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

PLAINTIFF-PETITIONER ALISON BEAVAN'S PETITION FOR CERTIFICATION

Dennis Donnelly, Esq., ID: 019811981
THE DONNELLY LAW FIRM, LLC
86 Summit Avenue, 4th Floor
Summit, NJ 07901-1522
(908) 275-1500

SHOOP | A PROFESSIONAL LAW CORPORATION
David R. Shoop, Esq. (Admitted PHV)
Thomas S. Alch, Esq. (Admitted PHV)
9701 Wilshire Blvd., Suite 950
Beverly Hills, CA 90212

PANISH SHEA, BOYLE & RAVIPUDI, LLP
Brian Panish, Esq. (Admitted PHV)
Adam Shea, Esq. (Admitted PHV)
11111 Santa Monica Blvd., Suite 700,
Los Angeles, CA 90025
Attorneys for Plaintiff, Alison Beavan

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Court Rules

Literature

Other Authorities

Statutes

TABLE OF ORDERS AND JUDGMENTS

TABLE OF PETITION APPENDIX ("Psa")

WHY CERTIFICATION SHOULD BE ALLOWED.

Plaintiff-Petitioner Alison Beavan went blind in her left eye because Defendant Allergan failed to warn her doctor that its drug, Ozurdex, may contain a foreign silicone particulate that could lead to ocular inflammation and visual disturbances. (Pa129-30.[1]) The Appellate Division erred in barring Plaintiff's experts under Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), when 1) this Court has never required a strict Daubert test in civil matters; and 2) Defendants' own admissions together with the experts' opinions demonstrated Allergan's lack of warning led to Beavan's injuries. (Pa129-30.)

Certification should be granted when the lower courts fail to follow this Court's precedent; here, the Appellate Division misconstrued this Court's holdings in both In re Accutane Litigation, 234 N.J. 340, 348 (2018) and Creanga v. Jardal, 185 N.J. 345, 357-58 (2005) that then led to the dismissal of Plaintiff's claims with prejudice. Plaintiff presented all that was required by the common law and common sense to withstand summary judgment dismissal for failure of proof of causation: her experts followed a proper differential diagnosis methodology and explained that it was the defendant's manufacturing defect in the admittedly bad defective lots and failure to warn that made it impossible for

[1] The following abbreviations are used: "Da" for Defendant-Appellant's appendix in support of appeal filed with the Appellate Division; "Pa" refers to Plaintiff-Respondent's appendix in opposition to appeal filed with the Appellate Division; "Psa" refers to Plaintiff-Petitioner Allison Beavan's appendix annexed hereto.

anyone to present the type of definitive, documentary proof beyond a reasonable doubt that the appellate panel mistakenly required. Nevertheless, this panel mistakenly took away what was a valid jury question on causation by instead requiring definitive, perfect and impossible proof of causation: for this panel unless the defective silicone particulate could be retrieved from inside this consumer's eye there was a fatal failure in causation as a matter of law. (Pa21.)

Here, Allergan admitted through its experts and its own testing that if there was a silicone particulate, it could lead to blindness. (Da256-57.) The Appellate Division erred in overlooking Beavan's experts opining as to why her dose was defective, and that the Ozurdex caused her left eye blindness. (Pa15-21.) The Appellate Division erred in applying Creanga and Accutane because there was no dispute that a contaminated batch could cause the injury – the question, which was one for the jury – was whether Beavan's batch was contaminated, and thus, caused her injury. As Dr. Lazelary concluded using Creanga's differential diagnosis theory of causation, because the only other possible causes of blindness were temporally remote, the injection of the Ozurdex was the most likely cause for the damage that led to an otherwise unexplainable degree of inflammation causing Beavan's blindness. (Da695-96.) Because the Appellate Division's error deprived Beavan her constitutional right to a jury trial, this Court should grant certification. N.J. Const. art. I, ¶ 9.

