). Third, based upon the evidence, if there is no other cause of the accident other than a manufacturing defect, a jury may find that a defect existed. See Myrlak v. Port Authority of New York, et al., 157 N.J. 84 (1999). Clearly, a plaintiff may rely on circumstantial evidence to prove manufacturing defect. Direct evidence of a product defect is not required under the PLA to demonstrate existence of a product defect.

Here, the testimony of Allergan's 30(b)(6) witness, Tracy Founds, by itself, establishes the presence of a manufacturing defect by admitting that any Ozurdex applicator that dispenses a silicone particulate, deviates from Allergan's own performance standards. (Pa108-Pa109) Because of this deviation from its own performance standards, Allergan immediately stopped the production of Ozurdex. (Da0583-Da0584; Pa108-Pa109) Additionally,

Allergan's other 30(b)(6) witness, Rory Turk, testified that the Ozurdex applicator was not designed to release a silicone particulate. (Da0720-Da0721)

Allergan's September 17, 2018 Field Alert Report to the FDA identified the cause of the silicone particulate to be a defect that occurred "as part of the manufacturing assembly process." (Da0640; Da0646). Allergan's October 3, 2018 Dear Health Care Provider letter, that Allergan never sent, sets forth that a silicone particulate was being dispensed by some of the Ozurdex applicators and that a number of Ozurdex applicators that Allergan had already distributed may contain the silicone particulate. (Da0648-Da0649) Allergan's October 25, 2018 Root Cause Analysis identified the cause of the silicone particulate defect as being created during the manufacturing assembly process and Allergan set forth a corrective action plan to prevent further injections of silicone particulate. (Da0229; Da0237-Da0238) Allergan's December 28, 2018 URGENT DRUG RECALL twice identified the silicone particulate as a **"defect."** (Da0256-Da0257. Emphasis added.)

As set forth in the Court's May 26, 2023 Order Denying Summary Judgment, quoting from the PLA, N.J. Stat. Sec. 2A:58C-2, "a manufacturer of a product shall be held liable if the claimant proves that the product causing harm deviated from the **'design specifications … or the performance standards of the manufacturer.'"** [(Da0825) Emphasis in original.]

Allergan's citation to Burbank v. BMW of N. Am., LLC, 2022 WL 833608, at *9 (D.N.J. Mar. 21, 2022) implies that Ms. Beavan is relying solely on the recall as evidence of the defect. As set forth hereinabove, Plaintiff has a multitude of evidence that substantiates the manufacturing defect in the subject applicator.

III. ALLERGAN'S ARGUMENT REGARDING A MANUFACTURING DEFECT EXPERT WITNESS IS UNSUPPORTED BY THE FACTS AND LAW. [ISSUE RAISED AND DECIDED (Pa001; Pa003-Pa007; Pa009-Pa011; Pa023; Da0791-Da0794; Da0798; Da0850-Da0853)]

Allergan misstates the law with respect to a requirement for an expert witness regarding the manufacturing defect. There simply is no case law requiring expert witness testimony to prove a manufacturing defect and, in particular, a manufacturing defect for a recalled product. See Sabloff v. Yamaha Motor Co., 113 N.J. Super. 279, 286 (App. Div. 1971); Moraca v. Ford Motor Co., 66 N.J. 454, 459 (1975); Scanlon v. Gen. Motors Corp., Chevrolet Motor Div., 65 N.J. 582, 598-599 (1974).

Allergan citation to McMillan v. Johnson & Johnson, No. CIV. 04-1180 (RBK), 2005 WL 2000203 at *3 (D.N.J. Aug. 19, 2005) does not support its claim that expert witness testimony is required to establish a manufacturing defect. In fact, McMillan v. Johnson & Johnson permits "expert testimony **or other additional evidence**" to prove a manufacturing defect. Id. at *3. Moreover, the McMillan case is clearly distinguishable as it does not involve a recalled product

due to an admitted manufacturing defect. The court in McMillan also cited Sabloff, 59 N.J. 365, 366, in which the Supreme Court of New Jersey held that "whenever the facts permit an inference that the harmful event ensued from some defect (whether identifiable or not) in the product, the issue of liability is for the jury." Id. at *3. The court's ruling in the McMillan case is consistent with New Jersey law in that evidence of a product defect can be demonstrated through evidence other than expert witness testimony.

Expert testimony is not invariably required for any of the methods used to prove defect. Macri v. Ames McDonough Co., 211 N.J. Super. 636, 642 (App. Div. 1986) Likewise, where a plaintiff alleges that there is a defect in a product, he is "not necessarily confined to the explanation his expert may advance." Sabloff v. Yamaha Motor Co., Ltd., 59 N.J. 365, 366, 283 A.2d 321 (1971); Moraca v. Ford Motor Co., 66 N.J. 454, 458-460, 332 A.2d 599 (1975).

A plaintiff may rely on circumstantial evidence to prove that a defect arose while a product was in the manufacturer's, distributor's, or seller's control. Scanlon, supra, 65 N.J. at 592-93, 326 A.2d 673, citing Jakubowski v. Minn. Mining & Mfg., 42 N.J. 177, 183-84, 199 A.2d 826 (1964). In Myrlak v. Port Authority of New York and New Jersey, 157 N.J. 84, 104-107, 723 A.2d 45 (1999), the Court adopted as the law in New Jersey the principles stated in Restatement (Third) of Torts: Products Liability § 3 (Am. Law. Inst.

1998) with respect to a finding of defect in a product liability case without the testimony of an expert witness. Accordingly, expert witness testimony regarding the manufacturing process is not required to prove a manufacturing defect.

IV. ALLERGAN ABROGATED ITS POST-SALE DUTY TO WARN OF THE DANGERS AND DEFECT INVOLVING THE OZURDEX APPLICATOR, PURSUANT TO N.J.S.A. SEC. 2A:58C-4. [ISSUE RAISED AND DECIDED (Pa003-Pa012; Pa024-Pa026; Pa033-Pa036; Da0852-Da0853)]

A. Failure to Warn Post-Sale [ISSUE RAISED AND DECIDED (Pa003-Pa012; Pa024-Pa026; Pa033-Pa036; Da0852-Da0853)]

Allergan has repeatedly attempted to obfuscate issues and mislead the court by claiming that its May 2018 package insert warning was sufficient, FDA approved and therefore preempted. However, this case has never concerned Allergan's May 2018 package insert warning. Instead, the case involves Allergan's failure to warn after it became aware of the Ozurdex defect on June 21, 2018, which months before Ms. Beavan was injured. Ms. Beavan and her board-certified ophthalmologist, Dr. Phillips, were never warned about the defect, nor was anyone else in the U.S. until after Ms. Beavan was blinded.

New Jersey Product Liability Act Sec. 2A:58C-4. Provides the following in relevant part:

> 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 or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after

> the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction.

Allergan also attempts to misconstrue the facts and the arguments through its focus on its failure to timely recall the defective Ozurdex applicator. In this proceeding, however, Allergan's failure to warn pertains to its failure and refusal to warn of the dangers involving the Ozurdex applicator – post sale – as provided in N.J.S.A Sec. 2A:58C-4. The standard in a failure-to-warn case is no different, whether the action is considered under the PLA or our common law jurisprudence. Whelan v. Armstrong Int'l, Inc., 242 N.J. 311, 331 (2020), See Zaza v. Marquess & Nell, Inc., 144 N.J. 34, 49, 675 A.2d 620 (1996) ("[U]nder the [PLA], as under the common law, the ultimate question to be resolved in ... failure-to-warn cases is whether the manufacturer acted in a reasonably prudent manner ...."). Whelan v. Armstrong, supra, 242 N.J. at 331.

A manufacturer has a duty under the Product Liability Act to warn of dangers that it knew, or that it should have known on the basis of reasonably obtainable available knowledge. Cornett v. Johnson & Johnson, 414 N.J. Super. 365 (A.D. 2010), certification granted 205 N.J. 317, affirmed as modified 211 N.J. 362. The presumption under the Products Liability Act of an adequate warning based on compliance with Food and Drug Administration (FDA) labeling regulations is a red herring and does not apply here. However, the presumption is deemed rebutted if there is (i) deliberate concealment or

nondisclosure of after-acquired knowledge of harmful effects of the drug, or (ii) manipulation of the post-market regulatory process. Bailey v. Wyeth, Inc., 424 N.J. Super. 278, 312 (2008), affirmed 422 N.J. Super. 360, certification denied 211 N.J. 274. Allergan deliberately concealed and failed to disclose its after-acquired knowledge for months, despite warning healthcare providers and patients in forty (40) countries outside the U.S. before blinding Ms. Beavan.

B. Plaintiff's Claim is Not for a Failure to Timely Recall. [ISSUE RAISED AND DECIDED (Pa003-Pa0012; Pa024-Pa026; Pa033-Pa036; Da0852-Da0853)]

Allergan argues that the "PLA does not recognize a 'failure-to-timely-recall' claim." Allergan's argument is again misplaced. As set forth by the Trial Court in its November 13, 2023 Statement of Reasons for its denial of Allergan's Motion for Reconsideration:

> "A failure to recall claim sounds under section b of N.J.S.A. 2A:58C-2 which provides for liability based on a manufacturer's or seller's failure to warn. Finegold v. Gen. Motors Co., 2021 WL 2810091, at Page 4 (D.N.J. June 30, 2021). Defendant cites Finegold in arguing that as a matter of law Plaintiff's claim for failure to recall is preempted by the PLA despite the case being unpublished and not binding on this Court. See Def. Br. Page 22. In Finegold the failure to recall claim (Count Four) was its separate claim for relief outside the claim under the PLA (Count Two). In Plaintiff's Complaint the failure to warn claim is alleged under or pursuant to the PLA. Count Two alleges: "Defendants intentionally and with wanton and willful disregard of persons who foreseeably might be harmed, recklessly and maliciously failed to recall the Subject Product in the United States [rest omitted]." See Pl. Compl. ¶ 48 Plaintiff raised two separate claims, one under the PLA and one for failure to recall as its own claim like as in Finegold, then

> Defendant might be correct in arguing that the failure to recall claim would be inert as its own claim and would be subsumed into the PLA claim. However, in the present matter Plaintiff argues one indivisible Count that they are entitled to relief under the PLA because of Defendant's failure to warn among other allegations under the PLA. If the Court followed Defendant's reasoning, they would strike Plaintiff's request for relief under the PLA altogether. Defendant's argument seeking dismissal of Count Two under the PLA for alleged failure to warn is denied." (Da0852-Da0853)

Plaintiff's claim is not for a "failure-to-timely-recall," but rather for failure to warn – post sale pursuant to N.J.S.A. Sec. 2A:58C-4. Ms. Beavan raised the issue of Allergan's failure to warn – post sale in her Complaint, filed on November 5, 2020, at paragraphs 39, 44, 45, 46, 47, 48 and 49. (Da0001 at ¶¶ 39, 44, 45, 47, 48 and 49) Ms. Beavan also addressed this argument in both of her Oppositions to Allergan's Motions for Summary Judgment. (Pa001, ¶¶ 9, 18-22, 24, 25, 31, 34-36; Pa037, ¶¶ 9, 18-22, 24, 25, 31, 34-36) Additionally, both of Ms. Beavan's Responsive Statements of Undisputed Material Facts address Allergan's abrogation of its duty to warn **after** it became aware of the defects on June 21, 2018. (Pa029, ¶¶ 14, 25, 29, 51-53; Pa066, ¶¶ 14, 25, 29, 51-53)

C. Allergan's Failure to Warn Post-Sale Was Both a Direct and Proximate Cause of Ms. Beavan's Injury. [ISSUE RAISED AND DECIDED (Pa129-Pa133; Da0823; Da0825-0829)]

Allergan's failure to warn physicians, including Ms. Beavan's ophthalmologist, Dr. Phillips, was a direct and proximate cause of Ms. Beavan's injuries.

On November 6, 2018, when Dr. Phillips injected Ms. Beavan's left eye with the defective Ozurdex, he was not aware of the defects with Ozurdex, nor of the risk of a silicone particulate being injected. (Pa129-Pa130) Allergan had not informed Dr. Phillips of the risks or defect, despite the fact that Dr. Phillips would have expected to be informed of this new, post May 2018 package insert danger and defect. (Pa132-Pa133) Had Dr. Phillips known of the risks of injecting a silicone particulate due to the Ozurdex defect, he would not have administered the Ozurdex to Ms. Beavan on November 6, 2018. (Pa130-Pa131)

V. ALLERGAN DISINGENUOUSLY ARGUES THAT IT NEEDED FDA APPROVAL TO WARN OF OR RECALL ITS ADMITTEDLY DEFECTIVE OZURDEX APPLICATORS. [ISSUE RAISED AND DECIDED (Pa003-Pa0012; Pa024-Pa026; Pa033-Pa036; Da0852-Da0853)]

A. FDA Approval Was Not Needed to Warn Health Care Providers and Consumers of the Dangerous and Defective Ozurdex Applicators that were in Continued Use by Health Care Providers Despite Allergan's Knowledge of their Defect. [ISSUE RAISED AND DECIDED (Pa003-Pa012; Pa024-Pa026; Pa033-Pa036: DA0852-Da0853)]

Allergan did not raise this argument in its Motions for Summary Judgment or Motion for Reconsideration. Instead, Allergan danced around the issue by referencing the FDA's **non-binding** Regulatory Procedures Manual, and

paragraphs 66-75 of the report of its expert, Dr. Arrowsmith. However, nowhere in the Regulatory Procedures Manual, nor in Dr. Arrowsmith's report, is it stated that FDA approval was needed to warn physicians or to issue a recall. For the first time, Allergan now claims that "Hence, Allergan could not, without FDA's authorization, engage in an ***earlier*** U.S. recall or **earlier** communication to U.S. healthcare providers." (Opening Brief, p. 21. Emphasis in original.)

In fact, the opposite is true. Allergan was authorized to warn health care providers in the United States - and did not need FDA approval to warn health care providers - of the defective Ozurdex applicators with the silicone particulate defect. Moreover, Allergan did not need FDA approval to recall its defective Ozurdex applicators. "A firm may decide on its own volition and under any circumstances to remove or correct a distributed product." 21 C.F.R. §7.46(a). A firm "need not delay initiation of its product removal or correction" pending the FDA's review. 21 C.F.R. §7.46(b).

Even Allergan's own "regulatory expert", Janet Arrowsmith, M.D. acknowledged in her report that FDA guidance or approval was not required. Dr. Arrowsmith cites in support of her opinions, the FDA publication "Guidance for Industry and FDA Staff, Dear Health Care Provider letters: Improving Communication of Important Safety Information." (Da0620) In that publication, the FDA makes clear that: "FDA's guidance documents, including this guidance,

do not establish legally enforceable responsibilities….The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required."[1] (Da0619; Da0623) Moreover, the phrase ***"Contains Nonbinding Recommendations"*** is printed at the top of every page of the FDA Guidance. [(Da619-Da639) Emphasis in original.]

There was no justification for Allergan's failure to warn physicians in the U.S., or to delay issuing a recall, months after Allergan became aware of the defect. Allergan did not need authorization from the FDA to act as a reasonably prudent manufacturer/distributor and communicate with U.S. healthcare providers regarding the Ozurdex applicator and silicone particulate defect. Accordingly, Allergan's failure to timely warn health care providers of the dangerous and defective Ozurdex applicator was clearly in violation of the New Jersey Product Liability Act Sec. 2A:58C-4 re: obligation to warn of the dangerous defects that Allergan discovered *after* the Ozurdex left its custody, and *after* it issued the May 2018 package insert. The dangerous defects were known to Allergan months before Ms. Beavan was injured by the defective Ozurdex on November 6, 2018.

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[1] **"Guidance for Industry and FDA Staff, Dear Health Care Provider letters: Improving Communication of Important Safety Information**" Da0620. The phrase ***"Contains Nonbinding Recommendations"*** is printed at the top of every page of the FDA Guidance. [Exhibit 4 throughout. Emphasis in original.]

B. Allergan's Duty to Warn Post-Sale is Not Preempted by Federal Law [ISSUE RAISED AND DECIDED (Pa003-Pa012; Pa024-Pa026; Pa033-Pa036; DA0852-Da0853)]

Allergan's failure to warn post-sale of the defective Ozurdex applicators is not preempted by federal law as alleged by Allergan in its Opening Brief. Federal law does not require that the manufacturer of a drug obtain prior approval from the Food and Drug Administration (FDA) before warning of a known or knowable danger. In fact, as briefed previously herein, the opposite is true. 21 C.F.R §7.46(a) and §7.46(b). Feldman v. Lederle Laboratories, a Div. of American Cyanamid Co., 125 N.J. 117 (1991), on remand 257 N.J. Super. 163, certiorari denied 112 S.Ct. 3027, 505 U.S. 1219. Federal law did not preempt state law liability of manufacturer for failure to warn that drug could cause tooth discoloration. Id.

