In The Superior Court of Pennsylvania

No. 1058 WDA 2006

DIANA K. BETZ, Executrix of the Estate of CHARLES SIMIKIAN, deceased,

Plaintiff/Appellant

V.

PNEUMO ABEX LLC, successor in interest to Abex Corporation; ALLIED SIGNAL, INC., in its own right and as successor in interest to Bendix Corporation, BORG-WARNER CORPORATION; CARLISLE COMPANIES, INC.; OKONITE COMPANY; GENERAL MOTORS CORPORATION; KELSEY-HAYES COMPANY; METROPOLITAN LIFE INSURANCE COMPANY, a/k/a Metropolitan Insurance Company; DAIMLERCHRYSLER CORPORATION, f/k/a Chrysler Corporation; FORD MOTOR COMPANY; VOLKSWAGEN OF AMERICA, INC.; NAPA AUTOMOTIVE PARTS GROUP; ROHRICH CADILLAC, INC.; DYKE MOTOR SUPPLY COMPANY, INC.; SOUTH HILLS AUTO PARTS CO.,

Defendants/Appellees

BRIEF OF AMICI CURIAE CATERPILLAR INC., CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AMERICAN TORT REFORM ASSOCIATION, COALITION FOR LITIGATION JUSTICE, INC. AND PROPERTY CASUALTY INSURERS ASSOCIATION OF AMERICA IN SUPPORT OF APPELLEES

Appeal from the Final Order of the Court of Common Pleas of Allegheny County, entered May 10, 2006, amended on May 30, 2006, and the Orders dated April 3, 2006, docketed at No. GD 05-4662, granting summary judgment in favor of Defendants DaimlerChrysler Corporation, Ford Motor Company, and General Motors Corporation

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STATEMENT OF INTEREST

Caterpillar Inc. is a worldwide manufacturer and distributor of heavy equipment. Although Caterpillar has never manufactured or sold asbestos or asbestos materials, in recent years it has been sued by asbestos plaintiffs based on the presence of chrysotile asbestos fibers bound or encapsulated in certain Caterpillar heavy equipment parts, namely brakes, gaskets, and clutch pads on some machines. The current state of asbestos law in some states permits plaintiff experts to testify against Caterpillar based on an "any fiber of exposure" theory, without adequate examination of the methodology underlying these opinions and the lack of scientific support for attribution of asbestos disease to heavy equipment mechanic work. Caterpillar thus has a significant interest in the outcome of this appeal of Judge Colville's well-reasoned opinion, as the appeal will likely affect Caterpillar's ability to defend itself against scientifically unfounded asbestos litigation in Pennsylvania.

The Chamber of Commerce of the United States of America ("the Chamber") is the world's largest business federation. The Chamber represents an underlying membership of more than three million businesses and organizations of every size, in every business sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in court on issues of concern to the business community. The Chamber, individually and on behalf of its members, has a continuing interest in the just and fair resolution of the asbestos crisis.

Founded in 1986, the American Tort Reform Association ("ATRA") is a broadbased coalition of more than 300 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 more than a decade, ATRA has filed *amicus curiae* briefs in cases before state and federal courts that have addressed important liability issues.

The Coalition for Litigation Justice, Inc. ("Coalition") is a nonprofit association formed by insurers to address and improve the asbestos litigation environment. The Coalition's mission is to encourage fair and prompt compensation to deserving current and future litigants by seeking to reduce or eliminate the abuses and inequities that exist under the current civil justice system. The Coalition files amicus curiae briefs in important cases before state courts of last resort that may have a significant impact on the asbestos litigation environment.

The Property Casualty Insurers Association of America ("PCI") is a trade group representing more than 1,000 property and casualty insurance companies. PCI members are domiciled in, and transact business in, all fifty states, plus the District of Columbia and Puerto Rico. Its member companies account for \$184 billion in direct written premiums. They account for fifty-two percent of all personal auto premiums written in the United States, and approximately forty percent of all homeowners' premiums, with personal lines writers of commercial and miscellaneous property/casualty lines. In addition to the diversified product lines they write, PCI members include all types of insurance companies, including stocks, mutuals, and companies that write on a non-admitted basis. The PCI membership is literally a cross-section of the U.S. property and casualty insurance industry. In light of its involvement in Pennsylvania, the PCI is

The Coalition for Litigation Justice includes ACE-USA companies, Chubb & Son, a division of Federal Insurance Company, CNA service mark companies, Fireman's Fund Insurance Company, General Reinsurance Corp., Liberty Mutual Insurance Group, and the Great American Insurance Company.

particularly interested in the resolution of the issue before the Court on behalf of its members and their interests.

INTRODUCTION AND SUMMARY OF ARGUMENT

The appeal of Judge Colville's decision provides this Court with the opportunity to consider whether the ordinary rules of tort law and expert testimony, as set forth, e.g., in Blum v. Merrell Dow Pharm., Inc., 764 A.2d 1 (Pa. 2000), will be applied to the "new wave" of low-dose, chrysotile asbestos exposure cases now being filed in the neverending asbestos litigation. Pennsylvania and other courts are facing a continuing proliferation of asbestos claims, with no end in sight, even though virtually all of the companies that manufactured and produced asbestos have been driven into bankruptcy through litigation. The expanding wave of asbestos litigation spreads the net far beyond the insulation, shipyard, and asbestos manufacturing world to target defendants whose products produce very minimal exposures, and, in the case of friction products, involve only bonded chrysotile products.

The science regarding asbestos has developed dramatically in the last twenty years and does not support this kind of asbestos litigation. In particular, researchers have extensively investigated whether mechanic work causes asbestos disease, including mesothelioma. Over fifteen mesothelioma studies, conducted by more than 60 researchers in seven countries over the last twenty-five years, have never identified any increased risk of pleural mesothelioma in mechanics, even those who worked their entire lives in this field as Mr. Simikian did. The lack of causation in these studies is backed up by (1) the documented low doses associated with this occupation, and (2) consensus scientific views that short chrysotile fibers – the kind found in mechanic exposures – are not a likely cause of mesothelioma at anything less than extremely heavy doses. The extensive epidemiology documenting a total lack of disease in this occupation

distinguishes this case from *Trach v. Fellin*, 817 A.2d 1102 (Pa. Super. Ct. 2003) and others holding that plaintiffs need no epidemiology to prove their case – here, they attempt to bring a case contradicted in every way by the controlling, peer-reviewed literature. Under *Blum v. Merrell Dow Pharm., Inc.*, this is not a scientific methodology and cannot survive *Frye*.

In light of the absence of scientific support, friction product cases like this one survive only when courts continue to apply alternative causation and expert admissibility rules, developed for the earlier, high dose amphibole cases, to this new wave of very different defendants. Most critically, the old "special asbestos" rules often eliminate any dose requirement, permitting plaintiff experts to testify merely that plaintiff breathed some fibers from a defendant's product to establish liability. Coupled with the refusal to require these experts to present a competent scientific methodology to back up their "any breath/any fiber" opinion, the rules are preventing defendants from exposing the lack of any scientific methodology behind these experts' opinions.

The trial court here was thus within its discretion, and entirely correct, to reject Dr. Maddox's unscientific methodology, including his "reasoning that if high dose exposure is bad for you, then surely low dose exposure (indeed, no matter how low) must still be bad for you[.]" Opinion at *7.2 A "methodology" by which an expert replaces the epidemiological testing (and rejection) of the expert's primary hypothesis with irrelevant animal studies, case reports, and unscientific assumptions contravenes the very essence of the scientific method itself, by which a hypothesis is "formulated"

² The page references to Judge Colville's Opinion set forth herein correspond to its publication at *In re Toxic Substance Cases*, 2006 WL 2404008 (Pa.Com.Pl. Aug. 17, 2006).

and then "empirically tested." Trach, 817 A.2d 1102, 1113 (Pa. Super. 2003) (emphasis added).

Other courts in the last two to three years have begun to awaken to the scientific implausibility of these low dose cases and reject expert testimony supporting them. Caterpillar and the joining *amici* urge this Court to begin applying the lessons of *Blum* and other standard causation/expert doctrines to asbestos litigation, as Judge Colville did.³

I. THE SCIENTIFIC ERROR IN PLAINTIFFS' ATTEMPT TO EXPAND ASBESTOS LITIGATION TO LOW DOSE CHRYSOTILE EXPOSURES

A. The Original Asbestos Litigation Typically Involved Workers <u>Who Experienced High Exposures in Old-Line Asbestos Industries.</u>

This friction product case is best understood in the context of how asbestos litigation developed from the old asbestos cases, which were typically filed against manufacturers and producers of raw asbestos or asbestos insulation products, to cases like this one against defendants whose products merely incorporate some form of encapsulated asbestos in minimal amounts.

The typical "old" asbestos case involved a plaintiff who spent his entire career working with insulation products that contained high levels of breathable amphibole fibers—long, rigid fibers that are known to be toxic, unlike the shorter chrysotile form of fiber that is at issue in this case. Occupations such as shipbuilders and Navy personnel experiencing heavy amphibole asbestos exposures on World War II ships; insulators blowing large clouds of free amphibole or mixed fibers; and asbestos factory workers exposed to "snowstorms" of raw amphibole or mixed fibers are the paradigm settings for

Amici adopt the counterstatement of issues on appeal submitted by DaimlerChrysler in its opposition brief.

asbestos disease. See Deborah Hensler et al., Asbestos Litigation in the U.S.: A New Look at an Old Issue, RAND Corp., 14-15 (2001), available at http://www.rand.org/pubs/documented_briefings/2005/DB362.0.pdf (last visited Jan. 13, 2007). Epidemiology studies have repeatedly confirmed that these high dose occupations are a major source of asbestos exposures and disease.

