IN THE SUPREME COURT OF PENNSYLVANIA

No. 56 EAP 2014

RICHARD ROST & JOYCE ROST,

Plaintiffs-Appellees,

v.

FORD MOTOR COMPANY,

Defendant-Appellant.

BRIEF OF COALITION FOR LITIGATION JUSTICE, INC., NATIONAL ASSOCIATION OF MANUFACTURERS, AMERICAN TORT REFORM ASSOCIATION, AND AMERICAN INSURANCE ASSOCIATION AS AMICI CURIAE IN SUPPORT OF APPELLANT

Appeal From the Judgment of the Superior Court of Pennsylvania Entered on May 19, 2014, at No. 404 EDA 2012, Affirming the Judgment Entered December 28, 2011, in the Court of Common Pleas, Civil Division, Philadelphia County at No. 1978 September Term, 2010

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TABLE OF CONTENTS

		Γ	age
TABLE OF	AUT	HORITIES	iii
STATEME	NT OI	F SUBJECT MATTER AND JURISDICTION	1
STATEME	NT OI	F THE ORDER IN QUESTION	1
STATEME	NT OI	F THE SCOPE AND STANDARD OF REVIEW	1
STATEME	NT OI	F QUESTION INVOLVED	1
STATEME	NT OI	F THE CASE AND FACTS	1
STATEME	NT OF	F INTEREST	2
SUMMAR	Y OF A	ARGUMENT	3
ARGUMEN	۱T		7
I.	SCIE IN TI	E AND EPIDEMIOLOGY ARE THE TOOLS ENTISTS USE TO DETERMINE CAUSATION HE CONTEXT OF LATENT DISEASES O SUBSTANCES OF VARYING TOXICITY Law and Science Must Intersect Only Where	
	B.	Science Has Demonstrated Causation First Epidemiology and Dose Are the Keys to Avoiding Speculation and Determining Causation in Latent Disease Exposure Circumstances	
		The Importance of Epidemiology in Determining Causation	. 10
		2. For Attribution to an Asbestos Exposure, the Dose Received by Plaintiff Should Be Similar to Those of Exposed Cohort in the Studies Who Incur Excess Mesothelioma	. 14

11.		THE SUPERIOR COURT ERRED IN ALLOWING DR. FRANK'S TESTIMONY TO SUPPORT THE JURY	
		VERDICT	
	A.	Dr. Frank's Failure to Conduct a Dose and Causation Assessment Violates <i>Betz</i> and <i>Howard</i> and Requires Reversal	18
	B.	Changing the Name of the Theory Is Not Sufficient	22
	C.	Simply Referring to the Plaintiff's Exposures Is Not Sufficient	24
	D.	The Superior Court Performed an Inadequate Review of Dr. Frank's Testimony and the Causation Evidence By Declining to Look Beyond the Expert's Self-Serving Statements	28
CONCLU	SION.		32
CERTIFIC	CATE (OF COMPLIANCE	End
CERTIFIC	CATE (OF SERVICE	End

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Anderson v. Ford Motor Co., 950 F. Supp. 2d 1217 (D. Utah 2013)
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Betz v. Pneumo-Abex, 615 Pa. 504, 44 A.3d 27 (2012)passim
Blum v. Merrell Dow Pharms., Inc., 564 Pa. 3, 764 A.2d 1 (Pa. 2000)8
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Bostic v. Georgia-Pacific Corp., 439 S.W.3d 332 (Tex. 2014) 10, 21
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STATEMENT OF SUBJECT MATTER AND JURISDICTION

Amici adopt Appellant's Statement of Subject Matter and Jurisdiction.

STATEMENT OF THE ORDER IN QUESTION

Amici adopt Appellant's Statement of the Order in Question.

STATEMENT OF THE SCOPE AND STANDARD OF REVIEW

Amici adopt Appellant's Statement of the Standard of Review.

STATEMENT OF QUESTION INVOLVED

Whether—contrary to *Howard ex rel. Estate of Ravert v. A.W. Chesterton, Inc.*, 621 Pa. 343, 78 A.3d 605 (2013), *Betz v. Pneumo-Abex*, 615 Pa. 504, 44 A.3d 27 (2012), and *Gregg v. V-J Auto Parts*, 596 Pa. 274, 943 A.2d 216 (2007)—a plaintiff in an asbestos action may satisfy the burden of establishing substantial-factor causation by an expert's "cumulative-exposure" theory that the expert concedes is simply an "any-exposure" theory by a different name?¹

STATEMENT OF THE CASE AND FACTS

Amici adopt Appellant's Statement of the Case and Facts.

This Court is also addressing whether the Philadelphia Court of Common Pleas' mandatory practice of consolidating unrelated asbestos cases—even where the defendants suffer severe prejudice as a result—is consistent with the Pennsylvania Rules of Civil Procedure and Due Process; whether consolidation in this case was proper; and whether the Superior Court has the authority to review a trial court's case-consolidation decisions in asbestos cases. Other *amici* supporting Appellant intend to brief those issues, so we do not address them here. We join Appellant and allied *amici* in opposing unfair consolidations.

STATEMENT OF INTEREST

Amici are organizations that represent companies named as asbestos defendants in Pennsylvania and their insurers.² Accordingly, amici have a substantial interest in ensuring that expert evidence admitted in asbestos cases is consistent with this Court's prior holdings, as well as sound science and public policy. Amici filed briefs in support of defendants in Betz and Howard ex rel. Estate of Ravert v. A.W. Chesterton, Inc., 621 Pa. 343, 78 A.3d 605 (2013), to explain the science behind today's low-dose asbestos lawsuits and to encourage the

The Coalition for Litigation Justice, Inc. is a nonprofit association formed by insurers in 2000 to address and improve the litigation environment for asbestos and other toxic tort claims. The Coalition includes Century Indemnity Company; Chubb & Son, a division of Federal Insurance Company; Fireman's Fund Insurance Company; Great American Insurance Company; and Nationwide Indemnity Company.

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 nearly 12 million men and women, contributes more than \$1.8 trillion to the U.S. economy annually, has the largest economic impact of any major sector and accounts for two-thirds of private-sector research and development. NAM's mission is to enhance the competitiveness of manufacturers and improve American living standards by shaping a legislative and regulatory environment conducive to U.S. economic growth.

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 appellate cases that have addressed important liability issues.