Allergan citation to *In re Hum. Tissue Prod. Liab. Litig.*, 488 F.Supp.2d 430, 432-433 D.N.J. (2007) fails to support its argument. The case does not state that N.J.S.A. Sec. 2A:58C-4 is preempted by federal law. The court *In re Hum. Tissue Prod. Liab. Litig.* also did not prevent the manufacturer from notifying a class of consumers about certain dangers about a product. In fact, it was noted in the *In re Hum. Tissue* case that "Defendants have undertaken certain measures to notify class members about the potential dangers arising from their receipt of unscreened tissue." Id. at 431. There was no requirement

set forth in the case that the FDA approve of any notice to physicians or patients or others. Id. In addition, Ms. Beavan's claim pertains to post sale failure to warn and not communications related to recalls.

Allergan also cites to Clark v. Activas Group hf, 567 F.Supp.2d 711, 714 (D.N.J. 2008) in support of its position. Again, the court in this case did not preclude a manufacturer from notifying consumers regarding a potential danger related to a product. The Clark case also did not federally preempt N.J.S.A. Sec. 2A:58C-4 and the requirement to warn post sale. Instead, the case involved the plaintiff consumers' request that the court order defendant manufacturer and distributor of a drug already recalled by the FDA to provide urgent notice to unnamed class members and physicians. Id.

The R.F. v. Abbott Labs., 162 N.J. 596, 618-20 (2000) case cited by Allergan does not preempt N.J.S.A. Sec. 2A:58C-4. Instead, the Court held that it should deny Abbott's claim that it was immunized from state tort law liability for failing to warn users of its blood test regarding the devastating consequences that could result from a false negative test reading of HIV contaminated blood. Id. at 655. The R.F. v. Abbott case, as well as the other cases set forth herein, do not support Allergan's arguments and certainly do not somehow lessen or remove Allergan's obligations to act like a reasonably prudent manufacturer/distributor pursuant to N.J.S.A. Sec. 2A:58C-4 and warn of the

dangerous defects that it learned about in June 2018, after the May 2018 package insert.

VI. ALLERGAN'S ARGUMENT THAT IT RECALLED OZURDEX LOTS BASED ON PRODUCT QUALITY (NOT SAFETY) IS UNFOUNDED. [ISSUE RAISED (Pa005-Pa007; Pa009, Pa011)]

Allergan's December 28, 2018 U.S Recall sets forth the Health Hazards from the defective Ozurdex, including a "corneal reaction," and further states that "transient visual disturbance or intraocular inflammatory reaction in sensitive patients are potential **safety risks."** [(Da256-Da0257) Emphasis added.] The fact that the Ozurdex applicator was not designed to dispense a silicone particulate – into a patient's eye - clearly created a health and safety concern that required notifying healthcare providers in the U.S., just as Allergan had done in forty (40) other countries. Thus, Allergan is in clear violation of N.J.S.A. Sec. 2A:58C-4.

VII. PLAINTIFF PREVIOUSLY AND EXTENSIVELY OPPOSED ALLERGAN'S PREMPTION ARGUMENTS [ISSUE RAISED (Pa001; Pa026; Pa029 at ¶¶51-53; Pa066 at ¶¶51-53)]

Ms. Beavan did in fact previously oppose Allergan's misplaced preemption argument regarding warnings. In Plaintiff's opposition to Allergan's Motion for Summary Judgment, Plaintiff states: "In response to Allergan's argument regarding the presumption of adequacy of its "approved" Ozurdex warnings, (motion, pages 19-21) such argument is not applicable here. The

presumption under the Products Liability Act of an adequate warning based on compliance with Food and Drug Administration (FDA) labeling regulations will be deemed rebutted based upon the following: (i) deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects of the drug, or (ii) manipulation of the post-market regulatory process. Bailey v. Wyeth, Inc., 424 N.J. Super. 278 (2008), affirmed 422 N.J. Super. 360, certification denied 211 N.J. 274." (Pa001, Pa026)

Moreover, both of Plaintiff's Responsive Statements of Undisputed Material Facts, set forth the fact that 21 C.F.R. §7.46(a)&(b) expressly permit a manufacturer/distributor like Allergan to issue warnings and recalls without prior FDA approval. (Pa029, ¶¶ 51-53; Pa066, ¶¶ 51-53) Contrary to the shell game Allergan repeatedly plays, Plaintiff is not asserting a state law recall claim for "failure to timely recall" or "failure to timely warn of a recall." Instead, Plaintiff is asserting a claim for Allergan's violation of the post-sale duty to warn of the defective Ozurdex applicators given Allergan's six (6) month delay in doing so. Accordingly, Allergan's argument that Plaintiff has conceded summary judgment on a warnings preemption theory is entirely baseless.

VIII. PLAINTIFF'S EXPERT WITNESS TESTIMONY IS ADMISSIBLE PURSUANT TO N.J.R.E. 702 AND 703 AND PREVAILING CASE LAW. [ISSUE RAISED AND DECIDED (Pa047, ¶33 - Pa057, ¶71; Da0790-Da0792; Da0794-Da0798, Da0819-Da0829)]

"As this Court has noted, 'we apply [a] deferential approach to a trial court's decision to admit expert testimony, reviewing it against an abuse of discretion standard.' " Townsend v. Pierre, 221 N.J. 36, 52-53 (2015). The admission or exclusion of expert testimony is committed to the sound discretion of the trial court. Townsend v. Pierre, supra, 221 N.J. at 52-53; State v. Berry, 140 N.J. 280, 293 (1995); Carely v. Lovett, 132 N.J. 44, 64 (1993).

N.J.R.E. 702 and 703 set forth the analysis for the admission of expert witness testimony. N.J.R.E. 702 states the following:

"(1) the intended testimony must concern a subject matter that is beyond the ken of the average juror; (2) the field testified to must be at a state of the art such that an expert's testimony could be sufficiently reliable; and (3) the witness must have sufficient expertise to offer the intended testimony."

N.J.R.E. 703 provides that expert opinion be grounded in "'facts or data derived from (1) the expert's personal observations, or (2) evidence admitted at the trial, or (3) data relied upon by the expert, which is not necessarily admissible in evidence, but which is the type of data normally relied upon by experts.'" Townsend at 52-55.

The rule does not mandate that an expert organize or support an opinion in a particular manner that opposing counsel deems preferable. Townsend, supra, 221 N.J. at 52-55. An expert's proposed testimony should not be excluded

merely "'because it fails to account for some particular condition or fact which the adversary considers relevant.'" Creanga v. Jardal, 185 N.J. 345, 360 (quoting State v. Freeman, 223 N.J. Super. 92, 116 (App.Div. 1988), certify. denied, 114 N.J. 525, 555 (1989). The expert's failure "to give weight to a factor thought important by an adverse party does not reduce his testimony to an inadmissible net opinion if he otherwise offers sufficient reasons which logically support his opinion." Rosenberg v. Tovarath, 352 N.J. Super. 385, 402 (App.Div. 2002), citing Freeman, supra, 223 N.J. Super. at 115-116. Such omissions may be "a proper 'subject of exploration and cross-examination at a trial.'" Id., quoting Rubanick v. Witco Chem. Corp., 242 N.J. Super. 36, 55, (App.Div. 1990), modified on other grounds, 125 N.J. 421 (1991); see also State v. Harvey, 151 N.J. 117, 277 (1997) The weight of the evidence is for a jury to decide. Id. at 277. "An expert witness is always subject to searching cross-examination as to the basis of his opinion." Id.

As is clear by the facts, the case law and the rulings by the Trial Court, Plaintiff's experts have based their opinions regarding the defective product causing Plaintiff's injuries on facts and data that are clearly admissible under N.J.R.E. Secs. 702 and 703.

IX. PLAINTIFF HAS PRESENTED EXTENSIVE EXPERT WITNESS TESTIMONY TO CREATE A TRIABLE ISSUE OF MATERIAL FACT ON CAUSATION. [ISSUE RAISED AND DECIDED (Pa047, ¶33 – Pa057, ¶71; Da0790-Da0792; Da0794-Da0798; Da0819-Da0829)]

Dr. Phillips and Dr. Lalezary testified that the Ozurdex applicator used to administer the steroid pellet to Plaintiff on November 6th injected a silicone particulate that caused Ms. Beavan's blindness. (Da0699-Da0700; Pa127; Pa134-Pa139) was defective with the silicone particulate and that such defect likely incited the retinal detachment that occurred within a week of the treatment. Dr. Phillips testified that the silicone particulate caused persistent inflammation and corneal edema in Ms. Beavan's left eye, which was an adverse effect identified in Allergan's December 28, 2018 Urgent Drug Recall. (Da0256-Da0257; Pa127; Pa134-Pa139) Further, Dr. Lalezary testified that the silicone particulate caused a mechanical traction on the retina leading to detachment which required surgery that resulted in the Ozurdex steroid entering Ms. Beavan's anterior chamber, thereby causing her to become blind. (Da0695-Da0696)

In addition to the arguments hereinabove, our courts have established that proximate cause questions should ordinarily be decided by a jury and not at the Summary Judgment stage. Sarris v. A. A. Pruzick & Co., 37 N.J. Super. 340 (App. Div. 1952) and Gardner v. Pawliw, 150 N.J. 359 (1997).

A. Plaintiff has Established General Causation [ISSUE RAISED AND DECIDED (Pa047, ¶33 – Pa057, ¶71; Da0790-Da0792; Da0794-Da0798; Da0819-Da0829)]

On the issue of general causation, Allergan's own recall notice contains the warnings of intraocular inflammatory reaction, and corneal reaction (if the Ozurdex migrates to the anterior chamber as in Ms. Beavan's case, as potential "Health Hazards" caused by the defective product. (Da0256-Da0257) Allergan has conceded general causation through its recall.

Plaintiff's Board-Certified Ophthalmology expert, Dr. Lalezary received his Medical Degree from the University of California San Diego School of Medicine in 2006. From 2006 to 2007, he performed a Transitional Internship at Harbor-UCLA County Hospital, Los Angeles. Thereafter, Dr. Lalezary performed and completed an Ophthalmology Residency from 2007 to 2010 at Vanderbilt Eye Institute. From 2010 to 2012, he performed and completed a Vitreo-Retinal Surgical Fellowship at Vanderbilt Eye Institute. Dr. Lalezary has been Board-Certified in Ophthalmology by the American Board of Ophthalmology since 2012. He has written twelve peer reviewed published articles and two book chapters and has lectured extensively in the field of ophthalmology. (Da0340-Da0343)

Dr. Lalezary has been administering Ozurdex to patients regularly every three to four months since 2010. (Pa115-Pa117) Accordingly, based upon his

education, training, research and experience, Dr. Lalezary knows and understands the "mechanisms and issues with regard to causation as it pertains to Ms. Beavan's left eye injury, including, but not limited to her loss of vision in her left eye." (Da0337) Dr. Lalezary received and reviewed the following materials: Ms. Beavan's medical records from William B. Phillips, MD, the Retina Group of Washington, and Dr. Jonathan Solomon, deposition transcripts of Alison Beavan, William B. Phillips, MD, Jonathan Solomon, MD and Allergan's, Tracy Founds (formerly Keough), Allergan's Benefit Risk Assessment for Ozurdex, Allergan's Field Alerts for Ozurdex, Allergan's recalls for Ozurdex worldwide, and the December 28, 2018 Urgent Drug Recall for Ozurdex in the United States. (Da0337)

After a complete and thorough review, Dr. Lalezary came to the following opinions to a reasonable degree of medical certainty: A. The November 6, 2018 Ozurdex injection resulted in a silicone particulate being unintentionally dispensed from the defective actuator; B. The silicone particulate likely migrated to the anterior chamber along with the Ozurdex steroid pellet; C. The defective Ozurdex with silicone particulate being injected into Ms. Beavan's left eye likely incited retinal detachment which occurred within a week of treatment. Following retinal detachment surgery, the anterior chamber migration of the silicone particulate was a substantial factor in causing significant vision loss and

the need for multiple subsequent surgeries in the left eye. The silicone particulate caused excessive ocular inflammation in Ms. Beavan's left eye and corneal edema, both of which were adverse effects identified in Allergan's Ozurdex recall. Despite corneal surgery, compounded damage from retinal detachment likely limited potential for recovery resulting in Ms. Beavan's loss of vision; D. Dr. Phillips complied with the requisite standard of care at all times with regard to his treatment of Ms. Beavan. He was not informed appropriately in a timely manner of the defective Ozurdex until early January, 2019; E. Dr. Solomon complied with the requisite standard of care at all times with regard to his treatment of Ms. Beavan. (Da0335-Da0339)

At deposition, Dr. Lalezary explained in detail the mechanism of the defective Ozurdex actuator with the injected silicone particulate causing Ms. Beavan to become blind in her left eye as follows:

> Q. Okay. So you said, then, there appeared to have been some concern about the Ozurdex pellets not being removed from the anterior chamber; is that correct?
>
> A. Yes.
>
> Q. Why is that concerning?
>
> A. That's known to damage the cornea. It's a known complication with anterior migration of the Ozurdex pellet.
>
> Q. What's the known complication?
>
> A. That it could damage the cornea.

Q. You mean the Ozurdex pellets being in an anterior chamber?

A. Yes.

Q. It's a known complication, which means it's well known among ophthalmologists?

A. Yeah, and it's in the labeling.

Q. Okay. And also in this first paragraph here, you say that "Based on your education, training, research, and experience, you know and understand the mechanisms and issues with regard to causation as it pertains to Ms. Beavan's left eye injury."

Q. So what do you mean by "mechanisms and issues with regard to causation"?

A. So part of my expertise is that I understand the physiology of the conditions that she dealt with. And so I can explain what mechanism was involved in her condition.

Q. When you say "condition," what are you referring to specifically?

A. She has an underlying condition of noninfectious uveitis, and she developed retinal detachment. So those two conditions are from different pathophysiologies and different mechanisms of disease. Uveitis is an inflammatory condition, where the retinal detachment is usually a tractional mechanical mechanism of onset.

Q. What is your opinion as to what caused Ms. Beavan's left eye injury?

A. So she had -- the particulate caused inflammation and traction in her peripheral retina that induced a retinal break and led to her retinal detachment. And subsequently, she had detachment repair that led to the anterior migration of the Ozurdex pellet. That compromised her vision because a patient with uveitis that develops

a retinal detachment has a poor prognosis for recovery and vision. (Da0695-Da0696)

Allergan's Ophthalmology Expert, Dean Eliott, M.D., agrees with plaintiff's general causation position that traction from a particle can, in fact, cause a retinal detachment. Dr. Eliott testified that "[A]ny traction or pulling or pushing on the vitreous can cause a retinal tear. The vitreous is like an egg white, raw egg white and it's gooey. So if a needle goes through and squirts out a drug or a device, that could potentially push the vitreous, and the vitreous can pull a retinal tear since the retina is in close proximity to the pars plana where you put the needle through, and it's peripheral retinal tears that result in retinal detachment." (Da0709; Da0711-Da0712) However, while Dr. Eliott testified that he felt the 300 micron silicone particulate was not large enough to cause traction and a retinal detachment, Dr. Eliott admitted that he is not aware of any literature regarding the minimum size a particle needs to be to cause traction and a retinal detachment. (Da0709; Da0713-Da0714) Further, Dr. Eliott admitted that he does not know what the smallest size particulate would be to cause traction resulting in a retinal detachment. (Da0709; Da0713-Da0714)

B. Plaintiff Has Established Specific Causation. [ISSUE RAISED AND DECIDED (Pa047, ¶33 – Pa057, ¶71; Da0790-Da0792; Da0794-Da0798; Da0822-Da0829)]

Dr. Lalezary testified to a reasonable degree of medical certainty as follows:

> Q. Is it your opinion to a reasonable degree of medical certainty that on November 6, 2018, with the injection of the Ozurdex, that the silicone particulate was injected in Ms. Beavan's eye that caused the retinal detachment, which required, then, the surgery that then resulted in the migration of the Ozurdex steroid pellet into her eye as well as the RETISERT detachment, and that ultimately led to her blindness in the left eye?
>
> A. Yeah, that summarizes.
> [Objection by defense counsel.]
>
> THE WITNESS: That summarizes the sequence of events that I agree with happened.
>
> Q. And then is it your opinion to a reasonable degree of medical certainty that the silicone particulate was injected into her eye?
>
> A. Yes.
>
> Q. And is it your opinion to a reasonable degree of medical certainty that the silicone particulate being injected into Ms. Beavan's eye on November 6, 2018, was a substantial factor and a cause of her blindness?
> [Objection by defense counsel.]
>
> A. Yes. (Da0699-Da0700)

Significantly, Allergan's ophthalmology expert, Dr. Eliott agrees Ms. Beavan's corneal degeneration is the result of "migration of the Ozurdex® implant (or pellet) from the vitreous cavity to the anterior chamber." (Da0346; Da0370) This is the exact same mechanism of injury testified to by Dr. Lalezary, except that Dr. Lalezary's testimony substantiates that the silicone particulate

caused the retinal detachment, that led to the need for surgery and the eventual migration of the Ozurdex steroid into Ms. Beavan's anterior chamber.

