ALISON BEAVAN, Plaintiff-Petitioner, v. ALLERGAN USA, INC., et al., Defendant-Respondent.	SUPREME COURT OF NEW JERSEY DOCKET NO: 090150 ON PETITION FROM THE SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO: A-1501-23T2 Sat Below: Hon. Hany A. Mawla Hon. Robert M. Vinci

BRIEF OF DEFENDANT-RESPONDENT ALLERGAN USA, INC. IN OPPOSITION TO PETITION FOR CERTIFICATION

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PRELIMINARY STATEMENT

This Court should deny certification. As a threshold matter, Plaintiff fails to establish ***any*** grounds for certification under Rule 2:12-4. Plaintiff fails to argue—much less demonstrate—that this appeal presents an unsettled question of general public importance, that the decision is in conflict with another appellate decision, or that certification is in the interest of justice. Instead, Plaintiff merely alleges garden-variety error and misconstrued precedent denied her a jury trial. Those are not grounds for certification. The Petition should be denied on this basis alone.

Plaintiff is also wrong on the merits. The Appellate Division got it right, correctly holding that Plaintiff's experts' net opinions fail to meet the admissibility standards of N.J.R.E 702 & 703 and *In re Accutane*, 234 N.J. 340 (2018), and without that compulsory expert proof in this product-liability case, summary judgment for Defendant Allergan USA, Inc. is required. Specifically, Plaintiff lacked qualified experts offering reliable opinions that the prescription Ozurdex® she received (i) had a defect that (ii) was capable of causing her claimed eye injuries and (iii) actually did cause them. The Appellate Division corrected a manifest injustice in the trial court's decision to allow a case to proceed to trial with "no evidence the Ozurdex injection plaintiff received was defective" and an "utter lack of evidence to support the existence of both general and specific causation." (Psa174-75) The interest of justice thus requires denying certification.

FACTS SUPPORTING THE APPELLATE DIVISION'S DECISION

Ozurdex® is an FDA-approved dexamethasone implant ("pellet") injected into the eye to treat serious eye conditions that can lead to vision loss. (Da105, 224, 374-75) To treat her chronic history of serious eye disease, Plaintiff received over 10 Ozurdex® injections. (Da87) Plaintiff claims the Ozurdex® injection she received on November 6, 2018 was defective and caused eye inflammation, a retinal detachment, and loss of vision. However, she admits she has no direct proof the Ozurdex® at issue was defective. Nor do her experts offer reliable opinions that the specific Ozurdex® unit used in her procedure had the alleged defect that prompted the recall: possible generation of a microscopic (300-micron) silicone particulate that potentially could be injected in the eye with the Ozurdex® pellet.[4]

The evidence instead established that ***only 2.2%*** of units in the lot at issue generated a silicone particulate. (Da229) Plaintiff's experts admit no one ever saw a particulate in the Ozurdex® unit used in her procedure or in Plaintiff's eye. Plaintiff's treater, Dr. Phillips, admits "there's no way [he] could possibly know

[4] Plaintiff notes that Allergan recalled lots and warned healthcare providers in other countries before the U.S. recall and before her injection at issue. (Pet. 3) That was not because Allergan sat on its hands. Allergan kept the FDA fully informed and made ***over 20 attempts*** to obtain authorization to communicate with U.S. healthcare providers about the recall issue. (Da229-54, 276-78, 281-85) FDA ultimately determined the potential generation of a silicone particulate was a "product quality" issue, not a "safety concern," but eventually authorized a communication to U.S. healthcare providers (that differed from Allergan's initial proposal) and a recall of affected lots in December 2018. (Da250, 255, 277)

whether there was a silicone particulate in [her] eye." (Da73-76) Plaintiff's retained expert, Dr. Lalezary, similarly admits he "can't say for certain that [she] had the particulate in her eye," likely because there is "no objective evidence" this Ozurdex® generated a silicone particulate. (Da156, 184, 186, 190-91, 197) To support their opinions on causation, they both ***assumed*** the Ozurdex® at issue was 'defective' because it was part of a recalled lot. (Da73-74, 186)[5] Given this testimony, the Appellate Division correctly concluded that evidence of defect in the specific Ozurdex® unit was speculative at best. (Psa174)

