BRANDI CARL and JOEL CARL, Plaintiffs-Respondents, v. JOHNSON & JOHNSON; JOHNSON CONSUMER COMPANIES, INC.; IMERYS TALC AMERICA, INC., F/K/A LUZENAC AMERICA, INC., PERSONAL CARE PRODUCTS COUNCIL, F/K/A COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION (CTFA), Defendants-Petitioners. --- DIANA BALDERRAMA and GILBERT BALDERRAMA, Plaintiffs-Respondents, v. JOHNSON & JOHNSON; JOHNSON CONSUMER COMPANIES, INC.; IMERYS TALC AMERICA, INC., F/K/A LUZENAC AMERICA, INC., PERSONAL CARE PRODUCTS COUNCIL F/K/A COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION (CTFA), Defendants-Petitioners	:	SUPREME COURT OF NEW JERSEY NO. 084871 On Appeal from the Superior Court of New Jersey, Appellate Division DOCKET NOS. A-0387-16T1 A-0978-16T1 Sat Below: Hon. Carmen H. Alvarez, P.J.A.D. Hon. Karen L. Suter, J.A.D. Hon. Patrick DeAlmeida, J.A.D. On Appeal from the Superior Court of New Jersey, Law Division, Atlantic County, Docket No. ATL-L-6540-14 Civil Action

BRIEF OF *AMICI* CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE COALITION FOR LITIGATION JUSTICE, INC., THE NATIONAL ASSOCIATION OF MANUFACTURERS, AND THE AMERICAN TORT REFORM ASSOCIATION IN SUPPORT OF DEFENDANT JOHNSON & JOHNSON'S PETITION FOR CERTIFICATION

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STATEMENT OF THE MATTER INVOLVED, QUESTIONS PRESENTED, AND ERRORS COMPLAINED OF

Amici adopt the Statement of the Matter Involved, Questions Presented, and Errors Complained of as submitted by Petitioner/Defendant Johnson & Johnson, Inc.

REASONS WHY CERTIFICATION SHOULD BE ALLOWED AND COMMENTS ON THE APPELLATE DECISION OPINION

The Chamber of Commerce of the United States of America, the Coalition for Litigation Justice, Inc., the National Association of Manufacturers, and the American Tort Reform Association (collectively herein, *Amici*), support Petitioner/Defendant Johnson & Johnson's request that the Court review and reverse the Appellate Division's decision in this matter. The *Carl* opinion does serious damage to any hope of rigorous trial judge review of a complex scientific record. The Appellate Division has essentially instructed trial judges to stand down if an expert can cite to "more than minimal" epidemiological support and explain away all contrary evidence.[1] That is not the standard for judicial gatekeeping as articulated in *In re Accutane*[2], and it cannot be the standard going forward. The Appellate Division decision will negatively impact not just the massive talc docket in New Jersey, but also the many other mass torts, pharmaceutical, and medical device cases alleging cancer, birth defects, cognitive injury, or countless other alleged but unproven harms from product or chemical exposure. *Amici* urge the Supreme Court to take review of this matter to restate and reemphasize the

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1 *Carl v. Johnson & Johnson,* __ A.3d ___, 2020 WL 4497263 at *27 (N.J. Super. Ct. App. Div., Aug.5, 2020).

2 *In re Accutane Litig.,* 234 N.J. 340, 191 A.3d 560 (N.J. 2018).

importance of a rigorous trial judge review of the experts' thinking and use of medical evidence, exactly as this trial judge did here.

I. THE SUPREME COURT NEEDS TO REINFORCE THE MESSAGE OF *IN RE ACCUTANE* IN CASES SUCH AS THIS ONE.

The *Carl* appeal represents a significant opportunity for this Court to restate and apply the lessons of *In re Accutane* to other, similar litigation. This Court's *In re Accutane* opinion should have set the course, for years to come, for exactly the kind of rigorous review that the *Carl* trial court engaged in. Instead, the Appellate Division effectively has returned to an older, less rigorous form of review.[3]

