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In The

Superior Court of Pennsylvania

No. 2811 EDA 2024

PAUL and DIANE GILL, h/w,
Plaintiffs/Appellees,
v.
EXXON MOBIL CORP., *et al.*
Defendants/Appellants.

BRIEF OF *AMICI CURIAE* PRODUCT LIABILITY ADVISORY COUNCIL, INC., NATIONAL ASSOCIATION OF MANUFACTURERS, DRI CENTER FOR LAW AND PUBLIC POLICY, FEDERATION OF DEFENSE AND CORPORATE COUNSEL, AND PENNSYLVANIA DEFENSE INSTITUTE IN SUPPORT OF APPELLANT

Appeal from Judgment entered September 23, 2024, in the Court of Common Pleas of Philadelphia County, Civil Division, at No. 1808, May Term 2020, Carmella Jacquinto, J.

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STATEMENTS OF INTEREST OF *AMICI CURIAE*

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

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs thirteen million men and women, contributes $2.94 trillion to the U.S.

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[1] A list of current PLAC corporate members is available at ********plac.com/PLAC/Membership/Corporate_Membership.aspx.

economy annually, has the largest economic impact of any major sector, and accounts for more than half of the nation's private-sector research and development. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs in the United States.

The DRI Center for Law and Public Policy (the "Center") is an international organization of more than 16,000 attorneys who defend individuals, corporations, and local governments in civil litigation. The Center participates as an *amicus curiae* in state and federal appellate courts in an ongoing effort to make the civil justice system fairer, more consistent, and more efficient.

The Federation of Defense & Corporate Counsel ("FDCC") is a not-for-profit corporation of 1,400 private-practice defense and in-house corporate counsel. Its members represent the interests of civil defendants—businesses, public entities, and individuals. The FDCC strives to protect the American system of justice, seeking to assist courts in addressing issues of importance to its membership that concern the fair and predictable administration of justice. Through its broad membership and nationwide perspective, the FDCC is well-positioned to address the important legal and public policy questions this case poses.

The Pennsylvania Defense Institute ("PDI") is a non-profit association of defense attorneys and insurance company executives. PDI is a forum for

developing public policy, exchanging ideas, and pursuing goals such as prompt, fair, and just claim resolution, improved administration of justice, enhancing the legal profession's public service, addressing court congestion and delays in civil litigation, and other public-minded activities. PDI represents its members in many areas, including legislation and litigation.

Amici and their members have a strong interest in a rational and consistent product liability regime that is fairly administered, comprehensible to judges and juries, and ensures consideration of only relevant evidence. They seek to ensure that established legal causation principles are not watered down. Expert opinions based on scientifically unsound principles that would permit recovery for any exposure to an allegedly toxic substance—no matter how small or remote—have no place in toxic tort litigation. Such "no-safe-threshold" opinions, however phrased, are not grounded in scientific consensus or the facts of the particular case, and invite juries to ignore the exposure evidence presented.

This *amicus curiae* brief is respectfully submitted to address these issues of public importance apart from and beyond the immediate interests of the parties.[2]

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[2] Pursuant to Pa. R.A.P. 531(b)(2), *amici* state that no person or entity, other than the *amici*, their members, and their counsel, paid for or authored this brief, in whole or in part.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes, Rules & Regulations

Other Authorities

BRIEF OF *AMICI CURIAE* PRODUCT LIABILITY ADVISORY COUNCIL, INC., NATIONAL ASSOCIATION OF MANUFACTURERS, DRI CENTER FOR LAW AND PUBLIC POLICY, FEDERATION OF DEFENSE AND CORPORATE COUNSEL, AND PENNSYLVANIA DEFENSE INSTITUTE IN SUPPORT OF APPELLANT

STATEMENTS OF JURISDICTION, ORDER IN QUESTION, SCOPE AND STANDARD OF REVIEW, QUESTIONS INVOLVED, AND CASE

Amici curiae accept Appellant Exxon Mobil Corp.'s ("ExxonMobil") statements concerning the Court's jurisdiction, the order in question, the scope and standard of review, the questions involved, and the case.

SUMMARY OF ARGUMENT

Without holding a *Frye* hearing under Pa.R.E. 702.1, the trial court denied defendant-appellant ExxonMobil's motion *in limine* to preclude Plaintiffs' experts from offering causation opinions that no safe threshold for benzene exposure exists, and that every exposure to ExxonMobil's benzene-containing gasoline substantially contributed to Plaintiff Paul Gill (hereafter "Plaintiff" singularly) developing acute myeloid leukemia ("AML"). At trial, Plaintiffs' two expert witnesses, Drs. Robert Laumbach and Rory Shallis, did precisely that. In closing argument, Plaintiffs repeatedly urged the jury to return a verdict on that basis.

It was error to deny ExxonMobil's *in limine* motion. Settled Pennsylvania law holds that "no-safe-threshold" causation theories are not generally accepted science in toxic tort or product liability litigation. Expert opinions espousing

such theories are therefore inadmissible under Pa.R.E. 702's *Frye*-based standard for evaluating expert testimony. The Pennsylvania Supreme Court and this Court have so held multiple times. Plaintiffs and their experts took full advantage of this error. It could not possibly be harmless.

Plaintiffs' experts offered other inadmissible, not generally accepted testimony. They improperly presented governmental regulatory standards as evidence of causation. Such standards are prophylactic, population-level thresholds, and bear no relation to the common law's more-likely-than-not causation standard for individual plaintiffs. Overwhelming precedent rejects use of regulatory exposure standards in civil litigation, demonstrating that Plaintiffs' experts' reliance on such material was not generally accepted methodology as required by *Frye* and Rule 702.