In part due to the press of many such cases, and in part due to the complexities of proof, some courts began to relax a number of standard evidentiary and proof rules to accommodate these claims. See, e.g., Victor E. Schwartz & Leah Lorber, A Letter to the Nation's Trial Judges: How the Focus on Efficiency is Hurting You and Innocent Victims in Asbestos Liability Cases, 24 Am. J. TRIAL ADVOC. 247 (2000)(Exh. 1);⁴ Richard O. Faulk, Dispelling the Myths of Asbestos Litigation: Solutions for Common Law Courts, 44 S. Tex. L. Rev. 945 (2003).

Most pertinent to this case, the causation rules changed. Ordinarily, under long-standing rules of tort law, courts would require asbestos plaintiffs, like any others, to demonstrate that each defendant's product was either a "but-for" cause or a "substantial factor" in the cause of plaintiff's disease. In the typical tort case, such a showing would require not only proof of exposure to the defendant's product, but exposure to enough of a dose of the defendant's product to actually cause disease. This dose concept is widely recognized in both science and courts as the foundation of causation and the basis for many medical tort decisions. See, e.g., McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1241 (11th Cir. 2005) ("In toxic tort cases, '[s]cientific knowledge of the harmful level of

⁴ Copies of articles and government materials not readily available on the internet have been included as exhibits in the appendix to this brief for the Court's convenience.

exposure to a chemical plus knowledge that the plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiffs' burden . . .") (emphasis added) (citing Allen v. Pa. Eng'g Corp., 102 F.3d 194, 199 (5th Cir. 1996)); David L. Eaton, Scientific Judgment and Toxic Torts—A Primer In Toxicology For Judges And Lawyers, 12 J.L. & Pol'y 5, 11 (2003) [hereinafter Eaton] ("[d]ose is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect").⁵

In asbestos cases, however, some courts, including some opinions from this Court, permitted plaintiffs to demonstrate merely that they were *exposed* to a defendant's product, rather than requiring proof that any particular exposure was high enough to cause a plaintiff's disease. The result is that in asbestos cases, the causation dose requirement – real *exposure*, at *quantities* demonstrated in the literature to cause disease – was reduced to merely a "breathing any fiber" test. In no other tort context would a court accept mere exposure as proof of causation – in fact, Pennsylvania's courts have directly refused to do so in other contexts. *See, e.g., Heck v. Beryllium Corp.*, 226 A.2d 87, 90 (Pa. 1966) (trial court erred in instructing jury that it could find defendant liable for toxic emission lower than standard established by Atomic Energy Commission). *See also Parker v. Mobil Oil Corp.*, 7 N.Y.3d 434, 449 (2006) (rejecting expert's "general, subjective and conclusory assertion" regarding plaintiff's level of exposure to benzene).

A fundamental tenet of toxicology is that "the dose makes the poison." Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, Federal Judicial Center, 403 (2000) (Exh. 2). The "father of toxicology," physician and philosopher Paracelsus first articulated this principle in the 16th Century, stating: "All substances are poisonous—there is none which is not; the dose differentiates a poison from a remedy." Eaton, supra at 11.

B. The "Old" Asbestos Rules Have Permitted Plaintiffs to Expand Asbestos Dockets Exponentially by Suing Companies with Minimal Asbestos in Their Products.

The "old" asbestos litigation involving insulators and other high-dose occupations is winding down, due to the closure of these WWII-era industries and to the bankruptcy of most, if not all, of the companies that manufactured and produced asbestos. The causation and proof approaches developed for those cases, however, have survived and even flourished to the present. Today, however, these doctrines are being applied in a very different world of asbestos litigation, in which they are manifestly unsound.

As a result, as the older high-exposure asbestos cases have been declining, asbestos litigation, resisting predictions, has not declined with them. Instead, asbestos dockets have ballooned, overwhelming many courts, and prompting the United States Supreme Court to observe that the country is in the midst of an "asbestos-litigation crisis," *Amchem Prods. Inc. v. Windsor*, 521 U.S. 591, 597 (1997), as a result of the "elephantine mass" of filed claims, *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 821 (1999).

See Hon. Griffin B. Bell, ASBESTOS LITIGATION AND JUDICIAL LEADERSHIP: THE COURTS' DUTY TO HELP SOLVE THE ASBESTOS LITIGATION CRISIS, National Legal Center the Public Interest, 15 - 16(2002),http://www.nlcpi.org/books/pdf/vol6number6june2002.pdf. (last visited Jan. 13, 2007) ("Courts . . . struggle to adapt to and manage the unexpected and unprecedented volume of asbestos personal injury claims. Hundreds of thousands of cases – and counting – have overtaken and incapacitated certain courts since the 1970s"); Stephen J. Carroll, et Asbestos Litigation, (2005),**RAND** Corp., 28 http://www.rand.org/pubs/monographs/2005/RAND MG162.pdf (last visited Jan. 13, 2007)[hereinafter RAND 2005]("as asbestos cases flooded courts in areas of the country where there had been heavy exposure to asbestos, federal and state courts struggled to manage asbestos caseloads"); Mark A. Behrens, Some Proposals for Courts Interested in Helping Sick Claimants and Solving Serious Problems in Asbestos Litigation, 54 BAYLOR L. REV. 331 (2002).

Ten years after *Amchem*, the crisis has not abated. The Pennsylvania Supreme Court, as recently as only two years ago, noted "the heavy toll that asbestos litigation is visiting upon certain Commonwealth corporations." *Ieropoli v. AC&S Corp.*, 842 A.2d 919, 932 (Pa. 2004). A similarly heavy toll is, of course, borne by the courts themselves. Yet asbestos claims – including claims of dubious merit – continue to proliferate.

The roots of this expansion are primarily two-fold: (1) plaintiff attorneys recruited and filed thousands of "unimpaired" claims, based on purported X-ray "findings" of lung anomalies without any apparent impairment; and (2) plaintiff attorneys expanded their net of defendants to encompass virtually any manufacturer, seller, or user of a product with any amount of asbestos in it. This Court was among the first to confront and address the first problem, ruling that asymptomatic asbestos plaintiffs cannot recover under Pennsylvania law. See Giffear v. Johns-Manville Corp., 632 A.2d 880 (Pa. Super. Ct. 1993), aff'd sub. nom. Simmons v. Pacor, Inc., 674 A.2d 232 (Pa. 1996).

The second root cause – massive expansion of the number of asbestos defendants – is a disaster threatening U.S. industry. One plaintiffs' attorney bluntly characterized

See Lester Brickman, Ethical Issues in Asbestos Litigation, 33 HOFSTRA L. REV. 833 (2005); Lester Brickman, On the Theory Class's Theories of Asbestos Litigation: The Disconnect Between Scholarship and Reality, 31 PEPP. L. REV. 33 (2003).

See Paul F. Rothstein, What Courts Can Do in the Face of the Never-Ending Asbestos Crisis, 71 MISS L.J. 1 (2001); Susan Warren, Asbestos Suits Target Makers of Wine, Cars, Soups, Soaps, WALL St. J., Apr. 12, 2000, at B1 (Exh. 3); Susan Warren, Asbestos Quagmire: Plaintiffs Target Companies Whose Premises Contained Any Form of Deadly Material, WALL St. J., Jan. 27, 2003 at B1 (Exh. 4).

this expansion as an "endless search for a solvent bystander." When asbestos litigation focused on actual producers of asbestos and asbestos-containing products, defendants numbered in the dozens or hundreds (in 1980, about 300 such defendant companies). Now, there are over 8,400 businesses who are being sued, representing approximately one-half of the U.S. business landscape. Once a company is caught in this net, it is nearly impossible to escape without serious financial consequences.

These new defendants are being sued over the most trivial of asbestos links — trace fibers in wine, soap, potholders, hairdryers, refrigerators and washing machines — virtually any part or piece with asbestos in it will do. See Susan Warren, Asbestos Suits Target Makers of Wine, Cars, Soups, Soaps, Wall St. J., Mar. 5, 2001, at A1 (Exh. 3); Susan Warren, Asbestos Quagmire: Plaintiffs Target Companies Whose Premises Contained Any Form of Deadly Material, Wall St. J., Jan. 27, 2003 at B1 (Exh. 4); Roger Parloff, The \$200 Billion Miscarriage of Justice: Asbestos Lawyers are Pitting Plaintiffs Who Aren't Sick Against Companies that Never Made the Stuff — And Extracting Billions for Themselves, FORTUNE, Mar. 4 2002, at 154, available at 2002 WLNR 11958234 (Exh. 7). The type of exposures sufficient to name one of these defendants can involve either a small number of exposure experiences, or a longer series

[&]quot;Medical Monitoring and Asbestos Litigation" – A Discussion with Richard Scruggs and Victor Schwartz, 17:3 Mealey's Litig. Rep.: Asbestos 5 (Mar. 1, 2002)(Exh. 5); Editorial, Lawyers Torch the Economy, WALL St. J., Apr. 6, 2001, at A14 (Exh. 6) ("the net has spread from the asbestos makers to companies far removed from the scene of any putative wrongdoing").

¹⁰ RAND 2005, *supra*, at 79.

See id. at 121-23 (describing bankruptcy of asbestos defendants and other economic effects of litigation on companies' retained earnings, investments, borrowing capacity, and jobs created).

of very low dose exposures, such as that of the plaintiff in this case, who was a career mechanic. In either circumstance, the lifetime dose is miniscule and far different from the world of known asbestos disease.

