	SUPREME COURT OF NEW JERSEY
ALISON BEAVAN, Plaintiff-Petitioner, v. ALLERGAN USA, INC., et al., Defendant-Respondent.	DOCKET NO.: 090150 Civil Action ON PETITION FOR CERTIFICATION FROM THE SUPERIOR COURT OF NEW JERSEY, APPELLATE DIVISION DOCKET NO. BELOW: A-1501-23 Sat Below: Hon. Hany Mawla, P.J.A.D. Hon. Robert M. Vinci, J.A.D.

SUPPLEMENTAL BRIEF OF DEFENDANT-RESPONDENT ALLERGAN USA, INC.

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PRELIMINARY STATEMENT

The Appellate Division corrected the manifest injustice arising from the trial court's decision to allow Plaintiff-Petitioner Alison Beavan to proceed to trial in this product-liability action with "no evidence the [specific product at issue] was defective" and an "utter lack of evidence to support the existence of both general and specific causation." (Psa174-75) The Appellate Division rightly held that Plaintiff's experts' net opinions "based on evidence that does not exist" could not satisfy Plaintiff's burden to prove product defect and causation. (Psa174) No matter how many darts Plaintiff and her supporting *amicus* aim at the Appellate Division's decision, no matter how many ways they contort and misrepresent the record, and no matter how many new theories they raise for the first time before this Court, they cannot overcome these fundamental deficiencies.

Instead of doing the scientific work necessary to prove the product at issue had a defect that caused her injuries, Plaintiff and her experts took a shortcut: they argue her injuries occurred in temporal proximity to administration of a prescription drug from a recalled lot, and therefore, the product 'must have been the cause,' rather than the host of other recognized factors Plaintiff's experts ***admit*** independently could have caused Plaintiff's injuries. But recalls and temporal proximity are not a substitute for the requisite scientific and medical proof of product defect and causation through qualified expert testimony. That is especially true where, as here,

neither expert offered—or was qualified to offer—a reliable opinion that the purported defect was capable of causing Plaintiff's injuries (general causation) and that the purported defect, rather than the many known alternate causes, actually caused those injuries (specific causation). The Appellate Division correctly held that the trial court abdicated its gatekeeping function and abused its discretion in allowing Plaintiff's experts to offer such unsupported and unscientific opinions.

Plaintiff and the New Jersey Association for Justice ("NJAJ") argue (falsely) that the Appellate Division rejected use of the differential diagnosis methodology. These arguments disregard the Appellate Division's acknowledgement that the method "is certainly permitted" to establish ***specific*** causation (Psa174) and outright ignore this Court's statement that "uttering the phrase 'differential diagnosis'" is not a panacea, *Creanga v. Jardal*, 185 N.J. 345, 356-57 (2005). The Appellate Division correctly held it an abuse of discretion to allow these experts' opinions that not only attempted to use differential diagnosis improperly as a method to prove ***general*** causation, but also failed to properly apply that method to the facts of the case, rendering their specific causation opinions unreliable and inadmissible.

Plaintiff and NJAJ try to excuse the experts' methodological failures on general causation with the repetitive argument that Defendant-Respondent Allergan USA, Inc. supposedly admitted general causation. That is simply false. The actual language of the supposed "admission" is equivocal and ambiguous, does not actually

"admit" anything, and certainly fails to constitute an admission by Allergan that the purported defect is capable of causing the injuries Plaintiff alleges.

Recognizing the manufacturing defect theory Plaintiff pled in her complaint fails under current New Jersey product-liability law, Plaintiff's Supplemental Brief and NJAJ's *Amicus* Brief pivot to an unpled post-sale failure-to-warn claim, attempting to convince the Court that a lower burden of proof should apply. But the medical malpractice and occupational exposure cases they rely on, and those limited instances where this Court held unique circumstances justified a lessened burden, are inapposite. None of those unique circumstances exists here, and neither Plaintiff nor NJAJ articulate any reason that would justify reducing Plaintiff's burden of proof in this pharmaceutical product-liability case.

Plaintiff's last gambit to save this case from its proper dismissal is a belated request for a Rule 104 hearing. Not only did Plaintiff waive any request for a Rule 104 hearing, but Plaintiff has never proffered what additional evidence such a hearing would reveal and how that would change the result. This is unsurprising considering Plaintiff had an unrestricted opportunity to present any evidence to the trial court she felt necessary to satisfy her burden to prove admissibility of her experts' opinions. Plaintiff's belated request for a 'do-over' to submit additional, unidentified evidence—only after the Appellate Division held, based on a full and complete record, that she did not meet her burden—is too little, too late and should

be rejected. Proponents of expert testimony are not entitled to multiple bites at the apple. This Court should affirm the Appellate Division's correct decision.

STATEMENT OF FACTS AND PROCEDURAL HISTORY

The facts and procedural history in NJAJ's *Amicus* Brief ("NJAJB") and Plaintiff's Supplemental Brief ("PSB") provide an incomplete picture of the record. Allergan supplements their statements to ensure this Court has the full context for the decision below. Allergan also relies on and incorporates its fulsome briefs submitted in the Appellate Division.

A. Additional Facts About Ozurdex® and Its Recall Relevant to the Issues on Appeal.

As NJAJ and Plaintiff state, this case is about the prescription drug Ozurdex®, a steroid pellet injected into the eye to treat serious and debilitating eye conditions. (Da105; Da224) Plaintiff's experts, practicing ophthalmologists, routinely use Ozurdex® and agree it is a safe and effective medication. (Da87; Da150, pp. 15-18)

Ozurdex® pellets come pre-loaded in single-use applicators with a needle sleeved in silicone. (Da105; Da229) A routine inspection in June 2018 discovered some Ozurdex® units had the potential for a single 300-micron silicone particulate to sheer off the needle sleeve when the applicator is actuated to eject the pellet. (Da240) There were no reports of injury attributed to the particulate.

Contrary to Plaintiff's theory that Allergan failed to take timely action in the U.S. in response to this discovery, the record reflects that Allergan promptly reported

the issue to FDA in July 2018. (*Id.*) Allergan then communicated regularly with FDA, providing updates, responding to requests for information, submitting Field Alerts and a Benefit-Risk Assessment, and advising of foreign regulatory actions.[1] (Da229; Da258, ¶¶ 49-50, 56, 64-65, 70-71, 74)

Plaintiff and NJAJ assert Allergan never tried to get the word out in the U.S. before Plaintiff's November 6, 2018 Ozurdex® injection. But the record reflects the opposite. On October 3, 2018, Allergan informed FDA of its desire to issue a Dear Health Care Provider ("DHCP") letter to U.S. physicians, submitting a draft letter to FDA for review. (Da229; Da238; Da258, ¶¶ 49-50, 56, 64-65, 70-71, 74) Allergan's draft DHCP letter described the potential for some Ozurdex® units to generate a 300-micron silicone particulate and stated:

> Intraocular inflammation. In sensitive patients this potential cannot be ruled out and it is difficult to predict which patient may have sensitivity to silicone particles.

(Da649) This statement reflected the state of the known science at that time, namely that there were no studies on whether a 300-micron particulate of this medical-grade silicone could cause eye inflammation in patients with "sensitivity to silicone

[1] Plaintiff tries to make much of the fact that Allergan undertook recalls and issued recall notices in other countries before the U.S. (PSB 2-3) But that was outside of Allergan's control. The different rules, processes, and timelines of foreign regulatory authorities dictate the timing of actions in their jurisdictions, as FDA does in the U.S. Allergan accordingly initiated recalls in foreign markets pursuant to those regulatory agencies' respective decisions and timelines, such as the Swiss recall in September 2018 at the recommendation of its regulator. (Da258, ¶ 70)

particles." Allergan thus suggested advising healthcare providers that, based on the information then available, the potential for such eye inflammation could not be "ruled out." (*Id.*)

Allergan followed up with FDA multiple times for feedback on its draft DHCP letter and the action FDA believed necessary. (Da229; Da258, ¶¶ 49-50, 56, 64-65, 70-71, 74) By the time Plaintiff received her Ozurdex® injection in November 2018, Allergan had made ***over 20 attempts*** to obtain authorization from FDA to communicate with U.S. healthcare providers about the silicone particulate issue. (Da258, ¶ 65) The unopposed testimony of Allergan's regulatory expert, Janet Arrowsmith, M.D., shows it was necessary for Allergan to wait for FDA's clearance to send the letter, as it would risk adverse regulatory action for a communication inconsistent with FDA's views of the issue. (*Id.*, ¶¶ 66, 71-75)

Meanwhile, Allergan continued investigating and submitting updated reports to FDA, including a Field Alert on October 25, 2018, reporting on Allergan's testing of retained samples from impacted lots (Da234), including the lot for the Ozurdex® unit used in Plaintiff's procedure showing particulate generation in 2.2% of units. (Da237). That Field Alert also reported on Allergan's ongoing investigation of potential risks:

> The patient impact assessment & benefit: risk assessment completed by the Global Safety and Epidemiology team concludes that the benefit: risk profile remains favorable despite the potential for a single silicone particle from the needle sleeve to be injected with the product implant.

