

In The
Supreme Court of Pennsylvania

Consolidated Appeals
Nos. 14 WAP 2019, 15 WAP 2019, 16 WAP 2019, 17 WAP 2019, 18 WAP 2019

RICHARD THOMAS WALSH, executor of the estate of THOMAS J. WALSH,
Plaintiff/Appellee,

v.

**BASF CORP., BAYER CORP. d/b/a BAYER CROPSCIENCE LP,
BAYER CROPSCIENCE HOLDING, INC., in their own right, BIOSAFE SYSTEMS
LLC, CHEMTURA CORP., CLEARY CHEMICAL CORP., DOW AGROSCIENCES
LLC, E.H. GRIFFITH, INC., E.I. DUPONT DE NEMOURS & CO., G.B. BIOSCIENCES
CORP., JOHN DEERE LANDSCAPING, INC., successor to LESCO, INC., MONSANTO
CO., NUFARM AMERICAS, INC., REGAL CHEMICAL CO., SCOTTS-SIERRA CROP
PROTECTION CO., and SYNGENTA CROP PROTECTION, INC.,**
Defendants/Appellants.

**BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC.,
ET AL., AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS**

**Appeal from Order of the Superior Court of Pennsylvania, Entered June 20, 2018
at No. 1661 WDA 2016, Vacating the Judgment of the Court of Common Pleas of
Allegheny County, Civil Division, at No. GD-10-018588, dated October 5 and 14, 2016**

JAMES M. BECK (#37137)
Reed Smith LLP
Three Logan Square
Suite 3100
1717 Arch Street
Philadelphia, PA 19103-7301
(215) 851-8168
jmbeck@reedsmith.com

**Counsel for *Amici Curiae* Product Liability Advisory Council, Inc., CropLife America,
Pennsylvania Chamber of Business & Industry, Chamber of Commerce of the United
States, National Association of Manufacturers, American Tort Reform Association,
Washington Legal Foundation, Coalition for Litigation Justice, Inc., Pennsylvania
Coalition for Civil Justice Reform, and NFIB Small Business Legal Center**

STATEMENTS OF INTEREST OF AMICI CURIAE

The Product Liability Advisory Council, Inc. (“PLAC”) is a non-profit professional association with scores of corporate members representing a broad cross-section of American and international product manufacturers.¹ These companies seek to contribute to the improvement and development of the law in the United States and elsewhere, particularly that governing the liability of manufacturers of products 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 1,100 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 affecting product risk management.

CropLife America (“CLA”), established in 1933, is the national trade association for the plant science industry, representing developers, manufacturers, formulators, and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA’s

¹ PLAC’s complete membership list is available at <https://plac.com/PLAC/AboutPLACAmicus>.

member companies produce, sell, and distribute virtually all the crop protection products, including herbicides, insecticides, and fungicides, which American farmers use to provide consumers with abundant food and fiber. CLA is committed to safe and responsible use of the industry's products.

The Pennsylvania Chamber of Business & Industry ("PA Chamber") is the largest broad-based business association in Pennsylvania. The over 10,000 current members of the PA Chamber range from sole proprietors to Fortune 100 companies, and employ nearly 50% of the private sector workforce. The PA Chamber is not affiliated with any political party and is not a part of government. The PA Chamber's mission is to act as a statewide voice of business and to advocate on those public policy issues that expand private sector job creation and lead to a more prosperous Commonwealth.

The Chamber of Commerce of the United States of America ("U.S. Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million U.S. businesses and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the U.S. Chamber is to represent the interests of its members before the courts. To that end, the U.S. Chamber regularly files *amicus* briefs in cases that raise issues of concern to the nation's business community.

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 fifty states. Manufacturing employs more than twelve million men and women, contributes \$2.25 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters 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 to compete in the global economy and to create jobs across the United States.

Founded in 1986, the American Tort Reform Association (“ATRA”) is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For over two decades, ATRA has filed *amicus* briefs in cases that have addressed important liability issues.

The Washington Legal Foundation (“WLF”) is a nonprofit, public-interest law firm and policy center with supporters in all 50 states, including Pennsylvania. WLF promotes free enterprise, individual rights, limited government, and the rule of law. To that end, WLF often appears as *amicus curiae* to advocate for judicial decisions based on scientifically valid principles and data.

The Coalition for Litigation Justice, Inc. is a nonprofit association formed by insurers to address problems in toxic tort litigation.² The Coalition files *amicus* briefs in cases with potentially significant impact on the toxic tort litigation environment. The Coalition has filed over 150 *amicus* briefs and has appeared as *amicus* in this Court several times.

The Pennsylvania Coalition for Civil Justice Reform is a statewide, nonpartisan alliance of organizations and individuals representing businesses, professional and trade associations, health care providers, nonprofit entities, taxpayers, and other perspectives. The coalition is dedicated to bringing fairness to our courts by elevating awareness of civil justice issues and advocating for legal reform.

The NFIB Small Business Legal Center is a nonprofit, public interest law firm established to be the legal voice of small businesses on issues of public interest affecting them. The National Federation of Independent Business (“NFIB”), founded in 1943, is the nation’s leading small business association representing members in Washington, D.C. and all 50 states. NFIB’s membership ranges from sole proprietorships to firms with hundreds of employees. The typical

² The Coalition includes Century Indemnity Company; Allianz Reinsurance America, Inc.; Great American Insurance Company; Nationwide Indemnity Company; Resolute Management, Inc., a third-party administrator; and TIG Insurance Company.

NFIB member employs 10 people and reports gross sales of about \$500,000 a year. The NFIB membership is a reflection of American small business.

Members of these *amici*, as defendants in product liability and other cases, frequently confront expert opinions involving exposure to allegedly toxic substances. To conform to generally accepted scientific and medical standards, expert causation opinions in toxic-substance cases must address: (1) the particular chemical substance alleged to have caused the plaintiff's injury, and (2) the particular injury claimed by the plaintiff. Generic opinions of the sort the Superior Court allowed here, which fail to distinguish between many different products and diseases with differing etiologies, are manifestly insufficient. Such opinions go far beyond "generally accepted" science under Pennsylvania's Frye expert standards.

