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ALISON BEAVAN, Plaintiff-Petitioner, v. ALLERGAN U.S.A., INC., Defendant-Respondent, and ALLERGAN, INC., f/k/a INAMED CORPORATION, ALLERGAN PLC, and ABBVIE INC., Defendants.	SUPREME COURT OF NEW JERSEY DOCKET NO. 090150 CIVIL ACTION On Petition for Certification from the Superior Court of New Jersey, Appellate Division DOCKET NO. BELOW: A-1501-23, MRS-L-151-21 Sat Below: Hon. Hany Mawla, P.J.A.D., Hon. Robert M. Vinci, J.A.D., and Hon. Louis S. Sceusi, J.S.C.

PROPOSED *AMICUS CURIAE* NEW JERSEY ASSOCIATION FOR JUSTICE'S PROPOSED MERITS BRIEF

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PRELIMINARY STATEMENT

Proposed Amicus Curiae, the New Jersey Association for Justice ("NJAJ"), seeks leave to file this merits brief and to participate in oral argument. A drug manufacturer owes a duty to prevent the release of a defective product into the stream of commerce. Here, the manufacturer knew that at least 2.2% of its lot was defective, but never notified Plaintiff nor her physician, who testified he would have never used the product had he known the batch was defective, which thus, provided admissible proof of "but for" causation.

NJAJ is concerned with the Appellate Division's resolution because it impacts the ability of the injured to prove causation given the Appellate Division did not permit these physicians to use a differential diagnosis to prove causation. The Appellate Division further overlooked this Court's accepted standards of proof of a defect in a failure-to-warn strict liability case.

Having granted certification, NJAJ offers its expertise in representing the injured in products liability cases as a friend of the Court. NJAJ respectfully submits this brief in support of its request to appear as *amicus curiae* and to appear at oral argument. If NJAJ's motion is granted, please accept this brief as NJAJ's brief on the merits. NJAJ urges this Court to reaffirm its prior precedent that the Appellate Division ignored and permit a plaintiff to prove causation through reliance on party admissions and a doctor's differential diagnosis.

STATEMENT OF INTEREST

NJAJ is a voluntary state trial lawyer association whose members primarily represent individual plaintiffs in personal injury cases and other civil actions. (Harvey Cert. ¶ 3.) Throughout its history, NJAJ has advocated to preserve fundamental protections, and to ensure that tort law is responsive to injured persons and provides effective legal recourse and remedies. (Harvey Cert. ¶ 6.) In the past, NJAJ has participated as *amicus curiae* in precedential cases, including, but not limited to, Morales-Hurtado v. Reinoso, 241 N.J. 590, 593 (2020); In re Accutane Litigation, 234 N.J. 340, 393 (2018); McCarrell v. Hoffman-LaRoche, Inc., 227 N.J. 569 (2017). (Harvey Cert. ¶ 7.)

This appeal will have a significant effect on NJAJ's members, clients, and the general public. Given the strong interest from drug manufacturers and their affiliated advocacy groups, NJAJ's participation on behalf of attorneys representing consumers and victims will not prejudice any litigant. For the reasons set forth in the attached certification of counsel, NJAJ respectfully submits that its participation will benefit the Court.

COMBINED STATEMENT OF FACTS AND PROCEDURAL HISTORY[1]

NJAJ accepts the Appellate Division's recitation of the facts and procedural history and summarizes the following relevant to NJAJ's concerns

[1] Due to the intertwined nature of the facts and procedural history relevant to the issue before this Court, the sections have been combined.

with the Appellate Division's decision. Plaintiff-Petitioner Alison Beavan went blind in her left eye because Defendant Allergan failed to warn her doctor that Allergan's drug, Ozurdex, may contain a foreign silicone particulate that could lead to ocular inflammation and visual disturbances. (Pa129-30.[2])

Ozurdex is a prescription drug used to treat various eye diseases, including non-infectious uveitis. (Psa143.) The drug is a dexamethasone implant injected into the vitreous of the eye with a preloaded single-use applicator. (Id.) On June 21, 2018, Allergan became aware that a silicone particulate "was observed in dispensed Ozurdex implants." (Psa144.) In mid-September 2018, Allergan began to recall affected lots in foreign countries. (Id.) Allergan knew that 2.2% of the units in Lot #E82852 were defective but distributed them anyway. (Id.)