This Court likely will need to issue more than one opinion to effect fully and to implement the gatekeeping requirements of *In re Accutane* in the lower courts. The tension between a Supreme Court opinion requiring more forceful gatekeeping, and some lower courts' failure to recognize its import, is not new. The United States Supreme Court, for instance, found it necessary to issue a string of three successive opinions to lock down the import of *Daubert* itself.[4] Other states have

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[3] In contrast, multiple other New Jersey courts since *Accutane* have applied that case to exclude various expert causation testimony. *See Robinson v. Port Authority of NY & NJ,* No. 4720-16T4, 2018 WL 6205089 (App. Div. Nov. 29, 2018) (rejecting opinion on snowy sidewalk conditions); *Palisadium Management Corp. v. Borough of Cliffside Park*, 456 N.J. Super. 293 (App. Div. 2018) (deferring to trial court rejection of software cost expert exclusion); *N.J. Outdoor Alliance v. N.J. Dep't of Envtl. Prot.,* No. 0525-18T4, 2018 WL 6005064 *13 (App. Div. Nov. 16, 2018) (citing *Accutane* to underscore need for reliable expert testimony). *See also Morales-Hurtado v. Reinoso,* 241 N.J. 590 (2020) (remanding and reinforcing trial court's role as gatekeeper).

[4] *Daubert v. Merrell Dow Pharms., Inc*., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993); *General Elec. Co. v. Joiner,* 522 U.S. 136, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997); *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999).

experienced this same failure to enforce expert gatekeeping,[5] and New Jersey apparently will need to follow a similar course.

Amici request that the Court focus on the errors made here not by the trial judge, but by the Appellate Division panel, in undercutting *In re Accutane* and tying the hands of trial judges. As set forth in Johnson & Johnson's opening Petition, the trial judge in this matter performed a rigorous review not only of the extensive literature, but more importantly the methodologies used by Plaintiffs' experts to derive their opinion from that literature. Judge Johnson, the trial judge in this matter, was also the trial judge in *In re Accutane.* In both matters, even before the Supreme Court's *In re Accutane* opinion had issued, Judge Johnson did exactly what trial judges should do under a methodology-based review standard – he read the studies, investigated what the Plaintiff experts were saying based on those studies, and found their methodology of deriving conclusions from the scientific material singularly lacking in reliability. The court did not, as the Appellate Division concluded, rule on the *conclusions* of the experts but on the unreliability of those

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[5] The Texas Supreme Court in *Borg-Warner Corp. v. Flores,* 232 S.W.3d 765 (Tex. 2007), rejected the "every exposure" theory of causation and instructed courts to require a competent dose quantification to support causation. But it took several more intermediate court opinions and another Supreme Court opinion to fully apply those lessons to Texas asbestos litigation. *See, e.g., Smith v. Kelly-Moore Paint Co*., 307 S.W.3d 829 (Tex. App. 2010); *Georgia-Pac. Corp. v. Stephens,* 239 S.W.3d 304 (Tex. App. 2007); *Bostic v. Georgia-Pacific Corp*., 439 S.W.3d 332 (Tex. 2014). Similarly, the New York Court of Appeals rejected vague expressions such as "significant" as sufficient to support exposures leading to causation and also required a competent dose assessment. *Parker v. Mobil Oil Corp. ,* 857 N.E.2d 1114, 1117-19 (N.Y. 2006). The Court then had to reapply that standard twice in mold and gasoline fumes litigation. *See Cornell v. 360 W. 51st St. Realty, LLC,* 22 N.Y. 3d 762, 784 (2014)*; Sean R. v BMW of North America,* 26 N.Y.3d 801, 810-11 (2016). The Court of Appeals then needed another opinion to apply the lessons of *Parker* to asbestos litigation. *See In re NYC Asbestos Litig.* (*Juni v. A.O. Smith Water Prods.*)*,* 11 N.Y.S.3d 416, 484 (Sup. Ct. N.Y. Cnty. 2015); *aff'd on appeal,* 148 A.D.3d 233 (1st Dep't Feb. 28, 2017), *aff'd*, 32 N.Y.3d 1116 (2018). Additional cases are on appeal to the New York Court of Appeals in which the intermediate court declined to apply the dose requirement of *Parker* appropriately to asbestos cases.

conclusions based on the supporting material. The Appellate Division should have commended the trial judge for his diligence and proper focus on the experts' misuse of the literature, and all the more so in *Carl* after the Court had commended the very same judge in *In re Accutane* for much the same review.