The Superior Court's unprecedented opinion allowing experts to opine that entire categories of chemicals generally could cause cancer (or any other broad category of disease) undermines both the trial courts' gatekeeping function and accepted causation principles. Many different chemicals are used as insecticides, herbicides, or fungicides – collectively referred to more broadly as "pesticides." Multiple prescription drugs may likewise treat the same medical conditions. Many different substances may be used as solvents, paints, petroleum additives, and cleaning agents. Allowing "aggregate" causation opinions threatens to confuse juries and to impose baseless, industry-wide liability for alleged toxic exposures.

Given the broad implications of allowing such expert testimony, well beyond the substances at issue in this case, *amici* are well suited to explain the public importance of these issues to the Court, apart from and beyond the immediate interests of the parties to this case.³

³ Under Pa. R.A.P. 531(b)(2), *amici* state that no person, other than the *amici*, their members, and their counsel, paid for or authored this brief, in whole or in part.

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**BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC.,
ET AL., AS AMICI CURIAE IN SUPPORT OF APPELLANTS**

QUESTIONS PRESENTED

The questions accepted by this Court for review are:

(1) Did the Superior Court majority commit reversible error in concluding that, when evaluating scientific evidence under the Frye standard, trial courts are not permitted to act as “gatekeepers” to ensure the relevance and reliability of scientific studies offered by experts to support their opinions by scrutinizing whether those studies actually support their opinions?

(2) Did the Superior Court majority commit reversible error in concluding that trial courts may not review experts’ opinions extrapolating from a broad class of products and injuries to a specific product and injury, thereby eliminating plaintiff’s burden to show product-specific causation of plaintiff’s specific injury?

(3) Did the Superior Court majority commit reversible error in concluding that the trial court erred without explaining how it abused its discretion because of manifest unreasonableness, partiality, prejudice, bias, ill-will or such lack of support from the evidence or the record so as to be clearly erroneous?

SUMMARY OF ARGUMENT

The Superior Court’s decision in this appeal is erroneous in several respects. First, it overturned a detailed and well-supported trial court expert exclusion order due to disagreement over how to weigh the bases of the experts’ opinions. Doing so ignored the applicable abuse of discretion standard.

Second, the Superior Court expressly denied that trial courts exercise any “proper role” as gatekeepers when determining whether expert testimony is “generally accepted” in the relevant scientific community. That narrow interpretation of judicial discretion is contrary to both Pennsylvania and nationwide precedent applying the Frye standard.⁴

Third, and finally, the “aggregate” causation opinions that the Superior Court permitted are flatly contrary to Pennsylvania law. Liability for defective products in Pennsylvania requires juries to determine that particular products have caused specific injuries – not that pesticides, in general, may cause cancer, also in general. Accordingly, plaintiff’s experts’ aggregate opinions could not help the jury decide this case, and should be excluded.

⁴ Frye refers to Frye v. United States, 293 F. 1013 (D.C. Cir. 1923), which originated the “general acceptance”-based standard for evaluating expert testimony that Pennsylvania follows.

ARGUMENT

I. THE SUPERIOR COURT’S DECISION FAILED TO RESPECT THE DISCRETIONARY ROLE OF JUDICIAL GATEKEEPING.

A. The Superior Court’s Decision Ignored The Applicable Abuse Of Discretion Standard Of Review.

Under Pennsylvania’s rules governing admissibility of expert testimony, the proponent of such testimony bears the significant burden of proving “that the methodology an expert used is generally accepted by scientists in the relevant field as a method for arriving at the conclusion the expert will testify to at trial.” Grady v. Frito-Lay, Inc., 839 A.2d 1038, 1045 (Pa. 2003). Trial court judges thus serve a crucial gatekeeper function, to evaluate proposed experts’ methodology for consistency with accepted standards and to avoid confusing jurors with testimony based on unaccepted methods.

Given the trial courts’ authority over evidence and trial management, the proper standard of review of a decision to admit or exclude expert testimony under Pennsylvania’s Frye standard is abuse of discretion. E.g., Rost v. Ford Motor Co., 151 A.3d 1032, 1044 (Pa. 2016); Betz v. Pneumo Abex, LLC, 44 A.3d 27, 54 (Pa. 2012).

Abuse of discretion is the most deferential standard of appellate review. An appellate court may not reverse a trial court’s Frye determination unless it resulted from “manifest unreasonableness, or partiality, prejudice, bias, or ill-will, or such lack of support from the evidence or the record so as to be clearly

erroneous.” Polett v. Public Communications, Inc., 126 A.3d 895, 914 (Pa. 2015) (citations and quotation marks omitted).

Put another way, an appellate court may not reverse and substitute its judgment for that of the trial court because it “might have reached a different conclusion.” Grady, 839 A.2d at 1046. But that is exactly what the Superior Court did here. Rather than reviewing for abuse of discretion, it “looked directly at [the expert’s] testimony, decided what it thought of it, and reversed the trial court because it assessed the testimony differently.” Id. As in Grady, that was reversible error.

Judge R. Stanton Wettick, Jr. excluded plaintiff’s experts because they failed to apply generally accepted methodology in forming their opinions that the defendants’ 14 chemically dissimilar products caused the acute myelogenous leukemia (“AML”), allegedly suffered by plaintiff’s decedent.⁵ Instead, plaintiff’s experts sought to draw upon research concerning numerous chemical products, not at issue, and to opine about aggregate risks posed by exposure to “pesticides” in general. As Judge Wettick noted, plaintiff’s own expert opined that, even if “some pesticides cause acute myeloid leukemia does not necessarily mean that all pesticides, as a class, can cause this disease.”

⁵ These chemically dissimilar products range from Daconil, a broad spectrum organochloride fungicide utilizing enzyme antagonism, to Dursban, an organophosphate with neurotoxic effects on insects. Appellants’ briefs describe the chemical diversity of these products in more detail.