Plaintiff's treating and board-certified ophthalmologist expert, Dr. Phillips, testified in deposition that the November 6, 2018 Ozurdex injection that he administered from the subsequently recalled lot contained the silicone particulate that caused Ms. Beavan to become blind in her left eye. Dr. Phillips received his Medical Degree in 1988 from Howard University College of Medicine. He then performed an Internship in Transitional Surgery at Howard University Hospital from July, 1988 – June, 1989. Thereafter, Dr. Phillips performed an Ophthalmology Residency at Wills Eye Hospital in Philadelphia from July, 1989 – June 1992. Dr. Phillips was then accepted into a two-year Vitreoretinal Diseases Fellowship at Wills Eye Hospital, which he successfully completed in June, 1994. Dr. Phillips has been Board-Certified by the American Board of Ophthalmology since 1993. Dr. Phillips has been the Director of the Vitreo-Retinal Fellowship Program at the Retina Group of Washington since 2000. (Da702-708)

Dr. Phillips further testified that the silicone particulate was injected into Ms. Beavan from the Ozurdex applicator on November 6, 2018. The silicone particulate caused a corneal reaction, corneal edema, corneal cloudiness,

persistent inflammation not controlled by steroids, which all caused Ms. Beavan to lose vision in her left eye. (Pa127; Pa134-Pa139)

Ms. Beavan's treating cornea specialist, Michelle Tarver, M.D., also agrees that the migration of the Ozurdex steroid into Ms. Beavan's anterior chamber and caused Ms. Beavan's injuries. On February 23, 2019, after performing a complete examination and assessment, Dr. Tarver documented that Ms. Beavan had received Ozurdex and suffered a retinal detachment. Thereafter, Ms. Beavan underwent a vitrectomy following which it was observed that the "Ozurdex had migrated to the anterior chamber and her cornea was swollen." Dr. Tarver concluded that Ms. Beavan had suffered "Corneal Degeneration, 2nd [secondary] to migrated Ozurdex OS [left eye]. It is likely that the corneal endothelium has undergone necrosis from toxic levels of steroid in the AC [anterior chamber] from the Ozurdex." (Da0690)

Lastly, the 300 micron silicone particulate was either aspirated out during the November 14, 2018 vitrectomy or remains embedded in scar tissue in Ms. Beavan's eye. As a result of Allergan's intentional concealment of the defect until December 28, 2018, Dr. Phillips could not have known or otherwise been aware to look for the silicone particulate during the November 14, 2018 vitrectomy surgery.

Dr. Lalezary testified that the offending silicone particulate is either still lodged in a portion of Ms. Beavan's eye "that becomes scarred and ingrained into her tissue," or that it was aspirated during the November 14, 2018 vitrectomy surgery. (Da0694; Da0697-Da0698) Allergan's expert agrees, and testified that "it is possible that it could have been sucked out," or missed during the vitrectomy surgery (Pa98; Pa103-Pa104) Dr. Eliott also agreed that the particulate could still be in Ms. Beavan's eye and not be visible to her ophthalmologists. "If it's off in the corner in one of the nooks and crannies, you won't be able to see it." Dr. Eliott added: "If it's way out in the crevices in the corner, yes, you wouldn't be able -- you will not be able to." (Pa98, Pa101-Pa102)

Accordingly, Allergan's claim that no one has seen the silicone particulate is a red herring created by Allergan's active concealment of the defect until well after the procedure.

C. Neither of Plaintiff's Experts Offer Net Opinions.[ISSUE RAISED AND DECIDED (Pa047, ¶33 – Pa057, ¶71; Da0790-Da0792; Da0794-Da0798; Da0819-Da0829)]

The "net opinion" rule is a "corollary" of N.J.R.E. 703, State v. Townsend, 186 N.J. 473, 494, 897 A.2d 316 (2006), which provides that an expert's testimony "may be based on facts or data derived from (1) the expert's personal observations, or (2) evidence admitted at the trial, or (3) data relied upon by the

expert which is not necessarily admissible in evidence but which is the type of data normally relied upon by experts in forming opinions on the same subject."

The net opinion rule is not a standard of perfection." Townsend v. Pierre, 221 N.J. 36, 54 (2015) An expert may ground an opinion in his or her personal experience and training. State v. Townsend, 186 N.J. 473, 495 (2006) (finding the expert's opinion was not a net opinion due to her "education, training, and most importantly, her experience"); See also Glowacki v. Underwood Mem'l Hosp., 270 N.J. Super. 1, 16-17 (App. Div. 1994) (declining to strike an expert's testimony as a net opinion as "[a]ny shortcoming in his method of analysis was explored and it was for the jury to determine the weight his opinion should receive").

Here, Ms. Beavan's expert witnesses on causation have set forth the "why and wherefore" of their opinions and not just the mere conclusions. The testimony has been given in terms of reasonable medical certainty or probability. Indeed, the expert witness testimony is supported by Ms. Beavan's medical records from Dr. Phillips, the Retina Group of Washington and Dr. Jonathan Soloman; deposition transcripts of Ms. Beavan, Dr. Phillips, Dr. Solomon and Allergan's Tracy Founds and Rory Turk; Allergan's Benefit Risk Assessment for Ozurdex; Allergan's Field Alerts for Ozurdex; Allergan's worldwide recalls; the December 28, 2018 Urgent Drug Recall for Ozurdex in the United States; as

well as the experts' own knowledge and experience. Plaintiff's experts have not only set forth their conclusions, but have also testified to the reasons for reaching their conclusions. Any alleged inconsistencies in their testimony goes to the weight to be given by the jury and not to the admissibility of the expert witness opinions.

Allergan, without citing to any supporting law, claims that Plaintiff has a duty "of conclusively negating" any other cause of Ms. Beavan's injuries. However, Allergan's own exhibits establish that Dr. Lalezary was aware of and considered all of the general potential risk factors, including prior surgeries, Retisert implant, uveitis, cataracts, smoking, trabculectomy and vitrectomy, before ruling them out in Ms. Beavan's specific case. (Da0150, Da0177-Da0183)

Allergan had also not previously raised its "this-time-is-different" argument in the trial court. (Opening Brief, page 31) Allergan cites to Zaza v. Marquess, 144 N.J. 34, 49 (Supreme Court of New Jersey 1996), but fails to include a key part of the quote from the case, i.e., "An inference of defectiveness may not be drawn from the mere fact that someone was injured. Liability should be imposed only when the manufacturer is responsible for the defective condition." Regardless, Plaintiff is not making such an argument. Instead, Plaintiff's causation argument is supported by detailed expert testimony with

facts and science, the opinions of her treating physicians, Allergan's own admissions, and the testimony of Allergan's experts, Dr. Eliott and Dr. Arrowsmith.

CONCLUSION

Plaintiff, Alison Beavan, respectfully submits that multiple triable issues of material fact exist herein. Plaintiff further submits that the subject applicator contained an obvious and admitted manufacturing defect and that Allergan's intentional failure to warn of the dangers associated with its affected applicators was a direct and proximate cause of Plaintiff's blindness. For the reasons discussed above, Plaintiff Alison Beavan respectfully requests that this Court affirm the trial court's denial of Allergan's motions for summary judgment and motion for reconsideration.

Date: April 18, 2024

Respectfully submitted,
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ALISON BEAVAN, Plaintiff-Respondent, v. ALLERGAN USA, INC., et al., Defendant-Appellant.	SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO: A-001501-23 Civil Action ON APPEAL FROM SUPERIOR COURT OF NEW JERSEY, LAW DIVISION: MORRIS COUNTY DOCKET NO. MRS-L-151-21 Sat Below: Hon. Louis S. Sceusi, J.S.C.

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PRLIMINARY STATEMENT

Plaintiff's Opposition highlights two critical points: (1) her case is premised entirely on the recall, and (2) she will contort the facts and the law in whatever way necessary to survive summary judgment.

On the first point, the Opposition underscores that Plaintiff's claims are based solely on the notion that if a product at issue was part of a recalled lot, that product must have a defect that caused the plaintiff harm. Plaintiff boldly asserts (i) the recall establishes that every single Ozurdex® unit in every recalled lot was defective and (ii) Allergan conceded general causation through its recall. That is not and cannot be the law. Unsurprisingly, Plaintiff does not cite a single case in New Jersey (or elsewhere) holding a plaintiff can meet her burden of proof by substituting a recall for admissible evidence of defect and causation. As Allergan explained, that would violate bedrock principles under the PLA and is the exact type of dangerous precedent and injustice this Court should immediately correct.

On the second point, to avoid reversal, Plaintiff plays fast and loose with the facts and law. She litters her Opposition with factual inaccuracies. Chief among them is her assertion that she does not pursue a claim for failure to timely recall. Apparently realizing such a claim is not authorized by New Jersey law and is preempted by federal law, Plaintiff attempts to disavow the plain language of her Complaint and asserts she pled a claim for failure to warn – post sale. This fallacy

is belied by Plaintiff's own Complaint:

> 48. Defendants intentionally and with wanton and willful disregard of persons who foreseeably might be harmed, recklessly and maliciously failed to recall the Subject Product in the United States even after they were certainly aware of the defect and the fact that they had recalled the same product for the same defect in twelve (12) other countries and were also aware of numerous claims and injuries relating to the Subject Product. The timeline of Defendants' intentional, wanton

Plaintiff also blatantly misrepresents Allergan's actions in the U.S. following discovery of the silicone particulate issue, asserting Allergan "did nothing" and "deliberately concealed" it. The undisputed record shows instead that Allergan worked extensively with FDA pursuant to its recall regulations and procedures, contacting FDA ***over 20 times*** to obtain authorization to send a communication to healthcare providers before FDA finally provided feedback, authorizing a ***different*** communication and strategy for a recall.

Plaintiff likewise misrepresents the law, starting with the wrong standard of review. She also wrongly claims that New Jersey law permits juries to engage in complex product-defect analyses without the aid of an expert and relies on a dissenting opinion where it suits her argument without disclosure to the Court.

These are but a few of Plaintiff's misguided efforts to avoid the actual facts and law that compel reversal of the Trial Court's misguided Orders. At bottom, Plaintiff's Opposition shows she has no viable 'failure-to-recall' claim, she lacks the mandatory expert testimony to establish a manufacturing defect in the specific

product at issue, and she cannot prove causation because her experts offer only speculative, inadmissible net opinions. Plaintiff cannot cure these deficiencies with "the recall." The Court should prevent this manifest injustice and reverse.

I. STANDARD OF REVIEW.

Plaintiff's Opposition erroneously suggests the Trial Court made factual findings that deserve deference. (Opp 15) Not true. Its summary judgment decision is reviewed de novo. (OB 16) And the standard is not whether there is the "slightest doubt" as to an issue of fact (Opp 16), but whether the evidence is "sufficient to permit a rational factfinder 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); *Scanlon v. General Motor Corp.*, 65 NJ 582, 590 n.1 (1974) (only send cases to a jury "where a reasonable man could find that a defect existed"). No rational or reasonable person could find for Plaintiff on this record.

II. PLAINTIFF'S 'FAILURE-TO-TIMELY-RECALL' CLAIM IS NOT RECOGNIZED BY NEW JERSEY LAW AND IS PREEMPTED BY FEDERAL LAW. [(Da0785; Da0816; Da0846); Court did not address preemption although it was raised in the briefing]

A. The PLA Does Not Recognize the 'Failure-to-Timely-Recall' Claim Pled in the Complaint.

Plaintiff concedes the PLA does not authorize a 'failure-to-timely-recall' claim. Rather than withdraw the untenable claim, she attempts to recast it as a post-sale failure-to-warn claim as if the language in the Complaint did not exist. The

very paragraphs she cites for her purported post-sale failure-to-warn claim (Opp 25) unambiguously demonstrate the claim she pled is for a failure to timely recall. Leaving aside the conclusory boilerplate allegations (Da0001, ¶¶ 39, 44-46), the facts alleged ***specifically for this case*** in paragraphs 47, 48, and 49 indisputably plead Allergan "failed to recall" Ozurdex® soon enough (*id.*, ¶¶ 47-49). Dispositively, ***none*** of the paragraphs cited by Plaintiff allege Allergan should have, but did not, provide a warning ***post sale***.

B. Federal Law Preempts Both Plaintiff's 'Failure-to-Timely-Recall' Claim and Any Unpled Claim that Allergan Should Have Provided a Post-Sale Warning About a Recall Issue.

Plaintiff indisputably waived any opposition to federal preemption by failing to address the issue below and is thus precluded from opposing it now.[1] (OB 14, 22) She contends she "extensively opposed Allergan's preemption arguments" (Opp 31), but this is yet another falsehood. She cites only her opposition to Allergan's different argument about the presumption of adequacy for FDA-approved labeling. (Opp 31-32) It is too late now for Plaintiff to oppose federal preemption. That should end the analysis.

The result would be the same even if Plaintiff had pled a post-sale failure-to-warn claim. That claim would still be preempted because a post-sale warning about

[1] Simply stated, federal law governs the entire field of prescription drug recalls, impliedly preempting state-law claims seeking to impose liability for not recalling

a recall issue ***constitutes a recall action***, and drug recalls ***and related communications*** are governed exclusively by federal law. (OB 6, 20-22) Plaintiff does not and cannot deny that federal law occupies the entire field of drug recalls; state law has no place and cannot interfere. (OB 19-21)

This was the upshot of *In re Human Tissue Prods. Liab. Litig.*, 488 F. Supp. 2d 430, 433 (D.N.J. 2007): "Congress clearly vested FDA with the regulatory authority to assess and manage the communications regarding product recalls." It thus denied a request to order the manufacturer to provide a warning to patients not authorized by FDA, noting it "could create a potentially dangerous situation" if that warning is inconsistent with the warning FDA decides should be issued. *Id.* *Clark v. Actavis Group hf*, 567 F. Supp. 2d 711, 717-19 (D.N.J. 2008), also denied a request to order a warning not approved by FDA, similarly explaining that FDA had exclusive "authority to monitor and supervise product recalls."[2]

This Court likewise should find that state law cannot compel Allergan to provide a post-sale warning involving a recall issue unless authorized by FDA, as doing so could create a potentially dangerous situation of inconsistent warnings.

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sooner or not 'stop selling' a drug FDA allows the defendant to market. (OB 19-22); *Mutual Pharm. Co. v. Bartlett*, 570 U.S. 472, 488-90 (2013).

[2] These cases undermine Plaintiff's argument that there is no preemption because the FDA's recall procedures in its Regulatory Procedures Manual ("RPM") constitute non-binding guidance. (Opp 26-28) Regardless of the RPM's binding nature, federal law undisputedly occupies the entire field of drug recalls, leaving no room for Plaintiff's state-law claims. Plaintiff cites nothing to the contrary.

(Da0258, ¶¶ 66, 72-73) That is why the comprehensive federal regulatory scheme occupies the entire field of drug recalls, including communications/warnings about recall issues. State law has no place and cannot interfere with or stand as an obstacle to implementing the federal scheme. Hence, any state-law claim that Allergan should have provided a warning about the recall issue not authorized by FDA is preempted. *R.F. v. Abbott Labs.*, 162 N.J. 596, 618-26 (2000), held such failure-to-warn claims are preempted where FDA regulations/decisions comprehensively govern the matter. Plaintiff's assertion that *R.F.* rejected preemption is based misleadingly on her cite to the decision's ***dissent***. (Opp 30)

Plaintiff tries to get around this law by arguing her claim does not pertain to "communications related to recalls." (Opp 30) Tellingly, this argument is followed by ***zero*** record citations or legal authority. It also ignores the true facts of this case (OB 5-7), where Allergan followed up over 20 times with FDA seeking approval before FDA finally provided changes to and authorized Allergan to send a recall communication that Plaintiff claims, under state law, it should have sent earlier.

Plaintiff's argument also ignores the uncontested record. The sole regulatory expert in this case, Dr. Arrowsmith, and the Allergan employee in charge of recalls, Ms. Founds, both explained that any communication about the silicone particulate issue would constitute a recall action subject to the recall regulations and guidance (OB 6, 20-22)—not the ***separate*** regulations Plaintiff cites regarding

Dear Health Care Provider ("DHCP") letters that allow voluntary communications ***outside the recall context***.[3] Given this undisputed record, Plaintiff's argument is disingenuous if not misleading.[4]

III. PLAINTIFF HAS NO PROOF THAT THE SPECIFIC PRODUCT AT ISSUE WAS DEFECTIVE. [Issue was raised (Da0785; Da0816; Da0846)]

A. Plaintiff Must Prove Defect and Causation Through Qualified and Reliable Expert Testimony.

Plaintiff does not grapple with the extensive New Jersey law cited by Allergan requiring expert testimony to establish a defect in a complex product—like a prescription drug and its delivery system—that is beyond the understanding of an average juror. (OB 24-29) Instead, she relies on cases involving simple products and defects that are a matter of common sense (like a steering wheel that locks) to argue experts are not required.[5] (Opp 20) As explained in *McMillan v.*

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[3] The undisputed record demonstrates the Guidance for Industry on DHCP letters (Opp 27) does ***not*** apply here because the three conditions for a DHCP letter are not met. (Da0258, ¶¶ 63-75) In particular, the Head of FDA's Division of Transplant and Ophthalmology Products expressly found the silicone particulate issue should be addressed "for the sake of product quality, however, ***we do not consider it to be a safety concern***." (Da0252) Allergan thus accurately stated in its Opening Brief that the recall was for product quality, not safety, concerns.

