[J-87-2011]
IN THE SUPREME COURT OF PENNSYLVANIA
WESTERN DISTRICT

CASTILLE, C.J., SAYLOR, EAKIN, BAER, TODD, McCAFFERY, ORIE MELVIN, JJ.

DIANA K. BETZ, EXECUTRIX OF THE ESTATE OF CHARLES SIMIKIAN, DECEASED	:	No. 38 WAP 2010
	:	Appeal from the Order of the Superior Court entered April 30, 2010 at No. 1058 WDA 2006, reversing the Order of the Court of Common Pleas of Allegheny County entered May 10, 2006 at No. GD 05-4662 and remanding.
v.	:	
PNEUMO ABEX LLC, SUCCESSOR-IN-INTEREST TO ABEX CORPORATION, ALLIED SIGNAL, INC., IN ITS OWN RIGHT AND AS SUCCESSOR-IN-INTEREST TO ALLIED CORPORATION, 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, DAIMLER CHRYSLER CORPORATION, F/K/A CHRYSLER CORPORATION, FORD MOTOR COMPANY, VOLKSWAGEN OF AMERICA, INC., NAPA AUTOMOTIVE PARTS GROUP, ROHRICH CADILLAC, INC., DYKE MOTOR SUPPLY COMPANY INCORPORATED, SOUTH HILLS AUTO PARTS CO.	:	ARGUED: October 19, 2011
APPEAL OF: ALLIED SIGNAL, INC. AND FORD MOTOR COMPANY	:	

OPINION

MR. JUSTICE SAYLOR **DECIDED: MAY 23, 2012**

The civil action underlying this appeal was selected as a test case for the admissibility of expert opinion evidence to the effect that each and every fiber of inhaled asbestos is a substantial contributing factor to any asbestos-related disease. The inquiry has proceeded under principles derived from Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

I. Background

In February 2005, Charles Simikian commenced a product liability action against Allied Signal, Inc., Ford Motor Company ("collectively Appellants"), and others, asserting causes of action grounded on multiple theories including strict liability. Mr. Simikian alleged that, throughout a forty-four year career as an automotive mechanic, his exposure to asbestos-containing friction products, such as brake linings, caused his mesothelioma. Upon Mr. Simikian's death, his wife, acting as executrix ("Appellee"), substituted as the plaintiff.

Appellee's action was among a number of similar ones pending in the court of common pleas. Two of the common defendants in these cases anticipated that the plaintiffs would rely on expert opinion that each and every exposure to asbestos -- no matter how small -- contributes substantially to the development of asbestos-related diseases. This opinion often is referred to as the "any-exposure," "any-breath," or "any-fiber" theory of legal (or substantial-factor) causation. See generally Summers v. Certainteed Corp., 606 Pa. 294, 316, 997 A.2d 1152, 1164-65 (2010) (discussing the requirement for a plaintiff to prove that a defendant's product was a substantial factor in causing injury).

Seeking to preclude such opinion testimony, these defendants filed global motions challenging its admissibility under the litmus of general acceptance in the

relevant scientific community applicable to novel scientific evidence.[1] See Pa.R.C.P. No. 207.1; Commonwealth v. Topa, 471 Pa. 223, 231-33, 369 A.2d 1277, 1281-82 (1977) (confirming Pennsylvania's adherence to the Frye test; explaining that it bars novel scientific evidence from the courtroom until it has achieved general acceptance in the relevant scientific community; and indicating that strict application of the test is required to ensure fairness). The defendants referenced a litany of techniques used for various purposes in science (e.g., chemical structure analysis; anecdotal case reporting; reliance on animal studies; and extrapolation to a cause-and-effect relationship), arguing that none of these -- alone or in combination -- supports the any-exposure theory. See, e.g., Amended Global Frye Motion of June 3, 2005, In re Toxic Substance Cases, No. A.D. 03-319 (C.P. Allegheny). Highlighting the trial court's role in screening scientific evidence for reliability before permitting such evidence to be put before a jury, see, e.g., Grady v. Frito-Lay, Inc., 576 Pa. 546, 557, 839 A.2d 1038, 1044-45 (2003), the defendants contended that the methodology underlying the any-exposure theory is

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[1] More broadly, the defendants sought to exclude general causation testimony that the chrysotile asbestos in friction products causes mesothelioma, since chrysotile is the least potent form of asbestos; the asbestos contained in friction products is embedded in resin; and published, peer-reviewed epidemiological studies concerning the experience of brake workers with asbestos disease have found no increased risk as compared to the general population. See generally Francine Laden et al., Lung Cancer and Mesothelioma Among Male Automobile Mechanics: A Review, 19 REVS. ON ENVTL. HEALTH 39 (2004); Michael Goodman et al., Mesothelioma and Lung Cancer Among Motor Vehicle Mechanics: a Meta-Analysis, 48 ANN. OCCUP. HYG. 309 (2003).

As related below, however, the common pleas court limited its ruling to substantial-factor causation and addressed this requirement from a different frame of reference. Since the court's approach, in this regard, serves as the main focus of our present opinion, we also decline to address whether the opinion that chrysotile asbestos fibers (contained in friction products or otherwise) cause mesothelioma is supported by generally accepted scientific methodology.

novel and scientifically invalid. Thus, they urged that the any-exposure theory should be deemed inadmissible at all trials of asbestos cases against them.

The common pleas court, per the Honorable Robert J. Colville, directed the parties to designate test cases through which to address the Frye challenge, among which the present one was selected. The court also required an exchange of expert reports, which were to identify, in particular, the opinions and methodology supporting the plaintiffs' theory that exposure to friction products was a proximate cause of asbestos-related disease. See Order of June 23, 2005, In re Toxic Substance Cases, No. A.D. 03-319 (C.P. Allegheny). The plaintiffs identified a pathologist as their primary causation expert -- John C. Maddox, M.D. -- and submitted his report. As relevant here, the core explanation Dr. Maddox provided for his opinion as to specific and proximate causation is as follows:

> Asbestos-related mesothelioma, like other diseases induced by toxic exposures, is a dose response disease: each inhalation of asbestos-containing dust from the use of products has been shown to contribute to cause asbestos-related diseases, including mesothelioma. Each of the exposures to asbestos contributes to the total dose that causes mesothelioma and, in so doing, shortens the period necessary for the mesothelioma to develop. . . . [E]ach exposure to asbestos is therefore a substantial contributing factor in the development of the disease that actually occurs, when it occurs.

Affidavit of John C. Maddox, M.D., of Aug. 4, 2005, at 12 (emphasis added). In his report, Dr. Maddox did not provide an assessment of the individual exposure histories for the test plaintiffs, presumably as this was thought to be unnecessary, given the breadth of the any-exposure theory.

In response, the defendants proffered a report from M. Jane Teta, Dr.P.H., M.P.H., an occupational environmental epidemiologist, who couched Dr. Maddox's any-

exposure opinion as nothing more than a mere assumption. See Expert Report of M. Jane Teta, Dr.P.H., M.P.H., of Aug. 16, 2005 ("Teta Report"), at 9. According to Dr. Teta, Dr. Maddox did not follow the scientific method in proceeding from hypothesis through scientific proof in support of his conclusions. Rather, she asserted, the pathologist ignored an established hierarchy of scientific evidence; employed a selective approach to the scientific literature; and, in particular, disregarded a wealth of epidemiological evidence to the effect that those who work with automotive friction products do not suffer from a higher incidence of mesothelioma than is found in the general population. See supra note 1. Additionally, Dr. Teta observed that the any-exposure opinion is inconsistent with the common understanding that the context and circumstances of exposure to toxic substances -- including the critical component of dose -- matter greatly in terms of determining the risk of disease. See generally Bernard D. Goldstein, Toxic Torts: The Devil Is In the Dose, 16 J.L. & POL'Y 551, 551 (2008) ("Dose is a central concept in toxicology -- 'the dose makes the poison' is the oldest maxim in the field."). Furthermore, she found that Dr. Maddox exceeded the range of his expertise in rendering a broad-scale opinion concerning the theoretical impact of a single asbestos fiber. See Teta Report at 10-11.

In ensuing arguments before Judge Colville, the plaintiffs contended that a Frye challenge was inapposite. In their view, Dr. Maddox's methodology in forming his any-exposure opinion was in no way novel, but rather, resided within the scientific mainstream.[2] The plaintiffs pointed to the wealth of scientific information developed

[2] See, e.g., N.T., Aug. 17, 2005, at 67 (reflecting the assertion of one of the plaintiff's attorneys that "[t]hey are trying to essentially just disagree with our experts, which is credibility for the jury[;] [t]hey really can't lay a glove on the underlying methodology, and they don't"); id. at 96 (asserting that Dr. Maddox "looks at some very classical factors that are used to determine causation"); id. at 67-68 ("[O]bviously, looking at (continued…)

over time concerning the hazards of asbestos, see N.T., Aug. 17, 2005, at 84-85 (reflecting the plaintiffs' observation that "[t]he medical literature has been talking about the effects of asbestos chrysotile since the 1920s"), and to government regulatory responses to protect human health. See, e.g., id. at 88-89 ("Now, the Environmental Protection Agency, their stance on this issue is that asbestos causes asbestos diseases, specifically chrysotile causes asbestos diseases and, more specifically, brake linings cause asbestos disease."). Downplaying the necessity for epidemiological evidence, see, e.g., id. at 99 ("[E]pidemiology studies are not the sine qua non as to whether there is cause and effect."), the plaintiffs asserted that conclusions favorable to their position could be drawn from such evidence in any event. Furthermore, they emphasized that their position was consistent with the admission of opinion evidence reflecting the any-exposure theory in other cases, most notably, Smalls v. Pittsburgh-Corning Corp., 843 A.2d 410 (Pa. Super. 2004). See id. at 414 (indicating that "this type of opinion evidence is not only admissible, it is sufficient to demonstrate a prima facie case of liability against an asbestos manufacturer if believed by the fact finder").

