IN THE COURT OF APPEALS OF MARYLAND
No. 82, September Term, 2012

BERNARD DIXON, et al.,
Petitioners/Cross-Respondents,

v.

FORD MOTOR COMPANY,
Respondent/Cross-Petitioner.

On Appeal from the Court of Special Appeals of Maryland
No. 536, September Term, 2011

AMICI CURIAE BRIEF OF COALITION FOR LITIGATION JUSTICE, INC., CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, NATIONAL ASSOCIATION OF MANUFACTURERS, AMERICAN INSURANCE ASSOCIATION, PROPERTY CASUALTY INSURERS ASSOCIATION OF AMERICA, AMERICAN PETROLEUM INSTITUTE, AMERICAN CHEMISTRY COUNCIL, ALLIANCE OF AUTOMOBILE MANUFACTURERS, AND NFIB SMALL BUSINESS LEGAL CENTER IN SUPPORT OF RESPONDENT/CROSS-PETITIONER

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QUESTION PRESENTED

Is plaintiffs' expert Dr. Laura Welch's "any exposure" theory of causation acceptable under good scientific practices or Maryland toxic tort causation standards to support the jury's verdict in an asbestos case?

INTEREST OF *AMICI CURIAE*

Amici[1] are organizations whose members are named as defendants in asbestos cases and their insurers. *Amici* write to address important issues of toxic tort causation standards and expert testimony. We ask the Court to assist Maryland trial courts by articulating an approach consistent with sound science and ordinary causation principles that should apply in all tort matters, including asbestos cases. This case, the first in a series of three appeals this Court will hear this Term,[2] presents the first and most fundamental issue — whether the *any exposure* theory has a place in Maryland tort litigation. Plaintiffs' experts who support this theory opine that any occupational or product-related exposure to asbestos fibers above or different from "background" exposures is a substantial contributing factor to the ultimate disease, without regard to assessing dosage.

This Court should reject the *any exposure* theory as a basis for expert testimony or causation evidence. The Pennsylvania Supreme Court did exactly this in *Betz v. Pneumo Abex, LLC*, 44 A.3d 27 (Pa. 2012), where the court rejected any reliance on the *any exposure* theory. *Amici* urge this Court to follow the lead of Pennsylvania and many other state and federal courts that have rejected *any exposure* testimony in recent years.

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[1] None of the parties or their counsel, or anyone other than the *amici*, their members, or their counsel, authored this brief in whole or in part or made a monetary contribution intended to fund the brief's preparation or submission.

[2] The other two matters accepted by the Court are *Georgia-Pacific, LLC v. Farrar*, No. 102, September Term 2012, scheduled to be heard on the same day as *Dixon*, and *Montgomery Mut. Ins. Co. v. Chesson*, No. 97, September Term 2012, which addresses *Frye* issues of expert admissibility. Certain *amici* participants anticipate filing separately in those matters to address related causation standards and sound science.

STATEMENT OF THE CASE

Amici adopt Respondent/Cross-Petitioner Ford Motor Company's Statement of the Case.

STATEMENT OF FACTS

Amici adopt Respondent/Cross-Petitioner Ford Motor Company's Statement of Facts as relevant to *amici*'s argument here.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Court of Special Appeals' decision rejecting Dr. Laura Welch's testimony is one of the more recent in a long line of cases rejecting plaintiffs' *any exposure* theory of causation. Since 2005, close to thirty courts around the country, applying both *Daubert* and *Frye* standards of admissibility, have excluded *any exposure* causation testimony in asbestos and other toxic tort cases.[3] These courts have recognized that the *any exposure* theory is not sound science and does not assist the trier of fact in determining whether a low-dose or *de minimis* exposure can be deemed a "substantial contributing factor" in a plaintiff's illness.

The most egregious use of *any exposure* testimony is found in asbestos litigation, where the theory has been used to expand that litigation to the most trivial of exposures. The most fundamental principle of toxicology is "The dose makes the poison;" this applies to asbestos just as it applies to any chemical exposure. Yet in asbestos cases, *any exposure* theorists ignore the principle of dose entirely. In lieu of any dose estimate, or any assessment of the risk associated with the plaintiff's dose, these litigation experts simply claim that all asbestos exposures that are not "background" cause mesothelioma.

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[3] *See* William L. Anderson et al., *The "Any Exposure" Theory Round II: Court Review of Minimal Exposure Expert Testimony in Asbestos and Toxic Tort Litigation Since 2008*, 22 Kan. J.L. & Pub. Pol'y 1 (2012); Mark A. Behrens & William L. Anderson, *The "Any Exposure" Theory: An Unsound Basis for Asbestos Causation and Expert Testimony*, 37 Sw. U. L. Rev. 479 (2008).

By shifting the burden of proof of actual causation away from plaintiffs, *any exposure* testimony undercuts any reasonable notion of "substantial contributing factor" under Maryland and similar causation standards. Testimony from experts like Dr. Welch effectively ensnares virtually every contact with an asbestos-containing product in the never-ending asbestos litigation.[4] The effect is to put an ever-expanding group of defendants at risk of highly emotive and potentially devastating jury verdicts, all for exposures so small that they have never been shown to cause asbestos disease.

Dr. Welch made no bones about her reliance on the *any exposure* theory at trial. She reached her causation opinion "regardless" of any quantitative information about plaintiff's asbestos exposure:

> Q: And with respect to someone who has been diagnosed with mesothelioma or reports exposure to asbestos-containing products, your opinion would be that each and every one of those exposures would be a substantial contributing factor, correct?
>
> A: Correct.
>
> Q: That would be true regardless of the source, correct, of the asbestos?
>
> A: Regardless of the product?
>
> Q: Right.
>
> A: Correct.
>
> Q: And regardless of the duration of the exposure?
>
> A: Correct.
>
> Q: Regardless of the concentration of the exposure?
>
> A: Correct.

[E. 599]. Dr. Welch added that "an exposure can be like one event . . . I think each one of those discrete exposures is a contributing factor." [E. 758]. Because of her extremist

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[4] In 1980, there were about 300 defendants in asbestos litigation, but today there are more than 10,000. The expansion to so many defendants, most of whom make or used products bound in resins and highly unlikely to cause any meaningful exposure, is largely attributable to the *any exposure* theory. *See* Mark A. Behrens, *What's New in Asbestos Litigation?*, 28 Rev. Litig. 501 (2009).

view, Dr. Welch never even attempted to answer the most fundamental question in toxicology, "How much was Ms. Dixon exposed to?"

Dr. Welch's *any exposure* testimony is based on a speculative hypothesis that is not proven in any peer-reviewed scientific literature. The same experts who urge the Court to equate *any exposure* with causation admit that the concept of "substantial contributing factor" "is not a term that is normally used in the published medical literature." Brief of *Amicus Curiae* Interested Physicians and Scientific Researchers in Support of Appellant, at 6 (Jan. 23, 2013). This is not surprising because the theory is at best an untestable and extreme hypothesis. No self-respecting scientist would likely attempt to publish the notion that every exposure to a toxin should be considered an actual cause of disease – thereby subjecting the unsupported claim to criticism by the scientific community. The theory is also illogical – its proponents testify that while the millions of "background" asbestos fibers we all breathe do not cause mesothelioma, *any* occupational exposure will readily do so. Both cannot be true. *See* Mark A. Behrens & William L. Anderson, *The "Any Exposure" Theory: An Unsound Basis for Asbestos Causation and Expert Testimony*, 37 Sw. U. L. Rev. 479 (2008).