Instead, the Appellate Division reverted to a much more passive version of gatekeeping in which trial judges are apparently not allowed to investigate whether an expert has reliably assessed the literature and drawn conclusions from it. Under this limited version of gatekeeping, if an expert can cite "more than minimal" epidemiological evidence,[6] and then explain away all the contrary evidence, the judge is not allowed to investigate the experts' reliability in assessing that literature. Nor is the judge allowed to inquire whether the scientific community and other experts would engage in such manipulation of the data, contrary to *In re Accutane's* direction. The state's judges may only gently wave at experts as they pass through the gate with a mish-mash of distorted science. This is not the approach adopted in *In re Accutane.*

The Appellate Court's analysis is riddled with several additional errors that are inconsistent with an *In re Accutane* level of review:

Prohibition on trial judge review of the literature: The Appellate Court engaged in a very lengthy (if decidedly one-sided) discussion of the literature, only to end up with a meager discussion of what exactly the trial court did wrong. And much of that limited criticism seems to be directed toward the very inquiry that *In*

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6 *Carl,* 2020 WL at *27.

re Accutane mandates – a comprehensive understanding by the trial judge of the scientific literature and whether the experts used it reliably.

Early in the opinion, the Appellate Court offered the criticism that the "judge relied upon his own reading of the supporting materials to dismiss the opinions of plaintiffs' principle experts as flawed." *Carl,* 2020 WL at *1. This remarkable statement seems to indicate that trial judges should not read the scientific literature. Instead, they must succumb to whatever reading the challenged expert chooses to derive from the literature, whether supportable or not. Under such an approach an expert could claim that an epidemiology study found a causative link between Product A and Disease Y, when in fact the study itself said no such thing. And the trial judge would be helpless to exclude that testimony.

As one clear example, the trial judge found it highly troubling that one expert, Dr. Colditz, cited to four studies for his biological plausibility theory, but when the judge *actually read the studies,* he learned that none of those studies supported the expert's statements.[7] The Appellate Division apparently believes the judge overstepped his bounds by identifying this gross misrepresentation. Under the Appellate Division's approach, a trial judge – even *knowing* that the study did not match the expert's use of it – could not take any action to keep that opinion away from the jury. That approach would lead straight into the *ipse dixit* problem

[7] *Carl v. Johnson & Johnson,* No. 300 (MCL), Order at 25 (Sep. 2, 2016).

identified in the Supreme Court's *Joiner* opinion[8], where the expert supports his opinion merely by his own say-so.

Substituting a Discussion of the Literature and Expert Opinions for an Actual Reliability Analysis: The second critical error by the Appellate Division was its attempt to substitute a long recitation of the literature and the experts' opinions in place of an actual analysis of the reliability of these opinions as derived from the literature. The Appellate Division's literature review is commendable for its length and detail, but in the end the court does nothing more than state the Plaintiffs' experts' views. The court set a low bar for admitting expert opinions: "the experts did not misread or miscite" any of the studies and they "addressed the contrary evidence."[9] The court required only "more than minimal support" in the scientific record, even though the opinions expressed by these experts are contrary to every scientific agency review and would dramatically convert many years of scientifically approved use of cosmetic talc into billions of dollars of claimed damages. "More than minimal" is not an appropriate standard for gatekeeping in such a case.

The Appellate Division opinion in fact reads much like an appellate *brief*, not an opinion – there is no recognition of the limited evidence supporting Plaintiffs' causation assertion, very little recognition of the compelling counter evidence, and virtually no explanation of why the trial court erred other than that the Appellate panel disagreed with the outcome. That conclusion may follow from the lenient standard of review applied by the panel, but it is inconsistent with the reliability

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8 *General Elec. Co. v. Joiner*, 522 U.S. at 146.