The American Insurance Association ("AIA"), founded in 1866 as the National Board of Fire Underwriters, is a leading national trade association representing major property and casualty insurers writing business nationwide and globally. AIA members range in size from small companies to the largest insurers with global operations. AIA files *amicus* briefs in significant cases, including before this Court, on issues of importance to the property and casualty insurance industry and marketplace.

Court to move asbestos litigation back into the world of mainstream medical knowledge and practice. The decision below violates these basic principles, and, if allowed to stand, would adversely impact *amici*'s members.

SUMMARY OF ARGUMENT

This appeal provides this Court, once again, with an opportunity to solidify the import of its ruling in *Betz v. Pneumo-Abex*, 615 Pa. 504, 44 A.3d 27 (2012), excluding *any exposure* testimony from the courts of Pennsylvania. *Amici* request that the Court provide clear direction to the state's judiciary that cases presented without a proper, expert-derived dose assessment and proof of causation at that dose will not proceed to trial in this state. That is the scientifically correct holding and the unequivocal import of *Betz*, *Howard*, and *Gregg v. V-J Auto Parts*, 596 Pa. 274, 943 A.2d 216 (2007). These holdings should be applied here and in future cases.

The Superior Court panel below erred on several fronts, and in ways that indicate the appellate court has not accepted the scientific necessity of the dose principle. Mr. Rost's experts, as they have done repeatedly in asbestos cases, refused even to estimate Mr. Rost's dose or take into account the weak carcinogenicity of the type of asbestos fiber (chrysotile) he alleged breathed. Nor did Mr. Rost's experts cite to any studies showing that exposure to chrysotile asbestos at Mr. Rost's levels would cause mesothelioma.

Mr. Rost's experts, particularly Dr. Frank, failed both critical steps of a causation assessment – identifying how much exposure occurred, and citing to competent studies showing causation from that substance at plaintiff's exposure levels. It was enough for these experts, and the Superior Court, that plaintiff must have breathed some asbestos during his work. From that premise, the experts speculated that his exposures were enough because "there is no known safe dose of asbestos" and "all exposures are cumulative." To Dr. Frank, the inability to categorically exclude any fibers as causative means that all (occupational) fibers must be considered part of the cause. This is the *any exposure* theory, no matter what it is called.

This is not how science works. Proving a causative dose must mean more than "some exposure to some kind of asbestos is enough." *See* David E. Bernstein, *Getting to Causation in Toxic Tort Cases*, 74 Brook. L. Rev. 51 (2008); *see also* Mark A. Behrens & William L. Anderson, *The "Any Exposure" Theory: An Unsound Basis for Asbestos Causation and Expert Testimony*, 37 Sw. U. L. Rev. 479 (2008).

The trial court and Superior Court's acceptance of this testimony is erroneous for at least the following reasons:

(1) Betz Applies and the Case Should Have Been Dismissed on Summary Judgment. The elephant in the Superior Court's living room is Betz. Despite the

panel's tortured efforts to distinguish *Betz*, this Court's ruling stands for the proposition that cases built on an *any exposure* theory, regardless of a plaintiff's subjective lay testimony, cannot go to a jury. The Superior Court's contrary decision boils down to its view that an unscientific theory ought to be excluded under *Frye* (per *Betz*), but the same unscientific theory can somehow support a jury verdict. The Panel's decision undermines *Betz* rather than applies this Court's ruling as it should.³

(2) Dr. Frank Cannot Testify, and the Case Cannot Proceed to Trial, Without a Competent Expert Determination of a Causative Dose. Whether Betz strictly applies or not, the case should not have proceeded to trial. Experts who testify without a dose/causation assessment in minimal exposure situations, such as in this case, have abandoned their scientific obligation to help the jury sort out impactful occupational exposures from those with little effect. Neither lay persons nor judges can discern the degree of exposure necessary to cause cancer without expert help. The result is what occurred here. The Superior Court Panel, with no expert testimony to support its conclusion other than the any exposure theory, decided that a maintenance worker doing non-asbestos work thirty feet from brake

Calling this approach by some name other than "each and every exposure" makes no difference at all – an opinion based on "whatever exposures plaintiff testified to" is unscientific speculation that cannot support a verdict. See infra.

repair work over a three month period is sufficient causation evidence. No scientific studies support such a determination, and the Plaintiff presented none.

(3) The Court's Superficial Review of Dr. Frank's Propositions Was Insufficient. The Rost opinion suffers from the same defect that some other court asbestos expert reviews do – the Superior Court panel repeatedly cited to Dr. Frank's statements and propositions and then took them at face value rather than examining them. The Court did not critically review the studies he cited, and made no attempt to determine if his conclusions were well-supported or not. His opinion is in fact based on high-dose and amphibole exposure situations that have nothing in common with Mr. Rost's limited chrysotile exposures.⁴

Amici request that this Court underscore the necessity of careful judicial review of the plaintiff's scientific testimony and the need to dismiss cases where no competent expert dose/causation evidence is presented. A different panel of the

Dr. Frank is no stranger to this debate in Pennsylvania. The *Gregg* Court determined that his opinions were insufficient for causation, and the Philadelphia trial judge later excluded his opinions under *Betz. See Gregg v. V-J Auto Parts, Inc.*, 943 A.2d 216, 218, 223, 226-27 (Pa. 2007) (Pennsylvania Supreme Court labeling the each-and-every-exposure opinion of Dr. Frank a "fiction"); *In re Asbestos Litig.*, 2008 WL 4600385 (Pa. Comm. Pl. Sept. 24, 2008) (Dr. Frank and other experts presented "no recognizable methodology" and instead relied on "bald conclusions"); *see also Bartel v. John Crane, Inc.*, 316 F. Supp. 2d 603, 611 (N.D. Ohio 2004) ("[T]he opinion of Dr. Frank, that every breath Lindstrom took which contained asbestos could have been a substantial factor in causing his disease, is not supported by the medical literature."), *aff'd sub nom. Lindstrom v. A-C Prod. Liab. Trust*, 424 F.3d 488 (6th Cir. 2005); *Daly v. Arvinmeritor, Inc.*, No. 07-19211, 2009 WL 4600385 (Fla. Cir. Ct. Nov. 30, 2009) (Dr. Frank's "any exposure above background" theory would eviscerate the standard established by Florida law (substantial contributing factor)).

Superior Court handled virtually the exact same issues correctly in *Nelson v. Airco Welders Supply*, 2014 WL 7274237 (Pa. Super. Ct. Dec. 23, 2014), by recognizing the game involved in throwing words like "significant" into an *any exposure* opinion to make it seem like something else. Minimal exposure cases such as *Rost*, especially those involving the weak carcinogen chrysotile, are not supported by competent science demonstrating that such fleeting exposures had anything to do with plaintiffs' disease. The scrutiny of these cases should be much higher, not lower, than past asbestos cases.

