The
Supreme Court of Pennsylvania

No. 38 WAP 2010

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/Appellants

BRIEF OF *AMICI CURIAE*

PENNSYLVANIA CHAMBER OF BUSINESS AND INDUSTRY, PENNSYLVANIA BUSINESS COUNCIL, NFIB/PENNSYLVANIA, PENNSYLVANIA MANUFACTURERS' ASSOCIATION, INSURANCE FEDERATION OF PENNSYLVANIA, INC., CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, COALITION FOR LITIGATION JUSTICE, INC., AMERICAN INSURANCE ASSOCIATION, AMERICAN CHEMISTRY COUNCIL, NFIB SMALL BUSINESS LEGAL CENTER, NATIONAL ASSOCIATION OF MANUFACTURERS, AND NATIONAL ASSOCIATION OF MUTUAL INSURANCE COMPANIES

IN SUPPORT OF APPELLANTS

Appeal from the Opinion of the Superior Court, Published as
Betz v. Pneumo Abex, 998 A.2d 962, 970 (Pa. Super. Ct. 2010),
Reversing the Trial Court Exclusion of Expert Testimony in Favor of Defendants.

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

OTHER AUTHORITIES

STATEMENT OF INTEREST

Amici are organizations that represent companies and their insurers that are involved in Pennsylvania asbestos cases.[1] *Amici* file this brief due to concern over the

[1] The Pennsylvania Chamber of Business and Industry is the state's largest broad-based business association, with thousands of statewide members representing businesses of all sizes and all industry sectors. The Pennsylvania Chamber is The Statewide Voice of Business™.

The Pennsylvania Business Council envisions a Commonwealth in which residents enjoy a very high quality of life in sustainable communities, where those who are seeking employment find high quality jobs with good compensation, and where those who invest their capital and hard work can grow firms that flourish and are profitable. The Pennsylvania Business Council is focused on solutions that make the Commonwealth more competitive, including efforts to achieve a more fair and predictable civil justice system. For that reason, the subject case is of substantial interest to the Pennsylvania Business Council and its members.

The National Federation of Independent (NFIB) is the nation's leading small business association with offices in all fifty state capitals. Founded in 1943 as a nonprofit, nonpartisan organization, NFIB gives small and independent business owners a voice in shaping the public policy issues that affect their business. NFIB/Pennsylvania's mission sis to promote and protect the right of its members to own, operate and grow their businesses.

The Pennsylvania Manufacturers' Association (PMA) is the leading voice for manufacturing in the Commonwealth. Since 1909, PMA has served Pennsylvania workers and employers by defending free enterprise and working to build a more competitive and prosperous Pennsylvania.

The Insurance Federation of Pennsylvania, with approximately 200 insurer members, is the Commonwealth's leading trade association for commercial insurers of all types.

The Chamber of Commerce of the United States of America (U.S. Chamber) is the world's largest business federation. The U.S. Chamber represents 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 U.S. Chamber is to represent the interests of its members in court on issues of national concern to the business community. Accordingly, the U.S. Chamber has filed more than 1,000 *amicus curiae* briefs in state and federal courts.

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The Coalition for Litigation Justice, Inc. is a nonprofit association formed by insurers to address and improve the asbestos and tort 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 for Litigation Justice includes Century Indemnity Company, Chubb & Son, a division of Federal Insurance Company, Fireman's Fund Insurance Company, Liberty Mutual Insurance Group, and the Great American Insurance Company.

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. On issues of importance to the property and casualty insurance industry and marketplace, AIA advocates sound and progressive public policies on behalf of its members in legislative and regulatory forums at the federal and state levels and files *amicus curiae* briefs in significant cases before federal and state courts, including this Court.

The American Chemistry Council represents the leading companies engaged in the business of chemistry. The business of chemistry is a key element of the nation's economy, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other business sector.

The NFIB Small Business Legal Center, a nonprofit, public interest law firm established to protect the rights of America's small-business owners, is the legal arm of the National Federation of Independent Business (NFIB). The NFIB is the nation's oldest and largest organization dedicated to representing the interests of small-business owners throughout all fifty states. The approxiamtely 350,000 members of NFIB own a wide variety of America's independent businesses from manufacturing firms to hardware stores.

The National Association of Manufacturers (NAM) is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all fifty states. 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 and to increase understanding among policymakers, the media, and the general public about the importance of manufacturing to America's economic strength.

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standard adopted by the Superior Court under which trial judges in Pennsylvania can no longer apply their own intellect and analysis to an expert *Frye*[2] review but instead must rely solely on positions raised by the parties – in essence, trial judges must now check their minds at the courthouse door. *Amici* also file this brief to advise the Court of the implications on Pennsylvania law and the asbestos docket of permitting the experts in this case to testify that any dose of occupational fibers, no matter how small, is a substantial factor in causing asbestos disease. The trial judge properly recognized the logical flaws in that theory and its inconsistency with longstanding causation standards.

INTRODUCTION

Five years ago, in the *Frye* hearings in this case, plaintiff's expert Dr. John Maddox testified that he did not take into account how much dose plaintiff received from his occupational work with brakes to determine causation – five minutes or forty years, high dose or low dose, it made no difference because of his view that any exposure to a brake pad, no matter how small the dose, was a substantial factor in causing mesothelioma. This version of medical causation testimony is known as the *any exposure* theory (also sometimes stated as the *each and every exposure* theory). The

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Founded in 1895, National Association of Mutual Insurance Companies ("NAMIC") is a full-service, national trade association with more than 1,400 member companies that underwrite more than 40% of the property/casualty insurance premium in the United States. NAMIC members account for 47% of the homeowners market, 39% of the automobile market, 39% of the workers' compensation market, and 34% of the commercial property and liability market. NAMIC benefits its member companies through public policy development, advocacy, and member services.

2 *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923).

theory stands in sharp contrast to normal causation methodology, which would require an expert to assess the dose first and then demonstrate that the dose received was sufficient to cause disease. Dr. Maddox declined to follow that methodology. No plaintiff expert even attempted to assess Mr. Simikian's actual or estimated asbestos dose.

The trial judge in this matter was one of the first judges in the country to pull the curtain back from the *any exposure* theory. What he saw was not pretty – these experts were relying on illogical and unscientific guesswork, not supported in any published literature, in an apparent attempt to draw as many defendants into asbestos litigation as possible. After reviewing an extensive record and holding a three-day *Frye* hearing in which Dr. Maddox and others testified, Judge Colville quietly but effectively exposed the logical and scientific flaws in that theory. He concluded that Dr. Maddox should not be permitted to testify without at least some reasonable attempt to assess Mr. Simikian's dose and demonstrate that his dose exceeded a dangerous level.

Judge Colville's opinion was an early version of a wave of similar opinions that subsequently issued from courts all over the country.[3] Today, there are at least twenty courts that have rejected the *any exposure* theory or similar approaches, under both *Frye* and *Daubert* standards, in asbestos and other toxic tort litigation. These are not merely inconsequential slip opinions – the courts rejecting this theory include the United States Sixth Circuit Court of Appeals (twice), the highest courts of Texas, New York, and this state (in the *Gregg* opinion), and trial and appellate courts in Texas, Washington, Florida,

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[3] *See* Behrens, M. & Anderson, W., *The "Any Exposure" Theory: An Unsound Basis for Asbestos Causation and Expert Testimony,* 37 S.W.U. L. Rev. 480 (2008) (summarizing case law rejecting *any exposure* theory).

Delaware, Ohio, Louisiana, Mississippi, and here in Pennsylvania.[4] Dr. Maddox's own *any exposure* testimony has been excluded three times.[5] Virtually all of these courts conducted their analyses independent of Judge Colville's and yet reached the same decision – the *any exposure* theory is scientifically bankrupt and litigation-driven and cannot support an asbestos case.

It is hard to believe, with this track record around the country, that Judge Colville could possibly have abused his discretion in reaching the same conclusion that so many