Appellants' Tab B, slip op. at 2. Those opinions' fatal lack of specificity also extended to plaintiff's alleged harm. Id. at 3 (observing that "chromosomal aberrations are not AML").

Judge Wettick's review of particular scientific articles, with which the Superior Court took issue, was appropriately limited to determining that the articles did not involve either the chemicals, or the alleged injury, at issue in this litigation. In City of Philadelphia Fire Dept. v. Workers' Compensation Appeal Board, 195 A.3d 197 (Pa. 2018) ("Sladek"), the Court recently confirmed that an expert opinion which, as here, "relied upon the total number of epidemiological studies supporting his opinion, without any suggestion that the content of the studies had to be considered," was "questionable" under Frye.⁶ If that level of judicial gatekeeping were held improper, then an expert may as well claim support from a telephone book, while the trial judge powerlessly looks on.

B. Frye Requires Trial Courts To Consider The Reliability Of Expert Methodology In A Case-Specific Context.

Contrary to what the Superior Court's decision would suggest, this Court has not restricted Grady/Frye evaluation of testimony to a mere rote evaluation

⁶ Id. at 209 n.15. Similarly "questionable" is the Superior Court's vague reliance on "more than 700 articles and studies," Appellants' Tab A, slip op. at 9, without identifying any of them or their conclusions. Although the opinion claims that "the record reveal[ed]" those articles, the record itself does not contain anywhere near 700 articles.

of scientific novelty. See Appellants' Tab A, slip op. at 19, citing a pre-Grady, pre-Betz decision, Trach v. Fellin, 817 A.2d 1102, 1104 (Pa. Super. 2003) (en banc), as authority that the Frye standard "must be construed narrowly." The Superior Court's position would leave trial courts no discretion to exercise.

In Grady, the relevant scientific principles were supposedly "as old as the pyramids," 839 A.2d at 1043, but that did not end the inquiry. Rather, Frye applies not only to "novel" science, but also to scientific methods utilized in a novel way. Id. at 1045. In Betz, the Court recognized that "a narrower approach would unduly constrain trial courts," and instead construed "novel" in a "reasonably broad" fashion – specifically including whether "an expert witness has not applied accepted scientific methodology in a conventional fashion in reaching his or her conclusions." 44 A.3d at 52 (Grady citations omitted).

Demonstrably, under Frye, Pennsylvania's trial courts are more than mere turnstiles that allow any opinion, provided only that an expert incants reliance on "scientific literature." Particularly, cases involving allegations of diseases caused by exposure to chemicals and other toxins involve complex issues of general and specific causation. For example, "[m]any types of

leukemia exist,”⁷ – just as do many different kinds of “cancer,” “autoimmune disease,” “cardiovascular disease,” “diabetes,” and “stroke.”⁸ Thus, it is critical that expert testimony address specific substances, specific injuries, and how they are connected. Aggregate opinions about chemical risks are thus contrary to accepted medico-legal practice. Nelson v. Airco Welders Supply, 107 A.3d 146, 158 (Pa. Super. 2014) (en banc) (inability “to establish the impact of incremental exposure posed by the products to which [plaintiff] was exposed” failed Frye as a matter of law); Snizavich v. Rohm & Haas Co., 83 A.3d 191, 193, 197 (Pa. Super. 2013) (non-specific expert opinion that some of the “thousands of chemicals” in plaintiff’s occupational history caused his particular cancer not generally accepted under Frye); Checchio v. Frankford Hospital, 717 A.2d 1058, 1061-62 (Pa. Super. 1998) (evidence that hypoxia caused brain damage could not support opinion that same injury caused autism). Conversely, product- and disease-specific opinions pass Frye muster.

⁷ Mayo Clinic, “Leukemia,” available at < <https://www.mayoclinic.org/diseases-conditions/leukemia/symptoms-causes/syc-20374373> > (last visited April 23, 2019).

⁸ See National Cancer Institute, Cancer Types < <https://www.cancer.gov/types> >; AARDA, “Autoimmune Disease List < <https://www.aarda.org/diseaselist/> >; World Health Organization, Types of Cardiovascular Disease < https://www.who.int/cardiovascular_diseases/en/cvd_atlas_01_types.pdf >; International Diabetes Federation, Types of Diabetes < <https://www.idf.org/aboutdiabetes/what-is-diabetes.html> >; CDC, Types of Stroke < https://www.cdc.gov/stroke/types_of_stroke.htm > (all last visited May 10, 2019).

See Rost, 151 A.3d at 1046 (expert properly testified to hypothetical including the plaintiff’s “actual exposures” to particular defendants’ products); Stange v. Janssen Pharmaceuticals, Inc., 179 A.3d 45, 55 (Pa. Super. 2018) (causation opinion that a particular drug (Risperdal) causes a specific condition (gynecomastia) held admissible). Accordingly, Judge Wettick’s analysis fell fully within his discretion.⁹

The Superior Court did just the opposite of its role under the applicable standard of review – substituting its own judgments and reweighing the evidence. For example, the Superior Court criticized Judge Wettick for discounting animal studies, in favor of its own approach that relied on “animal and in vitro studies” as well as “EPA assess[ment of] the cumulative risk of pesticides.”¹⁰ But this Court has recognized that an expert’s “efforts to invoke case reports, animal studies, and regulatory standards are also ineffectual in terms of substantial-factor causation, since the most these can do is suggest that

⁹ Other courts directly addressing this issue agree. See, e.g., Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d 1194, 1202, (11th Cir. 2002) (“[e]vidence suggest[ing] that [a chemical] may cause ischemic stroke does not apply to situations involving hemorrhagic stroke. This is ‘a leap of faith’ supported by little more than the fact that both conditions are commonly called strokes”).

