SUPREME COURT OF NEW JERSEY
Docket No. 090150

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| ALISON BEAVAN,<br><br>Plaintiff-Petitioner,<br>v.<br>ALLERGAN USA, INC., ALLERGAN INC., F/K/A INAMED CORPORATION, ALLERGAN PLC, ABBVIE INC., AND DOES 1 THROUGH 100, INCLUSIVE<br><br>Defendants-Respondents. | On Appeal from:<br>SUPERIOR COURT OF NEW JERSEY, APPELLATE DIVISION<br>Docket No.: A-001501-23T2<br>Sat Below:<br>Hon. Hany A. Mawla<br>Hon. Robert M. Vinci<br><br>Civil Action |

# *AMICUS CURIAE* BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF DEFENDANTS-RESPONDENTS

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## INTEREST OF *AMICUS CURIAE*

The Product Liability Advisory Council, Inc. (PLAC) is a non-profit professional association of corporate members representing a broad cross-section of American and international product manufacturers.[1] These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products and those in the supply chain. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the leading product litigation defense attorneys are sustaining (non-voting) members of PLAC. Since 1983, PLAC has filed more than 1,200 briefs as *amicus curiae* in both state and federal courts, including this court, on behalf of its members, while presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product risk management.

The trial courts' gatekeeper role in evaluating the reliability of proffered expert testimony is vitally important to PLAC's members. If this role is not properly exercised, the fundamental fairness of civil jury trials in complex cases such as this one is compromised. PLAC considers this case particularly important because it involves a key admissibility question that arises frequently in product liability

[1] *See* https://plac.com/web/Amicus.

lawsuits around the country: whether parties can overcome summary judgment when their expert witnesses rely on a differential diagnosis methodology based on a questionable temporal relationship.

PLAC is well-situated to address the fundamental concept of differential diagnosis both in medicine and litigation, and specifically, its interaction with the *Daubert* trilogy.[2] Indeed, this Court has reconciled *Daubert*'s gatekeeping principles regarding scientific expert testimony with its own standards set forth in New Jersey Rules of Evidence 702 and 703.[3]

PLAC's members are involved in defending an increasing number of product liability lawsuits in which expert testimony is the rule, not the exception. This *amicus curiae* brief is submitted to address the broad public importance of this Court's decision on these issues.

## PROCEDURAL AND FACTUAL BACKGROUND

PLAC adopts the Statement of Facts and Procedural History as stated in the Opening Brief of Defendant-Appellant Allergan USA, Inc., filed in the Superior Court of New Jersey, Appellate Division, Docket No. A-001501-23. (Allergan Br. at 3-14).

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[2] *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993); *Gen. Elec. Co. v. Joiner*, 522 U.S. 136 (1997); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999).

[3] *See In re Accutane Litig.*, 234 N.J. 340 (2018).

## ARGUMENT

### I. The Appellate Division properly fulfilled its gatekeeping obligations by reversing the trial court and concluding that Plaintiff's experts should be barred for failing to establish causation.

Expert testimony must meet a rigorous standard to be deemed admissible in New Jersey. In line with its gatekeeping function, the Appellate Division correctly held that Plaintiff's experts' opinions failed to satisfy that standard to be admissible under New Jersey law. *See In re Accutane Litig.*, 234 N.J. 340 (2018).

The admission of expert testimony is governed by New Jersey Rules of Evidence 702 and 703. Rule 702 provides the conditions under which experts may assist juries with technical knowledge. To be admissible under N.J.R.E. 702, the following three requirements must be established: "(1) the intended testimony must concern a subject matter that is beyond the ken of the average juror; (2) the field testified to must be at a state of the art such that an expert's testimony could be sufficiently reliable; and (3) the witness must have sufficient expertise to offer the intended testimony." *Kemp ex re. Wright v. State*, 174 N.J. 412, 424 (2002). The expert must also demonstrate that their "opinion or theory is generally accepted within the scientific community." *Id.*

Even if an expert satisfies Rule 702 to testify, Rule 703 requires that an expert opinion "be grounded in 'facts or data derived from (1) the expert's personal observations, or (2) evidence submitted 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 v. Pierre*, 221 N.J. 36, 53 (2015); N.J.R.E. 703. New Jersey courts also apply the "net opinion rule," which "forbids the admission into evidence of an expert's conclusions that are not supported by factual evidence or other data." *Townsend*, 221 N.J. at 53-54 (citations omitted). An opinion that is "circular," or contains "bare conclusions, unsupported by factual evidence, is inadmissible." *Buckelew v. Grossbard*, 87 N.J. 512, 524 (1981).

