FILED, Clerk of the Supreme Court, 06 Mar 2025, **090150**

ALISON BEAVAN, Plaintiff, vs. ALLERGAN USA, INC.; ALLERGAN INC., f/k/a INAMED CORPORATION; ALLERGAN plc; ABBVIE INC.; and DOES 1 through 100, inclusive, Defendants.	SUPREME COURT OF NEW JERSEY DOCKET NO.: 090150 ON PETITION FROM SUPERIOR COURT OF NEW JERSEY APPELLATE DIVISION DOCKET NO.: A-1501-23T2 Sat Below: Hon. Hany A. Mawla Hon. Robert M. Vinci

REPLY BRIEF OF PLAINTIFF-PETITIONER ALISON BEAVAN IN SUPPORT OF PETITION FOR CERTIFICATION

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PRELIMINARY STATEMENT

Plaintiff-Petitioner Alison Beavan submits this brief in further support of her Petition for Certification and in reply to Allergan USA, Inc. ("Allergan"). Despite Allergan's contentions, Beavan raised questions of substantial public importance, including the Appellate Division's failure to apply this Court's precedent applying Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 597 (1993), and by doing so, took away the province of the jury.

REPLY STATEMENT OF FACTS

The Appellate Division's reversal invaded the province of the jury, because there were facts from which a jury could determine that Allergan placed a defective product into the stream of commerce, and Allergan's failure to warn caused Beavan's injury. Even under the facts that Allergan cites, it was apparent that: 1) Allergan was aware that 2.2% of the Ozurdex units in a lot were contaminated with silicone; 2) Beavan received an Ozurdex injection from this lot; 3) Allergan admitted that contaminated Ozurdex caused the very issues that Beavan experienced, eye inflammation, retinal detachment, and loss of vision. (Ab2, Da256, Da237, Da373.[1])

Allergan complains that the experts assumed the Ozurdex at issue was 'defective' because it was part of a recalled lot," (Ab3), but this Court permits

[1] The term "Ab" refers to Allergan's Brief filed with this Court in opposition to the Petition for Certification. Beavan relies upon her prior abbreviations cited in her Petition.

the expert to make assumptions that the jury must resolve when the proofs will be presented to the jury, such as Allergan's recall notice. See Morales-Hurtado v. Reinoso, 241 N.J. 590, 593 (2020).

Allergan argues that Dr. Tarver could not provide an opinion as to causation without any basis for the statement. (Ab3.) But Dr. Tarver's treatment notes clearly state her opinion as to causation: "Extended HPI: The patient reports having had an ozurdex placed in the left eye 3 months ago after which she developed a retinal detachment and underwent a vitrectomy. At POD#1 it was noted that the ozurdex had migrated to the anterior chamber [and] her cornea was swollen." (Da691.) In fact, Dr. Tarver's diagnosis was: "Corneal Degeneration, 2nd [secondary] to migrated Ozurdex OS [left eye]. It is likely that the corneal endothelium has undergone necrosis from toxic levels of steroid in the AC [anterior chamber] from the Ozurdex." (Da691.) The only document that Allergan cited for their argument is Plaintiff's answers to interrogatories (Ab3 (citing Da329)), but Plaintiff raised Dr. Tarver's opinion in opposition to the motion for summary judgment, and thus, it was part of the record on appeal. (Pa14 ¶ 43.)

Allergan further argues that because factually Beavan's experts conceded there could have been a different cause, it means her experts must be barred entirely even though they offered a rational explanation why those other causes

were unlikely. (Cf., e.g., Ab4 with Da695-96.) Allergan's position, which the Appellate Division adopted over the trial court's finding, overlooked the fact that the jury must decide questions of causation not an appellate court.

Allergan incorrectly accuses Beavan of misrepresenting the record but it is only Allergan who makes bold, uncited statements that it disputed that "a silicone particulate . . . was capable of causing or actually did cause Plaintiff's injuries." (Ab5.) Allergan's own "Urgent Drug Recall" warned of health hazards including "transient visual disturbance or intraocular inflammatory reaction in sensitive patients." (Da256.) It further warned of a "possibility of corneal reaction if the particulate migrates to the anterior chamber." (Da256.)

Furthermore, Allergan's Patient Impact Assessment conceded that "it may cause vitreous opacity," "transient visual floaters, or visual defect." (Da249.) Additionally, Allergan conceded that "the foreign body has the potential to incite intraocular inflammatory reaction in sensitive patients," and the record reveals Beavan was a sensitive patient. (Da249, Da180 at 83:12-25.) The Appellate Division's decision denied Beavan the benefit of these inferences in dismissing her claims with prejudice. This Court should not condone Allergan's blatant misstatement of the record.