Based on the any-exposure theory, a plaintiff's attorney couched the plaintiffs' position with regard to specific causation as follows:

> [Y]ou don't have to look at each individual, you don't have to look at Mopar brakes and then look at Bendix brakes. You don't look at that. You don't even look at whether it is brakes or gaskets. You don't even look whether it is brakes or pipe covering. It doesn't matter. As a matter of law, you just say, hey, you breathed asbestos from a product, oh, you are going to the jury. Just as a matter of law, the courts, as a matter of law, you do not distinguish between products.

(…continued)
these case reports, looking at the epidemiological studies, looking at animal studies, like our expert does, is not new. It is utterly not novel.").

N.T., Aug. 17, 2005, at 75-76; see also id. at 83. Thus, from the plaintiffs' point of view, any questions concerning the any-exposure theory were credibility matters to be addressed by a jury. See id. at 80 ("This is not novel stuff. Any kind of problems they have with this is for cross-examination."). Finally, the plaintiffs highlighted a desire, on the part of courts, to limit the range of cases in which a Frye-type inquiry would be necessary. See id. at 84 ("The Trach case also says that, ['Our Supreme Court does not intend that trial courts be required to apply the Frye standard every time scientific experts are called to render an opinion at trial, a result that is nothing short of Kafkaesque to contemplate.']" (quoting Trach v. Fellin, 817 A.2d 1102, 1110 (Pa. Super. 2003) (en banc))).

The defendants, on the other hand, argued that the concept of "novelty," as applied to scientific evidence, does not necessarily mean "new," but, rather, applies where there is a colorable challenge to whether the methodology used by an expert enjoys general support in the relevant scientific community. From their perspective, this is the only approach that would allow trial judges to fulfill their screening function to assure sufficient reliability and thus lessen the possibility for jurors to be misled by expert witnesses. On the merits, the defendants' position was consistent with their motion and Dr. Teta's report.

Judge Colville felt the defendants had raised sufficient questions about Dr. Maddox's methodology to warrant further inquiry. He did not question the pathologist's opinion in terms of general causation, but he expressed circumspection concerning how that opinion translated to substantial-factor causation. See N.T., Aug. 17, 2005, at 105. For example, he remarked:

> The vast majority of what [Dr. Maddox] says seems to be based in long-standing traditional scientific principles, understood quantities and characteristics of asbestos

> generally, but that portion of what he says relates only to . . . the general risks associated with asbestos. Where Maddox' opinion becomes . . . novel in that it is new, original or striking is when he attempts to extrapolate down to the position that each and every fiber contributes to the disease process. . . . Without that statement, I have no causation as to any of the specific plaintiffs. You need that element of Maddox' report to prove causation to each plaintiff.

Id. at 105-06 (emphasis added).

Accordingly, the common pleas court centered its focus on the use of extrapolation, which it found to be a linchpin of Dr. Maddox's methodology and opinion supporting a finding of proximate cause. See N.T., Aug. 17, 2005, at 107-08. Along such lines, the court expressed concern with an "analytical gap" between the scientific proofs and the pathologist's conclusion. N.T., Oct. 17, 2005 (a.m.), at 21-22. A Frye hearing ensued, which was supplemented by other testimonial and documentary evidence.

A. The Frye Hearing

In his direct testimony, Dr. Maddox discussed the chrysotile asbestos fibers which were integrated into automotive friction products in relevant time periods, finding them to be carcinogenic along the lines of other, more potent varieties of such fibers. See, e.g., N.T., Oct. 17, 2005 (a.m.), at 64-66.[3] The pathologist discussed the different activities of automotive mechanics that can create dust from automotive friction products, such as opening boxes containing brake parts, sanding or grinding brake

[3] See, e.g., N.T., Oct. 17, 2005 (a.m.), at 66 (reflecting the pathologist's opinion that "'all types of asbestos fibers can and do cause malignant mesothelioma"); id. at 67 (indicating that "clinical and epidemiologic studies have established beyond all reasonable doubt that chrysotile asbestos causes cancer of the lung, malignant mesothelioma of the pleura and peritoneum, cancer of the larynx, and certain gastrointestinal cancers"); id. at 70 ("[C]hrysotile derived from brake linings can and does cause malignant mesothelioma."); id. at 102.

linings, and using compressed air to blow dust from friction product parts. See id. at 89-91, 101; N.T., Oct. 17, 2005 (p.m.), at 16-17. He also highlighted the long latency period between asbestos exposure and the manifestation of disease, with the minimum time lapse being about ten years. See id. at 15-16. As pertains to the risk of developing mesothelioma, Dr. Maddox indicated that no safe level of exposure has ever been determined for any type of asbestos. See N.T., Oct. 17, 2005 (a.m.), at 69.

As a component of this testimony in support of the plaintiffs' claim of general causation, Dr. Maddox frequently indicated that each and every exposure "should be considered," "contributes to" and "increase[s] the risk of" asbestos-related diseases. See, e.g., N.T., Oct. 17, 2005 (a.m.), at 80-81, 87, 93. According to his opinion, "it is the total and cumulative exposure that should be considered for causation purposes." Id. at 80-81; accord N.T., Oct. 17, 2005 (p.m.), at 89 (indicting that incremental exposure "would always have to be considered a contributing factor").

Dr. Maddox testified that he used generally accepted methodology in reaching his conclusion that exposure to asbestos fibers by automobile mechanics causes mesothelioma. See, e.g., Oct. 17, 2005 (a.m.), at 71; N.T., Oct. 17, 2005 (p.m.), at 12, 28. By way of further explanation, the pathologist explained that his reasoning followed a series of "small bridges," from "chrysotile is carcinogenic, to the product containing chrysotile, the product releasing chrysotile, people breathing chrysotile, and people developing tumors." N.T., Oct. 17, 2005 (a.m.), at 103; N.T., Oct. 17, 2005 (p.m.), at 11-12.

Dr. Maddox also said that he drew his conclusions from case reports, animal studies, government regulatory assessments, and other scientific and medical literature. See, e.g., N.T., Oct. 17, 2005 (a.m.), at 69-70, 71-82, 85, 94, 103-09; N.T., Oct. 17, 2005 (p.m.), at 7-15, 18. In various passages of his testimony, the pathologist indicated

that his opinion was supported by epidemiological science, see, e.g., N.T., Oct. 17, 2005 (a.m.), at 67; N.T., Oct. 17, 2005 (p.m.), at 159, albeit he couched the particular studies directed to automotive workers as "inconclusive," id. at 12, and he did not consider epidemiology appropriate to low-dose exposures, see id. at 13 ("So instead of the broad stroke to make the call from an epidemiologic study, I think one is forced to take the small steps to link together all the parts of the chain."); see also id. at 132. Additionally, while claiming some support in epidemiological science, the witness sought to avoid deeper discussion of the subject matter. See id. at 112 ("I am not really prepared to discuss epidemiology with you.").[4] Dr. Maddox did agree that epidemiology is "one branch" of science that addresses the cause and effect of disease in human populations, id. at 92, and that scientists in the field test causation hypotheses; conduct human health studies; accumulate research; publish studies in journals to be reviewed by disinterested peers; and thereby work toward achieving scientific consensus regarding disease causation. See id. at 92-93.

In his methodology, Dr. Maddox acknowledged that he "picked and chose" among studies in support of his opinion, although he didn't believe his selection process necessarily reflected bias. See N.T., Oct. 17, 2005 (p.m.), at 73-74. The following passage from Dr. Maddox's cross-examination reflects some further explanation of his approach to the literature in forming his opinion:

> Q. So to summarize your methodology on the specific issue of asbestos exposure and risk associated with being a vehicle

[4] Dr. Maddox did affirm that there were at least a dozen or more epidemiological studies that have specifically considered mesothelioma risks in relation to vehicle repair that were not encompassed within his review of the scientific literature. See N.T., Oct. 17, 2005 (p.m.), at 115. Of those, he acceded that at least twelve indicated that vehicle mechanics were not at an increased risk for mesothelioma as a result of their occupational exposures. See id.

> mechanic, . . . you chose to both not discuss and ignore numerous conclusions reached by scientist after scientist in the epidemiological field and industrial hygiene field that were consistent as showing no increased risk; correct?
>
> A. It was not a deliberate choice. It was simply an attempt to keep this paper of manageable size and directed at the issue of chrysotile exposure in general.
>
> Q. Dr. Maddox, is one of the reasons why you chose to ignore the epidemiological studies because of your -- I don't mean this condescendingly -- because you didn't understand the role of epidemiology and did not understand those studies? Is that the reason why you didn't include it?
>
> A. No, that is not really the reason. I made no conscious choice to exclude them for any particular reason. It is just that I had plenty of material upon which to base my decision and I used what I had.

N.T., Oct. 17, 2005 (p.m.), at 117-18.