The *any exposure* theory is not science; it is a litigation construct designed to support the endless spread of asbestos cases to increasingly attenuated defendants as the asbestos litigation enters its fourth decade and may continue until approximately 2050. The theory essentially reverses the burden of proof in asbestos cases by equating every exposure with causation. The theory renders the "substantial contributing factor" test meaningless – a legal standard intended to distinguish actual causative doses from the trivial is satisfied merely by these experts parroting a set of magic words.

The Court of Special Appeals' decision restores the proper burden of proof to asbestos cases. Refusing to accept "substantial contributing factor" testimony at face value, the Court correctly recognized that *any exposure* really means only exposure that is "more than nothing." *Dixon v. Ford Motor Co.*, 206 Md. App. 180, 196 (2012). But "more than nothing" falls far short of "substantial." As the Court stated, if the likelihood of causation is "infinitesimal," a cause of action cannot be sustained. *Id.*

Any exposure testimony, therefore, offers a jury no scientific basis on which to determine whether a plaintiff has had a sufficient dose to contribute in any meaningful way to the causation of his or her illness. Such testimony does not assist the trier of fact in applying the legal standard of causation to a plaintiff's exposure.

Contrary to plaintiff's argument, the court below did not "formulate[] a new causation standard" in asbestos cases. Nor did the court announce a new "probabilistic" standard of causation. The Court of Special Appeals simply acknowledged that an opinion about causation necessarily requires an expert to estimate the likelihood that a particular exposure actually contributed to disease rather than speculate that *any* exposure inevitably did so. The court did not mandate any particular probability of causation. Indeed, it explicitly declined to require a minimum relative risk as a legal standard or to require absolute certainty about either risk or dose. The court, moreover, did not contradict the "frequency, proximity and regularity" test of causation or disregard the cumulative nature of asbestos exposure. Rather, it faulted Dr. Welch for failing to identify *any* estimate of dose, establish *any* degree of intensity, frequency, or regularity, or testify to *any* connection between Ms. Dixon's probable dose and the dose likely to cause mesothelioma.

Amici urge this Court to state clearly, without exception, that *any exposure* testimony is not appropriate and cannot support either expert testimony or toxic tort causation. If the Court inspects carefully the underpinnings of the *any exposure* theory, the Court will recognize the flaws in the theory. Eliminating the *any exposure* theory from Maryland jury trials is essential to safeguarding the court's gatekeeper role under *Frye-Reed*, to protect defendants and courts from unlimited asbestos litigation, and to preserve courtroom time for plaintiffs with legitimate claims.[5]

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[5] *See* Victor E. Schwartz, *A Letter to the Nation's Trial Judges: Asbestos Litigation, Major Progress Made Over the Past Decade and Hurdles You Can Vault in the Next*, 36 Am. J. of Trial Advoc. 1 (2012).

ARGUMENT

I. THE *ANY EXPOSURE* THEORY, AND THUS DR. WELCH'S TESTIMONY, IS SPECULATIVE, UNRELIABLE AND NOT BASED ON CREDIBLE SCIENCE

The most important point for this Court to understand is that the *any exposure* theory represents a highly unscientific and illogical approach to causation. Whether reviewing expert testimony under *Daubert* or *Frye,* or simply considering the sufficiency of expert evidence to support causation, this Court should hold that the theory has no place in Maryland toxic tort cases.

A. The *Any Exposure* Theory Ignores the Most Fundamental Principle of Toxicology- Establishing the Dose Necessary to Cause Disease

The science of toxicology rests on the bedrock principle that "the dose makes the poison." Federal Judicial Center, *Reference Manual on Scientific Evidence, Reference Guide on Toxicology* 403 (2d ed. 2000). "Dose is the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect." David L. Eaton, *Scientific Judgment and Toxic Torts – A Primer In Toxicology For Judges and Lawyers*, 12 J.L. & Pol'y 5 (2003). The *any exposure* theory disregards this fundamental scientific principle and cannot be deemed acceptable expert testimony.

The human body is capable of defending itself against an array of daily exposures to known toxins. Disease results only when those exposures reach a "threshold" level that overwhelms our natural defenses. Aspirin, alcohol, sunlight, even known "poisons" such as arsenic, are toxic only at high enough doses and harmless — or even beneficial — at lower doses. For any given toxic response, there is a dose at which the effect begins to appear and a dose below which it does not. In short, *dose matters*.

This principle of "dose-response" holds true for carcinogens such as 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.

Eaton, *supra*, at 9. The body has numerous defenses to carcinogens and even to mutations in our DNA; the latter happens naturally, spontaneously, and continuously in the human body. Carcinogen-inducing exposures are those that overwhelm the body's cancer-preventing defenses. Nuclear fallout can cause cancers, but an ordinary x-ray does not.

Asbestos, likewise, is not a known carcinogen until levels exceed human tolerance. The best and most explicit evidence of this is the *background* exposures that we receive our entire lives. These exposures – from naturally occurring asbestos as well as dispersed industrial and building uses – can easily accumulate to millions of fibers inhaled over our lifetimes. These exposures are not considered a cause of asbestos disease. Even the *any exposure* theorists acknowledge this,[6] presumably because it is an exposure for which no one can be sued. Minor asbestos exposures, while the subject of frequent regulatory comment and action, have not appeared in epidemiology studies as a significant cause of mesothelioma.

Instead, for the most part, asbestos disease has resulted from the far more significant exposures received in the "dusty trades" work that largely ended with the advent of the Occupational Safety and Health Administration in the early 1970s. Originally and for many years, asbestos litigation typically pitted a "dusty trade" worker

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[6] Dr. Welch would not commit, when questioned directly in her deposition, as to whether background exposures alone were sufficient to cause mesothelioma. She evaded the issue by claiming she had "never thought about it" and had "never been asked" to express such an opinion. [E. 652-53]. She further stated "you need more specific information about the exposure of that individual" beyond "some ill-defined background exposures" to render a causation opinion (*id.*), a statement which essentially carves background exposures out of her causation opinion. In her trial testimony, when stating that "each and every exposure contributes," Dr. Welch was careful to refer only to "tasks" or "one day of work" or "discrete exposures" [E. 758-59] and did not opine that background exposures are a cause of disease. She is thus more evasive but does not fundamentally disagree with other experts whose testimony ruling background out and all occupational exposures in has been excluded in the many cases, as discussed herein.

with lung cancer, mesothelioma, or impairing asbestosis against defendants who manufactured the type of asbestos or product associated with the worker's high-level exposure job. *See* Stephen J. Carroll et al., *Asbestos Litigation* (RAND Corp. 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 — these are the paradigm settings for asbestos disease.[7]

The *any exposure* theorists are attempting to expand asbestos litigation well beyond these occupations known to cause disease to a whole host of far 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 backyard. These and others like them are typical exposures alleged in today's litigation. To support such claims, plaintiffs' experts have chosen to depart from established science – the need to demonstrate a causative dose. This is scientific and legal error.

