SUPREME COURT OF NEW JERSEY

IN RE: ACCUTANE LITIGATION	DOCKET NO.: 079958 ON PETITION FOR CERTIFICATION FROM SUPERIOR COURT OF NEW JERSEY, APPELLATE DIVISION Docket Nos.: A-4698-14T1 & A-0910-16T1 Sat Below: Hon. Susan L. Reisner Hon. Ellen L. Koblitz Hon. Thomas W. Sumners, Jr. On Appeal from: Superior Court of New Jersey Law Division, Atlantic County Case No. 271 Sat Below: Hon. Nelson C. Johnson, J.S.C. CIVIL ACTION

BRIEF OF AMICI CURIAE AMERICAN MEDICAL ASSOCIATION, MEDICAL SOCIETY OF NEW JERSEY, AMERICAN ACADEMY OF DERMATOLOGY, SOCIETY FOR INVESTIGATIVE DERMATOLOGY, AMERICAN ACNE AND ROSACEA SOCIETY, AND DERMATOLOGICAL SOCIETY OF NEW JERSEY IN SUPPORT OF PETITION FOR CERTIFICATION OF DEFENDANTS-PETITIONERS HOFFMAN-LA ROCHE INC. AND ROCHE LABORATORIES INC.

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PRELIMINARY STATEMENT

Medicine and the law are inextricably intertwined. The law relies upon expert testimony by physicians and other medical professionals to establish facts in disputes between litigants in health and science-related cases. The medical profession depends upon the courts to adhere to scientific principles so that verdicts are based on sound science. Medical testimony based on junk science reaches far beyond the case at hand and infects physicians' offices nationwide, skewing patient care away from proven treatments. Patients, physicians, and our system of justice all suffer when courts permit outlier experts to confuse juries with disproven theories based on scientifically unsound methodologies that contradict peer-reviewed medical studies.

Isotretinoin (trade name Accutane®) is the only medication that effectively treats severe nodular recalcitrant acne, a painful and often disfiguring condition. The theory that isotretinoin increases the risk of inflammatory bowel disease ("IBD") has been debunked by numerous peer-reviewed studies. Two studies have shown that isotretinoin may decrease the risk of IBD. The trial court properly applied this Court's precedents and excluded testimony from Plaintiffs' witnesses, whose methodologies failed to adhere to scientific principles. Amici Curiae urge the Court to grant Defendants' petition for certification and reverse the Appellate Division's decision to admit

the testimony of Plaintiffs' expert witnesses.

BACKGROUND

Most acne can be treated with a variety of medications, both prescription and over-the-counter. The most severe form of acne is known as nodular acne, which consists of large cysts up to several centimeters in diameter and can appear on the face, neck, shoulders, back, and upper arms. They can be painful and can leave permanent, disfiguring scars.

Isotretinoin is often the only medication that can successfully treat nodular acne and is vitally important to patients who suffer from this condition. Isotretinoin has been approved in this country since 1982. Bernstein et al., Isotretinoin Is Not Associated With Inflammatory Bowel Disease: A Population-Based Case-Control Study, 104 Am. J. Gastroenterology 2774, 2774 (2009). It cures approximately 90% of severe recalcitrant nodular acne and significantly reduces scarring. The most serious known side effect is its potential to cause fetal malformations, id. at 2774, and for this reason, its use is tightly controlled. See iPLEDGE, About iPLEDGE (2005).[1]

ARGUMENT

Numerous peer-reviewed epidemiological studies have refuted any link between isotretinoin and IBD. By permitting Plaintiffs' witnesses to attack this scientific consensus with anec-

[1] https://www.ipledgeprogram.com/AboutiPLEDGE.aspx.

dotal evidence, the Appellate Division flouted well-established scientific principles and the precedents of this Court. The Appellate Division's decision will open New Jersey courtrooms to what has been called "junk science," Landrigan v. Celotex Corp., 127 N.J. 404, 417 (1992), which in turn will harm patient care and the ethical standards of the medical community.

I. Peer Reviewed Medical Literature Shows No Statistically Significant Association Between Isotretinoin and IBD

Beginning in the 1980s, some physicians reported that isotretinoin users occasionally developed IBD. Rashtak et al., Isotretinoin Exposure and Risk of Inflammatory Bowel Disease, 150(12) JAMA Dermatology 1322, 1323 (2014). IBD includes both Crohn's Disease ("CD"), which is at issue in this appeal, and ulcerative colitis ("UC"). Correlation, of course, is not necessarily causation. Although the question of isotretinoin's impact on IBD warranted additional study to determine whether the perceived correlation was due to isotretinoin or merely coincidental, to date, the overwhelming weight of epidemiological evidence shows that isotretinoin does not increase the risk of IBD.