Further, the cause of most AML is medically unknown, or "idiopathic." Plaintiffs' experts used a differential diagnosis methodology—ruling out alternative causes—that was fatally flawed, as they did not, and could not, rule out unknown origins for Plaintiff's AML. Again, extensive nationwide precedent recognizes that the circumstantial differential diagnosis method is ineffective where, as here, most cases of a disease simply have no known cause, so that idiopathic origin cannot be excluded. This precedent establishes that differential diagnosis is not generally accepted causation methodology for largely idiopathic diseases like AML.

ARGUMENT

I. Pennsylvania's *Frye* Standard: General Acceptance And Informed Assessment Of Expert Testimony

Only expert testimony based on principles and methods having achieved "general acceptance" in the relevant scientific community is admissible in Pennsylvania. *Commonwealth v. Topa*, 369 A.2d 1277, 1281 (Pa. 1977); *see* Pa.R.E. 702(c) (expert's methodology must be "generally accepted in the relevant field"). The Supreme Court in *Grady v. Frito-Lay, Inc.*, concisely stated the elements of expert admissibility under *Frye* and Rule 702:

> [W]e reaffirm our adherence to the *Frye* rule; clarify that the rule applies to an expert's methods, not his conclusions; emphasize that the proponent of the expert scientific evidence bears the burden of proof on the *Frye* issue; and reiterate that the standard of appellate review on the *Frye* issue is the abuse of discretion standard.

839 A.2d 1038, 1047 (Pa. 2003).[3] In the context of novel scientific evidence, judicial "discretion is tempered by the standard established in *Frye*." *Interest of La.-Ra. W.*, 266 A.3d 1071, 1082 (Pa. Super. 2021) (citation and quotation marks omitted).

Admissibility of an expert opinion "depend[s] upon the general acceptance of its validity by those scientists active in the field to which [the evidence] belong[s]." *Topa*, 369 A.2d at 1281. This requirement "restricts the

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[3] Referencing *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), *abrogated*, *Motorola, Inc. v. Murray*, 147 A.3d 751, 757 (D.C. 2016).

scientific evidence which may be admitted as it ensures that the proffered evidence results from scientific research which has been conducted in a fashion that is generally recognized as being sound." *Interest of M.R.*, 247 A.3d 1113, 1121 (Pa. Super. 2021) (citation and quotation marks omitted). Experts may not "evade a reasoned *Frye* inquiry merely by making references to accepted methods in the abstract." *Betz v. Pneumo Abex, LLC*, 44 A.3d 27, 58 (Pa. 2012). *Frye* bars both novel science, and novel uses of established scientific methods. *Grady*, 839 A.2d at 1047 (method was "accepted," but not "in the relevant field"). Pennsylvania courts take a "broad" view of the "novelty" aspect of *Frye*:

> [A] reasonably broad meaning should be ascribed to the term "novel".... [A] narrower approach would unduly constrain trial courts in the appropriate exercise of their discretion in determining the admissibility of evidence.

Betz, 44 A.3d at 53 (citation omitted).[4]

Pennsylvania courts have repeatedly recognized "the influential nature of expert testimony on complex subjects, and the potential that distortions have to mislead laypersons." *Id.* Such evidence can "assume a posture of mystic infallibility in the eyes of a jury of laymen," requiring trial judges to exclude evidence lacking sufficient scientific foundation. *Topa*, 369 A.2d at 1282 (citation and quotation marks omitted). To be admissible, "expert testimony

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[4] Given the Supreme Court's express "novelty" holding in *Betz*, the trial court's reliance, Op. at 329-30, on the earlier contrary decision *Trach v. Fellin*, 817 A.2d 1102, 1109 (Pa. Super. 2003) (en banc), is error.

must be based on more than mere personal belief, and must be supported by reference to facts, testimony[,] or empirical data." *Snizavich v. Rohm & Haas Co.*, 83 A.3d 191, 195 (Pa. Super. 2013) (citation and quotation marks omitted).

A *Frye* hearing here was essential to the trial court's "informed assessment" of the defendant's *in limine* motion. "[T]he any-exposure opinion is precisely the sort of evidence that merits thoughtful inquiry." *Betz*, 44 A.3d at 54. *Frye* hearings are "the better way of insuring that only reliable expert scientific evidence is admitted at trial." *Grady*, 839 A.2d at 1045. They provide the opportunity for rebuttal experts from relevant fields to criticize and challenge questionable methodologies and to ensure that juries only hear evidence meeting the general acceptance threshold. *See* Pa.R.E. 702.1 (providing framework for this evaluation).[5]

"[A]rticulable grounds to believe that an expert witness has not applied accepted scientific methodology in a conventional fashion" "warrant a *Frye* hearing. *Betz*, 44 A.3d at 53. *Frye* hearings are appropriate whenever proffered "experts ha[ve] not applied generally accepted scientific methodolog[ies] in a conventional way." *Walsh v. BASF Corp.*, 234 A.3d 446, 454 (Pa. 2020). The

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[5] Denial of defendant's *in limine* motion preserved the issue. Pa.R.E. 103(b) ("Once the court rules definitively on the record—either before or at trial—a party need not renew an objection … to preserve a claim of error for appeal.").

issues here—need for "specific" dose evidence, misuse and omission of Bradford-Hill criteria, and a "differential diagnosis" that ignored the "idiopathic" nature of most AML cases, to mention a few—are precisely why it was error to not conduct a *Frye* hearing here. *Id.* at 460-61 (requiring these and other "relevant issues" be addressed under *Frye* in benzene/AML case).

