IN RE: ACCUTANE LITIGATION	SUPREME COURT OF NEW JERSEY Docket No.: 079958 On Petition for Certification from Superior Court of New Jersey Appellate Division Docket No.: A-4698-14T1 A-0910-16T1 Sat Below: Hon. Susan L. Reisner, P.J.A.D. Hon. Ellen L. Koblitz, J.A.D. Hon. Thomas W. Sumners, Jr., J.A.D. On Appeal from: Superior Court of New Jersey Law Division, Atlantic County Case No. 271 (MCL) Sat Below: Hon. Nelson C. Johnson, J.S.C. Civil Action **ORAL ARGUMENT REQUESTED**

Brief & Appendix of Amici Curiae HealthCare Institute of New Jersey, New Jersey Business & Industry Association, Commerce and Industry Association of New Jersey, and New Jersey Chamber of Commerce

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PRELIMINARY STATEMENT

Proposed amici curiae HealthCare Institute of New Jersey (HINJ), New Jersey Business and Industry Association (NJBIA), Commerce and Industry Association of New Jersey (CIANJ), and New Jersey Chamber of Commerce respectfully submit this brief in support of defendants-petitioners Hoffmann-La Roche Inc. and Roche Laboratories, Inc.'s ("Roche") Petition for Certification.

This case raises an issue of substantial public importance that this Court has considered, but has yet to resolve, for nearly two decades: whether New Jersey's standard for the admissibility of expert opinion should be clarified in order to ensure that unreliable and unfounded expert testimony is kept from New Jersey juries. That issue is particularly important to these proposed amici, which together represent a significant cross-section of New Jersey's vital life sciences industry, largest employers, and business leaders.

The absence of an effective standard to preclude "junk science" from reaching a jury gives rise to a paradox that flies in the face of sound public policy. In particular, under the standard articulated by the Appellate Division in this case, the state's research-based life sciences industry - an industry dedicated to developing lifesaving treatments derived from hard science - is forced to defend against specious product liability claims as long as a plaintiff's expert can assert that his or

her "novel" conclusions arise out of a methodology that "some expert consensus" accepts, irrespective of whether the methodology actually is scientifically reliable or actually yields testimony relevant to the facts of the case.

Adoption of the Daubert standard for admissibility of expert testimony in civil cases - a standard established in the federal courts nearly a quarter-century ago and adopted by 39 states and the District of Columbia in the ensuing years - would remedy that inequity. The differences between Daubert and the standard that lower courts in New Jersey have often applied in cases involving "novel" causation theories are real and deleterious to New Jersey's economy and its judiciary. Indeed, experts routinely precluded from testifying in Daubert jurisdictions are permitted to offer their questionable testimony in New Jersey, forcing New Jersey companies to defend against unreliable challenges to their important innovations and forcing New Jersey's already over-burdened court system to shoulder an inordinate volume of mass tort suits brought by out-of-state plaintiffs.

Accordingly, these proposed amici curiae respectfully submit that this Court should grant Roche's Petition for Certification and take this opportunity to determine, once and for all, whether New Jersey will join the federal courts and nearly all other state courts in adopting Daubert to ensure that

only reliable and reliably applied expert testimony enters New Jersey's courts.

STATEMENT OF INTEREST

Proposed amici curiae HINJ, NJBIA, CIANJ, and the New Jersey Chamber will, if granted leave to appear as amici curiae, provide this Court with unique perspectives on the broad implications of this case. As set forth in detail in the Certification submitted with this brief, their memberships consist of business leaders and the largest employers in the state, many of which are at the cutting edge of the research-based life sciences industry that contributes so vitally to New Jersey's economy and welfare. This Court should grant their motion to appear as amici curiae and consider the arguments and important public policy issues set forth in this brief.

HINJ is a 20-year-old organization comprised of 27 of New Jersey's leading pharmaceutical and medical technology manufacturers. HINJ's purpose is to speak for New Jersey's life sciences industry and to raise awareness of the significant impact that industry has on New Jersey's citizens' economic well-being and quality of life. HINJ also strives to increase public support for New Jersey's research-based pharmaceutical and medical technology industry by increasing awareness and understanding of the industry's importance among New Jersey's elected and appointed officials, media, citizens, and opinion

leaders. HINJ seeks to advance the development and implementation of sound public health and business policies that further the interests of New Jersey, its people, and its research-based life sciences industry. A list of HINJ's 27 member organizations is available at http://hinj.org/about-hinj/hinj-member-companies/.