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[4] *See Gregg v. V-J Auto Parts, Inc.*, 596 Pa. 274, 943 A.2d 216 (2007); *Borg-Warner Corp. v. Flores*, 232 S.W.3d 765, 774 (Tex. 2007); *Parker v. Mobil Oil Corp.,* 7 N.Y.3d 434, 857 N.E. 2d 1114 (Ct. App. 2006) (benzene); *Georgia-Pacific Corp. v. Stephens*, 239 S.W.3d 304, 312-21 (Tex. App. 2007); *In re W.R. Grace & Co*., 355 B.R. 462, 474, 478 (Bkrtcy. D. Del 2006); *Brooks v. Stone Architecture*, 934 So.2d 350, 255-56 (Miss. Ct. App. 2006); *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); *Anderson v. Asbestos Corp., Ltd*., No. 05-2-04551-5 SEA (Wash. Super. Oct. 31, 2006) (Transcript of Bench Ruling at 144-45); *In re Asbestos Litig.*, No. 2004-3964 (Tex. Dist. Ct., 11th Dist., Harris County Jan. 20, 2004) (Letter Ruling); *In re Asbestos Litig.*, Cause No. 2004-3964 (Tex. Dist. Ct. Jul. 18, 2007) (Letter Ruling); *Basile v. Am. Honda Motor Co.*, No. 11484 CD 2005 (Pa. Ct Com. Pl. Feb. 22, 2007) (Order Granting Caterpillar's Motion to Exclude Plaintiffs' Experts' Testimony); *Free v. Ametek*, No. 07-2-04091-9-SEA (Wash. King County Super. Ct. Feb. 29, 2008) (Barnett, J.) (ruling on motion *in limine*); *In re Asbestos Litig*., 59 Pa. D. & C. 4th 62, 65-66 (Pa. Ct. Com. Pl. June 11, 2002); *Martin v. Cincinnati Gas & Electric Co*., No. 07-6385, 2009 WL 188051 (6th Cir. Jan 7, 2009); *Smith v. Kelly-Moore Paint Co.*, No. 2-08-198-CV, 2010 WL 682343 (2d Dist. Texas Ct. App, Feb. 25, 2010); *Daly v. Arvinmeritor, Inc*., Case No. 07-19211 (Fla. Cir. Ct. Nov. 30, 2009); *Butler v. Union Carbide Corp.*, Civ. Act. No. 2008CA114, (Super. Ct. Morgan Cty, a., June 29, 2010) "Order Granting Defendant's Motion to Strike Certain Testimony of Plaintiff's Pathologist Dr. John Maddox" (Super. Ct. Morgan Cty, Ga., June 29, 2010); *Degrasse v. Anco Insulations,* No. 2007-12736 (Orleans Civ. Dist. Ct., La., Sep. 13, 2007); *Robertson v. Ashby,* No. 532,769, Motion Hearing Tr. (East Baton Rouge Parish, La., Jan. 19, 2010); *Henricksen v. ConocoPhillips Co.*, 605 F.Supp.2d 1142, 1165-66 (E.D. Wa. 2009) (benzene). A compendium of these cases is included in the Appendix to this brief.

[5] Dr. Maddox has been excluded in the *Betz* case by Judge Colville; in a subsequent Pennsylvania case, *Basile v. American Honda Motor*, by Judge Olson; and in a very recent Georgia state court decision, *Butler v. Union Carbide*, all cited *supra* at n. 2.

other judges in so many other jurisdictions also reached. In fact, he did not. He performed exactly the sort of careful gatekeeping that Pennsylvania law requires of a trial judge – one that does not accept what the experts say at face value but looks behind those statements to determine, under the *Frye* standard, whether their opinions are based on a generally accepted methodology. Most of the trial judge's criticisms were directed at logical errors that could only be viewed at best as speculation and at worst as outright attempts to mislead the jury. It was not logical to conclude, as Dr. Maddox did, that the smallest brake exposure causes mesothelioma irrespective of dose, but a lifetime dose of background fibers that we all experience does not. It was not logical for Dr. Maddox to conclude that because heavy exposure to asbestos causes mesothelioma, small doses would also (his extrapolation down approach). It was not logical for Dr. Maddox to conclude that mechanic work *causes* mesothelioma just because case reports of automotive mechanics with mesothelioma exist in the literature. It was not logical, nor was it consistent with the science we all learned in fifth grade, for Dr. Maddox to ignore dose entirely. It was not logical to opine that "no known safe level of exposure" is the same thing as "every exposure is a cause." These are errors of logic, which Judge Colville had every right and obligation under *Frye* to identify and exclude.

Some of Judge Colville's findings are based on law rather than science and thus fall squarely within his capacity as a judge. The *any exposure* theory has the pernicious effect – as many other courts have found – of shifting the burden of proof from plaintiff to defendant. These experts' opinion that exposure of any kind is a substantial factor puts defendants in the position of having to prove the amount of exposure that is *not* a causative factor. Other courts have noted that the theory makes a mockery of the

substantial factor standard since every exposure becomes substantial and nothing is insubstantial. In addition, some of the trial judge's criticisms of the *any exposure* theory were based squarely on his thorough review of the record and conclusion that the record was barren of support for this theory.[6] Such a careful, first-order review of the record is the job of a trial judge, and the judge here performed that task exactly as he should.

Instead of affirming the thoughtful and well-crafted ruling of the trial court, the Superior Court replaced Judge Colville's ruling with its own. The appellate court made two fundamental errors its review. First, the appellate court – astonishingly – has informed Judge Colville and other trial judges that they cannot use their own intelligence to dissect the logical errors in an expert opinion. The appellate court rejected all of the trial court's well-aimed criticisms for the simple reason that he did not cite to those same criticisms in a party's brief or in expert testimony. Apparently, the trial judges of Pennsylvania are no longer permitted to use their own cognitive powers and are constrained to ignore even the most illogical of expert positions if the parties chose not to criticize them. That is not the way trial court judges should conduct *Frye* reviews. Even the appellate court itself does not conform to such a standard, either in its own opinion here or in prior expert-related opinions.

Second, despite nominally recognizing the "abuse of discretion" standard, the appellate court instead re-reviewed the entire record itself and then replaced the trial court's analysis of the "small bridges" relied on by Dr. Maddox with its own. The appellate court then compounded that error by concluding that Dr. Maddox could cross

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[6] *In re Toxic Substances Cases*, No. A.D. 03-319, 2006 WL 2404008, at *9 (Colville, J.) (Pa. Com. Pl., Aug. 17, 2006), *rev'd* 998 A.2d 962 (Pa. Super. Ct. 2010).

the Mississippi River on nothing but small bridges. The "Mississippi" here is the enormous gulf between the epidemiology plaintiffs rely on – demonstrating that asbestos *can* cause mesothelioma in workers in the "dusty trades" like shipbuilding and spray insulation – and the much different exposure and disease history of brake mechanics. The "large bridge" required to cross this gap (e.g., studies demonstrating mesothelioma in mechanic populations or low-dose chrysotile occupations) exists nowhere in the scientific literature.

Despite the demise of serious asbestos exposure in this country more than thirty years ago, asbestos litigation keeps expanding, rather than dying out. The continued expansion is not due to expanding disease but instead to the aggressive theories pursued by plaintiffs' bar and ever-increasing net of defendants being brought into the courtroom. The litigation has become a neverland, with its own rules and causation standards not recognizable in any other docket. The *any exposure* theory is the leading example. The courts of Pennsylvania need a rational standard for asbestos causation, not a "let everything in" approach. Judge Colville provided a start, one that has been followed in part by at least two other trial judges in Pennsylvania; by this Court's declaring the *any exposure* theory a "fiction" in *Gregg v. V. J. Auto Parts*; and by the Superior Court's similar criticism of the theory in the *Summers* case in 2005. *Summers v. Certainteed,* 886 A.2d 240 (Pa. Super. Ct. 2005). *Amici* thus support defendants in requesting that this Court reverse the Superior Court's ruling and reinstate the trial court's rejection of the *any exposure* theory and dismissal of the *Betz* litigation.

I. The Trial Judge Properly Applied His Own Intellect and Analysis in Reviewing and Excluding Dr. Maddox's *Any Exposure* Opinion.

The bulk of this brief is devoted to a discussion of the *any exposure* theory and why it should not be given any credence or effect in asbestos or other toxic tort litigation. *Amici* The Coalition for Litigation Justice has filed Amici briefs on this and similar issues numerous times previously, including before the supreme courts of Texas and New York, both of whom rejected this approach in favor of an assessment of dose. *Amici* believe it is imperative that trial and appellate courts begin to look behind the façade utilized to support this theory as Judge Colville properly did.

Before turning to the *any exposure* issue itself, however, we first address what appears to be an unprecedented view of the limits of trial judge authority expressed by the Superior Court – the court's ruling that Judge Colville abused his discretion by applying his own intellect to determine that Dr. Maddox's opinions were illogical and could not survive *Frye*. The Court chastised the trial judge for not constraining his ruling strictly to the arguments made by the defendants against admissibility. This ruling cuts across far more than asbestos litigation and much more than just the *any exposure* theory. If this restriction now becomes the law of Pennsylvania, trial judges in this state will forever be hamstrung by whatever issues the parties deem fit to raise – no opinion, no matter how outrageous or illogical, could be excluded by the trial court on its own initiative.

The ruling cannot be correct. Trial judges have never been constrained in this state to limit their analyses and holdings to issues specifically raised by the parties, and the Superior Court cited no precedent to that effect. To the contrary, the Superior Court itself, both in this case and in prior rulings such as *Blum*, has readily applied its *own*

analysis to expert opinions and has upheld trial courts that did the same. We urge the Court to reject this limitation on state trial court flexibility and authority.[7]

A. Trial Courts in Pennsylvania Are *Required* to Use Their Own Cognitive Powers to Assess and Analyze Expert Testimony.

The Superior Court's first and foremost rationale for reversal in this case is that the trial court abused its discretion by applying "its own analysis of the relevant scientific principles involved" and "its own review of its version of the science." *Betz v. Pneumo Abex,* 998 A.2d 962, 970, 979 (Pa. Super. Ct. 2010). Specifically, the Superior Court criticized the trial court for ostensibly reaching its conclusion "based upon reasons never raised by any of the parties to the cases below," and "[w]ithout a single citation to the voluminous record[.]" *Id*. at 970. This criticism is stated repeatedly in the Superior Court's opinion:

> After our review of the evidence presented at the *Frye* hearing, we conclude that the trial court abused its discretion in finding, ***based on its own theories*** concerning Betz's experts' reliance on extrapolation from dose response relationships, that Dr. Maddox's methodology is not generally accepted in the relevant scientific community.

Id. at 976.