Unfortunately, unbeknownst to Beavan or her provider, Dr. Phillips injected from a bad batch of Ozurdex, Lot #E82852, into Beavan's left eye on November 6, 2018. (Psa143.) Within a week, Beavan returned with new complaints of severe left eye blurred vision, decreased vision, and a blind spot. (Psa143.) Dr. Phillips diagnosed Beavan with retinal detachment, and the next

[2] "Da" refers to Defendant Allergan USA, Inc.'s appendix in support of appeal filed with the Appellate Division; "Ab" refers to Allergan USA, Inc.'s Brief in opposition to Petition for Certification; "Pa" refers to Plaintiff's appendix filed with the Appellate Division; "Psa" refers to Plaintiff-Petitioner Allison Beavan's appendix filed with this Court; "Hb" refers to the brief of *amicus curiae* HealthCare Institute of New Jersey and New Jersey Business & Industry Association.

day he performed a pars plana vitrectomy on the affected eye. (Id.) When he performed the procedure, Dr. Phillips observed the increased inflammation. (Da82-83.) He then referred Beavan to Dr. Jonathan D. Solomon, who diagnosed her with corneal degeneration secondary to a contaminated pellet injection. (Psa143.)

Only after Beavan's injection, did Allergan notify American physicians of the recall. (Da216-17.) Allergan's December 2018 recall warned of the exact risk that occurred – increased corneal inflammation and ocular disturbances. (Da256-57, Da818.) Dr. Phillips stated he would not have administered the Ozurdex if he knew of the recall. (Pa130-31 at 17:24-18:9.) Plaintiff's vision went from 20/100 before the final Ozurdex injection to being completely blind by February 1, 2019. (Psa145.)

The trial court noted Allergen's urgent drug recall notice from December 28, 2018 warned that "Mild transient visual disturbance or intraocular inflammatory reaction in sensitive patients are potential safety risks[, and] [t]here is also a remote possibility of corneal reaction if the [silicone] particulate migrates to the anterior chamber." (Da818.) The trial court also noted that following Plaintiff's November 6, 2018-injection from the recalled Ozurdex lot, "Plaintiff developed a complication and subsequently experienced retinal detachment, loss of vision, and corneal damage." (Da818.)

Dr. Phillips and Dr. Lalezary opined that the Ozurdex administered to Plaintiff was defective with the silicone particulate and likely caused the retinal detachment within a week of the injection. (Da819.) These experts both opined that, consistent with the December 28, 2018 recall warning, the silicone particulate caused persistent inflammation and corneal edema in Plaintiff's left eye. (Da819.) Dr. Lazelary also opined that "the silicone particulate caused a physical 'mechanical' traction on the retina leading to detachment." (Da819.) Applying the differential diagnosis methodology, due to the proximity in time, he concluded the Ozurdex was defective and caused the injury, explaining:

> 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. Lalezary explained that the other causes were temporally remote so it is more likely the defect in the Ozurdex led to the increased inflammation: "on November 6, 2018, with the injection of the Ozurdex, the silicone particulate was injected in Ms. Beavan's eye that caused the retinal detachment, which required, then, the surgery." (Da699-700.) He added that the surgery "resulted in the migration of the Ozurdex steroid pellet into her eye as well as the RETISERT detachment," which "ultimately led to her blindness in the left eye." (Id.)

Dr. Lazelary provided support for his conclusion that the Ozurdex was defective because 1) if the Ozurdex was defective, it could cause ocular inflammation; 2) Plaintiff had ocular inflammation; 3) Plaintiff previously had multiple doses of Ozurdex without issue, and 4) her injury occurred within a week of the injection. (Pa15-21; Da697-98.) Dr. Lazelary further explained why the theory of defense expert, Dr. Eliott, that the Retisert implant from nine years earlier caused Plaintiff's retinal detachment mechanical traction 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; see Da368-69; Da357.)