[4] Even if the law allowed Plaintiff to proceed to trial on an unpled post-sale failure-to-warn claim (it does not), the Court should still reverse on this claim because (as discussed below) Plaintiff lacks admissible evidence that the Ozurdex® she received had a defect that caused her harm. Hence, any alleged post-sale failure-to-warn could not have possibly caused her harm.

[5] Plaintiff also cites *Marci v. Ames McDonough Co.*, 211 N.J. Super. 636, 640-41 (App. Div. 1986), but that case actually held a hammer that chipped was ***not*** self-

Johnson & Johnson, 2005 WL 2000203, at *3 (D.N.J. Aug. 19, 2005), when the product is complex, a plaintiff cannot prove defect under the common-sense, circumstantial-evidence cases Plaintiff cites; a qualified expert is required.

Plaintiff argues this situation is different because the recall constitutes "other evidence" establishing a defect,[6] but that argument ignores *Schweiger v. Standard Tile Supply, Co.*, 2019 WL 5783478, at *3-4 (N.J. Super. App. Ct. Nov. 6, 2019), which held discontinuation of a complex product did not dispense with the need for expert testimony to prove the product is defective. It also ignores the litany of cases here and around the country holding recalls are not proof of defect. (OB 28)

The determination of whether the specific Ozurdex® unit at issue had a manufacturing defect is far from a matter of common sense. It involves complex issues concerning FDA-approved manufacturing specifications, what constitutes a deviation under the product's regulatory submissions for approval, and biomedical principles that are unquestionably beyond the ken of an average juror. Plaintiff's Opposition concedes she has no expert to establish a manufacturing defect in the Ozurdex® at issue. This alone dooms her entire case.

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evidently defective and the plaintiff ***needed*** expert proof that the hammer's risks outweighed its utility and that there was a safe and reasonably feasible alternative.

[6] While Plaintiff asserts her evidence is not all based on the recall (Opp 20), she cites nothing apart from recall-related facts and documents.

B. The Trial Court Wrongly Denied Summary Judgment Despite Plaintiff's Complete Lack of Proof of a Manufacturing Defect.

Plaintiff's Opposition doubles down on the Trial Court's flawed finding that Allergan's witness, Ms. Founds, admitted the product deviated from performance standards and was thus defective. (Opp 18) Plaintiff ignores two important issues. First, Ms. Founds testified only to the hypothetical: ***if*** an Ozurdex® unit generated a 300-micron silicone particulate, it would deviate from performance standards; she never testified the Ozurdex® at issue generated such a particulate. (OB 15, 26)

Second, Plaintiff ignores that Ms. Founds was not designated by Allergan to testify on manufacturing performance standards and Plaintiff failed to establish she was qualified to testify on that topic. (OB 15, n.8) Instead, the Allergan witness designated and qualified to speak to that issue, Mr. Turk, testified a 300-micron silicone particulate would ***not*** deviate from performance standards. (OB 26, n.15) Hence, the only witness competent to testify on this issue testified a 300-micron particulate does not deviate from the standards—and is thus not defective.

Contrary to Plaintiff's argument, Allergan's recall of certain Ozurdex® lots due to the possibility that a very small number of units in those lots generated a silicone particulate is not a judicial admission that the Ozurdex® unit at issue was one of the few that generated a particulate. Plaintiff's Opposition acknowledges (Opp 20) but never disputes the law in New Jersey (and around the country) cited by Allergan (OB 28) holding the fact that a particular product is part of a recalled

lot is not competent evidence that the specific product was affected by the issue prompting the recall, much less that the product was defective.

Consistent with this established law, the evidence is that ***only 2.2%*** of units in Plaintiff's lot had the issue prompting the recall.[7] This undisputed fact requires summary judgment for Allergan, as no "reasonable man could find [by a preponderance of evidence] that a defect existed" based on only a 2.2% chance. *Scanlon*, 65 NJ at 590 n.1. Although Plaintiff asserts she received one of those rare units affected by the recall issue (Opp 8), that assertion is unsupported by ***any*** record citation.

Finally, Plaintiff argues she has sufficient circumstantial evidence of defect. She does not deny, however, this would be the first time a New Jersey appellate court would allow a plaintiff in a prescription drug case to prove a manufacturing defect through circumstantial evidence alone. Plaintiff cites no precedent.

Even if New Jersey law allowed Plaintiff to prove a defect in this complex product through circumstantial evidence without experts (it does not), Plaintiff's proof falls well short. Plaintiff generally refers the Court to her 71-paragraph statement of facts filed below without identifying what the evidence is or how it proves her case. (Opp 17) The Court should not do that work for Plaintiff because,

[7] Plaintiff does not deny that Dr. Phillips' opinion is based on his flawed belief that ***22-25%*** of units developed silicone particulates (OB 11), establishing his opinions should be excluded as based on incorrect facts and data under NJRE 703.

as Judge Posner once observed, "[j]udges are not like pigs, hunting for truffles buried in" the record. *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991); *accord Besada v. Attara*, 2016 WL 1387143, at *4 (N.J. Super. Ct. App. Div. Apr. 8, 2016) (quoting *Dunkel*).

At bottom, Plaintiff's theory is that injury in temporal proximity to use of a product from a recalled lot is sufficient to establish a defect. New Jersey law simply does not support that theory. (OB 28, 31) Moreover, under *Myrlak v. Port Authority*, 157 N.J. 84 (1999), proving defect with circumstantial evidence requires negating all other potential causes of the claimed harm other than the purported defect. Plaintiff's experts completely fail to negate the many other well-known and admitted potential causes of her claimed injuries. (OB 13-14, 29-33, 41-43) In fact, Plaintiff's experts concede her injuries could have occurred without exposure to the phantom silicone particulate no one ever saw. Dr. Phillips testified "***I don't think that the silicone particulate would be a cause of the [retinal] detachment certainly***." (Da0047, pp. 58-59) And Dr. Lalezary testified that "***she has multiple risk factors***" and "***all of those risk factors…could have led to a retinal detachment…[i]n the absence of a silicone particulate***." (Da0150, pp. 112-13)

Drs. Phillips and Lalezary did nothing to rule out the many recognized alternate causes, including Plaintiff's serious underlying inflammatory eye disease, years of surgeries and procedures, decades-long smoking history, over a dozen

intravitreal eye injections, and a ***Retisert® implant coated with silicone (10 times larger than a 300-micron silicone particulate)*** that dislodged at the same location and time as Plaintiff's retinal detachment. (OB 8, 13-14, 29-33, 41-43) Plaintiff devotes a single sentence to argue her experts were "aware of and considered" these independent causes (Opp 46), but fails to explain how they reliably ***excluded*** each when, as noted, they admit every one of the enumerated risk factors could have independently caused her injuries "***in the absence of a silicone particulate***."

IV. PLAINTIFF'S EXPERTS FAILED TO OFFER ANY GENERAL-CAUSATION OPINIONS AND THEIR SPECIFIC-CAUSATION OPINIONS ARE INADMISSIBLE "NET OPINIONS." [Issue was raised (Da0785; Da0816; Da0846)]

A. Plaintiff Lacks Proof of General Causation, Expert or Otherwise.

Plaintiff's Opposition does not deny that her experts offer no independent general-causation opinions and are unqualified to do so. The Opposition also makes clear Plaintiff has no admissible evidence a 300-micron silicone particulate is capable of causing eye inflammation, a retinal detachment, and vision loss.

For starters, Plaintiff has no evidence this medical-grade silicone is capable of causing eye inflammation. Plaintiff's Opposition ignores the only scientific study in the record—the rabbit toxicity study—that established the Ozurdex® silicone is inert and incapable of causing the inflammation Plaintiff claims. (Da0304) Plaintiff and her experts cite no contrary study or treatise. Nor does Plaintiff deny that doctors regularly use silicone to treat eye conditions because it

is inert. (Da0047, pp. 54-55) This means, even if Plaintiff could prove that the Ozurdex® unit at issue generated a silicone particulate (she cannot), she still has no ability to prove that a silicone particulate is capable of causing her injuries.

As with every other element of proof, Plaintiff and her experts just assume general causation ***based solely on the recall*** and misconstruing a recall document. But the recall is not proof of general causation. *In re: Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1094, 1285 (S.D. Fla. 2022). And Plaintiff does not deny (i) the recall document states only that inflammation is a "potential" risk to patients "sensitive" to silicone and (ii) Plaintiff's decade-long experience with her silicone-coated Retisert® implant conclusively establishes she is ***not*** sensitive to silicone. Plaintiff also does not deny that law and public policy do not support elevating statements in recall documents to evidentiary admissions. (OB 37-38)

Plaintiff also has no evidence to establish that a 300-micron particulate is capable of causing a tractional retinal detachment. After all, Dr. Phillips rejects the notion that "the silicone particulate would be a cause of the detachment," as it "can occur spontaneously…just with the injection." (Da0047, pp. 58-59) Dr. Lalezary offers no contrary study, treatise, or authority that a 300-micron particulate can cause a tractional retinal detachment.[8] Dr. Lalezary thus offers an inadmissible net

[8] Ironically, Plaintiff faults ***Allergan's*** expert for not having literature to show the minimum size a particle needs to be to cause a tractional retinal detachment. (Opp 40) This argument forgets that ***Plaintiff*** bears burden of proof.

opinion, supported by nothing but his say-so. While Plaintiff tries to give the appearance that Dr. Lalezary's opinion is reliable by citing his credentials and materials he reviewed, notably absent from that recitation is any explanation of how experience and items reviewed constitute accepted and reliable methodology to support an opinion that a 300-micron particulate is capable of causing a tractional retinal detachment.

These fundamental problems with Plaintiff's experts' opinions are not simply matters for cross-examination; they are methodological failures. *Lanzo v. Cyprus Amax Minerals Co.*, 467 N.J. Super. 476, 504-18 (App. Div. 2021). The Trial Court abdicated its gatekeeping role in allowing Plaintiff's experts' unqualified, unsupported, and unreliable general causation opinions. *In re Accutane Litig.*, 234 N.J. 340, 348, 389-90, 396-97 (2018).

B. Plaintiff's Experts Did No Work to Offer Reliable and Factually-Supported Specific-Causation Opinions.

The Trial Court also failed in its gatekeeping role by allowing Plaintiff's experts to offer specific-causation opinions despite their complete failure to rule out recognized alternate causes. As discussed, Drs. Phillips and Lalezary both admit Plaintiff had multiple recognized risk factors that explain her injuries besides the phantom silicone particulate. Neither expert did any work to reliably rule out the many alternate causes they acknowledge.

Plaintiff does not even try to defend Dr. Phillips' opinion, arguing only that

Dr. Lalezary ruled out the alternate causes. (Opp 46) But Dr. Lalezary fails to provide the "why and wherefore" for his net opinion, such as the tests, data, scientific methods, and analysis used to rule out other specific causes.[9] The pages of Dr. Lalezary's deposition Plaintiff cites discuss only his belief that the Ozurdex® was more likely the cause than Plaintiff's prior eye surgeries and procedures based solely on its "temporal relationship" to her injuries. (Da0150, pp. 82-83) But mere temporal relationship is insufficient to establish causation and survive summary judgment. *E.g.*, *Nicholson v. Bloomin Brands, Inc.*, 2018 WL 3614355, at *5-6 (N.J. Super. App. Div. July 30, 2018); *Moody v. Gen. Mills, Inc.*, 2006 WL 6872309, at *1 (D.N.J. Feb. 9, 2006) (collecting cases). Nor does that temporal relationship rule out the other recognized risk factors, including Plaintiff's serious underlying inflammatory eye condition, decades-long smoking history, silicone-coated Retisert® implant, and the injection procedure itself.

CONCLUSION

Allergan respectfully requests that this Court reverse and remand with directions to (i) exclude the unqualified and unreliable opinions of Plaintiff's experts and (ii) enter summary judgment for Allergan.

[9] Plaintiff abandons (Opp 46) her experts' 'this-time-is-different' rationale cited by the Trial Court (Da0796), apparently recognizing it is not an accepted and reliable methodology to establish causation.

Respectfully submitted,

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IN THE SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION

Docket No. A-001501-23

ALISON BEAVAN, Plaintiff-Respondent, v. ALLERGAN USA, INC.,ALLERGAN INC., F/K/A INAMED CORPORATION, ALLERGAN PLC, ABBVIE INC., AND DOES 1 THROUGH 100, INCLUSIVE Defendant-Appellant.	On Appeal from: SUPERIOR COURT OF NEW JERSEY, LAW DIVISION, MORRIS COUNTY DOCKET NO.: MRS-L-151-21 Sat Below: Hon. Louis S. Sceusi, J.S.C. Civil Action

***AMICI CURIAE* BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF DEFENDANT-APPELLANT**

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I. PRELIMINARY STATEMENT

Amici curiae agree with defendant Allergan USA, Inc. ("Allergan") that, whatever plaintiff now chooses to call her claims, they necessarily depend on a purported "duty to recall" an FDA-approved medicine that does not exist under either the common law or New Jersey's Product Liability Act ("PLA").

Throughout the proceedings in the trial court, plaintiff pursued a claim rooted in what her complaint explicitly pleaded as the defendant not issuing a recall sooner of the medicine at issue (an injectable eye treatment). That claim is necessarily premised on a purported duty to recall.

However, no "failure-to-recall" claim exists at common law, in New Jersey or elsewhere. Many states' laws reject such claims in many contexts. Nor did the PLA create any recall-based cause of action. No New Jersey precedent allows any failure-to-recall claim under the PLA. This is why, on appeal, plaintiff strenuously attempts to distance herself from what she alleged in her complaint.

Even if a failure-to-recall claim did exist, it would be preempted by federal law. A failure-to-recall claim inherently asserts, under State law, that the defendant cannot sell a product, despite the product being FDA-approved for sale. The Supreme Court, and many other courts, have held that so-called "stop selling" claims making such allegations are preempted. Once the FDA has said "yes, you can sell," state law cannot countermand the FDA's in-force decision and say "no."

Plaintiff now claims to be pursuing a manufacturing-defect claim, but she offers no non-recall-related evidence that the alleged defect – which occurred in only one of every 45 products tested (2.2%) – in fact manifested in this case. Neither her treating physician, nor her sole expert witness, points to anything other than the defendant's recall notice as a basis for claiming that the purported defect ever existed in the unit that plaintiff received. Thus, the claimed "manufacturing defect" is inseparable from the recall notice.

Plaintiff also contends that she is now pursuing a "post-sale duty to warn" claim. But once again, the purported inadequate warning is entirely subsumed by the recall. The information she claims should have been provided earlier, but was not, is precisely the information contained in the defendant's recall notice. Thus, the claimed "failure to warn," once again, is in fact an alleged failure to recall. These claims thus fail for the same reasons New Jersey has never recognized failure-to-recall claims in the first place.

II. INTEREST OF *AMICI CURIAE*

Amici curiae are the Product Liability Advisory Council, Inc. ("PLAC") and the Chamber of Commerce of the United States of America ("Chamber").

PLAC is a non-profit professional association of corporate members representing a broad cross-section of American and international product manufacturers.[1] Through PLAC, these companies

[1] A list of current PLAC corporate members is available at https://plac.com/PLAC/Membership/Corporate_Membership.aspx.

seek to contribute to the improvement and the reform of law in the United States and elsewhere, with emphasis on the law governing the liability of product manufacturers and others in the supply chain. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the nation's leading product-liability defense attorneys are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed more than 1,100 briefs as *amicus curiae* in both state and federal courts, including this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product risk management.

The Chamber is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

These organizations have members that manufacture, research, produce, and sell prescription drugs and medical devices regulated

by the FDA. They thus have a substantial interest in ensuring the proper relationship between FDA and state-law requirements. Under federal law, the FDA assesses the safety and effectiveness of prescription medical products. Once the FDA approves these products for marketing, states cannot prohibit regulated firms from doing what the FDA has approved. Only the FDA, not the State, can require a recall of an FDA-regulated product.

The common law has long reflected this reality, and has consistently refused to impose liability where, as here, a plaintiff claims that a product should have been recalled before the FDA (or some other governmental entity) has required such an action.[2]

III. LEGAL ARGUMENT

As more thoroughly detailed in Appellant Allergan's brief, the defendant discovered and notified the FDA of a problem with the eye medication Ozurdex®, in June-July 2018 (Da0229; Da0240). Defendant's FDA notice initiated a months-long process, involving more than twenty contacts with the FDA (Da0258 ¶65) that culminated in an FDA recall of several product batches on December 20, 2018 (Da0250; Da0258 ¶¶51-52; Da0255; Da0452 pp. 130-31; Da0479). The FDA's recall was for "product quality" reasons – because the agency determined the problem was "not a safety concern" (Da0250; Da0252). That was because the problem involved release of a tiny silicone particle, and it occurred

[2] No counsel for any party authored this brief in whole or in part and no entity or person, aside from *amici curiae*, their members, and their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

in only one of every 45 units tested (2.2%) (Da0229; Da0237; Da0240).