C. Asbestos Cases Involving Low Exposures, Less Toxic Fibers, and a Complete Absence of Epidemiology Require Critical Judicial Review of Plaintiffs' Methodologies and Lack of Proof.

1. Not All Doses of Asbestos Cause or Contribute to Disease.

The science regarding asbestos disease has advanced dramatically since the heyday of the old-style asbestos litigation. It is now widely accepted, for instance, that not all doses of asbestos cause disease. Even most plaintiffs' experts today readily admit that "background" exposures (such as those received by virtually any urban dweller or those living near natural asbestos outcrops) do not cause or contribute to asbestos disease. These background exposures can contribute millions of fibers to the lungs yet not produce disease, because the lungs are capable of processing and absorbing these background doses without incurring harm.¹² Nevertheless, many plaintiffs' experts claim that any fiber from an occupational source causes or contributes to disease, even while admitting that millions of fibers of background asbestos do not. This type of opinion, as Judge Colville rightly noted (Opinion at *4), defies logic, as there is no toxicological distinction between an "occupational" fiber and an "environmental" background fiber. Thus, there is no inherent reason to assume all occupational exposures cause disease, and, as discussed below, many epidemiology studies have demonstrated that low dose exposures like mechanic work in fact do not cause disease.

For example, at one calculation of the average urban ambient asbestos fiber level, 0.005 fibers/cc on a daily basis, an urban dweller by age 30 will have already inhaled over one billion asbestos fibers.

Moreover, it is clear today that many cases of mesothelioma have nothing to do with asbestos at all. Like every other cancer known to science, mesotheliomas likely have multiple causes, but we do not yet know what they are. It is widely accepted in the scientific community that between 10 and 20% of all mesotheliomas are not asbestos-related but are *idiopathic*, i.e., of unknown cause. Thus, it is improper to assume that every mesothelioma is an asbestos-caused disease – this conclusion would be wrong fully 20 percent of the time. See Victor Roggli, et al., PATHOLOGY OF ASBESTOS-ASSOCIATED DISEASES, 108 (2d ed. 2004)(Exh. 8). 13

2. Short, Chrysotile Fibers Like Those in Friction Products and Gaskets Are Far Less Potent than Other Asbestos Fibers.

In addition, much research has been conducted in recent years to determine precisely which types of asbestos fibers are responsible for disease. The research has great importance for the ongoing use and production of certain forms of asbestos, as well as in determining past occupations that were or were not at risk. The research has focused on two principal questions: (1) whether long asbestos fibers, generally greater than 5 micrometers, are principally responsible for asbestos disease, and (2) whether chrysotile asbestos (which breaks down easily into short sections) is less potent than other forms. Both of these questions were the subject of recent panels of top experts convened by the United States Environmental Protection Agency (the "EPA Panel") and the Agency for Toxic Substances Disease Research ("ATSDR"), an arm of the Centers for Disease Control. The first (EPA) panel, after reviewing the extensive literature, concluded, by consensus, that *chrysotile asbestos fibers are far less likely to cause*

Other possible causes, such as radiation, the SV40 virus, and tuberculosis, have all received investigative attention but are not confirmed as known causes. *See id.* at 109-110.

disease than amphiboles, by a factor of at least two orders of magnitude.¹⁴ The second (ATSDR) panel, likewise concluded, again by consensus, that "there is a strong weight of evidence that asbestos [fibers] shorter than 5 µm are unlikely to cause cancer in humans."¹⁵ Leading asbestos pathology textbooks have reached the same conclusion. ¹⁶

These two findings, which reflect a growing consensus on these points in the scientific community, describe the fiber type typically found in vehicle products — chrysotile rather than amphibole fibers, and/or fibers shorter than 5 micrometers. Even Dr. Maddox agrees that chrysotile is less potent than other forms of asbestos. Affidavit of John C. Maddox, M.D., Aug. 4, 2005, at 1 ("Maddox Aff.")(Exh. 10). Nowhere in his causation opinion, however, does he take this lesser potency into account in regard to Mr. Simikian's chrysotile-only exposures. In light of the growing scientific demonstration that not all fibers are the same, and that dose is clearly an issue for asbestos causation, it is no longer sufficient to state simply that all asbestos exposures are harmful. That is clearly not the case.

3. Epidemiology Is Critical to Distinguishing Legitimate from Unsupported Asbestos Disease Claims.

U.S. EPA, Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, viii (May 30, 2003), available at http://www.epa.gov/oswer/riskassessment/asbestos/pdfs/asbestos_report.pdf (last visited Jan. 13, 2007). Andrew Churg's textbook likewise notes that "fiber for fiber, amosite and crocidolite are more fibrogenic than chrysotile . . ." Andrew Churg, Nonneoplastic Disease Caused by Asbestos, in Churg, A. & Green, F., eds., PATHOLOGY OF OCCUPATIONAL LUNG DISEASE, 314 (2d ed. 1998)(Exh. 9).

ATSDR, Report on the Expert Panel on Health Effects of Asbestos and Synthetic Vitreous Fibers: The Influence of Fiber Length, vi (Mar. 17, 2003), available at http://www.atsdr.cdc.gov/HAC/asbestospanel/asbestostoc.html (last visited Jan. 13, 2007).

See Roggli, supra p. 13, at 108 ("[I]n contrast to the commercial amphiboles, low level exposures [to chrysotile] are not likely to increase [mesothelioma] risk."

Under *Blum*, the manner in which the expert addresses contrary epidemiology is unquestionably a factor for *Frye* analysis. We thus discuss in this section and the next the role of epidemiology in asbestos disease and the critical mechanic studies. For scientists, considering the reality that not all doses cause disease, epidemiology becomes vitally important to discern exactly which exposures are contributing to disease and which ones are not. Scientists look first to the epidemiology studies, the "gold standard" of causation, rather than inferring causation from less relevant evidence:

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.

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, 657 (1992) (emphasis added) [hereinafter Green]. Many courts have recognized the importance of epidemiology, including this Court in Wack v. Farmland Indus., Inc., 744 A.2d 265, 271 (Pa. Super. Ct. 1999), abrogated on other grounds, Trach v. Felllin, 817 A.2d 1102 (Pa. Super. Ct. 2003) ("epidemiology, which generalizes results gleaned from population samples, 'provides useful information as to whether there is a relationship between an agent and a disease and, when properly interpreted, can provide insight into whether the agent can cause the disease.") (citation omitted).

The lack of epidemiology supporting low dose asbestos cases like those predicated on mechanic work distinguishes them from the older cases involving significant exposure. Many epidemiology studies have documented the high "odds ratios" or measurements of association between occupations like shipbuilding and

insulator work and asbestos disease.¹⁷ In these studies, odds ratios of 4.0, 5.0, even 10.0 and above are common (the odds ratio for insulators in the McDonald study (n. 12) was 46.0). In contrast, no epidemiology study documents any increased incidence of asbestos disease from chrysotile exposures at or anywhere near the current OSHA standard of 0.1 f/cc. Studies of professions like mechanics, exposed only to low doses of chrysotile, have found that their disease incidence is no different from that in professions with little or no opportunity for asbestos exposure, such as traveling salesmen, teachers, librarians, office clerks, accountants, and farmers.¹⁸

The purported scientific basis for low dose asbestos litigation has been constructed by a small cadre of plaintiff experts, who are basically testifying about their own personal belief — an unproven hypothesis — that low exposures cause disease, without objective proof of that hypothesis. For a "methodology," if it can be called that, these experts select materials that are consistent with their preconceived theory and reject or ignore those that are not. They rely on "old" industry epidemiology of higher dose or amphibole occupations, and disregard low dose epidemiology studies of the very occupation at issue (e.g., the mechanic epidemiology) that contradict their opinions. They rely on prophylactic government pronouncements and warnings regarding asbestos as if those were proof of causation. They rely heavily on "case reports" of mechanics and other low-dose occupations who have asbestos disease, ignoring the fallacy of

See, e.g., Kay Teschke, Mesothelioma Surveillance to Locate Sources of Exposure to Asbestos, 88 CANADIAN J. Pub. HEALTH 163, Table II (1997) [hereinafter Teschke] (Exh. 11); AD & JC McDonald, Malignant Mesothelioma in North America, 46 CANCER 1650, 1653-54 (1980)(Exh. 12).

See, e.g., Teschke,, at 1653, Table II.

relying on case reports which cannot prove causation. ¹⁹ They acknowledge the lesser potency of short, chrysotile fibers but then fail to identify what the toxic level of exposure from those fibers would be, if any. Dr. Maddox has engaged in all of these practices, none of which are generally accepted in the scientific community.

D. The Mechanic Cases Illustrate How These New Cases Are Not Supported by Either Dose or Epidemiological Evidence.

Vehicle mechanics are among the most analyzed group of workers in the world when it comes to asbestos. We provide a summary of the science, most of which is available in published scientific journals, so that the Court will understand the implausibility of the causal connection posited by plaintiffs' experts.

Mechanics encounter asbestos through "bonded" products such as brake pads and clutch pads, which are hardened into solid blocks with resins. It is not possible to release fibers from these blocks without some form of serious disruption, like grinding or drilling. Plaintiffs thus typically allege exposures from grinding pads to fit them to the brake drum; from drilling some pads to create holes for bolts; from blowing "brake dust" remnants out of the drum before changing the pads; and sometimes from removing gaskets from engines and other parts.

Some concerns were raised in the late 1960s as to whether fibers released from automotive products might produce asbestos disease. Three sets of studies over the next two decades definitively established that they do not. The first studies investigated whether the brake dust found in a drum during replacement contained significant amounts of asbestos fibers. The answer came back, uniformly, that the quantity of brake

Green, supra, at 657 (in the hierarchy of scientific evidence, "case reports are at the bottom").

dust attributable to fibers, by weight, is typically much less than 1.0 percent.²⁰ Plaintiffs' experts generally do not contest these findings.