NJBIA, which has been granted leave to appear as amicus curiae in numerous cases before this Court, is the country's largest single state-wide organization of employers, with a membership consisting of more than 19,000 companies reflecting all industries and representing every region of New Jersey. Founded in 1910, NJBIA strives to provide information, services, and advocacy for its member companies in an effort to build a more prosperous New Jersey. Its membership ranges from most of the 100 largest employers in New Jersey to thousands of small and medium-sized employers from every sector of the economy. A primary goal of NJBIA is to reduce the costs of doing business in New Jersey, including by limiting unwarranted litigation burdens, in order to promote economic growth for all New Jerseyans. See New Jersey Business & Industry Association, About Us, http://www.njbia.org/JoinNJBIA/About.aspx.

Since its founding in 1927, CIANJ has been dedicated to leading free enterprise advocacy to provide an economic climate that fosters business potential through education, legislative

vigilance, and membership interaction. CIANJ's primary objective is to make New Jersey a better place to live, work, and do business. CIANJ's nearly 1,000 members consist of Fortune 100 companies and sole proprietors representing a variety of enterprises and industries. See Commerce and Industry Association of New Jersey, About Us, http://www.cianj.org/about-us/. CIANJ also has been granted leave to appear as amicus curiae in several cases before this Court.

Created in 1911, the New Jersey Chamber actively supports legislation, regulation, and policy initiatives designed to lead to economic growth, job creation, and prosperity throughout the state. Members of the New Jersey Chamber represent every industry doing business in the state and include New Jersey's most prestigious and innovative companies. The New Jersey Chamber consistently works to improve New Jersey's business climate and provide its members with opportunities to promote and grow their businesses. See New Jersey Chamber of Commerce, About Us, http://njchamber.com/index.php/about-the-nj-chamber-of-commerce.

These proposed amici curiae intend to address the significant public policy issues implicated by an important question raised by this appeal: whether New Jersey should join the federal courts, 39 other state courts, and the District of

Columbia by adopting the Daubert standard to ensure that juries are presented with only reliable and reliably applied expert testimony. As explained in greater detail in this brief, the differences between the Daubert standard and the more relaxed, plaintiff-friendly approach for evaluating the admissibility of expert testimony that lower courts in New Jersey have applied are real and consequential. As a result, defendants in New Jersey product liability cases - particularly the research-based life sciences entities that contribute so heavily to New Jersey's economy[1] - typically must proceed to trial and defend against unreliable expert testimony that would not be admitted in courts that apply the Daubert standard due to serious methodological flaws and/or a failure to demonstrate that the testimony actually fits the facts of the case in a manner that is helpful to the jury.

Proposed amici curiae HINJ, NJBIA, CIANJ, and the New Jersey Chamber's expertise as chief representatives of New Jersey's business community, including its crucial life sciences industry, will provide this Court with a valuable perspective

[1] See Industry Cluster - Focus, State of N.J. Dep't of Labor & Workforce Development, http://lwd.dol.state.nj.us/labor/lpa/pub/empecon/empeconomy_index.html (reporting that, pursuant to the "Bio Pharma Life Science Study: Summer 2017," "[t]he vitality of the biopharmaceutical and life-sciences cluster in New Jersey is fundamental to the state's economic health with its well-paying jobs").

from those responsible for and dedicated to employment, economic prosperity, and innovation in New Jersey. Indeed, the issue in this case is one that this Court and its Committee on the Rules of Evidence have considered for nearly two decades, and these proposed amici curiae have frequently submitted comments for this Court's consideration in the rule-making process. This case finally presents this Court with the long-awaited adversarial controversy in which to resolve the issue once and for all. HINJ, NJBIA, CIANJ, and the New Jersey Chamber therefore respectfully request that this Court avail itself of their expertise and unique perspective, and grant this motion or leave to appear as amici curiae.

LEGAL ARGUMENT

I. THE DIFFERENCES BETWEEN DAUBERT AND THE APPROACH TO EXPERT TESTIMONY APPLIED BY MANY NEW JERSEY COURTS ARE DETRIMENTAL TO NEW JERSEY'S INNOVATORS, EMPLOYERS, AND JUDICIAL SYSTEM.

Sound public policy compels granting certification to decide whether to clarify New Jersey's varying expert-admissibility standards to a single, uniform rule that ensures the admission of only reliable and reliably applied scientific opinion testimony. New Jersey's life sciences industry - which includes many of the state's largest employers - is a community of research-based companies that are in the business of thorough, well-developed, science. Yet, paradoxically, New Jersey's rules governing the admissibility of expert opinion are applied in a

way that unfairly exposes those innovators to civil liability simply because the claims brought against them are novel challenges to their exhaustive, often FDA-approved, scientific developments.