The Ozurdex® treatment at issue occurred on November 6, 2018 – after the defendant had notified the FDA of the issue, but before the agency authorized the recall (Da0087). Plaintiff had previously used Ozurdex® without incident several times (Da0087), because she suffered from several serious eye problems that independently could lead to blindness (Da0045; Da0047 pp. 13, 60).

Plaintiff alleged a failure-to-recall claim against Allergan (Da0001 ¶47-49; Da0846 pp. 5-8). The only purported fact (beyond mere timing) that plaintiff's witnesses cited to support her claim that the unit she received was actually one of the 2.2% that shed a silicone particulate was the unit's being from a "recalled lot" (Da0150 p. 102; Da0229; Da0237; Da0452 pp. 50, 54). No other "circumstantial evidence" exists that the claimed defect manifested in the applicator used during plaintiff's treatment. Similarly, plaintiff's treating physician cited only the FDA recall notice to support of his opinion that a silicone particulate caused inflammation that contributed to plaintiff's claimed injury (Da0047, p. 54).

Without the recall, this case would not exist. Plaintiff's brief admits as much. Plaintiff argues that the recall notice "identified" the "defect," Op. Br. at 19, and claims that defendant had "no justification ... to delay issuing a recall." Id. at 28. This is precisely the type of failure-to-recall claim that the common law has long rejected.

Moreover, plaintiff claims that: (1) what she now calls a "post-

sale duty to warn" began on June 21, 2018 – the precise date that the defendant discovered the problem that prompted the recall process – and (2) the "warning" duty required the same information that the FDA received, and that the recall notice later provided. Opp. Br. at 3, 22-23, 35-36, 38. Plaintiff argues that FDA approval was "not need[ed]" to "otherwise issue a product recall." Id. at 5. Plaintiff seeks to distinguish otherwise on-point precedent as "not involv[ing] a recalled product." Id. at 20.[3]

The failure-to-recall claim plaintiff alleged in her complaint does not exist, and no matter what label she now tries to attach to that non-existent claim – it still fails to state a cause of action.

A. THE LAW DOES NOT RECOGNIZE ANY PRODUCT-LIABILITY THEORY GROUNDED IN A DEFENDANT'S ALLEGED FAILURE TO RECALL A PRODUCT BEFORE ANY GOVERNMENT RECALL ORDER.

1. The Common Law Has Long Rejected Failure-To-Recall Claims.

The common law does not impose any duty on a manufacturer to recall its products in the absence of a government order to do so. The law does not require a defendant, such as Allergan, to remove a product from the market entirely, or else face universal liability simply for selling that product. Where consistent with the PLA, New Jersey law follows the Third Restatement in product-liability cases. E.g., Cavanaugh v. Skil Corp., 164 N.J. 1, 4-5 (2000); Myrlak v. Port

[3] Plaintiff's recall-based warning claim also fails because the recall here was not safety related (Da0252). See Asby v. Medtronic, Inc., 673 F. Supp.3d 787, 795 (E.D.N.C. 2023) (warning claim held "implausible" where "the FDA specifically stated in the recall notice that it was not prompted by any reports of injuries or death").

Auth. of New. York & New Jersey, 157 N.J. 84, 103-07 (1999); Mathews v. Univ. Loft Co., 387 N.J. Super. 349, 362 & n.10 (App. Div. 2006). The Third Restatement of Torts addresses recall-related liability. Comprehensively reviewing the law, §11 determined that such liability has never been recognized outside of two limited situations: (1) noncompliance **after** a government recall was **already** declared, or (2) negligently conducting a recall that the defendant voluntarily undertook:

> One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to recall a product after the time of sale or distribution if:
>
> (a)(1) a **governmental directive** issued pursuant to a statute or administrative regulation **specifically requires the seller or distributor to recall the product**; or
>
> (a)(2) the seller or distributor, **in the absence** of a recall requirement under Subsection (a)(1), **undertakes to recall** the product; and
>
> (b) the seller or distributor fails to act as a reasonable person in recalling the product.

Restatement (Third) of Torts, Products Liability §11 (1998) (emphasis added).

Thus, the Third Restatement's black letter law rejects the purported common-law obligation that plaintiff asserts here: demanding the anticipatory removal of products from the market before **any** recall was ordered or undertaken. Sound reasons support these constraints. An unlimited duty to recall, as plaintiff sought here, would impose "significant burdens" on commerce:

> Duties to recall products impose significant burdens on manufacturers. Many product lines are periodically redesigned so that they become safer over time. If every improvement in product safety were to trigger a common-law duty to recall, manufacturers would face incalculable costs every time they sought to make their product lines better and safer.

Restatement Third §11, comment a. Further, decisions about whether the public as a whole should be deprived of access to otherwise legal products should not be the province of judges and juries in common-law tort litigation:

> [A]n involuntary duty to recall should be imposed on the seller only by a governmental directive issued pursuant to statute or regulation. Issues relating to product recalls are best evaluated by governmental agencies capable of gathering adequate data regarding the ramifications of such undertakings.

Id. "Congress vested the FDA with the authority to monitor and supervise product recalls." Clark v. Actavis Group hf, 567 F. Supp.2d 711, 717 (D.N.J. 2008) (citation omitted).

> Implicit in this authority is the understanding that the FDA possesses the necessary expertise to determine when notice is required, what the [recall] notice should contain, and who the notice should be sent to.... Plaintiffs are essentially asking the Court to perform the tasks traditionally relegated to the FDA.

In re Human Tissue Products Liability Litigation, 488 F. Supp.2d 430, 433 (D.N.J. 2007).

For similar reasons, in State after State, in both common-law and statutory product-liability regimes, and whether the State otherwise follows the Second or Third Restatement, courts have refused

to expand liability by including claims that legal products should not have been sold, but rather should have been recalled.

For instance, in California, the State that invented strict liability, no duty to recall an FDA-regulated product (an over-the-counter medicine) exists unless the FDA has decided to authorize such action:

> We conclude ... as a matter of law, that defendant may not be held liable for failing to withdraw its product from the market.... A few scientific studies had shown [the risk plaintiffs allege] but ... the FDA had determined that further studies were needed to confirm or disprove the association. Pending completion of those studies, the FDA concluded that product warnings were an adequate public safety measure. **Although the FDA's conclusion is not binding on us, we think it deserves serious consideration.**

Ramirez v. Plough, Inc., 863 P.2d 167, 177-78 (Cal. 1993) (citations omitted) (emphasis added).[4]

The New York Court of Appeals similarly rejected a purported "post-sale duty to recall or retrofit a product" in Adams v. Genie Industries, Inc., 929 N.E.2d 380, 385 (N.Y. 2010). Adams involved a lift truck, rather than an FDA-regulated product. The court found "no justification for creating" a duty to recall, since – again as here – "plaintiff merely asserted that [defendant] should have

[4] Cf. Hernandez v. Badger Construction Equipment Co., 34 Cal. Rptr.2d 732, 756-57 (Cal. App. 1994) (allowing retrofit claim without discussing Ramirez's rejection of recall-based claims). Thus, "California recognizes a duty to recall or retrofit if a government agency has ordered a recall or if there was a shift in industry standards." Hamilton v. TBC Corp., 328 F.R.D. 359, 385 (C.D. Cal. 2018). No such facts support liability here.

recalled or retrofitted the [product] for the same reasons that it should not have sold it in the first place[.]" Id. at 386.

Likewise, Illinois law rejects both post-sale warning and recall duties. Jablonski v. Ford Motor Co., 955 N.E.2d 1138, 1160 (Ill. 2011). As to recalls, specifically:

> A duty may be imposed upon a manufacturer by a statute or administrative regulation which mandates the recall of the product.... However, in the absence of such an obligation, or a voluntary undertaking, Illinois has not imposed such a duty on a manufacturer[.]

Id. at 1160 n.1 (citing Third Restatement §11).[5]

Indeed, "virtually every court that has confronted the issue head-on has reached the same conclusion": "'that it is unnecessary and unwise to impose or introduce an additional duty to retrofit or recall a product' separate and apart from those duties to which manufacturers are already subject." Tabieros v. Clark Equipment Co., 944 P.2d 1279, 1298 (Haw. 1997) (quoting Gregory v. Cincinnati, Inc., 538 N.W.2d 325, 333-34 (Mich. 1995)).[6]

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[5] Jablonski also approvingly cited Modelski v. Navistar International Transportation Corp., 707 N.E.2d 239 (Ill. App. 1999), which held:

> The consequences of imposing upon manufacturers an extrastatutory duty to recall ... would be the equivalent of mandating that manufacturers insure that their products will always comply with current safety standards. This we are unwilling to do.

Id. at 247.

[6] Gregory "did not recognize any theory that would impose a postmanufacture duty to ... recall a product." Klein by Klein v. Caterpillar, Inc., 2023 WL 4760707, at *5 (E.D. Mich. July 26, 2023),

The Kentucky Supreme Court reached the same conclusion, rejecting liability "by judicial fiat" for alleged failure to recall products in Ostendorf v. Clark Equipment Co., 122 S.W.3d 530, 534 (Ky. 2003). Product recalls "are properly the province of administrative agencies, as the federal statutes that expressly delegate recall authority to various agencies suggest," and courts should not "arrogate to themselves a power equivalent to that of requiring product recall." Id.

> As Congress has recognized, administrative agencies have the institutional resources to make fully informed assessments of the marginal benefits of recalling a specific product.

Id. at 434-35 (citation and quotation marks omitted).

The Kansas Supreme Court agreed:

> [P]roduct recalls are properly the business of administrative agencies as suggested by the federal statutes that expressly delegate recall authority.... The decision to expand a manufacturer's post sale duty beyond implementing reasonable efforts to warn ... should be left to administrative agencies and the legislature. These institutions are better able to weigh the benefits and costs involved in locating, recalling, and retrofitting products.

Patton v. Hutchinson Wil-Rich Manufacturing Co., 861 P.2d 1299, 1315-16 (Kan. 1993) (citations omitted).[7] Accord Loredo v. Solvay America, Inc., 212 P.3d 614, 632 (Wyo. 2009) (quoting and following Ostendorf);

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aff'd, 2024 WL 1574672 (6th Cir. Apr. 11, 2024).

[7] Patton quoted V. Schwartz, "The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine," 58 N.Y.U.L. Rev. 892, 901 (1983).

Lovick v. Wil-Rich, 588 N.W.2d 688, 696 (Iowa 1999)(affirming that a manufacturer "ha[s] no duty to recall or retrofit" a product).[8]

Other state intermediate appellate courts have also held that failure-to-recall claims would create excessive and unmanageable liability. Perhaps the most thorough is Ford Motor Co. v. Reese, 684 S.E.2d 279 (Ga. App. 2009), cert denied (Ga. Feb. 8, 2010). Reese followed Restatement Third §11 and rejected failure-to-recall claims absent a government-mandated or negligently undertaken voluntary product recall. Id. at 284-85. "Georgia common law does not impose a continuing duty upon manufacturers to recall their products." Id. at 285. Reese also invoked "important public policy concerns" that support leaving recall decisions to administrative agencies. Id.

> Because the cost of locating, recalling, and replacing mass-marketed products can be enormous and will likely be passed on to consumers in the form of higher prices, the recall power should not be exercised without extensive consideration of its economic impact.

Id. (citation and quotation marks omitted). Accord Lance v. Wyeth, 4 A.3d 160, 167 (Pa. Super. 2010) ("this Court is persuaded by the majority of modern jurisdictions that have decided not to impose a common law duty to recall on a manufacturer") (citations omitted)[9];

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[8] The only contrary high court authority is a footnote in Izzarelli v. R.J. Reynolds Tobacco Co., 136 A.3d 1232 (Conn. 2016), that a "manufacturer separately may be deemed negligent for failing to recall a product[.]" Id. at 1268 n.8. That brief footnote cited no authority and was tangential to the issues being decided in that case.

[9] Aff'd in part & rev'd in part on other grounds, 85 A.3d 434 (Pa. 2014).

Bragg v. Hi-Ranger, Inc., 462 S.E.2d 321, 331 (S.C. App. 1995) (following the "law adopted by a majority of jurisdictions concerning a manufacturer's duty to recall or retrofit its products"); Morrison v. Kubota Tractor Corp., 891 S.W.2d 422, 429 (Mo. App. 1994) (finding "no such duty absent a state or federal law mandating a recall of the product"), transfer denied (Mo. Feb. 12, 1995); Lynch v. McStome & Lincoln Plaza Associates, 548 A.2d 1276, 1281 (Pa. Super. 1988) (finding no "precedent that imposes such a broad duty on a manufacturer, nor do we think that the imposition of such a duty would be appropriate").

Literally scores of federal courts have made state-law predictions that reject failure-to-recall claims under the laws of many other states. The sheer range of products against which recall claims have been asserted demonstrates how radical a legal change plaintiff's theory would entail, were it to be accepted.[10]

- **Alabama**: Wilhite o/b/o Est. of Wilder v. Medtronic, Inc., 2024 WL 968867, at *6 (N.D. Ala. Mar. 6, 2024) ("no duty to recall under Alabama law") (medical device); Harman v. Taurus International Manufacturing, Inc., 661 F. Supp.3d 1123, 1133 (M.D. Ala. 2023) ("no such duty exists under Alabama law" to "proactively recall[]" a product) (firearm); Harris v. Raymond Corp., 2018 WL 6725329, at *9 (N.D. Ala. Dec. 21, 2018) ("there is no duty to recall") (pallet jack).

- **Alaska**: Nelson v. Original Smith & Wesson Business Entities, 2010 WL 7125186, at *3-4 (D. Alaska May 18, 2010) (following "the weight of jurisdictions that have previously determined

[10] *Amici* have limited this list to no more than three decisions per State and do not include other decisions from the states with on-point high court authority discussed above. Many more decisions reject failure-to-recall claims on facts similar to this case.

that failure to recall ... is not a valid cause of action"), aff'd, 449 F. Appx. 581, 584 (9th Cir. 2011) (firearm).[11]

- **Colorado**: Perau v. Barnett Outdoors, LLC, 2019 WL 2145467, at *2-3 (M.D. Fla. May 15, 2019) (excluding all failure-to-recall evidence) (crossbow) (applying Colorado law).

- **Delaware**: Smith v. Daimlerchrysler Corp., 2002 WL 31814534, at *6 (Del. Super. Nov. 20, 2002) ("There is also no duty under Delaware law to recall defective [products]") (automobile).

- **Florida**: Howey v. Pirelli Tire, LLC, 2017 WL 10978505, at *2 (S.D. Fla. Oct. 31, 2017) (following Wright) (tire); Wright v. Howmedica Osteonics Corp., 2017 WL 4555901, at *4 (M.D. Fla. Oct. 12, 2017) ("find[ing] no Florida case recognizing a cause of action for breach of the duty to recall") (medical device), aff'd, 741 F. Appx. 624 (11th Cir. 2018); Thomas v. Bombardier Recreational Products, Inc., 682 F. Supp.2d 1297, 1302 (M.D. Fla. 2010) ("Florida law does not recognize that a manufacturer has a post-sale duty to recall or retrofit a product") (personal watercraft).

- **Georgia**: Clayton v. Alliance Outdoor Group, Inc., 2021 WL 1947886, at *2 (M.D. Ga. March 30, 2021) ("Georgia law generally does not recognize a cause of action based upon a manufacturer's failure to recall a product") (tree stand); Williamson v. Walmart Stores, Inc., 2015 WL 1565474, at *6 (M.D. Ga. April 8, 2015) (quoting and following Reese, supra) (gas container); Yarbrough v. Actavis Totowa, LLC, 2010 WL 3604674, at *4 (S.D. Ga. Sept. 13, 2010) ("product sellers are not required to issue recalls for defective products") (pre-Reese) (prescription drug).[12]

- **Indiana**: Timm v. Goodyear Dunlop Tires North America Ltd., 309 F. Supp.3d 595, 602 (N.D. Ind. 2018) (finding no "support" for a "claim of negligent recall") (tire); Cincinnati Insurance Companies. v. Hamilton Beach/Proctor-Silex, Inc., 2006 WL 299064, at *3 (N.D. Ind. Feb. 7, 2006) ("no Indiana state law cases indicate the existence of a separate negligent recall cause of action") (citations omitted) (toaster); Tober v. Graco Children's Products, Inc., 2004 WL 1987239, at *9 (S.D. Ind. July 28, 2004) (rejecting "the existence of a separate 'negligent

[11] Cf. Jones v. Bowie Industries, Inc., 282 P.3d 316, 335 n.70 (Alaska 2012) (clarifying that recognizing a post-sale duty to warn does not include any duty to recall).