The second set of studies involves numerous investigations by the National Institute for Occupational Safety and Health ("NIOSH"), the research arm of OSHA, and others that measured the amount of breathable fibers available during actual mechanic work. Many of these have been published in the peer reviewed literature. As OSHA's Assistant Secretary documented in an official "standard interpretation" letter to Sen. Patty Murray in 2004, more than thirteen of these studies confirmed that "brake mechanics' exposures to asbestos from brakes... have characteristically been below the currently applicable OSHA permissible exposure limits (PELs) for asbestos." Mechanic exposures are, and historically have been, far below those of asbestos factory workers, shipyard workers, or insulators and well within the realm that OSHA today considers acceptable. See Dennis Paustenbach, et al., An Evaluation of the Historical Exposures of Mechanics to Asbestos in Brake Dust, 18 APPLIED OCCUPATIONAL AND ENVIRONMENTAL HYGIENE, 786-804 (2003) (Exh. 17) (average lifetime mechanic exposures calculated at 0.04 f/cc or less).

J. Lynch, Brake Lining Decomposition Products, 18 J. AIR POLLUTION CONTROL ASSOC. 824 (1968) (Exh. 13); M.G. Jacko, et al., Brake and Clutch Emissions Generated During Vehicle Operation, Automotive Engineering Meeting, SAE Passenger Car Meeting, Detroit, MI (1973) (Exh. 14); Arnold E. Anderson, Asbestos Emissions from Brake Dynanomoter Tests, Ford Motor Co. Scientific Research Staff, Detroit, MI, Tech. Rep. No. SR 73-64 (1973) (Exh. 15). The bonded chrysotile fiber used in brakes is generally subject to intense heat from the friction of the braking process, converting the asbestos to a harmless, non-fibrous dust. Arnold E. Anderson, Friction and Wear of Auto. Brakes, 18 ASM Handbook 569, 574 (1992) (Exh. 16).

Letter from John Henshaw, Asst. Sec. OSHA, to Sen. Patty Murray, Feb. 10, 2004, <a href="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table="http://www.osha.gov/pls/oshaweb/owadisp.show_document."http://www.osha.gov/pls/oshaweb/owadisp.show_document."http://www.osha.gov/pls/oshaweb/owadisp.show_document."http://www.osha.gov/pls/oshaweb/owadisp.show_document."http://www.osha.gov/pls/oshaweb/owadisp.show_document."http://www.osha.gov/pls/oshaweb/osha

Finally, the third set of studies is an entire body of epidemiological investigations of the association between mechanic work and mesothelioma, the asbestos disease believed to require the lowest dose. There are more than fifteen of these studies, conducted over the last twenty-five years, published in seventeen peer-reviewed articles, and performed in seven different countries by over sixty different researchers. Not a single such study has ever found an increased risk of pleural mesothelioma in mechanics. All seven of the case control studies addressing mechanics found odds ratios at or below 1.0, meaning no causal association. An additional eight or more studies of either cohort design or proportional mortality or "PMR" design all likewise found no indication of any association between mechanics and pleural mesothelioma. Taken together, the case control, cohort, and PMR studies looked at thousands of cases of mesothelioma and many thousands of mechanics without identifying any risk of mesothelioma.

Surveying this extensive mechanic literature, one leading article from Harvard University researchers concluded: "When examined in aggregate, the evidence did not support an increase in risk of either lung cancer or mesothelioma among male

The studies are summarized and discussed in Francine Laden, Lung Cancer and Mesothelioma among Male Automobile Mechanics: A Review, 19 REVS. ON ENVIL. HEALTH 39 (2004) (Exh. 18); Michael Goodman, Mesothelioma and Lung Cancer Among Motor Vehicle Mechanics: a Meta-analysis, 48 ANN. OCCUP. HYG. 309 (2004) (Exh. 19). See also Patrick A. Hessel, et al., Mesothelioma among brake mechanics: An expanded analysis of a case-control study, 24 Risk Analysis 547, 550 (2004) (Exh. 20) (noting, in summary of the results of an examination of 208 cases and controls from California, New York, and 39 VA hospitals, that "[t]here was no association between mesothelioma and either occupational or nonoccupational [hobby] brake work").

automobile mechanics occupationally exposed to asbestos from brake repair." Laden, supra, at 39.

Backing up the substantial epidemiology on brake mechanics, Dr. Victor Roggli, a Duke University eminent pathologist, asbestos expert, and author of the leading text *Pathology of Asbestos Related Diseases*, who has testified for <u>plaintiffs</u> in many insulator and amphibole cases, today strongly agrees that mechanic work is <u>not</u> a cause of mesothelioma, contributing or otherwise. His conclusion is based in part on his lung studies of mechanics who did brake jobs:

[Our lung-fiber burden] findings, combined with data from prior lung fiber analyses... and epidemiological reports, strongly suggest that friction product exposure, such as that encountered by automotive mechanics, is unlikely to contribute to the development of [mesothelioma].²³

Dr. Roggli has never testified in support of a mechanic claim, and in fact frequently appears on behalf of defendants in those cases to tell the jury why he does not agree that mechanic exposures cause or contribute in any way to asbestos disease. Appellant's brief actually cites to Dr. Roggli (Appellant's Brief at 12, 19), as if Dr. Roggli supports their claims. He does not, as the above article notes.

In sum, the occupational asbestos exposures of mechanics have been extensively studied, and extensively documented as low exposures with no correlation to the development of asbestos disease. An opinion to the contrary is both novel and unsupported by any unbiased scientific methodology.

See Kelly J. Butnor, et al., Exposure to Brake Dust and Malignant Mesothelioma: A Study of 10 Cases with Fiber Mineral Analyses, 47 Ann. Occup. Hyg. 325, 329 (2003) (Exh. 21).

II. THE TRIAL COURT PROPERLY APPLIED PENNSYLVANIA LAW TO EXCLUDE THE TESTIMONY OF DR. MADDOX.

In *Grady v. Frito-Lay, Inc.*, 839 A.2d 1038 (Pa. 2003), the Supreme Court of Pennsylvania reaffirmed its longstanding adherence to the rule of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), for evaluating the admissibility of novel scientific evidence. The "proven and workable" rule of *Frye* is that "novel scientific evidence is admissible if the methodology that underlies the evidence has general acceptance in the relevant scientific community." *Grady*, 839 A.2d at 1043-44.²⁴ The Supreme Court reiterated its adherence to *Frye* in a case decided only a year ago. *Commonwealth v. Dengler*, 890 A.2d 372, 380-81 (Pa. 2005).

This appeal enables the Court to confirm that Pennsylvania's trial courts must apply Frye, as Judge Colville did, in the new generation of asbestos cases just as it would be applied in all toxic tort claims. As the history described above unfolded, Pennsylvania asbestos law developed along the same lines as many other states, in that courts adopted specialized asbestos rules allowing plaintiff experts to testify broadly and very generally on exposure. See, e.g., See Smalls v. Pittsburgh-Corning Corp., 843 A.2d 410, 412 (Pa. Super. Ct. 2004); Cauthorn v. Owens Corning Fiberglas Corp., 840 A.2d 1028, 1030-31 (Pa. Super. Ct. 2004); Lonasco v. A-Best Prods. Co., 757 A.2d 367, 376 (Pa. Super. Ct. 2000). The trial correctly recognized that this case is different. The product (bonded chrysotile brake pads) is different; the exposures (very low doses) are different; and the expert's novel opinion (extrapolating down from higher dose studies to friction product exposures) is different and unjustified. Amici urge the Court to consider

Grady put to rest a confusion in some earlier cases regarding whether the expert's conclusion, as well, was required to be "generally accepted" in the scientific community. General acceptance of the conclusion is *not* required. 839 A.2d at 1045.

the implications and lack of scientific justification for expanding special asbestos causation and expert rules to friction product cases. See Lindstrom v. A-C Prod. Liab. Trust, 424 F.3d 488, 493 (6th Cir. 2005) (rejecting "every exposure" testimony because it would "permit imposition of liability on the manufacturer of any product with which a worker had the briefest of encounters on a single occasion"). If the standard tenets of Frye are applied, Dr. Maddox should not be permitted to testify.

A. Dr. Maddox's "Any Fiber" Approach Is Internally Inconsistent, Based on Unfounded Assumptions, and Not Derived from Any Identifiable Accepted Methodology.

Like several other courts in the last two years,²⁵ Judge Colville took the time to investigate what lies behind the "any fiber" theory of plaintiff experts like Dr. Maddox. What he found was revealing – this theory is lacking a coherent methodology of any sort and the approach it is based on is not generally accepted in the scientific community. This is precisely the kind of inquiry that *Grady* requires.

1. Dr. Maddox's Opinion Is Logically Flawed as He Fails to Account for the Role of Dose and Idiopathic Disease.

²⁵ See Letter Opinion, In re Asbestos Litigation, No. 2004-3964 (Judge Davidson)(Jan. 20. 2004) available at http://www.justex.net/JustexDocuments/1/Rule%2013%20Asbestosis/Havner%20Ruling%20-%20January%2020%202005.pdf (last visited Jan. 13, 2007) (court rejected testimony of plaintiff expert Dr. Lemen, who disregarded the mechanic epidemiology as "equivocal" and could not otherwise produce any epidemiology to "establish a causation link"); DeMeyer v. Advantage Auto, 797 N.Y.S.2d 743, 748-49 (2005) (mechanic epidemiology supported a prima facie showing that plaintiffs' experts were not using a generally accepted methodology); In re W.R. Grace & Co., Bankruptcy No. 01-1139, Memorandum Opinion at 7, (Del. Bank. Dec. 14, 2006) (expert testimony did not provide scientific evidence that asbestos contaminated attic insulation would be released at levels that would actually cause any harm); Brooks v. Stone Architecture, 934 So.2d 350 (Miss. Ct. App. 2006) (excluding testimony of expert who failed to determine effective dose of asbestos in schools as cause of mesothelioma); Bartel v. John Crane Inc., 316 F. Supp. 2d 603, 611 (N.D. Ohio 2004), aff'd, Lindstrom v. A-C Prod. Liab. Trust, 424 F.3d 488 (6th Cir. 2005).