¹⁰ Appellants’ Tab A, slip op. at 16; see id. at 13 (discussing Judge Wettick’s determination that certain animal studies were “scientifically unacceptable”). Unlike courts and juries, administrative agencies “may make regulatory decisions ... based on postmarketing evidence that gives rise to only a suspicion of causation.” Matrixx Initiatives, Inc. v. Siracuso, 563 U.S. 27, 42 (2011) (citation omitted).

there is underlying risk from the defendants' products." Betz, 44 A.3d at 55. Accord Blum v. Merrell Dow Pharmaceuticals, Inc., 764 A.2d 1, 3-4 & n.5 (Pa. 2000) ("epidemiological studies," specifically "[o]ver thirty" of them, trumped "chemical structure analysis, *in vitro* (test tube) and *in vivo* (animal) teratology studies" as a matter of law).

The Superior Court also criticized as "narrow" Judge Wettick's view that experts are "limit[ed] ... to the conclusions reached by a study." Appellants' Tab A, slip op. at 13-14. But this Court has determined that "reach[ing] conclusions not reached by the original studies ... cannot be fairly described as generally accepted methodology for Frye purposes." Commonwealth v. Dengler, 890 A.2d 372, 382 (Pa. 2005) (citation and quotation marks omitted). Yet again, the Superior Court's review was both erroneously intrusive and substantively incorrect.

In sum, Judge Wettick acted well within his discretion. In each of Polett, Betz, and Grady, this Court reversed the Superior Court for inappropriately severe review of discretionary rulings by the trial courts. This Court should do likewise here. The Superior Court's repeated second-guessing of a trial court's discretionary authority under Frye greatly erodes such courts' obligation to act as "gatekeepers" of expert testimony.

C. Courts Across The Country Require Judicial Gatekeeping In Evaluating Expert Opinion Testimony Under Frye.

The Superior Court’s opinion disparaged the “accepted process” of “a trial court ... performing its gate-keeping function” under Frye. Commonwealth v. Walker, 92 A.3d 766, 792 (Pa. 2014). Appellants’ Tab A, slip op. at 10 (describing gatekeeping as “not the proper role of a trial court in a Frye inquiry”). Several members of this Court,¹¹ as well as prior Superior Court decisions,¹² have expressly endorsed the “gatekeeping” role of trial judges with respect to the general acceptance of expert testimony in civil cases. Courts are “right to be circumspect about the scientific methodology underlying” controversial opinions. Rost, 151 A.3d at 1044 (quoting Betz, 44

¹¹ Rost, 151 A.3d at 1064 (“courts should maintain a gatekeeping role relative to expert testimony about the critical issue of substantial-factor causation in toxic tort cases”) (Saylor, C.J. & Baer, J., dissenting); Commonwealth v. Safka, 141 A.3d 1239, 1260 (Pa. 2016) (“The civil rules address Frye and contemplate a gatekeeping function by the trial court.”) (Dougherty, J. dissenting); Vicari v. Spiegel, 989 A.2d 1277, 1288 (Pa. 2010) (supporting “the trial court’s evidentiary gate-keeping role ... regarding the admissibility of expert witness testimony”) (Castille, C.J., concurring); Blum, 764 A.2d at 6 (“the trial court judge’s role as ‘gatekeeper’ in applying the Frye test is a critical one”) (Cappy, J. dissenting).

¹² Grady v. Frito-Lay, Inc., 789 A.2d 735, 740 (Pa. Super. 2001) (“a Frye inquiry ... enable[s] the trial court, acting as a gatekeeper ... to ensure the reliability and relevancy of ... expert testimony”), rev’d in part on other grounds, 839 A.2d 1038 (Pa. 2003); Checchio, 717 A.3d at 1062 (“the judge as gatekeeper decides whether the expert is offering sufficiently reliable, solid, trustworthy science”) (quoting Blum v. Merrell Dow Pharmaceuticals, Inc., 705 A.2d 1314, 1322 (Pa. Super. 1997), aff’d, 764 A.2d 1 (Pa. 2000)).

A.3d at 53). Such opinions are “precisely the sort of evidence that merits thoughtful inquiry.” Betz, 44 A.3d at 54.

This Court has explained that Pennsylvania’s Frye test requires close evaluation of whether the proponent of expert testimony has satisfied its burden of establishing that the expert’s methodology “is generally accepted by scientists in the relevant field as a method for arriving at the conclusion the expert will testify to at trial.” Grady, 839 A.2d at 1045 (citation omitted). Grady “[h]ighlight[ed] the trial court’s role in screening scientific evidence for reliability before permitting such evidence to be put before a jury.” Betz, 44 A.3d at 31. This role often results in a hearing to test reliability. See Rost, 151 A.3d at 1044, 1046 (Frye hearing included a detailed evaluation of the factual and scientific underpinnings of the expert opinion at issue);¹³ Pa. R. Civ. P. 207.1. “The alternative is to permit experts to evade a reasoned Frye inquiry merely by making references to accepted methods in the abstract.” Betz, 44 A.3d at 58.

Eight other states retain Frye-based expert admissibility standards: (1) California; (2) New Jersey; (3) Maryland; (4) Florida; (5) Illinois; (6)

¹³ Review in Rost included the expert’s testimony about whether the plaintiff’s “actual exposures” to a defendant’s particular product caused “mesothelioma,” as distinguished from “other asbestos-related diseases.” Id. at 1046 (“taking into consideration exposure history, individual susceptibility, biological plausibility, and relevant scientific evidence (including epidemiological studies)”) (footnote omitted).

Minnesota; (7) Washington; and (8) New York. All of these states require trial courts to act as evidentiary gatekeepers against untrustworthy science.

California: The California Supreme Court recognizes that “the trial court acts as a gatekeeper” in three circumstances – where proffered expert testimony is: “(1) based on matter of a type on which an expert may not reasonably rely, (2) based on reasons unsupported by the material on which the expert relies, or (3) speculative.” Sargon Enterprises, Inc. v. University of Southern California, 288 P.3d 1237, 1252 (Cal. 2012). Under California’s “Kelly/Frye” regime:

[T]he gatekeeper’s role is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field.