> This assessment takes into consideration the dosing frequency of the product, the duration of treatment, the potential side effects and the potential impact to sensitive patients. Allergen maintains the position that the impact to patient is low based on the patient impact assessment. Allergen ha[s] also engaged with independent Consulting Ophthalmologists who are aligned with this position.

(Da237) Plaintiff asserts (without any record citation) that "Allergan's own reports showed increased ocular inflammation" from the recalled lots. (PSB 31) But the record contains no such reports, and Plaintiff has identified none.

Although FDA ultimately determined the potential for generation of a silicone particulate was not a "safety concern," it recommended Allergan address the issue "for the sake of product quality." (Da252) On December 18, 2018, FDA finally responded to Allergan regarding its proposed communication about the recall issue, providing edits/comments to Allergan's draft and directing Allergan to "update accordingly and please issue." (Da452, pp. 130-31; Da479)

So, on December 20, 2018, Allergan announced a U.S. recall of 22 Ozurdex® lots possibly impacted by the silicone particulate issue and, on December 28, 2018, sent an Urgent Drug Recall letter (as edited by FDA) to physicians who received any units from one of those lots. (Da255; Da258, ¶¶ 51-52) The recall letter included a "Health Hazard Assessment" upon which Plaintiff's entire case hinges, which states:

> Mild transient visual disturbance or intraocular inflammatory reaction in sensitive patients are potential safety risks.

(Da256) This statement in the recall letter was consistent with Allergan's October 2018 draft DHCP letter: given available information at that time, it could not be ruled out that the silicone particulate posed a potential risk of eye inflammation in patients sensitive to silicone. (Da649)

Additional information bearing on this question became available in 2019. NJAJ and Plaintiff's Briefs fail to apprise the Court that, in January 2019, a scientific study commenced seeking to determine if the medical-grade silicone used in the Ozurdex® needle sleeve—and that comprised the 300-micron particulate—***could cause*** eye inflammation. (Da305) Silicone particles greater in size and load than the 300-micron particulate were injected into living rabbits' eyes and observed for up to nine months, ending in October 2019. (*Id.*) The toxicity study concluded that the silicone at issue was inert[2] and biocompatible, causing no inflammation. (Da309)[3]

B. Additional Facts About the Multiple Independent Risk Factors for Plaintiff's Injuries.

Plaintiff claims a 300-micron silicone particulate was injected into her left eye with the Ozurdex® pellet on November 6, 2018, and that the particulate caused her

[2] In this context, "inert" means "lacking a usual or anticipated chemical or biological action." Merriam-Webster Dictionary, Definition of "inert," https://www.merriam-webster.com/dictionary/inert.

[3] Plaintiff blatantly misrepresents the record in stating that "[a]dditional testing and investigation conducted by Allergan confirmed that the silicone particulate defect, especially in sensitive patients like Ms. Beavan, could cause the exact injuries that Ms. Beavan sustained." (PSB 30) That is the exact opposite of the truth.

to experience eye inflammation and a retinal detachment, resulting in vision loss. Plaintiff's retained expert, Dr. Maziar Lalezary, opines Plaintiff's vision loss was caused by her retinal detachment, which he theorizes was induced by mechanical traction from the 300-micron particulate. (Da150, pp. 15, 64) Plaintiff's other expert, her treating physician Dr. William Phillips, disagrees that the particulate would induce a retinal detachment, and instead theorizes that the silicone particulate caused eye inflammation that resulted in her vision loss. (Da47, pp. 30-31, 58-60) The record indisputably reveals, and Plaintiff and NJAJ's Briefs fail to fully disclose, that a host of other factors could have caused vision loss in Plaintiff's left eye independent of the alleged particulate.

The only history Plaintiff provides about her left eye is that she had 20/100 vision before the November 6, 2018 procedure. (PSB 3) NJAJ and Plaintiff's Briefs fail to inform the Court that she actually has a long history of serious eye problems affecting both eyes going back years that could independently lead to vision loss, including inadequately-controlled cystoid macular edema[4] and non-infectious uveitis[5]. (Da45; Da47, pp. 13, 60) They also omit the fact that Plaintiff has had numerous eye surgeries and procedures, including:

[4] 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. (Da346, ¶ 91)

[5] 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

- multiple intravitreal eye injections, including with Ozurdex®;
- an intraocular lens implant;
- trabeculectomy (eye surgery to create a new drainage path to lower pressure);
- two vitrectomies (to completely remove vitreous fluid in the back of her eye); and
- implantation of a silicone-coated Retisert® tablet (trying to control her longstanding inflammation/ uveitis).

(Da346, ¶¶ 26, 81 n.3, 91) The silicone-coated Retisert® is 10 times larger than a 300-micron silicone particulate, and doctors discovered the Retisert® had dislodged from her retina ***at the precise location*** and ***around the time*** of her retinal detachment. (Da150, p. 130; Da346, ¶ 81 n.3) Plaintiff also continued to smoke, despite constant warnings over many years from her ophthalmologists that it worsened her chronic eye inflammation. (Da346, ¶ 91) It is also well known that eye inflammation, retinal detachment, and vision loss are inherent risks of any intravitreal injection, including an injection of Ozurdex® without a silicone particulate. (Da89, pp. 73-76; Da105;

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working-age population in the developed world. (Da47, 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.

Da121) Indeed, every intravitreal injection itself comes with an inherent and independent new risk of eye inflammation and retinal detachment. (Da150, pp. 78)

NJAJ and Plaintiff's Briefs omit the important fact that everyone—including Plaintiff's experts—agrees that Plaintiff's inflammation, retinal detachment, and vision loss could have been caused—independently—by any of these other factors. (Da47, pp. 40-41, 58-59; Da150, pp. 78-80, 112-13; Da346, ¶¶ 83, 91, 94) Dr. Lalezary testified that "we already established that she has multiple risk factors," that a "retinal detachment is a possible risk following any intraocular procedure" and "any intravitreal injection," and that "***all of those risk factors…could have led to a retinal detachment…[i]n the absence of a silicone particulate***." (Da150, pp. 78, 104, 109-10, 112-13 (emphasis added)) Meanwhile, Dr. Phillips testified that he does not believe a silicone particulate caused Plaintiff's 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***.

(Da47, pp. 58-59 (emphasis added)) Allergan's expert, Dr. Dean Eliott of Harvard Medical School, likewise opines that Plaintiff's multiple serious eye conditions, surgeries, procedures, and dislocation of the Retisert®, exacerbated by her long

history of smoking, are the obvious and likely causes of her vision loss. (Da346, ¶ 94)[6]

C. Plaintiff's Experts Speculate a Silicone Particulate Caused Her Injuries Based on Nothing But the Recall and Temporal Proximity.

Despite acknowledging the many independent risk factors that could not be ruled out, Drs. Lalezary and Phillips nonetheless opine that a silicone particulate from the Ozurdex® injection is what caused Plaintiff's injuries. As noted, Dr. Phillips opines that the Ozurdex® injected on November 6 caused Plaintiff's eye inflammation and resulting vision loss. (Da47, pp. 30-31, 58-60) Importantly, Dr. Phillips does not offer an independent general-causation opinion that a 300-micron particulate of medical-grade silicone is capable of causing eye inflammation. He is a practicing ophthalmologist with no expertise in toxicology, 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." (Da47, p. 39) Instead, he testified he uses "silicone oil in the eye to repair retinal

[6] Plaintiff claims to have a "third expert," Dr. Tarver, whose opinions she argues the Appellate Division overlooked. (PSB 9) But Plaintiff admits she disclosed only two experts (*id.* 4), neither of whom was Dr. Tarver (Da329). Dr. Tarver was never deposed, and her records do not indicate she believed the Ozurdex® at issue generated a silicone particulate that caused Plaintiff's injuries. To the extent Plaintiff points to her notes about migration of the Ozurdex® ***pellet*** (Da690), those notes have no relevance to Plaintiff's theory of migration of a phantom ***silicone particulate***.

detachments" and agreed it "is inert," depending on its purity (*id.*, pp. 54-55), which is consistent with the conclusion derived from the rabbit toxicity study (Da304).