Dr. Maddox's opinions cannot be derived from a scientific methodology because they are logically flawed and internally inconsistent. Dr. Maddox's opinion is farreaching, and totally removed from the facts regarding this particular plaintiff - of whose specific exposures to asbestos there is no assessment in the record. Rather than undertaking such an assessment, or even estimating any particular dose of asbestos required for causation, Dr. Maddox simply assumes that "any" occupational exposure is enough, no matter how small. This opinion permits him, and other plaintiff experts like him, to testify against the most trivial of asbestos defendants - one exposure or a dozen, many fibers or few, amphibole or chrysotile, bonded product or not, above background or not - none of this is relevant to Dr. Maddox's approach. He can completely (and improperly) ignore all of the science developed in the last twenty years, which proves that dose does make a difference; that differences among fiber types and lengths make a difference with respect to toxicity; and that some occupations, mechanics in particular, do not have enough exposure to cause disease. The issue in this appeal, therefore, is whether Dr. Maddox should be permitted to simply say "any fiber" and present that testimony to a jury.

The problem with this testimony is that it is both logically flawed and unscientific. As the trial court explained, it is undisputed that everyone is exposed to millions of "background" asbestos fibers without increasing their risk of disease. If that is the case, one must ask, "How much asbestos, then, does it take to cause disease?" Clearly, the answer "some" or "any" is not sufficient, as most of us have experienced "some" asbestos exposure (background) without causing disease. There must be a scientifically acceptable determination of how much is enough.

In addition, as discussed above, it is also undisputed that many cases of mesothelioma are not caused by asbestos (up to 20% of cases are "idiopathic," meaning that they have another, yet unknown cause besides asbestos). See Roggli, supra p. 16, at 108. If this is the case, it is imperative to determine whether a person with mesothelioma, and "some" asbestos exposure, is a victim of an asbestos disease, or simply has an idiopathic mesothelioma with an inconsequential and irrelevant asbestos exposure. Opinion at *12. Again, there must be a scientifically acceptable basis for distinguishing the two—an assumption that "any" occupational asbestos exposure makes the disease an asbestos-caused mesothelioma is completely circular reasoning with no logical or scientific basis. See In re R.O.C. Pretrial, 131 S.W.3d 129, 137 (Tex. App.—San Antonio 2004, no pet.) (rejecting a similar asbestosis diagnosis as "circular, from an assumption of exposure to a diagnosis based on that assumption").

This is the beginning point of the trial court's analysis: How can Dr. Maddox tell us that Mr. Simikian's mesothelioma is the result of his mechanic exposures, when (1) Dr. Maddox made no effort to determine what Mr. Simikian's exposures were, much less whether they were sufficient to cause disease; and (2) he failed to distinguish between a true asbestos-caused mesothelioma and an idiopathic disease, which Mr. Simikian could have developed irrespective of inconsequential mechanic exposures to asbestos? Other courts besides the Pennsylvania trial court have recognized the internal inconsistencies and illogic of the "any fiber theory." See, e.g., Chavers v. Gen. Motors, 79 S.W.3d 361, 364-70 (Ark. 2002) (rejecting mechanic exposures as basis for asbestos disease in part due to the inconsistency of "any exposure" theory); Bartel v. John Crane Inc., 316 F. Supp. 2d 603, 611 (N.D. Ohio 2004) (one fiber theory is "not supported by

the medical literature"), aff'd, Lindstrom v. A-C Prod. Liab. Trust, 424 F.3d 488 (6th Cir. 2005). Dr. Maddox has no answer to these questions, and he cannot explain the obvious inconsistencies in his opinion.

2. Dr. Maddox's Opinion Is Scientifically Flawed Because He Substitutes Unfounded Assumptions in Lieu of Dose Assessment and Proof of Actual Injury.

In lieu of the scientific method by which by which a hypothesis is "formulated" and then "empirically tested," *Trach*, 817 A.2d at 1113, Dr. Maddox relies wholly on his hypothesis, which is unsupported by any empirical evidence, that low dose exposures (here, to the extreme of "any fiber") cause the same result as high dose exposures. This is the "extrapolation down" methodology that received most of the trial court's attention. Claiming reliance on the well-recognized "dose-response curve" principle, 26 Dr. Maddox "[b]egins with th[e] generally accepted scientific principle [that] high dose exposure to asbestos may cause disease (and if high enough may be reasonably inferred to be the cause of a specific plaintiff's subsequently diagnosed asbestos related disease)." He then departs from accepted science, however, by "extrapolat[ing] down" from that principle, "reasoning that if high dose exposure is bad for you, then surely low dose exposure (indeed, no matter how low) must still be bad for you." Opinion at *7. Such "extrapolation down," as the trial court recognized, is essential to plaintiffs'

The concept of a dose-response curve is, of course, well-recognized, but it means only that the *more* of a toxic substance a population is exposed to, the *more* likely the injury/disease is to occur. Dose-response curves can take all sorts of shapes, including the most common which drops to zero incidence of disease long before zero exposures are reached. This is the equally well-recognized principle of a "threshold" exposure that is required before disease occurs. Eaton, *supra* p. 4, 16-17. Dr. Maddox cannot assert reliance on the dose-response curve for <u>low-dose</u> asbestos exposures because no such curve actually showing disease exists. To the contrary, there is almost certainly a threshold for asbestos exposures, as Dr. Maddox implicitly acknowledges by accepting the lack of harm from millions of background fibers.

experts' theory because the dose response curves used for this opinion are developed largely from high dose exposures – the insulators, shipyard workers, and others from older asbestos litigation. "Dose response curves, based upon generally accepted scientific methodology, for 'low dose' exposures . . . simply do not exist." Id. at *6. Dr. Maddox cannot opine, with anything approaching a reasonable degree of scientific certainty, that disease continues to occur all the way down the curve to zero exposure. He can only hypothesize that it does, and can only maintain that hypothesis by ignoring a wealth of contradictory evidence, including that of background exposures, the mechanic studies, and up-to-date literature as summarized in the above EPA and ATSDR panel reports.

This Court has decided that extrapolation as a methodology is generally accepted, but only under "limited circumstances." *Trach*, 817 A.2d at 1118.²⁷ Those circumstances do <u>not</u> include "extrapolation down" from high dose exposures to low dose exposures — because nowhere in any scientific literature is it accepted that substances causing injury at high doses must also cause the same injury at low doses. In fact, that proposition flies in the face of everything science knows about toxicity. As the trial court recognized, examples abound: e.g., many aspirin can kill, two aspirin cure

The expert in *Trach* "extrapolated from the known adverse effects of [the drug at issue] in recommended doses," to conclude that the symptoms suffered by the plaintiff resulted from his taking a massive overdose of the drug. *Id.* at 1118-19. This was acceptable, as the trial court here explained, because "when science knows that a certain deviation from a body's chemical norm causes harm, then a *greater* deviation from a body's chemical norm can be reasonably expected to cause increased harm (i.e., 'extrapolation up')." Opinion at *7 (emphasis added). Here, by contrast, plaintiffs' experts posit that, "where it is known that a certain deviation from a body's chemical norm causes harm, a *lesser* deviation from a body's chemical norm can be similarly presumed to cause harm (i.e. 'extrapolation down')." Id. (emphasis added).

headaches; large amounts of liquor inebriate, one glass is fine; even poisons like arsenic are necessary for the body in low doses. Dr. Maddox's blatant and unsupported assumption that any asbestos fiber can cause mesothelioma because larger doses cause mesothelioma finds no support from scientific literature and no precedent in Pennsylvania case law. The trial court was thus well within its discretion to strike this testimony as unreliable and not based on a generally accepted methodology.

Dr. Maddox's reliance on the assertion that there is "no known safe level of asbestos exposure" (which Dr. Maddox and other experts often misstate as "there is no safe level of asbestos exposure") falls equally far short of a generally accepted methodology. Opinion at *9. Given the lack of contribution from millions of background fibers, as admitted by Dr. Maddox, there clearly are exposures to asbestos that are safe, in the sense that they are not known to contribute to disease. The reality is that asbestos is the same as every other substance known to be toxic to humans – any substance can be either safe or harmful, depending on the dose. Lindstrom v. A-C Prod. Liab. Trust, 424 F.3d 488, 493 (6th Cir. 2005) (basing causation "on any hypothetical exposure, however slight, [is] insufficient" to avoid summary judgment); McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1241 (11th Cir. 2005) ("[s]cientific knowledge of the harmful level of exposure to a chemical plus knowledge that the plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiffs' burden . . . "").

3. The Failure to Require an Adequate Dose Assessment in Asbestos Cases Is Out of Step with Toxic Tort Law and Contributing to the Asbestos Crisis.

