SUPREME COURT OF NEW JERSEY

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| IN RE: ACCUTANE LITIGATION | DOCKET NO.: 079958<br><br>SUPERIOR COURT OF NEW JERSEY<br>APPELLATE DIVISION<br>DOCKET NOS.: A-4698-14T1<br>A-0910-16T1<br><br>Sat Below:<br>Hon. Susan L. Reisner<br>Hon. Ellen L. Koblitz<br>Hon. Thomas W. Sumners, Jr.<br><br>On Appeal from Superior Court,<br>Law Division, Atlantic County<br>Case No. 271<br>Sat Below:<br>Hon. Nelson C. Johnson, J.S.C.<br><br>CIVIL ACTION |

**AMICUS CURIAE BRIEF AND APPENDIX ADDRESSING DEFENDANTS-PETITIONERS, HOFFMAN-LA ROCHE INC. AND ROCHE LABORATORIES INC.'S PETITION FOR CERTIFICATION**

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## STATEMENT OF INTEREST

Amici consist of many of New Jersey's leading employers and innovators, who span the manufacturing, life sciences, hospital, and communications sectors and collectively employ over 62,000 people in New Jersey.

As companies who operate in New Jersey and frequently face lawsuits filed in its courts, we have a very real interest in fair, clear, and consistent standards for determining the admissibility of expert scientific testimony. The admission or exclusion of such expert testimony is often dispositive in the cases brought against us. Moreover, such rulings can have profound implications for the utility of and the market for our products outside the courtroom and well beyond New Jersey.

## INTRODUCTION

The fair administration of justice stands as a bedrock principle of our judiciary. As companies who have chosen to locate commercial activities in New Jersey, we may be subject to jurisdiction in its courts by virtue of that choice. Accordingly, we have a strong stake in the judicial process and its ability to fairly pursue the truth regarding claims against us. An essential component of a fair pursuit of truth is our ability at an early stage in the proceedings to challenge cases that lack scientific merit -- rather than having to proceed with multiple individual jury trials resulting in potentially

inconsistent verdicts. Most significantly, we should not face materially different standards in New Jersey courts than we face elsewhere when it comes to the quality of scientific evidence that must underlie an expert's opinion.

The Appellate Division's decision below contravenes those principles by allowing experts whose testimony has a tenuous relationship with actual science under a standard that is substantially out of step with the Daubert standard adopted by federal and most other states' courts. Compare Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996) ("The courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it."). The Appellate Division erected an unduly high bar to the exclusion of proffered expert testimony at odds with science offered by otherwise well-qualified experts. The Appellate Division's decision thereby incentivizes litigants to seek refuge in New Jersey for claims that could not survive scrutiny elsewhere. We therefore urge the Court to grant Defendant's Petition and to clarify that opinions that fail to flow from a reliable, scientifically-grounded methodology -- even when offered by

well-credentialed experts -- are no more admissible in New Jersey than they are elsewhere.[1]

## I. Courts Applying New Jersey's Standards for Expert Admission Are Out of Step with the Rest of the Country

This case presents the question of "whether, in the face of several epidemiological studies that do not demonstrate a statistically significant relationship between taking Accutane and developing Crohn's disease, plaintiffs can continue to rely on other types of evidence . . . to prove general causation." SCa75. The Appellate Division erroneously answered that question in the affirmative, holding that despite the uniform conclusion of nine epidemiology studies -- "the best evidence of general causation in a toxic tort case," Norris v. Baxter Healthcare Corp., 397 F.3d 878, 882 (10th Cir. 2005) -- that Accutane is not associated with Crohn's disease, such evidence