A. Epidemiological Studies Stand Above Case Reports in the Hierarchy of Evidence

Not all evidence is created equal. A "fundamental principle of evidence-based medicine," among others, "is that the strength of medical evidence supporting a [theory of medical association] is hierarchical." Fed. Judicial Ctr., Reference Man-

ual on Scientific Evidence 723 (3d ed. 2011). The top of that hierarchy—the best evidence—includes randomized clinical trials and epidemiologic studies, while the "bottom" includes "unsystematic clinical observations" or case reports. Id. at 723-24.

The utility of the different types of evidence varies with the state of scientific knowledge on a given issue. Although case reports, for example, may signal an association between a medication and a subsequent ailment, that association should be "later confirmed with larger or controlled epidemiological studies." Id. at 724. The principle reflected by the hierarchy of evidence—that good science should rely on the best available data, and build from less reliable evidence—is well-established and adhered to by scientists and courts alike.[2]

Therefore, the results of epidemiological studies may confirm or refute a signal initially raised by case reports. In the past decade, numerous epidemiological studies have established that isotretinoin use does not increase the risk of IBD.

B. Studies of Patients With IBD Show No Increased Risk From Isotretinoin

A team from the University of Manitoba linked data derived

[2] See, e.g., Norris v. Baxter Healthcare Corp., 397 F.3d 878, 881-87 (10th Cir. 2005) (affirming preclusion of expert testimony that emphasized case reports over epidemiologic evidence); Raynor v. Merrell Pharm. Inc., 104 F.3d 1371, 1375-77 (D.C. Cir. 1997) (finding that it is not "methodologically sound to draw an inference that a drug causes human birth defects from chemical structure, in vivo animal studies, and in vitro studies, when epidemiological evidence is to the contrary").

from the universal health insurance plan in Manitoba, Canada with a database of drugs prescribed to patients in the provincial health care system since 1995. Bernstein, supra, at 2775. The authors concluded that "[t]here was no statistical difference in isotretinoin usage before or after IBD diagnosis between IBD cases and controls." Id. at 2776.

Crockett studied cases extracted from a large database of health insurance claims. Crockett et al., Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Case-Control Study, 105(9) Am. J. Gastroenterology 1986, 1986 (2010). The study found that isotretinoin was associated with UC but not CD. Ibid. However, the association with UC in this study was subsequently criticized because the study identified far fewer IBD cases than would be expected in a population this size, which suggests a selection bias. Racine et al., Isotretinoin and Risk of Inflammatory Bowel Disease: A French Nationwide Study, 109 Am. J. Gastroenterology 563, 566 (2014). Also, the Crockett study did not control for "potential confounding factors, such as acne or systemic antibiotic use," which "is particularly important because a recent population-based cohort study suggested an association between IBD and acne and not with isotretinoin per se." Rashtak, supra, at 1323; see also Margolis et al., Potential Association Between the Oral Tetracycline Class of Antimicrobials Used to Treat Acne and Inflammatory Bowel Disease,

105 Am. J. Gastroenterology 2610, 2614 (2010).[3]

Etminan found no increased risk for IBD in patients who used isotretinoin. Etminan et al., Isotretinoin and Risk for Inflammatory Bowel Disease, 149(2) JAMA Dermatology 216, 216 (2013). Etminan queried a database overlapping with the one used by Crockett (and containing health insurance claims for 68 million individuals) to identify patients with IBD. Id. at 217. The authors also conducted a meta-analysis of several studies of isotretinoin and IBD. They concluded that "[g]iven the high burden of psychological stress associated with cystic acne in adolescents and young adults, clinicians should not be discouraged from prescribing isotretinoin therapy to their patients owing to concerns of an unproven association with IBD." Id. at 220 (footnotes omitted).

Sivaraman studied 509 gastroenterology patients from ages 14 to 45. Sivaraman et al., Abstract, Risk of Inflammatory Bowel Disease from Isotretinoin: A Case-Control Study (2014). The authors noted that previous studies of isotretinoin did not control for antibiotic use. Id. They found that antibiotic use prior to IBD diagnosis was associated with UC but not CD. After

[3] The authors noted that reports associating isotretinoin with IBD did not control for antibiotic use, even though "[n]early all patients with acne who are treated with isotretinoin will have previously been treated with chronic antibiotics, typically tetracyclines." Id. at 2610. They concluded that "[t]etracycline class antibiotics . . . may be associated with the development of IBD, particularly CD." Ibid.

adjusting for antibiotic exposure, they found that "[i]sotretinoin exposure does not appear to confer risk for either UC or CD." Id.