Dr. Maddox found particular support in reports of a 1997 conference of scientists conducted in Helsinki, Finland, which, he related, indicated that an occupational history of asbestos exposure should be enough to establish a causal link to asbestos-related diseases. See N.T., Oct. 17, 2005 (a.m.), at 83-84; N.T., Oct. 17, 2005 (p.m.), at 32-33. According to the pathologist, the conference concluded:

> [T]he likelihood that asbestos exposure has made a substantial contribution increases when the exposure increases. Cumulative exposure, on a probability basis, should thus be considered the main criterion for the attribution of a substantial contribution by asbestos to lung cancer risk.

N.T., Oct. 17, 2005 (a.m.), at 84-85.[5]

[5] While Dr. Maddox's opinion in this particular passage was framed in terms of lung cancer, his testimony with respect to mesothelioma was consistent.

Dr. Maddox also offered several analogies to illustrate his opinions, as follows:

> [T]he more common analogy that has been used is the example of a glass of water. One drops marbles into the glass of water until the water finally overflows from the glass.
>
> Is it the first marble or the last marble that causes the glass to overflow? Well, both, all of them. The marbles cause the glass to overflow. That's a cumulative effect. Likewise, on another analogy, who won the war? Was it General Eisenhower or every troop in the field?
>
> A third analogy that's been used is the analogy of the boxer who goes nine rounds and finally loses the fight. Was it every blow that the boxer took, or just the last blow that the boxer took? Well, the cumulative effect of all the blows would be the cause of the boxer finally going down.
>
> * * *
>
> Once [a fiber] enters the body through the nose, then it doesn't matter where it came from. Then everything becomes equal. That is Ellis Island. You are an American then.

N.T., Oct. 17, 2005 (a.m.), at 85-86; N.T., Oct. 17, 2005 (p.m.), at 141. Indeed, the pathologist expressed the same opinion relative to cigarette smoking, namely, that "[a]ll the cigarettes that one smokes are considered to be contributory to the development of the lung cancer." N.T., Oct. 17, 2005 (a.m.), at 86.[6] Accordingly, in his estimation, in

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[6] Along these lines, Dr. Maddox continued:

> Now, if an individual were to smoke one brand for most of his life, but then [when] away from home, had to buy another brand of cigarette, those particular cigarettes would contribute just as much as his regular brand.

N.T., Oct. 17, 2005 (a.m.), at 86.

terms of asbestos disease causation, it makes no difference if the plaintiff merely worked infrequently on a family vehicle or was a shipyard worker frequently exposed to friable asbestos of the most carcinogenic form. See N.T., Oct. 17, 2005 (p.m.), at 36.

In his testimony, Dr. Maddox frequently couched his role in general terms, namely, to render an opinion that chrysotile asbestos contributes to disease. See, e.g., N.T., Oct. 17, 2005 (p.m.), at 37. Indeed, with regard to the test cases, the pathologist's testimony reflected his unfamiliarity with the test-case plaintiffs' or decedents' history of exposure to asbestos. See id. at 51-52. The witness maintained, however, that exposure to a single asbestos fiber of any type was sufficient to establish causation. See id. at 154.

Nevertheless, Dr. Maddox also gave testimony which is in sharp tension with the any-exposure theory as applied to substantial-factor causation. Among other things, he said:

> Now, individual exposures differ in the potency of the fiber to which an individual is exposed, to the concentration or intensity of the fibers to which one is exposed, and to the duration of the exposure to that particular material. So those are the three factors that need to be considered in trying to estimate the relative effects of different exposures. But all exposures have some effect.

N.T., Oct. 17, 2005 (p.m.), at 37 (emphasis added).[7]

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[7] See also id. at 61-62 (affirming that different risks of contracting asbestos-related disease attend different occupations and levels of exposure), 64 (indicating that the risk of developing mesothelioma from a single encounter with brake dust is "very, very low"), 83 (explaining that the risk of disease increases with higher exposures), 142 ("I would say there is a finite amount of risk that is imparted by even one or one additional exposure to asbestos."); accord N.T., Oct. 17, 2005 (a.m.), at 84 (relating that an indication from the Helsinki conference that "the likelihood that asbestos exposure has made a substantial contribution increases when the exposure increases"), 93 ("[A]dmittedly the amount of the increase [in the risk of disease] at low [exposure] levels is small").

Upon cross-examination, Dr. Maddox agreed that scientists presently do not know the mechanism by which asbestos causes mesothelioma. See N.T., Oct. 17, 2005 (p.m.), at 46, 81, 83 ("The hypothesis of individual mechanisms of mesothelioma formation remains uproven[.]"). Additionally, he recognized that his opinions were not based on any sort of direct attribution, but rather, were grounded entirely upon an assessment of risk. See, e.g., id. at 136-37 ("I believe that once an individual develops a mesothelioma, the risk becomes the cause."). The pathologist further conceded that he was unaware of the guidelines for health assessments offered by a regulatory agency upon which he relied. See id. at 120-21. He also did not wish to agree with the defendants' position that his methodology entailed extrapolation from scientific findings concerning high-dose asbestos exposure (relating to trades such as asbestos mining, insulating, and ship working) to a scenario entailing low-dose exposure (automotive maintenance). See, e.g., id. at 81-83. Instead, Dr. Maddox preferred the word "interpolation" to describe his manner of thinking. Id. at 82.

Judge Colville attempted to engage Dr. Maddox on the topic of specific causation in the following discussion:

> THE COURT: . . . [Y]our statement that you can generalize regarding the causation issues once the fiber enters the body is related to what I characterize as general causation issues, not specific causation issues? Not the specific causation of disease in a specific individual, but generally the general causation of positive properties of fiber in a human being generally?
>
> Here is what I am drawing at. A fiber can enter my body and sit for a week, a month, a year and do nothing, or it may cause a disease process. You have no way of knowing what it may do with me?
>
> THE WITNESS: There are some observations that you can't really make because they alter --

> THE COURT: We can observe a fiber enter my lungs and see what happens?
>
> THE WITNESS: That is why we have to talk about risk. I would say there is a finite amount of risk that is imparted by even one or one additional exposure to asbestos.
>
> * * *
>
> THE COURT: . . . Dr. Maddox, if [one of the plaintiffs] has asbestosis, and showed exposure to the defendants' products, would you agree that the exposures to the defendants' products contributed to his asbestosis?
>
> THE WITNESS: And I would have to answer yes.

N.T., Oct. 17, 2005 (p.m.), at 141-43. After Dr. Maddox offered a similar opinion relative to mesothelioma and lung cancer, the following interchange ensued:

> THE COURT: . . . With regard to the mesothelioma and the lung cancer cases, because you don't know about the specific work history, I take it that you are relying on the stipulation that informs you that at a minimum each plaintiff inhaled at least a single fiber or had at least single exposure to each of the defendants' products; correct?
>
> THE WITNESS: I am relying on that.

Id. at 145.

In reply to Dr. Maddox, the defendants presented, among other evidence, testimony from Dr. Teta and Dennis J. Paustenbach, PhD, DABT, a certified industrial hygienist and environmental toxicologist. Consistent with Dr. Teta's report, both witnesses couched the any-exposure opinion as a mere hypothesis or assumption. See, e.g., N.T., Oct. 18, 2005 (a.m.), at 52. Both described the scientific method and the general hierarchy of scientific evidence and indicated that Dr. Maddox followed neither. See, e.g., N.T., Oct. 17, 2005 (p.m.), at 169, 171-72, 175-176; N.T., Oct. 18,

2005 (p.m.), at 15-16, 23. Rather, both testified that Dr. Maddox merely selected supportive extracts from the literature, while disregarding the science evidence disfavorable to his position. The following explanation by Dr. Paustenbach is illustrative:

> One of the claims [Dr. Maddox] made is that every exposure contributes, and my view on this -- and I think the literature supports it -- is without knowledge of the mechanism and given no disease increase or increase in disease in these brake workers, I can't see how [he] can support the claim that every exposure contributed with respect to brake mechanics.
>
> * * *
>
> I think they've selectively chosen things that support their argument. That's where I think Dr. Maddox and I would take issue.
>
> The point was raised yesterday, well, isn't it true that all experts go through the literature, and then they choose the ones they believe in the most. No, that's not the way it's done. That's not the scientific method. I differ with Dr. Maddox in that regard.
>
> The way it's done, you assemble all the information. Then you perform a weight of the evidence evaluation, and decide in the main, based on the most credible work, what story is being told.

N.T., Oct. 17, 2005 (p.m.), at 174; N.T., Oct. 18, 2005 (a.m.), at 9; see also N.T., Oct. 18, 2005 (a.m.), at 10 (reflecting Dr. Paustenbach's complaint that the plaintiffs' experts "don't cite a single paper in the last 25 years that has to do with the science of particles.").

Dr. Teta's similar perspective was as follows:

> I saw no indication in [Dr. Maddox's] report, actually of any method, let alone the scientific method. I did not see any description of a complete review of the literature. I did not

> see a discussion of whether the literature was adequate or not. I didn't see a discussion of the strengths and weaknesses of various studies that were relied on. I didn't see a summarization of the epidemiologic literature, which is the literature that is the one we prefer for relying on that does exist. No synthesis of that literature.
>
> Actually, what I saw most was going from hypothesis to conclusion. I saw reliance on a lot of case reports with a conclusion that indicates increased risk which is incorrect methodology. I saw a lot of epidemiology studies listed of different occupations, not the ones of relevance. . . .
>
> So I did not see the generally-accepted methodology or looking at disease causation, and I really couldn't even discern what the methodology was. It was a litany of irrelevant studies for the most part.