Likewise, Dr. Phillips provided support for his opinion that the Ozurdex was defective because Allergan admitted that if Ozurdex had a silicone particulate, it could cause persistent inflammation, and Plaintiff had increased inflammation within a week of the injection that she had never experienced with her multiple prior Ozurdex injections. (Pa127; Pa134-Pa139; Da256-57; Pa127.) Dr. Phillips noted that the "amount of inflammation" demonstrated that a silicone particulate was present. (Da766 at 71:1-11; Da81-83 at 58:19-60:8) Dr.

Phillips explained the silicone particulate must have been present with this injection because "she had already had multiple injections before . . . and just never had this much inflammation, despite the fact that she does have uveitis. So something was just different this time to cause that much inflammation." (Id.)

The trial court correctly found that a plaintiff does not need to present direct, objective evidence of silicone particulate when circumstantial evidence sufficiently demonstrates the defect, as exists here. (Da827) (citing Scanlon v. Gen. Motors Corp., Chevrolet Motor Div., 65 N.J. 582, 592-93 (1974)). Instead, the trial court found "the lack of 'objective evidence' goes to the weight of Plaintiff's expert's testimony, not its admissibility." (Da827.)

Allergan faults Plaintiff for not providing proof of general causation that "a 300-micron particulate of medical-grade silicone is capable of causing the injuries Plaintiff alleges," but Allergan itself provided this proof in its December 2018 recall. (Ab3.) Allergan attempts to argue that its recall letter "stated only that inflammation is a 'potential' risk in 'sensitive patients,' which refers to patients with sensitivity to silicone." (Ab11 (emphasis in original).) But the recall notice states: ". . . intraocular inflammatory reaction in sensitive patients are potential safety risks. There is also a remote possibility of corneal reaction if the particular migrates to the anterior chamber."

The trial court found both Dr. Phillips and Dr. Lazelary could provide opinions that Ozurdex was defective, and thus, denied Allergan summary judgment. (Da828-89.) Following an unsuccessful motion for reconsideration, Allergan sought and was granted leave to appeal. (Psa134.) The Appellate Division then reversed and dismissed Plaintiff's case finding both Dr. Phillips and Dr. Lazelary's methodologies to prove that the Ozurdex was defective were unreliable. (Psa174-76.) But in so holding the Appellate Division overlooked this Court's analysis of when the differential diagnosis is a reliable methodology. Plaintiff then filed a Petition for Certification, which was granted. NJAJ seeks leave to appear as *amicus curiae* and to present oral argument.

LEGAL ARGUMENT

This Court Should Reverse the Appellate Division's Decision Because Plaintiff Made a Prima Facie Case of a Product Defect. (Psa169-74).

As an organization that represents victims of defective products, NJAJ is concerned that the Appellate Division's decision created an incorrect additional burden for injured parties to make out a prima facie case that the product is defective in strict liability cases. First, NJAJ asks this Court to review the type of defect that must be proved in a failure-to-warn case as the Appellate Division's precedent conflicts with this Court's analysis in James v. Bessemer Processing Co., 155 N.J. 279, 297 (1998). Next, NJAJ further asks this Court to review prior precedent to conclude once again that a plaintiff may make a prima

facie case through circumstantial evidence. Finally, NJAJ asks this Court to provide protections that a N.J.R.E. 104 hearing is required when an appellate court finds the trial court abused its discretion in permitting an expert to testify.

In reviewing this matter, this Court should look to the history of New Jersey's Products Liability Act as the legislative intent is to "encourag[e] the safe production of products among manufacturers." Smith v. Alza Corp., 400 N.J. Super. 529, 550 (App. Div. 2008) (citing Stephenson v. R.A. Jones Co., 103 N.J. 194, 216 (1986)(noting public policy underlying products liability cases encourages "optimum investment in safety)(Stein, J., dissenting)); see also Michalko v. Cooke Color & Chem. Corp., 91 N.J. 386, 398 (1982)(explaining public's interest is served by encouraging safe manufacture). In fact, New Jersey's public policy regarding safeguarding of drugs is so strong that it is only one of two States that reject the learned intermediary doctrine in prescription drug cases. See Perez v. Wyeth Lab'ys Inc., 161 N.J. 1, 21 (1999). Due to this strong public policy, a jury should decide Allergan's liability when it knew its defective product held increased risks but, it did not advise Dr. Phillips or Beavan, the failure of which left Beavan blind in her left eye.