II. The Trial Court's Failure To Exclude Plaintiffs' Experts' No-Safe-Threshold Opinions That Any Exposure To Benzene Was Causal Was Reversible Error.

A. Expert Testimony Based On A No-Safe-Threshold Theory Is Inadmissible To Establish Causation In Pennsylvania.

"Courts accept a variety of sources as evidence that the expert's methodology is generally accepted, including judicial opinions, scientific publications, studies, and statistics." *M.R.*, 247 A.3d at 1123 (citation and quotation marks omitted). The Pennsylvania Supreme Court has repeatedly rejected expert testimony premised on no-safe-threshold theories of causation (*i.e.*, that any exposure to a toxic substance, no matter how small, is a substantial contributing factor to disease) in toxic tort cases.[6] *See, e.g., Gregg v. V-J Auto Parts Co.*, 943 A.2d 216, 226-27 (Pa. 2007); *Betz*, 44 A.3d 27; *Howard v. A.W. Chesterson Co.*, 78 A.3d 605, 608 (Pa. 2013); *Rost v. Ford Motor Co.*, 151 A.3d 1032, 1044 (Pa. 2016). So has this Court, in *Nelson v. Airco Welders Supply*,

[6] In asbestos cases, such opinions are variously described as "any-exposure," "any-breath," or "each-and-every-breath" theories.

107 A.3d 146, 158 (Pa. Super. 2014) (en banc). The trial court's contrary *in limine* ruling, which exposed the jury to no-safe-threshold opinions in this case, was error.

The first Supreme Court rejection of no-safe-threshold liability was not in a *Frye* context. *Gregg* held that "each and every exposure" opinions could not satisfy Pennsylvania's "frequency, regularity, proximity" causation test in asbestos cases. 943 A.2d at 226-27. The Court recognized that if "every exposure" opinions "were permitted to control, the substantial factor test would be rendered meaningless." *Id*. at 226 (citation omitted). Although such expert opinions were "common," they were "not couched within accepted scientific methodology." *Id.* Thus, *Gregg* held that it was not "a viable solution to indulge in a fiction that each and every exposure to [a substance], no matter how minimal in relation to other exposures, implicates a fact issue concerning substantial factor causation." *Id*. at 226-27.

The Supreme Court unanimously ruled that no-safe-threshold opinions did not comport with the *Frye* standard for expert testimony in *Betz*. Such testimony "obviates the necessity for plaintiffs to pursue the more conventional route of establishing specific causation." 44 A.3d at 54. *Betz* found no-safe-threshold opinions scientifically unsound and legally insufficient, as a disease cannot be dose-responsive if a single exposure is substantially causative. *Id*. at 53. An "any-exposure opinion is in irreconcilable conflict with itself" and with the basic

toxicological concept of dose-response. *Id.* at 56. Thus, "any exposure" theories are inadmissible as evidence of causation because they disregard the fundamental principle that dose matters in toxic tort cases. *Id*.[7]

These principles were "reaffirm[ed]" in *Howard*, which again rejected no-safe-threshold theories as a basis for establishing substantial-factor causation in toxic tort cases:

> The theory that each and every exposure, no matter how small, is substantially causative of disease may not be relied upon as a basis to establish substantial-factor causation for diseases that are dose-responsive.
>
> Relatedly, in cases involving dose-responsive diseases, expert witnesses may not ignore or refuse to consider dose as a factor in their opinions.

78 A.3d at 608 (*Betz* citations omitted).

In the *en banc Nelson* opinion, this Court followed the Supreme Court's "clear" and "dispositive" precedent, 107 A.3d at 155, and required a new trial where the plaintiff's expert "proffered an 'any-exposure' theory of causation" barred under *Gregg* and *Betz*. *Id.* at 154. The opinions that "any exposure above ... ambient air" and "each individual exposure" were "substantially causative" were inadmissible and could not be harmless. *Id.* at 158.

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[7] *See also id* at 511 ("Dose is a central concept in toxicology—'the dose makes the poison' is the oldest maxim in the field.") (quoting Bernard D. Goldstein, *Toxic Torts: The Devil Is in the Dose*, 16 J.L. & POL'Y 551, 551 (2008)).

Rost v. Ford Motor Co., reaffirmed the court's exclusion of no-safe-threshold causation theories. 151 A.3d 1032, 1044 (Pa. 2016). "[E]xpert testimony based upon the notion that 'each and every breath' of asbestos is substantially causative ... will not suffice to create a jury question on the issue of substantial factor causation." *Id.* at 1044. *Rost* likewise rejected the proposition "that where there is competent evidence that one or a *de minimis* number of asbestos fibers can cause injury, a jury may conclude the fibers were a substantial factor in causing a plaintiff's injury." *Id.* at 1048 (citation and quotation marks omitted). However, the expert in *Rost* "never testified that every exposure to asbestos was a 'substantial factor' in contracting the disease." *Id.* at 1045-46. Instead, the *Rost* expert permissibly testified about "cumulative" exposure based on "dose-response." *Id.*

> [Plaintiff's expert] testified that [plaintiff's] actual exposures to asbestos at [his employer] over three months was substantially causative of his mesothelioma. In other words, [he] did not testify that a single breath of asbestos while at [work] caused [plaintiff's] mesothelioma, but rather that the entirety of his exposures during [his period of employment] caused his disease.

Id. at 1046.

Unlike *Rost*, and like the testimony excluded in *Gregg*, *Betz*, *Howard*, and *Nelson*, Plaintiffs' experts here—due to the erroneous denial of the defendant's motion *in limine*—"unabashedly offered 'each and every breath' testimony." *Rost*, 151 A.3d at 1046. *Rost* thus supports exclusion here.