Dr. Maddox's obliteration of the dose requirement is a good example of how old asbestos case rules can only exacerbate the asbestos crisis, if they are applied in the

entirely different context of minimal lifetime exposures to bonded chrysotile products. To permit experts like Dr. Maddox to testify in such cases, without any critical examination, is to abandon traditional tort law requirements of causation. In other toxic tort cases, courts routinely reject simple "exposure" theories and require at least some assessment or comparison of the dose received with the levels known to cause injury. See, e.g., Parker v. Mobil Oil Corp., 7 N.Y.3d 434, 449 (2006) (upholding exclusion of expert's opinion, without supporting basis, that benzene in gasoline exposures would produce same effects as high-level, factory worker exposures to benzene). ²⁸

²⁸ See also Mitchell v. Gencorp Inc., 165 F.3d 778, 781 (10th Cir. 1999) ("plaintiff must demonstrate 'the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover.") (quoting Wright v. Willamette Indus., Inc., 91 F.3d 1105, 1106 (8th Cir 1996)); Allen v. Pa. Eng'g Corp., 102 F.3d 194, 199 (5th Cir. 1996) ("Scientific knowledge of the harmful level of exposure to a chemical, plus knowledge that the plaintiff was exposed to such quantities, are minimal facts necessary to sustain the plaintiffs' burden in a toxic tort case."); Nat'l Bank of Commerce v. Dow Chem. Co., 965 F.Supp. 1490, 1524 (E.D. Ark. 1996) ("To establish specific causation in the case it was incumbent upon plaintiffs to provide evidence from which a jury could responsibly assess the level of the exposure of Mrs. Smits to Dursban while she worked at the bank. . . . Then the plaintiffs must provide evidence from which the jury could determine whether the levels of exposure and dose experienced by Mrs. Smits and the fetus were likely to produce birth defects of the type experienced by Ashley."); Louderback v. Orkin Exterminating Co., Inc., 26 F.Supp.2d 1298, 1305 (D. Kan. 1998) ("[I]in order to recover in a toxic tort case, the plaintiff must prove the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the toxic substance.") (quoting Wright v. Willamette Indus., Inc., 91 F.3d 1105, 1106 (8th Cir. 1996)); Nelson v. Tenn. Gas Pipeline Co., No. 95-1112, 1998 WL 1297690, at *6 (W.D. Tenn. Aug. 31, 1998) (excluding opinion of expert who did not assess dose because "[a]n appropriate methodology requires evidence from which the trier of fact could conclude that the plaintiff was exposed to levels of toxin sufficient to cause the harm complained of."); Mancuso v. Consol. Edison Co. of N.Y., Inc., 967 F. Supp. 1437, 1453 (S.D.N.Y. 1997) (expert's testimony that plaintiffs' ailments were caused by exposure to PCBs was inadmissible because, inter alia, expert "did not make sufficient determinations of environmental PCB levels, nor of the extent of the plaintiffs' exposure thereto.").

Plaintiffs characterize as "commonplace" the thesis that "every asbestos exposure contributes to an asbestos disease[.]" App. Brief at 15. This view may be commonplace in the community of experts who testify for plaintiffs in asbestos cases. It is not commonplace in the scientific community. To the contrary, the "any fiber theory" has been disproven by many studies and rejected by mainstream science: "[T]he opinion of [plaintiffs' expert], that every breath [Plaintiff] took which contained asbestos could have been a substantial factor in causing his disease, is not supported by the medical literature." Bartel v. John Crane Inc., 316 F. Supp. 2d 603, 611 (N.D. Ohio 2004), aff'd, Lindstrom v. A-C Prod. Liab. Trust, 424 F.3d 488 (6th Cir. 2005). Permitting an expert to testify to such a theory - particularly in a case like this one involving bonded friction products, short chrysotile fibers, and low doses – will intensify the surge of unsupported asbestos claims that currently throng the courts. All that is necessary to prevent that result is to require expert testimony in an asbestos case -- as in any other -- to be predicated on a scientific assessment of dose and rational comparison to doses shown in human studies actually to cause disease. The science could not support such a comparison in mechanic cases.

No such assessment was offered in this case. Dr. Maddox summarily failed to demonstrate the level at which friction product asbestos exposures actually cause disease, or that Mr. Simikian experienced actual exposures at a level sufficient to cause his disease. Inasmuch as the Supreme Court has "emphasize[d] that the proponent of the expert scientific evidence bears the burden of proof on the *Frye* issue[,]" *Grady*, 839 A.2d at 1047, these deficiencies in Dr. Maddox's testimony require affirmance of the trial court's decision to exclude it.

B. The Methodology Used by Dr. Maddox Is Inconsistent with the Established Approach to Causation Science, Including Primary Reliance on Epidemiology.

Some courts, including the *Trach* court, have held that plaintiff experts do not need to present supporting epidemiology to testify about an alleged link between an exposure and disease. *Amici* do not agree that this is a scientific methodology, but for this case the rule of *Trach* does not matter – here, Dr. Maddox is testifying in the face of a large body of contrary epidemiology. Whatever the rule in cases where no epidemiology exists, where it does exist, experts like Dr. Maddox do not engage in a scientific process when they completely disregard the best evidence available. *See Blum*, 764 A.2d at 3.

1. The Mechanic Epidemiology Is the Single Most Important Evidence Regarding Causation and Should Not Have Been Disregarded by the Trial Court or Dr. Maddox.

The trial court chose not to rely on the extensive mechanic epidemiology as a ground for excluding Dr. Maddox's testimony, presumably because the court felt constrained by a statement in the *Trach* case which the trial court interpreted as limiting his utilization of epidemiology. Apparently, the court interpreted *Trach*'s holding that epidemiology is not required to prove a case as a reason not to consider any of the epidemiology contradicting Dr. Maddox's opinion. (This was not a correct interpretation of *Trach*, as discussed in section 2 below). Epidemiology, to the contrary, is the most important evidence available for scientists to determine causation. Dr. Maddox completely disregards the mechanic epidemiology evidence, and Pennsylvania's trial courts should not be prohibited or foreclosed, as Judge Colville apparently believed he was, from applying epidemiology in the same way scientists do.

Epidemiology studies – the science of investigating disease in humans – is the one science that is capable of determining whether exposures produce diseases when there is a latency period (as with asbestos) between exposure and disease and other causes of the disease (as with mesothelioma). All other forms of evidence, although useful to the inquiry, pale in comparison to a comprehensive series of studies, demonstrating across many researchers and populations that the exposed population does (or does not) have a greater degree of the disease than an unexposed population. Epidemiology has told us that cigarettes cause lung cancer, that drinking causes cirrhosis of the liver, and that high blood pressure causes strokes. Epidemiology has also told us that coffee does not cause pancreatic cancer, that smoking does not cause breast cancer, and (after much litigation) that breast implants do not cause connective tissue disease. See Marcia Angell, Science on Trial (W.W. Norton & Co. 1996) (discussing the flawed breast implant litigation and the role of epidemiology in bringing it to a close).

One of the best examples of courtroom application of epidemiology is in *Blum*, 764 A.2d 1. *Blum* involved Bendectin, a morning sickness pill, which was accused in litigation of causing birth defects. After the product had been driven off the market by lawsuits, epidemiology studies determined that in fact the drug was not associated with birth defects at all. *See* Joseph Sanders, *The Bendectin Litigation: A Case Study In The Life Cycle Of Mass Torts*, 43 HASTINGS L.J. 301, 345-48 (1992). The result is the famous *Daubert* decision, and many others like it around the country, in which courts accepted the primacy of epidemiology and rejected the testimony of plaintiff experts who tried to contradict it. *See, e.g., Daubert v. Merrell Dow Pharm.*, 509 U.S. 579

(1993); Lust v. Merrell Dow Pharm., 89 F.3d 594 (9th Cir. 1996); Daubert v. Merrell Dow Pharm., 43 F.3d 1311 (9th Cir. 1995).

In *Blum*, Pennsylvania's version of the Bendectin litigation, the Supreme Court, upholding the ruling of this Court, found that a "methodology" by which an expert disregarded the compelling volume of countervailing Bendectin epidemiology was "so flawed as to render [his] conclusions as unreliable and thus, inadmissible[.]" 764 A.2d at 1. The Court explained:

Over thirty published epidemiological studies have found no statistically-significant association between Bendectin and limb defects; the FDA, after complete review in the 1980s, found that available evidence showed no basis for a conclusion that Bendectin causes or increases the risk of birth defects in humans. Nevertheless, Dr. Done, who is not an epidemiologist, discounted such conclusions on the basis of a selective review of the data from several of these studies...

Id. at 4 (emphasis added). Both this Court and the Supreme Court, moreover, have recognized the importance of epidemiological and other empirical evidence in assessing "general acceptance" under Frye. This Court has noted that "epidemiology, which generalizes results gleaned from population samples, 'provides useful information as to whether there is a relationship between an agent and a disease and, when properly interpreted, can provide insight into whether the agent can cause the disease." Wack v. Farmland Indus., Inc., 744 A.2d 265, 271 (Pa. Super. Ct. 1999), abrogated on other grounds, Trach v. Fellin, 817 A.2d 1102 (Pa. Super. Ct. 2003) (citation omitted).

Many courts from other jurisdictions have likewise acknowledged the primacy of epidemiology as the best source of causation evidence in toxic tort situations:

• "Without a controlled [epidemiology] study, there is no way to determine if CML is more common in people who are exposed to benzene than those who are not. . . [I]n a case such as this [benzene toxic tort claim], the most conclusive type of evidence of causation is epidemiological evidence."

Chambers v. Exxon Corp., 81 F. Supp. 2d 661, 663-64 (M.D. La. 2000), aff'd, 247 F.3d 240 (5th Cir. 2001)(emphasis added).