STATEMENT OF THE MATTER INVOLVED

On December 28, 2018, Allergan issued an "urgent drug recall" for twenty-two lots of Ozurdex stating that "transient visual disturbance or intraocular inflammatory reaction in sensitive patients are potential safety risks." (Da256-57.) The recall stated that a routine inspection revealed a "silicone particulate has been confirmed to originate from the needle sleeve." (Da256.) Allergan's notice further stated, "[t]here is also a remote possibility of corneal reaction if the particulate migrates to the anterior chamber." (Da256.) Allergan asked recipients to quarantine recalled product inventory and to "cease supplying the recalled product lots to your customers." (Da256.) However, months earlier, Allergan had warned healthcare providers and patients in forty (40) countries outside of the United States of the defective Ozurdex's risks. (Da646.) Meanwhile, after Allergan warned these others, and before the December notice to physicians in the United States, Dr. Phillips unknowingly injected Ozurdex from one of the lots into Allison Beavan's eye on November 6, 2018. (Pa129-30 at 16:22-17:23.) Within a week of treatment, Beavan's retina detached requiring surgery that led to her blindness in her left eye. (Da339.)

Allergan's own testing of the lot showed a 2.2% defect rate. (Da237, Da373.) Although Allergan concluded the risk was low, adequate warning of the potential contaminate should have been made as Allergan admitted Ozurdex steroid migration into the anterior ocular chamber causes injury, including

visual disturbances, intraocular inflammatory reaction, and corneal reaction. (Da105, Da121, Da256-57.) Dr. Phillips testified he would never have injected Ozurdex from the defective lot had he been aware of the possible contamination. (Pa130-31.) There was, in essence, undisputed causation in fact: given this patient had no inflammation, retinal detachment, or other bad reaction to prior good batches of the same drug, if this injection from the bad lot had not occurred, the resulting excessive reactive inflammation would have not occurred. Id.

Plaintiff offered two separate board-certified ophthalmology experts to opine that Allergan's failure to warn was a proximate cause of Beavan's blindness, Dr. Phillips and Dr. Maziar Lalezary. Dr. Lalezary testified that the silicone particulate caused mechanical traction causing the retinal break and the retinal attachment, which resulted in the need for surgery and that the resulting, necessary postop positioning led to the migration of the Ozurdex into the anterior chamber. (Da695-96.) Dr. Lalezary explained that "on November 6, 2018, with the injection of the Ozurdex, that the silicone particulate was injected in Ms. Beavan's eye that caused the retinal detachment, which required, then, the surgery that then resulted in the migration of the Ozurdex steroid pellet into her eye as well as the RETISERT detachment, and that ultimately led to her blindness in the left eye." (Da699-700.) Dr. Lalezary testified that the offending silicone particulate is either still lodged in a portion of Beavan's eye "that

becomes scarred and ingrained into her tissue," or that it was aspirated during the November 14, 2018 vitrectomy surgery. (Da694; Da697-98.) He opined the Ozurdex was contaminated because Beavan had prior Ozurdex injections without issue, and her injury occurred within a week of administration of the Ozurdex from a bad lot where a known side effect to injecting silicone particulate is visual disturbance and ocular inflammation. (Pa15-21; Da697-98.)

Dr. Phillips opined that the silicone particulate caused a corneal reaction, corneal edema, corneal cloudiness, persistent inflammation not controlled by steroids, which all caused Beavan to lose vision in her left eye. (Pa127; Pa134-Pa139.) He also opined that the silicone particulate caused persistent inflammation and corneal edema, which were adverse effects identified in Allergan's December 28, 2018 drug recall. (Da256-57; Pa127; Pa134-39.)

Completely overlooked by the Appellate Division, Beavan had a third expert – her treating cornea specialist, Michele Tarver, M.D., who also opined after performing a complete assessment, examination, and review of the records that on February 23, 2019, Beavan suffered a retinal detachment, leading to a vitrectomy following which it was observed that the "Ozurdex had migrated to the anterior chamber and her cornea was swollen." (Da690.) Dr. Tarver opined that the toxic levels of Ozurdex led to Beavan going blind in her left eye. Id.