LEGAL ARGUMENT

I. This Court Should Grant Certification to Settle Confusion and Properly Guide Trial and Appellate Courts in Applying Daubert.

Without any citation, Allergan argues that a differential diagnosis is "a method of proving ***specific*** causation, ***not general causation or product defect***." (Ab8)(emphasis in original). But it is unclear why this distinction would matter. The question was whether Plaintiff's experts could use the differential diagnosis to base their opinion that Ozurdex caused Plaintiff's ocular injury when all other possible causes were too remote to be likely.

Allergan spends pages attempting to create a fake distinction between specific and general causation to conclude that the respective expert opinions that relied upon a differential diagnosis were properly excluded by the appellate court – after the trial court found them to be admissible. No where in Creanga v. Jardal, 185 N.J. 345 (2005) does this Court create any distinction between general causation versus specific causation. Thus, there was no basis for the Appellate Division in this case to then rule: "the issue here is the utter lack of evidence to support the existence of both general and specific causation. There was no evidence the Ozurdex injection plaintiff received was defective and no evidence of a particulate in her eye" constitutes a misapplication of the type of causation proof that this Court permitted in Creanga. See Psa174.

This Court permits a party to rule out all other causes as the doctor did in Creanga based upon the facts known and the temporal relationship. This is what

the doctor did in Creanga, 185 N.J. at 358, to conclude that the mother's premature labor was caused by the motor vehicle accident, and this is what the multiple experts did in this case to conclude that the cause of Beavan's ocular inflammation was the Ozurdex injection rather than other possibilities that occurred long ago and whose impact would have been observed sooner. (Da694-700, Pa15-21, Pa127, Pa134-39.) The Appellate Division states this issue is speculation, but this Court explained when the doctor uses a proper method, such as differential diagnosis, and explains that methodology, their opinion creates a jury question. Creanga, 185 N.J. at 357-363.

Allergan cites no New Jersey case that holds the differential diagnosis method can only be used to prove general causation, and only cites a handful of out-of-state cases for this proposition in a footnote. (Ab9, n.8.) First, in McManaway v. KBR, Inc., 852 F.3d 444, 454 (5th Cir. 2017), the Fifth Circuit held the differential diagnosis could not be used to prove causation because the plaintiff did not have any studies showing the ailment was caused by the exposure to the contaminant. But here, Allergan admitted it. (Da256.) The same holds true for the other cases upon which Allergan attempts to rely. See Leake v. United States, 843 F. Supp. 2d 554, 564 (E.D. Pa. 2011)(explaining differential diagnosis could not be used without proof that paint toxin was capable of causing acute liver failure); Soldo v. Sandoz Pharms. Corp., 244 F.

Supp. 2d 434, 518 (W.D. Pa. 2003)(excluding experts' use of differential diagnosis for failure to support basis for ruling out the other causes).

Allergan argues that Plaintiff's experts "failed to rely on (or conduct) any studies providing a microscopic, medical-grade silicone particulate ***can cause*** inflammation," but the experts did not need to do so because under N.J.R.E. 703, these experts were entitled to rely upon Allergan's own Drug Recall that stated the Ozurdex could cause "intraocular inflammatory reaction." Cf. (Da256) (emphasis added) with Ab9 (emphasis in original). Because the general causation that Ozurdex contaminated by a silicone particulate can cause "visual disturbance" and "intraocular inflammatory reaction" is established in Allergan's own admissions, Allergan's reliance on a distinction between specific and general causation is without merit. (Da256.)

While Allergan's recall admitted the damage that befell Beavan could occur, they now argue to this Court that its study regarding rabbits is more compelling than its own admission made when it recalled the product. (Ab10.) The position makes no sense – if the harm was not based upon its own scientific research, it would have never recalled its products internationally over the concerns. Plaintiff's experts were entitled to rely upon the science that Allergan provided to the world in the two separate recalls. (Da256.) In fact, Allergan attempts to argue that the letter was limited to ocular inflammation, yet its other

internal documents show that there also was a concern for "corneal reaction if the particulate migrates to the anterior chamber." (Da483.)