9 *Carl,* 2020 WL at *26, *27.

review required by *In re Accutane*. Perhaps most egregious is the one-sentence dismissal of Dr. Cramer's unsanctioned use of relative risk statistics to prove individual causation – a methodology with no basis in science and no cited support. The Appellate Division merely described this approach as "unobjectionable," without attempting to address its novelty or potential error rate.[10]

Ignoring the Hierarchy of Evidence: The Appellate Division's rejection of the hierarchy of evidence in cases such as this is highly troubling and inconsistent with *In re Accutane*. The *In re Accutane* Court did not need to parse between cohort and case control studies because all of the epidemiology studies in that matter consistently showed no association between the exposure and disease. Such uniformity of study results is somewhat anomalous – because of the vagaries of population studies and statistical analysis, it is not unusual for a few studies to flag potential associations even for products well-known not to cause disease. The false positives in some studies are usually smoothed out by the lack of such outcomes across the body of literature and in the stronger studies. Even though the *Accutane* Court did not have to deal with the hierarchy *within* epidemiology studies, that Court still adopted a hierarchy of evidence approach by rejecting reliance on lesser forms of evidence – case report and animal studies – to supplant the epidemiology.[11]

The Court should now apply that hierarchy of evidence review to different forms of epidemiology studies – those different designs are not equal in their ability to identify the causes of disease. In that hierarchy, cohort studies are widely

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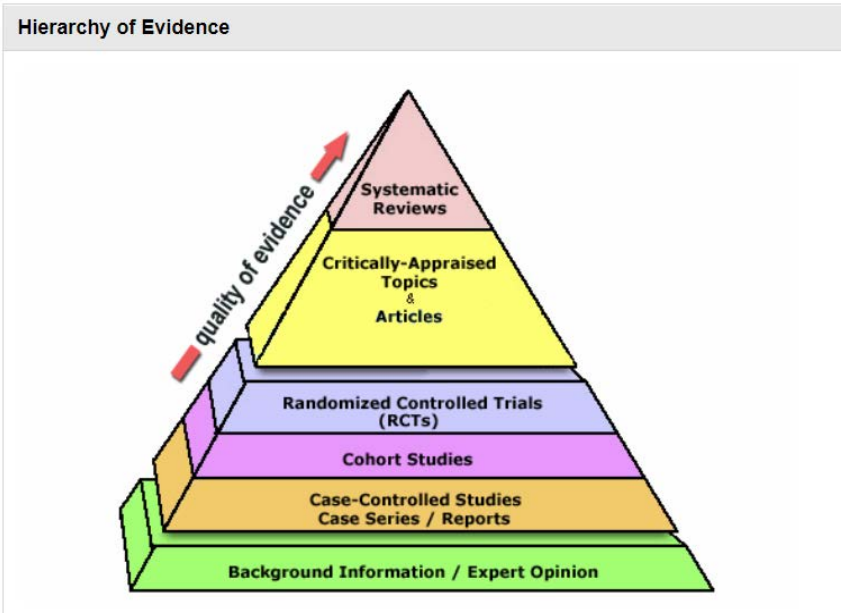
[10] *Carl,* 2020 WL at *30.

[11] *In re Accutane*, 234 N.J. at 355.

recognized as superior in power and persuasiveness to case-control studies – so much so that the ranking of these two appears repeatedly in published articles and websites describing the hierarchy of epidemiological evidence.[12] The hierarchy is typically illustrated, as on the MD Anderson website, as a pyramid in which "systematic reviews" of randomized trials are the highest level evidence, and cohort studies are listed as superior to case control:



[12] The hierarchy of epidemiology that ranks cohort studies above case control studies is widely published and accepted. The MD Anderson website includes such a ranking, *see* https://mdanderson.libguides.com/c.php?g=249812&p=1698782 (last visited Sept. 24, 2020). Johns Hopkins website includes an article with the same priority for cohort studies, *see* https://www.hopkinsmedicine.org/gynecology_obstetrics/pdfs/medstudent/rtc2014/Epi%20Study%20Design%20and%20Exploratory%20Analyses_abb.pdf (last visited Sept. 24, 2020); and the American Cancer Institute acknowledges the superiority of cohort studies in its website, *see* https://www.cancer.org/cancer/cancer-causes/medical-treatments/abortion-and-breast-cancer-risk.html (last visited Sep. 24, 2020).