Defense expert, Dr. Eliott, agreed that mechanical traction could cause a retinal tear and detachment. (Da711-12.) Dr. Eliott theorized that the Retisert implant caused the retinal detachment but it was implanted nine years earlier. (Da368-69; Da357.) Dr. Lazelary explained Dr. Eliott's theory was implausible:

> the temporal relationship with the Ozurdex injection is by far the more relevant significant risk compared to . . . having had cataract surgery in 2009 or trabeculectomy surgery or Reisert implanted. Those things in the near term incur a risk of retinal detachment for [Beavan]. So in the post-operative period of roughly 90 days, those risks are elevated, but beyond that, the risk is significantly less than a procedure that's done close to the complication.

(Da179-80.) Dr. Eliott further conceded that of 6,553 units, "there could have been approximately 130 cases of complications." (Da373, n.4.)

After discovery, Allergan moved for summary judgment, including the argument that Beavan's experts' opinions were net opinions. (Psa142.) The trial court denied the motion and reconsideration. (Id.) On leave to appeal, the Appellate Division reversed finding that Beavan's experts could not testify to proximate cause because of the lack of perfect causation proof. (Id.)

QUESTIONS PRESENTED

1. Did the Appellate Division undermine the purpose of the Products Liability Act ("PLA") by changing the standard for expert causation testimony?

2. Should the Appellate Division second-guess a trial court's decision that the expert causation testimony on a summary judgment motion was sufficient to create the usual jury question on causation?

3. Did the Appellate Division apply the wrong standard for proof of proximate cause in a failure-to-warn products liability matter?

ERRORS COMPLAINED OF

1. The Appellate Division undermined the purpose of the PLA by changing the standard for admission of expert testimony.

2. The Appellate Division erred in reversing the trial court's admission of the experts' opinions on causation when there was no 104 or Kemp ex rel. Wright v. State, 174 N.J. 412 (2002) Hearing.

3. The Appellate Division erred because under the substantial factor test, Allergan's admission of 2.2% of the Ozurdex doses were contaminated was sufficient to be a substantial factor in causing Beavan's blindness.

COMMENTS ON THE APPELLATE DIVISION DECISION

The Appellate Division committed multiple errors. The Appellate Division found Beavan's experts' opinions "would leave a jury to speculate whether there was ever a particulate in the applicator or particulate injected into plaintiff's eye." (Psa174.) But there was sufficient circumstantial evidence for the jury to consider this issue: 1) Allergan's admission that injections contained the silicone particulate; 2) the silicone particulate causing ocular inflammation

that can lead to blindness; 3) Beavan was administered Ozurdex from that recalled lot; 4) Beavan suffered from ocular inflammation that led to blindness. (Da256-57; Pa129-30.) Beavan did not need to prove that the medicine she was administered contained a silicon particulate because she had no way to do so. (Pa15-20.) Nor did she have to show evidence of the particulate in her eye, because like the jury charge that talks about inferring it snowed from waking up to find snow on the ground, Beavan became blind shortly after being administered a drug from a lot with a known particulate that can cause blindness. See James v. Bessemer Processing Co., 155 N.J. 279, 301 (1998)(explaining plaintiff often must rely upon circumstantial evidence in a products case).

I. The Appellate Division Erred in Rejecting Dr. Lazelary's Method of Using a Differential Diagnosis to Determine Causation. (Psa174.)

The Appellate Division erred in this case by ignoring basic tenents for admission of expert testimony. "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise." N.J.R.E. 702. Dr. Phillips and Dr. Lazelary possessed this technical knowledge and provided the necessary why and wherefore for their opinions. See Hisenaj v. Kuehner, 194 N.J. 6, 24 (2008) (reversing the appellate court's conclusion of inadmissibility and allowing a defense biomechanical engineer's expert

testimony to be presented to a jury, despite flaws in his analysis that could be impeached on cross-examination).