The correct inquiry in the courtroom, for carcinogens or otherwise, should be, "What is the dose and was it sufficient to cause disease?" A proper causation analysis

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[7] *See* Deborah Hensler et al., *Asbestos Litigation in the U.S.: A New Look at an Old Issue* (RAND Corp. 2001). In part due to the press of an enormous docket of such cases, and in part due to the complexities of proof, some courts began to relax a number of evidentiary rules and proof requirements to accommodate these claims. *See* 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). This "looseness" extended to causation requirements. Some courts permitted plaintiffs to demonstrate merely that they were *exposed* to a defendant's product (as one of many in the "snowstorm" of exposure), rather than require proof that any particular exposure was high enough to cause a plaintiff's disease. Whatever the value of those choices in the "old" asbestos litigation, this Court should establish that the new world of low-dose exposures requires a more sophisticated and scientific analysis to deal with vastly differing exposures, fiber potencies, and work activities.

should begin with a measurement, or at least a reasonable estimate,[8] of the likely dose received by the plaintiff. The expert should then compare that dose to the dose known (not speculated) to cause the disease in question, typically as demonstrated in a series of epidemiological studies of various exposed populations.[9] If the *any exposure* theorists refuse to consider background exposures as a potential cause of mesothelioma, then it should be incumbent on these theorists to demonstrate the effective dose that will do so and not merely presume that any amount of occupational exposure is enough.

Courts have repeatedly held that the plaintiff must offer proof of an actual toxic dose to prevail in a tort case. *See, e.g., In re Bextra and Celebrex Marketing Sales Practices and Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1174-75 (N.D. Cal. 2007) (studies did not show that dose at issue could cause the alleged injury; "The Court finds that dose matters."); *McLain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1241 (11th Cir. 2005) ("In toxic tort cases, '[s]cientific knowledge of the harmful level of exposure to a chemical, plus knowledge that [the] plaintiff was exposed to such quantities, are minimal

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[8] Plaintiffs often respond to the argument that dose matters by contending it is not possible to measure a precise dose or quantification of plaintiff's actual exposures because they occurred many years ago and were not measured at the time. This is a straw man argument – industrial hygienists, epidemiologist, and others frequently estimate past historical doses in studies designed to understand current, latent diseases. They do so by using comparable exposure analyses and the specifics of the plaintiff's work activities – how much, how often, how long, etc. Precise "quantification" is not required, but ignoring dose altogether is not acceptable either.

[9] 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) (emphasis added); *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 v. John Crane, Inc.*, 316 F. Supp. 2d 603, 611 (N.D. Ohio 2004) (rejecting any exposure theory as not supported by medical literature), *aff'd sub nom. Lindstrom v. A-C Prod. Liab. Trust*, 424 F.3d 488 (6th Cir. 2005); Federal Judicial Center, *Reference Manual on Scientific Evidence, Reference Guide on Epidemiology* 338 (3rd ed. 2011) (such experiments are considered the gold standard for determining the relationshipof an agent to a disease or health outcome).

facts necessary to sustain the plaintiff's burden....'") (quoting *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 199 (5th Cir. 1996)); *Nelson v. Tennessee Gas Pipeline Co.*, 243 F.3d 244, 252 (6th Cir.) (upholding exclusion of expert witness who "made no attempt to determine what amount of PCB exposure" the plaintiff received), *cert. denied*, 534 U.S. 822 (2001); *Mitchell v. Gencorp., Inc.*, 165 F.3d 778, 781 (10th Cir. 1999) ("[A] plaintiff must demonstrate the levels of exposure that are hazardous to human beings generally as well as the plaintiff's actual level of exposure to the defendant's toxic substance before he or she may recover"); *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278 (5th Cir. 1998), *cert. denied*, 526 U.S. 1064 (1999) ("Because he had no accurate information on the level of Moore's exposure to the fumes, Dr. Jenkins necessarily had no support for the theory that the level of chemicals to which Moore was exposed caused RADS."); *Abuan v. General Elec. Co.*, 3 F.3d 329, 332-34 (9th Cir. 1993) ("In cases claiming personal injury from exposure to toxic substances, it is essential that the plaintiff demonstrate that she was, in fact, *exposed to harmful levels* of such substances" (citation and quotation omitted) (emphasis in original), *cert. denied*, 510 U.S. 1116 (U.S. 1994).

It is not enough to opine that the plaintiff was "exposed" or worked in proximity to "dust." "Dose" must also be distinguished from "exposure." The key to understanding the flaws in the *any exposure* theory is to focus on the difference between *dose* — the cumulative amount of fibers actually inhaled over time — and mere *exposure* — the amount of fibers present in the breathing zone at a given time. Unlike exposure, dose takes into account the intensity, frequency, and duration of particular activities or exposures. The fact of exposure in itself says virtually nothing about the likelihood that the exposure caused a plaintiff's disease. As an example, a person who 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 be unlikely to contribute to disease.[10]

The need for a dose-based causation analysis is even more pronounced where, as here, a plaintiff's alleged exposures are "secondary" and not from the plaintiff's own use of an asbestos-containing product. Ms. Dixon herself never handled the asbestos-containing products at issue, nor did she receive any workplace exposures. She is claiming instead that her husband brought enough asbestos home on his clothing for the court to attribute her disease to her much-lesser exposures associated with washing his clothes. This "take-home" or "household" disease can in fact occur – but only rarely and only in the context of the old "dusty trades" and high dose amphibole exposures. No epidemiology study has identified an increased risk of take-home disease from mechanic work, and only rarely from the type of fiber involved here, chrysotile.[11] Given that lack of scientific evidence, it is even more incumbent on Dr. Welch to offer evidence of

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[10] It is not enough to say, as plaintiff does, that mesothelioma is caused by cumulative exposure to asbestos. This means only that more exposure makes disease more likely; it says nothing about whether the defendant's contribution to the dose or causation was "substantial" or whether minor exposures would contribute anything to disease causation. A bucket of water would not "cumulatively" cause the ocean to fill. *See Moeller v. Garlock Sealing Technologies, Inc.*, 660 F.3d 950, 955 (6th Cir. 2011) ("saying that exposure to Garlock gaskets was a substantial cause of Robert's mesothelioma would be akin to saying that one who pours a bucket of water into the ocean has substantially contributed to the ocean's volume "). Moreover, Dr. Welch did not testify only about cumulative exposure; plaintiffs are quick to point out that she opined that exposure to Ford's brake products was sufficient "standing alone" to cause plaintiff's mesothelioma. Brief of Pets. at 38.

[11] U.S. Department of Health and Human Services Public Health Service Centers for Disease Control and Prevention, Nat'l Inst. for Occupational Safety and Health, Report to Congress on Workers' Home Contamination Study Conducted Under the Workers' Family Protection Act (29 U.S.C. 671a) 6 (1995) ("The occupations associated with asbestos-related disease in family members are those where workers were exposed to asbestos dust during: construction and renovation; prospecting and mining; manufacturing textiles, tiles, boilers, and ovens; shipbuilding and associated trades; certain railroad shop trades; welding; insulation; use and manufacture of asbestos products such as cords, seals, and plates; and renovation and demolition projects within the construction industry.").