> To find a lack of general acceptance in Dr. Maddox's methodology, the ***trial court sua sponte engaged in an extended discussion without reference to the record*** of the science of human exposure to asbestos, including ambient levels of asbestos exposure, idiopathic occurrences of mesothelioma, the use of case reports, dose-response curves, and fiber load findings in the biological structures of asbestos-exposed individuals. . . . . ***Based upon its own review of its version of science***, the trial court concluded that Dr. Maddox's methodology is not generally accepted

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[7] The Superior Court also erred in going beyond the abuse of discretion standard of review by displacing the trial judge's analysis with its own review and selective use of the trial record. This is a determination *on the merits*, not an abuse of discretion review. *Amici* expect the defendants to brief this issue and will not address it further here.

> because it relies upon the use of extrapolation to arrive at the conclusion that low-dose occupational exposures to asbestos, just like high-dose occupational exposures, may cause mesothelioma.

Id. at 978-979.

> The trial court described Dr. Maddox's use of extrapolation to be "a simple logical error" and ***offered his own analogies to explain*** . . . . ***It was improper for the trial court to grant the Frye motion based upon arguments never raised by the Friction Product Defendants or supported by any expert witnesses***.

Id. at 979 (emphasis added throughout). These statements can only mean, as surprising as this holding is, that a trial judge ruling on a *Frye* motion is required to do so without reference to her own capacity for reasoning and logic.

The Superior Court's holding fundamentally misconceives both the proper function of a trial judge ruling on a *Frye* motion and its own function as the court reviewing that ruling. This Court has unequivocally committed the admissibility of scientific evidence to the *discretion* of the trial court. *Grady v. Frito Lay, Inc.*, 576 Pa. 546, 559, 839 A.2d 1038, 1046 (2003). The Court has been equally clear on what constitutes an "abuse of discretion," and emphasized that it "may not be found merely because an appellate court might have reached a different conclusion[.]" *Id*. Rather – at least prior to the new pronouncement by the Superior Court – an abuse of discretion "require[d] a result of manifest unreasonableness, or partiality, prejudice, bias, or ill-will, or such lack of support so as to be clearly erroneous." *Id*. No such abuses are at issue here, and the Superior Court did not identify any. Instead, the court inexplicably purports to find an abuse of discretion for no other reason than that the trial judge in fact *exercised* his discretion, logical thinking, and his own deductive powers in ruling on the record before him.

The right of a trial judge to use his or her own intellect is built into the abuse of discretion standard. This Court has also described an "abuse of discretion" as "synonymous with a failure to exercise a sound, reasonable, and legal discretion. . . . [it] means the clearly erroneous conclusion and judgment – one [that is] ***clearly against logic and effect of such facts as are presented*** in support of the application or against the ***reasonable and probable deductions*** to be drawn from the facts disclosed upon the hearing[.]" *Commonwealth v. Powell*, 527 Pa. 288, 297 n. 8, 590 A.2d 1240, 1244 n.8 (1991) (quoting Black's Law Dictionary, 5th Ed. (1979) (emphasis added)). A trial court is thus expected to use – rather than forbidden from using – "sound" exercise of discretion, "logic," and "reasonable and probable deductions." This language is inconsistent with the Superior Court's criticism of the trial judge in this case.

In the context of a *Frye* ruling, it is even more essential for the trial court to maintain intellectual vigilance. This Court adopted the *Frye* standard in the first place because it does not want Pennsylvania trial judges relying on the pronouncements of the experts themselves. *Commonwealth v. Topa*, 471 Pa. 223, 230, 369 A.2d 1277, 1281 (1977) (expert's own self-supporting statements are not sufficient).[8] Instead, to fulfill its function as "gatekeeper," the trial court *must* apply what the Superior Court here criticized as the trial court's "own analysis of the relevant scientific principles involved[.]" *Betz*, 998 A.2d at 970.

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[8] The Superior Court committed exactly this error by deferring to Dr. Maddox and his co-expert to self-approve their own testimony: "Both Dr. Maddox and Dr. Laman testified that the methodology employed by Dr. Maddox was generally accepted." *Betz*, 998 A.2d at 978.

The judge of course has at his disposal the tools of the parties' briefs, the experts' testimony, the literature, and whatever else the record contains. That does not mean the judge must stay in lockstep with the specific arguments the parties have provided and cannot ask hard questions independently. The Superior Court itself cogently explained that point in *Blum v. Merrell Dow Pharmaceuticals, Inc*., 705 A.2d 1314, 1325 (Pa. Super. 1997), *aff'd,* 564 Pa. 3, 764 A.2d 1 (2000), in which the trial judge *failed* to assess and dissect the flaws of the experts' opinion. The Superior Court explained how judges must play this role:

> [Therefore, the gatekeeping role of the court, far from detracting from the jury's function, is in fact essential to it: ***scientific methodology and conclusions must initially be scrutinized by the court*** to ensure that what might appear to the jury to be science is not in fact speculation in disguise.

705 A.2d at 1325 (emphasis added). *See also Commonwealth v. Zook*, 531 Pa. 79, 100, 615 A.2d 1, 12 (Pa. 1992) (trial court should "focus" on "the quality of the expert's testimony").

Somewhat ironically given its present holding, the Superior Court's decision in *Blum* actually exemplifies the type of "scrutiny" that *Frye* requires a court to apply and that Judge Colville himself engaged in here. In *Blum* the Superior Court reviewed the various methodologies used by plaintiffs' experts (animal and in vitro studies, epidemiology studies), all of which are common tools of the trade, but then determined that the *way* in which the experts used these tools was flawed. In particular, the Superior Court pointed out that the plaintiff expert's use of an epidemiology study – which consisted of recalculating the raw data without applying the study's standardization controls, and thereby eliminating the very methodology which renders an epidemiological study reliable in the first place – "was so flawed as to render his

conclusions unreliable and therefore inadmissible." 705 A.2d at 1325. Thus, in the course of its review, the appellate court "scrutinized" the scientific methodology underlying the proffered expert testimony "to ensure that what might appear to the jury to be science" was "not in fact speculation in disguise." *Id*. In doing so, the court did *not* accept at face value the testimony of either the plaintiffs' or the defendant's experts, both of which had testified to the scientific validity of the plaintiffs' experts methods as generic tools of the trade.

All of this Superior Court analysis in *Blum* took place ***with only a single citation to the trial record***.[9] This is an appellate court exercising its intellect, no doubt as educated by the scientists and parties, but nevertheless with independence to determine whether the testimony had validity. The Superior Court thus departed from its own practice in holding that "[i]t was improper for the trial court to grant the *Frye* motion based upon arguments never raised by the Friction Product Defendants or supported by any expert witnesses." *Betz,* 998 A.2d at 979. Ignoring obvious logical or scientific error staring the judge in the face, simply because no party raised that error, would constitute abdication of the court's "gatekeeper" role.

B. The Trial Judge Properly Exercised His Authority to Identify Logical and Scientific Errors in Dr. Maddox's Opinions.

The trial court in this case followed the process the Superior Court exemplified in *Blum*, only to have his careful work rejected by the very court that issued *Blum*. The

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[9] Given the Superior Court's own analysis in *Blum,* with virtually no citations to the record, the appellate court's criticism of Judge Colville for not including citations to the record seems trivial at best. Like the trial court here, the *Blum* court expressly noted the "enormous" size of the record, and stated that "we have reached our holding through an application of the relevant law to that ponderous record." *Id*. at 1325. *See In re Toxic Substances Cases*, 2006 WL 2404008 at *2.

judge "considered the testimony of the witnesses, voluminous scientific literature, and numerous legal authorities proffered in support of the plaintiffs' and the defendants' respective positions." *See In re Toxic Substances Cases*, 2006 WL 2404008 at *2. The trial judge then, as in *Blum,* defined the specific question which *Frye* required him to address, *i.e*., whether he should permit plaintiffs' experts to support asbestos causation through the *any exposure* theory. *Id*. at *4.[10] And, again similar to the *Blum* court, the trial court here "scrutinized" the actual methodology upon which the proffered opinion was based and found repeated ***logical*** as well as scientific errors in that methodology.

The Superior Court *itself* repeatedly undertook its own analysis of the experts' testimony, in much the same fashion as the trial court. For example, the Superior Court opined that the testimony of the Friction Product Defendants' experts "tended to support the generally accepted nature of Dr. Maddox's methodology[,]" *Betz,* 998 A.2d at 976; designated the point in the evidence at which it believed "the inquiry" as to general acceptance "should have ended[,]" *Id.* At 978; and rejected for its own reasons Judge Colville's analysis with respect to the logical flaw of Dr. Maddox's "extrapolation down" methodology. *Id*. at 979-980.

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[10] Frye requires that "the methodology an expert used is generally accepted by scientists in the relevant field as *a method for arriving at the conclusion the expert will testify to at trial." Grady*, 576 Pa. at 558, 839 A.2d at 1045 (emphasis added). Thus, it is essential on a *Frye* motion for the court to correctly identify the *purpose* for which the "methodology" at issue is "generally accepted." This point is well illustrated by the circumstances of *Grady*, in which the trial court determined – and this Court agreed – that while the methodology the expert used might be generally accepted for the purpose of determining the "crush strength" of Doritos chips, the plaintiffs had failed to prove that the methodology was generally accepted for the purpose of reaching the conclusion to which the expert intended to testify, *i.e.,* that Doritos remained too hard and too sharp during the eating process to be eaten safely. *Id.* at 561, 839 A.2d at 1047.