I. The Appellate Division Erred in the Proof Required for a Prima Facie Case of a Defect in a Failure-to-Warn Case. (Psa174-76).

Allergan and *amicus curiae* HealthCare Institute of New Jersey and the New Jersey Business & Industry Association (collectively "the Business *amici*")

argue that Plaintiff did not prove *this* particular Ozurdex was defective, but that position overlooks well-settled New Jersey law that applies in a strict liability, failure-to-warn case. NJAJ asks this Court to reverse the Appellate Division's decision and set forth once again that the defect in a failure-to-warn case is the lack of warning.

"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 harm." Bessemer, 155 N.J. at 297 (1998) (quoting Coffman v. Keene Corp., 133 N.J. 581, 594 (1993). Here, the defect was not warning that there could be silicone particulate that increased Ozurdex's risk of inflammation and ocular disturbances. It is irrelevant that only 2.2% of the recalled batches had this increased risk because it was still an additional risk to which Allergan had knowledge that was not disclosed to the user of the product. To relieve Allergan of its duty would be like saying just because only 2.2% of the time a user contracts cancer, the product is not defective. Consumers and their doctors deserve the right to know so that they may knowingly and voluntarily accept the medical treatment with the risks. See Matthies v. Mastromonaco, 160 N.J. 26, 36 (1999) (explaining informed consent doctrine).

Thus, in these failure-to-warn products liability cases, this Court approved a rebuttable presumption that the absence of a warning had proximately caused

the plaintiff's harm. Coffman, 133 N.J. at 598. This Court established the presumption due to the public policy concerns that "the failure to warn constitutes a product defect and that strict liability was more appropriate than negligence doctrine for resolution of inadequate warnings." Id. at 598 (quoting Freund v. Cellofilm Props., Inc., 87 N.J. 229, 237 (1981)). The Court explained that "[t]he use of the heeding presumption provides a powerful incentive for manufacturers to abide by their duty to provide adequate warnings." Id. at 599 (citation omitted).

This Court made clear, "in the failure-to-warn context, we impose on the plaintiff a very low threshold of proof in order to impute to a manufacturer sufficient knowledge to trigger the duty to provide a warning of the harmful effects of its product." Coffman, 133 N.J. at 599. The heeding instruction "serves to lighten a plaintiff's burden of proof concerning proximate causation," 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 (quoting Coffman v. Keene Corp., 257 N.J. Super. 279, 295 (App. Div. 1992) and citing Payne v. Soft Sheen Prods., 486 A.2d 712, 725 (D.C. 1985)).

In reliance on Coffman, other courts have applied the heeding presumption to drug cases. See e.g., McDarby v. Merck & Co., 401 N.J. Super.

10, 80 (App. Div. 2008) ("a heeding presumption may be applicable to claims of failure to warn of the dangers of pharmaceuticals"); see also In re Diet Drug Litig., 384 N.J. Super. 525, 540-41 (Law Div.2005) (applying heeding instruction because physician provides information to patient, who ultimately makes the informed decision regarding taking the medication).

This Court explained the plaintiff's burden in this type of case is "not onerous," and "product-defect causation" in the failure-to-warn context is presumed upon proof that the defendant had a duty to warn and does not require proof of actual causation to satisfy the plaintiff's burden on that element. Bessemer, 155 N.J. at 298. But the Appellate Division completely overlooked Coffman and Bessemer and held Plaintiff to a higher burden than required. (Psa175-76.)

Allergan and the Business *amici* argue that because only 2.2% of the doses were defective, Plaintiff cannot make out a prima facie case. (Ab19; Hb16.) But the question of whether Plaintiff's dose was defective belongs to the jury who will hear a) Allergan's own statements regarding its knowledge of the harm that the silicone particulate might cause; b) Plaintiff's experts explaining that these risks were additional harms beyond the normal risk of using Allergan's product; c) Dr. Phillips' observations that there was increased inflammation that had never occurred with nine prior Ozurdex injections that began within days of the

injection. (Psa81; Da57.) These facts make a prima facie case that the product itself was defective. Here, Allergan knew at least 2.2% of the doses in the bad batch had an increased risk of harm for patients, particularly sensitive ones. (Da256.) Allergan failed to warn of that increased risk, and the harm did occur.