When Dr. Phillips was asked why he ignored his experience and the science to assume this medical-grade silicone could cause inflammation, he answered: "one of the recall notices." (Da47, p. 54) Although the recall letter stated inflammation was a "potential" risk in patients "sensitive" to silicone (Da255; Da452, p. 39), Dr. Phillips never opines that Plaintiff is sensitive to silicone. Nor could he, as Plaintiff had a silicone-coated Retisert® in her eye, ***10 times larger*** than the particulate, for years without issue. (Da150, p. 130; Da346, ¶ 81 n.3)

As noted, Dr. Lalezary offers the different opinion that the particulate induced a retinal detachment by mechanical traction, resulting in vision loss. (Da150, pp. 15, 64) Like Dr. Phillips, however, Dr. Lalezary offers no independent general-causation opinion that a 300-micron, medical-grade silicone particulate can cause a retinal detachment by mechanical traction. But, unlike Dr. Phillips, Dr. Lalezary cites nothing—not even the recall letter—establishing general causation. This makes sense since the recall letter says nothing about a potential risk of a particulate inducing retinal detachment—*i.e.*, the words "retinal detachment" do not appear anywhere in the document. (Da255)

Drs. Lalezary and Phillips nevertheless concluded the "temporal relationship" between Plaintiff's injuries and the November 6 Ozurdex® injection from a recalled

lot supports their opinion that a particulate, rather than the other known potential causes, was "more likely" what caused her injuries. (Da150, pp. 82-83, 100, 102-04, 109; Da47, pp. 30-31, 50-51, 59-60.) Plaintiff and NJAJ acknowledge the experts' reliance on temporal proximity (PSB 6, 8, 10-11; NJAJB 5-7), but argue their use of differential diagnosis made their opinions reliable—without differentiating general from specific causation or that proper use of this methodology is limited to the latter.

D. Procedural History

Plaintiff's case has morphed on appeal. Plaintiff tells this Court she filed a "strict product liability action." (PSB 11) Plaintiff's Complaint includes claims for negligence, strict product liability, and breach of implied warranty based on allegations that (i) the Ozurdex® unit at issue had a manufacturing defect that resulted in a silicone particulate being injected into her eye causing her injuries, and (ii) those injuries could have been avoided if Allergan had recalled the product sooner. (Da1) On appeal, however, Plaintiff and NJAJ now couch Plaintiff's claim as one for post-sale failure to warn. No matter how the claim is couched, Plaintiff still must establish the Ozurdex® unit at issue was one of the 2.2% that generated a silicone particulate (*i.e.*, the product at issue had the claimed defect), that the particulate entered her eye, and that the 300-micron silicone particulate was capable of and did, in fact, cause her injuries (*i.e.*, medical causation).

In the trial court, Allergan moved to exclude Plaintiff's experts' unreliable opinions and for summary judgment based on her inability to prove defect and causation. (Da35; Da799) The trial court denied the motions, finding Plaintiff's experts "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. (Da816, pp. 9, 11-12)

The Appellate Division granted Allergan permission immediately to appeal and reversed because that decision worked a manifest injustice. (Psa141) The Appellate Division "appl[ied] an abuse of discretion standard" to the trial court's decision to allow Plaintiff's experts to testify. (Psa170-72) After reviewing the experts' opinions and the bases therefor, the Appellate Division held that:

> Our difficulty is not with the theory of causation espoused by each expert or that causation could be established through a differential diagnosis. This is certainly permitted. See Creanga v. Jardal, 185 N.J. 345, 357-58 (2005)….
>
> However, the issue here is the utter lack of evidence to support the existence of both general and specific causation. Plaintiff's experts' theory of causation is based on evidence that does not exist and would leave a jury to speculate whether there was ever a particulate in the applicator or particulate injected into plaintiff's eye.
>
> There was no evidence the Ozurdex injection plaintiff received was defective and no evidence of a particulate in her eye. Defendant's experts disagreed the particulate would cause a detachment in her eye. The Retisert silicone insert, which was ten times larger than the alleged Ozurdex particulate, dislocated contemporaneously with her injury and

> could have been a cause of her injury. Plaintiff also had other underlying medical conditions that could have caused the injury, including: chronic eye inflammation, inflammation from smoking, and a history of ophthalmic procedure and intravitreal injections. For these reasons, the differential diagnosis was unavailing.

(Psa174-75) The Appellate Division then noted this Court's recent adoption of the *Daubert* factors "to help guide trial courts to assess the reliability of scientific or technical expert testimony," and held:

> Aside from the lack of objective factual evidence of causation, there was no evidence presented by plaintiff's experts to convince us their theory of causation would pass muster under Daubert. The record is devoid of testing, error rates, peer reviews, publications, or general acceptance in the scientific community to support the method of causation in this case.
>
> For these reasons, we are constrained to conclude the trial court should have barred plaintiff's experts because they did not establish general or specific causation. Defendant should have been granted summary judgment due to the lack of proof of causation.

(Psa175-76) The trial court entered summary judgment for Allergan pursuant to the Appellate Division's decision. (Psa177) This Court subsequently granted Plaintiff's petition for certification to review the decision by the Appellate Division.

LEGAL ARGUMENT

I. PLAINTIFF HAS THE BURDEN TO PROVE PRODUCT DEFECT AND CAUSATION THROUGH QUALIFIED EXPERTS. [Psa 174-176].

A. In this Prescription Drug Case, Plaintiff Must Have Expert Proof of Product Defect and General and Specific Medical Causation.

Plaintiff's product-liability claims are governed by the Product Liability Act ("PLA"). Although NJAJ asserts the purpose of enacting the PLA was to encourage

safe products (NJAJB 9), this Court has repeatedly explained that the legislative intent in enacting the PLA was really "to limit the liability of manufacturers," *Kendall v. Hoffman-La Roche, Inc.*, 209 N.J. 173, 194 (2012), and "'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)), by "re-balanc[ing] the law in favor of manufacturers," *Rowe v. Hoffman-La Roche, Inc.*, 189 N.J. 615, 623-24 (2007) (internal quotes omitted).

To establish her PLA claim, Plaintiff must 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). For causation, Plaintiff must show "to a reasonable degree of probability" that the defect "was a substantial factor in bringing about the injuries." *Ralda Deleon v. Graco Inc.*, 2011 WL 2636993, at *6-7 (N.J. Super. Ct. App. Div. July 7, 2011); *accord* Model Civil Jury Charge 5.40I ("Proximate cause means that the defect in the product was a substantial factor which singly, or in combination with another cause, brought about the accident.").

Causation for this product-liability claim requires proof that Plaintiff was exposed to the defect in the product (product-defect causation) and that the defect caused Plaintiff's injuries (medical causation). *See James v. Bessemer Processing Co.*, 155 N.J. 279, 299 (1998) (noting plaintiffs must prove both product-defect

causation and medical causation).[7] Medical causation, in turn, requires proof that the defect was capable of causing those injuries (general causation) and the defect, rather than other potential causes, actually caused the injuries (specific causation). *In re PPA*, 2003 WL 22417238, at *20 (N.J. Super. Ct. Law Div. July 21, 2003).

As the Appellate Division observed (Psa169), and NJAJ and Plaintiff do not refute, when a case concerns a complex product beyond jurors' common knowledge, like a prescription drug, expert testimony is required to establish both defect and causation. *See, e.g.*, *Davis v. Brickman Landscaping, Ltd.*, 219 N.J. 395, 407 (2014) (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 needed where matter "is so esoteric that jurors of common judgment and experience cannot form a valid judgment").

Importantly, here, expert testimony is required—and circumstantial evidence is insufficient—to prove a defect involving this complex prescription drug and its

[7] NJAJ argues the Appellate Division decision conflicts with *James*. It does not. The cases are very different. *James* was an "environmental tort action," not governed by the PLA. 155 N.J. at 295-96. The issue was how to address medical causation in multi-defendant occupational exposure cases, where a plaintiff could not tie injuries to a specific product from a specific defendant. *Id.* at 286. To address that, the Court lowered the burden of proof from the product defect being a "substantial factor" in causing the injury to proving "frequent, regular and proximate exposure" to the product and "medical and/or scientific proof of a nexus between the exposure and the plaintiff's condition." *Id.* 299, 304. That 'lesser' burden for environmental occupational exposure cases is not applicable to Plaintiff's PLA claim.

medical-device delivery system ***even where the product has been recalled***. *See, e.g.*, *Schweiger v. Standard Tile Supply, Co.*, 2019 WL 5783478, at *4 (N.J. Super. App. Ct. Nov. 6, 2019) (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").