In addition to inability to prove defect, Plaintiff's two experts[6] were not qualified—and did not even try—to offer general causation opinions that a 300-micron particulate of medical-grade silicone ***is capable of*** causing the injuries Plaintiff alleges. To the contrary, the only study relevant to this question (testing the capacity of this silicone particulate to cause injury) concludes ***it could not***.[7]

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[5] Dr. Phillips's deficient opinion was also based on his mistaken belief that 22-25% of units in each recalled lot had the particulate issue. (Da70)

[6] Plaintiff improperly and with apparent desperation attempts to interject a "third expert," Dr. Tarver, whose opinions she claims the Appellate Division supposedly overlooked. (Pet. 5) But Plaintiff disclosed only two experts, neither of whom was Dr. Tarver. (Da329) In any event, 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. Her notes about migration of the Ozurdex® ***pellet*** (Da690) have no relevance to Plaintiff's silicone particulate theory.

[7] Plaintiff misrepresents that "Allergan itself had ***studies*** regarding the silicone particulate causing ocular inflammation." (Pet. 14 (emphasis added)) The Allergan documents she cites do not discuss "studies" at all, let alone studies that prove

Because Plaintiff's experts are not qualified and fail entirely to offer a general causation opinion—much less one based on reliable application of a recognized methodology to the facts of this case—the Appellate Division correctly held their opinions did not satisfy the admissibility requirements in N.J.R.E 702 & 703, including the *Daubert* factors which *Accutane* incorporated into New Jersey law.

Making matters worse, Plaintiff's experts' specific causation opinions fail because both ***admit*** Plaintiff's exact injuries could have resulted from numerous other recognized causes they could not exclude. They agree her injuries could have been caused by many obvious factors other than a silicone particulate (that no one ever saw), including her chronic eye inflammation, numerous eye surgeries, procedures and intravitreal injections, and a Retisert® implant. (Da64-65, 81-82, 175-77, 196-97, 370, 374) The ***silicone-coated*** Retisert® is 10 times larger than a 300-micron particulate, and dislodged from Plaintiff's retina at the precise location and around the time of the retinal detachment she claims was caused by the 10-times-smaller phantom particulate. (Da202, 368-69)

Plaintiff's experts did nothing to reliably exclude the detached Retisert® or the numerous other recognized causes. Dr. Lalezary admits that "***all of those risk factors…could have led to a retinal detachment…[i]n the absence of a silicone particulate***." (Da196-97) (emphasis added) The Appellate Division correctly held

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causation. Nor do Plaintiff's experts ever identify or state they relied on any such

the experts' "net opinions" on causation, which the Petition repeatedly highlights are ***based solely on temporal association***, are inadmissible. (Pet. 2, 6, 11-2, 15)

Unable to articulate valid grounds for certification, Plaintiff resorts to misrepresentations. She misrepresents how the Appellate Division applied this Court's precedent, falsely claiming it required "documentary proof beyond a reasonable doubt" and "perfect proof of causation." (Pet. 2, 6) She also falsely represents that Allergan admitted the Ozurdex® at issue generated a silicone particulate that could cause her injuries. (Pet. *passim*) Nothing could be further from the truth. Allergan hotly disputed that a silicone particulate was ever generated by this Ozurdex® unit or injected into Plaintiff's eye, and fiercely refuted that a silicone particulate (assuming it existed) was capable of causing or actually did cause Plaintiff's injuries. The Court should not be swayed by the many misrepresentations in the Petition.

Because Plaintiff fails to establish any of the requisite grounds for certification under Rule 2:12-4, let alone any error by the Appellate Division in its unpublished decision, Plaintiff's Petition should be denied.

I. PLAINTIFF ESTABLISHES NO GROUNDS FOR CERTIFICATION

Rule 2:12-4, Grounds for Certification, provides in relevant part that:

> [c]ertification will be granted ***only if*** the appeal presents a question of general public importance which has not been but should be settled by

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"tests" or "studies" for their opinions. (Da256-57, 644-46)

> the Supreme Court or is similar to a question presented on another appeal to the Supreme Court; if the decision under review is in conflict with any other decision of the same or a higher court or calls for an exercise of the Supreme Court's supervision and in other matters if the interest of justice requires.

(Emphasis added). Plaintiff's Petition ***does not even cite the Rule***, much less explain why the grounds set forth in the Rule are met here to warrant certification.