Ms. Dixon's dose and studies demonstrating that such dose is capable of causing her disease.[12]

Dr. Welch's testimony typifies the misuse of the *any exposure* theory to opine that a particular asbestos exposure caused a plaintiff's mesothelioma. Dr. Welch admitted that she did not take into account the dose, duration, or source of Ms. Dixon's alleged exposure to asbestos — whether the exposure was for five minutes or forty years, or to a high dose or low dose, made no difference to Dr. Welch. Instead, she testified that any exposure to any asbestos fiber, no matter how small the dose, was a substantial contributing cause of Ms. Dixon's mesothelioma.[13] This approach ignores fundamental toxicology principles and is without scientific foundation.

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[12] A great many cases of mesothelioma in women today are "idiopathic" or "spontaneous," not known to be associated with asbestos. *See, e.g.*, Victor Roggli et al., *Asbestos-Associated Diseases* 108 (Springer 2d ed. 2004); Christine Rake et al., *Occupational, Domestic and Environmental Mesothelioma Risks in the British Population: A Case Control Study*, 100 Brit. J. Cancer 1175, 1181 (2009) (unexplained cases accounted for 14% of male and 68% of female mesotheliomas in Britain); Mary Jane Teta et al., *US Mesothelioma Patterns 1973-2002: Indicators of Change and Insights into Background Rates*, 17 Eur. J. Cancer Prevention 525, 534 (2008) (upwards of 300 cases of mesothelioma every year "may be unrelated to asbestos exposure" and may "reflect spontaneous causes"); Brooke T. Mossman et al., *Asbestos: Scientific Developments and Implication for Public Policy*, Science (Jan. 19, 1990), at 294 ("approximately 20 to 30% of mesotheliomas occur in the general population in adults not exposed occupationally to asbestos"). Mesothelioma, like all cancers, can result from numerous causes, including the body itself producing cancerous cells in the pleura. The *any exposure* theorists do not acknowledge the existence of an idiopathic case (like Ms. Dixon's almost certainly is) that occurs in conjunction with inconsequential asbestos exposure. They simply assume, without proof, that the inconsequential exposures are the cause.

[13] Given the extreme nature of this opinion, it does matter to this appeal what Ms. Dixon's actual dose was – the Court of Special Appeals correctly recognized that Dr. Welch was attempting to avoid any dose assessment at all, an approach that required the court to reject her testimony regardless of the actual facts of the case. In any event, the "take-home" exposures alleged in this case would be considerably smaller than the occupational exposures from mechanic work, which themselves have never been shown to cause asbestos disease. *See* Section I.C *infra*.

B. The "Any Exposure" Theory Is a Speculative Hypothesis Rather than Appropriate Scientific Analysis

The *any exposure* theory stands in sharp contrast to an appropriate scientific causation analysis. Indeed, Dr. Welch's opinion cannot be said to have applied any scientific methodology at all; it was based entirely on the untested assumption or "guess" that any exposure to asbestos, regardless of dose, contributes in a meaningful way to the development of mesothelioma.

Courts have repeatedly recognized that the *any exposure* theory has no grounding in the peer-reviewed scientific literature; nor has the theory been adequately and repeatedly tested for reliability. In *Free v. Ametek*, 2008 WL 728387 (Wash. Super. Ct. King County Feb. 28, 2008), the court rejected the theory as an unproven hypothesis:

> The assumption that every exposure to asbestos over a life's work history, even every exposure greater than 0.1 fbrs/cc yr, is a substantial factor contributing to development of an asbestos-related disease, is not a scientifically proved proposition that is generally accepted in the field of epidemiology, pulmonary pathology, or any other field relevant to this case.

Id.; *see also Butler v. Union Carbide Corp.*, 712 S.E.2d 537, 552 (Ga. Ct. App. 2011) ("any exposure theory is, at most, scientifically-grounded speculation: an untested and potentially untestable hypothesis.").

An unproven hypothesis is not a permissible basis for courtroom expert testimony. *See Sanderson v. Int'l Flavors and Fragrances, Inc.*, 950 F. Supp. 981, 1003 (C.D. Cal. 1996) ("Plaintiff asks, 'Given the dearth of research on the neurotoxic effects of fragrances and fragrance chemicals, what is a plaintiff to do?' Unfortunately for plaintiff, the answer is: Wait. When a plaintiff can't prove her case with reliable scientific evidence, she can't prove her case.") (internal citation omitted). An expert opinion is likewise inadmissible when evidence of its general acceptance rests "solely on an expert's word that his conclusions is appropriate to the underlying data and methods." *Blackwell v. Wyeth*, 408 Md. 575, 606, 971 A.2d 235, 254 (2009). Rather, expert testimony must be helpful to the trier of fact to be admissible. *See Reed v. State*, 283 Md. 374, 390, 391 A.2d 364, 372 (1978).

The Court of Special Appeals properly rejected Dr. Welch's *any exposure* hypothesis, holding that it "provided no information that could help the finder of fact to decide whether the elevated risk [to Ms. Dixon] in *this* case was 'substantial.'" *Dixon*, 206 Md. App. at 196 (emphasis added).

C. The *Any Exposure* Theory, As Applied to Brake Mechanics' Exposure to Asbestos, Is Inconsistent with Asbestos Science

The scientific evidence not only contradicts the notion that *any* brake mechanic exposure causes disease, it in fact demonstrates that mechanics are not incurring mesothelioma at all from occupational exposure, even over a lifetime of work. If the workers themselves are not incurring disease, then their spouses would not either from washing work clothes. Plaintiffs' *any exposure* experts, like Dr. Welch here, ignore both differences in fiber potency and a mountain of contrary epidemiology.

As a number of courts have acknowledged, "all asbestos products cannot be lumped together in determining their dangerousness." *Gideon v. Johns-Manville Sales Corp.*, 761 F.2d 1129, 1145 (5th Cir. 1985). The fibers involved in mechanic work are chrysotile, a form of asbestos that virtually everyone, including Dr. Welch, 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.[14] Cohorts of workers exposed to amphiboles, especially prior to OSHA standards issued in 1972, show high levels of mesothelioma. But similar cohorts exposed chiefly or only to chrysotile fibers, during the same era of limited regulation, show very few mesotheliomas, if any. This is true even when the exposures are enormous, as high as 100 fiber/cubic centimeter or more:

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[14] *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."); Rake et al., *supra*, at 1182 ("The mesothelioma risk caused by amosite (brown asbestos) is two orders of magnitude greater than that by chrysotile (white asbestos).").

- In a study of incidence of mesothelioma in major industrial regions of South Africa, no reports of mesothelioma from purely chrysotile exposure were found, despite substantial numbers of miners in chrysotile mines from the 1930s to 1980s exposed to intense concentrations of dust. *See* David Rees et al., *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). *See* H.F. Thomas, *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. *See* Manfred Neuberger & Michael Kundi, *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. *See* Misty Hein et al., *Follow-Up Study of Chrysotile Textile Workers: Cohort Mortality and Exposure-Response*, 64 Occup. Envir. Med. 616, 618, Table 2, 620 (2007); *see also* John M. Dement et al., *Follow-Up Study of Chrysotile Textile Workers: Cohort Mortality and Case-Control Analyses*, 26 Am. J. Indus. Med. 431, 437-38 (1994).

The above populations all worked with large amounts of loose asbestos fiber. Mechanics, on the other hand, work only with bonded products producing much smaller (if any) exposures. Ms. Dixon, in turn, received, if anything, an even far-lower exposure from washing Mr. Dixon's clothes.