Id. (citations and quotation marks omitted). A trial court does not abuse its discretion when “act[ing] as a gatekeeper to exclude speculative expert testimony” – especially when it “presided over a lengthy evidentiary hearing and provided a detailed ruling.” Id. at 1251, 1255.¹⁴

New Jersey: Last year, New Jersey “broadened” its Frye-based expert standard while emphasizing the critical nature of the trial courts’ “gatekeeping” role. In re Accutane Litigation, 191 A.3d 560, 595 (N.J. 2018). As here, the

¹⁴ The gatekeeping role in California extends to all situations involving expert testimony. See Apple Inc. v. Superior Court, 228 Cal. Rptr.3d 668, 681-82 (Cal. App. 2018) (applying standard to expert testimony on class certification), review denied (Cal. May 16, 2018).

trial court in Accutane had issued a detailed opinion excluding questionable expert testimony, but the intermediate appellate court reversed and constrained the trial court's discretion. The New Jersey Supreme Court unanimously reversed. First, "[t]he gatekeeping role requires care. The process of making such determinations is complicated, and ... difficult." Id. at 589 (citations and quotation marks omitted). Second, the "rigorous" "gatekeeping role necessitates examination of a methodology espousing a new theory in medical cause-and-effect cases." Id. Third, gatekeeping exists to "prevent[] the jury's exposure to unsound science through the compelling voice of an expert." Id. (citation omitted).

Maryland: In Maryland, the prevailing expert analysis is called "Frye-Reed." "From even a limited review of our Frye-Reed history, it can be seen that our jurisprudence engages trial judges in a serious gate-keeping function, to differentiate serious science from 'junk science.'" Blackwell v. Wyeth, 971 A.2d 235, 245 (Md. 2009). "[D]etails [of expert methodology] are exactly pertinent to the Frye-Reed gatekeeping function, and [must] be presented at the Frye-Reed hearing." Savage v. State, 166 A.3d 183, 201 (Md. 2017).

Florida: Florida's Frye standard is similar. "Frye requires that the judge perform the function of gatekeeper." State v. Demeniuk, 888 So.2d 655, 658 (Fla. App. 2004). This "gatekeeping role require[s] [a court] to determine whether the methodology used to generate the statistical analysis satisfied the

Frye test.” Casias v. State, 94 So.3d 611, 615 (Fla. App. 2011). Indeed, Florida demands the same expert inquiry that the Superior Court prohibited here. Under Florida’s Frye standard, “[a] bald assertion by the expert that his deduction is premised upon well-recognized scientific principles is inadequate to establish its admissibility if the witness’s application of these principles is untested and lacks indicia of acceptability.” Ramirez v. State, 810 So.2d 836, 844 (Fla. 2001).

Illinois: In Illinois, a Frye analysis of scientific expert testimony is a “general gatekeeping question of whether [the testimony is] reliable enough for admission.” People v. Watson, 965 N.E.2d 474, 501 (Ill. App. 2012). The exercise involves the “trial court record . . . , sources outside the record, ... legal and scientific articles, as well as court opinions from other jurisdictions.” In re Commitment of Simons, 821 N.E.2d 1184, 1189 (Ill. 2004).¹⁵

Minnesota: The “foundational reliability standard” required by Minnesota’s “Frye-Mack” standard creates a gatekeeping role for the trial court. Review has two prongs, general acceptance, and “that [the methodology] produced reliable results in the specific case.” State v. Bailey, 677 N.W.2d 380, 398 (Minn. 2004). “The proponent of scientific evidence has

¹⁵ Simons expressly overruled Donaldson v. Central Illinois Public Service Co., 767 N.E.2d 314, 324 (Ill. 2002), which had held that “Frye does not make the trial judge a ‘gatekeeper’ of all expert opinion testimony.”

the burden to establish the proper foundation for the admissibility of the test by showing that the methodology used is reliable and in the particular instance produced reliable results.” Goeb v. Tharaldson, 615 N.W.2d 800, 816 (Minn. 2000) (affirming exclusion of causation opinions in Dursban litigation). “The district court, in exercising its authority as the gatekeeper for admitting evidence, must consider the reliability, consistency, and accuracy of the subject matter and ultimately determine whether the proffered evidence is reliable.” Ly v. North Memorial Medical Center, 2018 WL 1570150, at *4 (Minn. App. April 2, 2018), review denied (Minn. June 19, 2018).

Washington: Likewise, in Washington State, “[t]he courts serve [a] gatekeeping function” when Frye challenges are made. L.M. v. Hamilton, 436 P.3d 803, 810 (Wash. 2019). “The trial court’s gatekeeper role under Frye ... requir[es] careful assessment of the general acceptance of the theory and methodology,” which “ensure[s], among other things, that ‘pseudoscience’ is kept out of the courtroom.” State v. Copeland, 922 P.2d 1304, 1314 (Wash. 1996).

New York: The nation’s leading leukemia causation decision, Parker v. Mobil Oil Corp., 857 N.E.2d 1114 (N.Y. 2006), likewise enforced the “gatekeeping role of ensuring the reliability of the proposed scientific evidence.” Fraser v. 301-52 Townhouse Corp., 870 N.Y.S.2d 266, 281 (N.Y.A.D. 2008). Parker affirmed that courts considering causation of

leukemia “had to determine whether the accepted methods were appropriately employed in a particular case.” 857 N.E.2d at 1120. “The focus moves from the general reliability concerns of Frye to the specific reliability of the procedures followed to generate the evidence proffered and whether they establish a foundation for the reception of the evidence at trial.” Id. (citation and quotation marks omitted). “[W]e recognize the danger in allowing unreliable or speculative information (or ‘junk science’) to go before the jury.” Id.¹⁶

If allowed to stand, the Superior Court’s decision here – denigrating both the necessity for and extent of judicial gatekeeping as part of evaluating the admissibility of expert testimony – would turn Pennsylvania into an outlier among those states retaining Frye expert admissibility standards. Needless to say, the role of judicial gatekeeping concerning expert testimony is also at the heart of the approaches taken by the majority of states that have moved away from Frye, and largely follow a Daubert¹⁷ approach. As the Texas Supreme Court has held:

¹⁶ Thus Parker also held that “standards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation.” Id. at 1122.