Both Dr. Laumbach and Dr. Shallis repeatedly opined that every exposure to benzene in this case, regardless of magnitude, was a substantial contributing factor to the development of AML. For example, in the course of testifying that there is no benzene exposure threshold below which there is no increased risk (*i.e.*, no safe threshold), Dr. Laumbach used the same water-in-a-glass-analogy that *Betz* found "fundamentally inconsistent with both science and the governing standard for legal causation," and therefore inadmissible under *Frye*. 44 A.3d at 57; *cf.* 4/29/24 PM, 87:13-88:8. He asserted that multiple exposures, none of which could independently cause illness, were nevertheless all substantial causative factors:

> Q. We have multiple potential sources of exposure, ... where there's exposure from one source and maybe that, in and of itself, ***is not enough to cause an illness***, and we have exposure from a second source and maybe that second exposure, in and of itself, ***is not enough to cause an illness*** and then maybe exposure from a third source that, in and of itself, ***is not enough to cause an illness***. What is the concept of cumulative lifetime exposure say about those multiple sources contributing?
>
> A. That ***they are all substantial contributing factors because we don't know which one sort of finally filled the glass***, right, in almost every case.
>
> * * * *
>
> Q. We saw briefly a moment ago a picture. Here's what I was trying to describe. We have three factories that are polluting this lake. We can't say necessarily that it was one factory or the other that killed the fish, so but can we say that these factories all substantially contributed?
>
> A. Yes.

Q. Is that the concept of substantial contributing factor?

A. Yes.

4/29/24 PM, 89:18-90:8 & 90:16-25 (emphasis added).

This testimony was precisely what *Rost* declared was improper, conflating the scientific principle that each exposure contributes to overall dose with the legal question of "substantial contributing factor" to disease. *See Rost*, 151 A.3d at 1045 ("In this case, while [plaintiff's expert] clearly testified that every exposure to asbestos cumulatively contributed to [plaintiff's] development of mesothelioma, he never testified that every exposure to asbestos was a 'substantial factor' in contracting the disease."). *Rost* held that the first is a permissible statement of scientific fact, but the second inadmissibly espouses the no-safe-threshold theory. *Id*.

Dr. Shallis's opinions are even more problematic. He admitted that he formed his specific causation opinions without any quantification of Plaintiff's benzene exposure. *See* 5/2/2024 AM, 91:2-5. Asserting specific causation in the absence of exposure evidence is the *sine qua non* of the no-safe-threshold theory. His opinion did not require any dose or exposure information, thus violating the foundational dose/response principle. Dr. Shallis's complete disregard for dose-response (and toxicological principles, generally) recurred throughout his testimony. He told the jury, for example, that no safe threshold for benzene exposure exists, that ***a single molecule*** of benzene can cause cancer,

and that he would endorse any ***non-zero exposure*** as causative of AML. *See*, *e.g.*, 5/2/24 PM, 69:15-19, 39:25-40:2 & 38:3-7.

Both Plaintiffs' experts thus offered no-safe-threshold opinions of the sort repeatedly rejected by the Pennsylvania Supreme Court and this Court as not generally accepted in the scientific community—as the trial court's denial of defendant's motion *in limine* allowed them to do.

Further, in closing argument, Plaintiffs' counsel told the jury time after time that they could decide that "any" benzene-containing "product that ... you find that [plaintiff] was exposed to that contributed to the cause" without regard to exposure evidence. 5/8/2024 AM, 89:5-8; *see also id.* at 38:9-11 ("no safe level of exposure"), 42:8-9 ("there was no safe level of exposure"), 58:14-15 ("there is no safe level of exposure"), 59:16-19 ("no one ... believes there is some threshold of exposure below which benzene cannot cause cancer") & 87:2-88:11 (telling jury to find that several other products were "substantial[] contributing factors" without exposure evidence).

Thus, while Plaintiff's experts did purport to conduct a plaintiff-specific exposure analysis that—but for the other infirmities discussed below—might have passed muster under *Rost*, the jury here was repeatedly exposed to no-safe-threshold expert opinions that were undeniably inadmissible under Pennsylvania law.

Plaintiffs' closing then exhorted the jury to reach its verdict on that basis. This erroneous admission of no-safe-threshold evidence requires, at minimum, a new trial. "When improperly admitted testimony may have affected a verdict, the only correct remedy is the grant of a new trial." *Nelson*, 107 A.3d at 155 (citation and quotation marks omitted); *see also Commonwealth v. Molina*, 33 A.3d 51, 60, 70 (Pa. Super. 2011) (new trial required by comments on improperly admitted evidence during closing argument) (en banc), *aff'd*, 104 A.3d 430 (Pa. 2014); *Commonwealth v. Bieber*, 283 A.3d 866, 884 (Pa. Super. 2022) (same, due to "explicit reliance on ... inadmissible and irrelevant testimony ... [i]n its closing argument"). The error here was "of such consequence that, like a dash of ink in a can of milk, it cannot be strained out," and "the only remedy, so that justice may not ingest a tainted fare, is a new trial." *Charlton v. Troy*, 236 A.3d 22, 42 (Pa. Super. 2020) (citation and quotation marks omitted).

B. Nationwide Precedent Further Demonstrates That No-Safe-Threshold Causation Theories Are Anything But "Generally Accepted."

Courts across the country have reached the same result as Pennsylvania, frequently rejecting similar no-safe-threshold theories of the sort offered here as scientifically and legally insufficient in toxic tort cases. Courts nationwide require experts seeking to opine on specific causation to "pay careful attention to the ... dose-response relationship"—the foundational scientific concept that the risk and severity of harm from a toxicant are directly related to the amount

and duration of exposure. *McClain v. Metabolife Int'l, Inc*., 401 F.3d 1233, 1241 (11th Cir. 2005).