The Court need not be concerned that the trial judge attempted to supplant the scientists in the case – most of his criticisms were not based on science so much as simple logical errors made by Dr. Maddox. "Extrapolation," for instance – the subject of much discussion in both the trial and appellate court opinions – "is not science: in fact, it is a logical method used to estimate the value of a variable outside its tabulated or observed range or to infer (that which is not known) from that which is known." *Trach v. Fellin*, 817 A.2d 1102, 1114 (Pa. Super. 2003) (internal quotes and citation omitted). Judge Colville was entirely correct to identify the illogic of extrapolating from high doses to low doses (discussed in more detail in Section III below), and his analysis did not require complex scientific understanding. Similarly, his insistence that the experts at least assess the dose is based on the most elemental science, and for that matter on common sense. It does not take a neurosurgeon to understand why a toxicologist should at least attempt to understand what dose was received to render an opinion on whether that dose was causative. Likewise, the trial court recognized that case reports "cannot, alone, support a causal attribution opinion . . . because they only report associations – not causal correlations." *In re Toxic Substances Cases*, 2006 WL 2404008, at *5. Some of the court's grounding with respect to case reports no doubt came from the expert testimony, but his analysis is simple logic – two things occurring together does not mean one caused the other. Some of the Superior Court's own independent assessments in *Blum* required far more descent into the science than that exercised by Judge Colville here.[11]

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[11] Indeed, this Court in affirming *Blum* expressly recounted with approval the Superior Court's conclusion that the expert who recalculated the data from the

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Trial courts are not only permitted, they are required to determine whether "what might appear to the jury to be science" is in fact "speculation in disguise." *Blum*, 705 A.2d at 1325. No trial judge should feel constrained to admit speculative and biased testimony only because the parties did not brief that aspect of the expert's opinion. Judge Colville properly applied his own mental process to the *Frye* review and should not have been reversed for doing so.

II. The *Any Exposure* Theory Represents an Unscientific Expansion of Asbestos Causation Principles.

The *Betz* litigation and Dr. Maddox's opinion provide a classic example of what is wrong with asbestos litigation today and how a good judge acting responsibly can fix it. Dr. Maddox's extreme causation opinion would be considered bizarre in any litigation context other than asbestos. (Imagine a tobacco case in which an expert claimed that smoking a single cigarette was a substantial factor in causing lung cancer, or a pharmaceutical case in which the expert contended that one pill caused the same injury as years of medication.) Judge Colville decided correctly that the *any exposure* theory has no place in asbestos litigation either.

We begin the discussion below with a description of the extreme *any exposure* view espoused by Dr. Maddox in this case, followed by a discussion of how inconsistent this theory is with fundamental toxicology principles and causation standards.

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epidemiological studies without applying their standardization controls "[i]n effect... worked backwards through the science, from the statistical results back to the original mere associations that led to the studies in the first place. This procedure cannot be fairly described as generally accepted methodology for purposes of the *Frye* standard." 564 Pa. at 8 n.5, 764 A.2d at 4 n.5.

A. Dr. Maddox Eschewed Any Consideration of Dose, the Most Important Principle of Toxicology, in Relying Exclusively on the *Any Exposure* Theory for His Opinion.

The human body is capable of defending itself against a whole array of daily exposures to known toxins, up to a point. Disease results when those exposures reach a level that overwhelms our defenses, called the "threshold" point. Aspirin, alcohol, sunlight, even known "poisons" like arsenic are only poisonous if the dose is high enough to make them so and either harmless or beneficial at lower doses (e.g., the human body requires a certain amount of arsenic). For this reason, since the time of Paracelsus, toxicology has rested on the bedrock principle that "the dose makes the poison."[12]

As a result, for toxicologists "[d]ose is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." Eaton, *supra*, at note 10. This dose principle holds true for carcinogens like asbestos just as much as it does for any other toxin:

> Most chemicals that have been identified to have "cancer-causing" potential (carcinogens) do so only following long-term, repeated exposure for many years. Single exposures or even repeated exposures for relatively short periods of time (e.g., weeks or months) generally have little effect on the risk of cancer, unless the exposure was remarkably high and associated with other toxic effects.

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[12] FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, REFERENCE GUIDE ON TOXICOLOGY at 403 (the "fundamental tenet" of toxicology). 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." David L. Eaton, *Scientific Judgment and Toxic Torts—A Primer In Toxicology For Judges And Lawyers*, 12 J.L. & POL'Y 5, 11 (2003). The Eaton article and other scientific materials cited in this brief are included in the second part of the attached Appendix.

Eaton at 9. The same is true in the courtroom – a proper risk assessment of any job-related exposure, and any litigation claim of disease from such an exposure, would include a reasonable assessment of the likely range of dose received by the worker and a determination as to whether this dose is comparable to amounts known (not speculated) to cause disease.[13] This point does not involve complex science – no one would conclude that taking aspirin caused someone's death without first *at least asking the question* how many aspirin are involved.

The key to understanding what is wrong with the *any exposure* theory is to focus on the difference between *dose* – the cumulative amount of inhaled fibers over time – and mere *exposure* – the amount of fiber in the breathing zone at a given time. Unlike exposure, dose takes into account the frequency and duration of the activity throughout the worker's life. An exposure could be high or low over a short term or long term, and thus an exposure measurement alone says virtually nothing about the likelihood that the activity at issue would cause disease. As an example, a person who simply handles a piece of asbestos insulation once may well have an "exposure," and the short-term number of fibers in the air might be somewhat high. But the overall lifetime *dose* from that activity would be very low (it would disappear into the person's background asbestos exposures) and thus not likely to contribute to disease in any real sense. A longer-term,

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[13] Courts routinely require plaintiffs to demonstrate not just some exposure, but "evidence from which the trier of fact could conclude that the plaintiff was exposed to levels of toxins ***sufficient to cause the harm complained of.***" *Wintz v. Northrop Corp.,* 110 F.3d 508, 513 (7th Cir. 1997) (citing Reference Manual on Scientific Evidence); *Wright v. Willamette Indus., Inc.,* 91 F.3d 1105, 1107 (8th Cir. 1996). This is as true for asbestos as for any other potentially toxic substance. *See Bartel*, 316 F. Supp. 2d at 611 (N.D. Ohio 2004) (rejecting "one-fiber" asbestos theory as not supported by medical literature).

repeated, and significant exposure to insulation exposures, however, can create the dose necessary to cause asbestos disease.

The *any exposure* theorists, Dr. Maddox among them, ignore the principle of dose. In lieu of any sort of dose assessment, or determination of the point at which occupational asbestos actually causes real disease, these litigation experts simply claim that all exposures are causative. They were unabashedly extreme in the view they submitted here: "Drs. Maddox and Laman do not rely, in any respect, upon any actual quantity or quality of exposure suffered by any specific plaintiff, but rather, conclude that ***if the evidence supports a single exposure***, then causation can be opined and asserted." *In re Toxic Substances Cases*, 2006 WL 2404008 at *6 (emphasis added).[14] The Superior Court did not take issue with Judge Colville's formulation of Dr. Maddox's opinion and did not criticize the trial court for getting these experts' opinion wrong – this is, precisely, what these experts say, and what the Superior Court would allow them to say.

Judge Colville accepted, correctly, that this was Plaintiff's position, and he thus correctly analyzed the validity of the *any exposure* theory exactly as Plaintiff presented it, irrespective of Mr. Simikian's own history.[15] Since Judge Colville's decision in 2006, the same testimony has formed the basis for other low-dose cases around the country, and

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[14] As the trial judge noted, "Nowhere, however, do they even remotely attempt to quantify the actual exposure that they believe would be required …." *Id.* at *6.

[15] The trial judge understood that the *Frye* issue before him was not about whether a mechanic who worked for forty years might incur mesothelioma (Mr. Simikian worked for forty-four years as a mechanic) – the issue was whether these experts would be allowed to testify *in any such case* to such an extreme *single exposure* view without even attempting to consider plaintiff's actual dose. Apparently, Plaintiff here hoped to establish a standard by which not only expert opinions involving forty years of mechanic work, but also one year, one month, or presumably one day would also be henceforth admissible with no *Frye* challenge possible.

has in turn resulted in the rejection of the theory by an array of courts, as discussed in Section II.C below.

B. The *Any Exposure* Theory Has Created an Unwarranted Expansion of Asbestos Litigation.

The effect of the *any exposure* theory on the expansion of asbestos litigation is significant. The original asbestos litigation typically pitted an asbestos worker with lung cancer, mesothelioma, or impairing asbestosis against defendants who produced the type of asbestos or product associated with the worker's job. *See* Stephen J. Carroll *et al*., ASBESTOS LITIGATION, RAND Institute for Civil Justice at 28 (2005), *at* http://www.rand.org/pubs/monographs/2005/ RAND_MG162.pdf [hereinafter RAND 2005]. Many of the exposures in these occupations involved insulation containing long, rigid amphibole fibers, rather than the more common, but far less toxic, chrysotile form of fiber. Occupations such as shipbuilders and Navy personnel working around 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 asbestos are the paradigm settings for asbestos disease. *See* Deborah Hensler *et al*., *Asbestos Litigation in the U.S.: A New Look at an Old Issue*, RAND Corporation, August 2001 at 14-15, *available at* http://www.rand.org/pubs/documented_briefings/2005/DB362.0.pdf.

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 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); Richard O. Faulk, *Dispelling the*

Myths of Asbestos Litigation: Solutions for Common Law Courts, 44 S. TEX. L. REV. 945 (2003). This "looseness" extended to causation requirements, when some courts permitted plaintiffs to demonstrate merely that they were *exposed* to a defendant's product (as one of many in the "snowstorm"), rather than require proof that any particular exposure was high enough to cause a plaintiff's disease.