ARGUMENT

I. DOSE AND EPIDEMIOLOGY ARE THE TOOLS SCIENTISTS USE TO DETERMINE CAUSATION IN THE CONTEXT OF LATENT DISEASES AND SUBSTANCES OF VARYING TOXICITY

It is imperative in any low-exposure toxic tort case that the experts carefully assess the dose received, the potency of the substance to cause disease, and the epidemiological studies documenting disease at that level. Dr. Frank did none of this. The panel's ruling opens the door in Pennsylvania to a great deal of speculative testimony outside the boundaries of good science.

A. Law and Science Must Intersect Only Where Science Has Demonstrated Causation First

As many courts and commentators have noted, courts and the law cannot get ahead of scientific knowledge.⁵ Otherwise, courts and juries begin to engage in speculative causation determinations that time and again have proven to be wrong and have caused considerable harm.

One clear example is the series of cases that led to the original *Daubert* ruling in 1994. In that litigation, a series of epidemiology studies of the morning-sickness drug Bendectin showed no link to birth defects, yet a plaintiff expert claimed to discern such a link by reinterpreting those studies.⁶ His speculation was well outside the scientific evidence, but the litigation and allegations drove the drug off the market without good cause. Only later did the courts intervene via *Daubert* and its progeny and begin excluding this testimony. *See, e.g., Daubert v.*

See, e.g., "Introduction," Reference Manual on Scientific Evidence 4 (3d ed. 2011) ("The law must seek decisions that fall within the boundaries of scientifically sound knowledge.") (Breyer, S.).

See Marcia Angell, Science on Trial 75-76 (W.W. Norton & Co. 1996) (1,800 lawsuits filed by late 1980s); Blum v. Merrell Dow Pharms., Inc., 564 Pa. 3, 7 n.5, 764 A.2d 1, 4 n.5 (Pa. 2000) (Bendectin-birth defect link disproven by epidemiology). The cases began in the 1980s and finally petered out in the mid-1990s. See Michael Green, Bendectin and Birth Defects: The Challenges of Mass Toxic Substances Litigation (Univ. of Penn. Press 1996); Joseph Sanders, Bendectin on Trial: A Study of Mass Tort Litigation (Univ. of Mich. Press 1998). The most famous Bendectin case, of course, is Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993).

Merrell Dow Pharms., Inc., 43 F.3d 1311, 1314 (9th Cir.), cert. denied, 516 U.S. 869 (1995).

A second dramatic example is the breast implant litigation, exposed as scientifically baseless after several court-appointed expert panels found no legitimate epidemiological evidence to support the plaintiffs' claims. The highly-respected former editor of the New England Journal of Medicine, Dr. Marcia Angell, examined the dynamics that supported this misdirected litigation in her book, *Science on Trial*.

Asbestos litigation today is ripe for the kind of abuse seen in the Bendectin and breast implant litigations because the disease is latent, meaning far removed from the claimed exposure, and it is not possible to prove by examination of the tumor itself what caused the cancer.⁹ In such circumstances, science looks to epidemiology and dose.

⁷ See David E. Bernstein, Keeping Junk Science Out of Asbestos Litigation, 31 Pepp. L. Rev 11, 18 (2003).

See Angell, supra; see also Norris v. Baxter Healthcare Corp., 397 F.3d 878, 881-82 (10th Cir. 2005).

[&]quot;If a precise series of changes takes place, one cell becomes a malignant cell. A mesothelioma tumor consists of billions of cells but started from one single cell. Attempting to find that one cell to determine which fiber caused the initial malignancy is like 'looking for a needle in a haystack." *Bartel*, 316 F. Supp. 2d at 609-10 (internal citation omitted).

B. Epidemiology and Dose Are the Keys to Avoiding Speculation and Determining Causation in Latent Disease Exposure Circumstances

The key to determining causation in situations involving diseases like mesothelioma is epidemiology and dose. Epidemiology is the science that links latent disease to earlier exposures, and dose is the gateway through which an exposure must pass to justify attribution of disease to that exposure.

1. The Importance of Epidemiology in Determining Causation

The Court is going to find itself in this case dealing with the same issue that the Texas Supreme Court faced in *Bostic v. Georgia-Pacific Corp.*, 439 S.W.3d 332 (Tex. 2014) – trying to determine how exactly a plaintiff should prove causation in a low-dose mesothelioma case. The *any exposure* theory is clearly not good enough, but what is? Is it sufficient to resort to mere exposure testimony and the speculation that some asbestos exposure is enough?

The answer – no, it is not – is based on how science works. ¹⁰ Scientists deal with this situation all the time, and the tools they use should control in the courtroom too. The chief and first tool is epidemiology. For reasons that are unclear, some courts are afraid to rely on epidemiology. But they should not be. "[W]here epidemiology is available, it cannot be ignored." *Norris v. Baxter*

The *Bostic* court concluded that the *any exposure* theory is unscientific as applied to mesothelioma cases and that plaintiffs must quantify the dose and show that it compared favorably to epidemiology studies of similar circumstances. 249 S.W.3d at 338-39.

Healthcare Corp., 397 F.3d 878, 882 (10th Cir. 2005). Epidemiology that essentially disproved plaintiffs' claims unwound both the Bendectin and the breast implant litigation, and it should have its proper place in pushing asbestos litigation onto a scientifically valid playing field as well. Amici thus provide background on how epidemiologists and other medical professionals use this tool to help determine how much exposure is enough, the critical issue in a case like this one.

Epidemiology – considered the "gold standard" for human causation – is the key to determining whether latent diseases arise out of an occupational or environmental exposure.¹² The only way medical science determined that asbestos caused mesothelioma and other diseases in the first place was through epidemiology studies of workers exposed to certain types of fibers at what would

Judge Colville declined to discuss the mechanic epidemiology in his original *Betz* trial opinion, but this Court criticized Dr. Maddox's universal rejection of those studies in favor of case reports, and favorably cited to the *Norris* holding. *See Betz*, 44 A.3d at 57 ("where epidemiology is available, it cannot be ignored").