An "any level is too much" opinion "conflicts with the importance of individual responses to toxins" and "clearly contradicts the principles of reliable methodology." *Id.* at 1243; *accord Mitchell v. Gencorp, Inc*., 165 F.3d 778, 781 (10th Cir. 1999) ("a plaintiff must demonstrate the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover."); *Allen v. Pennsylvania Engineering Corp*., 102 F.3d 194, 199 (5th Cir. 1996) ("Scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs' burden in a toxic tort case."); *Wright v. Willamette Indus*., 91 F.3d 1105, 1106 (8th Cir. 1996) ("[A] plaintiff in a toxic tort case must prove the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover.").

Like Pennsylvania, state high courts across the country have rejected no-safe-threshold expert opinions. If "any exposure to asbestos is sufficient to establish liability, the result essentially would be not just strict liability but absolute liability against any company whose asbestos-containing product crossed paths with the plaintiff throughout his entire lifetime." *Bostic v.*

Georgia-Pacific Corp., 439 S.W.3d 332, 339 (Tex. 2014); *accord Scapa Dryer Fabrics, Inc. v. Knight*, 788 S.E.2d 421, 427 (Ga. 2016) (testimony that "invited the jury to find that causation was established by any exposure at all ... should have been excluded"); *Holcomb v. Georgia Pacific, LLC*, 289 P.3d 188, 197 (Nev. 2012) ("courts that adopt the three-factor test of frequency, regularity, and proximity regularly reject the "any" exposure argument. Thus, more than any exposure must be shown.").

The same is true in benzene-in-gasoline litigation. The "no safe threshold" theory of causation "flies in the face of the toxicological law of dose-response," and has "been rejected by the overwhelming majority of the scientific community." *Henricksen v. Conoco Phillips*, 605 F. Supp.2d 1142, 1165-66 (E.D. Wash. 2009) (citations and quotation marks omitted). *Henricksen* excluded expert no-threshold testimony, finding it contrary to the scientific consensus that risk and severity of harm from a toxin are directly related to the amount and duration of exposure. *Id*. at 1165-66.

Similarly, *Sutera v. Perrier Group of America Inc.,* excluded expert testimony that any exposure to benzene, no matter how small, could cause leukemia, because such methodology disregards the scientific concept of a threshold below which no appreciable harm occurs and "fail[s] the general acceptance" test. 986 F. Supp. 655, 667 (D. Mass. 1997). Other courts agree. *See e.g., De Los Santos v. Johnson & Johnson*, 2024 WL 3700205, at *20 (N.D.

Ala. Aug. 7, 2024) (expert engaged in "circular reasoning" and had "no support for his conclusion that there is no safe level of exposure to benzene"); *Milward v. Acuity Specialty Products. Grp*., 969 F. Supp.2d 101, 110 (D. Mass. 2013) ("the argument that any level of benzene is sufficient to cause leukemia—a so-called 'no safe level,' 'no threshold,' or 'linear' model—... is inadmissibly unreliable"), *aff'd*, 820 F.3d 469 (1st Cir. 2016). These decisions, while applying a *Daubert*[8] standard, specifically rested on general acceptance, the same foundational requirement of Pennsylvania's *Frye* analysis.

III. Reliance On Regulatory Standards In Reaching Causation Opinions Is Not Generally Accepted.

It is axiomatic that experts may not use regulatory standards to establish legal causation in toxic tort cases. "[E]fforts to invoke ... regulatory standards are also ineffectual in terms of substantial-factor causation, since the most these can do is suggest that there is underlying risk from the defendants' products." *Betz*, 44 A.3d at 55. Regulatory limits are prophylactic, population-level thresholds set by agencies—such as OSHA and EPA—to minimize public and occupational exposure to potentially harmful substances. *Industrial Union Department v. American Petroleum Institute*, 448 U.S. 607, 656 (1980) ("OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty" and "is free to use conservative assumptions in

[8] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection."). "[A]gencies' threshold of proof is reasonably lower than that appropriate in tort law, which traditionally makes more particularized inquiries into cause and effect." *Allen*, 102 F.3d at 198 (citation and quotation marks omitted). Regulatory standards are set well below levels known to cause harm to provide a safety margin for vulnerable subgroups, hence an agency's exposure standard "does not compel, or even necessarily support, the *ex post* conclusion that [plaintiff's] leukemia was caused by [benzene]." *Sutera*, 986 F. Supp. at 665. Such standards rely on "a number of protective, often 'worst-case' assumptions," leading to exposure limits that overestimate potential toxicity levels. *McClain*, 401 F.3d at 1249. Governmental "proof of risk" analysis entails different questions (and a lower bar) than the proof of causation required in toxic tort cases. *Id.* Regulatory standards therefore cannot and do not support legal causation opinions in tort.

