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, P.J.A.D. Hon. Robert M. Vinci, J.A.D.

SUPPLEMENTAL BRIEF OF PLAINTIFF-PETITIONER ALISON BEAVAN IN SUPPORT OF PETITION AND RESPONSE TO *AMICI CURIAE*

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PRELIMINARY STATEMENT

Plaintiff-Petitioner Alison Beavan files this supplemental brief to more fully address the issues for which certification has been granted and to address the arguments of the parties that have filed briefs as *amici curiae*.[1] Ms. Beavan adopts her arguments in her prior briefs to this Court and the arguments made by the New Jersey Association for Justice. Without repeating the prior arguments, she asks that this Court reverse the Appellate Division decision in order to reinstate her claims against Allergan. Ms. Beavan's two experts provided a reliable methodology for concluding there was specific causation, and this Court should clarify how a differential diagnosis may be used by a medical doctor to support a causation opinion. Furthermore, this Court should again reiterate that the Appellate Division is to defer to the trial court with regard to the trial court's gatekeeping function for admissible expert testimony. In doing so, this court would also reaffirm what has been the consistent stance of NJ law making jurors the deciders on causation where there is evidence that would first allow a jury to conclude that a manufacturer had distributed a

[1] There are four briefs submitted by various *amici* in this matter: 1) New Jersey Association for Justice; 2) the Chamber of Commerce of the United States of America which filed a brief with the New Jersey Civil Justice Institute (collectively "the Chamber"); 3) the HealthCare Institute of New Jersey and the New Jersey Business & Industry Association (collectively the "Business *amici*"); and 4) the Product Liability Advisory Council, Inc. ("the Advisory Council").

defective product and failed to give an adequate warning of an increased risk of harm their defective product posed for New Jersey consumers.

STATEMENT OF FACTS

In June 2018, Allergan became aware that "[d]uring a routine manufacturing inspection, a silicone particulate . . . was observed in dispensed Ozurdex implants." (Da581-82.[2]) On December 28, 2018, Allergan issued an "urgent drug recall" for twenty-two (22) lots of Ozurdex, including Lot #E82852, stating "transient visual disturbance or intraocular inflammatory reaction in sensitive patients are potential safety risks," and that a routine inspection revealed a "silicone particulate has been confirmed to originate from the needle sleeve." (Da256-57.) 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 [their] customers." (Da256.) However, months earlier, Allergan had warned healthcare providers and patients in forty

[2] 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 Petition appendix; "Ab" refers to Allergan's Brief in Opposition to Petition; "Cb" refers to the Chamber's *amicus* brief filed with this Court; "Bb" refers to the Business *amici*'s brief filed with the Appellate Division; "ACb" refers to the Advisory Council's *amicus* brief filed with this Court.

(40) countries outside of the United States of the defective Ozurdex's risks. (Da646.)

Meanwhile, on November 6, 2018, after Allergan warned these others, and before the December notice to physicians in the United States, Dr. Phillips unknowingly injected Ozurdex from Lot #E82852 into Ms. Beavan's eye. (Pa129-30 at 16:22-17:23.) Prior to this injection, Ms. Beavan's vision had been 20/100. (Da652.)

On November 13, 2018, Ms. Beavan returned to Dr. Phillips with severe blurred vision in her left eye, decreased vision, and a blind spot. (Da665.) Dr. Phillips diagnosed Ms. Beavan with retinal detachment requiring surgery. (Da666.) On November 14, 2018, Dr. Phillips performed a Pars Para Vitrectomy on Ms. Beavan's left eye to treat the retinal detachment. (Da671.) During Ms. Beavan's November 26, 2018 post-operation visit, Dr. Phillip noted the Ozurdex steroid pellet had migrated to Ms. Beavan's anterior chamber. (Da675-76.) By February 1, 2019, Ms. Beavan was almost completely blind in her left eye—which Dr. Phillips attributed to the December 2018 Ozurdex recall. (Da685; Pa138.) On January 15, 2019, upon learning of the recall, Dr. Phillips documented that the Ozurdex "recall was secondary to inflammation and a possible corneal reaction of which she has developed both." (Da681.)

Dr. Phillips referred Ms. Beavan to Dr. Solomon noting Ms. Beavan

> now has significant corneal edema in the left eye and was a patient who has received numerous Ozurdex implant[s] in the past, but most recently for her left eye, received an implant from the lot that was subsequently recalled and found to have a silicone oil particle that had caused significant inflammation and sometimes corneal edema. She does have persistent corneal edema, but the inflammation is slowing resolving. . .

(Da148.)

Allergan tested only ninety (90) applicators among the 6,553 units from defective lots." (Da373, n.4.) In other words, from only a partial sampling Ozurdex Lot #E82852 contained 6,553 applicators that Allergan knowingly, and without warning, distributed, that contained at least a staggering 145 (2.2% of 6,553) defective applicators, including the defective Ozurdex applicator that blinded Ms. Beavan. (Id.)

Plaintiff offered two separate board-certified ophthalmology experts to opine that Allergan's failure to warn was a proximate cause of Ms. Beavan's blindness, Dr. Phillips, Ms. Beavan's treating doctor, and Dr. Lalezary. Dr. Lalezary was well-credentialed and experienced in treating patients with Ozurdex. (Da336-7.) Dr. Lalezary graduated from University of California San Diego School of Medicine in 2006. (Da340.) He completed an ophthalmology residency from 2007 to 2010 at Vanderbilt Eye Institute. (Da340.) He further completed a Vitreo-Retinal Surgical Fellowship at Vanderbilt Eye Institute. (Da340.) He has been board certified in ophthalmology since 2012. (Da340.) At the time of the motion for

summary judgment, Dr. Lalezary had written twelve peer-reviewed articles and two book chapters as well as lectured extensively in ophthalmology. (Da340-43.)