In this context, plaintiff experts developed a highly standardized approach to their testimony, presenting essentially the same testimony regardless of job, exposure, dose or other factors. That testimony became the *any exposure* theory still being asserted in current cases. Today, however, most cases involve very different exposures – the removal of a few gaskets; the use of "dental tape" during dentistry work; removing the cloth insulation on electrical wires; walking by a brake or engine repair; merely handling boxes of brake pads; performing a few brake jobs in the back yard – all of these and more have been the subject of not only cases, but in some instances trials and large jury verdicts. In 1980 there were about 300 defendants in asbestos litigation, but today there are over 10,000, an expansion made possible in part due to the *any exposure* theory.[16]

The *any exposure* theory is the vehicle that permits these trivial or minimal exposure cases to get to a jury. Without it, plaintiffs would have to prove a real dose, consistent with occupations known through epidemiology studies to have caused asbestos disease – just like any other defendant in any other toxic tort litigation. To cut down on trivial lawsuits, Pennsylvania, like some other states, has adopted a "frequency, proximity, and regularity" test for asbestos cases that at least requires some minimum

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[16] *See* Towers Watson, *A Synthesis of Asbestos Disclosures From Form 10-Ks - Insights*, Apr. 2010, at 1, *available at* http://..com///1492/_Disclosures_Insights_4-15-10.pdf.

standard for exposure. *See Gregg*, 596 Pa. 274, 943 A.2d 216; *Lohrmann v. Pittsburgh Corning Corp*., 782 F.2d 1156, 1162-63 (4th Cir. 1986). The *any exposure* theory is on its face inconsistent with the "frequency, proximity, and regularity" test (also known as the *Lohrmann* test), but the Superior Court approved it regardless. In any event, the *Lohrmann* test does not explicitly address dose and is thus insufficient itself to deal with long-term but low cumulative dose exposures such as those incurred by mechanics. *See Borg-Warner,* 232 S.W.3d at 772. *Amici* suggest that the Court clarify that in low-dose litigation plaintiffs must assess and establish a causative dose before proceeding to trial, even if the exposures were frequent, regular, and proximate.

III. The *Any Exposure* Theory Is Neither Good Science Nor Good Law.

The scientific evidence not only contradicts the notion that *any* mechanic exposure causes disease, it in fact demonstrates that mechanics are not incurring mesothelioma at all in their jobs, even over a lifetime of work. The trial judge chose not to rely on much of this evidence, particularly the epidemiology studies, but nevertheless correctly concluded, as have so many other courts, that the *any exposure* theory is neither scientific nor logical. We provide a summary of the scientific causation evidence relating to mechanics here to counter some of the Superior Court's improper conclusions and give this Court a greater understanding, and perhaps comfort, that deserving plaintiffs are not being left without relief by Judge Colville's ruling.

A. The *Any Exposure* Theory Is Inconsistent with Asbestos Science and Evidence of Disease in Mechanics.

Plaintiff's experts face a heavy burden in attempting to demonstrate that the slightest exposure of a brake mechanic would be a substantial factor in causing disease –

their opinion ignores differences in fiber potency and a mountain of contrary epidemiology.

1. The *Any Exposure* Theory Disregards Fiber Potency.

As a number of courts acknowledge, not all asbestos is the same.[17] The fibers involved in mechanic work are chrysotile, a form of asbestos that virtually everyone (including Dr. Maddox) today agrees is considerably less potent than amphibole fibers. Unlike amphibole fibers found in insulation, chrysotile is not rigid, breaks down easily in the body, and much of it is quickly removed.[18] Cohorts of amphibole-exposed workers, especially prior to OSHA restrictions imposed in 1972, show high levels of mesothelioma consistent with their high levels of amphibole dose. Similar cohorts 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 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. Rees, D.,

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[17] *See, e.g., Gideon v. Johns-Manville Sales Corp.,* (5th Cir. 1985) 761 F.2d 1129, 1145 ("all asbestos products cannot be lumped together in determining their dangerousness").

[18] *See* Report on the Peer Consultation Workshop to Discuss a Proposed Protocol to Assess Asbestos-Related Risk, U.S. EPA, May 30, 2003, at viii ("The panelists unanimously agreed that the available epidemiology studies provide compelling evidence that the carcinogenic potency of amphibole fibers is two orders of magnitude greater than that for chrysotile fibers."), available at http://www.epa.gov/oswer/riskassessment/asbestos/pdfs/asbestos_report.pdf; (last accessed Feb. 9, 2011); Rake, C., et al., *Occupational, Domestic and Environmental Mesothelioma risks in the British Population: A Case Control Study,* 100 BRITISH J. CANCER 1175, 1182 (2009) ("The mesothelioma risk caused by amosite (brown asbestos) is two orders of magnitude greater than that by chrysotile (white asbestos)").

Case Control Study of Mesothelioma in South Africa, 35 Am. J. Indus. Med. 213, 220 (1999).

- A study of 1261 workers at an asbestos cement plant in Wales using only chrysotile asbestos after 1936 found only two cases of mesothelioma. Both of the employees worked at the plant prior to 1936 at a time the plant was using crocidolite asbestos (a highly potent amphibole). Thomas, H.F., *Further Follow-Up Study of Workers from an Asbestos Cement Factory*, 39 Brit. J. Indus. Med. 273, 275 (1982).

- A study of 2861 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. Neuberger, M. *Individual Asbestos Exposure: Smoking and Mortality – a Cohort Study in the Asbestos Cement Industry*, 47 Brit. J. Indus. Med. 615, 619 (1990).

- A cohort of 3072 workers exposed to chrysotile in a South Carolina asbestos textile plant with exposures of up to 700 f/cc years identified only three mesotheliomas. All three mesotheliomas occurred in workers employed in higher exposure jobs. Hein, M., *Follow-Up Study of Chrysotile Textile Workers: Cohort Mortality and Exposure-Response*, 64 Occup. Envir. Med. 616, 618, Table 2, 620 (2007); *see also* Dement, J., *Follow-Up Study of Chrysotile Textile Workers: Cohort Mortality and Case-Control Analyses*, 26 Am. J. Indus. Med. 431, 437-438 (1994).

The above populations all worked with large amounts of loose asbestos fiber, whereas mechanics only work with bonded products producing much smaller (if any) exposures. No study has ever demonstrated an increased incidence of mesothelioma in populations exposed chiefly or only to low levels of chrysotile, as mechanics are, even when the exposures are to loose fibers – much less from the bonded products mechanics use. The likelihood that a vanishingly small dose of chrysotile would cause asbestos

disease is nowhere found in the scientific literature. Neither Plaintiff's experts nor the Superior Court cited to any such study. [19]

The *any exposure* theorists ignore fiber potency and opine that the smallest dose of either fiber type is a substantial factor cause of asbestos-related disease. This is a fundamental scientific flaw in the theory.

2. The *Any Exposure* Theory Is Contradicted by Extensive Epidemiology.

The best example of why the *any exposure* theory has replaced science with guesswork is the manner in which these experts refuse even to acknowledge the message of the many epidemiology studies of vehicle mechanics. 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) (emphasis added).[20] If Dr. Maddox is correct that the

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[19] The Superior Court did briefly reference "medical literature reporting that exposure levels consistent with those experienced by brake mechanics can cause mesothelioma," but then did not identify or analyze any particular studies or reference any that are specific to chrysotile exposures. *Betz,* 998 A.2d at 968.

[20] *See also* Green, *Expert Witnesses*, 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."); *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 Litig.*, 52 FORDHAM L. REV. 732, 736 (April 1984) ("[E]pidemiology is the only generally accepted scientific discipline . . . to identify and establish the causes of human diseases."); Mary Carter Andrues, *Proof of Cancer Causation in Toxic Waste Litigation: The Case of Determinacy Versus Indeterminacy*, 61 S. CAL. L. REV. 2075, 2088 (Sep. 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.").

slightest exposure to brake pad fibers is a cause of disease – implying that those fibers would be among the most dangerous substances ever known if they could kill at such low levels – one would expect to see rampant mesothelioma among automotive mechanics (not to mention the more heavily exposed cohorts discussed above). There is no such study, and in fact the epidemiological evidence is exactly the opposite.

The automotive mechanic occupation ***has been studied***, and not once but many times. The studies have consistently produced odds ratios or risk measurements at or below 1.0, indicating no increased risk of mesothelioma in this population. 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 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 at least seventeen 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 researchers.[22]

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[21] *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]; McDonald, A.D., *Malignant Mesothelioma in North America,* 46 CANCER 1650, 1653-54, Table II (1980).

[22] The studies are summarized and discussed in Francine Laden, *Lung Cancer and Mesothelioma Among Male Automobile Mechanics: A Review*, 19 REVS. ON ENVTL. HEALTH 39 (2004); and Michael Goodman, *Mesothelioma and Lung Cancer Among Motor Vehicle Mechanics: a Meta-analysis,* 48 ANN. OCCUP. HYG. 309 (2004).