For starters, Plaintiff never argues this appeal presents an unsettled question of general public importance. Nor could she. The questions raised in her Petition are case-specific, intensely fact-dependent, and governed by established principles of New Jersey law. Indeed, the standards for admissibility of expert opinion in a case like this are well-settled. This appeal raises no "unsettled" questions. In addition, whether Plaintiff's experts reliably opined that ***this specific Ozurdex® unit*** generated a silicone particulate that was capable of and did, in fact, cause ***her specific injuries*** are questions important to the Parties, but not to the general public. *E.g.*, *Bandel v. Friedrich*, 122 N.J. 235, 237 (1991) ("judgments below reflect the application of established principles…to an intensely-factual situation, in no way implicating 'an unsettled question on general public importance'"); *Fox v. Woodbridge Twp. Bd. Educ.*, 98 N.J. 513, 516 (1985) (O'Hern, J., concurring) (denying certification where decision applied "settled principles to the facts of this case and does not therefore present a question of general public importance").

The Appellate Division's decision also is not "in conflict" with another New

Jersey appellate decision. Plaintiff argues the Appellate Division "misconstrued" the holdings in *Accutane* and *Creanga v. Jardal*, 185 N.J. 345 (2005), (Pet. 1), but never demonstrates (or even argues) the decisions are actually "in conflict," as required for certification. Misconstruing a holding is not the equivalent of being "in conflict." *See Askew v. Fla. Dep't of Children & Families*, 385 So. 3d 1034, 1037-38 (Fla. 2024) (holding, under similar standard, that misapplication of precedent does not qualify as being in "conflict"). Regardless, as explained below, the Appellate Division properly applied *Accutane* and *Creanga* to this case; it did not "misconstrue" them.

At bottom, the Appellate Division's case-specific holdings that Plaintiff's experts' opinions proffered for this particular case are inadmissible do not call for an exercise of this Court's supervision and do not warrant certification in the interest of justice. Not only did the Appellate Division reach the correct result, Plaintiff's Petition fails even to ***attempt*** demonstrating how this unpublished decision will somehow establish bad precedent for future cases. Plaintiff argues the decision denies her a right to a jury trial (Pet. 2, 11-12, 17, 19-20), but that is true of any ruling entering summary judgment and cannot possibly be a legitimate basis for certification.

This Court should deny Plaintiff's Petition for failure to establish certification is appropriate under Rule 2:12-4.

II. THE APPELLATE DIVISION APPLIED THE CORRECT LEGAL STANDARD IN HOLDING PLAINTIFF'S EXPERTS FAILED TO OFFER RELIABLE OPINIONS ON DEFECT AND CAUSATION. [Psa174].

Plaintiff argues the Appellate Division erred "by ignoring basic tenents for admission of expert testimony." (Pet. 8) She claims the panel "misconstrued the application of the differential diagnosis to provide the reliability for [her expert's] opinion on causation" and, as a result, "committed the same error that this Court rejected in *Creanga*." (Pet. 9-10) This argument fails for multiple reasons.

To begin, Plaintiff grossly overstates the significance of her experts' use of a differential diagnosis. Simply "uttering the phrase differential diagnosis" does not magically render all opinions claiming to use that method admissible. *Creanga*, 185 N.J. at 357. "A differential diagnosis is a patient-specific process of elimination…use[d] to identify the most likely cause of a set of signs and symptoms from a list of possible causes." *Id.* at 355 (quotation marks omitted). It is therefore a method for proving ***specific*** causation, ***not general causation or product defect***. Indeed, this Court explained in *Creanga* that:

> 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….

> [A]fter the expert rules in plausible causes, the expert then must rule out those causes that did not produce the patient's condition by engaging in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case.

Id. at 356 (emphasis added; quotation marks and citations omitted). Thus, not only is differential diagnosis an improper method to prove general causation, but the expert has not properly applied the method if he fails to (i) establish general causation for all causes considered and (ii) reliably eliminate the other causes. *Id.*

Here, the Appellate Division correctly rejected Plaintiff's experts' opinions because, on general causation, they had no basis to "rule in" a silicone particulate as capable of causing Plaintiff's injuries. They could not use differential diagnosis to prove general causation,[8] and they failed to rely on (or conduct) any studies proving a microscopic, medical-grade silicone particulate ***can cause*** inflammation, retinal detachment, and blindness. Nor did they identify any peer-reviewed literature supporting general causation or themselves publish for review by their peers in the field of ophthalmology the opinion that a silicone particulate of the

[8] *See McManaway v. KBR, Inc.*, 852 F.3d 444, 454-55 (5th Cir. 2017) ("[A] 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. Pa. 2011) ("A properly performed differential diagnosis, therefore, is built upon a reliable general causation finding — it does not establish general causation."); *Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 516 (W.D. Pa. 2003) ("the differential diagnosis is not a reliable methodology for determining general causation").

size and quality alleged here is capable of causing Plaintiff's alleged injuries.