Dr. Lalezary has been regularly administering Ozurdex to patients since 2010. (Pa115-17.) This education, training, research, and experience provided Dr. Lalezary with the knowledge of the "mechanisms and issues with regard to causation as it pertain[ed] to [] Beavan's left eye injury, including, but not limited to her loss of vision in her left eye." (Da337.) Dr. Lalezary's opinion was based upon extensive review including the medical records, depositions, and Allergan's admissions, including field reports and recall notices. (Da337.)

Dr. Lalezary testified that the silicone particulate caused mechanical traction causing the retinal break and the retinal detachment within a week of treatment, 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

> to a reasonable degree of medical certainty that on November 6, 2018, with the injection of the Ozurdex, that the silicone particulate was injected in Beavan's eye that caused the retinal detachment, which [then] required 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, after considering Ms. Beavan's medical history, opined the silicone particulate injected into Ms. Beavan's eye was a substantial factor and a cause of her blindness. (Pa126.) Dr. Lalezary testified that the offending silicone particulate is either still lodged in a portion of Ms. Beavan's eye "that becomes scarred and ingrained into her tissue," or that it was aspirated during the November 14, 2018-vitrectomy surgery. (Da694; Da697-98.) He opined the Ozurdex was contaminated because Ms. Beavan had prior Ozurdex injections without issue, and her injury occurred within a week of administration of the Ozurdex from a defective lot where a known side effect to injecting silicone particulate is visual disturbance and ocular inflammation. (Pa16.)

At his deposition, Dr. Lalezary explained how the defective Ozurdex caused Ms. Beavan to become blind in her left eye:

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

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

A. Yes.

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

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

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

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

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

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

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

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

A. So she had – the particulate caused inflammation and traction in her peripheral retina that induced a retinal break and led to her retinal detachment. And

> subsequently, she had detachment repair that led to the anterior migration of the Ozurdex pellet. That compromised her vision because a patient with uveitis that develops a retinal detachment has poor prognosis for recovery and vision.

(Da695-96.)

Like Dr. Lalezary, Ms. Beavan's treating physician, Dr. Phillips was equally well-credentialed to offer an ophthalmology opinion in this matter. He was board-certified in ophthalmology. (Da703.) He received his medical degree from Howard University College of Medicine in 1988. (Da702.) He finished an ophthalmology residency at Wills Eye Hospital in Philadelphia from 1989 to 1992. (Da703.) He also completed a two-year fellowship in Vitreoretinal Disease at Wills Eye in 1994. (Da703) Dr. Phillips has been the Director of the Vitreo-Retinal Fellowship Program at Retina Group of Washington since 2000. (Da703.)

Dr. Phillips testified Ozurdex typically improved Ms. Beavan's inflammation "fairly well" and "knowledge of the silicone particulate gave [him] a potential cause for why [Ms. Beavan] was getting so much inflammation" despite the injection. (Pa135 at 27:1-5.) Dr. Phillips noted increased inflammation that had not been present with other administrations of Ozurdex and which was not responding to treatment. (Id.) He explained if he "had to tie things together," the injection from the defective lot "would . . . be the only thing . . . that [he] could potentially consider as a causative factor." (Pa138-39 at 30:23 to 31:1.) He further testified he would never have injected

Ozurdex from the defective lot had he been aware of the possible contamination. (Pa130-31 at 17;24 to 18:9.)

Dr. Phillips opined that the silicone particulate caused a corneal reaction, corneal edema, corneal cloudiness, and persistent inflammation not controlled by steroids, which all caused Ms. 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; Pa134-39.) Dr. Phillips explained that due to Allergan's concealment of the defect until December 28, 2018, he was not aware to look for the silicone particulate during the November 14, 2018-vitrectomy surgery that was needed following the injection from a defective dose. (Pa124.) Thus, in addition to causing Dr. Phillips to inject Ozurdex from a defective contaminated lot, Allergan's failure to advise treating doctors like Dr. Phillips of its contaminated bad batches also prevented Dr. Phillips from visualizing direct evidence that the defective and dangerous silicone particulate was in Ms. Beavan's eye.

Completely overlooked by the Appellate Division, Ms. 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, Ms. 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." (Da691.) Dr. Tarver opined that the toxic levels of Ozurdex led to Ms. Beavan going blind in her left eye. (Da692.)

Defense expert, Dr. Eliott, agreed that mechanical traction could cause a retinal tear and detachment. (Da711-12.) He explained

> [a]ny traction or pulling or pushing on the vitreous can cause a retinal tear. The vitreous is an egg white, raw egg white and its gooey.
>
> So if a needle goes through and squirts out a drug or a device, that could potentially push the vitreous, and the vitreous can pull a retinal tear since the retina is in close proximity to the pars plana where you put the needle through, and its peripheral retinal tears that result in retinal detachment.

(Da711-12.) Although Dr. Elliott opined that the silicone particulate was not large enough to cause traction and a retinal detachment, he conceded he was not aware of any literature regarding the minimum size a particle needs to be to cause traction and a retinal detachment. (Da713-14 at 40:11 to 41:12.)

Dr. Eliott alternatively theorized that the Retisert implant caused the retinal detachment, but it was implanted nine years earlier. (Da368-69; Da357.) Dr. Lalezary explained why 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 Retisert implanted. Those things in the near term incur a risk of retinal detachment for [Ms. 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 closer to the complication.

(Da180 at 83:2-11.) Dr. Eliott further conceded that of 6,553 units, "there could have been approximately 130 cases of complications." (Da373, n.4.)

Dr. Elliott further agreed with Dr. Lalezary and Dr. Phillips' theory that the silicone particulate was either still in Ms. Beavan's eye or "sucked out." (Pa103-04; Pa697-98.) Dr. Elliott testified, "[i]f it's off in the corner of the nooks and crannies, you won't be able to see it." (Pa102 at 40:4-6.)