Epidemiology is universally recognized as the "most desirable evidence" for assessing causation in the science of toxicology. Michael Green, Expert Witnesses and Sufficiency of Evidence in Toxic Substances Litigation: The Legacy of the Agent Orange and Bendectin Litigation, 86 NW. U. L. Rev. 643, 646 (1992); see also id. at 648 ("The most desirable evidence is epidemiologic, because it can best be generalized to support inferences about the effect of an agent in causing disease in humans."); Bert Black, Epidemiologic Proof in Toxic Tort Litigation, 52 Fordham L. Rev. 732, 736 (1984) ("[E]pidemiology is the only generally accepted scientific discipline . . . to identify and establish the causes of human diseases."); Mary Andrues, Proof of Cancer Causation in Toxic Waste Litigation: The Case of Determinacy Versus Indeterminacy, 61 S. Cal. L. Rev. 2075, 2088 (1988) ("The only valid way to identify human carcinogens and establish medical causation is to observe differences in the incidence of cancer between humans exposed to toxic wastes and those who are not.").

today be considered extremely high exposure levels. As only one example, the seminal 1955 epidemiology study by Sir Richard Doll first linked asbestos to lung cancer in asbestos factory workers exposed to large amounts of raw asbestos. Those and hundreds of other studies since 1955 compared groups with an asbestos-related exposure (e.g. shipyards workers) to others without those exposures. If the exposed group incurred more mesothelioma than the unexposed group (and not all did), and the same result occurred in repeated studies of good quality, the medical community would consider the link established. The mere occurrence of a few cases of mesothelioma in the exposed group is not enough – those are called "case reports" and they cannot tell researchers whether this group had more cases than persons without the same exposures. ¹³ Comparative studies are essential.

This sort of epidemiological investigation has proven incredibly important to our society in identifying diseases caused by exposures from years earlier. For example, studies have shown that exposure to high levels of radiation can potentially cause cancer later in life.¹⁴

Other studies of the same type have helped us understand what exposures are *not* hazardous. As one example, some years ago a few researchers

See Green, 86 NW. U. L. Rev. at 657 ("There plainly is a hierarchy to these different indirect forms of toxic effect evidence. Epidemiology is at the top, and structural similarity, in vitro testing, and case reports are at the bottom.").

See, e.g., Am. Cancer Soc'y, Radiation Exposure and Cancer, at http://www.cancer.org/cancer/cancercauses/radiationexposureandcancer/index.

hypothesized that heavy coffee drinking might cause pancreatic cancer. Subsequent epidemiology studies of heavy coffee drinkers found no excess pancreatic cancer in that group compared to non-coffee drinkers.¹⁵ We drink our coffee without fear of cancer as a result. Likewise, some researchers have speculated for years that use of cell phones will cause brain cancer, yet no such excess disease has appeared in comparative studies. Our regular use of cell phones today is not accompanied by an irrational fear of brain cancer, and it need not be.¹⁶ Nor do we avoid commercial airline flights merely because low-level radiation exposures would not keep a rational person from traveling.¹⁷

Even plaintiffs' experts base their theories on epidemiology when they assert, for instance, that "all fibers types cause mesothelioma." They often cite to the chrysotile mining and textile or other high-exposure studies for support. Yet these same experts cannot, when pressed, cite to epidemiology studies that would

See Jie Dong et al., Coffee Drinking and Pancreatic Cancer Risk: A Meta-Analysis of Cohort Studies, 17 World J. Gastroenterol 1204 (2011) (finding that drinking coffee has no association with increased risk of pancreatic cancer in woman and is associated with a reduced risk of pancreatic cancer in men).

See Nat'l Cancer Inst., Cell Phones and Cancer Risk (2013), at http://www.cancer.gov/cancertopics/factsheet/Risk/cellphones (compiling studies).

See Health Physics Soc'y, Radiation Exposure During Commercial Airline Flights (2014), at http://www.hps.org/publicinformation/ate/faqs/commercial-flights.html; Health Physics Soc'y, Airport Screening Fact Sheet (2011), at http://hps.org/documents/airport_screening_fact_sheet.pdf (compiling studies).

See Brief of Appellees at 14 (Frank reliance on epidemiology studies); Betz, 44 A.3d at 40 (discussing Judge Colville's the "extrapolation down" from high-dose epidemiology studies to find causation at low levels of exposure).

support a claim that chrysotile-related work like Mr. Rost's would be anywhere near the level necessary to cause disease. Instead, they resort to the *any exposure* approach, precisely so they do not have to confront the lack of a sufficient dose. This is where the dose requirement comes in.

2. For Attribution to an Asbestos Exposure, the Dose Received by Plaintiff Should Be Similar to Those of Exposed Cohort in the Studies Who Incur Excess Mesothelioma

The asbestos docket today is rife with irrational speculation about disease causation. That speculation is largely due to the plaintiff expert's repeated refusal to account for the dose of the particular fiber type of asbestos required to cause disease.¹⁹ Today's cases less frequently involve the older insulation exposures because such exposures took place in the 1950s and 1960s. Instead, today's plaintiffs have far lower exposures – often only speculative in nature – and those exposures often involve chrysotile, not amphiboles like amosite and crocidolite.²⁰

One of the clearest descriptions in the literature regarding the importance of dose in toxic tort cases is in David L. Eaton, *Scientific Judgment and Toxic Torts – A Primer in Toxicology for Judges and Lawyers*, 13 J.L. & Pol'y 5, 39 (2003). Several courts have looked to Dr. Eaton's article to guide their decisions on low-dose proof requirements. *See, e.g., Baker v. Chevron USA*, 680 F. Supp. 2d 865, 880 (S.D. Ohio 2010); *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1156 (E.D. Wash. 2009).

Chrysotile is at best only a very weak carcinogen, and one that has not produced mesothelioma at all except in the very highest exposed worker groups. Unlike amphibole fibers found in insulation, chrysotile is not rigid, breaks down easily in the body, and much of it is quickly removed. *See* U.S. Envtl. Prot. Agency, Office of Solid Waste & Emergency Response, Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk vii (May 30, 2003) ("The panelists unanimously agreed that the available epidemiology studies provide compelling evidence that the carcinogenic (Footnote continued on next page)

While the issue of whether chrysotile exposures cause mesothelioma is not before the Court, comparing the potency of asbestos fibers is part and parcel of an acceptable causation opinion. Cohorts of workers exposed chiefly or only to chrysotile fibers, during the same era with limited regulation, show very few mesotheliomas if any, even when the doses are enormous, as high as 100 fiber/cubic centimeter years or more:

- In a study of incidence of mesothelioma in major industrial regions of South Africa, *no reports of mesothelioma from purely chrysotile exposure* were found despite substantial numbers of miners in chrysotile mines from the 1930s to 1980s exposed to intense concentrations of dust. *See* David Rees, *Case Control Study of Mesothelioma in South Africa*, 35 Am. J. Indus. Med. 213, 220 (1999).
- A study of 1,261 workers at an asbestos cement plant in Wales using only chrysotile asbestos after 1936 found *only two cases of mesothelioma*, *neither of them from chrysotile use*. Both of the employees worked at the plant prior to 1936 at a time the plant was *using crocidolite asbestos* (a highly potent amphibole). *See* H.F. Thomas *et al.*, *Further Follow-Up Study of Workers from an Asbestos Cement Factory*, 39 Brit. J. Indus. Med. 273, 275 (1982).
- A study of 2,861 individuals employed between 1950 and 1981 at an asbestos cement plant in Austria found *no incidence of mesothelioma* among the employees exposed only to chrysotile, some of whom had exposures in excess of 50 f/ml. See Manfred Neuberger & Michael Kundi, Individual Asbestos Exposure: Smoking and Mortality A Cohort

àsbestos).").

15

potency of amphibole fibers is two orders of magnitude greater than that for chrysotile fibers."); Christine Rake *et al.*, *Occupational*, *Domestic and Environmental Mesothelioma Risks in the British Population: A Case Control Study*, 100 Brit. J. Cancer 1175 (2009) ("The mesothelioma risk caused by amosite (brown asbestos) is two orders of magnitude greater than that by chrysotile (white

Study in the Asbestos Cement Industry, 47 Brit. J. Indus. Med. 615, 619 (1990).

• A cohort of 3,072 workers exposed to chrysotile in a *South Carolina* asbestos textile plant with exposures of up to 700 f/cc years – an enormously high exposure – identified only three mesotheliomas. See Misty Hein et al., Follow-Up Study of Chrysotile Textile Workers: Cohort Mortality and Exposure-Response, 64 Occup. Envtl. Med. 616, 618, 620 (2007); see also John M. Dement et al., Follow-Up Study of Chrysotile Textile Workers: Cohort Mortality and Case-Control Analyses, 26 Am. J. Indus. Med. 431, 437-38 (1994).

The above populations and others all worked with large amounts of loose chrysotile fibers, whereas mechanics only work with bonded products producing much smaller (if any) exposures. In contrast to the many epidemiology studies that have documented the association between occupations like shipbuilding and insulator work and asbestos disease, the studies of vehicle mechanics have found that their disease incidence is no different than that in professions with little or no opportunity for asbestos exposure, such as traveling salesmen, teachers, librarians, office clerks, accountants, and farmers.²¹ There are more than fifteen of these studies, conducted over the last thirty years, almost all published in peer-reviewed articles, and performed in seven different countries by over sixty different

See, e.g., Kay Teschke et al., Mesothelioma Surveillance to Locate Sources of Exposure to Asbestos, 88 Can. J. Pub. Health 163, 165 (1997); Alison D. McDonald & J. Corbett McDonald, Malignant Mesothelioma in North America, 46 Cancer 1650, 1653-54 (1980).

researchers.²² The most recent such study, the largest study ever performed comparing mesothelioma to populations, continued the trend by exonerating mechanic work:

We found *no evidence of increased risk* associated with non-industrial workplaces or those that were classified as "low risk," *including motor mechanics and workers handling gaskets* and mats that may have contained asbestos.²³

The likelihood that a vanishingly small dose of chrysotile would cause asbestos disease is nowhere found in the scientific literature.

Plaintiff experts in this appeal and similar cases gloss over this entire set of literature by calling it "inconclusive." It is, to the contrary, the most conclusive literature available with regard to whether exposures like Mr. Rost's produce mesothelioma. If lifetime mechanics do not incur any more mesotheliomas than schoolteachers and accountants, then Mr. Rost's three months of work on the far end of a mechanic shop would not either. Only speculation gets to a causation opinion in a case like this. Mr. Rost has not presented any evidence showing that his experienced dose is consistent with those that could cause disease. The

Most of the studies are summarized and discussed in Francine Laden et al., Lung Cancer and Mesothelioma Among Male Automobile Mechanics: A Review, 19 Revs. on Envtl. Health 39 (2004); Michael Goodman et al., Mesothelioma and Lung Cancer Among Motor Vehicle Mechanics: A Meta-analysis, 48 Annals Occup. Hygiene 309 (2004).

Julian Peto et al., Occupational, Domestic and Environmental Mesothelioma Risks in Britain: A Case-Control Study, UK Health & Safety Exec., at x (2009); Rake, 100 Brit. J. Cancer at 1182.

scientific community assesses causation based on such study and medical basis in the literature, and the courts should not stray far from that path.

II. THE SUPERIOR COURT ERRED IN ALLOWING <u>DR. FRANK'S TESTIMONY TO SUPPORT THE JURY VERDICT</u>

The Superior Court's disregard of *Betz* is sufficient alone to justify reversal.

Amici nevertheless discuss below the various arguments the panel made to demonstrate that they are all versions, one way or another, of allowing any exposure testimony to carry the day. The panel did not require the necessary dose and causation evidence; substituted its own expert determination of the sufficiency of exposure for the missing expert testimony; and failed to look behind any of Dr. Frank's self-serving pronouncements.

A. Dr. Frank's Failure to Conduct a Dose and Causation <u>Assessment Violates Betz</u> and <u>Howard</u> and <u>Requires Reversal</u>

The *Betz* and *Howard* decisions are more than sufficient to reverse the Superior Court. The *Betz* opinion is full of unequivocal statements regarding the unscientific nature and inadmissibility of *any exposure* testimony to support an asbestos case:

- "[Judge Colville] appreciated the considerable tension between the anyexposure opinion and the axiom (manifested in myriad ways both in science and in daily human experience) that the dose makes the poison." 615 Pa. at 546, 44 A.3d at 53.
- "Dr. Maddox's any-exposure opinion is in irreconcilable conflict with itself. Simply put, one cannot simultaneously maintain that a single fiber

among millions is substantially causative, while also conceding that a disease is dose responsive." 615 Pa. at 550, 44 A.3d at 56.

- "We do not believe that it is a viable solution to indulge in a fiction that each and every exposure to asbestos, no matter how minimal in relation to other exposures, implicates a fact issue concerning substantial-factor causation The result, in our view, is to subject defendants to full joint-and-several liability . . . in the absence of any reasonable developed scientific reasoning that would support the conclusion that the product sold by the defendant was a substantial factor in causing the harm." 615 Pa. at 551, 44 A.3d at 56-57 (quoting *Gregg*, 596 Pa. at 292, 943 A.2d at 226-27).
- "Certainly, a complete discounting of the substantiality in exposure would be fundamentally inconsistent with Pennsylvania law." 615 Pa. at 554, 44 A.3d at 58.