N.T., Oct. 18, 2005 (p.m.), at 56-57.

Both defense expert witnesses further explained that prophylactic government regulatory responses are not tantamount to proof of disease causation. See, e.g., N.T., Oct. 18, 2005 (a.m.), at 123 (reflecting Dr. Paustenbach's testimony that "[t]he no safe dose means, we have assumed as an agency that it's possible that there are some risks"). As to the criteria devolving from the Helsinki conference, Dr. Teta described these as one effort to establish a unified approach to compensation for workers suffering from asbestos disease. See N.T., Oct. 18, 2005 (p.m.), at 102. According to Dr. Teta, these criteria are not an endorsed methodology in the United States for risk assessment or cancer causation. See id. at 103. Additionally, she noted that two of the participants in the conference already had published a paper finding no increased risk of mesothelioma among brake workers. Based on this observation, Dr. Teta concluded that, "[o]bviously[,] they were not thinking about vehicle mechanics when they came to these criteria for compensation." Id. at 104.

In summary, both Drs. Paustenbach and Teta rejected the methodology underlying the any-exposure opinion as scientifically unsound and illogical. See, e.g., N.T., Oct. 18, 2005 (a.m.), at 124 (reflecting Dr. Paustenbach's perspective that, based on a prophylactic regulatory response, "some physicians take a -- take a leap of faith" to specific disease causation).[8] The parties also submitted prior testimony from witnesses in other court proceedings; scientific papers; government, industrial, commercial, and trade publications; and other documents referenced and relied upon by the witnesses.

B. Judge Colville's Opinion

Upon his consideration of the evidence presented by both sides, Judge Colville sustained the Frye challenge and precluded the plaintiffs from adducing the any-exposure opinion. He described his review as follows:

> In resolving this Frye challenge I have considered the testimony of the witnesses, voluminous scientific literature, and numerous legal authorities proffered in support of the plaintiffs' and the defendants' respective positions. In the end, my decision ultimately rests upon whether the plaintiffs experts' opinions were based upon methodologies utilizing discrete and specific scientific principles logically applied in a manner that can be affirmatively articulated, referenced, reviewed, and tested, and empirically verified or whether the testimony was based upon the "best estimate," the "gut instinct," or the "educated guess" of the experts.

See In re Toxic Substance Cases, No. A.D. 03-319, slip op., 2006 WL 2404008, at *2 (C.P. Allegheny, Aug. 17, 2006).

[8] Both Drs. Paustenbach and Teta also discussed in detail the epidemiological evidence concerning the carcinogenicity of short chrysotile asbestos fibers which were found in friction products in the relevant time era. As noted, the scientific weight of this evidence is beyond the scope of Judge Colville's opinion and, therefore, our own. See supra note 1.

Judge Colville opened his ensuing review with a general discussion of asbestos, noting its natural occurrence and background presence in ambient air. See, e.g., id. at *3 ("[O]ne would expect to find, on average, one fiber of asbestos in every 10 liters of air on every street corner in Pittsburgh."). Further, he observed that no one contended that mere background or ambient air exposure was sufficient to cause asbestos-related disease. See id. ("The argument in this Frye challenge, in part, revolves around the question of how much greater quantity of exposure is necessary to permit the causal attribution of an asbestos-related disease to a particular asbestos exposure.").

Judge Colville recognized that no direct or observational evidence of causation plausibly could be expected of the plaintiffs. See id. at *4. Nevertheless, he reasoned that reliable expert opinion evidence was required from which a jury could infer that each of the defendants' products was a substantial factor in causing the plaintiffs' or decedents' diseases. See id. (explaining that an opinion as to general causation is insufficient to establish a prima facie case for liability).

Focusing upon methodology, Judge Colville found no support for the any-exposure theory of specific causation in any of the sources upon which Dr. Maddox relied. For example, the court acknowledged the value of case reports, in that they assist scientists in developing hypotheses regarding the correlations and associations between disease and other known factors. See id. at *4-5. Nevertheless, Judge Colville explained, "[c]ase reports are nothing more than reports by other physicians and professionals confirming the development of a disease in an individual patient with additional information about that patient." Id. at *4. While he regarded such reports as

an impetus toward inquiry and development of scientific proofs, he observed that they were not proofs of causation in and unto themselves. See id. at *5.[9]

Overall, Judge Colville could find no credible explanation for how it was that Dr. Maddox was able to determine if it was exposure to a defendant's friction product that caused a plaintiff's mesothelioma, and not some other exposure to asbestos material. See id. at *12. Rather, he agreed with the defendants' experts that Dr. Maddox's methodology was plagued by unwarranted liberties and logical errors. See, e.g., id. at *7, *13. Indeed, the court's reasoning suggests that Dr. Maddox's acknowledgement of the association between amount of exposure and risk of developing disease (couched as a dose-response curve) substantially undermines the any-exposure theory in terms of establishing legal causation. While the court did not discount that a single fiber may possibly increase the risk of developing disease, it did not accept that an unquantified (and potentially infinitesimal) increase in risk could serve as proof that a defendant's product was a substantial cause of a plaintiff's or decedent's disease. See id. at *11 (stating that "the [plaintiffs'] experts do not offer support or methodology other than their subjective belief that each and every breath of asbestos causes or substantially contributes to the disease process suffered by the [plaintiffs].").

In terms of the extrapolation (or, as Dr. Maddox would have it, interpolation) methodology, Judge Colville explained:

> The fallacy of the "extrapolation down" argument is plainly illustrated by common sense and common experience.

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[9] See also id. at *5 ("The reason case reports (even multiple case reports) cannot, alone, support a causal attribution opinion is because they only report associations -- not causal correlations."); id. ("The scientific method's requirement of empirical verification saves us from the peril of confusing 'coincidental association' with 'causal correlation.' Case reports alone, or in conjunction with other methodology short of empirical verification, do not meaningfully support the plaintiff's expert's opinions.").

> Large amounts of alcohol can intoxicate, larger amounts can kill; a very small amount, however, can do neither. Large amounts of nitroglycerine or arsenic can injure, larger amounts can kill; small amounts, however, are medicinal. Great volumes of water may be harmful, greater volumes or an extended absence of water can be lethal; moderate amounts of water, however, are healthful. In short, the poison is in the dose.
>
> * * *
>
> Generally accepted scientific methodology may well establish that certain "high dose" asbestos exposure causes, or contributes to, a specific hypothetical plaintiff's disease, but the plaintiffs have not proffered any generally accepted methodology to support the contention that a single exposure or an otherwise vanishingly small exposure has, in fact, in any case, ever caused or contributed to any specific individual's disease, or even less so, that in this case such a small exposure did, in fact, contribute to this specific plaintiff's disease.

In re Toxic Substance Cases, No. A.D. 03-319, slip op., 2006 WL 2404008, at *7-8.

Judge Colville also drew support from the position articulated by Judge Klein in the evenly divided Summers v. Certainteed Corp., 886 A.2d 240 (Pa. Super. 2005) (equally divided court), rev'd, 606 Pa. 294, 997 A.2d 1152 (2010):

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

> asbestos from the brakes is a "substantial" factor in causing disease.

Id. at 244 (opinion in support of affirmance) (emphasis in original).

Judge Colville acknowledged the plaintiffs' position found some support in the Superior Court's decisions in Smalls and Andaloro v. Armstrong World Industries, Inc., 799 A.2d 71 (Pa. Super. 2002) (holding, inter alia, that the issue of whether a naval yard worker was exposed to a manufacturer's product was for the jury). Nevertheless, he reasoned that Smalls did not involve a Frye hearing, and, moreover, the Superior Court had not provided any analysis as to why the any-exposure theory is, in fact, generally accepted in the relevant scientific community. See In re Toxic Substance Cases, No. A.D. 03-319, slip op., 2006 WL 2404008, at *16. With regard to Andaloro, Judge Colville believed that the only relevant analysis was dictum, which he read as merely reflecting the fact that, for asbestos fibers to cause disease processes within the human body, they must first be inhaled. The court found greater guidance in Rafter v. Raymark Industries, 632 A.2d 897 (Pa. Super. 1993), where the Superior Court stressed that a jury instruction did not equate the mere inhalation of asbestos with substantial-factor causation. See id. at 901-02.

Finally, Judge Colville declined to base his holding on the epidemiological evidence presented by the defendants in support of their Frye motion. See In re Toxic Substance Cases, No. A.D. 03-319, slip op., 2006 WL 2404008, at *14. In this regard, the court found it appropriate to maintain a close focus on Dr. Maddox's particular methodology. See id. ("This ruling is based upon inadequacies in the [Plaintiffs'] experts' methodologies, not upon the proffered merit of Defendants' epidemiological studies, or other explanations for why 'friction products are different.'").