[1] Under this Court's existing precedents, judges are required to scrutinize an expert's methodology much more closely than the Appellate Division did here. See Landrigan v. Celotex Corp., 127 N.J. 404, 417 (1992) (expert's methodology must be "sound," "well-founded," and "supported by some expert consensus in the appropriate field"); Rubanick v. Witco Chem. Corp., 125 N.J. 421, 447 (1991) ("the data or information used" must have been "soundly and reliably generated" and be "of a type reasonably relied on by comparable experts in the particular field"). Moreover, although this Court declined more than a decade ago "to incorporate the Daubert factors into N.J.R.E. 702." Kemp ex rel. Wright v. State, 174 N.J. 412, 424 n.3 (2002), members of this Court have since expressed an interest in re-considering the adoption of Daubert's factors in "an adversarial context." Aa3-6, Tr. of 5/19/2015 Rules Hearing 43 (Rabner, C.J.). This case provides just that opportunity.

was "not a conclusive bar to plaintiffs' case," SCa75. One need only compare the Appellate Division's answer with the decisions of federal and state courts overseeing Accutane litigation outside of New Jersey, to know that New Jersey's standard as applied here is inconsistent with federal law and the law of its sister states.[2] Those decisions have repeatedly rejected as unreliable the very types of scientific claims that the Appellate Division allowed. See In re Accutane Prod. Liab., 511 F. Supp. 2d 1288, 1303 (M.D. Fla. 2007), aff'd sub nom., Rand v. Hoffmann-La Roche Inc., 291 F. App'x 249, 251 (11th Cir. 2008); In re Accutane Prod. Liab., No. 804-MD-2523-T-30TBM, 2009 WL 2496444, at *2 (M.D. Fla. Aug. 11, 2009), aff'd, 378 F. App'x 929 (11th Cir. 2010); Freeman v. Hoffmann-La Roche, Inc., No. CI 10-9312802, 2017 WL 385440, at *22 (Neb. Dist. Ct. Jan. 23, 2017).

This disparity is further demonstrated by comparing the decision below, review of which we seek, to those in two litigations involving analogous science: the Parlodel and silicone breast implant litigations. In each instance, courts repeatedly rejected the very methodology the Appellate Division

[2] Thirty-nine states have adopted Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993). See Michael Morgenstern, Daubert v. Frye -- A State-by-State Comparison, Expert Institute (Apr. 3, 2017), https://www.theexpertinstitute.com/daubert-v-frye-a-state-by-state-comparison; see also Fed. R. Evid. 702.

allowed here -- disregard of strong epidemiology in favor of less reliable forms of evidence.

Parlodel was approved by the FDA in 1980 to prevent post-partum lactation in women who elected not to breast-feed. In 1995, after Parlodel's manufacturer had received reports of women who suffered strokes while taking the medicine, the FDA withdrew Parlodel's post-partum lactation indication. Lawsuits against the manufacturer quickly followed. By 2001, however, four epidemiological studies had examined the putative association and "either show[ed] no relationship or a negative relationship" between Parlodel and stroke. Siharath v. Sandoz Pharm. Corp., 131 F. Supp. 2d 1347, 1358 (N.D. Ga. 2001), aff'd sub nom. Rider v. Sandoz Pharm. Corp., 295 F.3d 1194 (11th Cir. 2002).

Plaintiffs' experts sought to explain away the uniform epidemiology by mounting criticisms of the Parlodel studies and supplanting them with reliance on case reports, animal studies, and other data. Federal court after federal court held the experts' approach unreliable. See Soldo v. Sandoz Pharm. Corp., 244 F. Supp. 2d 434, 537-48 (W.D. Pa. 2003); Caraker v. Sandoz Pharm. Corp., 188 F. Supp. 2d 1026, 1032-37 (S.D. Ill. 2001) (finding experts unreliable who "generally attacked the existing epidemiological studies as fundamentally flawed, while, at the same time, selectively using data (which they admit is not

statistically significant)" -- along with case reports and animal studies -- "to support their opinions"); Siharath, 131 F. Supp. 2d at 1359-64, 1366-69 ("Plaintiffs' reliance upon case reports as a substitute for epidemiology cannot withstand the scrutiny that Daubert requires."; "[T]he Court must conclude that this [animal] study is not sufficiently reliable to make up for the absence of epidemiological studies."); Glastetter v. Novartis Pharm. Corp., 107 F. Supp. 2d 1015, 1028-31, 1041-42, 1044 (E.D. Mo. 2000) (holding that experts could not survive Daubert by "attack[ing] defendant's studies" and instead pointing to case reports and animal studies), aff'd, 252 F.3d 986 (8th Cir. 2001).