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, particularly those resulting from washing clothes after mechanic work, would cause asbestos disease is not supported in the scientific literature. And yet, the *any exposure* theorists ignore fiber

potency and opine that the smallest dose of either fiber type is a substantial cause of asbestos-related disease. This theory is scientifically and legally flawed.

Replacing science with guesswork, *any exposure* experts refuse 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).[15] If Dr. Welch is correct that the slightest secondary exposure to brake pad fibers is a cause of disease, mesothelioma should be rampant in epidemiologic studies of automotive mechanics (not to mention the more heavily exposed cohorts discussed above). There is no such study; in fact the epidemiological evidence is exactly the opposite.[16]

The automotive mechanic occupation *has been studied*, and not once but many times. The studies have consistently produced odds ratios or relative risks at or below 1.0, indicating no increased risk of mesothelioma in this population. The studies of mechanics have found that their disease incidence is no different than that in workers

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[15] *See also* Green, *supra*, 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.") (emphasis added); *id.* at 648 ("The most desirable evidence is epidemiologic, because it can best be generalized to support inferences about the effect of an agent in causing disease in humans."); Bert Black, *Epidemiologic Proof in Toxic Tort Litigation*, 52 Fordham L. Rev. 732, 736 (1984) ("[E]pidemiology is the only generally accepted scientific discipline . . . to identify and establish the causes of human diseases."); Mary Carter Andrues, *Proof of Cancer Causation in Toxic Waste Litigation: The Case of Determinacy Versus Indeterminacy*, 61 S. Cal. L. Rev. 2075, 2088 (1988) ("The only valid way to identify human carcinogens and establish medical causation is to observe differences in the incidence of cancer between humans exposed to toxic wastes and those who are not.").

[16] Though Dr. Welch testified that there is "a lot of data that the kind of asbestos that's in brakes, chrysotile, causes mesothelioma," she conceded that "we don't have a specific epidemiologic study of only brake workers" and that she is aware of no "prospective or retrospective cohort study of brake mechanics which shows them to be at an increased risk of developing mesothelioma." [E. 749].

with little or no opportunity for asbestos exposure, such as traveling salesmen, teachers, librarians, office clerks, accountants, and farmers.[17] There are at least seventeen of these studies, conducted over the last thirty years, almost all in peer-reviewed publications, and performed in seven different countries by over sixty different researchers. One of the more recent studies, the largest study ever performed comparing populations for rates of mesothelioma, 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.[18]

Dr. Welch cannot present *any* epidemiological evidence to the contrary. Instead, she brushes off this entire series of studies as inconclusive: "a study that doesn't find something doesn't mean there is no relationship." [E. 850]. She characterizes "limitations of those studies [a]s so significant that they don't . . . give us any good information." *Id.* This is not good scientific analysis. A lack of epidemiological evidence supporting causation is not necessary fatal to a case. But when an expert is opining *contrary* to twenty years of research by dozens of researchers, that expert's burden of proof should be *greatly escalated*, not lowered. Dr. Welch should present here not speculation, but something concrete and irrefutable, to support the notion that small

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[17] *See* Kay Teschke et al., *Mesothelioma Surveillance to Locate Sources of Exposure to Asbestos*, 88 Can. J. Pub. Health 164, Table II (1997); Alison D. McDonald & J. Corbett McDonald, *Malignant Mesothelioma in North America*, 46 Cancer 1650, 1653-54, Table II (1980).

[18] Julian Peto et al., *Occupational, Domestic and Environmental Mesothelioma Risks in Britain: A Case-Control Study*, UK Health and Safety Exec. x (2009) (emphasis added); Rake, *supra*, at 1182. Dr. Welch has frequently criticized the epidemiology as supported by automotive company funding, but that criticism (even if it had merit for the few studies thus supported) does not apply to most of the cited studies, and most certainly not to Dr. Peto's and Dr. Rake's work – they are among the most respected, independent epidemiologists publishing today. The consistency of the supported studies with those that were independently performed and funded demonstrates that Dr. Welch criticism is based simply on her unwillingness to accept the results of these studies.

amounts of brake exposure (including take-home) would cause disease. She has no such evidence.

Dr. Welch and others are engaged in the highly unscientific process of *cherry-picking*. They accept only the evidence that supports their theory and reject anything to the contrary as "inconclusive" or "not good information." Her rejection of the epidemiology, and stubbornness in refusing to adjust her testimony in light of it, falls outside the scope of scientific investigation or methodology and is unacceptable speculation.

D. The *Any Exposure* Theory Is Inconsistent With Maryland Causation Law Standards

Maryland, like many states, has adopted the "substantial contributing factor" test for toxic tort causation in circumstances where multiple causative agents may be involved. "'Substantiality' is a legal concept and not an objective property testable by the scientific method." *Dixon*, 206 Md. App. at 197. The point of this test is to avoid attributing liability to minimal or "insubstantial" contributors. The test keeps the burden of proving causation where it belongs – on plaintiffs, who must demonstrate a causative dose.

The *any exposure theory,* as numerous courts have noted, *see, e.g., Martin v. Cincinnati Gas & Elec. Co.*, 561 F.3d 439, 443 (6th Cir. 2009), renders the "substantial contributing factor" test of causation meaningless. If every exposure is deemed causative, then no exposure could ever be considered insubstantial. The pernicious effect is to shift the burden to defendants to prove the absence of causation. This Court should not permit such a dramatic change in Maryland law.

Amici will address only briefly here the issue of the *Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156 (4th Cir. 1986) ("*Lohrmann*") standard and how it should apply in asbestos cases, because the *Farrar* appeal will deal more directly with the impact of that standard. Maryland courts have adopted what is widely known as the *Lohrmann* test for asbestos cases, which uses as a marker for substantiality the notion that exposures should have been regular, frequent, and proximate to establish causation. That

test had some merit when all the exposures were to the same product in the same plant (e.g., the old insulation cases). In today's very different litigation, the *Lohrmann* standard is not sufficient. The *Lohrmann* test cannot distinguish, for instance, between frequent and regular exposures to different potency fibers. It also fails to account for the overall dose – e.g., a person exposed once a week for many years to vanishingly small amounts of asbestos could be said to satisfy *Lohrmann* but would in no way be at risk of disease. Background exposures are the perfect example. For purposes of this appeal, it is sufficient to point out that the *any exposure* theory is inconsistent even with the less-than-adequate *Lohrmann* standard. In no ways can expert testimony regarding any exposure – one time, one place – serve as a basis for a causation standard that requires frequent and regular contact. Dr. Welch's view that a single clothes-washing by Ms. Dixon would have caused her disease is completely inconsistent with *Lohrmann,* as well as toxic tort principles. Thus, whether the test is substantial factor or the more specific *Lohrmann* standard, *any exposure* testimony is not helpful to the jury and should be excluded.

II. OTHER COURTS HAVE REPEATEDLY REJECTED THE *ANY EXPOSURE* THEORY AS UNSCIENTIFIC AND INCONSISTENT WITH CAUSATION REQUIREMENTS

In the last eight years, many courts have carefully examined the *any exposure* theory and have routinely rejected it as unscientific.[19] The courts rejecting this theory include the Sixth Circuit Court of Appeals (three times), the highest courts of Texas, New York, and Pennsylvania (and arguably Virginia), at least five federal district courts, and trial and state appellate courts in Texas, Georgia, Florida, Delaware, Ohio, Mississippi, and Pennsylvania, among others.[20] These courts are attempting to regain control over tort

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[19] *See* David C. Landin et al., *Lessons Learned from the Front Lines: A Trial Court Checklist for Promoting Order and Sound Public Policy in Asbestos Litigation*, 16 Brook. J.L. & Pol'y 589, 637-641 (2008).