¹⁷ Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993). Like this Court’s decision in Blum, Daubert rejected unreliable causation testimony in Bendectin litigation.

[T]he trial court's gatekeeping inquiry will differ with each particular case.... In determining reliability, the trial court should undertake a rigorous examination of the facts on which the expert relies, the method by which the expert draws an opinion from those facts, and how the expert applies the facts and methods to the case at hand. A significant part of the trial court's gatekeeper function is to ... determine which factors and evaluation methodology are most appropriate to apply.

Mack Trucks, Inc. v. Tamez, 206 S.W.3d 572, 579 (Tex. 2006) (citations omitted). The highest courts of almost every other state expressly acknowledge the role of judicial gatekeeping in evaluating expert testimony. See, e.g., Commonwealth v. Camblin, 86 N.E.3d 464, 470 (Mass. 2017) (“The judge, acting as gatekeeper, is responsible for making a preliminary assessment whether the theory or methodology underlying the proposed testimony is sufficiently reliable”) (citation and quotation marks omitted); Tumlinson v. Advanced Micro Devices, Inc., 81 A.3d 1264, 1269 (Del. 2013) (“the trial court must act as a gatekeeper to determine whether the expert opinion testimony is both (i) relevant and (ii) reliable”) (footnote omitted); Terry v. Caputo, 875 N.E.2d 72, 77-78 (Ohio 2007) (the “gatekeeping function imposes an obligation upon a trial court to assess both the reliability of an expert’s methodology and the relevance of any testimony offered”).

Pennsylvania’s Frye-based standard for admission of expert testimony is actually “more restrictive” than the “less exacting” federal Daubert test,” which “may permit evidence based on scientific theory not yet generally accepted.”

Blum, 764 A.2d at 2-3, 9 (majority and dissenting opinions). Contrary to the Superior Court, however, nothing in the Frye standard is incompatible with the universally recognized judicial gatekeeping function. What is excludable under Daubert should *a fortiori* be excludable under Frye's analogous jurisprudential standards.¹⁸

II. PLAINTIFF'S AGGREGATE CAUSATION THEORY DOES NOT FIT PENNSYLVANIA LAW, WHICH REQUIRES PROOF THAT A PARTICULAR DEFENDANT'S PRODUCT CAUSED A PLAINTIFF'S PARTICULAR INJURY.

The Superior Court's unprecedented endorsement of "aggregate" causation opinions, the substantive reason for its disagreement with Judge Wettick, is contrary to Pennsylvania law. The Superior Court reversed summary judgment by endorsing the use of "aggregate" expert opinions – that "pesticides" in general can cause "cancer" or "leukemia" in general.

Although the epidemiological studies cited by [plaintiff's] experts did not explore whether exposure to one particular pesticide product caused AML, we reject Defendants' contention that such specific studies were required.

Appellants' Tab A, slip op. at 16.

That is simply wrong. "[D]ifferent types of cancers have different etiologies." Sladek, 195 A.3d at 208. All expert testimony must "help the trier of fact." Pa. R. Evid. 702(b). "[I]nherent in the rationale behind the use of

¹⁸ See Engstrom v. Bayer Corp., 855 A.2d 52, 58 (Pa. Super. 2004) ("any information which would satisfy Frye would, *a priori*, satisfy Daubert).

expert testimony ... is that it must be helpful in elucidating matters” for the jury. Checchio, 717 A.2d at 1062. Because Pennsylvania tort law does not determine causation in the aggregate, the reports at issue could only confuse the jury. Here, “the technique [plaintiff] sought to introduce” – opining on causation in the “aggregate” – “could not assist a jury in determining any fact in issue.” Grady, 839 A.2d at 1052 (Newman, J., concurring).

In any multi-exposure, strict liability case, Pennsylvania law requires that, “to create a jury question, a plaintiff must adduce evidence that exposure **to defendant’s** [allegedly harmful] **product** was sufficient[] ... to support a jury’s finding **that defendant’s product** was substantially causative of the disease.” Rost, 151 A.3d at 1044 (citation, quotation marks, and footnote omitted) (emphasis added). Likewise, in negligence, “[t]he plaintiff also must establish that the [defendant’s] negligence was a substantial factor in causing the harm to the injured party.” Welsh v. Bulger, 698 A.2d 581, 585 (Pa. 1997) (citation omitted). The requirement that a plaintiff identify a specific product as the cause of a specific injury is identical in both negligence and strict liability.¹⁹

¹⁹ Skipworth v. Lead Industries Ass’n, 690 A.2d 169, 172 (Pa. 1997) (applying same “general rule” of proximate cause developed in negligence to strict liability toxic product exposure case); Sherk v. Daisy Heddon, a Division of Victor Comptometer Corp., 450 A.2d 615, 618 (Pa. 1982) (“strict liability has made no change” in causation rules “well settled in negligence cases”) (citation and quotation marks omitted). Likewise, Tragarz v. Keene Corp., 980

Aggregate causation opinions do not fit with Pennsylvania’s adherence to the Restatement (Second) of Torts §402A (1965). The black letter of §402A demands product-specific causation. “One who sells any product in a defective condition unreasonably dangerous ... is subject to liability for physical harm **thereby** caused to the ultimate user or consumer” (emphasis added). Thus, in Pennsylvania, “those who sell a product are held responsible for damages caused to a consumer by the reasonable use of the product.” Tincher v. Omega Flex, Inc., 104 A.3d 328, 403 (Pa. 2014) (citations omitted). That product’s defect must be “causally connected to a compensable injury.” Id. at 383-84. The plaintiff has the “burden to prove that the harm suffered was due to the defective condition of the product.” Id. at 407.

The §402A element of product-specific causation is particularly important in cases, such as this, claiming exposure to alleged toxins. In such cases, the law has always required that “every tort plaintiff must prove that the defendant’s conduct caused his or her injury.” Ball v. Bayard Pump & Tank Co., 67 A.3d 759, 768 (Pa. 2013).