Similarly, thousands of lawsuits were filed against manufacturers of silicone breast implants after the FDA placed a moratorium on their manufacture due to reports hypothesizing a link to various autoimmune diseases. See Aa32-37, Kristin E. Schleiter, Silicone Breast Implant Litigation, 12 AMA J. Ethics 389, 391 (2010) (noting that 12,359 cases had been filed against a single manufacturer by the end of 1993). By 1998, the results from seventeen published epidemiological studies uniformly failed to show an association with any autoimmune disease. See In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1227 (D. Colo. 1998). In arguing for causation, Plaintiffs' experts "completely ignored or discounted" this epidemiology in favor of

case reports and animal studies. Norris, 397 F.3d at 884-85; see also Allison v. McGhan Med. Corp., 184 F.3d 1300, 1313-14 (11th Cir. 1999). Their testimony was properly excluded. Norris, 397 F.3d at 886, 887 n.6 ("Overcoming this large body of epidemiology requires more than simply stating that the studies are wrong."; "Non-epidemiological studies, singly or in combination, are not capable of proving causation in human beings in the face of an overwhelming body of contradictory epidemiological evidence."); Meister v. Med. Eng'g Corp., 267 F.3d 1123, 1132 (D.C. Cir. 2001) ("Ultimately, it is [plaintiff's] experts' heavy reliance on case reports that is [their] undoing. Although case reports may suffice under some circumstances, here the defendants introduced expert testimony that was supported by a uniform body of evidence including epidemiological studies failing to establish a causal link between silicone breast implants and connective tissue disease."); Allison, 184 F.3d at 1314 ("[Plaintiff] does not explain why the results of these animal studies should trump more than twenty controlled epidemiological studies of breast implants in humans which have found no valid increased risk of autoimmune disease."; "[I]n the face of controlled, population-based epidemiological studies which find otherwise, these case studies pale in comparison."); Grant v. Bristol-Myers Squibb, 97

F. Supp. 2d 986, 992 (D. Ariz. 2000); Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1406 (D. Or. 1996).

As the Parlodel and breast implant litigations demonstrate, federal courts do not hesitate to exclude the opinions of otherwise well-qualified experts[3] -- even in mass torts involving thousands of claimants -- when those experts rely on unreliable forms of evidence to argue causation. Indeed, these Plaintiffs' experts would be subject to challenge in federal court on at least four grounds identified by the trial court, but the Appellate Division gave Plaintiffs' experts a pass on all four:

**1) The Plaintiffs' experts' opinions are based on unreliable sources:** The Appellate Division faulted the trial court for rejecting the experts' reliance on "scientific evidence other than epidemiological studies," SCa4, and permitted the experts to overcome contrary epidemiology and testify to a jury using statistically insignificant results, SCa26-27, 36-37, 38-39, 68, anecdotal case reports and company ratings thereof (so-called causality assessments), SCa23-24, 32-

[3] Under Daubert, "the relevance and reliability inquiries . . . are separate from the threshold question of whether a witness is qualified." Nimely v. City of N.Y, 414 F.3d 381, 396 (2d Cir. 2005); see also, e.g., Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1336 (11th Cir. 2010) ("[A]t all times the district court must still determine the reliability of the opinion, not merely the qualifications of the expert who offers it. . . . To hold otherwise would encourage trial courts to simply rubber stamp the opinions of expert witnesses once they are determined to be an expert.").

34, and animal studies involving animals incapable of developing Crohn's, SCa39-40. None of those sources pass muster under Daubert, particularly where contradicted by an extensive body of epidemiologic literature:

- "[The expert's] methodology involved a rejection of the importance of replicated statistically significant epidemiological findings demonstrating an association . . . , [and] substituting a novel technique of drawing conclusions by examining 'trends' (often statistically non-significant) across selected studies. Her methods are not scientifically sound. In re Zoloft (Sertraline Hydrochloride) Prod. Liab. Litig., 26 F. Supp. 3d 449, 465 (E.D. Pa. 2014), aff'd, 858 F.3d 787 (3d Cir. 2017).