Here, Plaintiff's experts violated this fundamental principle by offering conclusions that were speculative, circular, and not supported by factual evidence or data. As the Appellate Division correctly observed, "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." *Beavan v. Allergan U.S.A., Inc.*, No. A-1501-23, 2024 WL 4847575, at *12 (N.J. Super. Ct. App. Div. Nov. 21, 2024). Plaintiff failed to present any evidence that her experts' theory of causation would satisfy *Daubert*, as the record was "devoid of testing, error rates, peer reviews, publications, or general acceptance in the scientific community to support the method of causation in this case." *Id.*

Accordingly, the Appellate Division properly concluded that "the trial court should have barred plaintiff's experts because they did not establish general or

specific causation" and that "Defendant should have been granted summary judgment due to the lack of proof of causation." *Id.* at *13. This Court should affirm.

### A. "Differential Diagnosis" is not a methodology used to determine general causation.

Plaintiff's experts failed to offer any reliable opinions that the Ozurdex® administered to Plaintiff had a defect capable of causing her claimed eye injuries. In other words, they have no evidence to establish "general causation." Sidestepping general causation, Plaintiff's experts claim they can prove causation through a differential diagnosis, a diagnostic methodology that, at most can, aid in the determination of "specific causation." Even then, differential diagnosis cannot prove causation, but may identify the disease or condition from which the Plaintiff suffers. Simply uttering the phrase "differential diagnosis" is not enough to render a causation opinion admissible. *Creagna v. Jardal,* 185 N.J. 345, 357 (2005).

Differential diagnosis is "a patient-specific process of elimination that medical practitioners use to identify the 'most likely' cause of a set of signs and symptoms from a list of possible causes.'" *Id.* (citations omitted). Inherently, then, differential diagnoses involve "assessing causation with respect to a particular individual." *In re Paoli R.R. Yard PBC Litig.*, 35 F. 3d 717 (3d Cir. 1994). Courts use the differential diagnosis term in a more general sense to

"describe the process by which *causes* of the patient's *condition* are identified." *Creagna v. Jardal*, 185 N.J. at 357 (emphasis in original) (citations omitted).

The first step, even before conducting a differential diagnosis, is for the expert to *rule in* all plausible causes for the patient's condition, including hypotheses that might "explain the set of salient clinical findings under consideration." *Clausen v. M/V New Carissa*, 339 F. 3d 1049, 1057 (9th Cir. 2003). This step requires a determination whether the competing causes are *generally* capable of causing the symptoms at issue. *Id.* Such a determination can be made only through rigorous application of the scientific method. Only after a particular substance has been determined to be capable of causing the type of injury in question may a differential diagnosis be employed to assess whether the specific patient actually has the condition in question. A differential diagnosis has not been properly conducted when causes *not* capable of causing the symptoms are ruled in, and when an expert fails to consider a plausible hypothesis explaining the condition. *Id.* at 1058.

After potential causes have been ruled in through application of the scientific method, the expert must attempt to *rule out* those causes that did not produce the patient's condition by "eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings." *Id.* In ruling out causes, an expert must use "sufficient diagnostic techniques to have good grounds for his or her conclusion." *Heller v. Shaw Indus.,*

*Inc.*, 167 F. 3d 146, 156 (3d Cir. 1999). Each stage of an expert's testimony must be reliable, and evaluated practically and with flexibility. *Id.* at 155.