PROCEDURAL HISTORY

Ms. Beavan commenced a strict product liability action against Allergan alleging the injection of the defective Ozurdex caused her to be blind in her left eye. (Psa84). After discovery, Allergan moved to exclude the reports and opinions of plaintiff's experts on summary judgment,-arguing that Ms. Beavan's experts' opinions were net opinions. (Psa69; Psa142.) The trial court denied the motions. (Psa96.) In resolving the motion to strike plaintiff's experts' testimony, the trial court found plaintiff's experts had sufficiently based their opinions on facts and evidence admissible under N.J.R.E. 703. (Psa90.) The trial court reviewed both Dr. Lalezary and Dr. Phillips' testimony in which they opined it was more likely than not that the silicone particulate was the proximate cause of

Ms. Beavan's injury. (Psa93-94.) The trial court addressed the lack of direct evidence, but explained the circumstantial evidence went to the weight of the expert testimony rather than its admissibility. (Psa94.)

Allergan moved for reconsideration of the trial court's denial of its motion to exclude plaintiff's expert opinions and for summary judgment. (Psa127.) The trial court denied reconsideration explaining:

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

(Psa129.) The trial court further stated "the weight of [Ms. Beavan's] expert testimony should be considered by a jury, not by the [c]ourt. Sufficient expert testimony has been shown to create an issue of material fact as to whether the defective Ozurdex applicator proximately caused [Ms. Beavan's] injuries." (Psa132.)

On leave to appeal, the Appellate Division reversed finding that Ms. Beavan's experts could not testify to proximate cause because of the lack of

perfect causation proof. (Psa176.) Admitting it must review the resolution of the expert testimony motion for an abuse of discretion, the Appellate Division stated "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": direct evidence that a silicone particulate was in this patient's eye. (Psa172, Pa174.) Specifically, the Appellate Division held the "differential diagnosis was unavailing" and "there was no evidence presented by plaintiff's experts to convince us their theory of causation would pass muster under Daubert [v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993)]." (Psa175-76.) In doing so, the two-judge appellate panel failed to note that a jury could find that that the defendants failure to provide a necessary warning of the increased risk of blindness posed by silicon particulates within their product not only exposed this patient to a silicone particulate into her eye but also prevented her treating doctors from knowledge that would have allowed them to visualize the particulate in her eye.

This Court then granted Ms. Beavan's Petition. Six *amici* have submitted four respective briefs. This brief is now submitted as Ms. Beavan's merits brief and also to address the arguments of the *amici*. For brevity, Ms. Beavan adopts and joins in the argument of the New Jersey Association of Justice.

LEGAL ARGUMENT

I. The Appellate Division Erred By Overlooking the Standard of Review. (Psa167-76.)

The trial court had appropriately reviewed whether Ms. Beavan's experts' opinions constituted net opinions. The Appellate Division was required to review the trial court's decision for an abuse of discretion. Townsend v. Pierre, 221 N.J. 36, 52-53 (2015). This Court recently re-affirmed that the Appellate Division should defer to "the trial court [which] has been entrusted with methodology-based review as the gatekeeper of expert testimony." In re Accutane Litig., 234 N.J. 340, 391 (2018). Here, the Appellate Division overstepped its authority in declaring that both of Ms. Beavan's experts' methodologies were not reliable when they utilized their knowledge, training, and experience to determine causation using a differential diagnosis approach. (Psa174-76.)

This Court has explained that under N.J.R.E. 703, an expert's opinion must be grounded in "facts or data derived from (1) the expert's personal observations, or (2) evidence admitted at the trial, or (3) data relied upon by the expert, which is not necessarily admissible in evidence, but which is the type of data normally relied upon by experts." Townsend, 221 N.J. at 52. Here, the Appellate Division not only substituted its own judgment for that of the trial court, but it overlooked that doctors regularly rely upon the information provided by the drug manufacturer when coming

to a conclusion on causation. As explained herein and in the Petition and Reply Brief, the Appellate Division's decision should be reversed because Ms. Beavan's two experts utilized a reliable method to come to their opinions, and as a result, Ms. Beavan made out a prima facie case for causation for both a products liability manufacturing defect case and a failure-to-warn case.

II. Plaintiff's Experts' Opinions Should Have been Deemed Admissible to Show a Prima Facie Case for a Manufacturing Defect. (Psa167-76.)

This Court should not use Daubert to bar an expert when the purpose behind Daubert was to expand admissibility of expert testimony rather than restrict it. Id. at 597. Because this Court has held a differential diagnosis may be used to demonstrate causation when the physician's method is reliable, the method should be sufficient under Accutane and this Court's narrow acceptance of certain portions of Daubert. See Accutane, 234 N.J. at 399 ("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.")

As more fully explained in the Petition, "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." Creanga v. Jardal, 185 N.J. 345, 361 (2005). This Court explained, "[a] differential diagnosis does not prove one hypothesis, but rather, it allows the expert to use the facts at hand

to disprove all other hypotheses." Id. Allergan erroneously argues that the expert must definitively rule out all other theories, but this Court had explained that the method is not an exact science, and inconsistencies may remain without requiring the complete bar of the expert's opinion. Id. at 363. In fact, in Creanga, the Court explained the inconsistencies went to the expert opinion's weight not admission. Id. at 362-63. Here, because both experts explained the basis for ruling in the silicone particulate as the cause of blindness after ruling out the other possible causes, Allergan's remaining qualms go to weight not admissibility. See id.