This Court should reject Allergan's argument that Beavan waived the ability to argue for a N.J.R.E. 104 or a hearing pursuant to Kemp ex rel. Wright v. State, 174 N.J. 412, 427 (2002), because it was never requested below. (Ab16, n.14.) However, Beavan never had a reason to ask for such a hearing before this Petition because the trial court had found the experts were qualified to give their opinions. (Psa82.) It was not until the Appellate Division ruled that the experts did not provide a basis for either specific or general causation that the issue of a N.J.R.E. 104 hearing became relevant. (Psa176.) This Court should grant certification on this basis alone given all of the precedents that Allergan relies upon only dismissed an expert's opinion after such a hearing and not on a discovery deposition transcript – taken by the adverse side. See In re Accutane Litig., 234 N.J. 340, 346 (2018) (noting trial court excluded expert testimony after N.J.R.E. 104 hearing); see e.g., Lanzo v. Cyprus Amax Mins. Co., 467 N.J. Super. 476, 513 (App. Div. 2021)(holding trial court erred in failing to hold "a Rule 104 hearing to test her theory and conducted no analysis as to whether the Daubert factors had been met").

Allergan again errs in its statement of evidence to the Court as to the proof in a failure-to-warn case. (Ab18.) Allergan's December 2018 recall warned of

the exact risk that occurred – increased corneal inflammation and ocular disturbances, and Dr. Phillips stated he would not have administered the Ozurdex if he was advised of the recall. (Da256-57; Pa130-31 at 17:24-18:9.) Without citation, Allergan argues "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." (Ab18.) But Beavan had reliable expert testimony as to general causation – Allergan's own recall notice. (Da256.) The Appellate Division erred in requiring Plaintiff's experts to provide their own testing when Allergan's own admissions warned the doctors about the risks that actually occurred to Beavan. (Psa176.)

The Appellate Division's analysis in this case is at odds with the less stringent standards that this Court permitted under Accutane when the Court instructed that Daubert's "factors for assessing the reliability of expert testimony will aid our trial courts in their role as the gatekeeper of scientific expert testimony in civil cases." Accutane Litig., 234 N.J. at 347–48. The Court's goal in Daubert was to expand rather than limit admissibility as it had been under the Frye standard: "'General acceptance' is not a necessary precondition to the admissibility of scientific evidence. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 597 (1993). Here, it makes no sense to limit the two Plaintiff's experts'

opinions when they rely upon information that they would ordinarily rely upon as physicians – the warnings that Allergan itself put out. (Da256); see N.J.R.E. 703.

As this Court explained about the gatekeeping function under Accutane, "an expert witness may rely on the opinion of another expert in a relevant field." Morales-Hurtado, 241 N.J. at 593. This Court held when the expert is relying upon information from another, the testimony cannot be barred without a N.J.R.E. 104(c) hearing. Id. at 594. But this is exactly what occurred – Plaintiff's experts relied upon Allergan's own notices regarding the risks of ocular inflammation to come to their conclusion based upon the entirety of Plaintiff's medical treatment and symptoms, that the reason for her injury was the administration of Ozurdex. (Psa176.) The trial court properly found the why and the wherefore for those opinions. (Psa82.) To the extent the Appellate Division disagreed, it could not do so without affording Plaintiff a 104 hearing. See Accutane, 234 N.J. at 391 (explaining standard of review requires review of record containing a "full Rule 104 hearing").

Allergan's argument as to substantial factor is also without merit. In a failure-to-warn case, a plaintiff may proceed to a jury when the manufacturer's failure to give a doctor a warning was a substantial factor in avoiding the injury. Hrymoc v. Ethicon, Inc., 467 N.J. Super. 42, 90 (App. Div. 2021), aff'd as mod.,

254 N.J. 446 (2023). Here, Dr. Phillips testified at deposition that had he known of the risks that Allergan knew but did not share with doctors in the United States, he would not have used the Ozurdex. The exact harm specified in the late December 2018 recall notice is the harm that occurred. Accordingly, the Appellate Division's decision requires your review and correction.

CONCLUSION

Certification should be granted to review whether an expert's opinion may be admitted when based upon the drug manufacturer's admission that the product can cause the harm that befell the injured party. Here, the Appellate Division erroneously vacated the trial court's finding that Beavan's experts' testimony was admissible. That error erroneously required the expert to conduct their own testing when the drug manufacturer had admitted the potential harm in the drug recall. Further, the Appellate Division erred because it dismissed the case without a hearing as this Court required in Accutane. As a result of the Appellate Division's failure to follow this Court's precedent, certification should be granted.

Respectfully submitted,

By:_____
DENNIS DONNELLY

Dated: March 6, 2025