- "[T]he most useful and conclusive type of evidence in a case such as this [ethylene oxide toxic tort claim] is epidemiological studies." Allen, 102 F.3d at 197 (emphasis added).
- "[T]he existence or nonexistence of relevant epidemiology can be a significant factor in proving general causation in toxic tort cases." Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1412-13 (D. Or. 1996) (emphasis added).
- "Epidemiologic studies are the *primary generally accepted methodology for demonstrating a causal relation* between a chemical compound and a set of symptoms or a disease." *Conde v. Velsicol Chem. Corp.*, 804 F. Supp. 972, 1025-26 (S.D. Ohio 1992) (emphasis added).
- "We agree with the district court that epidemiology is the best evidence of general causation in a toxic tort case." Norris v. Baxter Healthcare Corp., 397 F.3d 878, 882 (10th Cir. 2005); (citing to 17 epidemiology studies discounting any link between breast implants and connective tissue disease) (emphasis added).
- "The most important evidence relied upon by scientists to determine whether an agent (such as breast implants) cause [sic] disease is controlled epidemiologic studies." In re Breast Implant Litig., 11 F. Supp. 2d 1217, 1224 (D. Colo. 1998) (emphasis added).
- "[I]n the face of controlled, population-based epidemiological studies which find otherwise, these case studies [of alleged breast implant injury] pale in comparison." Allison v. McGhan Med. Corp., 184 F.3d 1300, 1316 (11th Cir. 1999) (emphasis added).

The preference of these courts for direct epidemiology is clearly the accepted scientific methodology.

In the case of mechanics, the epidemiology is conclusive. It is difficult to disregard fifteen consecutive studies, by 60 researchers in seven different countries, published in seventeen peer reviewed articles over a twenty-five year period, all of which reach the same conclusion – there is no association between mechanic work and pleural mesothelioma. Yet, disregard all those studies is exactly what Dr. Maddox

does.²⁹ His theory that all fibers cause disease has been tested directly and refuted by the mechanic studies – this is the essence of the scientific process.³⁰ If Dr. Maddox had tried this approach as to Bendectin in *Blum*, his testimony would have been stricken. Dr. Maddox's failure to follow accepted scientific causation principles is not justified simply because this is an asbestos case. His methodology cannot possibly be consistent with an accepted scientific approach when he feels free to disregard the most substantial piece of evidence on the table.³¹

Dr. Maddox's 12-page affidavit setting forth the bases of his opinions in this case cites many irrelevant studies of high dose occupations, yet, with one minor exception (McDonald 1980), fails to cite or address any of the 17 published peer-reviewed studies addressing the very occupation at issue, mechanics, and mesothelioma.

[&]quot;[T]he scientific method is 'a method of research in which a problem is identified, relevant data are gathered, a hypothesis is formulated from these data, and the hypothesis is empirically tested. . . . Within the meaning of the definition of the scientific method, 'empirical' means 'provable or verifiable by experience or experiment.'" Trach, supra, 817 A.2d at 1113 (citations omitted; emphasis added)

In re Asbestos Litigation, Cause No. 2004-03694 (Texas Havner Proceeding 2004) (court rejected testimony of plaintiff expert Dr. Lemen contradicting the mechanic epidemiology because it "does not establish a causation link"); DeMeyer v. Advantage Auto, 797 N.Y.S.2d 743, 748-49 (2005) (New York court preliminarily rejected opinion like Dr. Maddox's on the ground that the mechanic epidemiology supported a prima facie showing that plaintiffs' experts were not using a generally accepted methodology).

2. The Trach Case Does Not Shield an Expert Like Dr. Maddox from His Failure to Address Substantial Contradictory Epidemiology.

The trial court declined to consider the substantial epidemiological evidence that contradicts Appellant's expert's theory of causation because it interpreted this Court's decision in *Trach* as a "directive that plaintiffs are not required to advance epidemiological evidence to prove causation." Opinion at *14 n.28. The court added, however: "If I am mistaken in this regard, guidance from the appellate courts regarding the appropriate, required, or allowable consideration of epidemiological evidence countering the plaintiff's proffered methodologies within the context of a *Frye* challenge would be welcomed." *Id.* This caveat was well taken, because a review of *Trach* demonstrates that the trial court did indeed misinterpret that aspect of the decision, especially with respect to its applicability here.

Trach involved a plaintiff who, as a result of a pharmacist's error, inadvertently took a massive overdose of an antidepressant, which allegedly caused him to suffer ongoing cognitive and vision problems. In Trach — unlike here — no studies existed on the effects of a massive overdose of the drug, the exposure situation presented. The same circumstance applied in the two cases Trach cited, Donaldson v. Cent. Ill. Pub. Serv. Co., 767 N.E.2d 314, 328 330 (Ill. 2002) ((coal tar exposure and neuroblastomas), and Ferebee v. Chevron Chem. Co., 736 F.2d 1529, 1535-36 (D.C. Cir. 1984) (absence of studies on point).

The essential difference between this case and cases such as *Trach*, *Donaldson* and *Ferebee* is readily apparent. Where a consistent, significant, and clear set of epidemiology exists, experts are not permitted to ignore it and speculate from other evidence in contradiction of the epidemiological conclusion:

This is not a case where there is no epidemiology. It is a case where the body of epidemiology largely finds no association between silicone breast implants and immune system diseases. . . .

We are unable to find a single case in which a differential diagnosis that is flatly contrary to all of the available epidemiological evidence is both admissible and sufficient to defeat a defendant's motion for summary judgment.

Norris, 397 F.3d at 882, 885-886 (emphasis added).³² As the epidemiology discussion above demonstrates, the question as to whether mechanics get mesothelioma from their work is not one in which the causal connection has never been studied. Even if *Trach* is properly interpreted as a "directive" that epidemiological evidence cannot be required to prove causation (which is questionable, given its facts), this Court plainly did not "direct" that parties be permitted to put forth, under the guise of "generally accepted" methodology, expert opinion testimony which contravenes the most compelling evidence available.

3. Dr. Maddox Improperly Relies on Inferior Forms of <u>Evidence to Contradict the Unrebutted Epidemiology Studies.</u>

Dr. Maddox eschews the epidemiology by relying instead on a number of sources for his opinion that have repeatedly been rejected by courts and scientific publications as part of an improper approach to a causation opinion. The first, and most

See also Allen, 102 F.3d at 197 (numerous reputable epidemiology studies contradicted plaintiffs' theory); Daubert, 43 F.3d at 1314 (every published epidemiology study demonstrated that Bendectin did not cause birth defects); Allison, 184 F.3d at 1316 (plaintiffs' "proffered conclusions . . . were out of sync with the conclusions in the overwhelming majority of the epidemiological studies presented to the court"); Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 826 (D.C. Cir. 1988) (plaintiffs' theory was "undermined by an overwhelming array of contrary opinion published in the scientific literature and presented by the defense"), cert denied, 493 U.S. 882 (1989); Chambers, 81 F. Supp. 2d at 665 (causation claim contradicted by "a number of scientifically performed studies which demonstrate no association" between benzene and CML).

critical, error is Dr. Maddox's reliance on case reports.³³ Appellant's Brief at 10; Opinion at *5. As the trial court noted, case reports are not evidence of causation. A case report (sometimes referred to as "anecdotal evidence") is a mere notation that an individual with a particular disease also happened to have a particular exposure. Textbooks and scientific publications repeatedly caution that such reports cannot be used to prove causation. See, e.g., Mary Sue Henifin, et al., Reference Guide on Medical Testimony, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, Federal Judicial Center, 474-75 (2d ed. 2000) (Exh. 2) ("Case reports lack controls and thus do not provide as much information as controlled epidemiological studies do . . ."); Green, 86 NW. U. L. Rev. at 657 ("There plainly is a hierarchy to these difference indirect forms of toxic effect evidence. Epidemiology is at the top, and structural similarity, in vitro testing, and case reports are at the bottom.") (emphasis added).³⁴

As to mechanics, Dr. Maddox's affidivat relies heavily on case reports in various studies and from an Australian registry of mesothelioma cases. Maddox Aff. 5-6. These are virtually the only references in his affidivat to support a mechanic opinion.

See also Norris v. Baxter Healthcare Corp., 397 F.3d 878, 884-85 (10th Cir. 2005); Allen v. Pa. Eng'g Corp., 102 F.3d 194, 197-98 (5th Cir. 1996); Daubert v. Merrell Dow Pharm., 43 F.3d 1311, 1321-22 (9th Cir. 1995) (all rejecting plaintiff reliance on case reports and animal evidence to establish causation), cert denied 516 US 869 (1995); Raynor v. Merrell Pharm., Inc., 104 F.3d 1371, 1374-75 (D.C. Cir. 1997) (expert theories drawn from in vitro and animal studies had been disproven by established epidemiology); Michael D. Green, et al., Reference Guide on Epidemiology, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, Federal Judicial Center, 347 n. 39 (2d ed. 2000) (Exh. 2) ("[W]hen there is a substantial body of epidemiologic evidence that addresses the causal issue, animal toxicology has much less probative value.")

Courts regularly reject reliance on case reports in lieu of epidemiology. The Northern District of California federal district court stated the problem with case reports as follows:

Such case reports are not reliable scientific evidence of causation, because they simply described reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation.

Casey v. Ohio Med. Prods., 877 F. Supp. 1380, 1385 (N.D. Cal. 1995). Anecdotal evidence like this "pale[s] in comparison" to population-based, controlled epidemiology. Allison, 184 F.3d at 1316. See also Hall, 947 F. Supp. at 1411 ("[C]ase reports and case studies are universally regarded as an insufficient scientific basis for a conclusion regarding causation because case reports lack controls."). At best, case reports are only suggestive of a possible cause or hypothesis that needs to be tested.