In stating "temporal association at most can establish *correlation*, not causation, and thus cannot serve as a sufficient basis for a reliable opinion," (Cb3), the Chamber entirely overlooks this Court's analysis and holding in Creanga. This Court explained "'[w]hen a patient develops symptoms after encountering an agent which is known to be capable of causing those symptoms' a court is more likely to admit the testimony." Id. at 359 (alteration in original) (quoting Carlson v. Okerstrom, 675 N.W.2d 89, 106 (Neb. 2004)). Here, Dr. Phillips and Dr. Lalezary both were persuaded by the fact that Allergan's documents demonstrate that the silicone particulate causes increased ocular inflammation and that within a week of administration of a batch from the affected lot, Ms. Beavan developed increased ocular inflammation that she had not experienced during her nine prior administrations of the drug.

The temporal element is an important part of Ms. Beavan's experts' conclusions, and it was error for the Appellate Division to find the differential diagnosis method was unreliable when this Court cited its use with approval in a nearly identical causation setting in Creanga. There, the treating physician was aware that trauma causes premature labor, and he concluded that because the woman went into labor a couple days after a motor vehicle accident, that the trauma of the accident must have caused her to go into premature labor. Id. at 362. Likewise, Ms. Beavan's treater knew that a defective batch of Ozurdex containing a silicone particulate could cause increased inflammation; and he was aware within a week of administration that she had increased inflammation that she had never had with nine prior administrations of Ozurdex and which was not responding to treatment. (Pa135.) Thus, he concluded that Ms. Beavan's injury must have been caused by a defective batch.

The Chamber concedes that the experts provided a basis for ruling out other potential causes: "that Plaintiff had been exposed to them before and had not suffered this injury." (Cb20 (citing Da187.) The Chamber even emphasizes the strength of Dr. Lalezary's analysis by noting "Dr. Lalezary agreed that each time Plaintiff received an Ozurdex injection, it constituted an 'independent risk factor' for developing retinal detachment." (Cb21 (citing Da175).) Thus, the Chamber points out the reason why the temporal element is so important in this case. However,

despite these concessions, the Chamber argues without any explanation why the temporal association is "not a sound method." (Cb21.) Given this Court has held it is a sound method in Creanga, and even the Chambers' argument demonstrates Dr. Lalezary explained why this injection is more likely than the other more remote in time causes, there is no basis to overrule Creanga.

Allergan and the *amici* supporting it argue that Ms. Beavan's experts should have been barred because they did not provide testing as to whether a silicone particulate could cause the injury. (See e.g., Ab3-4.) But the Third Circuit has explained, an expert may use the differential diagnosis in place of such testing because "most of the Daubert factors—testability, general acceptance, peer review, and degree of production of errors ... are of only limited help in assessing whether the methodologies . . . are reliable." In re Paoli R.R. Yard PCB Lit., 35 F.3d 717, 758 (3d Cir.1994). The Third Circuit explained that the expert need not rule out all alternative causes, but the expert must offer a reasonable explanation why an alternative cause offered by the adversary is unlikely. Id. at 759-60. Here, Ms. Beavan's experts fulfilled that requirement. (See e.g., Pa15-21; Pa124-26; Pa134-39; Da183; Da256-57; Da695-700.)

Moreover, the Advisory Council argues there is a distinction between a differential diagnosis and a differential etiology (ACb9-11), but such a distinction does not change this Court's precedent in Creanga, 185 N.J. at 357, where it held

that a physician may utilize a differential diagnosis to provide an opinion as to causation as long as the physician's method is reliable. This is exactly what both Dr. Phillips and Dr. Lalezary did as explained above, and this Court should reverse the Appellate Division's finding the method was unreliable.

In Accutane, the reason the expert's opinions were not reliable were because they ignored epidemiological studies. Accutane, 234 N.J. 340, 392 (2018). But neither Dr. Lalezary nor Dr. Phillips overlooked studies – instead, they relied upon Allergan's proofs regarding the harm that injecting the silicone particulate could cause, and then they applied Ms. Beavan's medical history and symptoms to determining that the dose must have been defective.

The Appellate Division erred in concluding Dr. Lalezary and Dr. Phillips' opinions were net opinions because each expert relied upon their knowledge, training and experience and utilized a reliable methodology. See State v. Townsend, 186 N.J. 473, 494 (2006). Allergan asked the Appellate Division to reverse based upon an application of the Daubert factors arguing that neither Dr. Phillips nor Dr. Lalezary "tested the theories that a 300-micron particulate of the medical-grade silicone used in the Ozurdex® needle sleeve (a) is capable of causing eye inflammation," (Db39), but Ms. Beavan's experts did not need those tests when Allergan conceded the silicone particulate was capable of causing eye inflammation.

Daubert, 509 U.S. at 593. Nor has Allergan cited or done such studies, nor could such studies be done on humans.

While Allergan advocates for a form of perfect causation (Db33-34), this Court has previously explained that an expert's opinion may still be admitted as reliable even without general consensus in the scientific community. Rubanick v. Witco Chem. Corp., 125 N.J. 421, 434 (1991). The Chamber argues Rubanick shows a more restrictive approach to admission of expert testimony, but this Court's stated goal was to increase admission of expert testimony rather than limit it. (Cf. Daubert, 509 U.S. at 597 with Cb5.) The Court recognized that "plaintiffs in toxic-tort litigation, despite strong and indeed compelling indicators that they have been tortiously harmed by toxic exposure, may never recover if required to await general acceptance by the scientific community of a reasonable, but as yet not certain, theory of causation." Rubanick, 125 N.J. at 434. This Court cited with approval the Appellate Division quoting "[t]he question here is not the acceptance of the 'general acceptance' standard but whether there are sufficient factual and scientific underpinnings to the expert's causation theory . . .." Ibid. (quoting 242 N.J. Super. 36, 44 (App. Div. 1990).