Racine conducted a large study from a French database of over 50 million people and found no increased risk of UC from isotretinoin and a decreased risk of CD. Racine, supra, at 563. The results were similar in men and women. Id. at 566.

Just last year, a meta-analysis of six studies concluded that "there was no increased risk of developing IBD in patients exposed to isotretinoin."[4] Lee et al., Does Exposure to Isotretinoin Increase the Risk for the Development of Inflammatory Bowel Disease? A Meta-Analysis, 28(2) Eur. J. of Gastroenterology & Hepatology 210, 210 (2016). The study is the largest meta-analysis of this issue and included 31,059 IBD patients. Id. at 211, 214. Lee also found no increased risk of CD or UC. Id. at 210. The study concluded that the "results of this meta-analysis suggest that physicians prescribing the medication for the treatment of refractory acne need not be concerned about the risk of development of IBD with isotretinoin." Id. at 215.

C. Studies of Patients With Acne Show No Increased Risk of IBD From Isotretinoin

The diagnosis of acne may be associated with increased risk of IBD. For this reason, studies that examine isotretinoin use

[4] The studies were Alhusayen, infra; Rashtak, infra; Crockett, supra; Racine, supra; Etminan, supra; and Bernstein, supra.

in populations of IBD patients could falsely correlate isotretinoin with IBD because all isotretinoin users have acne. Several researchers therefore studied the incidence of IBD in populations of acne patients, comparing those who used isotretinoin with those who did not. These studies showed either no increased risk of IBD from isotretinoin or a decreased risk.

Alhusayen studied twelve years of claims in a database of approximately 4.5 million residents of British Columbia, Canada and "found no association between isotretinoin and IBD." Alhusayen et al., Isotretinoin Use and the Risk of Inflammatory Bowel Disease: A Population-Based Cohort Study, 133(4) J. Investigative Dermatology 907, 908 (2012). Their findings did, however, "suggest a possible association between IBD and acne itself." Id. at 910.

Fenerty identified 176,889 patients in a Medicaid database who received an acne diagnosis. Fenerty et al., Abstract, Impact of Acne Treatment on Inflammatory Bowel Disease, J. Am. Acad. Dermatology 6751 (2013). Fenerty found "no association between the use of isotretinoin and the incidence of IBD . . . ." Id.

Rashtak queried a Mayo Clinic database of patient visits between June 2006 and June 2011. Rashtak, supra, at 1323. The authors concluded that "of patients who were mainly seeking acne treatment, exposure to isotretinoin was associated with a lower

risk of IBD." Id. at 1324.

II. The Appellate Division Incorrectly Applied New Jersey's Expert Witness Testimony Standard

The overwhelming epidemiological evidence shows that isotretinoin use does not increase the risk of IBD and may even reduce the risk. The Appellate Division would permit Plaintiffs to upend the established hierarchy of scientific evidence by using case reports and other weaker evidence to refute epidemiological evidence. The Appellate Division's decision is contrary both to this Court's precedents and to well-established scientific standards.

Plaintiffs' experts fail to meet the test established by this Court in Rubanick v. Witco Chemical Corp., 125 N.J. 421 (1991) and Kemp v. State, 174 N.J. 412 (2002). Even if Plaintiffs could have argued a decade ago that their theory was one in "which a medical cause-effect relationship has not been confirmed by the scientific community but compelling evidence nevertheless suggests that such a relationship exists," Kemp, supra, 174 N.J. at 430, the scientific landscape has changed dramatically today. Plaintiffs' proposed cause-effect relationship between isotretinoin and CD has been rejected by every epidemiological study to examine the issue. The only study to find a link to UC was Crockett in 1986, but that study suffered from flaws. Its results have not been replicated. Thus, no compel-

ling evidence suggests that isotretinoin increases the risk of IBD. To the contrary, some preliminary evidence suggests that isotretinoin may even reduce the risk of IBD. Plaintiffs' theory is not "reasonable but unconfirmed." Ibid. Rather, Plaintiffs' theory is unreasonable because it has been refuted.