As the American Cancer Society states: "Researchers generally consider the conclusions from cohort studies to be stronger than those from case-control studies."[13]

The trial judge quite appropriately questioned how these experts, if they were in fact engaged in an unbiased, scientific investigation, could ignore the more powerful outcomes of three cohort studies – finding no association between talc and ovarian cancer – and substitute instead a handful of case control studies that were themselves contradicted by other case control studies.[14] One lesson from a hierarchy of evidence standard is that if the expert cannot satisfy the highest evidence, then the *bar for proof should go up, not down*. A mixed set of case control studies involving at most weak associations between ovarian cancer and talc is not enough to overcome the lack of *any* evidence of causation in the more persuasive cohort studies, or for that matter the lack of consistency in the case control studies themselves.

The hierarchy and inconsistency of these studies has never proven, at least in the record of this case, sufficient for the scientific bodies reviewing this evidence to deem talc a cause of ovarian cancer.[15] The National Cancer Institute today continues to sum up the evidence in a way that undercuts these experts' claims:

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[13] https://www.cancer.org/cancer/cancer-causes/medical-treatments/abortion-and-breast-cancer-risk.html, under "Cohort and Other Prospective Studies" (last visited Sep. 24, 2020).

[14] *Carl*, No. 300 (MCL), Order at 18.

[15] The trial judge noted that neither the Food and Drug Administration nor the National Cancer Institute had found the evidence of talc causation sufficient. *See Carl,* No. 300 (MCL) Order at 16, 22-24. Similarly, the International Agency for Review of Carcinogens – one of the most aggressive at flagging potential cancer-causing agents – has listed talc only as a "possible" cause with no ability to eliminate bias and confounding from the studies.

> The weight of evidence does not support an association between perineal talc exposure and an increased risk of ovarian cancer. Results from case-control and cohort studies are inconsistent.[16]

That evidence is likewise not sufficient under a *Daubert*-like review – the trial judge as gatekeeper must not allow a jury verdict to form around insufficient and speculative scientific proof.

Disregarding Other Indicia of Unreliability: The expert opinions in *Carl* have other indicia of unreliability that the trial court recognized and the Appellate Court inappropriately dismissed. Despite publishing multiple articles on talc and ovarian cancer, Dr. Cramer, for instance, has never clearly stated in his published opinions that talc causes ovarian cancer.[17] The trial judge found this gap in Dr. Cramer's published work to be significant, and indeed it is. Dr. Cramer has subjected his actual causation opinion to review only in court and not to his scientific peers. Likewise, none of the other plaintiff experts had expressed their talc causation opinion in any published literature. The test under *In re Accutane* and New Jersey law, as applied to this case, is whether other experts in the field would hand-select a few case control studies and use those to override three cohort studies and other,

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https://monographs.iarc.fr/wp-content/uploads/2018/06/mono93.pdf at 412-13 (last visited Sept. 29, 2020).

[16] National Cancer Institute website, Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Prevention (PDQ®)–Health Professional Version, Factors with Inadequate Evidence, at https://www.cancer.gov/types/ovarian/hp/ovarian-prevention-pdq#_183_toc (last visited Sept. 24, 2020).

[17] *Carl,* 300 (MCL), Order at 30. Dr. Cramer in fact participated in a 2016 publication of a peer reviewed article, after he had begun testifying in litigation, that was intended to identify risk factors for ovarian cancer for treating physicians, including environmental factors. Even in that publication, the authors (including Dr. Cramer), omitted any reference to talc as a risk factor. *See* Clyde Merlise, et al., *Risk Prediction for Epithelial Ovarian Cancer in 11 United States-Based Case-Control Studies: Incorporation of Epidemiological Risk Factors and 17 Confirmed Genetic Loci,* 184 Amer. J. Epidem. 579, Table 2 (2016). Dr. Cramer published this article only one month after Judge Johnson had rejected his causation opinion in the *Carl* case.

contradictory case control studies. The answer is no, as no other published experts or scientific panels have done so.