[20] Federal court cases include *Pluck v. B.P. Oil Pipeline Co.*, 640 F.3d 671 (6th Cir. 2011) (benzene); *Moeller v. Garlock Sealing Technologies, Inc.*, 660 F.3d 950 (6th Cir. 2011); *Martin*, 561 F.3d at 439; *Bartel*, 316 F. Supp. 2d at 611; *Smith v. Ford Motor Co.*, 2013 WL 214378 (D. Utah Jan. 18, 2013); *Newkirk v. ConAgra Foods, Inc.*, 727 F. Supp. 2d 1006 (E.D. Wash. 2010), *aff'd*, 438 Fed. Appx. 607 (9th Cir. 2011) (popcorn);

causation principles in which "anything goes" is increasingly becoming "not in our courts."[21]

Beginning with the federal courts, the Sixth Circuit Court of Appeals has rejected the *any exposure* theory as a basis for asbestos causation in *Martin v. Cincinnati Gas & Electric Co.*, 561 F.3d 439 (6th Cir. 2009); *Lindstrom v. A-C Product Liability Trust*, 424 F.3d 488 (6th Cir. 2005); and *Moeller v. Garlock Sealing Technologies, LLC*, 660 F.3d 950 (6th Cir. 2011). The court was particularly troubled by the inconsistency of the *any exposure* approach with the substantial factor causation requirement: this logic "would

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Henricksen v. ConocoPhillips Co., 605 F. Supp. 2d 1142 (E.D. Wash. 2009) (benzene); *In re W.R. Grace & Co.*, 355 B.R. 462 (Bankr. D. Del. 2006), *appeal denied*, 2007 WL 1074094 (D. Del. Mar. 26, 2007); *see also Barabin v. AstenJohnson, Inc.*, 700 F.3d 428 (9th Cir. 2012) (reversing trial verdict based in part on *any exposure* theory due to trial court's inadequate *Daubert* analysis).

State court cases include *Ford Motor Co. v. Boomer*, 2013 WL 119703 (Va. Jan. 10, 2013) (declining to address *any exposure* theory directly but requiring plaintiff's experts to "opine as to what level of exposure is sufficient to cause mesothelioma, and whether the levels of exposure at issue in this case were sufficient"); *Betz*, 44 A.3d at 27 (affirming *In re Toxic Substances Cases*, 2006 WL 2404008 (Pa. Ct. Com. Pl. Allegheny County Aug. 17, 2006)); *Gregg v. V-J Auto Parts Co.*, 943 A.2d 216 (Pa. 2007); *Borg-Warner Corp. v. Flores*, 232 S.W.3d 765 (Tex. 2007); *Parker v. Mobil Oil Corp.*, 857 N.E.2d 1114 (N.Y. 2006) (benzene); *Butler v. Union Carbide Corp.*, 712 S.E.2d 537 (Ga. Ct. App. 2011); *Smith v. Kelly-Moore Paint Co., Inc.*, 307 S.W.3d 829 (Tex. Ct. App.-Ft. Worth 2010); *Georgia-Pacific Corp. v. Stephens*, 239 S.W.3d 304 (Tex. Ct. App.-Houston 2007); *Georgia-Pacific Corp. v. Bostic*, 320 S.W.3d 588 (Tex. Ct. App.-Dallas 2010), *review granted*, Feb. 15, 2013; *Daly v. Arvinmeritor, Inc.*, 2009 WL 4662280 (Fla. Cir. Ct. Broward County Nov. 30, 2009); *In re Asbestos Litig. (Certain Asbestos Friction Cases Involving Chrysler LLC)*, 2008 WL 4600385 (Pa. Ct. Com. Pl. Phila. County Sept. 24, 2008); *Free*, 2008 WL 728387, at *1 (trial order); *In re Asbestos Litig. (Pena v. Bondex)*, 2007 WL 5994694 (Tex. Dist. Ct. Harris County July 18, 2007); *Basile v. American Honda Motor Co., Inc.*, 2007 WL 712049 (Pa. Ct. Com. Pl. Indiana County Feb. 22, 2007); *Brooks v. Stone Architecture, P.A.*, 934 So. 2d 350 (Miss. Ct. App. 2006).

[21] *See* David E. Bernstein, *Getting to Causation in Toxic Tort Cases*, 74 Brook. L. Rev. 51, 59 (2008) ("The recent, increasingly strict exposure cases . . . reflect a welcome realization by state courts that holding defendants liable for causing asbestos-related disease when their products were responsible for only *de minimis* exposure to asbestos, and other parties were responsible for far greater exposure, is not just. . . .").

make every incidental exposure to asbestos a substantial factor." *Martin*, 561 F.3d at 443; *Moeller*, 660 F.3d at 955.

Several state supreme courts have also rejected the *any exposure* theory. Most recently, the Pennsylvania Supreme Court unanimously affirmed the exclusion of expert testimony based on the *any exposure* theory in *Betz v. Pneumo Abex, LLC*, 44 A.3d 27 (Pa. 2012). The *Betz* court found that an *any exposure* opinion was in "irreconcilable conflict with itself" because "one cannot simultaneously maintain that a single fiber among millions is substantially causative, while also conceding that a disease is dose responsive." *Id.* at 56. The Pennsylvania Supreme Court's decision in *Betz* is consistent with the court's prior ruling in *Gregg v. V-J Auto Parts, Inc.*, 943 A.2d 216 (Pa. 2007). In *Gregg*, while affirming the use of the "frequency, regularity, proximity" standard, the court specifically addressed the *any exposure* theory as insufficient for legal causation:

> 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.

Id. at 226-227 (emphasis added). The *Gregg* 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. (emphasis added).

The Texas Supreme Court also rejected the *any exposure* approach in the widely-recognized case of *Borg-Warner Corp. v. Flores*, 232 S.W.3d 765 (Tex. 2007), involving an exposure even less attenuated than that alleged here. There, the plaintiff was a forty-year automotive mechanic, yet as here, plaintiff's experts in that case made no attempt to assess his dose; they simply assumed that "some" mechanic exposure was enough. The court held that a plaintiff cannot satisfy the "substantial contributing factor" causation test

without showing the plaintiff's exposure level and its contribution to the aggregate dose. Texas courts both before and after *Borg-Warner* have consistently rejected the any exposure theory.[22]

In January of this year, the Virginia Supreme Court, while declining to address *any exposure* testimony directly, nevertheless required plaintiff's experts to "opine as to what level of exposure is sufficient to cause mesothelioma, and whether the levels of exposure at issue in this case were sufficient." *Ford Motor Co. v. Boomer*, 2013 WL 119703 (Va. Jan. 10, 2013). Dr. Welch's testimony here could not possibly satisfy that test because she undertook neither of these analyses. Georgia's intermediate appellate