The Superior Court repeated Plaintiff's mantra that these studies were funded by the automotive industry and should be discounted. Only one of these original studies (Hessel) and the two reviews articles cited above (Goodman and Laden), however, were supported by such funding, and even these articles were published in highly respected

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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]

There are, of course, automotive mechanics who have died of mesothelioma, just as they have died of many other cancers. Automotive mechanics are just as susceptible as any other worker population to cases of *idiopathic* mesothelioma, cases that occur with no known contribution by asbestos.[24] Lung cancer, for instance, despite such a strong link to smoking and other causes, still has about a ten percent idiopathic rate. In part, these cancers arise because the body's own cells mutate, without any outside help, and can with age and time defeat the body's defenses and become a cancer. The rate of idiopathic mesotheliomas is believed to be about 1 in 1 million, or 10-20% of all cases, and there are approximately 350 such idiopathic mesothelioma cases arising every year

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journals after thorough peer review. The rest are by independent researchers. Assuming bias affected one or two of the funded studies (a completely unproven assertion), bias could not account for the same results in many other studies by many other researchers.

[23] Peto, J., et al., *Occupational, Domestic and Environmental Mesothelioma Risks in Britain: A Case-Control Study ,* UK Health and Safety Executive, at x (2009); Rake, C., et al., *Occupational, Domestic and Environmental Mesothelioma risks in the British Population: A Case Control Study,* 100 BRITISH J. CANCER 1175, 1182 (2009).

[24] Dr. Maddox has readily admitted, in this case and more recently, that such idiopathic cases of mesothelioma exist and are not due to asbestos exposure: "Dr. Maddox stated that there are idiopathic causes of mesothelioma. Without quantification of the dose-response and its threshold for asbestos when does one scientifically rule out this as a cause and not asbestos?" *Butler v. Union Carbide Corp.*, ("Order Granting Defendant's Motion to Strike Certain Testimony of Plaintiff's Pathologist Dr. John Maddox") at 12.

in the United States. A few would likely occur in mechanics.[25] Those "case reports" of mesothelioma in mechanics obviously do not prove causation. One very large study in England, for instance, found 60 automotive mechanics in that country who died of mesothelioma – and also found 114 sales managers, 132 postal workers, 225 retail workers, 232 storekeepers, 255 retailers/dealers, and 401 office workers who also died of mesothelioma even though their jobs have nothing to do with asbestos.[26] The key evidence is that the epidemiology studies consistently cannot find any higher level of mesothelioma in mechanics than is found in background-exposed populations or work groups with no clear asbestos contact.

Dr. Maddox and others are thus pushing against a mountain of contradictory evidence in concluding that mechanics incur mesothelioma due to asbestos at all, even from a lifetime of work like Mr. Simikian. Their job becomes all the more difficult when they try to assert that *any* exposure by a mechanic causes mesothelioma. This opinion falls outside the scope of scientific investigation or methodology and has entered the realm of pure speculation, as Judge Colville properly concluded.[27]

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[25] Many of the cases in mechanics are also probably due to unreported or unknown amphibole exposure from the Navy or prior industrial work. In one study of ten mechanics with mesothelioma, none of whom reported any other asbestos exposure, half were found to have excessive *amphiboles* in their lungs, obviously not from brake work. Butnor, K., *Exposure to Brake Dust and Malignant Mesothelioma: A Study of 10 Cases with Mineral Fiber Analyses*, 47 Ann. Occup. Hyg. 325, 327 (2003).

[26] McElvenny, D.M., *Mesothelioma Mortality in Great Britain from 1968 to 2001*, 55 Occ. Med. 79, 83 (2005) (*citing* HSE, *Mesothelioma Occupation Statistics for Males and Females aged 16-74 in Great Britain*, 1980-2000, Health Saf. Exec. 2003; available at http://www.hse.gov.uk/statistics/causdis/occ8000.pdf); (last accessed Feb. 9, 2010).

[27] The trial court's ruling does not mean that deserving plaintiffs will be locked out of the courtroom. For instance, Judge Colville did ***not*** rule that he would never entertain a case involving a mechanic. He only ruled that plaintiffs may not bring such cases

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B. The *Any Exposure* Theory Is Inconsistent with Pennsylvania Law and the Vast Majority of Other Court Opinions.

The *any exposure* theory not only faces insurmountable scientific hurdles, it is also out of touch with the prior rulings of this and the Superior Court itself, and with many other courts around the country. This array of cases from other courts at a minimum demonstrates that Judge Colville did not abuse his discretion in rejecting the *any exposure* approach but instead helped establish a clear path that many other courts have also followed.

Beginning with the federal courts, the Sixth Circuit Court of Appeals has rejected the *any exposure* theory as a basis for asbestos causation in two different appeals, *Martin v. Cincinnati Gas and Elec. Co*.[28] and *Lindstrom v. A-C Product Liability Trust*.[29] Both times the court was troubled by the inconsistency of the *any exposure* approach with the substantial factor causation requirement: this logic "would make every incidental exposure to asbestos a substantial factor." Also in federal court, the Delaware bankruptcy court rejected the notion that any exposure to vermiculate insulation containing minor amounts of asbestos made all homes containing such material

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relying on the assumption that all exposures are causative. To be sure, a mechanic case should be difficult to prove and should require substantial evidence of causation to overcome the contrary epidemiology. Whether those cases and opinions survive *Frye* review is for another day. The cases that Judge Colville's ruling will keep out of Pennsylvania courts are those that should not be there in the first place – cases based on a theory that dose is not important and all exposures are causative.

[28] 561 F.3d at 439.

[29] 424 F.3d at 493 (internal quotes and citation omitted).

hazardous.[30]

Several state supreme courts have also rejected the *any exposure* theory, including this one if the comment in *Gregg* is to be taken seriously. In *Gregg*, while affirming the use of the frequency, regularity, proximity standard, the Court took pains to address specifically the theory that any exposure to asbestos would be sufficient for legal causation:

> We appreciate the difficulties facing plaintiffs in this and similar settings, where they have unquestionably suffered harm on account of a disease having a long latency period and must bear a burden of proving specific causation under prevailing Pennsylvania law which may be insurmountable. Other jurisdictions have considered alternate theories of liability to alleviate the burden. [Citations omitted.] Such theories are not at issue in this case, however, and ***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*** in every "direct-evidence" case.

Gregg, 596 Pa. at 292, 943 A.2d at 226-227 (emphasis added). This Court went on to point out why that approach would contradict Pennsylvania substantial factor law and create joint and several liability without scientific evidence of harm:

> The result [of applying the *any exposure* theory], in our view, is to ***subject defendants to full joint-and-several liability for injuries and fatalities in the absence of any reasonably developed scientific reasoning that would support the conclusion that the product sold by the defendant was a substantial factor*** in causing the harm.

Id. This is very strong language – a declaration by this Court that a proffered expert theory is a "fiction" cannot be easily disregarded. But disregard it is precisely what the Superior Court did. Sup. Ct. Op. at 45 ("we will not equate the *Gregg* Court's analysis of

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30 *In re W.R. Grace & Co*., 355 B.R. 462, 476 (Bankr. D. Del. 2006).

a *de minimis* exposure under the 'regularity, frequency and proximity' test . . . with a *de minimis* exposure of asbestos for purposes of a *Frye* challenge . . . ").

The Texas Supreme Court has also rejected the *any exposure* approach in the widely-recognized *Borg-Warner* decision on facts very similar to this case. Like Mr. Simikian, the plaintiff Flores in *Borg-Warner* was a forty-year automotive mechanic, yet as here, plaintiff's experts in that case made no attempt to assess his dose but assumed that "some" mechanic exposure was enough.[31] The New York Court of Appeals, in a benzene case, also rejected testimony that a gas station attendant's exposures were "substantial" or "significant" and a cause of his leukemia, without any comparison of the dose to factory workers who incurred leukemia. *Parker,* 857 N.E. 2d at 1121-22.

A number of state courts have also increasingly rejected *any exposure* testimony under both *Frye* and *Daubert* standards. Washington state, a *Frye* jurisdiction, has twice rejected asbestos *any exposure* testimony, which one of those courts found to be "hypothetical" and "not a scientifically proven proposition."[32] Other courts in Florida, Mississippi, and Louisiana have all issued rulings rejecting or criticizing *any exposure* asbestos litigation testimony within the last five years.[33] Texas courts both before and after *Borg-Warner* have consistently rejected the any exposure theory since 2004.[34]

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31 *Borg-Warner Corp.*, 232 S.W.3d at 771.

32 *Free,* 2008 WL 728387 at *4; *Anderson*, *supra* n. 3.

33 *Brooks*, 934 So.2d at 255-56; *Daly v. Arvinmeritor, Inc*., Case No. 07-19211 (Fla. Cir. Ct. Nov. 30, 2009); *DeGrasse v. Anco Insulations, Inc*., Docket No. 2007-12736 (Orleans Civ. Dist. Ct., La., Sep. 13, 2007); *Robertson v. Ashby*, at 62.

34 *Stephens*, 239 S.W.3d at 312-21; *In re Asbestos Litig.*, No. 2004-3964 and *In re Asbestos Litig.*, both *supra* n. 3; *Smith,* 2010 WL 682343, at *3-5.

(continued…)

Judge Colville included several strongly-worded findings about the scientific unreliability of this theory, such as:

- "[T]here is no medical authority or generally accepted methodology that would support the conclusion that . . . 'each and every exposure' substantially contributed" to a particular plaintiff s disease process." *In re Toxic Substances Cases*, 2006 WL 2404008, at *13.