This Court cited with approval a decision from the District of Columbia Circuit Court where Judge Mikva explained,

> In a courtroom, the test for allowing a plaintiff to recover in a tort suit of this type is not scientific

> certainty but legal sufficiency; if reasonable jurors could conclude from the expert testimony that paraquat more likely than not caused Ferebee's injury, the fact that another jury might reach the opposite conclusion or that science would require more evidence before conclusively considering the causation question resolved is irrelevant.

Id. at 439 (quoting Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1536 (D.C. Cir. 1984)).

> This Court further explained that prior to barring an expert's opinion for being unreliable, the party should be offered a hearing where the trial court will conduct a preliminary inquiry focusing on (1) the soundness and reliability of the process or technique used in generating the evidence, (2) the possibility that admitting the evidence [will] overwhelm, confuse, or mislead the jury, and (3) the proffered connection between the scientific research or test result to be presented, and particular disputed factual issues in the case.

Id. at 446 (quoting United States v. Downing, 753 F.2d 1224, 1237 (3d Cir. 1985) (footnote omitted)). Here, as argued by the New Jersey Association for Justice, the Appellate Division erred in finding the experts' opinions were unreliable when their opinions were consistent, relied upon the process used by ophthalmologists, and the trial court had found the opinions admissible without the need for a hearing. Since the Appellate Division reversed without hearing, the decision cannot stand since even if one could arguendo claim that more explanation was needed, Ms. Beavan

was deprived the opportunity to develop a more extensive record as to the reliability of both of her experts' methodologies.[3]

For instance, this Court cited with approval a Third Circuit decision where the critical issue was whether the opinions were "of a type reasonably relied upon by experts in the particular field." Rubanick, 125 N.J. at 446 (quoting re Paoli R.R. Yard PCB Lit., 916 F.2d 829, 854 n.29 (3d Cir.1990) (quoting F.R.E. 703)). This Court in Rubanick emphasized that whether a method of reaching a conclusion is reliable depends on the expert's own field for admissibility:

> A scientific theory of causation that has not yet reached general acceptance may be found to be sufficiently reliable if it is based on a sound, adequately founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field. The evidence of such scientific knowledge must be proffered by an expert who is sufficiently qualified by education, knowledge, training, and experience in the specific field of science. The expert must possess a demonstrated professional capability to assess the scientific significance of the underlying data and information, to apply the scientific methodology, and to explain the bases for the opinion reached.

[3] Allergan argues this position was waived because a hearing was not requested of the trial court, but the trial court had found no hearing was required because the experts' methods were reliable; thus, there was no basis or reason to request a hearing. It was only after the Appellate Division threw out Ms. Beavan's claims that the issue became relevant.

Id. at 449. Thus, Allergan's position is not supported by this Court's precedent. Dr. Lalezary and Dr. Phillips both relied upon Allergan's own materials as to the consequences of administering a defective batch – increased ocular inflammation. (Da256-57.) Based upon that information, both doctors separately used their knowledge, training, and experience to conclude Ms. Beavan's blindness was caused by a defective batch of Ozurdex. Thus, the issues that Allergan cites go to weight, not admission. See Creanga, 185 N.J. at 362.

Moreover, this Court has further warned that a court should not substitute its determination for that of an expert: "The critical determination is whether comparable experts accept the soundness of the methodology, including the reasonableness of relying on this type of underlying data and information. Great difficulties can arise when judges, assuming the role of scientist, attempt to assess the validity of a complex scientific methodology." Rubanick, 125 N.J. at 451. But this is exactly what the Appellate Division did – it found both of Ms. Beavan's experts used an unreliable methodology when even Dr. Elliot used the same methodology, but he just came to a different conclusion. Our courts should not bar experts based upon an appellate judge's determination of medicine – only a jury should be able to weigh the different expert's opinions when all of the experts employ the same methodology to come to their conclusions on causation.

Allergan argues that Dr. Phillips and Dr. Lalezary's opinions are at odds (as to whether the silicone particulate caused the detached retina that Ab38), but this Court explained any inconsistencies go to weight not admissibility. Creanga, 185 N.J. at 362.

a. Ms. Beavan Established General Causation.

Under the PLA, the claimant makes out a violation when the product causing harm deviated from "design specifications . . . or the performance standards of the manufacturer." N.J.S.A. 2A:58C-2. As the trial court noted, a plaintiff only needs to show the manufacturing defect was a substantial factor in causing an injury. (Da828.) In the case at bar, the trial court noted general causation was established because Ms. Beavan provided evidence from Allergan's "own expert that the disbursement of a silicone particulate would deviate from Allergan's own performance standards for the product, and that the Ozurdex applicator was not designed to dispense a silicone particulate with the Ozurdex steroid medication." (Da583-84 at 39:14 to 40:1; Da825.) The trial court further noted Allergan's recall notice contained the warning of intraocular inflammation and corneal reaction that sufficiently supports a finding of general causation. (See Da828.)

The Legislature under the PLA created liability when a "claimant proves that the product causing harm deviated from the **design specifications . . . or the performance standards of the manufacturer.**" (Da825 (quoting N.J.S.A. 2A:58C-2 (emphasis in original).) This Court has held that a plaintiff can demonstrate a

manufacturing defect under the PLA "through circumstantial evidence . . . which would permit an inference that a dangerous condition existed prior to sale." Scanlon v. Gen. Motors Corp., Chevrolet Motor Div., 65 N.J. 582, 592-93 (1974).

The proof is limited to "'something was wrong' with the product." Id. at 591. Allergan and the *amici* supporting it seek to create a new standard of direct evidence of a product defect, but this Court has stated "direct evidence of a product defect is not required under the PLA to show a product defect existed." Scanlon, 65 N.J. at 592-93. This Court has held that "whenever the facts permit an inference that the harmful event ensured form some defect (whether identifiable or not) in the product, the issue of liability is for the jury." Sabloff v. Yamaha Motor Co., Ltd., 59 N.J. 365, 366 (1971).