The subsequent *Howard* opinion, if anything, was even more forceful in rejecting any form of *any exposure* testimony from experts or as trial evidence:

- "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." 621 Pa. at 348, 78 A.3d at 608.
- "Expert witnesses may not ignore or refuse to consider dose as a factor in their opinions." *Id*.
- "Bare proof of some *de minimis* exposure to a defendant's product is insufficient to establish substantial-factor causation" 621 Pa. at 348-49, 78 A.3d at 608.
- "As explained in detail in the unanimous decision in *Betz*, the any-exposure opinion is simply unsupportable both as a matter [of] law and science." 621 Pa. at 350, 78 A.3d at 609.

These statements foreclose any asbestos lawsuit that does not include an expert assessment of the plaintiff's individualized dose and a comparison of that

dose to known causative levels. Dr. Frank's testimony fails this test in multiple ways:

- Dr. Frank performed no dose assessment at all. Nowhere does he even estimate the potential range of fibers/cc year dose from Mr. Rost's limited contacts with asbestos in this job. He has no f/cc measurement of a person doing Mr. Rost's job, including from sweeping general garbage in the garage.²⁴
- Dr. Frank did not consider the potency differential of chrysotile and how much more exposure Mr. Rost would need to cause disease. He treated this exposure as if it were the same as an amphibole exposure.²⁵
- Dr. Frank did not perform any reasonable assessment of the factors that would have minimized or decreased Mr. Rost's exposures e.g., the great distance away he was from the source; the limited time any measureable asbestos would have remained in his breathing zone; or the ventilation provided by open bay doors during this summer work.

Dr. Frank's citation to a study showing 17 f/cc from mechanic blowout exposures is irrelevant for two reasons. First, Mr. Rost did not do any blowout work and was dozens of feet away from this activity. There is no record evidence he received any exposure from those events because no plaintiff expert conducted a dose assessment. Second, Dr. Frank does not care what the exposure level from blow out work actually is. It is irrelevant to his opinion whether the figure is 17, or 0.17, or 0.0017 f/cc. All such exposures are causative, and that is what he told the jury.

Potency by its very terms means it takes more of one substance to cause harm than of another. Experts cannot legitimately treat materials of different potency the same, nor can they treat all types of asbestos as if they are the same substance. See, e.g., In re Garlock Sealing Tech., LLC, 504 B.R. 71,76, 78 (W.D.N.C. 2014) ("[I]t is clear under any scenario that chrysotile is far less toxic than other forms of asbestos," and the "most reliable and probative" peer-reviewed scientific reports "confirm[] that exposure to asbestos from end users of encapsulated asbestos products is minimal."); Bartel v. John Crane, Inc., 316 F. Supp. 2d at 605 ("While there is debate in the medical community over whether chrysotile asbestos is carcinogenic, it is generally accepted that it takes a far greater exposure to chrysotile fibers than to amphibole fibers to cause mesothelioma."); In re Asbestos Litig., 911 A.2d 1176, 1181 (Del. Super. Ct. 2006) ("[I]t is generally accepted in the scientific community and among government regulators that amphibole fibers are more carcinogenic than serpentine (chrysotile) fibers.").

- Dr. Frank did not provide any alternative methodology to *any exposure* for drawing a line between substantial and insubstantial exposures instead, he continues to embrace the *any exposure* concept by calling it "all cumulative exposures" and opining that whatever plaintiff testified to is sufficient.
- Dr. Frank did not identify what kind of exposure for Mr. Rost would have been *insufficient*. Two months of work instead of three? Weekly sweeping instead of daily? Fifty feet away instead of thirty? He is guessing, and he almost certainly would accept any level of work-related exposure Mr. Rost experienced as causative.
- Dr. Frank did not compare Mr. Rost's exposures from his mechanic shop work to his other lifetime exposures to amphiboles in other settings to determine whether the mechanic-exposure work is really irrelevant to his disease. ²⁶

This type of speculative opinion is why this Court's opinions in *Betz* and *Howard* are so important, not just for Pennsylvania but for the development of asbestos law generally. Since those opinions issued, more courts have joined in the movement to stop *any exposure* and other forms of testimony that ignore dose. In addition to the Texas Supreme Court's opinion in *Bostic*, the Virginia Supreme Court (while not ruling directly on *any exposure*) held that "[t]he experts must opine as to what level of exposure is sufficient to cause mesothelioma, and whether the levels of exposure at issue in this case were sufficient." *Ford Motor Co. v.*

Comparing exposures in a multiple exposure case like this one is an imperative for competent expert testimony. "[T]here are cases where a plaintiff's exposure to asbestos can be tied to a defendant, but that exposure is minuscule as compared to the exposure resulting from other sources. Proof of any exposure at all from a defendant should not end the inquiry and result in automatic liability." *Bostic*, 439 S.W.3d at 341.

Boomer, 736 S.E.2d 724 (Va. 2013). Two federal courts in Louisiana and two more in Utah have also recently rejected the expert's replacement of a dose assessment with any exposure testimony. See Comardelle v. Pa. Gen. Ins. Co., 2015 WL 64279 (E.D. La. Jan 5, 2015); Davidson v. Georgia Pacific LLC, 2014 WL 801342 (W.D. La. Feb 28, 2014); Anderson v. Ford Motor Co., 950 F. Supp. 2d 1217 (D. Utah 2013); Smith v. Ford Motor Co., 2013 WL 214378 (D. Utah Jan. 18, 2013). And the U.S. Court of Appeals for the Ninth Circuit overturned an \$11 million asbestos trial verdict because the trial court did not perform a thorough enough review of an any exposure expert's testimony under Daubert. See Barabin v. AstenJohnson, Inc., 740 F.3d 457 (9th Cir.), cert. denied, 135 S. Ct. 55 (2014). This Court took the right step in affirming Judge Colville's decision in Betz. The reluctance of courts like the panel in *Rost* to follow these changes is the result of inertia and the monumental difficulty of changing anything about asbestos litigation. The changes usually have to come from the state's highest court, as in Texas, and can take several repeated appellate opinions to install the change permanently.