New Jersey law thus requires that Plaintiff have admissible expert proof that the Ozurdex® unit she was exposed to was one of the 2.2% that generated a silicone particulate that entered her eye, and that the silicone particulate was capable of causing and actually did cause her injuries. Otherwise, "summary judgment is appropriate [because] required expert testimony is absent." *In re Mirena IUD Prods. Liab. Litig.*, 202 F. Supp. 3d 304, 312 (S.D.N.Y. 2016); *see, e.g.*, *McMillan v. Johnson & Johnson*, 2005 WL 20000203, at *3 (D.N.J. Aug. 19, 2005) (finding that, without expert testimony, the plaintiff had "insufficient proof of product defect").

B. Courts Must Act as Gatekeepers and Exclude Unqualified Experts Offering Opinions Not Supported by Facts and Data and the Proper Application of Reliable Methodologies.

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. Plaintiff 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 Litig.*, 234 N.J. 340, 348 (2018). Courts 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." *Id.* at 389-90, 396-97. When an expert provides a "mere conclusion" that lacks a foundation and the "why and wherefore," it must be excluded as an inadmissible "net opinion." *Davis,* 219 N.J. at 410.

II. THE APPELLATE DIVISION DID NOT OVERLOOK OR MISAPPLY THE STANDARD OF REVIEW. [Psa 174-176].

All agree that a ruling on the admission of expert testimony is reviewed for an abuse of discretion. *Accutane,* 234 N.J. at 348. Contrary to NJAJ and Plaintiff's contention (PSB 13-14; NJAJB 15), the Appellate Division properly applied this standard of review (Psa172), reversing the trial court because the experts' opinions are "based on evidence that does not exist" (Psa174). Allowing an opinion unsupported by facts and data—a classic "net opinion"—unquestionably constitutes an abuse of discretion and an error clearly capable of producing an unjust result. *Lanzo v. Cyprus Amax Minerals Co.*, 467 N.J. Super. 476, 517-18 (App. Div. 2021).

The Appellate Division further supported its abuse of discretion finding by noting the experts' opinions did not "pass muster" under the *Daubert* factors this

Court adopted in *Accutane*. (Psa175-76) Allowing expert opinions on scientific issues where, as here, "[t]he record is devoid of testing, error rates, peer reviews, publications, or general acceptance in the scientific community to support the method of causation" (Psa176) is undeniably an abuse of discretion. Further, the Appellate Division's finding fully satisfies the test for "abuse of discretion" cited in NJAJ's Brief: a ruling that is "so wide off the mark" it must be reversed. (NJAJB 24 (quoting *Hisenaj v. Kuehner*, 194 N.J. 6, 25 (2008)).[8] Because the Appellate Division properly applied the standard of review, and NJAJ and Plaintiff show no error in that decision, this Court should affirm.

III. THE APPELLATE DIVISION CORRECTLY HELD IT AN ABUSE OF DISCRETION TO ALLOW PLAINTIFF'S EXPERTS' OPINIONS. [Psa 174-176].

A. Plaintiff's Experts Do Not and Cannot Reliably Opine that the Specific Ozurdex® Unit At Issue Had a Manufacturing Defect.

Plaintiff's case hinges on her claim that a silicone particulate generated by a defectively manufactured Ozurdex® unit was injected into her eye on November 6, 2018. Whether Plaintiff characterizes her claim as one for manufacturing-defect and

[8] In *Hisenaj*, the Court held the Appellate Division did not properly apply the abuse of discretion standard because it reversed based on matters outside the record. 194 N.J. at 25. NJAJ and Plaintiff point to nothing similar in the Appellate Division decision here that would establish the court did not faithfully follow the standard of review. Their argument appears to be that the standard of review was not followed because the Appellate Division reversed instead of deferring to the trial court on matters of expert admissibility. But that cannot be the test because, if so, no decision on expert admissibility (or any other discretionary decision) could ever be reversed.

failure-to-recall (as originally pled) or as one for post-sale failure-to-warn (as recast on appeal), Plaintiff still must prove the Ozurdex® unit generated a silicone particulate that was injected into her eye. That the subject Ozurdex® unit came from a lot that was recalled is alone "insufficient to establish that the defect which was the subject of the recall was present in the particular product" used in Plaintiff's procedure. *Velazquez v. Abbot Labs., Inc.*, 901 F. Supp. 2d 279, 305 (D.P.R. 2012).

Because the undisputed record reflects only a 2.2% chance the subject unit generated a particulate, "no reasonable factfinder could find that the plaintiff has proven [that specific unit was defective] by a preponderance of the evidence." *Townsend v. Pierre*, 221 N.J. 36, 60 (2015).[9] Just like the plaintiff in *Pusey v. Becton Dickinson & Co.*, 794 F. Supp. 2d 551, 564-65 (E.D. Pa. 2011), was unable to establish a defect in the specific product at issue when the evidence showed only a 26% chance of defect, Plaintiff here cannot establish a defect in her Ozurdex® unit when the evidence shows only a 2.2% chance it generated a silicone particulate. The

[9] *Accord Scanlon v. Gen. Motor Corp.*, 65 N.J. 582, 590 n.1 (1974); *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.").

Appellate Division correctly held summary judgment should be entered for Allergan because Plaintiff's experts did not fill this evidentiary gap.[10]

Plaintiff's experts, practicing ophthalmologists, admittedly have no expertise in manufacturing a prescription drug like Ozurdex® and its medical-device delivery system. They were thus not designated to offer an opinion that the subject Ozurdex® unit had a manufacturing defect that caused it to generate a silicone particulate (Da329), and they admit they cannot offer such an opinion to the requisite reasonable degree of scientific and medical certainty. Dr. Phillips admits no one ever saw and "***there's no way [he] could possibly know*** whether there was a silicone particulate in [her] eye." (Da452, pp. 50-52) He just assumed it was there solely because the unit came from "a recalled lot" and his erroneous belief that 22-25% of recalled units generated a particulate. (*Id.*, pp. 47, 50-51) Dr. Lalezary similarly admits there is "no objective evidence" the unit generated a silicone particulate, and he "***can't say for certain that [Plaintiff] had the particulate in her eye***." (Da150, pp. 15, 100, 102, 106-07, 113) He likewise assumed it was defective because it was part of a recalled lot. (*E.g.*, Da186) Their speculative assumptions that a defect existed in the subject product renders their opinions unreliable and inadmissible. *See Murray v. Consolidated Rail Corp.*, 2023 WL 2193825, at *5 (N.J. Super. Ct. App. Div. Feb.

[10] *See Amici Curiae* Brief of Healthcare Institute of New Jersey and New Jersey Business & Industry Association (explaining why Plaintiff and her experts failed to establish that the Ozurdex® unit at issue was one that generated a particulate).

24, 2023) (holding expert should be excluded where "opinion clearly and admittedly was based on an assumption about" exposure to allegedly harmful product).

Plaintiff nevertheless submits her experts can opine the subject Ozurdex® unit generated a particulate through the back door of their purported differential diagnoses. Allergan recognizes this Court has held that, in certain circumstances, a product defect can be established through circumstantial evidence and negating alternate causes. *E.g.*, *Myrlak,* 157 N.J. at 98; *Scanlon,* 65 N.J. at 592-93. But those circumstances, typically involving ordinary (not complex) products, do not exist here. In any event, as discussed below in Section III(B)(2), the Appellate Division correctly found Plaintiff's experts failed to properly rule out alternate causes and their "differential diagnosis was unavailing." (Psa175)

B. Plaintiffs' Experts Do Not and Cannot Reliably Opine on General or Specific Medical Causation.

Even assuming a silicone particulate from the Ozurdex® unit was generated and entered Plaintiff's eye, she must also provide "expert testimony to satisfy [her] burden with respect to both general causation and specific causation." *In re PPA*, 2003 WL 22417238, at *20. This Court repeatedly has made clear that "[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 (quoting *Davidson v. Slater*, 189 N.J. 166, 185 (2007)). The Appellate Division correctly recognized that is the case here.

Plaintiff falsely asserts that Allergan advocates for, and the Appellate Division reversed due to, the lack of "perfect causation proof." (PSB 12-13, 20, 33) The Appellate Division did not get "lost in a desire for mathematical certainty." (PSB 35) It reversed because of an "utter lack of evidence to support the existence of both general and specific causation." (Psa174) This is not "perfect proof" of causation; it is New Jersey law. Plaintiff and NJAJ fail to show any error in that holding. That is because Plaintiff's experts simply did not do the work and do not have the qualifications necessary to offer reliable causation opinions—most notably on general causation.

1. Plaintiff's Experts Are Not Qualified to and Did Not Offer General Causation Opinions Based on Any Methodology Whatsoever, But Instead, *Assumed* a Silicone Particulate Can Cause Eye Inflammation or Retinal Detachment.