The Model Civil Jury Charge confirms that circumstantial evidence is sufficient to prove a manufacturing defect. Model Jury Charges (Civil), 5.40B, "Manufacturing Defect" (rev. Aug. 2011). Not only may circumstantial evidence be sufficient, but the Model Charge discusses that a plaintiff can show a defect existed when there is no other cause for the accident except a manufacturing defect. Myrlak v. Port Auth. Of New York and New Jersey, 157 N.J. 84 (1999).

The evidence was sufficient to demonstrate a manufacturing defect because Allergan's own corporate representative, Tracy Founds, testified that any Ozurdex applicator that dispenses a silicone particulate deviates from

Allergan's own performance standards. (Pa108-09.) Because of this deviation, Allergan immediately stopped its production of Ozurdex. (Da583-84; Pa108-09.) Similarly, Allergan's witness, Rory Turk, testified that the Ozurdex applicator was not designed to release a silicone particulate. (Da720-21 at 16:25 to 17:6.)

Allergan further admitted that a silicone particulate was being dispensed by some Ozurdex applicators and that a number already distributed contained the silicone particulate. (Da649.) Two months before Ms. Beavan's injection, Allergan disclosed to the FDA that the cause of the silicone particulate found to be a defect occurred "as part of the manufacturing assembly process." (Da646.) One month before Ms. Beavan's injection, Allergan conducted a root cause analysis identifying the cause of the silicone particulate defect as created during the manufacturing assembly process. (Da237.) Allergan admitted twice in its December 28, 2018 "Urgent Drug Recall" notice that the silicone particulate was a "**defect**." (Da256-57 (emphasis added).)

Given these proofs, the Chambers' argument that "the experts did nothing more than point to the fact of the recall," is simply a misrepresentation of the record before the trial court. (Cb19.) Likewise, the Business *amici*'s argument that the only basis for finding a manufacturing defect was the corporate representative's response to a hypothetical overlooks the proofs that were before the trial court to demonstrate

Allergan admitted a manufacturing defect. (Cf. Da583-84 at 39:14 to 40:1 and Da720-21 at 16:25 to 17:6 with Bb3.)

Moreover, Allergan and the Chambers' public policy concern that jurors will speculate or that using recall documents will "chill free and frank discussion by manufacturers," 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. (Ab12; Cb20.)

Furthermore, the case upon which Allergan and the Chamber relies is distinguishable from the facts before this Court. (Ab11-12 & Cb190-20 (both citing In re Mirena IUD Prods. Liab. Litig., 202 F. Supp. 3d 304, 320 (S.D.N.Y. 2016), aff'd, 713 F. App'x 11 (2d Cir. 2017), cert. den., 583 U.S. 1182 (2018)). In the Mirena case, the plaintiff attempted to use warnings from the product label *for a different IUD device* regarding Mirena's risk of perforation of the uterus to support the product liability case because the manufacturer did not object to the FDA's recommendation to use the same warnings. Id. at 321 (emphasis added). The district court explained the statement could not be deemed an admission as to secondary perforation. Id. The district court further explained that an unambiguous statement in the label could be used as an admission, but the statements in the Mirena label did "not clearly admit the existence of secondary perforation." Id. at 322. Importantly, the district court noted an unambiguous statement could be offered as an admission

against the manufacturer. Id. at 320. Thus, the statements at issue in Mirena are vastly different from the multiple admissions that Allergan made in this case. (Cf. id. with Da237-38, Da256-57, Da649-50, Da583-84, and Pa108-09.)

b. Ms. Beavan Established Specific Causation.

The trial court found that Ms. Beavan's two experts had relied upon a reliable methodology of the differential diagnosis to opine that a defective product caused Ms. Beavan's blindness. However, the Appellate Division erred in failing to apply the abuse of discretion standard of review in reversing and dismissing Ms. Beavan's case. The Appellate Division's error misinterpreted how a physician can use a differential diagnosis to support an opinion on specific causation. Ms. Beavan urges this Court to provide guidance to lower courts regarding the reliability of a differential diagnosis. Unlike what Allergan and the *amici* supporting it argue, a differential diagnosis does not need to rule out every other cause. As this Court explained in Creanga, an expert's opinion is not excluded merely "because it fails to account for some particular condition or fact which the adversary considers relevant." Creanga, 185 N.J. at 360 (quoting State v. Freeman, 223 N.J. Super. 92, 116 (App. Div. 1988)). The Advisory Council's statement that Ms. Beavan's experts failed to "rule out" other possible causes is not accurate; these physicians did rule out other causes as set forth above. (Cf. Pa15-21; Pa124-26; Pa134-39; Da183;

Da256-57; Da695-700 with ACb12.) The *amicus*' mere disagreement with the experts' analysis goes to weight and not admissibility. See Creanga, 185 N.J. at 363.

As the Appellate Division has explained an expert's failure "to give weight to a factor thought important by an adverse party does not reduce his testimony to an inadmissible net opinion if he otherwise offers sufficient reasons which logically support his opinion." Rosenberg v. Tovarath, 352 N.J. Super. 385, 402 (App. Div. 2002) (citing Freeman, 223 N.J. Super. at 115-16). The expert's omission or failure goes to weight not admissibility. Rubanick v. Witco Chem. Corp., 242 N.J. Super. 36, 55 (App. Div. 1990), mod. on other grounds, 125 N.J. 421 (1991).

The trial court further found that Ms. Beavan demonstrated specific causation. (Da825.) The trial court cited Dr. Lalezary's deposition testimony that "the silicone particulate proximately caused Plaintiff's injuries by causing inflammation and traction that induced a retinal detachment in Plaintiff's eye." (Da826, Da695-96.) The trial court also found Dr. Phillips' opinion was sufficient because he "opined that the alleged silicone particulate created persistent inflammation in Plaintiff's eye that proximately caused her injuries." (Da826.)