[12] Cf. Ontario Sewing Machine Co. v. Smith, 572 S.E.2d 533, 535 (Ga. 2002) ("disapprov[ing]" of decision that had allowed a failure-to-recall claim, but not reaching issue).

recall' cause of action"), aff'd, 431 F.3d 572 (7th Cir. 2005) (baby swing).

- **Iowa**: Burke v. Deere & Co., 6 F.3d 497, 510 (8th Cir. 1993) ("we find no independent duty to retrofit or recall under Iowa law") (combine); Doe v. Baxter Healthcare Corp., 2003 WL 27384538, at *5 (S.D. Iowa June 3, 2003) ("no court interpreting Iowa law has recognized a duty to recall"), aff'd, 380 F.3d 399 (8th Cir. 2004) (blood product).

- **Louisiana**: Weams v. FCA US L.L.C., 2019 WL 960159, at *23 (M.D. La. Feb. 27, 2019) ("failure to recall is not a theory of liability under the" exclusive Louisiana product-liability statute) (automobile).

- **Massachusetts**: Ahern v. Sig Sauer, Inc., 2021 WL 5811795, at *4 (D. Mass. Dec. 7, 2021) (plaintiff "cites no legal duty to impose a mandatory recall") (firearm); National Women's Health Network, Inc. v. A.H. Robins Co., 545 F. Supp. 1177, 1181 (D. Mass. 1982) ("[n]o court has ever ordered a notification and recall campaign on the basis of state law") (contraceptive device) ("NWHN").

- **Minnesota**: Kladivo v. Sportsstuff, Inc., 2008 WL 4933951, at *5 (D. Minn. Sept. 2, 2008) ("Minnesota courts have not recognized a cause of action for negligent recall") (inflatable swimming tube); Hammes v. Yamaha Motor Corp., 2006 WL 1195907, at *11 (D. Minn. May 4, 2006) ("this Court declines to impose a separate duty to recall") (motorcycle); Berczyk v. Emerson Tool Co., 291 F. Supp.2d 1004, 1016 (D. Minn. 2003) ("Minnesota would refuse to impose a duty on manufacturers to recall and/or retrofit a defective product because the overwhelming majority of other jurisdictions have rejected such an obligation") (power saw).[13]

- **Mississippi**: Goodwin v. Premier Ford Lincoln Mercury, Inc., 2020 WL 3621317, at *4 n.2 (N.D. Miss. July 2, 2020) ("there is no post-sale duty to warn or recall in Mississippi") (automobile); Clark v. General Motors, 2016 WL 3574408, at *7 (S.D. Miss. June 23, 2016) (same) (automobile); Murray v. General Motors, 2011 WL 52559, at *2 (S.D. Miss. Jan. 7, 2011) (plaintiffs "cannot show that [defendant] breached its duty by not recalling their vehicle"), aff'd, 478 F. Appx. 175 (5th Cir. 2012) (automobile).

[13] Quoting McDaniel v. Bieffe USA, Inc., 35 F. Supp.2d 735, 743 (D. Minn. 1999).

- **Missouri**: Horstmyer v. Black & Decker, (U.S.), Inc., 151 F.3d 765, 774 (8th Cir. 1998) (finding "no indication ... that the Missouri Supreme Court would create a common law duty to recall under these circumstances") (power saw); Smith v. Firestone Tire & Rubber Co., 755 F.2d 129, 135 (8th Cir. 1985) ("Since no duty to recall was established, a fundamental prerequisite to establishing negligence was absent") (tire); Haskell v. PACCAR, Inc., 2021 WL 5407853, at *3 (W.D. Mo. Nov. 18, 2021) ("There is no common law duty to recall under Missouri law absent a mandated recall by a governmental agency.") (citations omitted) (commercial truck).

- **Nebraska**: Anderson v. Nissan Motor Co., 139 F.3d 599, 602 (8th Cir. 1999) ("limiting [Nebraska] products liability law to actions or omissions which occur at the time of manufacture or sale") (forklift); Dubas v. Clark Equipment Co., 532 F. Supp.3d 819, 830 (D. Neb. 2021)("claims asserting post-sale duties to ... recall ... are dismissed") (forklift).

- **New Hampshire**: Bartlett v. Mutual Pharmaceutical Co., 2010 WL 3659789, at *10 (D.N.H. Sept. 14, 2010) ("'almost all of the opinions which have addressed the issue have found that there is no common law duty to recall' products from the market, even if they are unreasonably dangerous") (prescription drug).[14]

- **New Mexico**: Morales v. E.D. Etnyre & Co., 382 F. Supp.2d 1285, 1287 (D.N.M. 2005) (rejecting a "duty to retro-fit or recall"; following Third Restatement §11) (road paving machine).

- **North Dakota**: Eberts v. Kawasaki Motors Corp., 2004 WL 224683, at *2-3 (D.N.D. Feb. 2, 2004) (following Third Restatement §11 and "the overwhelming majority of other jurisdictions [that] have refused to impose a duty on manufacturers to recall ... a defective product") (ATV).

- **Ohio**: Kondash v. Kia Motors America, Inc., 2016 WL 11246421, at *14 (S.D. Ohio June 24, 2016) (given the weight of contrary precedent, "[t]he Court cannot conclude that Ohio law recognizes a duty in negligence to recall") (automobile).

- **Pennsylvania**: Liebig v. MTD Products, Inc., ___ F. Supp.3d ___, 2023 WL 5517557, at *4 n.6 (E.D. Pa. Aug. 25, 2023) ("Pennsylvania law does not recognize a duty to recall or retrofit products") (snow blower); Cleaver v. Honeywell International, LLC, 2022 WL 2442804, at *4 (E.D. Pa. March 31,

[14] Quoting 5 L. Frumer & M. Friedman, Products Liability, §57.01[4], at 57-9 (2010).

2022) ("Under Pennsylvania law, manufacturers and distributors do not have a duty to recall or retrofit products.") (vacuum truck); Talarico v. Skyjack, Inc., 191 F. Supp.3d 394, 401 (M.D. Pa. 2016) (no "independent negligence cause of action exists in Pennsylvania under a duty to recall") (forklift).

- **South Carolina**: Andrews v. CBS Corp., 2015 WL 12831309, at *1 (D.S.C. June 24, 2015) ("there is no-post sale duty to recall or retrofit products"; citing and following Bragg, supra) (asbestos containing products).

- **South Dakota**: Robinson v. Brandtjen & Kluge, Inc., 2006 WL 2796252, at *8 (D.S.D. Sept. 27, 2006) ("[n]othing ... indicates that South Dakota permits a claim based on a manufacturer's duty to recall"; citing Restatement Third §11), aff'd, 500 F.3d 691 (8th Cir. 2007) (printing press).

- **Tennessee**: Spence v. Miles Laboratories, Inc., 810 F. Supp. 952, 959 (E.D. Tenn. 1992) (product-liability statute did not "require manufacturers and suppliers of [their] products to recall and test a product already on the market") (blood product).

- **Texas**: Syrie v. Knoll International, 748 F.2d 304, 311-12 (5th Cir. 1984) ("Texas does not impose on manufacturers the duty ... to recall products") (stool); Gomez v. ALN International, Inc., 2021 WL 3774221, at *8 (S.D. Tex. Mar. 24, 2021) ("there is no general, post-sale, duty to retrofit or recall under Texas law") (medical device); Nester v. Textron, Inc., 2015 WL 9413891, at *13 (W.D. Tex. Dec. 22, 2015) (Texas rejects failure-to-recall claims prior to any actual recall) (utility vehicle).

- **Utah**: Marcovecchio v. Wright Medical Group, Inc., 2019 WL 1406606, at *7 (D. Utah March 28, 2019) ("Plaintiff has alleged only that [defendant] failed to recall the product, which is insufficient to state a claim"; following Restatement Third §11) (medical device); Dowdy v. Coleman Co., 2011 WL 6151432, at *3 (D. Utah Dec. 12, 2011) ("declin[ing] to recognize a post-sale duty to recall or retrofit"; citing Restatement Third §11) (propane heater).

- **Virginia**: Boyer v. Abbott Vascular Inc., 2023 WL 4269764, at *2 (N.D. Cal. June 29, 2023) (predicting that Virginia would follow Restatement §11 and dismissing recall claim; quoting Powell, supra) (catheter) (applying Virginia law); In re General Motors LLC Ignition Switch Litigation, 202 F. Supp.3d 362, 371-72 (S.D.N.Y. 2016) (same) (automobile) (applying Virginia law); Powell v. Diehl Woodworking Machinery, Inc., 198 F. Supp.3d 628, 634 (E.D. Va. 2016) ("Virginia law does not recognize a duty to recall") (ripsaw).

- **Washington**: Bear ex rel. Bloom v. Ford Motor Co., 2007 WL 870344, at *3 (E.D. Wash. Mar. 20, 2007) (failure-to-recall claim does not exist because "the issue of recall is not addressed in the Washington Products Liability Act") (automobile).

- **Wisconsin**: Carlson v. Triton Industries, Inc., 605 F. Supp.3d 1124, 1138 (W.D. Wis. 2022) (rejecting "failure to recall" theory as "much more drastic" than anything Wisconsin law has permitted) (boat).

The overwhelming weight of precedent nationwide thus rejects failure-to-recall claims like this plaintiff pleaded and pursued in the trial court, before attempting to camouflage them on appeal. That a recall occurred later, or was "voluntary," does not matter. Recall-based claims go far beyond ordinary negligence and strict-liability theories. They usurp executive and legislative powers to regulate the public's access to lawful products. New Jersey law, like that of other State, does not permit that result.

2. The New Jersey Product Liability Act Did Not Create Any Failure-To-Recall Claims Not Recognized at Common Law.

Before the New Jersey Product Liability Act ("PLA"), N.J.S.A. 2A:58C-1, *et seq.*, was enacted in 1987, nothing in this State's common law allowed failure-to-recall claims, in either negligence or strict liability. Indeed, the only pre-PLA reference to such possible claims was non-substantive, a two-sentence allusion to a negligence-based recall claim as adequately pleaded in Matter of Cadillac V8-6-4 Class Action, 93 N.J. 412, 430 (1983).[15] Pre-PLA New Jersey law also

[15] Cadillac V8-6-4 solely decided unrelated class certification issues.

rejected any obligation to "retrofit" products or to impose "a continuing duty to protect a purchaser" even "after the sale." Bottignoli v. Ariens Co., 234 N.J. Super. 353, 361 (App. Div. 1989).

The PLA is "a New Jersey tort-reform statute." Sun Chemical Corp. v. Fike Corp., 243 N.J. 319, 332 (2020). It extends to "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim[.]" Sinclair v. Merck & Co., 195 N.J. 51, 62 (2008) (quoting N.J.S.A. 2A:58C-1(b)(3)). The PLA was intended to "rebalanc[e] the law in favor of manufacturers[.]" Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 196 (2012) (citations omitted). Through the PLA, "the Legislature intended to limit the liability of manufacturers so as to balance the interests of the public and the individual with a view towards economic reality." Sinclair, 195 N.J. at 62 (citations omitted).

The Supreme Court thus held that, consistent with the Legislature's purpose in enacting the PLA, any attempt to "expand" product liability with novel claims not recognized before the PLA is "best directed to the Legislature," which had enacted the PLA. Id. at 65 (refusing to expand product liability by allowing a no-injury medical-monitoring claim against a prescription-drug manufacturer).

Further, in enacting the PLA, the Legislature specifically intended "to reduce the burden on **manufacturers of FDA-approved products** resulting from products liability litigation," Kendall, 209 N.J. at 194 (emphasis added), and recognized the "importance of the federal regulatory process in relation to the PLA." In re Accutane

Litigation, 235 N.J. 229, 266 (2018).

Therefore, the PLA imposes a statutory presumption that prescription medications such as Ozurdex® that comply with the FDA's requirements are not defective. "[A]bsent deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects, compliance with FDA standards should be virtually dispositive." Perez v. Wyeth Laboratories, Inc., 161 N.J. 1, 25 (1999).

In this case, plaintiff asserts a novel theory of liability that pre-PLA New Jersey common law did not recognize. Moreover, she nowhere claims that the defendant ever violated any FDA requirement. Instead, the crux of her complaint is precisely the opposite: that defendant should **not** have waited for the FDA to authorize the product recall that occurred on December 20, 2018. What plaintiff now claims – without having pleaded it in her complaint or citing anything in the record – to be "deliberate concealment," Op. Br. at 23-24, 43-44, is nothing of the sort. Rather, plaintiff admits that **the same facts she claims were "concealed" were disclosed** in numerous "countries outside the U.S.," id. at 24, that had different, less protracted regulatory schemes for pharmaceutical products. Defendant reported this overseas activity to the FDA (Da0258 ¶70).

The product here – a prescription medicine – and the defendant here, which scrupulously complied with everything the FDA required, are precisely what the PLA was enacted to protect from broad, unprecedented common-law liability theories such as plaintiff's

failure-to-recall claim.[16]

As for the PLA, in terms of post-sale duties, the statute created a limited post-sale duty to warn and went no further. See N.J.S.A. 2A:58C-4 (product manufacturer "shall not be liable" if it "provides an adequate warning or instruction" about "dangers [it] discovers or reasonably should discover after the product leaves its control"). No precedent supports plaintiff's attempt to transform that limited duty into a broad recall obligation by alleging, as a "warning," everything that formed the basis for the FDA's eventual recall. As in Sinclair, such an expansion of liability lies with "the Legislature," not the judiciary. 195 N.J. at 65.

The Trial Division mistakenly relied on Finegold v. General Motors Co., 2021 WL 2810091 (D.N.J. June 30, 2021). See Op. Br. at 24 (quoting opinion). But unlike this case, and similarly to the Third Restatement, Finegold involved a recall that preceded a plaintiff's alleged injuries. 2021 WL 2810091, at *1, 4 ("pointing to a recall for the same defect in ... model years 2015-2017" whereas the vehicle at suit was a "2019" model). Finegold thus in no way supports the claim here, which would impose state common-law liability for failure to recall a drug in advance of any FDA action to that effect.

[16] A product recall does not create any inference of a regulatory violation. E.g., Est. of Benn v. Medtronic, Inc., 2023 WL 3966000, at *4 (D.N.J. June 13, 2023) ("Courts have consistently held that a product recall alone, without more, does not suggest [an FDCA] specification violation.") (collecting cases).

Far more apropos is Leslie v. U.S., 986 F. Supp. 900 (D.N.J. 1997), aff'd mem., 178 F.3d 1279 (3d Cir. 1999). As here, the plaintiff in Leslie asserted a failure-to-recall claim under New Jersey law prior to any governmental recall. Leslie held that a manufacturer's mere intention to recall a product at a future date was not enough to impose PLA liability:

> Plaintiffs have cited no authority, and the Court's research has yielded none, which requires manufacturers of legally distributed [products] to ensure instantaneous removal of their products from the shelves upon an announced intention to discontinue product sales.... Having failed to establish a duty, plaintiffs cannot state a cognizable claim for negligence.

Id. at 913. The "negligent recall" claim in Leslie was thus dismissed. Id.

In any event, Finegold itself defeats plaintiff's position. First, it held that the plaintiff's "failure to recall claim[]," even assuming a post-recall claim could otherwise exist, was "subsumed" by the PLA, since that "Act 'is both expansive and inclusive, encompassing virtually all possible causes of action'" involving product liability. Id. at *4 (quoting Gupta v. Asha Enterprises, L.L.C., 422 N.J. Super. 136, 145 (App. Div. 2011)). Second, Finegold found no authority "delineating a cause of action for failure to recall separate from the [PLA]." 2021 WL 2810091, at *4. As such, dismissal here should be *a fortiori* from Finegold, because plaintiff's liability theories (however denominated) demand a recall before any government action – and that theory has never been recognized in New

Jersey, pre- or post-PLA.

The law is indisputable: (1) failure-to-recall claims have been rejected overwhelmingly nationwide; (2) New Jersey common law never allowed such a claim prior to the 1987 PLA; (3) the PLA was intended to limit product liability for manufacturers generally and FDA-compliant drugmakers specifically; and (4) failure-to-recall claims under the PLA have failed whenever they have demanded product recalls prior to either the government ordering, or the defendant undertaking, such an effort.

B. IF A CLAIM FOR FAILURE TO RECALL AN FDA APPROVED PRODUCT EXISTED UNDER THE COMMON LAW, IT WOULD BE PREEMPTED BY THE FDA'S PRODUCT APPROVAL AND RECALL AUTHORITY.

Even if plaintiff's claim were otherwise viable, federal law would preempt it. A "duty to recall" claim is simply another way of asserting that the defendant should "stop selling" its product. Bartlett, supra, 2010 WL 3659789, at *10.

> [T]here is no common law duty to recall products from the market, even if they are unreasonably dangerous.... [S]trict products liability requires that manufacturers compensate consumers ... not necessarily that they remove such products from the market.

Id. (citations and quotation marks omitted). The question of the viability of the recall/stop selling claim in Bartlett reached the United States Supreme Court in Mutual Pharmaceutical Co. v. Bartlett, 570 U.S. 472 (2013), and the Supreme Court held that such claims were necessarily preempted.