In addition, the trial court also recognized severe "cherry-picking" – a favorite technique of experts who reach a conclusion first and then find the evidence to support it. The Appellate Division ignored that red flag. The experts also eschewed any need to demonstrate odds ratios exceeding 2.0, but did not explain why odds ratios far below this level and in fact approaching the null 1.0 somehow constituted adequate proof. The trial court noted the weakness of the experts' odds ratios and could not justify the experts' reaching such an important and dramatic causation conclusion based on such weak evidence.[18]

At bottom, the Appellate Division was willing to allow these experts to rely on exceptions to a number of widely recognized scientific principles to reach their conclusions (*see* Section II below). But the mere existence of possible exceptions does not justify throwing out the rules. If anything, the proof requirement should be more stringent if exceptions are all the experts can muster.

In re Accutane reinforced a more rigorous review era in New Jersey for expert opinions such as this. The *Carl* appellate opinion, to the contrary, invites trial courts to accept at face value expert assertions, dismiss clear contrary evidence, and then allow experts to present opinions that are neither adopted by any medical or scientific body nor clearly or consistently supported in the literature. The trial

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[18] *Carl,* 300 (MCL), Order at 29-30. Dr. Colditz also resorted to another favorite technique of litigation-driven experts, the use of the word "significant" with no grounding of that description in anything related to causation. *Id.* at 27.

judge did not exceed his gatekeeper authority – instead, the Appellate Division has opened the door for "weak" associations[19] and secondary evidence to destroy useful and safe products. The Petition should be granted to address the Appellate Division's methodology, even more so than the experts' methodology. The appellate opinion in this case should be reversed, and the trial judge's *In re Accutane* version of gatekeeping restored.

II. THE *CARL* OPINION, IF NOT REVERSED, WILL LEAVE TRIAL COURTS WITH UNCERTAINTY AS TO THE GATEKEEPING ROLE IN NEW JERSEY'S MANY DRUG, TORT, AND PRODUCT LAWSUITS.

The Court's review in this matter is vital for the additional reason that the *Carl* opinion will cause significant judicial and public harm if left unaddressed.

First, other than disagreeing with the trial judge's decision, the Appellate Court opinion offers no guidance for trial judges as to the depth and focus of their gatekeeping inquiry. New Jersey has a large number of mass tort cases beyond the talc-ovarian cancer docket, which it itself very large. Thus, the impact of such a confusing decision – and its seeming disregard of *In re Accutane* – will be significant not only for the talc litigation itself, but also for the state's drug, medical device, and mass tort dockets. The Court should accept the Petition to prevent unwarranted confusion for trial judges attempting to apply both *In re Accutane* and *Carl v. Johnson & Johnson* to other complex medical causation cases.

In addition, the Petition should be granted to correct the contradiction between the opinion and *In re Accutane's* insistence on a rigorous review of the

[19] *Carl,* No. 300 (MCL), Order at 30 ("The 0/R of 1.29 reported by Dr. Cramer is admittedly "weak" and neither he nor any other witness explained when/how a "significant" association becomes causal.").

expert's methodology. The *In re Accutane* court stated unequivocally, "We now reinforce the rigor expected of the trial court in [the gatekeeping] role under our existing case law."[20] In contrast, the Appellate Division, equally unequivocally, criticized the trial judge for reading and trying to understand the experts' use of the studies.[21] This trial judge invested enormous time and energy in a Rule 104 hearing, including collecting all the relevant studies, and then questioned the experts closely to determine the validity of their approach. The intermediate court rejected all of that in favor of a highly passive form of gatekeeping, in which the expert need only review the relevant materials and offer a subjective and self-serving explanation for the challenged opinion. The trial judge is not allowed, under the *Carl* opinion, to look behind the curtain and determine if things are amiss. This approach is not the rule of *In re Accutane,* and yet trial courts must now question whether a review of the scope and focus of the *Carl* trial judge – an approach that was fully upheld in *In re Accutane* but now somehow exceeds the scope of the court's authority. The Supreme Court needs to step in again, as it may in the future, to solidify the rigorous approach of *In re Accutane.*

Finally, the Petition should be granted to undo the significant confusion over the standard rules of science and how they should apply in toxic tort litigation in New Jersey created by the *Carl* opinion. The trial judge acknowledged and

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[20] *In re Accutane,* 234 N.J. at 388-89.