The trial court found sufficient basis for the opinion that "a microscopic particulate of silicone *could have* caused a retinal detachment in a human eye." (Da828.) The trial court found that "[d]efendant's own recall contained those very same warnings of intraocular inflammatory reaction and corneal reaction as potential

safety risks." (Da828.) Allergan was aware of these potential injuries more than three months before Ms. Beavan's fateful injection and five months before Allergan issued its Urgent Drug Recall. Allergan's July 18, 2018-Patient Impact Assessment internal report established these safety risks. (Da246, Da249.) Additional 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. (Da229, Da237; Da256-257.) And Allergan's own testing and internal conclusions were reached on microscopic foreign body silicone particulates.

The Business *amici* misconstrue the findings of Dr. Phillips, Ms. Beavan's treating physician, who administered the defective Ozurdex. The Business *amici* argue Ms. Beavan "experienced known risks that could have occurred *without* any product issue or recall." (Bb8-9). However, Dr. Phillips explained there was increased inflammation that he had not observed after prior administration of the drug and the inflammation did not respond to treatment. (Pa135.) And of course, those prior batches were not bad batches with the added increased risk of inflammation that posed.

The Chamber argues that this Court should adopt the federal rule for admissibility of expert testimony. (Cb13.) Specifically, the Chamber argues that the expert's opinion may only be admitted when the specific application of the

expert's methodology is reliable. (Id.) But here, the two experts' methodology of differential diagnosis has been recognized by this Court to be reliable.

Although this Court has stated Daubert factors can sometimes be relevant, applying them to the experts' testimony in this case was error where the experts relied upon Allergan's own admissions as to what happens when a defective applicator is used. (Da256-57.) Allergan's own reports showed increased ocular inflammation from a defective batch with a microscopic piece of silicone. Thus, it was error for the Appellate Division to exclude these experts who used Allergan's admission as one of the premises to conclude the applicator was defective.

III. Plaintiff's Experts Provided a Sufficient Prima Facie Claim for a Failure-to-Warn of a Product Defect Claim. (Psa167-76.)

Allergan had a duty to warn of the increased risk of harm from the silicone particulate. The PLA sets forth an exception to liability only if "in the case of dangers a manufacturer . . . discovers. . . after the product leaves its control, if the manufacturer . . . provides an adequate warning or instruction." N.J.S.A. 2A:58C-4. But here, Allergan never warned Dr. Phillips or Ms. Beavan. (Pa129-30 at 16:22 to 17:12.)

As explained in the Petition, "[w]hen 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 v. Keene Corp., 133 N.J.

581, 594 (1993) (citing Campos v. Firestone Tire & Rubber Co., 98 N.J. 198 (1984)). This Court permitted the use of a heeding presumption to increase an injured party's ability to recover due to the difficult nature in proving the failure to warn was a substantial factor in the harm caused by the exposure to the product. Id. at 600 (citation omitted). Similar to the informed consent doctrine, the manufacturer has a duty to warn of the risk from exposure to its product so that consumers may make a choice. See 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.) A defective batch of Ozurdex was a substantial factor in causing the injury because Allergan admitted increased inflammation could occur, and the increased risk factors were the actual cause of Ms. Beavan's injury.

Thus, the two-judge appellate panel here ignored two different reasons that established a prima facie case for a jury finding of causation due to Allergan's failure to supply a necessary warning of an increased risk in its product:

1. This court's prior support for a legal heeding presumption that an adequate warning would be followed, and

2. Here beyond the presumption, Dr. Philips' direct testimony was that he would not have injected Ozurdex from a known bad batch into this patient's eye in an operation which then indisputably led to this patient's blindness if he had been given the necessary warning,

The appellate panel's requirement for perfect proof of causation, limiting recovery to only those patients whose doctors can find and produce a silicone piece found at surgery, ignored both that legal and evidential support for jury resolution of causation. Of course, as explained further below the appellate panel's perfect proof requirement for causation also ignored another indisputably valid inference a jury could apply: Allergan's failure to alert doctors of known bad batches of its product prevented Dr. Phillips from any recognition that there was a need to search within his patient's eye for a piece of plastic.

Common sense applied to the common law confirms the critical sequence in which a jury's finding of causation occurs: a jury only reaches causation after they have found that a defendant was legally at fault for either supplying a product with a known increased risk of harm due to a manufacturing error and failing to warn about increased risk of harm or some other failure supporting liability.

Moreover, unlike this appellate panel, wherever a manufacturer or physician may be properly found to have failed to give a necessary warning or failed to perform a required diagnostic test, and that failure itself makes proof of causation more difficult, New Jersey has reduced the burden of proof for New Jersey residents injured as a result. See Coffman v. Keene Corp., 133 N.J. 581, 597 (1993)(explaining heeding presumption is grounded in public policy); see also Gardner v. Pawliw, 150 N.J. 359, 379-80 (1997) (holding where the defendant doctor's failure to use an imaging test the standard of care required increased the risk of harm but also made precise proof of causation more difficult, Plaintiffs would have the benefit of a presumption similar to the heeding presumption). This court explained, "[w]e reach that conclusion to avoid the unacceptable result that would accrue if trial courts in such circumstances invariably denied plaintiffs the right to reach the jury, ***thereby permitting defendants to benefit from the negligent failure to test and the evidentiary uncertainties that the failure to test created.***" Gardner, 150 N.J. at 387 (emphasis added)(citing Scafidi v. Seiler, 119 N.J. 93, 108 (1990) and Evers v. Dollinger, 95 N.J. 399, 417 (1984)); see also Sara M. Peters, Shifting The Burden Of Proof On Causation: The One Who Creates Uncertainty Should Bear Its Burden, 13 J. Tort L. 237 (October, 2020 Symposium, "What Practitioners Can Teach Academics about Tort Litigation") (citing RESTATEMENT (SECOND) OF TORTS § 433B cmt. f (AM. LAW INST.