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[22] *See Stephens*, 239 S.W.3d at 312-21; *In re Asbestos Litig.*, 2004 WL 5183959 (Tex. Dist. Ct. Harris County Jan. 20, 2004); *In re Asbestos Litig.*, 2007 WL 5994694; *Smith*, 307 S.W.3d at 838. 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 a New Jersey appellate court in *Buttita v. Allied Signal, Inc.*, 2010 WL 1427273 (N.J. Super. Ct. App. Div.), *cert. denied*, 4 A.3d 1025 (N.J. 2010), and several memoranda opinions by the federal asbestos multi-district litigation court in Philadelphia, *see In re Asbestos Prods. Liab. Litig. (No. VI) (Anderson v. Saberhagen Holdings, Inc.)*, 2011 WL 677290 (E.D. Pa. Feb. 16, 2011); *In re Asbestos Prods. Liab. Litig. (No. VI) (Rabovsky v. Air & Liquid Sys. Corp.)*, 2012 WL 252919 (E.D. Pa. Jan. 25, 2012); *In re Asbestos Prods. Liab. Litig. (No. IV) (Breedlove v. CSX Transp., Inc.)*, 2011 WL 499993 (E.D. Pa. Feb. 10, 2011) (adopting identical analysis and citing *Schumacher*); *In re Asbestos Prods. Liab. Litig. (No. VI) (Larson v. Bondex Int'l)*, 2010 WL 4676563 (E.D. Pa. Nov. 15, 2010); *In re Asbestos Prods. Liab. Litig. (No. VI) (Schumacher v. Amitco)*, No. 2-10-1627 (E.D. Pa. Nov. 2, 2010). None of the MDL opinions were taken up on appeal. A federal MDL magistrate, however, in another opinion noted that "substantial factor" causation principles require more than a mere minimal exposure or mere showing that defendant's product was somewhere at plaintiff's job site. *See In re Asbestos Prods. Liab. Litig (No. VI) (Sweeney v. Saberhagen Holdings, Inc.)*, 2011 WL 346822, *6 (E.D. Pa. Jan. 13, 2011) (quoting *Lindstrom*, 424 F.3d at 492 (6th Cir. 2005)), *report and recommendation adopted*, 2011 WL 359696 (E.D. Pa. Feb. 3, 2011). The magistrate stated that "the plaintiff must show a high enough level of exposure that an inference that the asbestos was a substantial factor in the injury is more than conjectural." *Id.* (internal quotations omitted). The handful of courts that have permitted some version of *any exposure* testimony are based on an inappropriate deference to the experts (typically accepted the expert's statements at face value) and do not contain the level of analysis of the *any exposure* theory in the many opinions rejecting the theory.

court rejected *any exposure* testimony in 2011, holding that a "no threshold" theory was scientifically unreliable." *Butler v. Union Carbide Corp.*, 712 S.E.2d 537, 543 (Ga. Ct. App. 2011). State and federal trial courts have also repeatedly rejected *any exposure* testimony under both *Frye* and *Daubert* standards. Very recently, for example, a Utah federal court eviscerated the theory with very strong language:

> Dr. Hammar's opinion is, as a matter of law, unsupported by sufficient or reliable scientific research, data, investigations or studies, and is inadmissible under Rule 702.... [T]he court agrees with the growing number of published opinions from other courts that have reached a similar result: that the every exposure theory as offered as a basis for legal liability is inadmissible speculation that is devoid of responsible scientific support....
>
> The every exposure theory does not hold up under careful examination .... It is questionable whether it can even properly be called a theory .... The every exposure theory is based on the opposite: a lack of facts and data.... It seeks to avoid not only the rules of evidence but more importantly the burden of proof."

Smith v. Ford Motor Co., 2013 WL 214378, *2 (D. Utah Jan. 18, 2013).

The State of Washington, a *Frye* jurisdiction, has twice rejected asbestos *any exposure* testimony, which one of the courts found to be "hypothetical" and "not a scientifically proven proposition." *Free v. Ametek*, 2008 WL 728387, *4 (Wash. Super. Ct. King County Feb. 28, 2008). Courts in Florida and Mississippi have also rejected or criticized *any exposure* testimony in asbestos litigation. *See Brooks v. Stone Architecture, P.A.*, 934 So. 2d 350 (Miss. Ct. App. 2006); *Daly v. Arvinmeritor, Inc.*, 2009 WL 4662280 (Fla. Cir. Ct. Broward County Nov. 30, 2009).

These and other courts regularly conclude that the *any exposure* theory is not a scientifically proved proposition that is accepted in the field of epidemiology, pulmonology, or any other field relevant to this case. The Court of Special Appeals has it right here — *any exposure* testimony does not assist the trier of fact in determining whether an alleged asbestos exposure caused a plaintiff's illness. And, as the Court implied, the *any exposure* theory has no place in Maryland law either.

III. THE *ANY EXPOSURE* THEORISTS RELY ON ILLOGICAL AND UNSCIENTIFIC FALLACIES

Plaintiff experts who subscribe to the *any exposure* theory rely upon common fallacies in an attempt to overcome the lack of evidence to support their opinions. In the recent Pennsylvania Supreme Court *Betz* case, the experts described these as "small bridges" they utilized to cross a large river. It does not take much to find the flaw in this – anyone trying to cross the Chesapeake Bay on small bridges would get wet quickly. There is an ocean of difference between Ms. Dixon's very minimal chrysotile brake exposures and the kinds of epidemiology studies of the dusty trades that have demonstrated increased incidence of disease. This ocean cannot be crossed with small bridges any more than the Chesapeake Bay.

In reality, the "small bridges" used by Dr. Welch and others are nothing but misdirections and fallacies. They either do not prove the point at issue, or they are logically insufficient to support the expert's opinion. The flaws in the most prominent of these arguments are as follows:

The "Background" Fallacy: As noted previously, the *any exposure* theorists will not opine that millions of background asbestos fibers deposited over a lifetime in a human lung contribute to or cause mesothelioma. [E. 652-54]. These experts have thus tacitly *accepted* the importance of dose – a background dose is not enough – but then failed to apply this acknowledgement to occupational or take-home exposures. Dr. Welsh, for instance, has not demonstrated that Ms. Dixon's minimal take-home exposures were greater than her lifetime of background exposures. Nor does Dr. Welch even take the trouble to identify the dose that would be enough to cause disease. She claims, without scientific support, that the smallest of workplace exposures is sufficient. Dose does, in fact, matter—and it matters whether the dose comes from background, occupational, or other sources. This conclusion is supported by several courts.[23]

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[23] *Borg-Warner*, 232 S.W.3d at 773; *Butler v. Union Carbide Corp.*, No. 2008CA114, at 11 (Ga. Super. Ct. Morgan County June 29, 2010), *aff'd*, 712 S.E.2d 537 (Ga. Ct. App. 2011); *Free*, 2008 WL 728387, at *4-5; *In re Asbestos Litig.*, 2007 WL 5994694, at *2-3.