"[A] regulatory agency … may choose to err on the side of caution." *Rider v. Sandoz Pharmaceuticals Corp.*, 295 F.3d 1194, 1201 (11th Cir. 2002). Courts around the country evaluating the admissibility of expert testimony in benzene cases agree that regulatory standards are insufficient to prove legal causation. *See*, *e.g.*, *Parker v. Mobil Oil Corp.*, 857 N.E.2d 1114, 1122 (N.Y. 2006) ("standards promulgated by regulatory agencies as protective measures [are] inadequate to demonstrate legal causation"); *De Los Santos*, 2024 WL 3700205

at *19 ("regulatory agencies conduct risk-utility analyses involving a much lower standard than that which is demanded by a court of law") (citation and quotation marks omitted); *Baker v. Chevron USA, Inc.*, 680 F. Supp.2d 865, 880 (S.D. Ohio 2010) ("mere fact that Plaintiffs were exposed to benzene emissions in excess of mandated limits is insufficient to establish causation") (citation omitted); *O'Neal v. Dep't of the Army*, 852 F. Supp. 327, 333 (M.D. Pa. 1994) (administrative risk figures are "appropriate for regulatory purposes in which the goal is to be particularly cautious," but "overstate the *actual* risk and, so, are inappropriate for use in determining" civil liability) (emphasis original). These cases reflect the consensus that expert testimony relying on regulatory thresholds as evidence of legal causation is unreliable and inadmissible.

Contrary to this generally accepted principle, Dr. Laumbach repeatedly relied on various regulatory standards. Dr. Laumbach testified regarding multiple regulatory standards, such as those issued by the American Petroleum Institute, the Consumer Product Safety Commission, and OSHA, and their position that no safe limit exists. *See* 4/29/2024 PM, 86:18-24 (CPSC position that there was no safe level of benzene exposure),[9] 98:8-100:8 (referencing OSHA exposure limit; claiming OSHA does not consider individuals "safe from

[9] CPSC's proposed ban never went into effect and was withdrawn in 1981. 46 Fed. Reg. 27910 (CPSC May 13, 1981).

cancer" at lesser exposures) & 103:6-18 (comparing NIOSH exposure limit and claiming NIOSH takes a "no safe level" position).

Dr. Laumbach then contrasted Plaintiff's supposed exposure with these regulatory levels and opined that Plaintiff's exposure exceeded them. 4/30/2024 AM, 73:11-74:3 (comparison with OSHA standard) & 75:10-12 ("ten times: higher than NIOSH standard). As *Betz*, 44 A.3d at 55, and abundant precedent nationwide establish, this methodology is highly prejudicial and not generally accepted. Even assuming exposure above regulatory limits, that does not support—let alone establish—a causal relationship between benzene and Plaintiff's injuries.

Moreover, even if regulatory standards were generally accepted as grounds for legal causation opinions, standards related to benzene (what Dr. Laumbach referenced) say nothing about gasoline. In *Parker*, the highest court in New York, a *Frye* state, recognized that the "key" issue in cases involving gasoline-related benzene exposure is exposure to gasoline—not to benzene alone.

> [Plaintiff's expert's] submissions were likewise insufficient.... [He] concentrates on the relationship between exposure to benzene and the risk of developing AML—an association that is not in dispute. Key to this litigation is the relationship, if any, between exposure to ***gasoline*** containing benzene as a component and AML. [The expert] fails to make this connection perhaps because, as defendants claim, no significant association has been found between gasoline exposure and AML.

857 N.E.2d at 1122 (emphasis original).

Benzene is ubiquitous, "both as a result of human activity and due to natural processes." *Sutera*, 986 F. Supp. at 659. Individuals are routinely exposed to benzene through food, beverages, and drinking water. *Id.* But gasoline is a complex mixture of more than 150 chemical compounds and additives, of which benzene is only one minor component. *Henricksen*, 605 F. Supp.2d at 1150. "[E]ven small differences in chemical structure can sometimes make very large differences in the type of toxic response that is produced." *McClain*, 401 F.3d at 1246; *accord Rider* 295 F.3d at 1201; *Glastetter v. Novartis Pharmaceuticals Corp.*, 252 F.3d 986, 990 (8th Cir. 2001). Thus, regulators have always distinguished between gasoline and benzene exposure.[10] Neither Plaintiffs' experts' reliance on prophylactic government standards, nor their blindly equating benzene with gasoline are generally accepted.

Divergent regulatory approaches to benzene and gasoline underscore what Dr. Laumbach and Dr. Shallis avoided: benzene and gasoline are distinct substances with different toxicological profiles. Yet Plaintiffs' experts treated them interchangeably, using standards and literature on benzene in support of causation opinions about gasoline exposure. This conflation was driven not by

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[10] *See*, *e.g.*, *Henricksen*, 605 F. Supp.2d at 1151 (discussing differences in the regulatory approaches of OSHA and the American Conference of Governmental Industrial Hygienists to gasoline and benzene).

science, but by necessity—as ExxonMobil discusses in detail, no scientific evidence supports Plaintiffs' gasoline-causes-AML theory.

IV. "Differential Diagnosis" That Ignores The Largely Idiopathic Nature Of A Disease At Issue Is Not Generally Accepted.

"AML is one of the most common types of leukemia in adults in the U.S., with approximately 13,000 new cases diagnosed each year." *Henricksen*, 605 F. Supp.2d at 1149. The risk of developing AML increases with age. *Id.* Unlike some diseases, "AML is not a disease that implicates its cause." *Id.* AML is often idiopathic—or "*de novo*"—meaning it develops without any known environmental or external stimulus. *Id.* Alternatively, AML can occur secondary to exposures such as radiation or environmental toxins, including benzene. *Id.* Critically, "[t]he majority (80-90%) of all adult AML cases are *de novo* or idiopathic, with no readily identifiable cause." *Id.*

The largely idiopathic nature of AML presents a scientific barrier to reaching specific causation opinions through a differential diagnosis.[11] Differential diagnosis assumes that the universe of potential causes is sufficiently

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[11] The technically correct term is "differential etiology." *See C.W. v. Textron, Inc.*, 807 F.3d 827, 832 n.4 (7th Cir. 2015) ("differential etiology is a process-of-elimination approach to determining a subject's cause of injury.... Although the parties … refer to this method as a 'differential diagnosis,' that term is really a misnomer. A 'diagnosis' is concerned only about naming the condition or ailment, not establishing its cause"). If applied properly, differential etiology/diagnosis is a "generally accepted" methodology. *Stange v. Janssen Pharmaceuticals, Inc.*, 179 A.3d 45, 55 (Pa. Super. 2018).

limited to permit meaningful exclusion of alternatives. But in the context of largely idiopathic diseases, such as AML, this foundational assumption collapses. For diseases where most cases have no known cause, precedent establishes that differential diagnosis cannot reliably establish specific causation.