Plaintiff's experts' opinions in this case are particularly egregious. First, Plaintiff's experts admitted no one ever saw a silicone particulate in Plaintiff's eye, or in the Ozurdex® unit used in her procedure. Indeed, Plaintiff's treating physician, Dr. Phillips, admitted "there's no way [he] could possibly know whether there was a silicone particular in [her] eye." (Da73-76). Likewise, Plaintiff's retained expert Dr. Lalezary stated he "[couldn't] say for certain that [she] had the particulate in her eye," even admitting there was "no objective evidence" of a silicone particulate from the Ozurdex® at issue. The evidence established that only 2.2% of the units in the relevant Ozurdex® lot were found to generate a silicone particulate. (Da229).

Instead, Plaintiff's experts merely speculated that the administered Ozurdex® at issue caused Plaintiff's injuries, assuming it was defective because it came from the recalled lot. (Da73-74, 186). Moreover, they failed to support their general causation opinions with any scientific study and failed to rule out other causes of Plaintiff's injuries such as chronic eye inflammation, eye surgeries and procedures, and other treatments. (Da64-65, 81-82, 175-77, 196-97, 370, 374).

The Appellate Division correctly held that summary judgment was required because Plaintiff's experts' opinion based on differential diagnosis

failed to meet New Jersey's admissibility standards set forth in Rule 702, Rule 703, and *In re Accutane Litig.*, 234 N.J. 340 (2018).

### 1. Differential Diagnosis vs. Differential Etiology

Differential diagnosis is a process whereby physicians diagnose diseases. But as this matter illustrates, the term has been misused by attorneys, courts, and medical experts.

"Differential diagnosis" refers to "the clinical treatment process of rendering a diagnosis to *identify the illness* causing the patient's symptoms," as opposed to "the process of determining the specific scientific or medical *cause of the illness* diagnosed." Howard Weiner, et al., *Medical Causation and Expert Testimony: Allergists at this Intersection of Medicine and Law*, 12(6) Current Allergy and Asthma Rep. 595 (2012) (emphasis added);[4] *see also McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1252 (11th Cir. 2005). What courts need to determine general causation—and what *Daubert* requires—is "a causal assessment with a high degree of empirical or scientific and medical support and proof, not a differential diagnosis." Weiner, et al., *supra* at 595; *see also In re Breast Implant Litig.*, 11 F. Supp. 2d 1217, 1229 (D. Colo. 1998).[5]

[4] *See* http://doi.org/10.1007/s11882-012-0294-z.

[5] This Court may look to relevant federal case law for guidance. *See Roa v. Roa*, 200 N.J. 555, 573 (2010).

Numerous court filings and orders "have mixed the two methodologies by sometimes equating a causal assessment to a differential diagnosis." *Id.* That is a mistake. "Differential diagnosis…is really a misnomer," because a diagnosis is "concerned only about naming the condition or ailment, not establishing its cause." *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 832 n.4 (7th Cir. 2015).

While diagnosing ailments is the "bedrock" of clinical practice, the usual question in court "is not what [the plaintiff] was suffering from but what caused his ailments, and a better term to describe it is a 'differential etiology.'" Weiner, et al., *supra*, at 591; *Myers v. Illinois Cent. R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010); *see also Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 674 (6th Cir. 2010); *Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 705 (7th Cir. 2015); Michael D. Green, Michael Freedman & Leon Gordis, *Reference Guide on Epidemiology*, in *Reference Manual on Scientific Evidence* 549, 617 & n.1 (Fed. Jud. Ctr. ed., 3d ed. 2011).

Conflating "differential diagnosis" and "differential etiology,"[6] is an error.[7] They are distinct concepts, and it is important to analyze them

[6] "Etiology" is defined as the "science and study of the causes of disease and their mode of operation." *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1195 (11th Cir. 2010) (quoting *Stedman's Medical Dictionary* 542 (25th ed. 1990)) (adding that "the relevant methodology used in this case is differential etiology, *i.e.*, the process of determining which of two or more causes is responsible for the patient's symptoms," rather than "differential diagnosis").