Just like an increased risk of harm case, Allergan increased Plaintiff's risk of harm and it should not be able to escape liability by changing the level of proofs required to prove this defect. See Scafidi v. Seiler, 119 N.J. 93, 112 (1990) (explaining modified proximate cause requirements in increased risk of harm case); see also Velazquez v. Jiminez, 336 N.J. Super. 10, 31-32 (App. Div. 2000) (holding 3% satisfied the substantial factor test), aff'd, 172 N.J. 240 (2002). By way of analogy, a plaintiff in an increased risk of harm case may not be able to show what the diagnostic test might show that was not performed, but the plaintiff still gets to a jury by showing the "tests are helpful in a small proportion of cases." Gardner v. Pawliw, 150 N.J. 359, 387 (1997). Likewise, Allergan should not be able to escape a jury when it withheld information it knew about increasing the very risk of harm that Plaintiff then experienced.

NJAJ urges in line with precedent that to make a prima facie case, the plaintiff only must show that the manufacturer failed to warn about its knowledge that the batch had an increased risk of harm. This holding properly ensures that the consumer and medical user can make a knowing decision about

the use of the product. While Allergan and the Business *amici* all argue Ozurdex has a risk of inflammation and ocular disturbances, this position overlooks the significance to the *increased* risk of harm of which Allergan knew but failed to disclose. (Da256.) The risk was not only increased but Allergan knew a sensitive patient like Beavan had an even further increased risk. (Id.)

II. Even If the Defect is Not the Failure-to-Warn, Plaintiff Made a Prima Facie Case Using Circumstantial Evidence. (Psa169-172.)

The Appellate Division dismissed Plaintiff's case upon a finding that she did not prove the product was defective. (Psa175-76.) As explained in Point I, the Court applied the wrong standard. That said, even if this Court requires proof that the actual Ozurdex that was administered was defective, Plaintiff provided sufficient circumstantial evidence to support that finding. NJAJ asks this Court to re-affirm that circumstantial evidence can be used to prove the product is defective.

Plaintiff in "a strict liability case must establish that the product was defective, that the defect arose while in the control of the defendant, and that the plaintiff suffered injury thereby." Scanlon, 65 N.J. at 590 (citing Jakubowski v. Minn. Mining & Mfg., 42 N.J. 177 (1964); Newmark v. Gimbel's Inc., 54 N.J. 585 (1969); Corbin v. Camden Coca-Cola Bottling Co., 60 N.J. 425 (1972): Prosser, Law of Torts (4th ed. 1971) §103). To prove this defect, the plaintiff only must show "something was wrong" with the product. Id. at 591. This Court

identified several ways a plaintiff can meet that low threshold, including expert testimony. Id. The Court explained, "additional circumstantial evidence, such as proof of proper use, handling or operation of the product and the nature of the malfunction, may be enough to satisfy the requirement that something was wrong with it." Id. (citing Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 409 (1960) (steering malfunction); Cintrone v. Hertz Truck Leasing & Rental Serv., 45 N.J. 434, 452 (1965) (brake failure); Sabloff v. Yamaha Motor Co., Ltd., 113 N.J. Super. 279, 286-287 (App. Div.), aff'd, 59 N.J. 365 (1971) (wheel locked)). The Appellate Division misconstrued the Plaintiff's burden for making out a prima facie case as explained herein.

a. The Appellate Division Erred in Finding Use of a Differential Diagnosis Violated Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). (Psa175-76).

The Appellate Division erred in barring Plaintiffs' experts under Daubert, when 1) this Court has never required a strict Daubert test in civil matters; 2) Defendants' own admissions together with the experts' opinions demonstrated Allergan's lack of warning led to Beavan's injuries; and 3) the Appellate Division violated the standard of review in barring Plaintiff's experts when the trial court within its discretion properly found the experts' opinions were sufficiently stated. (Pa129-30.)