- "[S]tudies without statistical significance are insufficient to support a causation opinion." In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig., 174 F. Supp. 3d 911, 926 (D.S.C. 2016).

- "Statistically insignificant results do not constitute proof" of causation. Dunn v. Sandoz Pharm. Corp., 275 F. Supp. 2d 672, 681 (M.D.N.C. 2003).

- "Uncontrolled anecdotal information offers one of the least reliable sources to justify opinions about both general and individual causation." McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1250 (11th Cir. 2005).

- "Case reports are not reliable evidence of causation." In re Mirena IUD Prod. Liab. Litig., 202 F. Supp. 3d 304, 325 (S.D.N.Y. 2016).

- "[T]he causality assessments . . . constitute a synopsis of complaints received by Roche from various reporters (a patient, parent, doctor, or attorney) regarding their subjective beliefs as to the causes of particular ailments. . . . The 'causality assessments' do not support an opinion of causation." Accutane, 511 F. Supp. 2d at, 1297-98.

- "[A]nimal studies cannot overcome the contrary results of human epidemiological studies." In re Zoloft (Sertraline

Hydrochloride) Prod. Liab. Litig., 176 F. Supp. 3d 483, 494 (2016).

- "[T]he theory of plaintiff's expert witnesses that they can directly extrapolate from experimental animal studies without supportive positive human studies to opine as to causation in humans is one that has an extraordinarily high rate of error . . . , and this fact weighs against the admissibility of opinions based upon those methodologies." Wade-Greaux v. Whitehall Labs., Inc., 874 F. Supp. 1441, 1480 (D.V.I.), aff'd, 46 F.3d 1120 (3d Cir. 1994).

**2) The Plaintiffs' experts cherry-picked data:** The trial court faulted the experts for relying on studies that supported their opinions and ignoring the rest. For example, the trial court faulted the experts for embracing results from a single epidemiologic study showing a statistically insignificant "trend" toward a positive association between Accutane and Crohn's, but discarding the four studies trending toward a negative association. PSCa22-23. And it faulted the experts for relying on a twenty-six person study to prove that Crohn's has a prolonged prodrome but ignoring a much larger study reaching contrary results. PSCa10-11, 22-23, 28. Daubert similarly prohibits such unbridled advocacy:

- "The fact that [the expert's] conclusions are drawn from trends she observed in a self-selected subset of supportive studies, not the totality of the epidemiological evidence, further underscores her problematic methodology." Zoloft, 26 F. Supp. 3d at 461-62.

- "This Court rejects the plaintiffs' experts opinions inasmuch as they rely on selective data from epidemiological studies." Caraker v. Sandoz Pharm. Corp., 172 F. Supp. 2d 1046, 1049 (S.D. Ill. 2001).

- "[The expert] has seen fit to 'pick and chose' [sic] from the scientific landscape and present the Court with what he believes the final picture looks like. This is hardly scientific." Lust v. Merrell Dow Pharms., Inc., 89 F.3d 594, 596 (9th Cir. 1996).

- "[C]herry-picking of data is unreliable and 'fails to satisfy the scientific method and Daubert.'" Lipitor, 174 F. Supp. 3d at 931-32.

- "[C]herry-picking observational studies that support [an expert's] conclusion and rejecting or ignoring the great weight of the evidence that contradicts his conclusion . . . does not reflect scientific knowledge, is not derived by the scientific method, and is not 'good science;' it is therefore inadmissible." In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007).

- "[A]ny theory that fails to explain information that otherwise would tend to cast doubt on that theory is inherently suspect," and "courts have excluded expert testimony 'where the expert selectively chose his support from the scientific landscape.'" In re Rezulin Prod. Liab. Litig., 369 F. Supp. 2d 398, 425 & n.164 (S.D.N.Y. 2005) (citation omitted).