[7] The trend toward inaccurate interchangeable usage includes the opinion in *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 262 (4th Cir. 1999). This case offers an excellent opportunity to clarify this issue.

accordingly, because this is no mere semantic technicality. The confusion of these terms and the concepts they represent has major implications for *Daubert* jurisprudence.

Merely asserting that an expert used "differential diagnosis" is not "some incantation that opens the *Daubert* gate to allow an expert's opinions to be admitted at trial." *Bowers v. Norfolk S. Corp.*, 537 F. Supp. 2d 1343, 1360 (M.D. Ga. 2007), *aff'd*, 300 F. App'x 700 (11th Cir. 2008). Differential diagnosis, properly understood, does not allow a witness to simply identify potential causes and choose the one that best fits plaintiff's claims.[8] Yet when courts conflate the trusted "standard scientific technique" of differential diagnosis with the less clinically common inquiry of differential *etiology*, there is a substantial risk of importing a less stringent standard of "proof" from the clinic into the courtroom, such that a method valid for clinical practice is passed off as a method for determining general causation.

Clinical differential diagnosis "is a mixture of science and art, far too complicated for its accuracy to be assessed quantitatively or for a meaningful

[8] *See* Weiner, et al., *supra* at 592 ("If it were true that the diagnostic process uncovered an external cause with no further analysis required, a physician could ascribe any cause of his/her choosing to an ailment, whether or not there was even a modicum of scientific support for such a connection. He could simply assert that the patient suffers from a disorder of his own invention and that his conclusion was the result of having excluded all other conditions in the differential diagnosis. A causal conclusion requires an analysis quite separate from a diagnosis.").

rate of error to be calculated." John M. Conley & John B. Garver, III, *Judge William C. Keady and the Law of Scientific Evidence*, 68 Miss. L.J. 39, pg. 51 (1998). It is easy to understand why this is so: "in clinical practice physicians must often act upon reasonable guesses based on whatever information happens to be available because they must take some action to treat their patients and thus do not have the option of inaction in the face of incomplete, inconclusive, and unreliable evidence." *Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 508 (W.D. Pa. 2003).

Importantly, "doctors sometimes believe that they have found a cause when they have not necessarily done so," as they "stumble upon coincidental occurrences and random events and often follow human nature, which is to confuse association and causation." *Siharath v. Sandoz Pharm. Corp.*, 131 F. Supp. 2d 1347 (N.D. Ga. 2001), *aff'd*, 295 F.3d 1194 (11th Cir. 2002). "As a practical matter, the cause of many diseases remains unknown; therefore, a clinician who suspects that a substance causes a disease in some patients very well might conclude that the substance caused the disease in the plaintiff simply because the clinician has no other explanation." *In re Breast Implant Litig.*, 11 F. Supp. 2d at 1230. Yet such a "clinical guess…is not a scientifically reliable approach when used to assess causality." *Soldo*, 244 F. Supp. 2d at 508.

For these reasons, when courts determine whether an expert is showing the level of intellectual rigor that characterizes the practice of an expert in the relevant field, and whether his or her methodology of differential etiology (*not* "diagnosis") is typical or accepted in that field, "the relevant scientific field is epidemiology or toxicology and not clinical medicine." *Siharath*, 131 F. Supp. 2d at 1363.

### 2. General Causation Cannot be Established Through Differential Etiology

Having clarified that differential etiology, not differential diagnosis, is the actual methodology at issue, it becomes even more apparent that Plaintiff's experts' "method" of using differential etiology to "rule in" a silicone particulate as a possible specific cause of Plaintiff's injuries due to the temporal relationship of the administration of Ozurdex® (but failure to "rule out" other possible causes), is an exercise in circular reasoning that begins and ends with an unsupported assertion that the Ozurdex® at issue *can* cause Plaintiff's injury. In other words, Plaintiff's experts start from the beginning with an assertion of general causation. But differential etiology cannot prove general causation, and specific causation cannot exist without general causation. Thus, granting summary judgment was appropriate.