Extrapolation Down: Dr. Welch and other *any exposure* supporters rely on high-dose studies (e.g., those among insulators and asbestos factory workers) to conclude that *small* exposures would also cause mesothelioma. It is illogical and unscientific to conclude that because high doses of a substance cause disease, low doses of the same substance down to the smallest levels must also cause disease. *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."). As several courts have already noted, it is logical and scientific nonsense to make such an assumption and then offer that assumption as proof in a medical causation case.[24]

"No Safe Dose" and related theories: In formulating her opinion, Dr. Welch relied on the statements of regulatory agencies 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 on a dose-response graph through the doses known to cause mesothelioma — at the high end of the exposure range — and then *assume* that the line continues straight down all the way to zero, rather than stopping at a threshold. Regulators, of course, operate under a different mandate than courts of law – they try to anticipate causes rather than adjudicate claims of actual causation – and may make decisions in certain circumstances even in the face of 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

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[24] 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*, 151 F.3d at 278; *see also Wheat v. Pfizer, Inc.*, 31 F.3d 340, 343 (5th Cir. 1994); *Braun v. Lorillard Inc.*, 84 F.3d 230, 235 (7th Cir.), *cert. denied*, 519 U.S. 992 (1996); *Cavallo v. Star Enter.*, 892 F. Supp. 756 (E.D. Va. 1995), *aff'd in part*, 100 F.3d 1150 (4th Cir. 1996), *cert. denied*, 522 U.S. 1044 (1998).

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 such as asbestos do have thresholds; they typically require repeated exposures over many years to produce cancers. Once again, numerous other courts have decried expert reliance on the linear no-threshold and other theoretical approaches to low-dose causation.[25] As a Washington federal court 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."[26]

Case Reports: Dr. Welch additionally relies on case reports and series, 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 of the above associations in case reports were proven false by epidemiology studies.[27]

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[25] *In re W.R. Grace & Co.*, 355 B.R. 462, 475-76 (Bankr. D. Del. 2006), *appeal denied*, 2007 WL 1074094 (D. Del. Mar. 26, 2007); *Free*, 2008 WL 728387, at *3-4. The linear no-threshold theory "has been rejected by the overwhelming majority of the scientific community." *Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1166 (E.D. Wash. 2009); *see also Sutera v. Perrier Group of Am., 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).

[26] *Henricksen*, 605 F. Supp. 2d at 1165-66. Dr. Welch and others often rely on the "Helsinki Criteria" to support any exposure testimony, but that document says no such thing. At most, it merely claims that "low doses" could be causative but without distinguishing fiber types. This is a classic example of these experts pointing to literature that does not in fact support the *any exposure* notion.

[27] *See Blum v. Merrell Dow Pharm., Inc.*, 764 A.2d 1, 4 n.5 (Pa. 2000) (Bendectin-birth defect link disproven by epidemiology); Dominique Michaud et al., *Coffee and Alcohol Consumption and the Risk of Pancreatic Cancer in Two Prospective United*

Dr. Welch does not use case reports of mechanics with mesothelioma to generate a hypothesis; she uses them to opine that causation exists. As the Court of Special Appeals held, this is not a scientific methodology. She may be using a "tool" of science (case reports) but she is using it in an entirely improper way.[28] Put another way, there are thousands of "case reports" of persons with mesothelioma who also had background exposures, but Dr. Welch does not rely on those incidents to find that background exposures cause mesothelioma. Instead, she relies on only a handful of mechanic-mesothelioma case reports to find causation for that activity. This approach is flawed and illogical.

All fibers can cause disease: The *any exposure* theorists typically contend that since all fibers types (including chrysotile) are known to cause mesothelioma, they should be allowed to testify that small amounts of chrysotile could be the cause of diseases like Ms. Dixon's. The flaw in this theory is the differences in potency and dose. Some studies (as noted above) have found that chrysotile fibers are significantly less potent, but the *any exposure* theorists fail to take that difference into account in their opinions. Medically, it is obvious that a less potent substance requires a higher dose to have any effect — *e.g.*, it would require a much greater quantity of beer to have the same impact as drinking a bottle of 180-proof whiskey. A scientific approach to asbestos, then, requires an estimate of the different doses of fibers of different toxicity to determine whether they contributed to disease. Dr. Welch does not do this. She agrees that chrysotile is less potent [E. 609], but does not assess, for example, how Ms. Dixon's

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States Cohorts, 10 Cancer Epidemiology, Biomarkers, & Prevention 429-437 (2001) (finding no increased risk of pancreatic cancer with increased consumption of coffee).

[28] Counting cases is a fallacious tactic. There is a wealth of case law on this issue. *See 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); *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387, 1411 (D. Or. 1996) ("case reports and case studies are universally regarded as . . . insufficient"); *see also Casey v. Ohio Med. Prods.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995); *Wade-Greaux v. Ohio Med. Labs., Inc.*, 874 F. Supp. 1441, 1483 (D. V.I.), *aff'd*, 46 F.3d 1120 (3rd Cir. 1994).

purported exposures to chrysotile fibers compare to the level of amphibole exposures known to cause disease.

There is no scientific principle that would permit an expert to opine that all exposures with different potency are equally causative, yet that is a fundamental underpinning of the *any exposure* theory, and the basic premise of Dr. Welch's view that "asbestos is asbestos." [E. 733]. The notion that "all fibers cause mesothelioma" is largely an attempt to dodge the real issue — whether low doses of chrysotile cause disease at all.

Signature disease: Dr. Welch, like other experts who rely on the *any exposure* theory, notes that mesothelioma is a "signature" disease, meaning that asbestos is the only known cause.[29] [E. 750] ("asbestos is, in my opinion, the only recognized cause of mesothelioma"). 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. *Butler v. Union Carbide Corp.*, 712 S.E.2d 537, 551 (Ga. Ct. App. 2011) ("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."). Dr. Welch has no way of distinguishing between an idiopathic or "spontaneous" case of mesothelioma occurring in a person with inconsequential asbestos exposure – which science has demonstrated to exist – and those cases in which a defendant's asbestos actually caused the disease.

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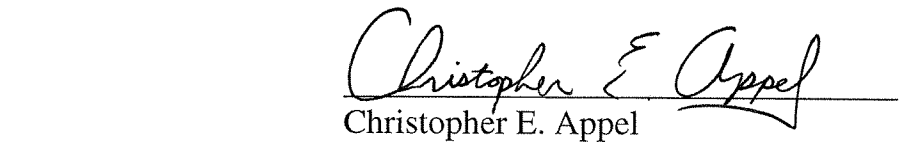
[29] Even this point is not correct. Radiation therapy causes mesothelioma years later, as documented in several recent studies. *See, e.g.*, Mary Jane Teta et al., *Therapeutic Radiation for Lymphoma: Risk of Malignant Mesothelioma*, 109 Cancer Radiotherapy & Mesothelioma 1432 (2007).

CONCLUSION

The *any exposure* theory is a litigation-generated sleight-of-hand that distracts a court from the true causation issue on the table. Under the *any exposure* theory, sound science no longer matters and the "substantial contributing factor" test of causation is reduced to meaningless wordplay. This Court should join others that have begun conform expert testimony and causation requirements in asbestos cases to standard toxicology and tort principles. The *any exposure* theory has no place in asbestos litigation, and the Court of Special Appeals, like several other courts, correctly rejected it. The decision below should be affirmed.

Respectfully submitted,



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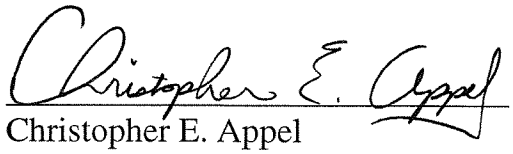
Dated: February 22, 2013

STATEMENT OF RULE 8-504 COMPLIANCE

Pursuant to Rule 8-504(a)(8), I certify that the foregoing brief is in Times New Roman font with a 13-point typeface.



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CERTIFICATE OF SERVICE

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