[C]ourts [are] to make a reasoned determination at the summary judgment stage as to whether the plaintiff has proffered sufficient evidence to permit a jury to make the necessary inference of a

F.2d 411 (7th Cir. 1992) (applying Illinois law) – relied on by both Rost and Gregg – held, “whether based on strict liability or negligence, the plaintiff must identify the manufacturer of the product and demonstrate a causal relationship between the injury and the manufacturer’s product.” Id. at 418.

sufficient causal connection between the defendant's product and the asserted injury.

Rost, 151 A.3d at 1043 (citation and quotation marks omitted). Where, as here, multiple exposures to different defendants' products are alleged, the plaintiff "bear[s] a burden of proving specific causation" that requires "evidence that there is a sufficiently significant likelihood that the defendant's product caused his harm." Gregg v. V-J Auto Parts Co., 943 A.2d 216, 225, 226 (Pa. 2007). Product specific expert causation testimony is essential to avoid creating "liability for injuries and fatalities in the absence of any reasonably developed scientific reasoning that would support the conclusion that the product sold by the defendant was a substantial factor in causing the harm." Betz, 44 A.3d at 57 (quoting Gregg, 943 A.2d at 227).²⁰ The Court has thus rejected "aggregate" causation theories as a matter of law. Plaintiffs cannot use the same theories recast as expert "opinions" as a backdoor to liability that does not exist.

Even in asbestos cases, where at least various defendants' products are allegedly chemically similar, this Court has rightfully refused to adopt liability theories that would eliminate the product-specific causation element of §402A.

²⁰ This Court has repeatedly required "substantial factor" causation in product liability cases. E.g., Rost, 151 A.3d at 1037 n.2; Betz, 44 A.3d at 58; Summers v. Certaineed Corp., 997 A.2d 1152, 1165 (Pa. 2010); Gregg, 943 A.2d at 227; Harsh v. Petroll, 887 A.2d 209, 213 n.9 (Pa. 2005); Spino v. John S. Tilley Ladder Co., 696 A.2d 1169, 1172 (Pa. 1997).

The potpourri of chemically disparate pesticides that plaintiff's experts lump together is several steps beyond what the law allows. Liability that would, as here, hold an entire industry responsible without regard to which product caused what injury "would result in a significant departure from" current law and a "depart[ure] from our time-tested general rule." Skipworth v. Lead Industries Ass'n, 690 A.2d 169, 172 (Pa. 1997) (rejecting market share liability). This refusal to countenance fundamental changes in bedrock tort elements reflects a "judicial modesty ... that we [are] content to permit the common law to develop incrementally." Tincher, 104 A.3d at 406.

Other appellate decisions applying Pennsylvania law have likewise rejected a variety of theories that sought to decouple liability from exposure to a particular defendant's products. See Bushless v. GAF Corp., 585 A.2d 596, 500-01 (Pa. Super. 1990) (no "generalized product identification"); Eckenrod v. GAF Corp., 544 A.2d 50, 52 (Pa. Super. 1988) ("plaintiff must establish that the injuries were caused by a product of the particular manufacturer"); City of Philadelphia v. Beretta U.S.A. Corp., 277 F.3d 415, 422 (3d Cir. 2002) (public nuisance cannot avoid product-specific causation requirement); Robertson v. Allied Signal, Inc., 914 F.2d 360, 379 (3d Cir. 1990) (same for "fiber drift" liability).²¹

²¹ See also Tragarz, 980 F.2d at 425 ("the plaintiff's exposure to each defendant's product should be independently evaluated").

As explained in more detail in the appellants' briefs, each of these defendant's products, although intended for the general purpose of eradicating agricultural pests, utilizes a different type of chemical activity. Each is individually registered by the U.S. Environmental Protection Agency, following the Agency's evaluation of "the level and degree of potential beneficial or adverse effects on man and the environment." 7 U.S.C. §136a. That one particular substance caused an injury cannot be determined based on risks of other substances.

Since expert "aggregate" opinions contradict governing legal principles, such theories cannot "assist" or "help" the jury, as required by Rule 702. Rather, allowing them "would potentially open a Pandora's box of wide-open liability." Pennfield Corp. v. Meadow Valley Electric, Inc., 604 A.2d 1082, 1088 (Pa. Super. 1992) (anticipating Skipworth). As the California Supreme Court held in a similar case:

[C]oncern about overbroad litigation is wholly understandable. The law cannot tolerate lawsuits by prospecting plaintiffs who sue multiple defendants on speculation that their products may have caused harm over time through exposure to toxins in them, and who thereafter try to learn through discovery whether their speculation was well-founded.

Bockrath v. Aldrich Chemical Co., 980 P.2d 398, 405 (Cal. 1999).

Bockrath involved chemicals used in aerospace. Similar "aggregate" causation opinions would inevitably emerge in litigation concerning any

industry that uses multiple chemicals – from welding to water purification.²² Both the plastics and the petrochemical industries utilize an almost unlimited number of complex organic chemicals.²³ Makers of perfumes and similar aromatics would be another target.²⁴ Pharmaceutical product liability could be impacted, because small changes in chemical structure can have dramatic and unpredictable biological effects. Applying Pennsylvania law, Soldo v. Sandoz Pharmaceuticals Corp., 244 F. Supp.2d 434 (W.D. Pa. 2003), recognized that “evidence concerning the effect of allegedly ‘similar’ chemicals on the body cannot substitute for direct evidence about the drug in question.” Id. at 548.²⁵

²² See, e.g., Tamraz v. Lincoln Electric Co., 620 F.3d 665, 668, 673 (6th Cir. 2010) (“a family of movement disorders encompass[es] Parkinson's Disease along with an assortment of other disorders”; rejecting as “speculative” testimony that “conflate[d]” these “very distinctive diseases” in welding rod case); Setliff v. E.I. Du Pont de Nemours & Co., 38 Cal. Rptr.2d 763, 767-69 (Cal. App. 1995) (aggregate causation theories rejected against “manufacturers of paint, solvents, strippers, and glue products”); Davis v. DuPont, 729 F. Supp. 652, 655 (E.D. Ark. 1989) (no causation where plaintiff “worked for several years in an environment [auto repair shop] that would likely expose him to a variety of toxic fumes”).