Instead, Plaintiff's expert, Dr. Phillips, admits he is not "aware of any study showing that the silicone particulate causes any injury to patients." (Da62) In fact, he uses "silicone oil in the eye to repair retinal detachments" and agreed it "is inert," depending on its purity. (Da77-78) Plaintiff's other expert, Dr. Lalezary, similarly fails to identify any scientific or medical basis to support general causation. Aside from citing recall documents (discussed below), his expert report and opinions rely upon no tests, studies, or peer-reviewed literature establishing that a 300-micron particulate of medical-grade silicone is capable of causing inflammation, retinal detachment, and vision loss. (Da336-43) Both experts simply ***assume*** general causation and, as the Appellate Division held, fail to support their causation theory with any "testing, error rates, peer reviews, publications, or general acceptance in the scientific community." (Psa176)

Plaintiff's Petition tries to get around this problem by repeatedly, and incorrectly, arguing that Allergan admitted general causation. (Pet. 2, 14-15) This is blatantly false. Allergan commissioned a study in which silicone particles greater in size and load than the particulate identified in the recall were injected into living rabbits' eyes and found to be biocompatible, causing no inflammation or toxic reaction. (Da304) Demonstrating the unreliability of the methodology he used to opine on causation, Dr. Lalezary refused to accept the results of this

highly-relevant study—indeed, the ***only*** study in the record—pointing instead to Allergan's Urgent Drug Recall letter. (Pet. 2-5, 7-8, 14, 18)

That recall letter, however, said nothing about a retinal detachment[9] and stated only that inflammation is a "potential" risk in "sensitive patients," which refers to patients with ***sensitivity to silicone***. (Da255, 458) Plaintiff's experts had no reliable basis to conclude she is sensitive to silicone since she had a silicone-coated Retisert®, 10-times larger than 300 microns, in her eye for years.[10] (Da357, 368-39, 374) Opinions by Plaintiff's experts that nonetheless assume she is a "sensitive patient"—and are thus inconsistent with the evidence—are unreliable and inadmissible. *E.g.*, *Townsend v. Pierre*, 221 N.J. 36, 57-58 (2015) (affirming exclusion of expert opinion that diverged from the evidence).

In any event, such equivocal statements in recall documents cannot establish causation: "there may be myriad reasons, including an abundance of caution or the

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[9] The Petition tries to cure Plaintiff's experts' inability to establish that a microscopic silicone particulate could cause a retinal detachment by claiming Allergan's expert "agreed that mechanical traction could cause a retinal tear and detachment." (Pet. 8) In the cited testimony, however, Dr. Eliott merely explains that a retinal detachment is an inherent risk of any intravitreal injection because it can occur just from the process of injecting the Ozurdex® ***pellet*** into the vitreous of the eye. (Da711-12) As discussed herein, Plaintiff's experts had no reliable basis to rule out this inherent risk and instead claim the cause was a phantom particulate.

[10] Dr. Lalezary's testimony that Plaintiff qualifies as a "sensitive patient" was based on her long-standing uveitis (chronic inflammation), rather than whether she was sensitive to silicone. (Da180) But there was neither scientific support nor record evidence that uveitis can make a patient "sensitive" to a silicon.

avoidance of lawsuits, why a manufacturer may warn of a possible phenomenon without being convinced that it is a genuine risk." *In re Mirena IUD Prods. Liab. Litig.*, 202 F. Supp. 3d 304, 323 (S.D.N.Y. 2016). Public policy principles prohibit elevating such recall documents to evidentiary admissions because it "would chill free and frank discussion." *Id.* at 320. The Appellate Division correctly concluded the recall letter cannot substitute for Plaintiff's lack of proof on general causation.