In Bartlett the Supreme Court recognized that common-law "stop-

selling" claims against FDA-approved prescription drugs are inherently preempted, because they conflict with FDA's product approval authority. Initially, Bartlett reaffirmed that "[e]ven 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. at 480 (citation and quotation marks omitted).

Bartlett flatly rejected the contention that a drug manufacturer "could escape the impossibility of complying with both its federal- and state-law duties by 'choos[ing] not to make [its FDA-approved drug] at all." 570 U.S. at 488. "[T]his 'stop-selling' rationale [i]s incompatible with our pre-emption jurisprudence." Id. The Bartlett Court explained:

> Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be all but meaningless.
>
> The incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases. In every instance in which the Court has found impossibility pre-emption, the "direct conflict" between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting.

Id. (citation and quotation marks omitted).

Consequently, "the mere fact that a manufacturer may avoid liability by leaving the market does not defeat a claim of impossibility." Id. at 489 n.5. State-law tort litigation, such as

this, that "require[s] a manufacturer to choose between leaving the market and accepting the consequences of its actions," is preempted. Bartlett, 570 U.S. at 491.[17]

Since Bartlett, state-law tort claims that would "require[]" the manufacturer of an FDA-approved drug "to exit the market" have been uniformly preempted, however pleaded. Drager v. PLIVA USA, Inc., 741 F.3d 470, 476 (4th Cir. 2014); accord Hernandez v. Aurobindo Pharma USA, Inc., 582 F. Supp.3d 1192, 1213 (M.D. Fla. 2022). ("any argument that [the defendant] should have stopped selling the drug is unavailing").[18]

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[17] Such litigation conflicts with FDA authority fully as much as a state "statutory mandate" that "directly prohibit[s] the product's sale." Id. at 489 n.5.

[18] Accord Trejo v. Johnson & Johnson, 220 Cal. Rptr.3d 127, 162-63 (Cal. App. 2017) (OTC drug); Yates v. Ortho-Mcneil-Janssen Pharmaceuticals, Inc., 808 F.3d 281, 300 (6th Cir. 2015) ("never start selling" claim); Beaver v. Pfizer, Inc., 2024 WL 234725, at *3 (W.D.N.C. Jan. 22, 2024); GenBioPro, Inc. v. Sorsaia, 2023 WL 5490179, at *8 n.10 (S.D.W. Va. Aug. 24, 2023) (FDA REMS, anti-abortion statute); Bossetti v. Allergan Sales, LLC, 2023 WL 4030681, at *5-6 (S.D. Ohio June 15, 2023); Beaver v. Pfizer, Inc., 2023 WL 2386776, at *3 (W.D.N.C. March 6, 2023), aff'd, 2023 WL 4839368 (4th Cir. July 28, 2023); In re Zantac (Ranitidine) Products Liability Litigation, 548 F. Supp.3d 1225, 1252-53 (S.D. Fla. 2021); Silver v. Bayer Healthcare Pharmaceuticals, Inc., 2021 WL 4472857, at *5 (D.S.C. Sept. 30, 2021); Evans v. Gilead Sciences, Inc., 2020 WL 5189995, at *9-10 (D. Haw. Aug. 31, 2020); Javens v. GE Healthcare, Inc., 2020 WL 2783581, at *6 (Mag. D. Del. May 29, 2020) (claim that defendants should have marketed a different product), adopted, 2020 WL 7051642 (D. Del. June 18, 2020); Drescher v. Bracco Diagnostics, Inc., 2020 WL 1466296, at *5 (D. Ariz. Mar. 26, 2020); Mahnke v. Bayer Corp., 2019 WL 8621437, at *5 (C.D. Cal. Dec. 10, 2019); Trisvan v. Heyman, 305 F. Supp.3d 381, 405 (E.D.N.Y. 2018); Utts v. Bristol-Myers Squibb Co., 251 F. Supp.3d 644, 678 (S.D.N.Y. 2017), aff'd, 919 F.3d 699 (2d Cir. 2019); In re Lipitor Atorvastatin Calcium Marketing, Sales Practices & Products Liability Litigation, 185 F. Supp.3d 761, 771 (D.S.C. 2016); In re Fosamax Products Liability Litigation, 965 F.

Even before Bartlett, the inherent conflict between FDA product-approval authority and state-law failure-to-recall claims demanding removal of FDA-approved products from the market had supported preemption. As early as 1982, a purported Massachusetts state-law claim demanding recall of an FDA-approved product was preempted in NWHN, supra. "No court has ever ordered a notification and recall campaign on the basis of state law." 545 F. Supp. at 1181. The FDA has the sole "discretion" to require recall of a product that it approved. Id. at 1181.

> [E]ven if there were state law authority for a notification and recall campaign, such authority would be preempted by the FDCA for the same reasons that there is no implied right of action.... [A]ny state law which would put these same powers in other hands must be deemed foreclosed.... Since the federal interest in this area is "dominant" and the regulatory scheme is "pervasive," preemption must follow.

Id. (citations omitted).[19]

In Cupek v. Medtronic, Inc., 405 F.3d 421, 424 (6th Cir. 2005), the plaintiffs' proposed failure-to-recall claim "undermine[d] their preemption arguments, because those claims assert that Defendant has duties independent of any obligations ... to comply with applicable federal regulations." Id. at 424-25 (quotation marks omitted). "Any

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Supp.2d 413, 420 (S.D.N.Y. 2013).

[19] Similarly, federal preemption has precluded claims in automotive cases that state law could force recalls of cars and trucks where the federal government has not done so, or to a greater extent. See Cohen v. Subaru of America, Inc., 2022 WL 721307, at *38 (D.N.J. March 10, 2022) (collecting cases).

claim ... that Defendant ... failed to recall a product without first going through the PMA supplement process" was "futile" because it necessarily diverged from the FDA's recall-related requirements. Id. Differing FDCA and state-law recall obligations pertaining to the same FDA-regulated products inherently conflict:

> [F]ederal regulations place a duty on manufactures to inform the FDA of problems, and a duty on the FDA to recall [such products]. Plaintiffs' proposed duties would add to this scheme by requiring the manufacturer to notify patients of potential defects or to pull possibly deficient devices from the market. Therefore, a state action for failure to notify or recall would impose an additional requirement from those prescribed by federal law; such a cause of action is preempted.

Hunsaker v. Surgidev Corp., 818 F. Supp. 744, 754 (M.D. Pa. 1992), aff'd, 5 F.3d 1489 (3d Cir. 1993).[20]

[20] All these cases predate the Supreme Court's 2008 recognition of broad express preemption in pre-market approved medical device cases. See Riegel v. Medtronic, Inc., 552 U.S. 312 (2008). *A fortiori*, post-Riegel medical device cases continue to hold failure-to-recall claims preempted. Sundaramurthy v. Abbott Vascular, Inc., 2023 WL 2311661, at *3 & n.3 (D. Mass. Mar. 1, 2023) (following Cupek); Poozhikala v. Medtronic, Inc., 2022 WL 610276, at *5 n.4 (C.D. Cal. Jan. 31, 2022) (FDCA recall is a voluntary action that state law cannot make mandatory); Bryant v. Thoratec Corp., 343 F. Supp.3d 594, 604-05 (S.D. Miss. 2018) (preempting claims that "Defendants should have sooner issued a recall"; preemption not defeated because "the FDA permits voluntary recalls"); Kubicki v. Medtronic, Inc., 293 F. Supp.3d 129, 185 (D.D.C. 2018) (state-law recall claim that ignored FDA supplementation requirements preempted); Bentzley v. Medtronic, Inc., 827 F. Supp.2d 443, 451-52 (E.D. Pa. 2011) (state-law claim that FDA recall should have included unrecalled products preempted); Franklin v. Medtronic, Inc., 2010 WL 2543579, at *6 (Mag. D. Colo. May 12, 2010), adopted, 2010 WL 2543570 (D. Colo. June 22, 2010) (same as Poozhikala); In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp.2d 1147, 1159 (D. Minn. 2009) ("claims alleging that [defendant] should have recalled the [product] sooner than it did are ... preempted"), aff'd, 623 F.3d 1200 (8th

Preemption of plaintiff's claim that the defendant should have immediately recalled Ozurdex® – without waiting for the FDA to complete its independent review and order the recall – also comports with the PLA, because "[t]he Legislature, by attaching a presumption of adequacy to FDA-approved warnings, 'recognized the preeminent role of federal regulation of drugs and medical devices.'" Accutane, 235 N.J. at 266 (quoting Cornett v. Johnson & Johnson, 211 N.J. 362, 387 (2012)[21]). In this case, plaintiff's failure-to-recall "claim is no more than a challenge to [the FDA's] approval of" this product and is therefore impliedly preempted. Cornett, 211 N.J. at 391.

Plaintiff's argument against preemption, Op. Br. at 29, is largely based on the 1991 Feldman v. Lederle Laboratories, 125 N.J. 117 (1991) decision. But a lot has changed concerning FDCA preemption since then – most notably Bartlett. Feldman accepted, as precluding preemption, **precisely** the sort of "stop selling" claim that the United States Supreme Court later found preempted in Bartlett. "[W]e find no basis for concluding that [defendant] was required to continue marketing [the drug] in [the] forms and packaging [at issue] – or indeed to continue marketing at all." 125 N.J. at 152. See R.F. v. Abbott Laboratories, 162 N.J. 596, 629 (2000) (viewing Feldman as holding "that even if the drug manufacturer could not have provided a warning, it could have suspended production of the drug"). Since

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Cir. 2010).

[21] Abrogated on irrelevant grounds by McCarrell v. Hoffmann-La Roche, Inc., 227 N.J. 569 (2017) (choice of law).

Bartlett, the remove-from-the-market rationale Feldman employed to reject preemption is no longer viable.

To the contrary, defendants are "not required to cease acting altogether in order to avoid liability." Bartlett, 570 U.S. at 488. Plaintiff's reliance on Feldman's decades-old preemption argument, directly repudiated by the United States Supreme Court in Bartlett, only further demonstrates that her state-law demand for an anticipatory recall is preempted.

Where "[p]laintiffs' state law claims would directly contradict the FDA's requirements and interfere with the FDA's objectives," such claims under New Jersey law are preempted by reason of that conflict. R.F., 162 N.J. at 627 (2000). Here, the decision when, and how, to recall the defendant's medication "was the FDA's decision; [and] we should not second guess it." Id. 630.

IV. CONCLUSION

For the foregoing reasons, *amici* respectfully request that the Court reverse the ruling below and hold that New Jersey law does not allow failure-to-recall claims in the absence of a prior government recall order.

Alternatively, *amici* respectfully request that the Court hold that any failure-to-recall claim in this case is preempted by the FDCA, as state-law recall duties preceding or exceeding any FDA recall would necessarily prohibit sale of FDA-approved prescription drugs,

and thus conflict with both the FDA's drug approval and recall authority.

Respectfully submitted,

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Dated: May 2, 2024

ALISON BEAVAN, Plaintiff-Respondent, v. ALLERGAN USA, INC., ALLERGAN INC., F/K/A INAMED CORPORATION, ALLERGAN PLC, ABBVIE INC., AND DOES 1 THROUGH 100, INCLUSIVE, Defendant-Appellant.	SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO. A-001501-23 CIVIL ACTION ON APPEAL FROM: SUPERIOR COURT OF NEW JERSEY, LAW DIVISION: MORRIS COUNTY DOCKET NO. MRS-L-151-21 SAT BELOW: HON. LOUIS S. SCEUSI, J.S.C.

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PRELIMINARY STATEMENT

Proposed amici curiae HealthCare Institute of New Jersey ("HINJ") and New Jersey Business & Industry Association ("NJBIA") submit this Brief in support of their Motion for Leave to Appear as amici curiae in this matter. This case carries serious implications for New Jersey's life sciences industry and product manufacturers more broadly because the trial court denied summary judgment even though Plaintiff offered no admissible "evidence" in opposition, but mere hypothetical assertions and speculative expert testimony. Its decision misapplies the summary judgment standard and lowers the level of evidence necessary to overcome it so far that it upends New Jersey law on defect and causation under the Product Liability Act ("PLA"). If affirmed, the trial court's interpretation will invite meritless litigation, drain valuable resources from life sciences companies, the business community, and the courts, and chill future investment in New Jersey.

The life sciences industry plays a pivotal role in the health of New Jersey's economy. The biopharmaceutical industry accounts for 340,751 jobs through direct and indirect employment. HINJ, New Jersey's Life Sciences By the Numbers, https://hinj.org/new-jersey-by-the-numbers/ (last visited March 23, 2024). Another 12,000 workers are employed by New Jersey's medical technology companies. Id. According to the Department of Labor and Workforce Development, "[t]he vitality of the biopharmaceutical and life-sciences cluster in New Jersey is fundamental to

the state's economic health with its well-paying jobs." Dep't of Labor & Workforce Dev., Labor Market Information, https://www.nj.gov/labor/labormarketinformation/tools-resources/publications-reports/industrysectorfocus.shtml (last visited March 23, 2024).

Additionally, New Jersey boasts that it is the "#1 state for FDA registered manufacturing establishments" and "the birthplace of immunotherapy and the cure for hepatitis C." NJEDA, Life Sciences, https://www.njeda.gov/life-science/ (March 23, 2024). More than 3,200 life science companies call New Jersey home, and there are more than 3,000 active clinical trials in the State. Id. Indeed, "New Jersey is the medicine chest to the world." Id.

Mindful of the significant role the life sciences industry plays in this state, the Legislature has made concerted efforts over the years to attract and retain biopharmaceutical and medical technology companies in New Jersey. In fact, part of the rationale for the PLA was to "rebalance" the law to reduce the amount of burdensome litigation for life sciences companies while also protecting the public. The proposed amici curiae have a strong interest in this litigation, as the trial court's summary judgment decision represents a significant departure from previous rulings regarding the sufficiency of evidence at the summary judgment stage of product liability cases.

In particular, the trial court erred in relying on a response to a hypothetical question during which plaintiff's counsel asked a corporate representative "**if**" an Ozurdex applicator had contained a silicone particulate, would that have deviated from Allergan's specifications, as sufficient credible evidence that the applicator used to provide Ozurdex to Plaintiff on November 6, 2018 actually **did** deviate from Allergan's specifications. The conclusion that a hypothetical could somehow enable a plaintiff to defeat summary judgment is contrary to law. If plaintiffs can make it to a jury by simply having a defendant acknowledge that **if** one of its products contained a defect, that product would deviate from the company's performance standards, countless meritless cases will proceed to trial, risking a miscarriage of justice.

Likewise, the trial court's decision to admit testimony from Plaintiff's experts also constitutes reversible error, given that one expert's opinion relies on false assumptions and the other's on pure speculation. Reliable expert testimony is essential in the complex litigation faced by New Jersey's manufacturing and life sciences industries, particularly in light of the Supreme Court's recent decision in In re Accutane, which strengthened the requirements for admissibility of expert testimony in New Jersey. The trial court mistakenly lowered the bar for admission of expert testimony even below the level that existed before In re Accutane, and certainly below that which exists now. Letting its decision stand contravenes the

law, will increase the amount and cost of litigation in this State, and will not promote fairness or efficiency in the judicial system. Accordingly, HINJ and NJBIA ask this Court to correct these legal errors, reverse the trial court's ruling and enter summary judgment for Defendants.

STATEMENT OF INTEREST

Proposed amici curiae HINJ and NJBIA will, if granted leave to appear as amici curiae, provide this Court with unique perspectives on the broad implications of this case. Their memberships consist of business leaders and the largest employers in the state, many of which are at the cutting edge of the research-based life sciences industry that contributes so vitally to New Jersey's economy and welfare. This Court should grant their motion to appear as amici curiae and consider the arguments and important public policy considerations set forth in this brief.

HINJ is the trade organization for New Jersey's leading research-based biopharmaceutical and medical technology companies. Among other efforts, HINJ promotes policies that support the life sciences industry's mission to discover and develop new cures, treatments, therapies, diagnostics and technologies to safeguard and improve global human health. HINJ also strives to increase public support for New Jersey's research-based biopharmaceutical and medical technology industry by increasing awareness and understanding of the industry's importance among New Jersey's elected and appointed officials, media, citizens, and opinion leaders. A list

of HINJ's member organizations is available at https://hinj.org/member-companies/. HINJ has been granted leave to appear as amicus curiae in numerous cases before this Court and the New Jersey Supreme Court.

NJBIA is New Jersey's largest statewide business association, representing member companies in all industries and regions of our state. Its mission is to provide information, services, and advocacy for its member companies and build a more prosperous New Jersey. NJBIA's members include most of the top 100 employers in the State, as well as thousands of small to medium-sized employers, from every sector of New Jersey's economy. One of NJBIA's goals is to reduce the costs of doing business in New Jersey, including unwarranted litigation burdens, in an effort to promote economic growth and benefit all of New Jersey. See N.J. Bus. & Industry Ass'n, About Us, http://www.njbia.org/JoinNJBIA/About.aspx. NJBIA has been granted leave to appear as amicus curiae in numerous cases before this Court.