²³ Over 62,000 chemicals appear on the EPA’s Toxic Substances Control Act chemical substance inventory. See https://www.epa.gov/sites/production/files/2018-04/tsca_inventory_042018_mdb.zip.

²⁴ See Sanderson v. International Flavors & Fragrances, Inc., 950 F. Supp. 981, 988 (C.D. Cal. 1996) (Brautbar’s expert opinion inadmissible where “Plaintiff was exposed to countless different fragrance products”).

²⁵ “[I]n human or veterinary medicine ... both the nature and the degree of useful effect can radically alter even with apparently small changes in

Anyone exposed to numerous printing chemicals could bring a similar claim. See Klein v. Council of Chemical Associations, 587 F. Supp. 213, 222 (E.D. Pa. 1984) (aggregate chemical liability claim dismissed).

Plaintiff's "aggregate" causation expert opinions seek by indirection to create a non-specific product liability causation regime that this and other Pennsylvania courts have foreclosed each and every time they have encountered such theories directly.

chemical structure." Application of Blondel, 499 F.2d 1311, 1317 (C.C.P.A. 1974). "Even minor changes in molecular structure can alter a substance's effect. The metabolic process stands as an unknown intervening variable between the original chemical structure and the adverse effect." In re Propulsid Products Liability Litigation, 261 F. Supp.2d 603, 616 (E. D. La. 2003) (citation and quotation marks omitted). See Shackil v. Lederle Laboratories, 561 A.2d 511, 516 (N.J. 1989) (rejecting aggregate liability in vaccine case where "[e]ach [defendant's] process was separately licensed by the Food and Drug Administration").

CONCLUSION

For all of these reasons, the Court should reverse the Superior Court and reinstate Judge Wettick's well-reasoned decision that expert causation opinions addressing neither the defendant's particular product nor the plaintiff's particular medical condition fail the Frye "general acceptance" gatekeeping standard as well as the substantive requirements of Pennsylvania law.

Respectfully submitted,

May 14, 2019

/s/ James M. Beck

JAMES M. BECK (#37137)
Reed Smith LLP
Three Logan Square
Suite 3100
1717 Arch Street
Philadelphia, PA 19103-7301
(215) 851-8168

Counsel for *Amici Curiae* Product Liability Advisory Council, Inc.,
CropLife America, Pennsylvania Chamber of Business & Industry,
Chamber of Commerce of the United States,
National Association of Manufacturers, American Tort Reform Association,
Washington Legal Foundation, Coalition for Litigation Justice, Inc.,
Pennsylvania Coalition for Civil Justice Reform, and
NFIB Small Business Legal Center

CERTIFICATE 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 6,924 words based on the word count of Microsoft Word 2010, the word processing system used to prepare the brief.

I hereby 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 and documents.

I hereby further certify that on May 14, 2019, I caused two true and correct copies of the foregoing Brief of Product Liability Advisory Council, Inc., *et al.*, as *Amici Curiae* in Support Of Appellants to be served by via U.S. Mail upon the following counsel:

Anthony J. D'Amico, Esq.
Michael J. D'Amico, Esq.
D'AMICO LAW OFFICES, L.L.C.
310 Grant Street
Suite 825 Grant Building
Pittsburgh, PA 15219
(*Counsel for Plaintiff-Appellee*)

Christopher D. Stofko, Esq.
DICKIE, MCCAMEY & CHILCOTE, P.C.
Two PPG Place. Suite 400
Pittsburgh, PA 15222-5402

Robert Kelly, Esq.
Christine M. Emery, Esq.
(Both Admitted Pro Hac Vice)
LITTLETON PARK JOYCE UGHETTA &
KELLY LLP
141 West Front Street
Suite 120, Red Bank, NJ 07701
(*Counsel for BASF*)

Michael R. Borasky, Esq.
ECKERT SEAMANS CHERIN &
MELLOTT, LLC
USX Tower, 44th Floor
600 Grant Street
Pittsburgh, PA 15219

Casey A. Coyle, Esq.
ECKERT SEAMANS CHERIN &
MELLOTT, LLC
213 Market Street, 8th Floor
Harrisburg, PA 17101
*(Counsel for Bayer CropScience LP,
Bayer Corporation and Bayer
CropScience Holding Inc.)*

William J. Witte, Esq.
Sandra L. Alven, Esq.
RILEY, HEWITT, WITTE
& ROMANO, P.C.
650 Washington Road, Suite 300
Pittsburgh, PA 15228
(Counsel for Deere & Company)

Kimberly A. Brown, Esq.
JONES DAY
500 Grant Street
Suite 4500
Pittsburgh, PA 15219

William E. Padgett, Esq.
(Admitted Pro Hac Vice)
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, IN 46204-3535
(Counsel for Dow AgroSciences LLC)

Stanley B. Green, Esq.
Dawn Mistretta, Esq.
(Both Admitted Pro Hac Vice)
STRAUCH GREEN & MISTRETТА, P.C.
911 Paverstone Drive, Ste. F
Raleigh, NC 27615

Mark Dausch, Esq.
Mark D. Shepard, Esq.
BABST, CALLAND, CLEMENTS &
ZOMNIR, P.C.
Two Gateway Center, 6th Floor
Pittsburgh, PA 15222
*(Counsel for Syngenta Crop
Protection Inc.)*

Michael W. Burns, Esq.
Edwin B. Palmer, Esq.
Ira L. Podheiser, Esq.
BURNS WHITE LLC
Burns White Center
48 26th Street
Pittsburgh, PA 15222

Eric Lasker, Esq.
(Admitted Pro Hac Vice)
HOLLINGSWORTH LLP
13501 I Street, N.W., #900
Washington, D.C. 20005
(Counsel for Monsanto Company)

/s/ James M. Beck

James M. Beck