Subsequent to the issuance of the common pleas court's Frye decision, Appellants sought and were awarded summary judgment, premised on the court's

disapproval of the any-exposure theory. Appellee lodged an appeal in the Superior Court, which reversed. See Betz v. Pneumo Abex LLC, 998 A.2d 962 (Pa. Super. 2010) (en banc).[10]

C. The Superior Court's Opinion

The Superior Court majority was very critical of Judge Colville's treatment of the Frye challenge on several fronts. First, the majority rejected the court's threshold finding of novelty. According to the majority, the defendants' Frye motion and supporting proffers were premised entirely upon the favorable epidemiological studies they offered and had nothing to do with the mechanics of Dr. Maddox's methodology.[11] See Betz, 998 A.2d at 975. Thus, the majority regarded Judge Colville's review of such mechanics, and decision not to address the epidemiological studies, as inapt. See id. Further, the majority attributed to Judge Colville a "preconceived opinion" on the

[10] The ordinary nine-member complement for the en banc panel was reduced due to attrition to six judges, as of the opinion's entry.

[11] In this regard, the Superior Court majority offered an unduly cramped perspective concerning the amended Frye motion, which repeatedly challenged the methodology underlying the any-exposure opinion. See, e.g., Amended Global Frye Motion of June 3, 2005, In re Toxic Substance Cases, No. A.D. 03-319, at ¶7 (C.P. Allegheny) (indicating that "any methodology or analysis which could possibly be used to arrive at or support [the any-exposure opinion] is inconsistent with the scientific method and not generally accepted in the relevant scientific communities"). While certainly the defendants stressed the epidemiological evidence supporting their position, they simultaneously mounted a direct attack on the methodology underlying the any-exposure theory and sought to put the plaintiffs to their proofs in establishing general acceptance of the underlying methodology. Notably, this understanding dovetails with Dr. Teta's report, which, as developed above, was submitted in response to Judge Colville's pre-hearing directive and provided an extensive critique of Dr. Maddox's methods. The defendants' position also is reflected in extensive argumentation and evidence they offered throughout the record. See, e.g., N.T., Aug. 17, 2005, at 21-22, 25-41; N.T., Oct. 17, 2005 (a.m.), at 25-43.

ultimate issue of general acceptance, which was grounded in his own personal concerns with the extrapolation-down methodology. See id.

While finding error in the threshold determination, the Superior Court nevertheless proceeded to review Judge Colville's finding as to general acceptance, concluding that he had abused his discretion. See id. at 976. Initially, the majority recognized that the burden of proof in a Frye hearing is on the proponent of the scientific evidence, in this case, Appellee. See Grady, 576 Pa. at 558, 839 A.2d at 1045. The majority then summarized Dr. Maddox's testimony, referencing his reliance on scientific literature, case reports, the Helsinki criteria, in-vitro studies, and government publications. See Betz, 998 A.2d at 976. The majority also noted Dr. Maddox's rejection of the epidemiological evidence concerning brake mechanics, as well as similar testimony by other expert witnesses in asbestos litigation. See id. According to the majority, "[t]he Friction Product Defendants did not respond with any expert testimony that Dr. Maddox's methodology . . . is not a generally accepted method for evaluating the causes of asbestos-related disease." Id. Indeed, the majority regarded various testimony presented by the defendants' experts as being consistent with the pathologist's statements. See id. at 976-77.[12] With regard to the Helsinki criteria, the court observed that an expert relied upon by the defendants had testified in other litigation that these are generally accepted. See id. at 977. The court also suggested that the only medical doctor upon whom the defendants relied could not testify, in other litigation at least, that the methodology upon which Dr. Maddox relied was not generally accepted. See id. at 977-78.

[12] In developing this point, the Superior Court majority did not make any distinction between the bulk of Dr. Maddox's testimony – which pertained to general causation – and the specific opinion at issue, namely, that any asbestos fiber inhaled by a plaintiff is a substantial cause of that plaintiff's asbestos-related diseases.

As a centerpiece of its opinion, the majority returned to the idea that Judge Colville had sua sponte questioned the validity of extrapolation from scientific findings pertaining to high-dose exposures to low-dose scenarios. See Betz, 998 A.2d at 978-79. According to the majority, the common pleas court's approach violated the tenet that judges are to be guided by the scientists in assessing the reliability of a scientific method, not the reverse. See id. at 979 (citing Grady, 576 Pa. at 557, 839 A.2d at 1044-45). Moreover, on the record discussed above, the majority stated "we have been unsuccessful in finding any record support for the trial court's analysis or conclusions." Id. at 980.

Additionally, the Superior Court relied on Trach as approving methodologies incorporating extrapolation. See id. at 980-81 ("[I]n Trach this Court concluded that scientists may extrapolate from a 'sound scientific basis' when formulating opinions about the etiology of disease, and that in these circumstances the use of extrapolation is 'not novel'" (quoting Trach, 817 A.2d at 1118-19)). The majority recognized that Trach involved extrapolation from the effects resulting from a smaller dose to a larger one, rather than the converse, but it found such distinction to be irrelevant, as the Trach court made no such distinction. See id. Furthermore, the majority found support in Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C. Cir. 1984), which the majority believed involved an "extrapolation down" scenario. Moreover, the majority quoted Ferebee for the proposition that:

> Judges, both trial and appellate, have no special competence to resolve the complex and refractory causal issues raised by the attempt to link low-level exposure to toxic chemicals with human disease. On questions such as these, which stand at the frontier of current medical and epidemiological inquiry, if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony.

Betz, 998 A.2d at 982 (quoting Ferebee, 736 F.2d at 1534).

Finally, the Superior Court acknowledged that, in Gregg v. V-J Auto Parts Co., 596 Pa. 274, 943 A.2d 216 (2007), this Court rejected the any-exposure opinion, as baldly stated in an expert report, as sufficient to overcome a plaintiff's threshold burden of product identification. See Betz, 998 A.2d at 982. Given the context of Gregg, however, the majority deemed it to be of limited relevance to the matter at hand. See id. Indeed, the majority observed, another en banc Superior Court panel recently had rejected a similar Frye challenge. See Estate of Hicks v. Dana Cos., 984 A.2d 943 (Pa. Super. 2009) (en banc).

In her concurring opinion, Judge Shogan agreed that Trach was instructive. Presumably in light of the tone set by the majority, however, she offered a defense of Judge Colville, highlighting the difficulty of his task and crediting him for his well-intentioned and conscientious efforts to address a confusing area of the law arising in a mass tort setting. See Betz, 998 A.2d at 984 (Shogan, J., concurring).

II. Arguments

The briefs of Appellants, as well as their amici,[13] provide a vigorous defense of Judge Colville's approach to the any-exposure opinion. In terms of his decision to

[13] The amici supporting Appellants' position include: 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 (collectively, "Pennsylvania Chamber, et al."); Product Liability Advisory Council, Inc. ("PLAC"); Crane Company; and a group of the following scientists: Richard Wilson, Patricia Buffler, John Henderson Duffus, Kenneth R. Foster, Ronald E. Gots, Thomas A. Kubic, Steven Lamm, A. Alan Moghissi, Robert Nolan, Malcom Ross, Emanuel Rubin, and James D. Watson (collectively, "Scientists").

conduct of a Frye hearing, Appellants maintain that such a hearing is appropriate where a colorable challenge is presented concerning general acceptance of an expert's methodology. They believe this was accomplished, at the very least, via the defendants' proffer that Dr. Maddox failed to follow the scientific method in forming the any-exposure opinion. In particular, while acknowledging that Dr. Maddox ostensibly accepted the applicability of the dose-response principle relative to asbestos-related diseases including mesothelioma, Appellants contend that his any-exposure opinion, in substance, nevertheless disregards this elemental precept in its entirety.[14]

Amici Scientists find it particularly troubling that the Superior Court quoted the decision of the United States Court of Appeals for the District of Columbia Circuit in Ferebee for the proposition that, so long as an expert is willing to testify to an extrapolation, courts should permit its admission. See Betz, 998 A.2d at 982. In their view, the notion that courts have no screening function "is at odds with the last 17 years of federal court evidence law, just as it was at odds with most federal circuits at the time it was written, and with states that have adopted Daubert[v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 113 S. Ct. 2786 (1993),] and those that adhere to Frye." Brief for Amici Scientists at 50.

Furthermore, Appellants and their amici contend, Judge Colville cannot have been wrong to be circumspect about permitting such an opinion to be put before a jury

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[14] Accord McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1241-42 (11th Cir. 2005) (characterizing dose as "the single most important factor to consider in evaluating whether an alleged exposure caused a specific adverse effect," (quoting Science for Judges I: Papers on Toxicology and Epidemiology, 12 J.L. & Pol'y 1, 11 (2003)), and explaining that an expert's failure to lay a reliable groundwork for assessing the dose-response relationship in a toxic tort scenario "signals a methodology problem" (emphasis added)); see also id. at 1242 ("The expert who avoids or neglects this principle of toxic torts without justification casts suspicion on the reliability of his methodology.").

of lay persons without testing. In this regard, Appellants highlight this Court's continuing concern with ensuring sufficient reliability of scientific evidence brought into the courtroom, see, e.g., Grady, 576 Pa. at 557, 839 A.2d at 1044; Topa, 471 Pa. at 232, 369 A.2d at 1282,[15] which, they add, scientists share. See, e.g., Brief for Appellant Allied Signal, Inc. at 15 n.25 (citing Alberto M. Marchevsky & Mark R. Wick, Current Controversies Regarding the Role of Asbestos Exposure in the Causation of Malignant Mesothelioma: The Need for an Evidence Based Approach to Develop Medicolegal Guidelines, 7 ANN. DIAGN. PATH. 321, 321-22 (2003) (characterizing the opinion

[15] Appellant Ford Motor Company also points to the more developed explanation by the Honorable Phyllis W. Beck:

> It is true that effective cross-examination is a powerful tool, and suffices to reveal the weaknesses in a witness's testimony where the lay jury is faced with common-sense questions of credibility or abilities of observation. However, the complex, confusing and possibly misleading details of scientific testimony do not so readily lend themselves to accurate assessment by even the most discerning jury. Much of such testimony is sophisticated and difficult to comprehend, and an analysis of the scientific validity of the methodologies underlying the testimony is simply beyond the capabilities of most lay persons. 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. Properly supported scientific evidence, however complex, can then reach the jury for its consideration, while material whose complexity merely hides its unreliability is winnowed out. This is, in essence, the teaching of Frye, and that teaching remains valid.