This Court has permitted physicians to offer causation opinions using a differential diagnosis in tort cases, including toxic tort cases. Creanga v. Jardal,

185 N.J. 345, 356 (2005) (citing Lapka v. Porter Hayden Co., 162 N.J. 545, 557 (2000); Rubanick v. Witco Chem. Corp., 125 N.J. 421, 450–51 (1991)). NJAJ is concerned that the Appellate Division's rejection of both Dr. Phillips and Dr. Lazelary's use of a differential diagnosis as the methodology supporting their causation opinions creates a new, erroneous increased burden in products liability cases that should be corrected by this Court.

Dr. Lazelary concluded that the Ozurdex injection caused his patient's blindness using Creanga's differential diagnosis theory of causation, because all the other possible causes of blindness were temporally remote. The Appellate Division improperly weighed the circumstantial evidence to conclude that Plaintiff did not create a triable question of fact as to causation. (Psa170.) The Appellate Division noted, "If the proofs permit an inference that the accident was caused by some defect, whether identifiable or not, a jury issue at to liability is presented. (Id. (citing Moraca v. Ford Motor Co., 66 N.J. 454, 458 (1975)).

But then the Appellate Division overlooked the circumstantial evidence that demonstrated Beavan's blindness was caused by the defect: she received the Ozurdex from a defective batch; Allergan admitted that the defective batch could cause inflammation and migration of the pellet; Dr. Lazelary explained that the blindness was caused by the inflammation and led to migration of the Ozurdex pellet; the Ozurdex was the most likely cause because it had just

occurred prior to the injury and Plaintiff had prior injections without issue; and Dr. Phillips opined that the batch was defective because past administrations of Ozurdex controlled rather than exacerbated Plaintiff's inflammation. (Cf. Psa171 with Da256, Da695-700, Pa127-39.)

The Appellate Division conducted its analysis in a vacuum looking only at Plaintiffs' experts' opinions without the context of the admissions of Allergan, which led to the wrong conclusion. As explained herein, the experts were entitled to rely upon Allergan's statements because physicians ordinarily rely on those statements in treating patients. See Morales-Hurtado v. Reinoso, 241 N.J. 590, 593 (2020). Following this Court's decision in Accutane, 234 N.J. at 391, this Court provided further guidance regarding the sufficiency of experts in Morales-Hurtado, 241 N.J. at 593. The Court reviewed the trial court's barring the opinion of a life care planner as unreliable where the life care planner based her opinion on a treating physician's response to a questionnaire and the medical records. Id. In remanding to determine the reliability of the life care planner's opinion, this Court clarified how the trial court may assess the reliability of the expert's opinion. Id.

Importantly, this court explained "an expert witness may rely on the opinion of another expert in a relevant field." Id. (citing N.J.R.E. 703). The Court added that the expert's reliance on facts and data is permissible when of the "type reasonably relied upon by experts in the particular field in forming opinions or inferences upon

the subject." Id. (quoting Biunno, Weissbard & Zegas, Current N.J. Rules of Evidence, cmt. 8 on N.J.R.E. 703). The expert may rely on that information as long as competent evidence will be presented to the jury. Id. at 593-94.

Based upon the Appellate Division's resolution in this case, there is confusion as to the evidence on which an expert may rely. NJAJ asks this Court to clarify its opinion in Morales-Hurtado to explain that a defendant's admission can be used to satisfy this "competent evidence" standard. The Business *amici* cite concerns with relying on the recall itself to conclude the product was defective when 2.2% of the lot had the issue leading to the recall. (Hb16.) Yet the experts did not strictly conclude that because the lot was recalled, the product was defective. (Psa169.) Instead, the experts relied on Allergan's admissions that the defective product would cause inflammation and pellet migration. (Da256; Da173; Da186-87.) They both separately concluded that because there was this increased inflammation of which Allergan warned others but not Dr. Phillips occurring shortly after the injection, Plaintiff was administered a defective batch. (Da82-83; Pa15-21; Da697-98.) The jury is able to review this circumstantial evidence to conclude that the product was, in fact, defective.