Although this Court has emphasized that the gatekeeping analysis focuses on the reliability of an expert's methodology, see Landrigan v. Celotex Corp., 127 N.J. 404, 417 (1992) (requiring experts "to identify the factual bases for their conclusions, explain their methodology, and demonstrate that both the factual bases and the methodology are scientifically reliable"); accord Kemp ex rel. Wright v. State, 174 N.J. 412, 427 (2002), New Jersey courts have not formally adopted the Daubert factors, see Kemp, 174 N.J. 424, n.3, which give concrete guidelines to consider in determining whether the expert has demonstrated that the methodology actually is reliable and that it was applied reliably and in a manner that actually "fits" the facts of the case and helps the jury evaluate the specific case before it. See Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 591 (1993) (holding that in addition to satisfying federal reliability criteria, expert testimony must "fit" the facts and issues in the case, i.e., it must be "'sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute'" (quoting U.S. v. Downing, 753 F.2d 1224, 1242 (3d Cir. 1985))).

As a practical matter, the differences between Daubert and the standard applied in many New Jersey cases can be consequential, and demonstrate the very real risk of unfair imposition of tort liability on New Jersey's vital life sciences industry. Even though this Court's Kemp/Rubanick jurisprudence requires a type of gatekeeping akin to that required by Daubert, the practical reality is that it has not been applied that way.[2]

In fact, New Jersey courts have permitted the very same litigation-driven expert opinion testimony that courts applying Daubert routinely exclude, essentially holding that under New Jersey's standard it is for the jury to decide whether the plaintiffs' expert opinion really is "junk science." Compare In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig. ("Zoloft I"), 26 F. Supp. 3d 449, 465 (E.D. Pa. 2014) (excluding plaintiffs' epidemiology expert's testimony under Daubert in

[2] These proposed amici recognize that when considering this issue in the rule-making process, this Court has questioned whether there is something in Daubert that is not in Kemp. See Webcast of Supreme Court of New Jersey, Hearing on Proposed Amendments to N.J.R.E. 702, May 19, 2015, at 14:40-15:57 (Justice Patterson inquiring "What would you say is in Daubert that is not in Kemp?," and considering the significance of the much more extensive body of federal case law under Daubert compared to the paucity of reported New Jersey decisions applying Kemp), available at https://www.youtube.com/watch?v=CJfJiYbd6SI&feature=youtu.be). As discussed herein, these proposed amici respectfully submit that there are real-world consequences that arise out of the differences between the two standards, not the least of which is the admission of specious expert testimony in New Jersey courts that is precluded in cases pending in Daubert jurisdictions involving the same products and the same experts.

light of serious methodological flaws in case alleging SSRI medicine caused birth defects); In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig. ("Zoloft II"), 26 F. Supp. 3d 466, 480-81 (E.D. Pa. 2014) (excluding plaintiffs' embryology and pediatric cardiology experts for similar reasons), with Transcript of Motion Rulings at 21:17-22 (Aa21[3]), Capicotti v. Forest Research Institute, Inc., No. HUD-L-3895-14 (Law Div., May 27, 2016) (denying Kemp motions to bar very same experts in New Jersey SSRI birth defect litigation, and observing that "[u]nlike the Daubert factor-based approach, in New Jersey, the Trial Court need not consider factors as to whether the experts' hypotheses can be tested[,] whether the methodology is subject to peer review in publication, and whether the methodology has actually been accepted")[4]; and compare Jones v. AstraZeneca LP,

[3] "Aa" refers to Amici's Appendix accompanying this brief.

[4] In addition to denying Kemp motions to bar the same expert testimony that already had been barred in Daubert jurisdictions, the trial court in Capicotti also concluded with a rhetorical inquiry that underscores the ripeness of this matter for certification in order to clarify New Jersey trial courts' understanding and application of the crucial role they play in screening experts' novel causation testimony: "Despite the poetry [written about the court's gatekeeping function], the [c]ourt is left to ask the question as to what we, as trial [j]udges, are gatekeeping." Transcript of Motion Rulings at 39:22-24 (Aa39), Capicotti, supra, No. HUD-L-3895-14. "Rhetorical as this question might be," the court ruled that the filing of Kemp motions by both sides "essentially" asked the court "to thwart the ability of each side to present their individual cases to an impartial jury, and have the community decide the elements in dispute." Id. at 39:24 to 40:4 (Aa39-40).