PROCEDURAL HISTORY AND STATEMENT OF FACTS

The proposed amici curiae adopt and incorporate by reference the Procedural History and Statement of Facts set forth in Allergan USA, Inc.'s ("Allergan") opening brief filed in this appeal.

LEGAL ARGUMENT

I. THE TRIAL COURT'S RULING DISRUPTS THE BALANCE THE LEGISLATURE STRUCK IN ENACTING THE NEW JERSEY PRODUCT LIABILITY ACT BY ALLOWING A PLAINTIFF TO SURVIVE SUMMARY JUDGMENT WITHOUT ESTABLISHING A DEFECT IN THE SPECIFIC PRODUCT SHE RECEIVED

In denying Allergan's motion for summary judgment, the trial court rewrote basic principles of New Jersey's product liability law and the summary judgment standard, usurped the Legislature's role and the Supreme Court's rule-making authority, and made it nearly impossible for a manufacturer to obtain summary judgment, regardless of the lack of evidence to show that the particular product at issue was defective. The trial court's ruling cannot stand.

A. New Jersey Product Liability Act

As the New Jersey Supreme Court has recognized, the New Jersey Product Liability Act, N.J.S.A. 2A:58C–1 to –11, ("PLA"), "was enacted as a remedial measure to limit the liability of manufacturers by establishing 'clear rules with respect to certain matters . . . including certain principles under which liability is imposed.'" Kendall v. Hoffman-La Roche, Inc., 209 N.J. 173, 194 (2012) (quoting N.J.S.A. 2A:58C-1(a)); see also Zaza v. Marquess & Nell, Inc., 144 N.J. 34, 47 (1996) ("The Act has been interpreted as evincing a legislative policy 'to limit the expansion of products-liability law.'" (quoting Roberts v. Rich Foods, Inc., 139 N.J. 365, 374 (1995))). Indeed, the "Legislature intended for the Act to limit the liability of

manufacturers so as to 'balance[ ] the interests of the public and the individual with a view towards economic reality.'" Rowe v. Hoffman-La Roche, Inc., 189 N.J. 615, 623-24 (2007) (alteration in original) (quoting Zaza, 144 N.J. at 47-48). "In particular, in enacting the PLA, the Legislature intended to reduce the burden on manufacturers of FDA-approved products resulting from products liability litigation." Kendall, 209 N.J. at 194; accord Rowe, 189 N.J. at 623 (stating the PLA was enacted "to re-balance the law in favor of manufacturers").

Here, the trial court's decision to allow the case to proceed to trial based on speculation of a product defect disrupts the balance of interests the Legislature sought to achieve through the PLA. Although the PLA applied strict liability principles, the Legislature still required a plaintiff to prove certain basic, prima facie, elements to establish a product liability claim. N.J.S.A. 2A:58C-2 (requiring plaintiff to prove "by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer…"); see also Myrlak v. Port Auth. of N.Y. & N.J., 157 N.J. 84, 97 (1999) ("[A] plaintiff must prove that the product was defective, that the defect existed when the product left the manufacturer's control, and that the defect proximately caused injuries to the plaintiff . . . ."). It is axiomatic that proof of a product defect is an essential element of a product liability claim. Zaza, 144 N.J. at

49 ("A prerequisite of any recovery under strict tort liability is the existence of a defective condition."). Moreover, a plaintiff must prove the product was defective, "by a preponderance of the competent evidence." Boyle v. Ford Motor Co., 399 N.J. Super. 18, 34 (App. Div. 2008); see also N.J.S.A. 2A:58C-2. Importantly, the plaintiff must establish that a defect existed in the specific product the plaintiff used. N.J.S.A. 2A:58C-2 (plaintiff must prove that "*the product causing the harm*" contained a manufacturing, design or warnings defect) (emphasis added); Sun Chem. Corp. v. Fike Corp., 243 N.J. 319, 333 (2020) (observing that the PLA requires "proof 'that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose'" (quoting N.J.S.A. 2A:58C-2)). Evidence of a defect in some other product does not suffice to defeat summary judgment, but that is all Plaintiff has. Cf. Courtois v. General Motors Corp., 37 N.J. 525, 547 (1962).

This critical element distinguishes New Jersey's strict liability statutory scheme from one that imposes absolute liability and must be heeded. See O'Brien v. Muskin Corp., 94 N.J. 169, 179-80 (1983) ("The necessity of proving a defect in the product as part of the plaintiff's prima facie case distinguishes strict from absolute liability, and thus prevents the manufacturer from also becoming the insurer of a product."). Here, the trial court allowed plaintiff to survive summary judgment merely based on the facts that (1) a recall occurred, and (2) plaintiff experienced known risks that could have occurred *without* any product issue or recall. Plaintiff

attempts to rely on these two facts as "circumstantial evidence" of a defect, but it is pure speculation. Plaintiff has not connected the dots between the recall generally, the alleged defect in the specific product she used, and her alleged injuries. Without evidence that the actual product she received had the defect that led to the recall, and that that defect could cause, and in fact did cause, her injuries, the trial court transformed strict liability into absolute liability. Clearly, that outcome contravenes the statutory plain language of the PLA and undermines the Legislature's intent to rein in product liability litigation in this State. See Kendall, 209 N.J. at 194.

B. Summary Judgment Standard

The trial court's ruling improperly allowed Plaintiff to survive summary judgment by showing only the mere *possibility* of a product defect. See Triffin v. Am. Intern., 372 N.J. Super. 517, 523-24 (App. Div. 2004) (respondent must show more than "some metaphysical doubt as to the material facts" to survive summary judgment); see also Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 529 (1995) (noting that a party cannot survive summary judgment based on "a mere scintilla" of evidence). That is not the law. Summary judgment should be granted where, as here, there is no genuine dispute over the existence of an element of the cause of action. Canesi ex rel. Canesi v. Wilson, 295 N.J. Super. 354, 364-65 (App. Div. 1996), aff'd in part, rev'd in part, 158 N.J. 490 (1999); see also R. 4:42-6 (requiring motion to be granted where "there is no genuine issue as to any material fact

challenged and that the moving party is entitled to judgment or order as a matter of law").

Moreover, the trial court's diminished standard is a far cry from the preponderance of evidence standard plaintiffs must satisfy at trial, which the court must consider. See R. 4:46-2; Vizzoni v. B.M.D., 459 N.J. Super. 554, 567 (App. Div. 2019) ("The motion court must analyze the record in light of the substantive standard and burden of proof that a factfinder would apply in the event that the case were tried." (quoting Globe Motor Co. v. Igdalev, 225 N.J. 469, 480 (2016)). "[N]either the motion court nor an appellate court can ignore the elements of the cause of action or the evidential standard governing the cause of action." Ibid. (quoting Globe Motor, 225 N.J. at 480). Furthermore, a court's summary judgment decision must be based on "reasonable conclusions a rational jury can draw from the evidence." Brill, 142 N.J. at 535.

Lowering the bar for plaintiffs to survive summary judgment will undoubtedly invite more litigation, thus adding additional pressure to already stressed judicial resources and forcing manufacturing and life sciences companies to devote funds to defending lawsuits that would be better spent on research and development of life-saving and life-improving products. Undoubtedly, the specter of gratuitous litigation will discourage companies from investing in New Jersey. Indeed, as explained above, the PLA was enacted to rein in product liability litigation in this State—

particularly lawsuits involving pharmaceutical and other FDA-regulated manufacturers—but rulings like the one at issue here undermine the Legislature's intent by greatly weighting the scales in favor of plaintiffs. See Kendall, 209 N.J. at 194 ("In particular, in enacting the PLA, the Legislature intended to reduce the burden on manufacturers of FDA-approved products resulting from products liability litigation."); see also N.J.S.A. 2A:58C-1.

II. A PLAINTIFF DOES NOT, AND CANNOT, PRESENT SUFFICIENT CREDIBLE EVIDENCE OF PRODUCT DEFECT, NOR DEFEAT SUMMARY JUDGMENT, BY RELYING ON A HYPOTHETICAL DEPOSITION QUESTION

The trial court erroneously concluded that a company witness's affirmative response to a hypothetical deposition question—**if** an Ozurdex unit had dispensed a silicone particulate, would it have deviated from Allergan's performance standards—was sufficient evidence of a product defect. But "a hypothetical question cannot be invoked to supply the substantial facts necessary to support the conclusion." Townsend v. Pierre, 221 N.J. 36, 59 (2015) (quoting Stanley Co. of Am. v. Hercules Powder Co., 16 N.J. 295, 305 (1954)). Thus, a response to a hypothetical question that "lacks the requisite foundation in the facts" is not credible evidence on which a plaintiff can rely to defeat summary judgment. Ibid.

Yet, the trial court allowed Plaintiff to do just that:

> First, the court finds that Plaintiff has presented sufficient evidence that the Ozurdex applicator was defective to survive summary judgment. Despite Defendant's argument that the Ozurdex applicator did not deviate from the allowable "manufacturing specifications," Plaintiff presents testimony from Defendant's own expert that the disbursement of a silicone particulate *would deviate* from Allergan's own performance standards for the product, and that the Ozurdex applicator was not designed to dispense a silicone particulate in the steroid medication. Under the PLA, a manufacturer of a product shall be liable if the claimant proves that the product causing harm deviated from the "design specification . . . or the performance standards of the manufacturer. Therefore, the court finds that there is sufficient evidence that the subject Ozurdex applicator *was defective* under the PLA.
>
> [(Da0794 (citations omitted) (emphases added).)]

To be clear, Ms. Founds did not testify that Plaintiff's Ozurdex unit in fact generated a silicone particulate. She merely responded affirmatively to a hypothetical question about whether an Ozurdex unit that had dispensed a silicone particle would deviate from Allergan's standards. Nonetheless, the trial court made the illogical leap that this *hypothetical* testimony somehow sufficed to establish *the fact* that the specific applicator used to dispense Plaintiff's medicine *was* indeed defective. Ibid. Clearly, that was an unjustifiable inference even at the summary judgment stage.

If plaintiffs can survive summary judgment simply because a corporate representative acknowledges that a hypothetically-defective product would deviate from the company's standards, meritless cases would go to trial, resulting in needless

litigation and an enormous burden on all of New Jersey's manufacturers, including those in the life sciences industry, and the courts. See Brill, 142 N.J. at 541 ("To send a case to trial, knowing that a rational jury can reach but one conclusion, is indeed 'worthless' and will 'serve no useful purpose.'"). There is no discernible benefit to allowing plaintiffs to reach a jury on insufficient hypothetical proofs.

Accordingly, this Court should reverse the trial court's order granting summary judgment based only on hypothetical evidence that Plaintiff's Ozurdex unit was defective, and enter judgment for Defendant.

III. THE TRIAL COURT FAILED IN ITS GATEKEEPING ROLE BY ADMITTING UNRELIABLE EXPERT TESTIMONY

"Expert testimony is required when the issue is beyond the 'common knowledge of lay persons.'" Froom v. Perel, 377 N.J. Super. 298, 318 (App. Div. 2005) (quoting Kelly v. Berlin, 300 N.J. Super. 256, 265-66 (App. Div. 1997)). Consequently, trial courts are tasked with determining the reliability of expert testimony and ensuring jurors are not exposed "to unsound science through the compelling voice of an expert." In re Accutane Litig., 234 N.J. 340, 389 (2018). "The danger of prejudice through introduction of unreliable expert evidence is clear. While juries would not always accord excessive weight to unreliable expert testimony, there is substantial danger that they would do so, precisely because the evidence is labeled 'scientific' and 'expert.'" Id. at 390 (quoting State v. Cavallo,

88 N.J. 508, 518 (1982). Thus, the trial court serves as a gatekeeper, requiring the court "to assess both the methodology used by the expert to arrive at an opinion and the underlying data used in the formation of the opinion." Id. at 396-97. "When a proponent [of expert testimony] does not demonstrate the soundness of a methodology, both in terms of its approach to reasoning and to its use of data . . . the gatekeeper should exclude the proposed expert testimony on the basis that it is unreliable." Id. at 400.

Additionally, the net opinion rule "forbids the admission into evidence of an expert's conclusions that are not supported by factual evidence or other data." Townsend, 221 N.J. at 53-54 (quoting Polzo v. Cnty. of Essex, 196 N.J. 569 (2008)). "An expert's conclusion is excluded if it is based merely on unfounded speculation and unquantified possibilities." Id. at 55. Indeed, "when an expert speculates, he ceases to be an aid to the trier of fact and becomes nothing more than an additional juror." Ibid.

Both of Plaintiff's experts offered opinions that were patently unreliable. Most glaringly, Dr. Phillip's view that it was "more likely than not" that Plaintiff's injuries were caused by a silicone particulate was based on an inaccurate estimate of the percentage of affected Ozurdex units in the lot at issue. (Da0796.) Dr. Phillips testified that he believed twenty-two to twenty-five percent of the units had issues, which is simply wrong. (Da0070.) Again, only two percent of the lot had the

particulate issue. (Da0229.) Thus, Dr. Phillip's opinion was predicated on false data and inherently unreliable.

Separately, Dr. Lalezary's opinions were based on deeply flawed reasoning. During his deposition, Dr. Lalezary repeatedly described Plaintiff's Ozurdex unit as defective. When asked how he knew the applicator was defective he replied, "It was part of the lot that was recalled." (Da0186.) Dr. Lalezary then went on to opine that Plaintiff's retinal detachment must have been caused by "a defective Ozurdex" because the purportedly defective applicator was the only variation from Plaintiff's previous treatments. (Da0187.) Defense counsel asked Dr. Lalezary again how he knew the Ozurdex was defective, and the doctor replied, "Because it's from a defective lot." (Id.) Surprisingly, Dr. Lalezary came to that conclusion despite knowing that only "two to three percent" of the lot was affected. (Da0193.) The flaw in Dr. Lalezary's reasoning is obvious—the fact that Plaintiff's Ozurdex unit came from a lot where two percent of the units had an issue is far from conclusive evidence that the product was defective. To the contrary, given that such a small percentage of the lot had problems, it was far more likely that Plaintiff's applicator was *not* one of the affected units. Moreover, Dr. Lalezary acknowledged that Plaintiff had "multiple risk factors" that could have led to a retinal detachment "in the absence of a silicone particulate," which made his reasoning regarding the applicator's defectiveness all the more speculative and improper. (Da0196-97.)

Surely, an expert cannot properly claim that a product is defective because "[i]t was part of the lot that was recalled," (Da0186), when only 2.2% of the lot had the issue that led to the recall. Townsend, 221 N.J. at 55 ("An expert's conclusion is excluded if it is based merely on unfounded speculation . . . ."). Nor can an expert rely on a plaintiff's alleged injury as evidence of product defect. Cf. Zaza, 144 N.J. at 49 ("An inference of defectiveness may not be drawn from the mere fact that someone was injured."); O'Brien, 94 N.J. at 179-80 ("Proof that the product was defective requires more than a mere showing that the product caused the injury."). That is particularly important where, as here, the plaintiff alleges injuries that could have occurred *without* any alleged defect or because of her other pre-existing medical conditions, and the expert conducted no analysis and applied no methodology to rule out any of those other potential causes.[1] See In re Accutane, 234 N.J. at 397 (examining "whether an expert's reasoning or methodology underlying the testimony is scientifically valid"). Dr. Lalezary's opinion is a classic net opinion that should have been excluded, Townsend, 221 N.J. at 55, and it cannot create a dispute of material fact or defeat summary judgment, Smith v. Est. of Kelly, 343 N.J. Super. 480, 496-97 (App. Div. 2001).

[1] For these reasons, Plaintiff's experts' opinions on the issue of causation were wholly unreliable and should have been excluded. Amici agree with Defendant's arguments in its opening brief on that point and do not repeat them here. (Db33-43.)

Undoubtedly, trial courts—as gatekeepers—must shield jurors from such unsound, speculative expert testimony. See Accutane, 234 N.J. at 396-97. The need for courts to be effective gatekeepers is particularly acute in cases involving pharmaceuticals and medical devices, given how there will nearly always be confounding variables that require more than a rudimentary analysis to sort through. Experts who misapprehend essential facts or draw inappropriate conclusions from simple percentages cannot be permitted to testify before a jury. Moreover, the dangers of unreliable expert testimony are even more pronounced in cases like this, where the plaintiff's claims are based entirely on speculation, and jurors have little else to go on to decide the case. See id. at 390.

CONCLUSION

The trial court erred in concluding that Plaintiff had presented sufficient evidence to survive summary judgment. The court's discussion about the significance of a company witness's testimony skips the critical step of identifying actual evidence that supports an inference that Plaintiff's Ozurdex applicator disbursed a particulate. Instead, the court wrongly concluded that a hypothetical acknowledging that if such a disbursement had occurred, it would be a deviation from performance standards, was sufficient evidence of a product defect under the PLA. Moreover, the record reveals significant problems with the methodology and reasoning of Plaintiff's experts such that the court should have exercised its

gatekeeping function and excluded their opinions. Accordingly, this Court should reverse the decision of the trial court and enter summary judgment for Defendants.

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