Brief for Appellant Ford Motor Co. at 52-53 (quoting Blum v. Merrell Dow Pharms., Inc., 705 A.2d 1314, 1325 (Pa. Super. 1997), aff'd, 564 Pa. 3, 764 A.2d 1 (2000)).

"attribut[ing] the causation of [malignant mesothelioma] to virtually any amount and any type of alleged asbestos exposure" as "clearly an extreme one")). Further, they argue, trial judges cannot meaningfully screen against "junk science" if they must take claims of reliance on scientific evidence and methods merely at face value. Brief for Appellant Allied Signal, Inc. at 14.[16]

Appellants and various amici also explain that the traditional and appropriate method of establishing disease etiology requires a case-specific investigation of the relevant exposure history.[17] They believe the any-exposure theory is also novel in that

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[16] Accord Brief for Amici Pennsylvania Chamber, et al. at 39-40 (indicating that Dr. Maddox "may be using a 'tool' of science (case reports) but he is 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."); Brief for Amicus PLAC at 7 ("Magic words and anecdotal evidence are no substitute for scientifically reliable data in resolving issues properly within the realm of science."); cf. Bert Black, A Unified Theory of Scientific Evidence, 56 FORDHAM L. REV. 595, 633 (1988) ("[A]n uncritical approach to acceptance allows a group that advocates a technique or method to self-validate it simply by declaring acceptance.").

[17] This observation finds support, inter alia, in the Federal Judicial Center's Reference Manual on Scientific Evidence, as follows:

> An expert who opines that exposure to a compound caused a person's disease engages in deductive clinical reasoning. . . . The opinion is based on an assessment of the individual's exposure, including the amount, the temporal relationship between the exposure and disease, and other disease-causing factors. This information is then compared with scientific data on the relationship between exposure and disease. The certainty of the expert's opinion depends on the strength of the research data demonstrating a relationship between exposure and the disease at the dose in question and the presence or absence of other disease-causing factors (also known as confounding factors).

Bernard D. Goldstein & Mary Sue Henifin, Reference Guide on Toxicology, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 665 (3d ed. 2011).

it obviates such inquiry. See, e.g., Brief for Amicus PLAC at 6 ("Neither the relevant scientific community nor the courts recognize 'evidence-free' causation opinions as scientifically valid. With precisely zero information concerning the decedent's exposure, plaintiff's expert could not possibly opine upon 'cumulative' or 'dose-related' grounds."). Indeed, Appellant Ford Motor Company reads the responsive expressions of members of this Court in two recent decisions as recognizing that the any-exposure opinion facially implicates the Frye test. See Summers, 606 Pa. at 318-24, 997 A.2d at 1166-69 (Saylor, J., concurring); Gregg, 596 Pa. at 296-97, 943 A.2d at 229-30 (Baer, J., dissenting, joined by Baldwin, J.).

Next, Appellants criticize the Superior Court's application of the appellate review standard applicable to a Frye ruling. They argue that the intermediate court's approach fails to reflect the necessary deference inherent in the applicable abuse-of-discretion standard. See Grady, 576 Pa. at 559, 839 A.2d at 1046 (explaining that the abuse of discretion standard applies in the context of a Frye ruling, and "[a]n abuse of discretion may not be found merely because an appellate court might have reached a different conclusion, but requires a result of manifest unreasonableness, or partiality, prejudice, bias, or ill-will, or such lack of support so as to be clearly erroneous" (citing Paden v. Baker Concrete Constr. Inc., 540 Pa. 409, 412, 658 A.2d 341, 343 (1995))). Rather, they assert, the Superior Court simply ignored the extensive evidence as well as the strong logic supporting Judge Colville's disposition and improperly substituted its judgment for his.[18] In particular, Appellants argue that the Superior Court's decision

[18] As a component of this analysis, Appellants and their amici point out that some of the Superior Court's explanations are flatly contradicted by the record. For example, the intermediate court indicated that Dr. Maddox testified that the dose-response curve pertaining to asbestos disease is linear, see Betz, 998 A.2d at 982; whereas, Dr. Maddox's actual testimony was that he could not say whether the dose-response relationship was linear. See N.T., Oct. 17, 2005 (a.m.), at 83. As another example, (continued…)

hinges, in large part, upon its crediting of Dr. Maddox's own assertions that his methods were generally accepted. Additionally, the briefs of Appellants and their amici generally convey incredulity as concerns the understanding of the Superior Court that Judge Colville's finding of a lack of general acceptance takes no support from the record. See, e.g., Brief for Appellant Ford Motor Company at 54 ("[I]t is a bit of a mystery how, after its 'exhaustive search,' the Superior Court could be 'unsuccessful in finding any record support for the trial court's analysis or conclusions.'" (quoting Betz, 998 A.2d at 980)). In their view, Judge Colville's position finds overwhelming support both in the record of the Frye hearing -- to which they provide extensive citation -- and otherwise. See, e.g., Brief for Appellant Allied Signal, Inc. at 41 ("[T]he trial court's rejection of the 'every breath' mantra, while logical in its analysis, is also firmly rooted in the common law, as well as in the current science and medicine regarding toxic exposures in the workplace.").

On this topic, Appellants and their amici offer extensive critiques of Dr. Maddox's methodology from both scientific and logical perspectives, with myriad cross-references to the testimony of Drs. Maddox, Paustenbach, and Teta. In general, consistent with the testimony of Drs. Paustenbach and Teta, Appellants maintain that the any-exposure opinion remains a hypothesis or assumption, accord, e.g., Whiting v. Boston Edison Co., 891 F. Supp. 12, 24 (D. Mass. 1995) (rejecting expert's "non-threshold" theory as an unverifiable hypothesis which was incapable of assisting a jury in resolving the ultimate issue of disease causation), while stressing Dr. Maddox's inability to identify any peer-reviewed scientific support undergirding the opinion. According to Appellants,

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(…continued)
amici Scientists regard the Superior Court's assertion that the testimony of the defendants' experts demonstrated the general acceptance of Dr. Maddox's methodology as a "misreading of the record." Brief for Amici Scientists at 22 n.5.

moreover, the pathologist's self-admitted selectivity in his approach to the literature is decidedly inconsistent with the scientific method. Accord Brief for Amici Scientists at 17 n.2 ("'Cherry picking' the literature is also a departure from 'accepted procedure.'").

The briefs develop the limited role which should be accorded to anecdotal reports in legitimate scientific methodology, on account of the possibility of false associations. See generally David H. Kaye & David A. Freedman, Reference Guide on Statistics, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 217-19 (3rd ed. 2011); cf. Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1411 (D. Or. 1996) ("[C]ase reports and case studies are universally regarded as an insufficient basis for a conclusion regarding causation because case reports lack controls."). As to Dr. Maddox's reliance on animal studies, Appellants point out the need to demonstrate reasonable similarity in effect. See, e.g., General Elec. Co. v. Joiner, 522 U.S. 136, 143-45, 118 S. Ct. 512, 518 (1997) (holding that a district court did not abuse its discretion in excluding an opinion relying, in part, on extrapolation from high-dose animal studies to low-dose human disease scenarios, where there was no attempt to explain how the animal subjects and humans have similar physiological makeup and rate of chemical absorption).

With regard to regulatory standards and thresholds, Appellants and their amici reference many sources -- including the United States Supreme Court -- for the proposition that these do not establish legal causation given their cautionary, prophylactic nature.[19] See, e.g., Brief for Appellant Allied Signal, Inc. at 26-27 ("[T]o

[19] Accord Matrixx Initiatives, Inc. v. Siracusano, ___ U.S. ___, 131 S. Ct. 1309, 1320 (2011) (indicating that administrative agencies "may make regulatory decisions . . . based on postmarketing evidence that gives rise to only a suspicion of causation"); McClain, 401 F.3d at 1250 (explaining that administrative risk-utility analysis does not focus on the question of causation in individuals, and, therefore, it "is unreliable proof of medical causation in the present [tort] case"); Rider v. Sandoz Pharms. Corp., 295 F.3d 1194, 1201 (11th Cir. 2002) (explaining that a regulatory "risk-utility analysis involves a much lower standard that that which is demanded by a court of law"); Sutera v. Perrier (continued…)

take a highly protective precautionary governmental policy on risk assessment and bootstrap it into causation opinions in court, is not only scientifically improper, but also nonsensical because it bastardizes a social and political policy, which was unproven scientifically, by attempting to make it scientific fact." (footnote omitted)). In terms of the Helsinki criteria, created under the auspices of the Finish Ministry of Social Affairs and Health, Appellants observe that participation in the conference was selective; the purpose was to fashion a recommended compensation scheme unto itself, not to provide a measure of legal causation appropriate to longstanding requirements of Pennsylvania tort law; and, in any event, the conference reports do not state anywhere that every exposure to asbestos, regardless of dose, is causative. See generally Asbestos, Asbestosis, and Cancer: the Helsinki Criteria for Diagnosis and Attribution, 23 SCAN. J. WORK, ENV'T. & HEALTH 311, 313 (1997). More broadly, Appellants stress that the scientific method is grounded in testing, see, e.g., Daubert, 509 U.S. at 593, 113 S. Ct. at 2796; accord Brief for Amici Scientists at 28 (explaining that "empirical testing is the hallmark of scientific methodology"), and that Dr. Maddox's opinion remains wholly untested.