- The opinion that "each and every exposure" was a substantial factor in contributing to mesothelioma is "fundamentally flawed and not generally accepted by the relevant scientific community." *Id.*

- "I have been unable to find, and I do not believe that [plaintiffs' experts], or any other witness or authority offered on behalf of the plaintiffs have offered any generally accepted methodology to support this [*any exposure*] proposition." *Id.* at *6.

These findings – deemed an "abuse of discretion" by the Superior Court – are almost identical to findings made repeatedly by other judges who did not abuse their discretion:

- The *any exposure* hypothesis "is not a theory which is generally accepted in the scientific community . . . [T]here are no techniques, experiments, or studies that are capable of producing reliable results or otherwise replicating that thesis." *Anderson*, *supra* note 2, at 144-45.

- "If an opinion such as [this] would be sufficient for plaintiff to meet his burden, the Sixth Circuit's 'substantial factor' test would be meaningless…" *Bartel*, 316 F. Supp. 2d at 611.

(continued…)

Given the breadth of asbestos litigation and the entrenched nature of weakened asbestos rules, it is not surprising that some courts have permitted *any exposure* testimony to go forward. Those decisions include, for instance, those of the intermediate appellate court in New Jersey (*Buttita v. Allied Signal,* 2010 WL 1427273 (N.J.Super. A.D. 2010) and Nebraska Supreme Court (in a benzene case, *King v. Burlington Northern Santa Fe Ry. Co.,* 762 N.W.2d 24 (Neb. 2009) (decided under the more generous causation standard of FELA). These opinions typically follow the "old" asbestos rules" and do not reach the significance or level of analysis of many of the cases rejecting the theory.

- "[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." *Id.*

- "[T]he assumption that every exposure to asbestos … is a substantial factor contributing to development of an asbestos-related disease, is not a scientifically proved proposition that is accepted in the field of epidemiology, pulmonology, or any other field relevant to this case." *Free*, 2008 WL 728387 at *4.

- "Dr. Frank's [any exposure] testimony appears to disregard the legislature's specific inclusion of the word "substantial" and treats all exposures as the same." *Daly,* Case No. 07-19211, at 8 (emphasis in original).

Three of the above findings are from *Frye* reviews (*Free, Anderson, Daly*). Even more conclusive is the recent ruling from a Georgia state court that specifically examined the testimony of the same expert at issue here, Dr. Maddox:

- "Dr. Maddox's opinion squarely, inseparably relies on the theory that 'any exposure' to the asbestos of Defendant's product will cause injury, also called "the linear non-threshold model for causation…."

- "[While] Dr. Maddox is undoubtedly a qualified doctor, he has not properly utilized the scientific method to make scientifically valid decisions in reaching his specific causation opinions as required by *Daubert*...."

- "In the instant case, the Court finds that any general acceptance shown for the Plaintiff's expert opinion is far outweighed by its lack of scientific validity."

2*,* Order at p. 18. Even more damaging is the assessment by the Georgia court of Dr. Maddox as a "quintessential expert for hire" – which supports *Amici's* position that the *any exposure* theory is a litigation construct, not a scientific principle. *Id.*

Courts have regularly rebuffed attempts to export the *any exposure* theory to non-asbestos litigation:

> The use of the no safe level or linear "no threshold" model for showing unreasonable risk "flies in the face of the toxicological law of dose-response, that is, that 'the dose makes the poison,' which refers to the general tendency for a greater dose of a toxin to cause greater

> severity of responses in individuals, as well as greater frequency of response in populations."

Henricksen, 605 F.Supp.2d at 1165-66; *see also Parker,* 857 N.E. 2d at 1121-22. The trial judge here had the right and obligation to make an abuse of discretion judgment, and he made it. The Superior Court failed to discuss or cite any of these other opinions rejecting the *any exposure* theory[35] or consider how Judge Colville's ruling could be an abuse of discretion in light of such a body of case law.

C. Judge Colville Properly Rejected the "Small Bridges" Dr. Maddox Relies on to Overcome the Lack of Evidence Supporting His Position.

In rejecting the *any exposure* approach, these other courts have had before them virtually the same proposed rationales to justify the *any exposure* approach that Judge Colville also considered and rejected. Dr. Maddox and the Superior Court referred to these rationales as "small bridges." These "bridges" are very small indeed – so small that they cannot possibly bridge the gap from high-dose epidemiology studies to "each and every exposure from mechanic work is a substantial factor in disease." The key to understanding this set of evidence is to consider carefully the proposition that Dr. Maddox claims this evidence supports – ***whether any exposure to chrysotile, no matter how low, has been shown through scientific evidence to cause mesotheliomas in humans***. The issue is not amphibole fibers, and the issue is not high doses of any kind of fiber, and the issue is not speculation about what might occur at low doses but instead what has been proven scientifically to occur.

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[35] *Amici* below provided the Superior Court with a compendium of all such opinions that existed at the time, yet none were referenced or cited in the court's opinion.

The bridges on which Dr. Maddox relies are a sleight of hand – they either contradict or do not even relate to the proposition he presented to the court. The Superior Court, in its replacement of Judge Colville's opinion, failed the "gatekeeper role" itself by merely parroting Dr. Maddox's claims regarding these references without examining the studies, articles and support he cited to determine whether or not they justify his extreme position. Taking them one at a time:

The "Background" Fallacy: All of the *any exposure* experts exclude background exposures as causative, even though these exposures are nearly universal and occur almost nonstop for a person's entire lifetime. By this exclusion, these experts have tacitly disavowed the notion that any exposure, even the smallest, is a cause of disease – an entire lifetime of background exposures apparently is not enough. Having made this concession, as the trial judge noted, it is incumbent on these experts to identify where the actual causative line is, and not just draw an arbitrary line between background and those exposures that can be attributed to a litigation defendant. Dose does, in fact, matter – and it matters whether the exposures occur through background or occupational sources. Judge Colville exposed this major flaw in Dr. Maddox's approach, and the court has been supported in that conclusion since by several other courts.[36]

Extrapolation Down: Much attention is given to this approach both by Judge Colville and the Superior Court, and the parties will likely brief it extensively as well.

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[36] *Borg-Warner Corp. v. Flores*, 232 S.W.3d 765, 773 (Tex. 2007); *Butler v. Union Carbide Corp.*, Civ. No. 2008CA114 (Super. Ct. Morgan Cty, Ga., June 29, 2010) (Order Granting Defendant's Motion to Strike Certain Testimony of Plaintiff's Pathologist Dr. John Maddox) at 11; *Free v. Ametek*, No. 07-2-04091-9-SEA (Wash. King County Super. Ct. Feb. 29, 2008) (Barnett, J.) (ruling on motion *in limine*) at 4-5; *In re Asbestos Litig.*, Cause No. 2004-3964 (Tex. Dist. Ct. Jul. 18, 2007) (Letter Ruling) at 2-3.

Amici will only address it in the most concrete way we can – *it is absolutely illogical to assume that because high doses of a substance cause disease, therefore low doses will also. See Whiting v. Boston Edison Co.,* 891 F.Supp. 12, 23 (D. Mass. 1995) ("In layman's terms, the [extrapolation down] model assumes that if a lot of something is bad for you, a little of the same thing, while perhaps not equally bad, must be so in some degree. The model rejects the idea that there might be a threshold at which the neutral or benign effects of a substance become toxic."). Whether this is extrapolation up, down, or sideways, it is logical and scientific nonsense to make such an assumption and then offer that assumption as proof in a medical science case.[37] Judge Colville captured the folly of this reasoning perfectly. No Pennsylvania court, in *Trach* or otherwise, has authorized an expert to make such a leap without scientific support.[38]

"Extrapolation" is not a scientific methodology but only a means of drawing conclusions from information. The extrapolation at issue is only as good as the reasoning behind it, and the concept of extrapolation is no magic word or talisman that an expert can utter and then be free to reach any conclusion the expert wishes. The trial judge must

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[37] The experts' "extrapolation" down from high-dose amphibole studies to conclude that small doses of all fibers are deadly represents a fundamental error in reasoning expressed by the following syllogism: "If some asbestos exposures cause disease, therefore all asbestos exposures cause disease." This is classic logical error. It may be true theoretically, but it may not. Certainly in the world of toxicology, where substances must achieve a certain dose to become toxic, it is quintessentially a false statement.

[38] Several federal cases have cautioned about extrapolating from an accepted scientific premise to an unsupported one; the extrapolation must be "reasonable and scientifically valid." *Moore v. Ashland Chemical,* 151 F.3d 269, 278 (5th Cir. 1998); *see Wheat v. Pfizer, Inc.,* 31 F.3d 340, 343 (5th Cir. 1994); *Braun v. Lorillard Inc.,* 84 F.3d 230, 235 (7th Cir. 1996); *Cavallo v. Star Enter.*, 892 F. Supp. 756 (E.D. Va. 1995), *aff'd in part,* 100 F.3d 1150 (4th Cir. 1996).

examine the underpinnings of the proffered extrapolation, read the studies at issue, and determine whether the leap makes sense and is justified. That is exactly what Judge Colville did in rejecting the extrapolation down at the heart of the *any exposure* theory.

"No Safe Dose" and related theories: Dr. Maddox and the Superior Court both relied on the "small bridge" of regulatory agency statements that "there is no known safe dose of asbestos." The genesis of this statement is something called the "linear no-threshold theory." Under this theory, regulators draw a line through the known doses that have caused mesothelioma – at the high end of the exposure range – and then *assume* that the line continues straight down to zero, rather than curving downward as any toxic substance with a threshold would do. Regulators, of course, operate under a different mandate than courts of law and frequently make decisions, in the interests of precaution, based on theory or uncertainty.