In addition to being unable to "rule in" the silicone particulate as a potential cause, Plaintiff's experts also admit they fail reliably to "rule out" the many other recognized causes, rendering their use of the differential diagnosis methodology improper, unreliable, and inadmissible under *Creanga*. For starters, any injection into the eye's vitreous has a number of inherent risks, including inflammation, retinal detachment, and vision loss. (Da105, 121) Dr. Lalezary admits a "retinal detachment is a possible risk following any intraocular procedure" and "any intravitreal injection." (Da175, 188, 193-94) Yet, Plaintiff's experts provided no reliable basis to exclude those inherent risks.

Further, Plaintiff's long history of eye problems could independently cause her injuries. (Da45, 54, 83, 374) She had chronic eye inflammation exacerbated by her cigarette smoking; received numerous intravitreal injections (including Ozurdex®); and had several eye surgeries, including a lens implant, a trabeculectomy (removing fluid to lower eye pressure), two vitrectomies (to

remove vitreous fluid), and surgery to implant a Retisert® tablet.[11] (Da357, 368-69, 374) Importantly, the Retisert® dislodged from Plaintiff's retina at the precise location and at around the same time as her retinal detachment. (Da202, 368-69)

Plaintiff's experts agreed her injuries could have been caused by any of these and other factors ***independent*** of a silicone particulate (that no one ever saw). (Da63-64, 81-82, 175-77, 196-97, 370, 374) Despite acknowledging these recognized causes, Plaintiff's experts did nothing to reliably rule them out. Dr. Lalezary admits "***all of those risk factors…could have led to a retinal detachment…[i]n the absence of a silicone particulate***." (Da196-97) (emphasis added) And Dr. Phillips does not even believe the phantom particulate caused Plaintiff's retinal detachment: "***[T]he 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***." (Da81-82 (emphasis added))

Creanga explains that, "[i]n rejecting the alternative hypotheses, the expert must use 'scientific methods and procedures' and justify an elimination on more than 'subjective beliefs or unsupported speculation.'" 185 N.J. at 358 (quoting *Claar v. Burlington N. R.R. Co.*, 29 F.3d 499, 502 (9th Cir. 1994)). Here, however, Plaintiff concedes the only basis upon which her experts ruled out the other known

[11] Retisert® is an FDA-approved, steroid-containing intravitreal implant encased in a silicone reservoir used to treat non-infectious uveitis (*i.e.*, chronic eye

causes was temporal proximity. (Pet. 2, 6, 11-12, 15) But as this Court and the Appellate Division have observed, "[t]he mere occurrence of an accident and the mere fact that someone was injured are not sufficient to demonstrate the existence of a defect." (Psa168 (quoting *Myrlak v. Port Auth. of N.Y. & N.J.*, 157 N.J. 84, 98 (1999)); *see also Nicholson v. Bloomin Brands, Inc.*, 2018 WL 3614355, at *5-6 (N.J. Super. App. Div. July 30, 2018) (temporal association between product exposure and injury insufficient to survive summary judgment).[12]

Plaintiff's argument that "[o]nly the jury could determine whether Dr. Lalezary's use of the differential diagnosis was correct" defies New Jersey law, ignoring this Court's direction that courts act as a "gatekeeper" and "rigorous[ly]" assess the methodology and data to prevent the jury from hearing unsound science "through the compelling voice of an expert." *Accutane*, 234 N.J. at 389-90, 396-97.

Because Plaintiff and her experts applied no recognized or reliable methodology to prove general causation, and failed to correctly and reliably use the differential diagnosis method to prove specific causation by never "ruling in" a silicone particulate as a possible cause and never "ruling out" the other admittedly

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inflammation). (Da275, 357) Retisert® remains in the eye for long periods while slowly delivering the active drug. (Da357)

[12] *Accord Lauder v. Teaneck Volunteer Ambulance Corps.*, 386 N.J. Super. 320, 332 (App. Div. 2004); *Moody v. Gen. Mills, Inc.*, 2006 WL 6872309, at *1 (D.N.J. Feb. 9, 2006) (collecting cases). While *Creanga* said consideration of temporality was proper in that case, it was only because ***general causation was undisputed***. 185 N.J. at 359. In stark contrast, here, Plaintiff has no proof of general causation.