(…continued)
Group of Am. Inc., 986 F. Supp. 655, 666 (D. Mass. 1997) (explaining that a regulatory standard or pronouncement, "rather than being a measure of causation is a public health exposure level that an agency determines pursuant to statutory standards set by Congress") (citing Indus. Union Dep't, AFL-CIO v. Am. Petrolium Inst., 448 U.S. 607, 632, 100 S. Ct. 2844, 2859 (1980))); Parker v. Mobil Oil Corp., 857 N.E.2d 1114, 1122 (N.Y. 2006) ("[S]tandards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation."). See generally Edward J. Schwartzbauer and Sidney Shindell, Cancer and the Adjudicative Process: The Interface of Environmental Protection and Toxic Tort Law, 14 AM. J.L. & MED. 1, 12 (1988) ("[T]he no-threshold, or linear assumption, can be better understood if it is clearly recognized as a bit of regulatory science policy, and not a principle of science subject to proof through the scientific method.").

In terms of extrapolation, Appellants dismiss the pathologist's protestations as to whether he employed it, while highlighting the Superior Court's acceptance of as much in any event. See Betz, 998 A.2d at 983 (observing that, in order to reach his conclusion regarding causation, Dr. Maddox "utilized the method of logic known as extrapolation").[20] Appellants do not discount that the approach may validly be employed as a component of generally accepted scientific methodology, but they contend that an opinion based on extrapolation can be sound only to the degree that it is supported by a sufficiently strong logical inference. See, e.g., Brief for Amici Pennsylvania Chamber, et al. at 37 ("The extrapolation at issue is only as good as the reasoning behind it[.]").[21] While no one disputes that long-term, direct, high-dose exposure to the more potent forms of friable asbestos fibers causes disease,[22] Appellants and their amici point to various sources in the scientific literature as confirming that no rational inference

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[20] Although Dr. Maddox preferred the term "interpolation," Appellants point out that interpolation entails placement on a continuum between known quantities; whereas, Dr. Maddox's methodology extrapolating from a single known (high-dose exposure causes asbestos disease) all the way down to zero. In either event, the principles derived from Trach -- namely, the requirement of sufficiently strong logic supporting the inference, see infra -- would apply either to extrapolation or interpolation.

[21] Accord Blackwell v. Wyeth, 971 A.2d 235, 253 (Md. 2009) (explaining that "extrapolation requires more than mere conjecture to pass reliability scrutiny" under Frye); cf. Moore v. Ashland Chem. Inc., 151 F.3d 269, 279 (5th Cir. 1998) (commenting that "[s]everal post-Daubert cases have cautioned about leaping from an accepted scientific premise to an unsupported one").

[22] See, e.g., Brief for Appellant Allied Signal, Inc. at 7 ("The asbestos epidemiological studies regarding the health hazards of asbestos insulators and shipyard workers of Dr. Irving Selikoff and his associates at the Mount Sinai School of Medicine in the mid-1960's revealed the risks of long-term, high intensity occupational exposure to asbestos.").

justifies large-scale downward toxicological extrapolations from such proposition.[23] Brief for Amici Pennsylvania Chamber, et al. at 7-8 (contending that the Superior Court erred in "concluding that Dr. Maddox could cross the Mississippi River on nothing but small bridges"). They also reference decisional law from other jurisdictions as supportive of their position. See, e.g., In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig., 524 F. Supp. 2d 1166, 1180 (N.D. Cal. 2007) ("The justification for extrapolating drug effects between biologically similar demographic groups . . . does not logically extend to the argument that all doses of a compound are harmful; accordingly, plaintiffs' experts could not cite to a single piece of evidence that suggests that their experts' extrapolation is scientifically valid.").

Furthermore, it is Appellants' position that the any-breath opinion is fundamentally inconsistent with substantial-factor causation, since the former obviates the latter by converting proof of the very smallest exposure into causation.[24] In this

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[23] Accord ANDREW CHURG & F.H.Y. GREEN, PATHOLOGY OF OCCUPATIONAL LUNG DISEASE 342 (2d ed. 1998) (characterizing the scientific validity of extrapolating from high- to low-dose exposures as "at best dubious"); W. RAYMOND PARKES, OCCUPATIONAL LUNG DISORDERS 480-81 (Butterworth-Heinemann 1994) ("Extrapolation without any supporting data to very low doses followed, first as a convenience, but then as a popular article of faith, despite the acknowledged statistical illegitimacy of this procedure and despite the biological absurdity of the assumption that the body has no defense against inhaled fibers at any level, however low."); cf. Burleson v. Tex. Dep't of Crim. Justice, 393 F.3d 577, 587 (5th Cir. 2004) (observing that, under the Daubert regime at least, "[a] court may rightfully exclude expert testimony where a court finds that an expert has extrapolated data, and there is 'too great an analytical gap between the data and the opinion proffered.'" (quoting Joiner, 522 U.S. at 146, 118 S. Ct. at 519)).

[24] See, e.g., Brief for Appellant Allied Signal, Inc. at 44 ("No threshold for risk means no threshold for causation. If permitted to stand, such a legal proposition effectively eliminates the common law axiom that the legal cause for harm be a 'substantial contributing factor' in the cause of that harm."); accord Martin v. Cincinnati Gas and Elec. Co., 561 F.3d 439, 443 (6th Cir. 2009) (explaining that "an expert's opinion that 'every exposure to asbestos, however, slight, was a substantial factor' . . . would render (continued…)

regard and others, Appellants draw support from Gregg, 596 Pa. at 291-92, 943 A.2d at 226-27 (rejecting the any-exposure opinion as a means to circumvent the frequency-regularity-proximity threshold pertaining to product identification).

Finally, Appellants and their amici highlight that Judge Colville's approach to the any-exposure opinion finds strong support in various decisions of other Pennsylvania tribunals and courts of other jurisdictions. The following Pennsylvania decisions are cited: Summers, 606 Pa. at 310 n.14, 997 A.2d at 1161 n.14 ("[T]his Court recently rejected the viability of the 'each and every exposure' or 'any breath' theory."); Gregg, 596 Pa. at 291-92, 943 A.2d at 226-27; In re Asbestos Litig., No. 0001, 2008 Phila. Ct. Com. Pl. LEXIS 229 (C.P. Philadelphia, Sept. 24, 2008) (Tereshko, J.); Basile v. Am. Honda Motor Co., No. 11484 CD 2005, 2007 Pa. Dist. & Cnty. Dec. LEXIS 444 (C.P. Indiana, Mar. 1, 2007) (Olson, J.). The many cases cited from other jurisdictions include those referenced above.[25]

(…continued)
the substantial factor test 'meaningless'" (citing Lindstrom v. A-C Prod. Liab. Trust, 424 F.3d 488, 493 (6th Cir. 2005))). See generally Brief for Amici Pennsylvania Chamber, et al. at 6-7 ("Other courts have noted that the theory makes a mockery of the substantial factor standard since every exposure becomes substantial and nothing is insubstantial.").

[25] See also Wills v. Amerada Hess Corp., 379 F.3d 32, 49-50 (2d Cir. 2004) (rejecting an any-exposure opinion as a means to obviate the need to address other potential causes); Nat'l Bank of Commerce v. Associated Milk Producers, Inc., 191 F.3d 858, 860-61 (8th Cir. 1999) (outlining the proposition that the only conclusion properly drawn from the methodology underlying an any-exposure opinion is that the risk of disease "is not zero," but this "does not provide a scientific basis for a jury to find that it was more likely than not that [a plaintiff's] cancer was caused by [a defendant's product]"); Henricksen v. ConocoPhillips Co., 605 F. Supp. 2d 1142, 1165-66 (E.D. Wash. 2009) ("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 (continued…)

In her responses to the above arguments by the Appellants, Appellee maintains that Dr. Maddox's methodology is "utterly mainstream" and has been utilized in a similar context before the Pennsylvania courts by numerous well qualified experts over many years. Brief for Appellee at 9. In support, Appellee provides pages of citations to trial and deposition transcripts, see id. at 6-8, as well as references to several Superior Court opinions, including Smalls.[26] Appellee submits that application of a theory that for

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(…continued)
response in populations.'" (citation omitted)); Bartel v. John Crane, Inc., 316 F. Supp. 2d 603, 611 (N.D. Ohio 2004) (rejecting the any-exposure theory as unsupported by medical literature), aff'd Lindstrom, 424 F.3d at 488; Sutera, 986 F. Supp. at 666 ("[T]here is no scientific evidence that the linear no-safe threshold analysis is an acceptable scientific technique used by experts in determining causation in an individual instance."); In re W.R. Grace & Co., 355 B.R. 462, 476 (Bankr. D. Del. 2006); Borg-Warner Corp. v. Flores, 232 S.W.3d 765, 773 (Tex. 2007) (rejecting the any-exposure opinion, in favor of "[d]efendant-specific evidence relating to the approximate dose to which the plaintiff was exposed, coupled with evidence that the dose was a substantial factor in causing the asbestos-related disease"); Butler v. Union Carbide Corp., 712 S.E.2d 537, 552 (Ga. Ct. App. 2011) ("Dr. Maddox's 'any exposure' theory is, at most, scientifically-grounded speculation: an untested and potentially untestable hypothesis."); Smith v. Kelly-Moore Paint Co., 307 S.W.3d 829, 839 (Tex. App. 2010) ("'[W]ithout . . . scientific evidence of the minimum exposure level leading to an increased risk of development of mesothelioma' . . . Dr. Maddox's opinion lacks [] factual and scientific foundation . . . and, thus, is insufficient to raise a fact issue."). See generally Michael 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) (discussing, with approval, the case law rejecting any exposure theory). As an appendix to their brief, amici Pennsylvania Chamber, et al., have included a compendium of cases which includes additional intermediate and trial court decisions from other jurisdictions.