No. 07C-01-420-SER, 2010 Del. Super. LEXIS 128, *3-4 (Aa59) (Del. Sup. Ct., Mar. 31, 2010) (excluding endocrinologist's specific-causation testimony under Delaware's Daubert standard because she "refused to expand the explanation of her methodology beyond her mantra that she had read 'everything' relating to the case and had applied her extensive training and experience to consider these materials and reach the conclusion that [the drug at issue] had caused [the plaintiff's] diabetes"), with Baker v. AstraZeneca Pharms. LP, No. MID-L-1099-07-MT (Law Div. Feb. 5, 2010) (slip op. at 1-25) (Aa70-94) (denying Kemp motion to exclude testimony of same endocrinologist in New Jersey mass tort involving same claims and same drug).[5]

Adoption of Daubert therefore would be sound public policy to ensure that real, reliable science - not junk science presented to lay juries - dictates whether to impose civil liability on New Jersey's research-based biopharmaceutical innovators. Like the examples discussed above, the Appellate Division's decision in this case is a stark reminder that New

[5] Although denying the motion to bar the endocrinologist's testimony, the trial court in Baker nevertheless suggested that its ruling could have been different if New Jersey applied the Daubert standard, because that rule "permits an expert to testify only 'if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the methods reliably to the facts of the case.'"). Baker, supra, No. MID-L-1099-07-MT (slip op. at 3 n.5 (quoting Fed. R. Evid. 702)) (Aa72).

Jersey finally should join the federal courts and almost all other state courts and the District of Columbia in adopting a standard that faithfully reflects a trial court's essential gatekeeping role.

Providing a clear definition of the contours of that gatekeeping role has never been more crucial to New Jersey's research-based life sciences industry -- and to the judiciary itself, for that matter. The approximately 20,000 pharmaceutical product liability cases already pending in New Jersey are likely to be joined by a substantial influx of additional cases brought by out-of-state plaintiffs, given the United States Supreme Court's recent decision holding that state courts lack specific jurisdiction over non-resident pharmaceutical companies for injuries allegedly sustained by plaintiffs in other states. See Bristol-Myers Squibb Co. v. Sup. Ct. of Cal., 137 S. Ct. 1773 (2017).

That influx is even more likely, and would be even more overwhelming to New Jersey's court system, if plaintiffs' lawyers continue to believe that New Jersey is a more hospitable environment for novel (even scientifically unsound) causation theories because, in their view, trial courts are not required to conduct a robust evaluation of the reliability and helpfulness of expert testimony. See, e.g., Letter from Arthur Luxenberg, Weitz & Luxenberg, P.C., to Plaintiffs' Counsel, at 2

(Aa96) (Dec. 29, 2004) (encouraging out-of-state plaintiffs' lawyers to file Vioxx lawsuits in New Jersey Superior Court because, unlike the Daubert or Frye standards, New Jersey's Rubanick standard does not permit the trial court to "determine the soundness even of the methodology, much less of the study itself").

II. THIS COURT SHOULD GRANT CERTIFICATION TO RESOLVE THE SIGNIFICANT, AND LONG-PENDING, ISSUE OF WHETHER NEW JERSEY SHOULD ADOPT DAUBERT AS THE STANDARD FOR ADMISSIBILITY OF EXPERT OPINION TESTIMONY IN NEW JERSEY CIVIL CASES.

This case presents this Court with the long-awaited opportunity to answer an important question that has remained unanswered for nearly two decades: whether New Jersey should join the federal courts, the District of Columbia, and nearly all other state courts [6] in adopting the more thorough and effective Daubert standard and factors for ensuring that only reliable expert evidence is admitted at trial.

The history of that pressing issue underscores the propriety of granting certification in this matter. This Court and its Committee on the Rules of Evidence have studied the question presented by this case several times dating back to its

[6] Thirty-nine of the fifty states and the District of Columbia have adopted Daubert as their standard for admissibility of expert opinion testimony. See Motorola Inc. v. Murray, 147 A.3d 751, 757 (D.C. Ct. App. 2016); Michael Morgenstern, Daubert v. Frye - A State-by-State Comparison, Expert Institute (Apr. 3, 2017), available at, https://www.theexpertinstitute.com/daubert-v-frye-a-state-by-state-comparison/.

2000-2002 term, but this Court has yet to provide a conclusive answer. Despite substantial commentary from all sides, recommendations from the Committee, and a hearing before this Court - and despite decades of well-developed case law explaining and applying the Daubert reliability criteria - New Jersey's Rule 702 has remained unchanged and its courts remain bound by a standard that eschews a true "gatekeeping" assessment of actual reliability and helpfulness to the factfinder.