It is well-established that a plaintiff cannot get past summary judgment in a complex product-liability case without expert proof of general causation—that the claimed product defect is capable of causing the plaintiff's injuries. *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); *Rutigliano v. Valley Bus. Forms*, 929 F. Supp. 779, 783 (D.N.J. 1996) (stating the plaintiff's expert must first prove general causation).

In this case, neither of Plaintiff's experts affirmatively offered ***any opinion at all*** on general causation. Dr. Phillips does not offer an independent general-causation

opinion to support his theory that a 300-micron medical-grade silicone particulate can cause eye inflammation resulting in vision loss. Dr. Lalezary does not offer an independent general-causation opinion that such a microscopic particulate can cause a tractional retinal detachment resulting in vision loss. Instead, both experts just assumed a 300-micron silicone particulate was capable of causing the injuries Plaintiff alleges. And, because both ***assumed*** general causation, neither identified any scientific data, analysis, or literature on the composition of the silicone needle sleeve, whether it is capable of causing an inflammatory reaction or a retinal detachment, or by what mechanism. Neither performed (or relied on) any testing on the needle sleeve; neither published an opinion on how the silicone could cause the injuries Plaintiff alleges; neither cited a single peer-reviewed published article supporting that the silicone used in the Ozurdex® needle sleeve is capable of causing any injury at all. Most tellingly, both ignored or glibly dismissed without any scientific basis the ***only*** scientific evidence in the record: the rabbit toxicity study, which ***disproves*** that a microscopic particle of this medical-grade silicone is capable of causing eye inflammation.[11] (Da304)

[11] While Dr. Lalezary criticizes the rabbit study, he offers no contrary analysis, test, study, or peer-reviewed published literature. Courts across the country have rightly held "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").

a. Plaintiff Wrongly Argues that Her Manufacturing Defect Evidence Also Proves General Causation.

Plaintiff argues she established general causation with the hypothetical testimony that, if the Ozurdex® used in her procedure had generated a silicone particulate, it would deviate from design specifications and constitute a manufacturing defect. (PSB 24-27) This most certainly is not proof of general causation. Plaintiff conflates manufacturing defect and general causation—despite that these are separate elements she must prove with considerably different evidence. *Ralda Deleon*, 2011 WL 2636993, at *10 ("the law does not permit an expert to infer causation merely on the basis that a defect exists"). While evidence of a deviation from design specifications can establish a manufacturing defect, N.J.S.A. § 2A:58C-2, general causation requires completely different evidence: that the defect is scientifically and medically capable of causing the claimed physical injuries. Plaintiff's reliance on evidence of a hypothetical deviation from manufacturing specifications is insufficient—if not "completely off the mark"—to meet her burden to prove general causation through admissible opinion by a qualified expert using a reliable methodology properly applied to the true facts.

b. Plaintiff's Experts' (Mis)use of Differential Diagnosis Methodology Cannot Excuse the Lack of Scientific and Medical Proof of General Causation.

The Appellate Division correctly concluded Plaintiff's experts did not and could not provide the necessary proof of general causation. Aware of this fatal

deficiency, Plaintiff and NJAJ now assert with great repetition that an independent general-causation opinion is irrelevant because the experts used a "differential diagnosis method," which they apparently believe is sufficient for both general and specific causation. (*E.g.*, PSB 18-19; NJAJB 8) But this is contrary to New Jersey law. Use of a differential diagnosis methodology first requires proof of general causation; it is not a method to prove it. As this Court explained in *Creanga*:

> The first step in properly conducting a differential diagnosis is for the expert to rule in all plausible causes for the patient's condition by compiling a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration. At this stage, the issue is ***which of the competing causes are generally capable of causing the patient's symptoms or mortality. A differential diagnosis that rules in a potential cause that is not so capable*** or fails to consider a plausible hypothesis that would explain the condition ***has not been properly conducted***.

185 N.J. at 356 (emphasis added; quotation marks and citations omitted); *see also Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 528-29 (W.D. Pa. 2003) ("Without sufficient reliable evidence of general causation, plaintiff's experts could not reliably apply a differential diagnosis that comports with the scientific method, notwithstanding the fact that physicians in clinical practice may be required to proceed with a differential diagnosis on the basis of guesses or hypotheses due to the exigency of the need to treat their patients.").[12] The experts' misuse of this

[12] *See also McManaway v. KBR, Inc.*, 852 F.3d 444, 454-55 (5th Cir. 2017) ("differential diagnosis presumes that chemical X can cause condition Y generally, but does not itself so prove"); *Leake v. United States*, 843 F. Supp. 2d 554, 564 (E.D.

methodology alone justifies the Appellate Division's holding that the trial court abused its discretion in admitting their causation opinions. *Accutane*, 234 N.J. at 396 (holding a general causation opinion not developed using a reliable scientific method is inadmissible).[13]

NJAJ and Plaintiff also unsuccessfully try to distinguish *Accutane*. NJAJ argues the experts in *Accutane* did not use the differential diagnosis methodology approved in *Creanga*. (NJAJB 20) But the law is clear that differential diagnosis cannot establish general causation. Plaintiff further argues that "neither Dr. Lalezary nor Dr. Phillips overlooked studies," like the experts in *Accutane*. (PSB 19-20) But that is simply untrue. Plaintiff's experts overlooked the only study in the record—the rabbit toxicity study—and, like the experts in *Accutane*, disregarded that study in favor of "lessor forms of evidence" suited to their opinions—here, an ambiguous and equivocal warning in a recall notice. (NJAJB 20-21 (quoting *Accutane*, 234 N.J. at 395)).[14]

Pa. 2011) ("A properly performed differential diagnosis, therefore, is built upon a reliable general causation finding—it does not establish general causation.").

[13] *See Amici Curiae* Brief of the Chamber of Commerce of the United States of America and the New Jersey Civil Justice Institute (explaining that expert opinions must be excluded when based on an improper application of an otherwise accepted and reliable methodology).

[14] *See* Section III(B)(1)(e) below (explaining why the recall notice cannot be proof of general causation).

Plaintiff wrongly argues this case is "in a nearly identical causation setting" as *Creanga*. (PSB 17) In *Creanga*, general causation was not the issue the experts were offered to prove; the experts relied on the already-established general causation principle "that trauma frequently induces premature labor." *Creanga*, 185 N.J. at 360. Here, in stark contrast, it is not already-established—but, rather, hotly disputed based on the complete lack of reliable scientific support—that a 300-micron medical-grade silicone particulate can cause eye inflammation or a mechanical-tractional retinal detachment.

c. The Experts' Knowledge, Training, and Experience as Practicing Doctors Are Not a Substitute for Scientific and Medical Proof of General Causation.

Plaintiff and NJAJ insist that Plaintiff's experts should not have been excluded because they applied their knowledge, training, and experience. (*E.g.*, PSB 19) NJAJ cites *Accutane*'s concern that an "expert is adhering to the norms accepted by fellow members of the pertinent scientific community," and argues Plaintiff's experts, as treating physicians, adhered to the norms of their fellow treating physicians. (NJAJB 21) But this begs the question: what is the "pertinent scientific community" for opinions that a microscopic medical-grade silicone particulate is capable of causing eye inflammation and a mechanical-tractional retinal detachment? The pertinent scientific community is not practicing clinicians who have never studied, tested, analyzed, or even looked for peer-reviewed literature on the composition, mass,

characteristics, cytotoxicity, or biocompatibility of the silicone in the Ozurdex® needle sleeve, or how it may behave *in vitro* or *in vivo*. Rather, the relevant scientific expertise includes toxicology, pathology, biomaterials, and biomechanics.

Neither of Plaintiffs' experts even purports to have "knowledge, education, training or experience" in the pertinent areas of expertise. Neither holds himself out as an expert in these fields, neither has conducted or even relied on any tests or studies in the pertinent fields, and neither explains how his experience as a practicing ophthalmologist qualifies him to opine on the composition, character, size, and nature of the purported silicone particulate, its propensity (or not) to induce an inflammatory response, or whether it can cause a retinal detachment by mechanical traction. Given their undisputed lack of qualifications in the relevant subject matter, the Appellate Division correctly held any possible general-causation opinion they could offer is inadmissible as unhelpful to the trier of fact. *See* N.J.R.E 702; *e.g.*, *Agha v. Feiner*, 198 N.J. 50, 54 (2009) (directing defense judgment for lack of expert qualified to offer needed opinion).

d. The Experts Identify No Factual, Scientific, or Medical Evidence that a Microscopic Silicone Particulate Can Cause Inflammation.