While this Court has stated that expert testimony must be reliable to be admissible, the Appellate Division misconstrued the application of a differential diagnosis to provide the reliability for his opinion on causation. Creanga, 185 N.J. at 355. Reliability may be shown by demonstrating the expert's opinion is "generally accepted within the [medical] community." Id. (citing Kemp ex rel. Wright v. State, 174 N.J. 412, 424 (2002). This Court further explained: "the purpose of differential diagnosis is that it allows experts to make conclusions on medical causation in circumstances where they do not have all the necessary facts to prove a single hypothesis. A differential diagnosis . . . allows the expert to use the facts at hand to disprove all other hypotheses." Id. at 361.

In Creanga, 185 N.J. at 352, a woman went into premature labor two days after a motor vehicle accident causing the loss of one of her twin fetuses. Her treating obstetrician opined that the motor vehicle accident caused the premature labor because other things that could cause premature labor were unlikely causes. The Supreme Court explained a differential diagnosis may be used to provide an opinion on causation when the expert: 1) rules in all possible causes; 2) then uses that list to "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.

The Appellate Division here committed the same error that this Court rejected in Creanga. This Court explained that even if the treating doctor did not know whether the plaintiff had any actual trauma to her abdomen, it did not render his opinion a net opinion, explaining "that fact simply would have supplemented the doctor's conclusion; its absence does not denote that his opinion was 'based solely on his subjective belief' as was found by the Appellate Division." Id. at 361-62. The Creanga doctor's logic is nearly identical to the logic of Dr. Lazelary who explained:

> Whether it migrated to the anterior chamber or it lodged into her vitreous space, I can't say for certain because nobody documented that. But it's more than coincidence that she developed a problem when a defective Ozurdex was implanted. So it's the only variable that coincides with her retinal detachment.

(Da184 at 100:1-7.) Dr. Lazelary explained all the other factors had been present for years earlier - including prior Ozurdex injections, and that the only change was the injection of Ozurdex from a batch that had been recalled due to 2.2% being contaminated with the silicone particulate. (Da187-88 at 103:8-104:8.)

The Appellate Division here committed the same error the Creanga court rejected when it found "[t]here was no evidence the Ozurdex injection plaintiff received was defective and no evidence of a particulate in her eye." (Psa175.)

But like the physician in Creanga without knowledge of actual trauma to the abdomen, there were facts from which the expert could infer they were true: Allergan admitted the lot contained defective injections, which were defective due to the particulate being present. (Da646.) Both Dr. Lazelary and Dr. Phillips relied on this inference, and it was up to a jury – not an appellate court – to determine whether it was true. In essence, the Appellate Division confused the method for coming to experts' conclusions, with the judges' own erroneous perfectionist interpretation of what is a valid differential diagnosis.

The Appellate Division's foundational error for their erroneous conclusion was in finding the defense experts more persuasive than Beavan's experts, when that is necessarily a jury issue. See Creanga, 185 N.J. at 363 (explaining any inconsistencies in expert's opinion are weighed by the jury, not the court). The Appellate Division noted that "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." (Psa175.) But like the doctor in Creanga, Dr. Lazelary specifically addressed why the prior surgeries performed years earlier, although having the same risk factor for blindness, were not a likely cause: "the risk is significantly less than a procedure that's done closer to the complication." (Da179-80 at 82:21-83:11.) He further explained by considering

her medical history, why Beavan was at higher risk to develop her complications and that these factors made her more susceptible to the injury from the Ozurdex particulate. (Da180-82 at 83:12-85:19.) Thus, the Appellate Division rejected Dr. Lazelary factually and not from any improper methodology in contravention of this Court's admonitions in Creanga.