Plaintiffs seek to overcome the scientific consensus on isotretinoin by inverting the well-established hierarchy of scientific evidence. Plaintiffs' weak attempt to place case reports above epidemiological evidence must fail because their theory is not "based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field." Rubanick, supra, 125 N.J. at 449. Medical experts recognize that epidemiological studies stand far above individual case reports in the hierarchy of evidence.

Although the Appellate Division acknowledged the evidence hierarchy, it neutered its significance, asserting that it should not provide "a rigid hierarchy for the acceptance or rejection of evidence in a legal setting." Op. at 78. The Appellate Division largely ignored the hierarchy in assessing expert reliability. Instead, the Appellate Division equated limited hypothesis-generating evidence (such as case reports and animal studies) with hypothesis-testing evidence (such epidemiologic studies and meta-analyses). By constraining a trial court's

ability to consider the traditional hierarchy, the Appellate Division ensured that the best evidence will not be used to support expert opinion.

The Appellate Division also cast aside the "component of good science" that research and opinions should be subject to the "scrutiny of the scientific community."[5] Daubert, supra, 509 U.S. at 593, 113 S.Ct. at 2797, 125 L.Ed.2d. Indeed, both in New Jersey and under Daubert, whether a "theory or technique has been subjected to peer review and publication," ibid., is a key "landmark" in assessing expert reliability, Landrigan, supra, 127 N.J. at 417.

Peer review is a foundational aspect of good science, in part, because it "increases the likelihood that substantive flaws in methodology will be detected." Daubert, supra, 509 U.S. at 593, 113 S.Ct. at 2797, 125 L.Ed.2d. By its very nature, publication of research in a peer-reviewed outlet "indicates that a competent scientist had read it in advance of publication and found it competently drawn and carefully quali-

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[5] Although this Court has not expressly adopted the federal evidentiary standard established in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed. 469 (1993), and its progeny, amici respectfully suggest that the Court may find that large body of law persuasive because both New Jersey Rule of Evidence 703 and Federal Rule of Evidence 703 set similar standards. Under the New Jersey Rule, the basis of an expert's testimony must be "of a type reasonably relied upon by experts in the particular field," while the Federal Rule requires that "experts in the particular field would reasonably rely on those kinds of facts or data."

fied." Marc S. Klein, Expert Testimony in Pharm. Product Liab. Actions, 45 Food Drug Cosm. L.J. 393, 426 (1990). This vetting by scientific peers serves the interest of justice as a "surrogate screening advice" for "generalist judges," who may lack the expertise to independently evaluate an expert's methodology and opinion. Michael D. Green, Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litig.: The Legacy of Agent Orange and Bendectin Litig., 86 Nw. U. L. Rev. 643, 694-95 (1992).

In this action, the trial court properly considered whether the opinions of Plaintiffs' experts had been published and subject to peer review, which they had not. It also correctly found that the unanimous body of reliable, published epidemiologic research did not support a conclusion that isotretinoin causes IBD. The unwillingness of Plaintiffs' experts to submit their opinions to peer review served as an "important signal" that was rightfully weighed by the trial court in assessing reliability. In re Air Crash Disaster at New Orleans, 795 F.2d 1230, 1234 (5th Cir. 1986). By emphasizing that an expert "need not subject his or her own analysis to peer review," Op. at 66, while faulting the trial court for considering the complete lack of peer review of Plaintiffs' experts' opinions, the Appellate Division trivialized the significance of this well-recognized component of good science.

Scientific consensus, when it can be reached, is an espe-

cially strong indicator of good science. Courts should consider the "particular degree of acceptance within [a scientific] community." Daubert, supra, 509 U.S. at 594, 113 S.Ct. at 2797, 125 L.Ed.2d; see also Landrigan, supra, 127 N.J. at 417 (providing for courts to "determine whether the expert's opinion is derived from a sound and well-founded methodology that is supported by some expert consensus in the appropriate field"). Plaintiffs' experts not only lack corroboration, but are in direct conflict with the "large amount of high-quality evidence [that] now exists that disproves the relationship between isotretinoin and the risk of IBD." Brian Feagan & Reena Khanna, Editorial, Isotretinoin, Acne, and Crohn's Disease: A Convergence of Bad Skin, Bad Science, and Bad Litig. Creates the Perfect Storm, 9 Gastroenterology & Hepatology 752, 754 (2013); see also Am. Acad. of Dermatology ("AAD") Ass'n, Position Statement on Isotretinoin (Nov. 20, 2010) ("Current evidence is insufficient to prove either an association or a causal relationship between isotretinoin use and inflammatory bowel disease (IBD).").[6]

Such a unanimity of findings in the epidemiologic literature is telling, and the subsequent consensus in the scientific and medical community should not be so profoundly denigrated in favor of the un-vetted postulations of two paid experts. Given

[6] www.aad.org/media/news-releases/aada-introduces-updated-isotretinoin-position-statement.

the clear scientific consensus, the trial court rightly discounted the reliability of Plaintiffs' experts' outlier opinions. The Appellate Division erred in rejecting this consensus when evaluating the reliability of these experts.