Allergen further argues that Plaintiff's experts cannot testify because they did not "rule out' the many other recognized causes, rendering their use of the differential diagnosis methodology improper, unreliable, and inadmissible under

Creanga," but Plaintiff's experts had ruled out the other causes. Dr. Lalezary explained that the other causes were temporally remote so it is more likely the defect in the Ozurdex that led to the increased inflammation. (Da179-80.) Likewise, Dr. Phillips explained that as Plaintiff's treating provider, he believed the increased inflammation that led to blindness was caused by the defect with the Ozurdex because Plaintiff had many prior injections and did not have an issue with increased inflammation until shortly after this injection from a recalled batch. (Da57, Da82-83.) While Allergan may have disputed these facts, it went to the weight of the experts' testimony and not the admissibility.

b. The Appellate Division Erred by Rejecting the Temporal Exposure Element to Proximate Cause. (Psa170-76.)

This Court expanded on the need to rely upon circumstantial evidence to prove causation in toxic tort cases. Bessemer, 155 N.J. at 301. In fact, this Court explained in toxic exposure cases, a plaintiff can proceed to show medical causation through proximity of exposure to the product. Id. at 303. The Court explained, "the frequency, regularity and proximity of exposure will be an important and fundamental factual link in plaintiff's experts' analysis and methodology in reaching an ultimate theory of causation." Id. This Court has even explained that the temporal element is important in a treating physician's use of differential diagnosis: "[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." Creanga, 185 N.J. at 359 (citation omitted). In fact, this Court held the physician's "reliance upon the temporal factor is entitled to greater weight." Id.

But here, the Appellate Division expressly rejected Dr. Lazelary's position that the temporal element affected his conclusion as to causation. (Psa170-76.) This was error that this Court should correct. A jury – and not two appellate judges – should weigh the strength of Dr. Lazelary and Dr. Phillips' reliance on the temporal element.

c. The Appellate Division Confused Weight with Reliability Such That This Court Should Reverse. (Psa174-76.)

Allergan argues the expert's opinions lack reliability citing to Accutane, 234 N.J. at 393, but the issue there was the methodology employed where the experts "disregarded eight of nine epidemiological studies and relied on case reports and animal studies to support their opinion." But here, the experts relied on their differential diagnosis, a methodology that this Court approved in Creanga, 185 N.J. at 357-58.

In Accutane, this Court found the trial court did not abuse its discretion in finding the plaintiff's methodology unsound: "The trial court reasoned that the overall approach taken by Dr. Kornbluth -- rejecting the evidence from the epidemiological studies, which all found no causal association, and proffering his own alternative opinion that a causal association was present based on lesser

forms of evidence -- was based on an unsound methodology." Id. at 395. But here, the Appellate Division found the trial court abused its discretion in finding that the experts had provided the why and wherefore for their causation opinions. (Psa172-76.) This Court's concern about ensuring an "expert is adhering to the norms accepted by fellow members of the pertinent scientific community," is not at issue because the trial court here noted that both experts had based their opinions on admissible facts and data, including Defendant's own admissions as to the risks for intraocular inflammatory reaction and corneal reaction. (Da828.)

The Business *amici* trivialize Plaintiff's proofs arguing "the trial court allowed plaintiff to survive summary judgment merely based on the facts that (1) a recall occurred, and (2) plaintiff experienced known risks that could have occurred *without* any product issue or recall." (Hb8.) But this position overlooks the quantum of evidence establishing the product was defective set forth supra.

All that must be shown is a genuine dispute of material fact facts; the jury must decide the facts to determine whether the product is defective. And but for the Appellate Division's reversal, a jury would have heard sufficient proofs. The Business *amici* argue reversal lowers the bar, but this Court has explained "[a] dispute of fact is genuine if, considering the burden of persuasion at trial, the evidence submitted by the parties on the motion, together with all legitimate

inferences therefrom, could sustain a judgment in favor of the non-moving party." Brill v. Guardian Life Ins. Co. of Am., 142 N.J. 520, 538 (1995); (see Hb10.) The trial court did not lower any standard; instead, the trial court afforded Plaintiff the benefit of all reasonable inferences including that the two experts could rely on Allergan's own admissions regarding the injury that the defective product would cause, that Plaintiff suffered such injuries, and that due to Plaintiff's past favorable responses to the Ozurdex, this batch was defective. (Da828.) The Appellate Division's requirement to prove a defect by the Plaintiff performing testing, error rates, or peer reviews creates a standard that this Court did not intend given the doctors explained their analysis through the differential diagnosis method that is generally accepted in the medical community. Cf. Psa174-76 with Creanga, 185 N.J. at 359.