1965) ("the injustice of permitting proved wrongdoers ... to escape liability because the nature of their conduct and the resulting harm has made it difficult or impossible to prove which of them has caused the harm")).

Applying similar fairness policy rationales our courts have already concluded that when wrongful conduct creates difficulties in proving causation, the wrongdoer not the wronged party must bear the resulting uncertainty they created. Neither Dr. Phillips nor his patient received what they were entitled to: an accurate warning from a party who knew of a "new" increased risk of being blinded from receiving one of the Ozurdex implants which defendants concede was from one of their bad batches which actually did contain silicone foreign bodies admittedly present in at least 2.2 % of the implants. However, instead, this appellate panel rewarded the manufacturer for their failure to warn, and thus, mismanaged the uncertainty created by Allergan's failure to warn United States doctors by getting lost in a desire for mathematical certainty: "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." (Psa174.)

The appellate panel's reliance on the absence of definitive evidence that the implant injected into this patient's eye was one of the implants from known defective batches which actually did contain a silicone foreign body fails when

subjected to another rationale in medicine which is also part of differential diagnosis: "absence of evidence is not evidence of absence," also known as *argumentum ad ignorantiam*). It was Allergan's failure to warn that created the absence of evidence here in two ways:

1. First, Allergan's failure to warn was the only reason Dr. Phillips would have ever injected this implant into this patient's eye (Pa129-31), and
2. To add insult to injury, Allergan's failure to belatedly warn Dr. Phillips and other doctors of the likelihood that this implant was from a bad batch deprived him and his patient of the knowledge that he should be probing for a foreign body during his first surgery.

The appellate panel overlooked the fact that failure to warn of small percent chance of a danger is enough to constitute a substantial factor for jury resolution under New Jersey law. See Velazquez v. Jiminez, 336 N.J. Super. 10 (App. Div. 2000), aff'd, 172 N.J. 240 (2002) (upholding 3% to be a basis for a jury finding of 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).

The late Judge Charles Walsh well stated the reason why strict liability favors presumptions such as the heeding presumption even where drug manufacturers and *amici* argue they should not apply to prescription drugs:

> The public policy goals articulated included: focusing on the underlying purpose of product liability law which concentrates on a product rather than a defendant's negligence; encouraging "manufacturers to produce safer products, and to alert users of the hazards arising from the use of those products through effective warnings"; simplifying the trial process and plaintiffs burden of proof and minimizing the likelihood that causation decisions will be based on unreliable evidence.

In re Diet Drug Litig., 384 N.J. Super. 525, 532 (Law. Div. 2005) (citing Coffman, 133 N.J. at 599).

This case includes specific evidence that at least 2.2% of Allergan's Ozurdex inserts in the bad batch that was supplied to Dr. Phillips posed an increased risk and direct testimony from Dr. Phillips that had he been advised of that risk Dr. Phillips would not have injected this product into his patient's eye. A 2.2% defect rate meant that at least one out of every forty-five patients would be injected with a silicone particulate. No reasonable physician or patient would ever knowingly take such a risk, especially not with a sensitive and vulnerable patient like Ms. Beavan.

So, although such confirmation was not present in that case, Canesi v. Wilson, 158 N.J. 490 (1999) is yet another example of how this appellate panel ignored prior controlling New Jersey Supreme Court precedent on the proof necessary for causation. Canesi was a claim by parents that their doctors' failure to warn them that the use of Provera during the first four months of pregnancy

was dangerous and could cause limb defects on children born thereafter. While it turned out that the suspected nexus between Provera and limb deficiencies was later not proven, the plaintiff's wrongful birth claim was premised on the fact its use during the first four months of pregnancy at the time was believed to increase the risk of limb defects. Therefore, the plaintiff-parents alleged that their doctor's failure to disclose that risk and to take additional steps to monitor for limb defects prevented them learning that their child to be did have severe limb defects and electing as was their right to terminate the pregnancy.

The majority opinion in Canesi ruled that although Provera could not be proven to have caused the afterborn child's limb defects, upon proof that the parents would have terminated with a proper warning, a jury could still properly find that under those facts the doctor's failure was a substantial factor in depriving the patients of informed consent which would have led to termination of the pregnancy. Thus, New Jersey Supreme Court precedent has already recognized that in the right circumstances, where a proper, necessary warning would have eliminated the injury causing event is not given, but for causation alone can be enough to require jury resolution of proximate causation.

As explained above, Ms. Beavan demonstrated a basis for both general and specific causation through her two experts. The Appellate Division abused its discretion in reversing the trial court's finding that these experts' method of

using a differential diagnosis to establish causation was reliable. Because of this abuse of discretion, this Court should reverse the decision of the Appellate Division and reinstate Ms. Beavan's claims against Allergan.

CONCLUSION

The Appellate Division erred in reversing the trial court's finding that Ms. Beavan's two experts could testify. Even if there was any doubt as to the reliability in Ms. Beavan's experts' use of the differential diagnosis method – which there was not – then the remedy should have been to remand for a hearing to provide the reliability of the experts' method. There was simply no basis to summarily bar both experts who relied upon their knowledge training and experience and used a method that ophthalmologists use in the field – the medical history and symptoms of their patients plus the reports provided by the drug manufacturer regarding the injury that a defective product could cause. Because the Appellate Division substituted its judgment for that of the trial court, this Court should reverse and reinstate Ms. Beavan's claims.

Respectfully submitted,

By:_____
DENNIS DONNELLY

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