Likewise, Dr. Maddox relies on animal studies and many studies of occupations other than mechanics who were exposed to high dose/amphibole fibers, not low dose chrysotile fibers. Animal studies have been rejected as a basis for a human causation opinion by dozens of courts, including the United States Supreme Court. Gen. Elec. v. Joiner, 522 U.S. 136, 144-45 (1997). Irrelevant occupational studies are also not a basis for determining that entirely different occupations, with very different exposures (as with the bonded brake products at issue here) would generate the same diseases. See, e.g., Merrell Dow Pharm., Inc. v. Havner, 953 S.W.2d 706, 716-17, 719 (Tex. 1997)

The Maddox affidavit, for example, <u>starts</u> with animal studies as the first line of proof of his proposition (p. 2-3), and cites numerous studies from irrelevant occupations such as railroad workers, asbestos miners, textile workers, shipbuilders, and asbestos gas mask manufacturing. See Maddox Aff. 4-7.

(epidemiology studies relied on by plaintiffs must involve similar exposures and circumstances); Minn. Mining & Mfg. Co. v. Atterbury, 978 S.W.2d 183, 191-92 (Tex. App. – Texarkana 1998, pet. denied) ("similar" studies would include "proof that the injured person was exposed to the same substance, [and] that the exposure or dose levels were comparable to or greater than those in the studies . . ."; one study is insufficient); Austin v. Kerr-McGee Refining Corp., 25 S.W.3d 280, 288-90 (Tex. App. – Texarkana 2000, no pet.) (rejecting plaintiff's reliance on six epidemiological studies, which focused on different disease and much higher exposures than alleged by plaintiff).

What Dr. Maddox has done is assemble a set of pre-selected "evidence," all designed to support his preconceived opinion, disregarded all contrary evidence, and then proffered the assemblage as the basis for a legitimate expert process. Dr. Maddox's biased approach is not "generally accepted by scientists" in the fields of medicine or disease etiology "as a method for arriving at the conclusion" that a particular agent caused illness to a particular plaintiff. *Grady*, 839 A.2d at 1045. This Court has upheld the exclusion of expert testimony that "scrupulously avoided the medical literature and was based entirely on subjective assessments of both cause and effect[,]" in addition to lacking any foundation in clinical proof or research. *Checchio v. Frankford Hosp.*, 717 A.2d 1058, 1062 (Pa. Super. Ct. 1998). *Cf. Commonwealth v. Blasioli*, 713 A.2d 1117, 1125 (Pa. 1998) (emphasis added) (no empirical data existed to support attacks on reliability of DNA method).

4. <u>Dr. Maddox's Opinion Qualifies as Novel under Frye.</u>

The trial court held an entire separate hearing on the subject of whether Dr. Maddox's opinion was novel, and had no difficulty concluding that it is. That opinion is readily justified as within his discretion, and supported by the various unscientific an novel approaches Dr. Maddox used that are described above. Dr. Maddox's testimony clearly qualifies as novel, particularly under the "fluidity" of Pennsylvania's novelty requirement and the abuse of discretion standard that applies to Judge Colville's decision. See Commonwealth v. Dengler, 890 A.2d 372, 382 (Pa. 2005) ("[w]hat constitutes novel scientific evidence has historically been decided on a case-by-case basis, and there is some fluidity in the analysis[.]")

Dr. Maddox's extrapolation down from high dose studies, to the general determination that any fiber of mechanic work exposure contributes substantially to mesothelioma, is sufficiently novel by itself to justify *Frye* review, as the trial court determined. R. 445-446a. No Pennsylvania court to *amici*'s knowledge has accepted testimony based on extrapolation down in any context – and the "methodology" is rendered particularly dubious here by the fact that it disregards the differences among asbestos fibers and a substantial body of contrary epidemiology. Add to this Dr. Maddox's unsupported reliance on case reports, animal studies, and irrelevant epidemiology, while disregarding extensive and more probative evidence to the contrary, also a novel approach not used in the scientific community. Neither of these

approaches, particularly as directed to the very different circumstances of friction product exposure, has been presented to this court on appeal.³⁶

Even if Dr. Maddox's approach were not viewed as novel, simply because other plaintiff experts testify similarly (the basis of Plaintiff's argument), that is not a sufficient basis to let him testify to entirely unscientific and unsupported opinions. "The admissibility of any experimental or scientific evidence depends upon presenting an adequate foundation." Commonwealth v. McGinnis, 515 A.2d 847, 849 (Pa. 1986). Recently the New York Court of Appeals, considering a similar low dose extrapolation opinion in a benzene case, upheld the exclusion of the testimony, stating that, while "[t]here is no particular novel methodology at issue for which the Court needs to determine whether there is general acceptance. . . [T]he inquiry here is more akin to whether there is an appropriate foundation for the experts' opinions." Parker, supra, 7 N.Y.3d at 447. The exclusion of Dr. Maddox's testimony here was similarly proper based on its lack of foundation in any of the applicable science, as set forth in detail above.

None of the three Superior Court decisions relied on by plaintiff to challenge the trial court's finding of novelty -- Smalls, Cauthorn and Lonasco, supra - involved a plaintiff auto mechanic. Further, Cauthorn and Lonasco did not involve challenges to admissibility at all. In Smalls, the only case of the three in which admissibility was at issue, there is no indication that an assessment of novelty, much less an actual Frye analysis, was undertaken by the trial court. In addition, this Court's discussion of the admissibility issue was only two paragraphs long and relied primarily on the "manifest abuse of [] discretion" standard applicable to its review of evidentiary rulings. Smalls, 843 A.2d at 414.

C. Applying Standard Pennsylvania Causation and *Frye* Law to Low-Dose Asbestos Cases Would Ensure That Cases Without Scientific Merit Do Not Proceed.

As the opinion of Judge Colville demonstrates, it is not necessary to create any new rules to bring the explosion of asbestos litigation under control. The simple and direct application of ordinary expert and tort principles is all that is required.

In non-asbestos cases, the courts of this Commonwealth have utilized the "proven and workable rule" of Frye to maximum effect in ensuring that scientific reliability underlies the opinion of any expert permitted to testify before a jury. Grady, supra, 839 A.2d at 1044. The Supreme Court's decision in Blum, which speaks directly to the situation at issue on this appeal, is a prime example. By recognizing that a "methodology" which "discount[s]" the conclusions of a solid body of epidemiological research "cannot be fairly described as generally accepted methodology for purposes of the Frye standard," Blum, supra, 764 A.2d at 4, the Supreme Court fulfilled the central objective of the Frye rule, which is to "assur[e] that judges [are] guided by scientists when assessing the reliability of a scientific method." Grady, 839 A.2d at 1044-45 (emphasis added). The "guidance of scientists" here is exactly what compels the conclusion that Dr. Maddox's testimony regarding friction products and mesothelioma is not reliable – because, just like the expert in Blum, he "discounts the conclusions" of every scientist to have studied that subject using proper techniques and controls.

Conversely, Frye operates equally well to authorize the admission of scientific testimony based on methodologies which have gained general acceptance through empirical testing. Thus, in Commonwealth v. Blasioli, supra, the Supreme Court upheld the admissibility of statistical probabilities with respect to DNA matching in a criminal case, finding – based on an extensive review of the applicable science – that the

scientific community had put to rest certain prior disputes about the reliability of the "product rule" method used to calculate those probabilities. In short, the *Frye* standard has earned its stature as "a proven and workable rule" that enables courts to distinguish good science from bad science, and to rule accordingly on the admissibility of proffered expert testimony.

That standard should govern in this case. Courts should not tolerate bad science in an asbestos case any more than they would in any other. Indeed, this point accords with a view that some members of this Court recently articulated in an evenly divided *en banc* decision:

Just because a hired expert makes a legal conclusion does not mean that a trial judge has to adopt it if it is not supported by the record and is devoid of common sense. For example, Dr. Gelfand used the phrase, "Each and every exposure to asbestos has been a substantial contributing factor to the abnormalities noted." However, suppose an expert said that if one took a bucket of water and dumped it in the ocean, that was a "substantial contributing factor" to the size of the ocean. Dr. Gelfand's statement saying every breath is a "substantial contributing factor" is not accurate. If someone walks past a mechanic changing brakes, he or she is exposed to asbestos. If that person worked for thirty years at an asbestos factory making lagging, it can hardly be said that the one whiff of the asbestos from the brakes is a "substantial" factor in causing disease.

Summers v. Certainteed Corp., 886 A.2d 240, 244 (Pa. Super. Ct. 2005)(Opinion in Support of Affirmance) (emphasis in original), appeal granted, 897 A.2d 460 (Pa. 2006).

The application of normal rules of admissibility and causation in the low dose asbestos cases that are currently flooding the courts in no way compromises the ability of plaintiffs to recover for asbestos-related disease. These plaintiffs simply must meet the burden of all tort plaintiffs, and prove causation on the basis of reliable scientific evidence.

CONCLUSION

For the foregoing reasons, amici curiae Caterpillar Inc., Chamber of Commerce of the United States of America, American Tort Reform Association, Coalition for Litigation Justice, Inc. and Property Casualty Insurers Association of America respectfully urge the Court to affirm the trial court's grant of summary judgment to defendants based on the inadmissibility of Dr. Maddox's testimony.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Brief of Amici Curiae Caterpillar Inc., Chamber of Commerce of the United States of America, American Tort Reform Association, Coalition for Litigation Justice, Inc. and Property Casualty Insurers Association of America in Support of Appellees was served upon the following counsel of record, by United States Mail, postage prepaid, this 16th day of January, 2007, pursuant to Pa. R.A.P. 121.

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