The Business *amici* argue that the only proof that Plaintiff provided in opposition to summary judgment was a hypothetical of "if a product contained a defect," (Hb3), but that position overlooks the important admission made by Allergan that 2.2% of the products were defective. The jury determines whether the expert's assumptions and facts are true. Higgins v. Owens-Corning Fiberglas Corp., 282 N.J. Super. 600, 614 (App. Div. 1995)(citations omitted).

The Business *amici* argue that a party cannot prove a defect through a hypothetical, but this argument misconstrues Plaintiffs' experts' testimony.

(Hb11.) Although this Court found a plaintiff had not made out a prima facie case for a products liability defect when the expert testified to hypotheticals, in that case, "[t]he expert offered no hypothesis as to how or why the plastic cam broke and in fact never said in so many words that it was defective, although that was the purport of his testimony." Scanlon, 65 N.J. at 589. On the other hand, Allergan's own affirmative statements stated what injury would be caused by its defective product; both Dr. Lazelary and Dr. Phillips testified that they believed the product was defective because that same injury occurred and further excluded other possible causes. (Da256; Pa13-22.) The hypothetical question provided further circumstantial evidence of a defect, but was not the only evidence. (Da794.)

d. When the Trial Court Finds the Expert's Opinion is Sufficient, the Appellate Division Should Not Be Able to Dismiss With Prejudice Without a Hearing. (Psa36.)

Allergan argues that Plaintiff waived the ability to obtain a N.J.R.E. 104 hearing by not arguing it below, but the trial court had found the experts' opinions sufficient. This Court should reject any argument that a party can waive the ability to obtain a N.J.R.E. 104 when the trial court had found the expert's opinion admissible and it is the appellate court that then reverses. This Court should not permit a reversal without the ability to present testimony and have an expert cross examined to determine the sufficiency of the expert's opinion.

Allergan repeatedly argues that the experts' use of the differential diagnosis is "unreliable," but these experts were never given the opportunity for Plaintiff to present direct testimony regarding these issues. (Ab11.) When a party's claim is at issue before dismissal, the party should be able to have a N.J.R.E. 104 hearing as to the expert's opinion. Allergan asks this Court to reject such a position where the expert was deposed, but a deposition is an examination by the adverse party not the party proffering the testimony. See Ab16-17, n.14 (citing Fairfax Fin. Holdings Ltd. v. S.A.C. Cap. Mgmt., L.L.C., 450 N.J. Super. 1, 100, n.50 (App. Div. 2017)).

The Appellate Division erred in reversing the trial court's finding that the experts properly grounded their opinions in the factual record, including that Beavan had previously received ten prior successful Ozurdex injections in both eyes without incident. (Psa143.) This Court has made clear that an appellate court may not substitute its own assessment of expert testimony for that of the trial court. Indeed, unless the trial court's decision to admit expert testimony was "so wide of the mark" as to amount to "a manifest denial of justice and an abuse of discretion," it must be upheld. Hisenaj v. Kuehner, 194 N.J. 6, 25 (2008) (citing State v. Wakefield, 190 N.J. 397, 435 (2007); Verdicchio v. Ricca, 179 N.J. 1, 34 (2004)). The Appellate Division displaced a well-reasoned trial court ruling with its own judgment. That outcome conflicts with settled law.

NJAJ respectfully asks this Court to reverse in accordance with the governing standards on abuse of discretion, differential diagnosis, and product defect in failure-to-warn cases.

CONCLUSION

This Court should reverse the Appellate Division's decision because the trial court did not abuse its discretion in finding that Plaintiffs' two experts used an appropriate methodology for their causation opinions. If this Court has any doubt in the methodology, then the proper remedy is to require a N.J.R.E. 104 hearing rather than a dismissal without providing a party with a remedy to demonstrate the expert did have a why and wherefore for the expert's opinions. Fundamental fairness is providing parties with the opportunity to address the court's concerns before a dismissal with prejudice.

Respectfully submitted,
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