In noting the other medical conditions, the Appellate Division erroneously rejected the fact that differential diagnosis could be used by the experts to opine that the defective Ozurdex caused the blindness rather than the other causes. But ignoring this Court's warning in Creanga, 185 N.J. at 363, the Appellate Division substituted its judgment when that issue was reserved for the jury. Since both experts provided the why and the wherefore for their conclusion and properly relied on their medical training and experience upon a review of the patient's history and medical treatment, the opinions were not net opinions. Creanga, 185 N.J. at 363. For instance, Dr. Lazelary explained that he ruled out the other causes, like the Retisert implant, because temporally, the things that occurred nearer in time, like the Ozurdek injection within nine days, were more likely to increase the risk than things that occurred years earlier. (Da179-80.)

Only the jury could determine whether Dr. Lazelary's use of the differential diagnosis was correct. Because Dr. Lazelary explained why he rejected Dr. Eliott's theory that the cause was Retisert insert from 2009 was the

cause of the blindness in 2018, the Appellate Division erroneously resolved genuine disputes of material fact. (Da179-80.) Given the remedial nature of the PLA, this Court should grant certification to ensure the lower courts apply proper not perfect standards for gatekeeping experts' causation opinions.

II. The Appellate Division Erred by Requiring Daubert. (Psa175-76.)

The Appellate Division threw out Beavan's claim finding "[a]side 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." (Pa176.) But this Court has never adopted Daubert be used to exclude relevant expert testimony in a civil case. Accutane, 234 N.J. at 399. This Court explained the Daubert factors are "pertinent for consideration, but not dispositive or exhaustive." Id. at 398. Importantly, this Court said, "[i]n adopting use of the Daubert factors, we stop short of declaring ourselves a 'Daubert jurisdiction.' Like several other states, we find the factors useful, but hesitate to embrace the full body of Daubert case law as applied by state and federal courts." Id. (citations omitted).

This Court's reasoning for looking to Daubert in products liability cases was due to the limited causation evidence in the Accutane litigation. Id. at 352. This Court noted plaintiffs' claims relied on "epidemiology[, which] focuses on the question of 'general causation,' that is, whether the agent under study is "capable of causing disease," and does not focus on specific causation in a

particular individual." Id. Such was not the case here where Allergan itself had studies regarding the silicone particulate causing ocular inflammation. (Da256-57.) Thus, the Appellate Division erred in finding "[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 in this case," and incorrectly limited the experts' ability to provide an opinion based upon their "knowledge, training, and experience," which has been the hallmark for expert testimony in this State for decades. Cf. Pa176 with Creanga, 185 N.J. at 354-55.

The appellate panel's conclusion was both legally and factually incorrect. (See Pa176.) First, Allergan admitted that the silicone particulate causes inflammation. (Da256-57.) Second, legally, the statement was incorrect because in a products liability case, Plaintiff must prove medical causation and not scientific causation. Coffman v. Keene Corp., 133 N.J. 581, 594 (1993). In stating the lack of testing, peer reviews, or general acceptance, the Appellate Division overlooked this Court's analysis in Creanga where it adopted the use of the differential diagnosis to prove causation in a personal injury matter stating "differential diagnosis generally is a technique that has widespread acceptance in the medical community." Creanga, 185 N.J. at 357 (quoting In re Paoli R.R. Yard PCB Lit., 35 F.3d 717, 758 (3d Cir. 1994) (noting "sometimes differential diagnosis can be reliable with less than full information") and citing (Westberry

v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir.1999) (stating that differential diagnosis "has widespread acceptance in the medical community, has been subject to peer review, and does not frequently lead to incorrect results") (citation omitted). Dr. Lazelary's opinion was proper under Creanga because, after ruling in all possible causes, he ruled out all other causes based on his knowledge, training, and experience. (Da174-81.) He explained the close time between the injection and injury combined with proof this patient had no reaction to prior good doses of Ozurdek, the bad batch injection was more likely the cause of blindness rather than a procedure nine years earlier. (Id.)