Differential etiology seeks to identify "the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*,

178 F.3d at 262 (4th Cir. 1999).[9] The process entails "listing possible causes, then eliminating all causes but one." *Id.* (quoting *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995)). For a differential etiology to be "validly conducted, an expert must systematically 'rule in' and 'rule out' potential causes in arriving at her ultimate conclusion." *Higgins*, 794 F.3d at 705 (7th Cir. 2015). Unless a substance has been reliably demonstrated to be capable of causing the condition, it should never be put on the differential list.

The putative result of a differential etiology analysis can only be reliable if "the final, suspected 'cause' remaining after this process of elimination" was properly listed (or "ruled in") in the first place, having been validly determined to be "actually…capable of causing the injury." *Cavallo v. Star Enter.*, 892 F. Supp. 756, 771 (E.D. Va. 1995), *aff'd in relevant part*, 100 F.3d 1150 (4th Cir. 1996). *See also Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 989 (8th Cir. 2001) (court properly excluded differential-etiology experts who "lacked a proper basis for 'ruling in' [the agent] as a potential cause of [the disease] in the first place"); *McClain*, 401 F.3d at 1252 (11th Cir. 2005) (differential etiology could not "overcome the fundamental failure of laying a scientific groundwork for the general toxicity of the drug and that it can cause the harm a plaintiff

[9] *See also Wood*, 807 F.3d at 832, n.4 (describing differential etiology as a "process-of-elimination approach").

suffered"); *Tamraz*, 620 F.3d at 674 (expert's "efforts to 'rule in'" exposure to the agent at issue "turned on speculation, not a valid methodology").

Differential etiology is "not a reliable methodology for determining *general* causation." *Soldo*, 244 F. Supp. 2d at 516-17 (emphasis in original). It is only to be used for "assessing *specific* causation (once general causation has first been established)," *id.*, because it "assumes the existence of general causation." *Kilpatrick v. Breg, Inc.*, 613 F.3d 1329, 1342 (11th Cir. 2010).

The circular reasoning that "rules in" the suspected cause determining general causation is fallacious. Rather, reliable scientific evidence proving that a drug can cause a medical condition is a necessary predicate to "ruling in" the drug to justify its placement on the differential. *Soldo*, 244 F. Supp. 2d at 516-17; *see also Young v. Burton*, 567 F. Supp. 2d 121, 137 (D.D.C. 2008), *aff'd*, 354 F. App'x 432 (D.C. Cir. 2009) (expert "used circular reasoning to work backwards from diagnosis to proof of exposure").

Here, as in *Cavallo*, 892 F. Supp. at 771, the Appellate Division properly found that the differential-etiology testimony of Plaintiff's experts was insufficient where the experts' "ruling in" of the suspected agent was founded primarily on the temporal connection between exposure and the development of symptoms, coupled with an unsupported assertion that the agent "can cause" the types of injuries at issue. *See* Murphy Report (Doc. 70-1), p. 6-8; Order (Doc.

1283), p. 12-13. The latter assertion is "unsupported" because the only evidence of general causation, and thus the only basis for "ruling in" a silicone particulate from Ozurdex® she received as the cause of her injuries, were the general causation experts' opinions. Accordingly, much like in *Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 476 (1st Cir. 2016), in which the expert had "ruled in" the suspect agent "solely by relying" on other excluded expert testimony, Plaintiff's experts here failed to establish a "scientifically reliable basis to 'rule in'" Ozurdex®, and thus their differential-etiology testimony is unreliable and inadmissible.

## CONCLUSION

The Appellate Division carefully considered the evidence presented to support the admissibility of Plaintiff's expert testimony and properly held that their net opinions failed to meet the standards of N.J.R.E. Rule 702, Rule 703, and the *Daubert* factors which *Accutane* incorporated into New Jersey law. Plaintiff's experts failed to offer reliable opinions that the Ozurdex® administered to Plaintiff had a defect and caused her alleged injuries. This Court, recognizing the risks of misapplying differential diagnosis to determine general causation, should affirm the Appellate Division's finding of an "utter lack of evidence to support the existence of both general and specific causation." (Psa174).

Respectfully submitted,

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