B. Changing the Name of the Theory Is Not Sufficient

Since 2005, numerous courts have rejected Dr. Frank's *every exposure* approach as unscientific and insufficient evidence of causation. Yet he is nothing if not adamant about his theories – they never change, despite these rulings. Here,

he simply recited the alleged exposures and concluded they were sufficient – dose is irrelevant to his opinion and appears nowhere in his opinions.

Yet what Dr. Frank and the others who follow this route *have* learned is to change the name of the opinion they deliver. Initially, experts like Dr. Frank were fond of testifying that "a single fiber" of asbestos could cause disease, and thus the alleged exposures in the case, whatever they might be, were sufficient. *See Betz*, 615 Pa. at 518, 44 A.3d at 36 (expert maintained that exposure to a "single asbestos fiber of any type was sufficient to cause mesothelioma"). After several rejections of the "single fiber" theory, Dr. Frank and others stopped using that term and began to claim that they did not need to testify about the effects of a single fiber because every breath of workplace asbestos included thousands of fibers. The opinion morphed into the "each and every exposure" approach prevalent over the last several years, but continued to encompass all occupational exposures without any regard for how minimal the dose was.

Now, however, courts all over the country have rejected "each and every exposure" testimony as inadequate speculation. But instead of conforming to scientific principles, some plaintiffs' experts changed the name again. Dr. Frank now testifies that it is the "cumulative dose" of the plaintiff that caused his disease. But under this version of his theory, no fibers can be excluded because they are all

cumulative, and thus all of plaintiff's workplace exposures must also be the cause of his mesothelioma. Dose still does not matter in Dr. Frank's opinion.

Some courts have been taken in by this sophistry.²⁷ The trial judge in this case may not have understood that he was simply admitting *any exposure* testimony under another name. Yet in the *Nelson* case, the Superior Court correctly recognized that simply calling all workplace exposures "significant" did not change the testimony or the theory. *See* 2014 WL 7274237, at *7-8. This Court, likewise, need not succumb to this fairly transparent tactic. The key is not the name but the way the expert handles or ignores the critical dose and causation assessments.

C. Simply Referring to the Plaintiff's Exposures Is Not Sufficient

In the absence of *Betz*-required testimony, the trial judge and Superior Court decided that the "record" of exposure in this case was sufficient to "establish [the *any exposure* opinion's] scientific legitimacy." *Rost v. Ford Motor Co.*, 2014 WL 2178528, at *10 (Pa. Super. May 19, 2014). In light of this Court's pronouncements in *Betz* and *Howard*, it is difficult to see any legitimacy in *any exposure* testimony under any circumstances. The resort to the "record," however,

See, e.g., Bobo v. Tenn. Valley Auth., 2014 WL 4269128 (N.D. Ala. Aug. 25, 2014) (allowing expert to testify that only "significant" exposures were causative without any definition of what constituted significant other than the expert's own say-so).

is a tactic used by a few courts recently to avoid ruling out *any exposure* testimony.²⁸ The argument goes something like this: "We will accept that *any exposure* testimony may be too far, but the plaintiff in this case testified to several instances of exposure. Plaintiff thus is not relying on the *any exposure* theory for causation because there is more than 'any' exposure in this case."

This approach is illogical and does nothing to cut back on *any exposure* testimony. Under this approach, the expert can still guess at the degree of exposure necessary, and it seems almost no testimony of exposure is too small. Mr. Rost's own exposures are infinitesimally small compared to textile plant workers and mining workers, who are virtually the only workers to incur mesothelioma from chrysotile-related workplace exposures. The "record" exposures in this case are also far smaller than the many cohorts of professional and lifetime automotive mechanics who in multiple studies have shown no increased incidence of mesothelioma. There is no competent scientific evidence that Mr. Rost's exposures would cause mesothelioma. In addition, neither Dr. Frank nor the Superior Court made any effort to distinguish "sufficient" from

See, e.g., Robertson v. Doug Ashby Bldg. Materials, Inc, 2014 WL 7277688 (La. Ct. App. Dec. 23, 2014); Scapa Dryer Fabrics v. Saville, 16 A.3d 159 (Md. 2011) (allowing case to proceed under Lohrmann standard based only on testimony of plaintiff of periodic "dust" exposure).

"insufficient" – they merely cited the Plaintiff's exposure history and declared it sufficient. This is just another form of *any exposure* testimony.

The Superior Court's reliance on the "record" also improperly divorces the causation finding from expert opinion. Here, the Panel seemed to believe that expert testimony is unnecessary to support a jury verdict in a low dose case – either the judge or jury (or both) can simply speculate as to whether ten brake jobs, or five brake jobs, or - as in this case - no brake jobs at all but merely three months of being in a garage is enough. If this is the rule, Dr. Frank did not even need to testify. Plaintiffs could go to a jury based on their own testimony of "dust" To the contrary, as noted above, the determination of how much asbestos is sufficient to cause mesothelioma is far beyond the ken of a juror, or a judge for that matter. It requires competent assessment of the epidemiology and dose situation, and Dr. Frank refused to perform that assessment. Without that foundation, the Court itself cannot provide the missing expert analysis and declare a set of exposures "sufficient" based on some unknown and unseen medical standard.

The Superior Court also tried to fall back on the older *Lohrmann* standard²⁹ from *Gregg* to contend that Mr. Rost's exposures thirty feet or more from the mechanics (and his once a day sweeping) were sufficiently frequent, regular and

proximate to suffice for causation.³⁰ This analysis is error. *Lohrmann* is only a surrogate for a dose assessment – if the exposures are not regular, frequent, and proximate, then the dose is too low to go to a jury. But it is not a *substitute* for a dose assessment. If the frequent, regular, and proximate exposures still do not create a dose anywhere near those of the cohort that actually incurred excessive disease, there is no scientific proof that such exposures cause disease and the case should not go to the jury.

Even under *Lohrmann*, the trial court should not substitute its lay judgment for that of an expert as to the degree of exposure necessary to cause disease. Whatever *Lohrmann* meant in the old insulation cases – where one worker was exposed to many brands of insulation – it makes no sense in the new wave of low dose/chrysotile cases. In low dose cases, where there certainly can be frequent, regular and proximate exposures that do *not* cause disease (such as background exposures), an expert must step in to add the additional element of *dose* and prove that the dose rose to causative levels. *See Flores v. Borg-Warner Corp.*, 232 S.W.3d 765, 772 (Tex. 2007); *Bostic*, 439 S.W.3d at 338. *Lohrmann* can thus be seen as a floor above which plaintiffs must climb to even start the process – but if

See Lohrmann v. Pittsburgh Corning Corp., 782 F.2d 1156 (4th Cir. 1986).