**3) The Plaintiffs' experts reached conclusions contrary to the studies on which they relied:** The trial court faulted the experts for relying on the preliminary results of a study -- i.e., the raw results prior to adjustment to account for potential confounding variables -- to contradict the conclusion of the study's author (based on the final, adjusted results) that Accutane exposure "does ***not*** appear to confer risk for Crohn's disease." PSCa27-28. Daubert similarly prohibits experts from using studies to contradict the conclusions of those who conduct them:

- "'It is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation had been proven.'" Happel v. Walmart Stores, Inc., 602 F.3d 820, 826 (7th Cir. 2010) (quoting Huss v. Gayden, 571 F.3d 442, 459 (5th Cir. 2009)).

- "[W]hen an expert relies on the studies of others, he must not exceed the limitations the authors themselves place on the study. That is, he must not draw overreaching conclusions." Accutane, 2009 WL 2496444, at *2.

- "[The expert's] inclination to draw overreaching conclusions from self-limiting medical articles[] show[s] the speculative nature of his opinions." McClain, 401 F.3d at 1247.

- An expert must not "draw[] impermissibly speculative conclusions from the[] studies that exceed the limitations the authors themselves placed on these studies." In re Mirena IUD Prods. Liab. Litig., 169 F. Supp. 3d 396, 431 (S.D.N.Y. 2016).

- "The case law . . . warns against use of medical literature to draw conclusions not drawn in the literature itself. . . . Reliance upon medical literature for conclusions not drawn therein is not an accepted scientific methodology. Rutigliano v. Valley Bus. Forms, 929 F. Supp. 779, 785 (D.N.J. 1996), aff'd sub nom., Valley Bus. Forms v. Graphic Fine Color, Inc., 118 F.3d 1577 (3d Cir. 1997).

**4) The Plaintiffs' experts gave opinions inside the courtroom that they were unwilling to express to their peers:** The trial court found it highly significant that these experts declined to subject the opinions they offered in this case -- that Accutane use causes Crohn's disease -- to the scrutiny of their peers by publication or any other medium. PSCa17. Under Daubert, such failure weighs against reliability and thus admissibility. See, e.g., Zoloft, 26 F. Supp. 3d at 481; In re

Bausch & Lomb, Inc. Contact Lens Sol. Prod. Liab. Litig., No. CIV A 2:06MN77777DCN, 2009 WL 2750462, at *11 (D.S.C. Aug. 26, 2009); Rezulin, 369 F. Supp. 2d at 424. And with good reason: other experts in the field are best qualified to assess the scientific reliability and validity of their conclusions.

## II. New Jersey's Standards for Expert Admission Are Critically Important to Us

Few areas of law present greater litigation risk to us than products liability. According to one estimate, forty-five percent of companies faced products liability litigation in 2016. The Product Liability Litigation Outlook, BTI Consulting Group (Sept. 27, 2016), http://www.bticonsulting.com/themadclientist/2016/9/27/the-product-liability-litigation-outlook. Last year alone, plaintiffs filed 55,283 products liability lawsuits in federal court, representing more than one quarter of all non-prisoner civil cases filed. See Admin. Office of the U.S. Courts, Table C-2A: U.S. District Courts--Civil Cases Commenced, by Nature of Suit, During the 12-Month Periods Ending September 30, 2012 Through 2016, http://www.uscourts.gov/sites/default/files/data_tables/jb_c2a_0930.2016.pdf. Today, out of 230 pending federal multidistrict litigation proceedings, seventy-three involve products liability claims. See U.S. Judicial Panel on Multidistrict Litig., MDL Statistics Report - Distribution of

Pending MDL Dockets by District (Aug. 15, 2017), http://www.jpml.uscourts.gov/sites/jpml/files/Pending_MDL_Dockets_By_District-August-15-2017.pdf. Even that statistic understates the magnitude of individual products liability cases, which constitute 87% of all individual actions within the pending MDLs -- 110,094 cases in total. See id. In New Jersey, the nearly 20,000 individual products liability cases pending in Multi-County Litigations (MCLs) represent nearly one quarter of all civil litigation in the state. See N.J. Judiciary, Multicounty Litigation, https://www.judiciary.state.nj.us/attorneys/mcl/index.html (last visited Aug. 26, 2017); N.J. Judiciary, Annual Report 2014-2015, at 70, https://www.judiciary.state.nj.us/public/assets/annualreports/AnnualReportCY15_web.pdf.