recognized causes, the Appellate Division correctly held Plaintiff could not prove causation. *E.g.*, *Accutane*, 234 N.J. at 396 (expert's opinion on general causation inadmissible absent use of a reliable scientific methodology); *Lanzo v. Cyprus Amax Minerals Co.*, 467 N.J. Super. 476, 508-11 (App. Div. 2021) (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); *Scanlon v. Gen. Motor Corp.*, 65 N.J. 582, 600 (1974) (directing defense judgment for "fail[ure] to prove the defendants' responsibility for the defect by the negation of the other most likely probable causes").[13]

III. THE APPELLATE DIVISION CORRECTLY APPLIED *ACCUTANE*, INCLUDING ITS ADOPTION OF THE *DAUBERT* FACTORS. [Psa175-176].

Plaintiff argues the Appellate Division reversed because it found Plaintiff's experts' "theory of causation would not pass muster under Daubert" and "this Court has never adopted Daubert." (Pet. 13) This is yet another misrepresentation.

[13] *See also 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"); *Jakubowski v. Minnesota Min. & Mfg.*, 42 N.J. 177, 183 (1964) (insufficient evidence of causation where expert "failed to exclude other possible causes"); *Vuocolo v. Diamond Shamrock Chemicals Co.*, 240 N.J. Super. 289, 300 (Ct. App. 1990) (experts' "net opinions" that "fail to negative [those] other possible causes" are inadmissible to prove defect). Contrary to Plaintiff's assertions, the Appellate Division applied the correct law, not an "erroneous perfectionist interpretation of what is a valid differential diagnosis," and did not find "the defense experts more persuasive than [Plaintiff's] experts." (Pet. 11)

The Appellate Division did not apply *Daubert* ***in lieu of*** N.J.R.E. 702 & 703 and *Accutane*. It instead applied "the Daubert factors" ***just as this Court instructs*** in *Accutane*, 234 N.J. at 398. (Psa175-76) The Appellate Division began by correctly noting this Court "recently adopted the Daubert factors to help guide trial courts." (Psa175 (citing *Accutane*)) It then quoted the factors, properly applied them, and concluded Plaintiff's experts' "theory of causation would not pass muster under Daubert." (Psa175-76) That analysis does not misconstrue this Court's precedent, as Plaintiff claims. Rather, it faithfully follows *Accutane* in applying the *Daubert* factors to find Plaintiff's experts' methodology and opinions unreliable and inadmissible.

Plaintiff also argues "the Appellate Division erred in not abiding by the abuse of discretion standard, particularly where there was no N.J.R.E. 104 or *Kemp* hearing." (Pet. 17) That is simply false. The Appellate Division identified the correct standard of review as abuse of discretion and then dutifully applied it; the panel did not substitute its judgment for that of the trial court. Moreover, because there was no Rule 104 or *Kemp* hearing involving live testimony, the trial court did not make any credibility determinations deserving deference.[14]

[14] To the extent Plaintiff is arguing a Rule 104 or *Kemp* hearing should have occurred, Plaintiff waived that argument by never making it below. *Murray v. Conrail*, 2023 N.J. Super. Unpub. LEXIS 259, at *12 n.1 (App. Div. Feb. 24, 2023). Regardless, Plaintiff never explains how the lack of a Rule 104 or *Kemp* hearing prevents the Appellate Division from reversing an erroneous decision to

This case is totally unlike *Hisenaj v. Kuehner*, 194 N.J. 6, 25 (2008), cited by Plaintiff, where this Court held the Appellate Division did not properly apply the abuse of discretion standard because it reversed a ruling on expert admissibility based on matters ***outside*** of the record created in the trial court:

> [W]e are compelled to restrict ourselves to the record made before the trial court. The Appellate Division did not do so. It engaged in an unconstrained review that included material not part of the evidentiary record and argument that went beyond that which was advanced before the trial court. That resulted in avoidance of the reviewing court's proper role, the application of the abuse-of-discretion standard.

Plaintiff fails to identify a single instance where the Appellate Division reviewed or relied upon material outside of the record. That is for the obvious reason that the court did not go outside the record. It based its decision on the record before the trial court, concluding Plaintiff's experts should have been excluded because, due to their methodological failures, "they did not establish general or specific causation." (Psa176) As discussed, Plaintiff's experts offered zero studies, literature, peer-reviewed publications, or other reliable generally-accepted method to establish general causation (ignoring the only study in the record, which disproves general causation), and admitted they could not exclude other known

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allow expert opinions for which the record fails to establish reliability. After all, the experts were deposed and that testimony is part of the record considered by the Appellate Division. *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" because the expert "was examined at great length at

causes in connection with their specific causation opinions. The Appellate Division correctly held that the trial court's fundamentally-flawed ruling allowing Plaintiff's experts' unsupported and unreliable opinions was an abuse of discretion.