Numerous state appellate courts have recognized the fundamental incompatibility between idiopathic conditions and differential diagnosis. *Blackwell v. Wyeth*, applying a *Frye*-based standard, affirmed exclusion of an expert whose purported differential diagnosis ignored "unknown genetics," holding:

> [The trial court] did not err in finding that "a gene or series of interacting genes that have not yet been identified" is the "most prevalent alleged cause of [the condition], based upon our review of the record. We agree that [plaintiffs' expert] did not sufficiently consider genetics in his differential diagnosis equation.

971 A.2d 235, 260 (Md. 2009). This failure to consider medically unknown causes meant that the expert's "theory is no more than hypothesis and conjecture." *Id.* at 261.

Likewise, *Valentine v. PPG Industries, Inc.*, declared that "[t]o state that nothing else caused the [plaintiff's injury] is contrary to the medical and scientific fact that the cause of [that injury] is unknown." 821 N.E.2d 580, 599 (Ohio App. 2004).

> At this point, medical science does not enable physicians and other scientists to pinpoint a cause.... Thus, under the circumstances of this case ... differential diagnosis is not a reliable technique for

> identifying causation.... [T]he present state of scientific knowledge on the cause of [the disease] precludes reliability in this context.

Id. at 599-600. The Ohio Supreme Court affirmed, holding that "[a]lthough differential diagnosis is a standard scientific method for determining causation, its use is appropriate only when considering potential causes that are scientifically known." *Valentine v. Conrad*, 850 N.E.2d 683, 688 (Ohio 2006) (citation omitted); *see* also *Blanchard v. Goodyear Tire & Rubber Co.*, 30 A.3d 1271, 1277 (Vt. 2011) ("a large percentage of cases of [AML] are of unknown origin, so any attempt to establish causation by ruling out other causes must fail"); *Garcia v. City of New Orleans Police Dep't,* 115 So.3d 515, 519 (La. App. 2013) (by admitting "that it is possible that the [condition] was idiopathic," plaintiff's expert "did not perform a differential diagnosis"); *Coastal Tankships, U.S.A., Inc. v. Anderson*, 87 S.W.3d 591, 614 (Tex. App. 2002) ("in this case there are both unknown and ubiquitous causes, both of which it is impossible to 'rule out'") (Brister, J., concurring).

Plentiful federal precedent likewise recognizes the inability of differential diagnosis to evaluate frequently idiopathic medical conditions. "Because idiopathy accounts for more than half of the cases of [AML], a differential diagnosis could be considered inherently unreliable." *Hall v. Conoco Inc.*, 886 F.3d 1308, 1315 (10th Cir. 2018) (affirming exclusion).

> [T]hat decision is particularly critical here given the extensive number of [disease] cases that are idiopathic. Under such

> circumstances, eliminating a number of potential causes—without properly and explicitly "ruling in" a cause—is simply of little assistance. ... [Plaintiff's expert] needed some other method to "rule out" an idiopathic diagnosis…. [T]he extraordinary number of idiopathic [] cases, coupled with the lack of a reliable means to rule out an idiopathic diagnosis here, muted [plaintiff's expert's] ability to reliably apply this methodology.

Milward v. Rust-Oleum Corp., 820 F.3d 469, 476 (1st Cir. 2016) (citation and quotation marks omitted).

Similarly, in *Kilpatrick v. Breg, Inc.*, an expert "could not explain why potentially unknown, or idiopathic alternative causes were not ruled out.... Thus, the key foundation for applying differential diagnosis was missing." 613 F.3d 1329, 1343 (11th Cir. 2010).

> [Plaintiff's expert] ignored such background risks. While recognizing the existence of idiopathic (or unknown) causes of [the condition], he dismissed them by merely stating that the risk of idiopathic [disease] is essentially zero. The failure to take into account the potential for idiopathically occurring [disease] … placed the reliability of [the expert's] conclusions in further doubt.

Id. at 1342 (citations omitted); *accord Chapman v. Procter & Gamble Distributing, LLC*, 766 F.3d 1296, 1311 (11th Cir. 2014) (plaintiff's expert "omitted consideration of idiopathic causes …, rendering his differential diagnosis unreliable"); *Tamraz v. Lincoln Electric Co.*, 620 F.3d 665, 675 (6th Cir. 2010) (expert causation opinion inadmissible because "the vast majority of ... cases" involved "unknown (idiopathic) causation," "making it impossible to ignore and difficult to rule out"); *Bland v. Verizon Wireless, (VAW) LLC*, 538

F.3d 893, 897 (8th Cir. 2008) (an expert's "attempt to use a differential diagnosis ... fails because ... the cause of [the condition] in the majority of cases is unknown").

Trial court precedent holding differential diagnosis unreliable in cases with high levels of unknown cause is legion. In *Soldo v. Sandoz Pharmaceuticals Corp.*, unknown causes were fatal to the plaintiff's attempted differential diagnosis:

> [G]iven plaintiffs experts' admissions that many [incidents] occur for which a particular cause cannot be ascertained even after extensive investigation, consistent application of their own methodology requires them to rule out such idiopathic [incidents] before reliably concluding that [the drug] caused [this incident]. It is impossible to reasonably rule out a cause that cannot even be specifically identified.