Even if Plaintiff's experts had the qualifications required by Rule 702 (they do not), they do not have the facts and data required by Rule 703 to reliably opine that a microscopic particle of medical-grade silicone can cause eye inflammation. In

fact, Plaintiff's expert testified that doctors use silicone in the eye all the time. (Da47, pp. 54-55) The Appellate Division correctly observed that neither expert performed or relied on any testing differentiating his experience successfully using silicone from the supposedly-harmful silicone at issue here. (Psa175-76) Applying the *Daubert* factors, the Appellate Division noted that both Plaintiff's experts' causation theories did not "pass muster" because they had not been tested, published, subjected to peer review, had their error rates determined, or achieved general acceptance in the relevant scientific community. (*Id.*)

Once again, NJAJ and Plaintiff try to avoid this Court's instruction to apply the *Daubert* factors by using "differential diagnosis" as a panacea. They argue none of this is necessary when they use "the differential diagnosis method" (NJAJB 22), and "an expert may use the differential diagnosis in place of such testing" (PSB 18).[15] This, of course, is circular and incorrect. There is no such thing as a

[15] Plaintiff also makes the absurd argument that *Daubert* cannot be cited to exclude expert testimony because the purpose of *Daubert* was to expand the admissibility of expert testimony. (PSB 15) While it may be true that *Daubert* permitted expert opinions that had not yet been generally-accepted in the scientific community, it established a test and factors to ensure such new opinions are supported by facts and the application of reliable methodologies before admitting them into evidence. This is consistent with this Court's shift toward a test "based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field" that began in *Rubanick v. Witco Chemical Corp.*, 125 N.J. 421, 449 (1991). Plaintiff's experts' cannot avoid the *Daubert* factors to test the reliability of general causation opinions that are, as here, not established as generally-accepted in the relevant scientific communities.

"differential diagnosis" to establish general causation, and this Court has been clear that the scientific proof required to establish general causation is judged by the *Daubert* principles adopted in *Accutane*. It is precisely this critically necessary scientific proof of general causation—established through qualified experts properly applying a reliable and accepted methodology—that is missing here, which is why the Appellate Division correctly held the experts' causation opinions inadmissible.

e. The Recall Letter Is Not Scientific and Medical Proof that a Particulate Can Cause Eye Inflammation.

The only facts or data Plaintiff and NJAJ identify as support for general causation is Allergan's recall letter stating inflammation is a "potential" risk in "sensitive patients." (Da255; PSB16; NJAJB 7, 22) They call this an "admission" of general causation by Allergan, and argue the Appellate Division erred in not recognizing it as such. (*E.g.*, NJAJB 7; PSB 14-16, 19, 24) In fact, the statement in the recall letter is not an "admission" of anything, much less general causation.

The letter simply provided a precautionary note regarding a "potential" risk that Allergan could not "rule[] out" at that time. (Da255, Da649) That is a far cry from a "clear, unambiguous, and concrete" statement that could possibly constitute an "admission" of general causation. *Mirena*, 202 F. Supp. 3d at 315;[16] *In re Benicar*

[16] Plaintiff attempts to distinguish *Mirena* by claiming the Mirena warning that court rejected as an "admission" was not as clear as the "admission" here. (PSB 27-28) Not so. The Mirena warning that was rejected as an "admission" warned of potential risks in the same ambiguous and equivocal manner as the statement in the recall

(Olmesartan) Prods. Liab. Litig., 2016 U.S. Dist. LEXIS 156182, at *161, 179 (D.N.J. Nov. 9, 2016) (finding purported admission insufficient to prove general causation because not "clear, unambiguous, and concrete"); *see also Velazquez*, 901 F. Supp. 2d at 303 (finding recall and FDA notices discussing possibility of product defect and possibility defect can cause injuries is not an "admission of a party"; "plaintiffs still need to establish that indeed the product consumed had the defect and could cause the damage alleged"); *Malin v. Union Carbide Corp.*, 219 N.J. Super. 428, 439 (App. Div. 1987) (holding opinion expressed in terms of possibilities instead of probabilities is inadmissible).

The warning in the recall letter cannot be a judicial "admission" 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." *Mirena*, 202 F. Supp. 3d at 323. The recall timeline above shows that is exactly the case here. At the time of the recall letter, the rabbit toxicity study had not been completed and thus it "c[ould] not be ruled out" that this silicone could "potential[ly]" cause eye inflammation. (Da649) Allergan thus provided a warning (as edited by FDA) even though it was not "convinced that it is a genuine risk." *Mirena*, 202 F. Supp. 3d at 323.

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letter. *Compare Mirena*, 202 F. Supp. 3d at 322 ("Perforation…may occur most often during insertion….") *with* Da255 ("Mild transient visual disturbance and intraocular inflammatory reaction in sensitive patients are potential safety risks.").

Under these circumstances, the precautionary warning in the recall letter cannot be deemed an "admission" of general causation, and any such interpretation would "discourage pharmaceutical companies…from open discourse, if such discussion might later be held to concede the issue of general causation." *Id.* at 319-20.[17] A contrary finding would "provid[e] potential users with less information rather than more where the science is debatable, a result inimical to the public health." *Id.* at 323.[18]

Even if the warning in the recall letter could be considered an "admission," Plaintiff, her experts, and NJAJ misinterpret and misuse the warning. They think Plaintiff qualifies as a "sensitive patient"—for which the silicone presents a "potential" risk of eye inflammation—based on her history of eye problems. (Da180; PSB 30, 37; NJAJB 14) But the record indisputably establishes that "sensitive patients" actually refers to patients ***sensitive to silicone***. (Da649; Da452, p. 39) Plaintiff, her experts, and NJAJ point to nothing demonstrating Plaintiff is sensitive

[17] *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).

[18] Plaintiff asserts the concern of chilling discussions "does not apply here where the admissions relate to the effect that the silicone particulate will cause on the eye rather than the recall itself." (PSB 27) To the contrary, "free and frank discussion" in recall documents of potential health risks is exactly the type of thing manufacturers should be incentivized—not discouraged—from doing. *Mirena,* 202 F. Supp. 3d at 320.

to silicone. Nor could they, given she had a silicone-coated Retisert® implant 10-times larger than a 300-micron particulate in her eye for years without a problem.[19]

This purported "methodology"—relying on a misinterpretation of a warning in a recall letter about "potential risks" in a subpopulation of patients that excludes the Plaintiff—amounts to no methodology at all. Because Plaintiff's experts not only fail to employ any reliable methodology, but also misconstrue what they rely on for their general causation assumptions, their opinions are untethered to the facts, unreliable, and were properly excluded by the Appellate Division. *E.g.*, *Townsend*, 221 N.J. at 57-58 (affirming exclusion of expert opinion that diverged from the evidence); *Vuocolo v. Diamond Shamrock Chemicals Co.*, 240 N.J. Super. 289, 299 (Ct. App. 1990) ("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 evidence.").

Plaintiff argues the Appellate Division overlooked that doctors can rely on information from drug manufacturers. (PSB 14-15) NJAJ cites *Morales-Hurtado v. Reinoso*, 241 N.J. 590 (2020), for the principle that experts are entitled to rely on

[19] Notably, the parties' divergent views on the meaning of "sensitive patients" underscores the ambiguous nature of this precautionary warning and why it is not a "clear, unambiguous, and concrete" statement that can constitute an admission of general causation. *Mirena*, 202 F. Supp. 3d at 315; *Benicar*, 2016 U.S. Dist. LEXIS 156182, at *161, 179.

other experts, and thus Plaintiff's experts are entitled to rely on Allergan's recall notice. (NJAJB 17-18) But *Morales-Hurtado* held that, "***[i]n appropriate circumstances***, an expert may rely on the opinion of another expert." 241 N.J. at 593 (emphasis added). Appropriate circumstances require that the proponent of the evidence "demonstrate that the [non-testifying] expert actually holds the opinion attributed to him or her" and that the non-testifying expert's opinion is "'couched in terms of reasonable medical certainty or probability.'" *Id.* at 593-94 (quoting *Creanga*, 185 N.J. at 260). Those circumstances clearly do not exist here. Allergan's statement about "potential" risks is not "couched in terms of reasonable medical certainty or probability." *Id.* Moreover, Allergan does not "actually hold[] the opinion attributed to" it. *Id.* Based on the sole and undisputed record evidence on biocompatibility of the silicone used in the Ozurdex® needle sleeve (the rabbit study showing ***no*** inflammation (Da304)), Allergan holds the exact opposite opinion.

Plaintiff and her experts offer no contrary analysis, test, study, or peer-reviewed published literature. *E.g.*, *Rutigliano*, 929 F. Supp. at 784-86 (excluding general-causation opinion not supported by facts or data); *Lanzo*, 467 N.J. Super. at 508-11 (abuse of discretion to admit opinion where expert had no studies or authorities supporting general causation and had not published his opinion for peer

review).[20] For these reasons, the Court should reject Plaintiff and NJAJ's argument that Allergan has admitted general causation.

f. There Is No Factual, Scientific, or Medical Proof that a 300-Micron Particulate Can Cause a Retinal Detachment by Mechanical Traction.