IV. THE APPELLATE DIVISION APPLIED THE CORRECT LEGAL CAUSATION STANDARD. [Psa174-176].

Plaintiff contends that, because she is pursuing a failure-to-warn claim, she needs to prove only that her doctor would not have administered the drug if he had received a warning. (Pet. 18) This contention ignores Plaintiff's admitted burden to prove medical causation. (*Id.* 14) New Jersey law requires Plaintiff to prove not only that her doctor administered the drug due to the lack of a warning, but also that the drug was the medical cause of her injuries. *See 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). Hence, evidence a failure to warn led to administration of a drug (*i.e.*, product-defect causation) is insufficient without reliable expert medical causation testimony that the drug was capable of causing and actually did cause the claimed injuries. The Appellate Division did not err in requiring reliable expert testimony on medical causation. *Townsend*, 221 N.J. at 60 ("[a] mere possibility of such causation is not enough") (quoting *Davidson v. Slater*, 189 N.J. 166, 185 (2007)).

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his deposition about his methodology and that deposition testimony was available to and considered by the trial judge at the time of his ruling").

Plaintiff's "substantial factor" argument (Pet. 18-19) also is entirely irrelevant to the Appellate Division's determination that she cannot prove medical causation. That there was a 2.2% chance the Ozurdex® Plaintiff received dispensed a silicone particulate (*i.e.*, had the claimed defect) has nothing to do with the unreliability and inadmissibility of Plaintiff's experts' medical causation opinions under N.J.R.E. 702 & 703 and *Accutane*. Plaintiff confuses and collapses the separate and distinct elements of product defect and causation. *See Whelan*, 242 N.J. at 333 (stating the three separate elements of a failure-to-warn claim). Evidence of a 2.2% chance of ***defect*** cannot "create a question of fact" on ***causation***. (Pet. 20)

Ultimately, evidence that only 2.2% of units in the lot at issue generated a silicone particulate demonstrates Plaintiff's inability to prove a defect. Where the only evidence is a 2.2% chance, and the standard of proof is preponderance of the evidence, the Appellate Division correctly concluded Plaintiff could never meet her burden to prove defect. *See Townsend*, 221 N.J. at 60 ("summary judgment may be granted dismissing the plaintiff's claim" if "no reasonable factfinder could find that the plaintiff has proven causation by a preponderance of the evidence").[15]

[15] This case thus falls within the *Townsend* holding that, when "the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant." 221 N.J. at 60-61 (quoting *Davidson*, 189 N.J. at 185). Assuming a defect exists, as Plaintiff's experts did here (*e.g.*, Da176), renders their opinions unreliable and inadmissible. *See Murray*, 2023 N.J. Super. Unpub. LEXIS 259, at

Plaintiff tries nevertheless to shoehorn her 2.2% argument into the causation analysis by citing medical-malpractice cases involving preexisting conditions that allowed claims to go to the jury based only on increased risk of harm. (Pet. 18-20 (citing *Dubak v. Burdette Tomlin Mem'l Hosp.*, 233 N.J. 441 (1989), and *Velazquez v. Jiminez*, 336 N.J. Super. 10 (App. Div. 2000), *aff'd*, 172 N.J. 240 (2002)) Those cases and their unique "increased risk" holdings, which "lessened the traditional burden of proof," *Gardner v. Pawliw*, 150 N.J. 359, 375 (1997), have no application to the causation analysis in this product-liability case. The most that can be said about those cases is that they stand for the proposition that findings of small percentages of relative fault can be "consistent with" or "equated to" findings of causation ***in medical-malpractice cases applying a lower causation standard***. That proposition has no relevance to the causation analysis in this product-liability case, and certainly does not demonstrate any error by the Appellate Division in finding "the utter lack of evidence to support the existence of both general and specific causation." (Psa174)

CONCLUSION

The Court should deny the Petition for Certification.

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*8-9 (holding expert should be excluded where "opinion clearly and admittedly was based on an assumption about" exposure to allegedly harmful product).

Respectfully submitted,

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