[21] *Carl,* 2020 WL at *1 ("The judge relied upon his own reading of the supporting material to dismiss the opinions of plaintiffs' principle experts as flawed.").

discussed these rules, in part taken from the Bradford Hill criteria, and found that the Plaintiff experts violated every one of them:

- *The hierarchy of scientific evidence.* The primacy of cohort studies over case control studies is a standard tenet of epidemiology, yet these experts inverted the pyramid, much as the experts in *In re Accutane* unsuccessfully did.

- *Statistical significance and strength of outcome.* Standard epidemiology has long held to a rough guide of a 2.0 odds ratio before drawing conclusions from a study. Courts generally are not rigid about that standard, but a much lower odds ratio should draw serious scrutiny from the trial judge, as it did here. The Appellate Division allowed the experts to rely on a cherry-picked and exceedingly low ratio, 1.29, that is not much better than chance.

- *Consistency of results.* Without a consistent set of results across well-designed studies, a specific set of positive associations cannot support a causation opinion. That includes the lack of dose response in these studies. The Appellate Division allowed the experts to avoid both conditions.

- *The lack of biological plausibility.* These experts made very little effort to identify why talc might cause ovarian cancer other than that it gets to the ovaries and can cause "inflammation." The trial judge challenged the experts on this point in the hearing, and they failed to support their theory as more than a guess.

- *Misuse of Bradford Hill.* These experts feign compliance with the Bradford-Hill criteria, but they are instead violating its most critical requirements, including consistency across study designs and odds ratios much higher than the miniscule 1.29 identified here.[22]

- *Litigation-driven methodology.* These experts are guilty of one hallmark of a *Daubert*-insufficient methodology, the failure to present their actual litigation conclusions in the scientific community for peer review. The Appellate Division has upended even this standard test.

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[22] *See* Sir Austin Bradford Hill, *The Environment and Disease: Association or Causation?,* 108 J. Royal Society Med. 32 (1965) at 32-33, 34 ("I would myself put a good deal of weight up on similar results reached in quite different ways, e.g., prospectively and retrospectively" [i.e., cohort and case control]).

As one final point, the impact of the Appellate Court's decision here will be significant in any case where there are clear alternative causes of the disease. Ovarian cancer is relatively common and has a number of known risk factors, which the experts all acknowledged. In addition, recent genetic studies demonstrate that a great many human cancers are the result of the body's own genetic errors in cell reproduction. The seminal research by Tomasetti and Vogelstein, published in the journal *Science,* concludes that about two-thirds of all cancers occur spontaneously, i.e., without any external exposure. Ovarian cancer is directly in the middle of that list.[23]

This demonstrated preponderance of genetically-caused ovarian cancers greatly increases the burden on an expert to explain why the disease of these two women is not simply genetic rather than the result of a speculative exogenous agent such as talc. Genetic discoveries of the causes of disease are occurring on a daily basis as that scientific field explodes. As New Jersey tort litigation moves forward, the genetic basis of disease is likely to become a major issue. The trial judges need clear guidance that plaintiff experts must rationally and reliably eliminate all alterative causes, including genetically-caused disease.

The Appellate Division instead brushed aside the trial judge's concerns over the existence of alternative causes of these cancers. The impact for future litigation is enormous. If plaintiffs are now allowed to bring talc-ovarian cancer cases, they could likely blame almost any such instance of ovarian cancer on talc, given that

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[23] *See* Cristian Tomasetti and Bert Vogelstein, *Cancer Etiology: Variation in Cancer Risk Among Tissues Can Be Explained by the Number of Stem Cell Divisions,* 347 Science 78, Fig. 2 (2015).

product's widespread use. And yet, even if talc were in fact a cause of ovarian cancers, under the Tomasetti findings *fully two-thirds or more of those verdicts would be wrong* because they are genetic and spontaneous. And this estimation does even account for the other risk factors such as obesity. This level of false positive outcomes in jury verdicts is not acceptable, especially considering the enormous amounts of damages plaintiffs seek (and often obtain) in today's tort litigation.

CONCLUSION

For the reasons stated above and in Petitioner's brief, *Amici* support the request for appeal and urge the Court to take this matter and reinforce the rule of *In re Accutane.*

Respectfully submitted,

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