Dr. Lalezary's retinal detachment theory fares no better. His theory is not based on eye inflammation and thus has no connection to the recall letter—which is devoid of any statement or warning about (or even the words) 'retinal detachment.' NJAJ and Plaintiff tellingly cite no other study, text, or treatise upon which Dr. Lalezary relies to support his theory. Thus, his assumption that a 300-micron silicone particulate is capable of causing mechanical traction that can result in a retinal detachment is supported by nothing but his own *ipse dixit*. *See Accutane*, 234 N.J. at 385 (explaining trial courts should not "admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert") (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)); *Suanez v. Egeland*, 353 N.J. Super. 191, 201 (App. Div. 2002) (same).

The Appellate Division correctly observed that Dr. Lalezary did not do what reliable scientists do when offering new opinions: the "record is devoid of testing,

[20] *See also Townsend*, 221 N.J. at 53 (noting 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).

error rates, peer reviews, publications, or general acceptance in the scientific community to support the method of causation." (Psa176) For example, Dr. Lalezary does not identify any study, literature, or test showing how big a silicone particulate must be to cause mechanical traction in the eye. In an ironic passage, Plaintiff faults ***Allergan's*** expert (who rejects Dr. Lalezary's theory) for not being "aware of any literature regarding the minimum size a particle needs to be to cause traction and a retinal detachment." (PSB 10) But ***Plaintiff*** has the burden of proof, *Accutane*, 234 N.J. at 381, and the onus was on ***Plaintiff*** to produce scientific evidence supporting Dr. Lalezary's opinion.

Dr. Lalezary's theory is the epitome of an inadmissible "net opinion," which the Appellate Division correctly ordered excluded. *Id.* at 396 (finding that, absent reliable scientific methodology, expert's opinion on general causation cannot be admissible); *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).[21]

[21] *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.").

Similar to the *Zantac* MDL, where the court found the plaintiffs' experts' general-causation opinions lacking when based only on a recall, it is telling that "there is no scientist outside this litigation who" holds the general-causation opinions that Drs. Lalezary and Phillips assert in this case. *In re: Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1094, 1285 (S.D. Fla. 2022). Because Plaintiff 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 Appellate Division correctly held the trial court failed to perform its gatekeeping function to exclude their unreliable general-causation opinions. *Accutane*, 234 N.J. at 400.

Given Plaintiff and her experts' "utter lack of evidence" to support ***general*** causation (Psa174), the Court can affirm without any need to reach the issue of ***specific*** causation. But if it does, the Appellate Division correctly held this proof was similarly lacking.

2. Plaintiff's Experts' Specific-Causation Opinions Are Inadmissible Because Temporal Proximity to a Recall Is Not a Reliable Scientific Method.

This Court explained in *Creanga* that, when an expert offers an opinion that one of several potential causes is the actual cause, the expert "must use scientific methods and procedures" to "reject[] the alternative hypotheses." 185 N.J. at 358 (quotation marks omitted). Such a differential diagnosis, if properly performed, can

be an accepted method to establish specific causation. *Id*. at 355-56. Contrary to Plaintiff and NJAJ's repeated assertions that the Appellate Division rejected differential diagnosis as a methodology, it actually stated that a properly-performed differential diagnosis is "certainly permitted" to prove specific causation. (Psa174)

Here, however, the Appellate Division correctly held that Plaintiff's experts' "differential diagnosis was unavailing" and resulted in net opinions. (Psa175) Plaintiff concedes an "expert must offer a reasonable explanation why an alternative cause offered by the adversary is unlikely," but claims her "experts fulfilled that requirement." (PSB 18) To the contrary, they did no testing, research, or scientific or medical analysis to 'rule in' a silicone particulate as a possible cause, and they likewise failed to 'rule out' the many alternatives they ***agree*** are likely causes of Plaintiff's injuries "***in the absence of 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 ***chronic eye inflammation***. While Plaintiff is correct that her experts did not need to rule out every conceivable alternate theory (PSB 28), they at least needed to rule out these known alternate causes.

Their failure to rule out the Retisert® and its dislocation from her retina is alone a sufficient basis to reject their purported differential diagnosis. To the extent Plaintiff blames her injuries on the particulate's silicone, the Retisert® in her eye for

nearly a decade was not only encased in silicone, but was ***10 times larger*** than the alleged 300-micron particulate. To the extent Plaintiff blames her retinal detachment on mechanical traction from a microscopic particulate, the 10-times larger Retisert® was found dislodged from her retina contemporaneously with and at the precise location of her retinal detachment.[22]

Dispositively, Dr. Lalezary agreed these other "risk factors…could have led to a retinal detachment…[i]n the absence of a silicone particulate." (Da150, pp. 112-13) Dr. Phillips similarly agreed that "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." (Da47, pp. 58-59)[23]

The Appellate Division correctly held it an abuse of discretion to allow such unsubstantiated and unreliable specific-causation opinions. *E.g.*, *Vuocolo,* 240 N.J.

[22] Excluding Retisert as a possible cause solely because it was in Plaintiff's eye for nine years is not a reliable scientific/medical explanation for ruling it out. The importance of the Retisert is that it ***dislocated from her retina precisely where the retinal detachment occurred and at around the same time***. That the Retisert had been there for nine years is immaterial.

[23] The fact that Plaintiff's experts acknowledge this uncertainty about alternate causes, but still offered a causation opinion, exemplifies the difference between a practicing doctor performing a differential diagnosis in the course of treatment, as opposed to an expert performing a differential etiology to determine the cause. *See Amicus Curiae* Brief of Product Liability Advisory Council, Inc. (explaining that differential diagnosis may be an appropriate methodology for a practicing doctor, but it is not an appropriate methodology to determine causation in a court); *see also Soldo*, 244 F. Supp. 2d at 516 (explaining the same).

Super. at 300 (holding expert "net opinions" that "fail to negative [those] other possible causes" are insufficient); *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); *Murray*, 2023 WL 2193825, at *5-6 (holding expert's specific-causation opinion was inadmissible "net opinion" based on assumptions and speculation where expert could not explain why he attributed the cause to one of many potential causes).

This Court consistently 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 v. Matriss*, 55 N.J. 193, 208 (1970) (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 conjection[sic] or speculation."); *Jakubowski*, 42 N.J. at 183 (insufficient evidence of causation where expert "failed to exclude other possible causes").

This bevy of precedent belies Plaintiff's contentions that whether experts ruled out other possible causes goes "to weight not admissibility" and that only a jury determines whether an expert's stated basis for an opinion is sufficient. (PSB

16, 29; NJAJB 19, 22) These contentions ignore this Court's directive in *Accutane* that courts act as a "gatekeeper" to prevent the jury from hearing unsound science "through the compelling voice of an expert." 234 N.J. at 389-90, 396-97. An example of such unsound science is where, as here, experts performing a differential diagnosis fail to use "scientific methods and procedures" to "reject[] the alternative hypotheses." *Creanga* 185 N.J. at 358.

Finally, Plaintiff and NJAJ argue that Plaintiff's experts competently ruled out the alternate causes because they were temporally remote. (PSB 10-11, 16-17, 30; NJAJB 5-6, 16, 19-20)[24] Allergan acknowledges that *Creanga* said temporal proximity was properly considered in that case, but as Plaintiff's Brief also acknowledges, general causation was undisputed in *Creanga*. 185 N.J. at 359. In any event, temporal proximity cannot be the sole purported "scientific method[] and procedure[]" used to "reject[] the alternative hypotheses," *Creanga*, 185 N.J. at 358, as it was here by Plaintiff's experts. *See Amici Curiae* Brief of Chamber of Commerce and the New Jersey Civil Justice Institute at 17-18 (explaining and citing cases that temporal proximity "at most establishes correlation not causation" and is

[24] This necessarily includes Dr. Phillips' "this time is different" theory—that Plaintiff's amount of inflammation after the subject injection was greater than with prior Ozurdex® injections, and so there 'must have been' something different this time, which had to be that this Ozurdex® came from a recalled lot. (PSB 8, 30; NJAJB 7, 19) This argument ignores the evidence that ***every injection comes with an independent and new risk of those injuries***, which is likely why "this time is different" is not a recognized scientific methodology to prove specific causation.

alone insufficient to support a reliable opinion). Contrary to Plaintiff's contention, Dr. Lalezary's admission that each injection Plaintiff received was an independent risk factor for retinal detachment does not make temporal proximity important. (PSB 17-18) The fact it could happen with each injection underscores why experts need a reliable scientific and/or medical basis to exclude that known risk if a detachment occurs following an injection.