Moreover, as explained above, Dr. Lazelary and Dr. Phillips' knowledge, education, training, and experience supported that ocular inflammation can cause blindness. (See e.g., Da179-81.) Here, Allergan admitted that the lot E83364 was contaminated – even if it was unaware whether every dose was contaminated. (Da644.) Allergan also admitted that the silicone particulate could cause ocular inflammation. (Da644-46.) As a result, Beavan's experts met the standards for expert testimony. The Appellate Division erred by finding that an expert would need to conduct her/her own testing under Daubert to state the Ozurdex contained the silicone when Allergen conceded through its own studies that silicone particulate could cause ocular disturbances. (Da644-46.) Because Allergan warned of these risks of a contaminated Ozurdex but only after

Beavan's injection, and such warnings are relied upon by treating physicians, including Beavan's treating physician, the Appellate Division erred in excluding two treating and one consulting expert's causation opinions under Daubert.

This Court clarified that it is not a Daubert jurisdiction. Accutane, 234 N.J. at 399-400. Offering guidance to the trial courts, this Court required "the proponent to demonstrate that the expert applies his or her scientifically recognized methodology in the way that others in the field practice the methodology." Id. An expert's opinion should only be excluded when the expert cannot "demonstrate the soundness of a methodology, both in terms of its approach to reasoning and to its use of data, from the perspective of others within the relevant scientific community, the gatekeeper should exclude the proposed expert testimony on the basis that it is unreliable." Id. But here, Beavan's experts relied on Allergan's own admissions as to the effect of a silicone particulate potentially causing visual disturbances. (Da644-46.) The only question was whether the Ozurdex was actually contaminated, and Beavan's experts explained why Beavan's dose of Ozurdex was contaminated. (Pa15-21.) As a result, the Appellate Division misconstrued the gatekeeping function that this Court required in Accutane, 234 N.J. at 389 (holding "some expert consensus that the methodology and the underlying data are generally followed by experts in the field"). Beavan's experts properly applied

information received from Allergan, including that Ozurdex contaminated with silicone can lead to ocular disturbances, including blindness.

Importantly, the Appellate Division erred in not abiding by the abuse of discretion standard, particularly when there was no N.J.R.E. 104 or Kemp hearing. Hisenaj, 194 N.J. at 20. The two Judges on the panel were not supposed to substitute their judgment when the trial court's decision was proper – Beavan's experts provided the why and the wherefore for their opinions, their methodology was consistent with those of ophthalmologists who rely on information from the drug manufacturer, and their logic was supported by this Court's decision in Creanga. Accordingly, the Appellate Division's decision constituted a misapplication of this Court's precedent, and in so doing, denied Beavan her constitutional right to a trial by jury. N.J. Const. art. I, ¶ 9. The proper remedy is for this Court to grant certification to correct this injustice.

III. The Appellate Division Erred in Applying the Wrong Proximate Cause Standard in a Failure-to-Warn Case. (Psa174-76.)

The Appellate Division erred in ignoring the type of causation that this Court requires in a failure to warn products liability case. As this Court has stated, "When the alleged defect is the failure to provide warnings, a plaintiff is required to prove that the absence of a warning was a proximate cause of his [or her] harm." Coffman, 133 N.J. at 594 (citing Campos v. Firestone Tire & Rubber Co., 98 N.J. 198 (1984)). This Court explained a heeding presumption is used

because "in a failure to warn case, establishing that the absence of a warning was a substantial factor in the harm alleged to have resulted from exposure to the product itself is particularly difficult." Id. at 600 (citation omitted)).

This Court has explained, "the defect is the absence of a warning to unsuspecting users that the product can potentially cause injury." Coffman, 133 N.J. at 593–94 (citing Freund v. Cellofilm Properties, Inc., 87 N.J. 229, 242 (1981) (holding "duty to warn in the strict liability cause of action is based on the notion that absent a warning or adequate warning a product is defective, in that it is not reasonably fit, suitable or safe for intended purposes")). The informed consent doctrine goes hand-in-hand with a failure-to-warn claim against a drug manufacturer. In re Diet Drug Litig., 384 N.J. Super. 525, 540 (Law. Div. 2005). Allergan's December 2018 recall warned of the exact risk that occurred – increased corneal inflammation and ocular disturbances. (Da256-57.) Dr. Phillips stated he would not have administered the Ozurdex if he knew of the recall. (Pa130-31 at 17:24-18:9.) Ozurdex was a substantial factor in causing the injury because Allergan admitted a sensitive patient was more susceptible to damage, and the increased risk factors were the actual cause of Beavan's injury.