244 F. Supp.2d 434, 517 (W.D. Pa. Jan. 13, 2003); *accord*, *e.g.*, *De Los Santos*, 2024 WL 3700205 at *43-44 (excluding differential diagnosis that "fails to reliably rule out idiopathic causes"); *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, 2023 WL 6626581, at *6 (E.D. Pa. Oct. 11, 2023) ("When unexplained causes are common, a differential diagnosis is insufficient when it does not eliminate these causes."); *G v. Fay School, Inc.*, 282 F. Supp.3d 381, 391 (D. Mass. 2017) (plaintiff's expert's "use of the differential diagnosis method failed to reasonably survey other potential causes" because she "neglects to account for the possibility of an idiopathic etiology"), *aff'd*, 931 F.3d 1 (1st Cir. 2019); *Jones v. Novartis Pharmaceuticals Corp.,* 235 F. Supp.3d 1244, 1280

(N.D. Ala. 2017) ("an unreliable application of a background risk methodology leads to the same result as a failure to consider the background risk at all: the expert's opinion will be excluded"), *aff'd*, 720 F. Appx. 1006 (11th Cir. 2018); *McCarty v. Arch Wood Protection, Inc.*, 2016 WL 1306067, at *7 (E.D. Ky. March 31, 2016) ("[T]he experts' differential etiology is not reliable as they failed to rule out an idiopathic cause."); *Hendrian v. Safety-Kleen Sys.*, 2014 WL 1464462, at *7 (E.D. Mich. April 15, 2014) (idiopathic component of AML precluded reliance on differential diagnosis); *Perry v. Novartis Pharmaceuticals Corp.*, 564 F. Supp.2d 452, 470 (E.D. Pa. 2008) ("where most diagnoses of a disease are idiopathic …, analysis beyond a differential diagnosis will likely be required").

Here, neither Dr. Laumbach's nor Dr. Shallis's purported differential diagnoses addressed the primarily idiopathic nature of AML. Dr. Laumbach reviewed radiation exposure, smoking, obesity, and formaldehyde exposure as potential causes of AML, but he never mentioned "idiopathic" or "*de novo*" AML and provided no explanation of how—or even whether—he considered and excluded it as a potential cause. *See* 4/30/2024 AM, 77:9-82:7. Dr. Shallis offered similarly flawed testimony. The only potential causes of AML he addressed were benzene, age, sex, formaldehyde exposure, tobacco smoke, genetics, obesity, and radiation. 5/2/2024 AM, 83:20-84:16, 86:18-23 & 87:13-19. He testified that "[t]here was no evidence of other causes of AML [aside

from benzene]," *id*. at 100:4-22, but on cross-examination, acknowledged that "*de novo*" AML refers to AML "with no known cause." 5/2/2024 PM, 41:2-17. Like Dr. Laumbach, Dr. Shallis offered no methodology or explanation for how, or even if, he ruled out unknown or idiopathic causes of AML.

These omissions fail the *Frye* "generally accepted" standard. A "credible differential diagnosis" must "eliminate as possible causes" all those that appear in the record. *Garced v. United Cerebral Palsy of Philadelphia*, 307 A.3d 103, 122 (Pa. Super. 2023). That necessarily includes idiopathic causes. *See Walsh*, 234 A.3d at 460-61 (evidence "that up to 85% of AML cases are idiopathic" required "renew[ed]" *Frye* motions on remand). For this reason, as well, the verdict here cannot stand. "A rose by another name may smell as sweet—but simply calling an analysis a differential diagnosis doesn't make it so." *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Prods. Liab. Litig.*, 892 F.3d 624, 643 (4th Cir. 2018).

CONCLUSION

The Pennsylvania Supreme Court has repeatedly disapproved of lax expert opinions, like the ones at issue here, which do not comport with Pennsylvania's general acceptance standard for expert testimony, and which are legally insufficient to establish causation. This Court should reinforce those prior decisions and reverse the trial court's judgment.

Respectfully submitted,

June 23, 2025

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COMBINED CERTIFICATES OF COMPLIANCE AND SERVICE

I hereby certify that the foregoing brief complies with the word limit of Pennsylvania Rule of Appellate Procedure 531(b)(3). Specifically, it contains 6892 words based on the word count of Microsoft Word 2010, the word processing system used to prepare the brief.

I further certify that this filing complies with the provisions of the Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts that require filing confidential information and documents differently than non-confidential information.

I further certify that on June 23, 2025, I caused true and correct copies of the foregoing Brief of Amici Curiae Product Liability Advisory Council, Inc., National Association of Manufacturers, DRI Center for Law and Public Policy, Federation of Defense and Corporate Counsel, and Pennsylvania Defense Institute in Support of Appellant to be electronically served on all parties listed in this Court's docket.

Dated: June 23, 2025

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IN THE SUPERIOR COURT OF PENNSYLVANIA

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v.	:	
Shell Oil Company, Berryman Products, Inc., Univar USA, Inc., Ashland, LLC, Brenntag Southwest, Union OIl Company of California, Blaster Corporation, Illinois Tool Works, Inc., Henkel Corporation, Root Oil Company, Exxon Mobil Corporation, United States Steel Corporation, Radiator Specialty Company, Atlantic Richfield Company, CRC Industries, Inc., Sunoco, LLC (R&M) Sun Company, Safety-Kleen Systems, Inc.	:	
Appeal of: Exxon Mobil Corporation		

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