The *any exposure* theorists convert the regulators' "there is no known safe dose" approach to something very different – "every dose is causative, no matter how small." Those statements are not the same. At best, the "no safe dose" premise, rejecting the notion of any threshold for a carcinogen, is a theory that these experts cannot prove and have not proven. And they are almost certainly wrong. As noted in the Eaton text above, carcinogens like asbestos do have thresholds, such that carcinogens typically require repeated exposures over many years to produce cancers. Once again, numerous other courts have joined Judge Colville in decrying expert reliance on the linear no-threshold and other theoretical approaches to low-dose causation.[39] As a Washington federal court

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[39] *In re W.R. Grace & Co*., 355 B.R. at 475-76; *Butler v. Union Carbide Corp.*, *supra*, at 11; *Free v. Ametek*, *supra*, at 3-4. The linear no-threshold theory "has been

(continued…)

held: "[The] no safe dose [premise] flies in the face of the toxicological law of dose-response, that is, that the dose makes the poison."[40]

Case Reports: Dr. Maddox relies heavily on case reports, but case reports are nothing more than an incidence in which a particular disease occurs in a person who also engaged in a certain activity. Case reports are valued as "hypothesis-generating" but they almost never suffice as proof of causation. As examples, case reports of coffee drinkers incurring pancreatic cancer, or users of Bendectin whose children were born with birth defects, or smokers who have mesothelioma might raise a hypothetical concern. But that concern would not typically translate into a real public health issue unless and until epidemiology studies documented increased disease. In fact, all three of the above associations in case reports were proven false by epidemiology studies.[41]

Dr. Maddox does not use case reports of mechanics with mesothelioma to generate a hypothesis. He uses them to conclude that causation exists. This is not a scientific methodology. He may be using a "tool" of science (case reports) but he is

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(continued…)

rejected by the overwhelming majority of the scientific community." *Henrickson,* 605 F. Supp. 2d at 1166. *See also Sutera v. Perrier Group of America Inc.,* 986 F.Supp. 655, 666 (D. Mass. 1997) ("there is no scientific evidence that the linear no-safe threshold analysis is an acceptable scientific technique" to determine causation).

[40] *Henricksen*, 605 F. Supp.2d at 1165-66.

[41] *Blum*, 764 A.2d at 4 n.5 (Bendectin-birth defect link disproven by epidemiology); *Pancreatic Cancer Is Not Linked with Drinking Coffee or Alcohol,* American Cancer Society website, located at *http://ww2.cancer.org/docroot/NWS/content/NWS_1_1x_Pancreatic_Cancer_Is_Not_Linked_With_Drinking_Coffee_or_Alcohol.asp* (last accessed Feb. 8, 2011). The smoking literature has never documented an increased incidence of mesothelioma in smokers, a point Dr. Maddox and other plaintiff experts testify to themselves.

using it in an entirely improper way. It is the gatekeeper's job to make sure experts are not using screwdrivers to pound nails and hammers to saw lumber, and that is what Judge Colville did here.[42]

All fibers can cause disease: Both Dr. Maddox and the Superior Court rely on the notion that all fiber types, including chrysotile, can cause mesothelioma. Dr. Maddox derives this conclusion from high-dose chrysotile studies involving miners, cement workers, and textile workers, and from animal studies in which chrysotile, injected directly into the animal in large doses, can induce mesotheliomas. Whether chrysotile at high doses causes mesothelioma, however, is not the issue[43] – the question is what happens at low doses like mechanics experience. And here, Dr. Maddox falls back on his faulty extrapolation down approach. The citation to "all fibers cause mesothelioma" is largely an attempt to dodge the real issue – whether low doses cause anything at all.

Signature disease: Dr. Maddox and other experts who rely on the *any exposure* theory often note that mesothelioma is a "signature" disease, meaning that asbestos is the

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[42] The fallacy of relying on case reports is illustrated by the United Kingdom study discussed above that identifies far more mesothelioma cases in office workers, postal workers, sales clerks, and other obviously non-asbestos careers than in automotive mechanics. Counting cases is a fallacious tactic. There is a wealth of case law on this issue. *In re W.R. Grace & Co*., 355 B.R. at 481 ("The fundamental scientific limitations of anecdotal evidence have led federal courts to consistently reject individual case reports as a reliable basis for medical causation opinions.") (citing many other cases); *see also Hall v. Baxter Healthcare Corp*., 947 F.Supp. 1387, 1411 (D. Or. 1996) ("case reports and case studies are universally regarded as … insufficient"); *Casey v. Ohio Medical Products*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995); *Wade-Greaux v. Ohio Medical Laboratories, Inc*., 874 F. Supp. 1441, 1483 (D. V.I. 1994).

[43] The debate today is over whether the mesotheliomas that have appeared in chrysotile-only cohorts is the result of the chrysotile itself or contaminating tremolite in that chrysotile. Given the extreme position taken by Dr. Maddox – that very small doses of chrysotile cause mesothelioma – it is not necessary to deal with the issue of whether even very high doses are a cause. Dr. Maddox has ***no*** evidence that ***low*** doses are a cause.

only known cause.[44] They raise this point to conclude that if a person with mesothelioma also has any identifiable asbestos exposure, then the disease must have been caused by the exposure. This is completely circular reasoning – the proof that the asbestos exposure caused the disease is that the disease occurred. Judge Colville again identified the error in this approach. Dr. Maddox has no way of distinguishing between an idiopathic case of mesothelioma (which Dr. Maddox admits exist) occurring in a person with inconsequential, irrelevant asbestos exposure, and those cases in which the asbestos actually caused the disease. *Butler v. Union Carbide Corp.*, *supra*, at 12. The Georgia state trial judge who rejected Dr. Maddox's testimony also made a point of criticizing his circular reasoning:

> It is improper for an expert to presume that the plaintiff "must have somehow been exposed to a high enough dose to exceed the threshold [necessary to cause the illness], thereby justifying his initial diagnosis." This is circular reasoning.

Id. at 11 (citing *Mancusco v. Consolidated Edison of New York,* 967 F. Supp. 1437, 1450 (S.D.N.Y. 1997).

Helsinki Criteria and Government Publications: Finally, although Judge Colville did not address these references, the Superior Court pointed to the Helsinki Criteria and several government publications as supporting Dr. Maddox's *any exposure is enough* position. The fundamental flaw in relying on these small bridges is that none of these documents actually state that *any* occupational exposure is enough to attribute causation. The Helsinki criteria, for instance, states that "significant exposures" should be

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[44] Even this point is not correct. Radiation therapy causes mesotheliomas years later, as documented in several recent studies. *See, e.g.,* Teta, J., et al., *Therapeutic Radiation for Lymphoma*: *Risk of Malignant Mesothelioma,* 109 Cancer Radiotherapy and Mesothelioma 1432 (2007).

considered a cause, with no definition or guidance as to what "significant" means.[45] Most of the other publications typically only state that all fibers are known to cause disease and that there is no *known* safe dose – both fallacious grounds for testifying that any exposure is a cause, as addressed above. In addition, none of these publications even addresses what would happen in a chrysotile-only exposure circumstance, the very issue put before the trial court by Dr. Maddox's opinion.

Fundamentally, the trial court did not ignore Dr. Maddox's small bridges but instead dissected every one and found them lacking. The principle Dr. Maddox wished to testify to – that he does not need to consider dose but may consider any dose, any exposure causative – was derived from materials or methodologies that either made no sense or did not support the extremity of his position. The trial court looked for, and could not find, any reference, any publication in peer-reviewed literature demonstrating that the *any exposure* theory as asserted by Dr. Maddox (and not some other construct) was published and confirmed in peer-reviewed literature. Neither Dr. Maddox nor the Superior Court cited to such a study either. The trial court's rejection of the theory is consistent with the direction of law nationwide and is a necessary step in bringing asbestos litigation back into the fold of ordinary toxic tort law.

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[45] *Asbestos, asbestosis, and cancer: the Helsinki criteria for diagnosis and attribution,* 23 Scan. J. Work Environ. Health 311, at 313 (1997). The Helsinki criteria also state that "an occupational history of brief or low level exposures" should be considered causative but again provides no guidance as to what this means or what fiber type is encompassed. Nowhere does the Helsinki criteria state that every single exposure is a cause, regardless of dose (nor does Helsinki anywhere address chrysotile-only exposures). The Helsinki document was generated by only nineteen researchers and has never been adopted by any medical body.

CONCLUSION

This Court's pronouncement in *Gregg* was not wrong – it truly is a "fiction" to consider each and every exposure a cause of asbestos disease. *Amici* urge the Court to forcibly re-declare what it already declared in *Gregg*. Judge Colville took a courageous position in drawing the line, and his opinion should be reinstated.

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Brief of *Amici Curiae* Pennsylvania Chamber of Business and Industry, Pennsylvania Business Council, NFIB/Pennsylvania, Pennsylvania Manufacturers' Association, Insurance Federation of Pennsylvania, Inc., Chamber of Commerce of the United States of America, Coalition for Litigation Justice, Inc., American Insurance Association, American Chemistry Council, NFIB Small Business Legal Center, National Association of Manufacturers, National Association of Mutual Insurance Companies was served upon the following counsel of record, by United States Mail, postage prepaid, this 25th day of April 2011, pursuant to Pa. R.A.P. 121.

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