III. The Appellate Division's Decision Will Interfere With the Practice of Medicine

The criteria for admitting scientific testimony into the courtroom has a profound impact, not only on the outcome of this litigation, but on the practice of medicine and patient health and welfare. The Appellate Division's decision to admit testimony not based on scientifically sound reasoning will interfere with the ability of physicians and their patients to make informed medical decisions based on the best available evidence.

The American Medical Association ("AMA") Code of Medical Ethics emphasizes that "[i]nformed consent to medical treatment is fundamental in both ethics and law." AMA, AMA Code of Med. Ethics, Op. 2.1.1 (2016).[7] Reliance on the best available evidence is essential to medical decision making and patient autonomy. When this evidence is clouded by inaccurate and unfounded scientific opinions legitimized by the courts, physicians have an uphill battle helping their patients make the best informed decisions. The Appellate Division's decision effectively undermines the fundamental trust that is the basis of the relation-

[7] https://www.ama-assn.org/delivering-care/ama-code-medical-ethics.

ship between patient and physician. See id. at 1.1.1.

The Appellate Division's decision imbues the medical decision-making process with court-approved, unsound scientific testimony. This infringes on a patient's basic right to receive essential, relevant information from their physicians and their physicians' obligation to "provide guidance about what they consider the optimal course of action . . . based on the physician's objective professional judgment." Id. at 1.1.3; see also id. at 1.1.4.

Unscientific determinations in the courtroom further complicate the already difficult decision-making processes of healthcare providers and their patients. Medical decisions by both patients and physicians involve a variety of factors that must be weighed—this already complex process will be further clouded if physicians must contend with unproven theories legitimized by the courts. Once an expert opinion is rubber stamped as legitimate, it can be difficult for physicians to counteract it outside the courtroom.

In obtaining informed consent for treatment, a dermatologist (or any treating physician) is "obligated to present to the patient, or person responsible for the patient, in understandable, terms, pertinent medical facts and recommendations consistent with good medical practice." AAD, Code of Med. Ethics

for Dermatologists r. I.D. (2014) (emphasis added);[8] see also AMA, Informed Consent and Decision-Making in Health Care H-140.989.[9] By permitting expert testimony that flies in the face of the overwhelming consensus of valid scientific research, the court tells physicians that this unsubstantiated information is relevant and therefore may (or must) be disclosed to patients, either purely based on relevance or out of fear of litigation, regardless of whether it is based on principles of sound science. As a result, patients may decline these treatments out of fear based on discredited theories, or practitioners may veer away from recommending certain reliable treatments altogether. This poses a real danger to patients who need treatment, particularly in this case, given the lack of other treatment options for severe cystic acne.

A foundational principle of the practice of medicine is that "a physician must recognize responsibility to patients . . . as well as to society, to other health professionals, and to self." AMA, AMA Code of Med. Ethics: Principles of Med. Ethics (2016). Just as a substandard scientific methodology inevitably impacts the reputation and trustworthiness of the scientific and medical community, its admission into the court-

[8] https://www.aad.org/Forms/Policies/Uploads/AR/ AR%20CODE%20OF%20MEDICAL%20ETHICS%20FOR%20DERMATOLOGISTS.pdf.
[9] https://policysearch.ama-assn.org/policyfinder/detail/140.989?uri=%2FAMADoc%2FHOD.xml-0-520.xml (last modified 2016).

room undermines the reputation and trustworthiness of the judicial process. The very "integrity of the judicial process depends, in part, on the honest, unbiased testimony of expert witnesses on both sides of courtroom controversies." AAD & AAD Ass'n, Position Statement on Expert Witnesses, 1.[10] The court must be able to distinguish between reliable and unreliable scientific inquiry—that is the very purpose of the court's gatekeeping role under New Jersey law. By allowing expert testimony that disregards core scientific principles, the Appellate Division's decision lends legitimacy to unfounded theories and undermines medical research essential to the practice of medicine and patient health and welfare.