Even conceding that there was only a 2.2% chance that the Ozurdex administered was defective, as Allergan concedes both through its testing and its expert, Dr. Eliott, the Appellate Division overlooked that this percentage is

enough to constitute a substantial factor under New Jersey law. See Velazquez v. Jiminez, 336 N.J. Super. 10 (App. Div. 2000), aff'd, 172 N.J. 240 (2002)(holding 5% to be substantial factor); see also Dubak v. Burdette Tomlin Memorial Hospital, 233 N.J. Super. 441, 452 (App. Div.), certif. den., 117 N.J. 48 (1989)(finding of 10% fault satisfied the substantial factor test).

This Court has recognized that a plaintiff has a difficult time in showing what might occur if properly warned. Gardner v. Pawliw, 150 N.J. 359, 381–82 (1997)(quoting Hamil v. Bashline, 392 A.2d 1280, 1288–89 (Pa. 1978)(citing Restatement (Second) of Torts § 323(a)). In such situations, "courts have generally let a jury find the failure caused the harm, though it is often a pretty speculative matter whether the precaution would in fact have saved the victim." Id. at 382(quoting Hamil v. Bashline, 392 A.2d 1280, 1287 (Pa. 1978))(quoting 2 Fowler V. Harper & Fleming James, Jr., The Law of Torts § 20.2 at 1113 (1956)). Similar to an increased risk case, a jury should consider if Allergan's failure to warn increased Beavan's risk of harm because Allergan knew 2.2% of the lot contained the silicone particulate that its own testing showed an increased risk of harm to all patients, including a greater risk for those with additional complicating factors that Beavan had. See id. at 388 (quoting Scafidi v. Seiler, 119 N.J. 93, 118 (1990) (Handler, J., concurring)(citing Herskovits v. Grp. Health Co-op of Puget Sound, 664 P.2d 474 (Wash. 1983) (holding plaintiff only

has the burden to show the negligence increased the risk of harm, and a jury must decide if the increased risk caused injury)).

This Court previously corrected the same error by the Appellate Division:

> Because the Appellate Division required proof to a reasonable degree of medical probability that the fetus's preexisting condition would have been detected if defendant had ordered the [] tests, the court determined that [the expert]'s inability to determine the fetus's specific condition on December 21, 1988, precluded him from providing an expert opinion that met that standard.

Gardner, 150 N.J. at 390 (citing 285 N.J. Super. at 122–25). This Court reversed explaining the Appellate Division based its decision on a "misperception of the relevant burden of proof." Id. Like a Scafidi case, in a failure to warn products case, Plaintiff need not show that the Ozurdex caused the blindness; instead, by failing to warn Beavan's doctor of the defective batch, the company's failure increased Beavan's risk of developing blindness. Even a 2.2% increase of the risk is sufficient to create a question of fact for the jury. See Velazquez, 172 N.J. 240 (affirming 5% is a substantial factor).

CONCLUSION

The Appellate Division misconstrued this Court's prior precedents both in terms of how a differential diagnosis may be used by a physician to offer a causation opinion and how a drug manufacturer's admissions regarding causation can be relied upon by experts to support their opinions. As a result, certification should be granted.

CERTIFICATION OF GOOD FAITH

I, Dennis Donnelly, Esq., hereby certify that the within Petition is filed in good faith, presents a substantial question of public importance, and is not filed for purposes of delay. I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Respectfully submitted,

By:_____
DENNIS DONNELLY

Dated: January 10, 2025