IV. NEW ARGUMENTS CITING FAILURE-TO-WARN, MEDICAL MALPRACTICE, AND WORKPLACE EXPOSURE CASES DO NOT SAVE PLAINTIFF'S CASE. [Psa 174-176].

A. Plaintiff Cannot Save Her Case By Pushing for the First Time on Appeal an Unpled Post-Sale Failure-to-Warn Theory.

Plaintiff and NJAJ argue that her repackaged claims, based on a post-sale failure-to-warn theory, no longer require proof the Ozurdex® unit used in Plaintiff's procedure had a manufacturing defect that generated a silicone particulate. (PSB 1-2, 32-33, 36; NJAJB 10-13) They cite this Court's adoption of the "heeding presumption" in failure-to-warn cases and argue the law presumes Dr. Phillips would have heeded a warning about the potential silicone particulate and would not have administered it to Plaintiff. (*Id.*) NJAJ argues this rises to "a rebuttable presumption that the absence of a warning had proximately caused the plaintiff's harm" and that, "to make a prima facie case, the plaintiff only must show that the manufacturer failed to warn about its knowledge that the batch had an increased risk of harm." (NJAJB 10-11, 13; *accord* PSB 1-2)

This grossly overstates New Jersey failure-to-warn law. Presuming Dr. Phillips would have heeded a warning and not used the subject Ozurdex® (which he testified to anyway, making the presumption irrelevant here) does not help Plaintiff meet her burden of proof on the first case-dispositive question above: was this Ozurdex® unit one of the few that generated a particulate? The Appellate Division correctly held "[t]here was no evidence the Ozurdex injection plaintiff received was defective and no evidence of a particulate in her eye." (Psa175) That decision should be affirmed regardless of whether the lack of a warning meant Dr. Phillips was not alerted to look for a particulate and thus Plaintiff did not have direct evidence that a particulate was injected into her eye. (PSB 9) As the Appellate Division recognized, New Jersey law allowed Plaintiff to establish the Ozurdex® unit at issue generated a particulate through circumstantial evidence or negating all other causes (Psa168), but Plaintiff's experts utterly failed to supply such proof. They admit they are speculating because they cannot say with the necessary scientific and medical certainty that it was there. The absence of that necessary expert proof dooms Plaintiff's case.

Presuming Dr. Phillips would have heeded a warning also does not help answer the second case-dispositive question above: was the silicone particulate the medical cause of Plaintiff's injuries? *James*, 155 N.J. at 297 (noting the heeding presumption shifts the plaintiff's burden from whether the plaintiff was exposed to

the product (product-defect causation) and toward proof that the product defect caused the plaintiff's injury (medical causation)); *see also Whelan v. Armstrong Int'l Inc.*, 242 N.J. 311, 333-34 (2020) (failure-to-warn claim requires proof of product-defect causation and medical causation); *Coffman v. Keene Corp.*, 133 N.J. 581, 594 (1993). As explained, Plaintiff has no admissible expert proof of general or specific medical causation to answer this question.[25]

B. The Court Should Not Lower Plaintiff's Burden of Proof.

With apparent understanding that this Court's product-liability precedent does not support Plaintiff's case, Plaintiff advocates for a different, lesser burden of proof.[26] The Court should not accept this invitation to import *sui generis* principles from distinguishable non-PLA cases to this prescription drug product-liability

[25] Plaintiff cites *Canesi v. Wilson*, 158 N.J. 490 (1999), for the proposition that, in a failure-to-warn case, she did not need to prove medical causation, only product-defect causation. (PSB 37-38) But *Canesi* is a medical-malpractice, wrongful-birth action that did not seek personal-injury damages, and thus medical causation was not at issue. 158 N.J. at 502. This Court explained that, "[b]ecause in a wrongful birth action damages for the birth defect itself are not recoverable, the parents are not required to prove that the doctor's negligence caused the defect." *Id.* But when physical-injury damages are at issue, including cases involving prescription drugs, "there must be medical causation, that is, a causal connection between the undisclosed risk and the injury ultimately sustained." *Id.* at 505.

[26] Tellingly, Plaintiff and NJAJ do not cite PLA cases, but instead, medical malpractice and multi-defendant occupational exposure cases that are entirely distinguishable. This Court determined that the unique fact patterns in those cases warranted different standards of proof of defect and causation. Contrary to Plaintiff and NJAJ's arguments (*e.g.*, PSB 34), this is not a case in which a reduced burden of proof applies.

action. This is particularly true for the issue of causation, where Plaintiff and NJAJ identify nothing unique about this case that warrants lessening Plaintiff's burden to prove general and specific medical causation. After all, nothing stopped Plaintiff's experts from testing their theory, determining if there were error rates, and publishing it for peer review.

V. PLAINTIFF WAIVED A RULE 104 HEARING, AND IT WOULD NOT CHANGE THE RESULT. [Psa 174-176].

The Court should reject Plaintiff and NJAJ's last-ditch argument that the case be reversed for a Rule 104 hearing for multiple independent reasons.

First, Plaintiff waived this argument by never requesting a Rule 104 hearing below, either in the trial court or the Appellate Division. *Murray*, 2023 WL 2193825, at *4 n.1. Plaintiff claims she had no reason to request a Rule 104 hearing before the trial court because she was winning there. (PSB 22, n.3) But the rule cannot be that a party automatically gets a Rule 104 hearing when the Appellate Division reverses to exclude an expert. That is especially true where, as here, the party had an unfettered ability to submit anything she felt necessary to meet her burden (both on summary judgment and as part of reconsideration proceedings), never requested a Rule 104 hearing to submit more, and the Appellate Division then held, on a full and complete record, the party failed to meet her burden. A blanket rule to always remand for a Rule 104 hearing should be rejected because it would (1) excuse a party's failure to meet their burden and (2) overburden trial courts with Rule 104

hearings that no one has demonstrated are needed. Instead, the Court should preserve the Appellate Division's discretion to decide if a determination regarding admissibility of the expert's opinion can be made on the record as it stands, or if remand is necessary for further development of an insufficient evidentiary record.

Second, a Rule 104 hearing is not warranted here because Plaintiff's experts were examined at length in their depositions about their methodologies, and that testimony is part of the record. *Fairfax Fin. Holdings Ltd. v. S.A.C. Cap. Mgmt., L.L.C.*, 450 N.J. Super. 1, 100 n.50 (App. Div. 2017) (finding "no error in the failure to conduct [a Rule 104] hearing" where expert "was examined at great length at his deposition about his methodology and that deposition testimony was available to and considered by the trial judge"). NJAJ argues Plaintiff did not have "the ability to present testimony" of her experts, and was denied the opportunity to develop a more extensive record supporting her experts. (NJAJB 23; PSB 21-22) This is not true. Plaintiff's counsel conducted full direct examinations of both Drs. Phillips and Lalezary at their depositions. (*E.g.*, Da53-60, Da699-700) Plaintiff also could have filed expert affidavits to explain anything she believed was not sufficiently developed at deposition, but she did not take that opportunity. Hence, NJAJ's arguments that "these experts were never given the opportunity for Plaintiff to present direct testimony regarding these issues" and that the depositions in the record are only "an examination by the adverse party not the party proffering the testimony"

are plainly false. (NJAJB 24) Plaintiff is not entitled to a do-over because she is unhappy with the Appellate Division's decision on the record she created.

Finally, Plaintiff never proffers any new evidence that would be revealed in a Rule 104 hearing, much less information that would change the result. Plaintiff's failure to proffer such evidence speaks volumes and demonstrates such a hearing is unnecessary. *Wean v. U.S. Home Corp*., 2020 WL 1082327, at *5 (N.J. Super. Ct. App. Div. Mar. 6, 2020) (concluding Rule 104 hearing "not necessary" where proponent of expert did not file affidavit from expert "explaining the deficiencies in [] deposition testimony" and did "not identif[y] any facts [the expert] would explain at a hearing"); *Ralda Deleon*, 2011 WL 2636993, at *11 ("[C]ounsel did not explain how [the expert]'s support for that conclusion would differ from his deposition testimony. Because counsel did not identify any facts that would come to light in a hearing, the judge properly denied plaintiff's request for a *Rule 104* hearing.").

For each of these independent reasons, the Appellate Division did not err in reversing for the exclusion of Plaintiff's experts without ordering an unnecessary Rule 104 hearing.

CONCLUSION

Allergan respectfully requests that this Court affirm the well-reasoned decision of the Appellate Division.

Respectfully submitted,

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