Thirty feet away from a minor source of asbestos exposure is not "proximate" at all and should have been enough to take this case from the jury under *Lohrmann*.

the expert does not demonstrate that the overall dose reached a causative level, the case should not go to the jury.

D. The Superior Court Performed an Inadequate Review of Dr. Frank's Testimony and the Causation Evidence By Declining to Look Beyond the Expert's Self-Serving Statements

Both the trial court and the Superior Court fell into a common trap by citing only to the expert's statements and not examining the basis for those statements. This is classic error under either *Frye* or *Daubert* and represents a wholly inadequate review.

The trial court in *Rost* had at least three opportunities to evaluate – and stop – Dr. Frank's speculative opinions: (1) Ford's motion to exclude Dr. Frank's testimony under *Frye*; (2) Ford's motion for summary judgment based on the insufficiency of *any exposure* testimony to support the jury verdict; and (3) the revisitation of summary judgment through the post-trial motions. Despite the *Betz* and *Howard* rulings which should have governed his decision, this trial judge failed to act at any of those critical junctions. The Superior Court, in turn, fell into the trap of simply citing Dr. Frank's (or Dr. Brody's) pronouncements and then taking them at face value. The opinion is full of paragraphs starting with "Dr. Frank said," "Dr. Frank opined," and "Dr. Frank concluded." Nowhere did the Court look behind these statements to see if they were logically supported by

the evidence or the studies, or whether the statements actually supported the causation opinion.

This is the classic *ipse dixit* error identified by the United States Supreme Court in *General Elec. Co v. Joiner* 522 U.S. 136 (1997): "But nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." *Id.* at 146. Failing to examine closely such expert statements as "there is no safe dose of asbestos," or "all fiber types cause mesothelioma" and their logical connection to Dr. Frank's opinions is error and leads to speculative testimony.

As only one example, Dr. Frank and other similar experts are fond of stating that very short exposures to asbestos, even as small as one day, have been shown to cause mesothelioma. *See Rost*, 2014 WL 2178528, at *2. Even a brief look behind this statement shows how blatantly misleading it is in a case like this one. The "studies" they cite are typically case reports only – not comparative studies showing increased disease at such low levels – and thus they do not even demonstrate that these reported cases were asbestos-induced at all. The authors of these studies virtually never conclude that exposures as short as one day actually

cause mesothelioma.³¹ The cited studies also involve a different fiber, *amphiboles*, not chrysotile, and they often involve egregiously high exposures. To illustrate, one of the favorite sources cited for this proposition is the International Agency for Research on Cancer's (IARC) asbestos monograph, which cites to an article reporting on two mesotheliomas occurring in employees who worked with crocidolite (not chrysotile) in an enclosed hut from 1928-1929, with no ventilation and in conditions so dusty they could barely see across the room.³² This is not Mr. Rost's experience.

The Panel's reliance on such statements is unfortunate because these experts are engaged in a sleight of hand. When they are challenged to prove that low doses of chrysotile cause mesothelioma, they cite to amphibole and high dose studies or the irrelevant proposition that "all fibers are known to cause mesothelioma." When they are asked to produce actual studies demonstrating increased disease from exposures like Mr. Rost's, they point instead to government or regulatory

See, e.g., Morris Greenberg & T.A. Lloyd Davies, Mesothelioma Register 1967-68, 31 Brit. J. Indus. Med. 103 (1974) ("[T]he briefest occupational exposure to asbestos associated with a mesothelial tumor was three weeks, but if asbestos was a cause of mesothelioma it cannot be assumed that lesser exposures are safe."). This statement reflects a hypothesis, with no reference to fiber type or degree of exposure, but experts like Dr. Frank misrepresent it as a finding supporting low dose chrysotile exposures.

World Health Org. Int'l Agency for Research on Cancer, Monographs on the Evaluation of Carcinogenic Risks to Humans, Overall Evaluations of Carcinogenicity: An Updating of IARC Monographs Vols. 1 to 42 (Sept. 7, 1998) (citing Hilt, B., Occurrence of Cancer in a Small Cohort of Asbestos Exposed Workers, 7 Scan. J. Work Envir. Health 185 (1981)).

cautionary statements that "there is no known safe dose of asbestos." When they are challenged on the potency differential between chrysotile and amphiboles, they acknowledge that it exists but make no adjustment in their dose opinion – all exposures are still causative at all levels. When they are confronted with background exposures, which they agree are not causative, they still do not determine whether plaintiff's exposures even exceeded the lifetime level of a background dose. They claim Mr. Rost was exposed to "a million asbestos fibers while he worked at the garage," *Rost,* 2014 WL 2178528, at *8, yet fail to tell the jury that mere background exposures place *hundreds of millions* of fibers in a human lung. They testify that Mr. Rost's exposures at thirty feet were "greater than background," *Rost,* 2014 WL 2178528, at *2, but never demonstrate that "above background" is a causative level.

Trial judges need to terminate this kind of speculative opinion through a careful review of the expert's testimony, or the asbestos litigation will extend indefinitely to increasingly small and vanishing exposure scenarios. Unsupported claims will continue to be presented to juries unless this Court takes steps to uphold the science.

³³ Betz, 44 A.3d at 56.

CONCLUSION

Reversal of this case is fully justified by *Betz* and *Howard*. *Amici* also request that the Court use this opportunity to reinforce the following:

- All cases require a competent dose assessment and not merely qualitative statements ("significant" or "high" exposure) or mere references to Plaintiff's exposure testimony.
- In all asbestos cases, experts must demonstrate that disease occurs from the fiber type and at the levels experienced by Plaintiff based on competent epidemiology or similar studies and may not resort to "no safe dose" and similar generalities.
- Lohrmann serves only as a starting point low dose cases still require the same dose and causation assessment even if exposures were frequent, regular, and proximate.
- Trial judges cannot accept and repeat expert statements at face value to survive *Frye* review or a substantial evidence review courts must determine whether the cited studies and reasoning are scientific, logical, and correctly support the point.

Despite the Panel below, several Superior Court opinions such as *Nelson* have correctly applied *Betz*. This Court should continue to encourage the fullest implementation of *Betz*'s principles.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Brief contains 8,529 words, excluding the supplementary matter excluded by Pa. R.A.P. 2135(b).

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Dated: January 20, 2015

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing was served upon the following counsel of record, by U.S. Mail, postage prepaid, pursuant to Pa. R.A.P. 121.

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