The cost of defending against these suits is immense. Over the last two years, companies spent nearly $4 billion defending against products liability suits.[4] The direct expense of this volume of cases is matched by their impact beyond the courtroom. Even when they lack merit, products liability suits have the potential to cause significant reputational harm, thereby

[4] See BTI Consulting Grp., BTI Litigation Outlook 2017: Changes, Trends and Opportunities for Law Firms: Executive Summary 7 (2016), https://static1.squarespace.com/static/51bb6aabe4b0820e6e778761/t/57d2c2fb8419c276f91cbc0a/1473430269664/BTI_Litigation_Outlook_2017_Executive_Summary.pdf.

adversely affecting the very real public benefit derived from the products. See, e.g., Memorandum from Public Opinion Strategies to Institute for Legal Reform 2 (June 13, 2017), available at http://www.instituteforlegalreform.com/uploads/sites/1/2017_ILR_Rx_Drug_Survey_Key_Findings_D1c.pdf (reporting survey result that "[o]ne-in-four people who see an actual trial lawyer ad regarding a medicine they currently take say they would immediately stop taking the medicine without consulting their doctor").

Almost all products liability cases involve expert testimony. Indeed, "the substantive law across all . . . jurisdictions holds . . . that where a causal link is beyond the knowledge or expertise of a lay jury, expert testimony is required to establish causation." Mirena, 202 F. Supp. 3d at 310 (citation and quotation marks omitted); see also, e.g., In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Prod. Liab. Litig., 227 F. Supp. 3d 452, 469 (D.S.C. 2017) ("While the specific language used by courts vary to some degree, all jurisdictions require expert testimony at least where the issues are medically complex and outside common knowledge and lay experience."); Kelly v. Borwegen, 95 N.J. Super. 240, 2444 (Super. Ct. App. Div. 1967) (expert testimony is needed where the harm allegedly suffered is "not obviously related to an identifiable injury"). Because expert testimony

is required in all but the simplest products liability cases, the standards governing the admissibility of expert testimony are of immense importance to us and to the public.

## III. Fairness Dictates that New Jersey Courts Exclude Unreliable Expert Testimony

Just as fairness demands that a plaintiff whose case is grounded in science be allowed to present his case to a jury, so too does fairness require that cases lacking in scientific validity get resolved at an earlier stage. Two factors make this especially important in products liability cases. First, expert causation testimony frequently is highly technical, and the adversarial setting can be poorly suited to resolving disputes between well-credentialed experts. See Rubanick, 125 N.J. at 433 (recognizing "the dangers of allowing the jury to consider expert testimony the reliability of which has not been sufficiently demonstrated"); Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 595 (1993) ("Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it."). Second, the potentially large number of products liability cases alleging the same injury makes it critical that there be a mechanism for weeding out and dismissing product liability cases that are not supported by science. The harm that results when a single case goes to trial based on junk science is magnified exponentially when

potentially thousands of cases are tried to verdict, with the risk that juries address the same science inconsistently and incorrectly.

No rational approach to products liability would make manufacturers the insurers of injuries that their products did not in fact cause. Yet the Appellate Division's decision will have precisely that effect, and thus this Court should grant the Petition and bring New Jersey law in line with federal courts and the vast majority of states that have adopted the Daubert standard for admission of expert scientific testimony.

Dated: September 20, 2017

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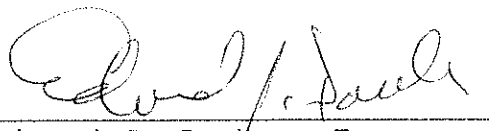
By: 
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