The Committee's first examination of the issue in its 2000-2002 term yielded the Committee's decision not to recommend any changes to N.J.R.E. 702 at that time, given the relative nascence of Federal Rule of Evidence 702's codification of Daubert. Returning to the issue in its 2007-2009 term, the Committee issued a nineteen-page report and recommended that this Court update N.J.R.E. 702 to require that "the basis for the testimony [be] generally accepted or otherwise shown to be reliable" before it would be admissible. These proposed amici and other stakeholders submitted comments opposing that recommendation due to its vagueness and lack of explicit criteria for ascertaining whether the proffered opinion is "otherwise shown to be reliable." This Court declined to adopt the Committee's 2009 recommendation, thereby leaving in place the New Jersey rule that mirrored the pre-2000 version of the federal rule.

The Committee again considered the issue in its 2011-2013 term upon receipt of amendment proposals by various members of New Jersey's medical, biopharmaceutical, and business communities. In response to the Committee's request for direction concerning this Court's amenability to further study of the issue, this Court instructed the Committee to prepare a report on whether N.J.R.E. 702 and related case law have led to application of inconsistent standards by trial courts and/or turned New Jersey into a magnet for a disproportionate number of negligence and mass tort cases that more appropriately belong in other jurisdictions. In its 2015 report, the Committee stated that its "fact-finding" did not indicate that trial courts were applying inconsistent standards and that there was "no definite or conclusive evidence" that current New Jersey law attracted a disproportionate number of personal injury and mass tort cases from other states.[7] Given the limited scope of its charge,

[7] The Committee made that statement despite the known reality that plaintiff-side personal injury law firms advertise New Jersey as a plaintiff-friendly jurisdiction due to an expert-admissibility standard that would permit specious causation opinion testimony that would be barred in other jurisdictions under the Daubert standard. See, e.g., Letter from Arthur Luxenberg, Weitz & Luxenberg, P.C., to Plaintiffs' Counsel, supra, at 2 (Aa96). Moreover, although referring to an absence of "definite or conclusive evidence," the Committee acknowledged that approximately 93% of the plaintiffs in cases filed against New Jersey-based pharmaceutical manufacturers and pending in New Jersey's Multi-County Litigation system reside outside of New Jersey. See 2013-2015 Report of the Sup. Ct. Comm. on the Rules of Evid., Part II, at 15, 108 (Jan. 15, 2015), available at

however, the Committee did not evaluate the crucial question of whether current New Jersey law has allowed the admission of unreliable expert testimony.

In May 2015, this Court held a hearing on the issues and arguments raised in the Committee's report and in the comments submitted in response by these proposed amici and other stakeholders. During that hearing, this Court expressed concern that its rule-making procedure was not a suitable vehicle for modification or amendment of New Jersey's expert-admissibility standard, and instead suggested that any potential change should await the appropriate case so that it may be decided in an adversarial context and with amici curiae presenting arguments on both sides of the issue.[8] This is that case.

Certification is warranted because this "appeal presents a question of general public importance which has not been but should be settled by the Supreme Court," "calls for an exercise of the Supreme Court's supervision," and because "the interest of justice requires" a ruling from this Court. R. 2:12-4. This

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https://www/njcourts.gov/courts/assets/supreme/reports/2015/evidence22015.pdf.

[8] See, e.g., Webcast of Supreme Court of New Jersey, Hearing on Proposed Amendments to N.J.R.E. 702, May 19, 2015, at 22:30-22:45 (Chief Justice Rabner inquiring whether the more suitable approach would be to await an appeal that raises the issue and "consider it in an adversarial context" with amici curiae appearing in support of each side) (available at https://www.youtube.com/watch?v=CJfJiYbd6SI&feature=youtu.be).

Court now has the opportunity to address in a zealously litigated appeal an issue of significant public importance that has been considered by this Court and its Rules Committee without resolution for nearly two decades. In a state whose citizens rely so heavily on its substantial community of innovators, the importance of ensuring a fair and reliable expert-admissibility standard in cases that rise and fall on scientific opinion testimony cannot be understated.

Accordingly, this Court should grant Roche's Petition for Certification and decide whether New Jersey will join the federal courts and the majority of its sister state courts in adopting a standard that ensures admissibility of only reliable and reliably applied expert opinion testimony that "fits" the facts and issues involved in the case.

CONCLUSION

For the foregoing reasons, proposed amici curiae HealthCare Institute of New Jersey, New Jersey Business and Industry Association, Commerce and Industry Association of New Jersey, and New Jersey Chamber of Commerce respectfully request that this Court grant them leave to appear as amici curiae, grant Roche's Petition for Certification, reverse the Appellate Division's decision, and adopt the federal Daubert standard as New Jersey's test for the admissibility of expert opinion testimony in civil cases. Proposed amici curiae also respectfully request leave to file a brief on the merits of this appeal in the event their motion for leave to appear is granted and Certification is granted.

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