IV. The Appellate Division's Decision Encourages Medical Experts to Deviate From Ethical Standards Requiring Testimony Based on Sound Scientific Evidence and Methods

To ensure appropriate and quality medical testimony, numerous national medical societies have established ethical and professional standards that guide medical professionals serving as expert witnesses. These ethical and professional standards subsume medical testimony within the practice of medicine. It is critically important that the legal standards for the admissibility of expert witness testimony comport with ethical and professional standards. The Appellate Division's decision will en-

[10] https://www.aad.org/Forms/Policies/Uploads/PS/PS%20-%20Expert%20Witnesses.pdf (last revised May 21, 2016).

courage physicians to deviate from these ethical standards.

Medical societies have long recognized that members of their profession play a critical role in certain legal proceedings by providing scientifically valid expert witness testimony. See, e.g., AMA, AMA Code of Med. Ethics, Op. 9.7.1 (2016). In order to assist in the administration of justice, however, testimony must be accurate, objective, reliable, and unbiased. AAD & AAD Ass'n, Position Statement on Expert Witnesses, 2;[11] Kenneth J. Robinson & Patricia P. Nouhan, Expert Witness, NCBI.[12]

These ethical and professional standards often explicitly require or recommend that expert witness testimony be based on sound scientific evidence and methods. Notably, the AMA Code of Medical Ethics requires that a physician serving as an expert witness testify honestly, evaluate cases objectively, and provide an independent opinion. AMA, AMA Code of Med. Ethics, Op. 9.7.1 (2016). The AMA Code of Medical Ethics expressly states that the physician must ensure that his or her testimony "reflects current scientific thought and standards of care that have gained acceptance among peers in the relevant field." Ibid.

Similarly, the American Academy of Dermatology's Code of

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[11] https://www.aad.org/Forms/Policies/Uploads/PS/PS%20-%20Expert%20Witnesses.pdf (last revised May 21, 2016).
[12] https://www.ncbi.nlm.nih.gov/books/NBK436001/ (last updated May 31, 2017).

Medical Ethics for Dermatologists provides that a dermatologist serving as an expert witness should ensure that his or her testimony is "unbiased, scientifically correct, clinically accurate, and otherwise truthful." AAD, Code of Med. Ethics for Dermatologists r. IX.C. (2014).[13] The AAD's Position Statement on Expert Witnesses further emphasizes that scientifically valid, non-partisan expert witness testimony "contributes to equitable outcomes based on generally accepted medical principles." AAD & AAD Ass'n, Position Statement on Expert Witnesses, 1.[14] The AAD expects an expert witness to offer testimony that is based solely on medical knowledge and never on the litigation posture of the parties involved. Id. at 2.

The Appellate Division's decision encourages medical expert witnesses to deviate from established ethical and professional standards by permitting the admission of testimony based on unsound scientific principles and unreliable methodologies to reach a predetermined conclusion. The Appellate Division did not adequately scrutinize the experts' methodology to ensure scientifically sound reasoning. By permitting testimony that flies in the face of the overwhelming weight of peer-reviewed evidence, the Appellate Division emboldens medical experts to

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[13] https://www.aad.org/Forms/Policies/Uploads/AR/AR%20CODE%20OF%20MEDICAL%20ETHICS%20FOR%20DERMATOLOGISTS.pdf.

[14] https://www.aad.org/Forms/Policies/Uploads/PS/PS%20-%20Expert%20Witnesses.pdf (last revised May 21, 2016).

deviate from ethical and professional principles demanding scientifically valid, non-partisan expert witness testimony.

Ethical and professional standards in the medical practice address the value of evidence accepted among peers. See, e.g., ibid. The AAD has explicitly indicated that an expert witness should not provide testimony that he or she "would not be willing to submit for independent peer review." Ibid. The Appellate Division failed to properly analyze whether Plaintiffs' experts used data accepted among peers in the relevant fields or give adequate weight to the importance of peer review.

Ethical and professional standards also direct medical expert witnesses to provide an unbiased, objective evaluation of the issues involved. See, e.g., AMA, AMA Code of Med. Ethics, Op. 9.7.1 (2016). Cherry-picking advantageous evidence based on a party's litigation position rather than on generally-accepted medical principles arguably constitutes unethical conduct. Legal principles that do not bar unreliable testimony open the door for potentially unethical testimony. The Appellate Division's decision improperly encourages medical experts to deviate from established ethical and professional standards requiring testimony to be based on sound scientific evidence and methods.

CONCLUSION

For the foregoing reasons, amici curiae urge the Court to grant Defendants' petition for certification.

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