[26] See also Cauthorn v. Owens Corning Fiberglas Corp., 840 A.2d 1028, 1038-39 (Pa. Super. 2004) (approving expert testimony to the effect that "[e]ach breath of air that contained asbestos fibers substantially contributed to the development of [the plaintiff's] diseases," explaining that "[b]ecause any asbestos fiber will cause some degree of injury . . . each fiber will have some small effect and it's the cumulative effect of all the different fibers."); Lonasco v. A-Best Prods. Co., 757 A.2d 367, 275 (Pa. Super. 2000) (approving the opinion that "each exposure to asbestos . . . before the latency period . . . has . . . been a substantial, contributing cause").

years has routinely been espoused by experts in the field and admitted by courts cannot fairly be termed "novel." According to Appellee, the general acceptance of the attribution of mesothelioma to any occupational history of asbestos exposure is widely recognized by the courts, and has been embodied in the Helsinki criteria, which Appellee characterizes as a consensus statement of experts in the relevant field. Thus, she sees no justification for conducting a Frye hearing in the first instance.[27]

Appellee also argues that, as a matter of law, epidemiologists are not competent to render an opinion concerning the method by which a medical doctor should determine the etiology of a disease. See Brief for Appellee at 17 (quoting Toogood v. Rogal, 573 Pa. 245, 262, 824 A.2d 1140, 1149 (2003) ("The cause and effect of a physical condition lies in a field of knowledge in which only a medical expert can give a competent opinion.")). In this regard, Appellee labels Appellants' challenge as "generic" and, thus, inconsistent with the particularized nature of the Frye inquiry. See id. at 18 (citing Grady, 576 Pa. at 554, 839 A.2d at 1044 (explaining that the Frye inquiry is focused on "the field to which the evidence belongs")).

Like the Superior Court, Appellee regards Appellants' primary substantive line of attack as being bound up inextricably with the epidemiological evidence they presented.

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[27] See, e.g., Brief for Appellee at 10 ("This case does not involve an expert trying to break new ground with a novel, not-yet accepted methodology; rather, it concerns an effort by the Friction Product Defendants to enlist the aid of the courts in erecting/imposing a limitation on a universally accepted scientific principle that has not been so limited by medical experts in the field."); id. at 13 ("By eschewing any argument concerning the novelty or general acceptance of Dr. Maddox's methodology in his particular field of expertise, and urging instead that the methodology is unreliable based on purported principles from outside of that field, Appellants are in effect inviting this Court to abandon the Frye test in favor of a more activist judicial role as arbiter of scientific orthodoxy.").

She stresses, however, that the trial court refused to address that evidence.[28] Moreover, she questions its relevance in relation to the position of a practicing pathologist.

Appellee does not squarely address Appellants' arguments concerning differences in potency among asbestos fibers, or the potential that exposure to asbestos from a defendant's product might be minimal in comparison to others. Rather, she focuses, more broadly, on the uniquely strong relationship between asbestos and mesothelioma.[29] Based on this relationship, Appellee asserts, "the accepted method for

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[28] Additionally, citing to concerns raised by Mr. Chief Justice Castille in his dissenting opinion in Blum, 564 Pa. at 25, 764 A.2d at 14 (Castille, J., dissenting), Appellee suggests that friction-product defendants commissioned the epidemiological studies upon which Appellants rely, and that such involvement impairs their reliability. See, e.g., Brief for Appellee at 22. In reply, Appellants indicate that defendants' involvement was limited to only a few of the relevant studies. See, e.g., Brief for Appellant Ford Motor Company at 19 n.8.

[29] For instance, Appellee supplies the following quotation:

> Mesothelioma is a classic example of a signature disease. A signature disease is one which is "extremely rare in the general population but far more prevalent among those exposed to a particular substance; the disease in a sense bears the signature of the substance." . . .
>
> The causal link between asbestos exposure and mesothelioma contraction has been demonstrated to such a high degree of probability, while at the same time few if any other possible causes have been identified, that a universal causal relationship had been recognized; to wit: if A is diagnosed as having mesothelioma and A was exposed to asbestos, A's exposure to asbestos is recognized to be the cause of A's mesothelioma.

Torregon v. Mobil Oil Corp., 876 So.2d 877, 892-93 (La. Ct. App. 2004) (quoting Daniel A. Farber, Toxic Causation, 71 MINN. L. REV. 1219, 1251-52 (1987)).

causal attribution of mesothelioma is simple: If a subject with mesothelioma has a history of exposure to asbestos, pathologists and other experts in the field of asbestos disease etiology deem the mesothelioma to be caused by the asbestos exposure." Brief for Appellee at 11. According to Appellee, "this principle does not distinguish among types of asbestos, or types of asbestos-containing products, and does not require extensive high-level exposure." Id. at 12. Moreover, because, Appellee contends, the present case involves substantial occupational exposure to asbestos-containing products over a decades-long career, it is not an appropriate vehicle for addressing issues concerning attribution of disease to de minimus exposure, which Appellee believes is solely the concern of the frequency-regularity-proximity test addressed in Gregg.[30]

According to Appellee, the trial court's conclusion that the methodology underlying the any-exposure opinion lacks general acceptance is not founded upon expert opinion in the relevant field, but, rather, rests entirely on the court's own view of the applicable science. She regards such an approach as being fundamentally inconsistent with the Frye rule, which requires that judges be guided by the scientists, and not the converse. See Grady, 576 Pa. at 557, 839 A.2d at 1044-45; cf. Kennedy v. Collagen Corp., 161 F.3d 1226, 1230 (9th Cir. 1998) ("Judges in jury trials should not exclude expert testimony simply because they disagree with the conclusions of the expert."). See generally Brief for Appellee at 20 ("The reasoning of the Trial Court in the present case illustrates the perils of unguided judicial forays into the realm of science.").

[30] In their reply brief, Appellants take issue with Appellee's assertion that Dr. Maddox relied on Mr. Simikian's occupational history, since he testified that he was unfamiliar with it and had no need for it given his any-exposure opinion. See Joint Reply Brief for Appellants at 3 ("Ms. Betz's assertion that Dr. Maddox's opinion was in any manner based on Mr. Simikian's occupational history of exposures is simply a misrepresentation of fact.").

With regard to extrapolation, it is Appellee's position that Dr. Maddox did not use this technique as part of his methodology. Appellee sets out her position on this point as follows:

> [T]he Trial Court simply presumed that Dr. Maddox's endorsement of the proposition that every exposure contributes to causation of mesothelioma must have been based upon downward extrapolation. But that presumption was manifestly mistaken. Dr. Maddox did not opine that each exposure was sufficient unto itself to cause mesothelioma, and he did not attempt to attribute Mr. Simikian's disease to a minimal dose. Rather, he testified that every exposure contributes "in a cumulative and dose-related manner." Dr. Maddox's recognition that the cumulative exposure (which is deemed causal under generally accepted principles) is made up of the aggregate of individual exposures does not in any way depend on any method involving downward extrapolation.

Brief for Appellee at 25-26 (citations omitted).[31]

Like Appellants, Appellee also claims the weight of authority from the decisional law is on her side. Cases from other jurisdictions she references include: Berger v. Amchem Prods., 818 N.Y.S.2d 754, 761-62 (Sup. Ct. N.Y. Cnty. 2006) (refusing to conduct a Frye hearing relative to testimony similar to that of Dr. Maddox in an action against defendants including friction-product manufacturers); Chapin v. A&L Parts, Inc., 732 N.W.2d at 587, 587 (Mich. Ct. App. 2007) (approving the admission of the plaintiffs' expert testimony in a similar scenario); see also In re Asbestos Prods. Liab. Litig., No. 10-cv-61118, 2011 WL 605801, at *7 (E.D. Pa. Feb. 16, 2011) (citing the Superior

[31] In this way, like Dr. Maddox, Appellee appears to prefer to address general rather than substantial-factor causation. However, there should be no mistake, based on this record, that Judge Colville's primary concern from the outset was with the use of the any-exposure theory to prove substantial-factor causation.

Court's Betz decision with approval and finding the any-exposure opinion "sufficiently reliable to meet the admissibility standard" of Federal Rule of Evidence 702).

Appellee finds it to be the consensus view of experts in the field of asbestos disease etiology, that, where a mesothelioma subject has a history of exposure, the disease is attributable to that exposure, with every instance in the pre-latency time period contributing. Under Frye, she maintains, an expert should be permitted to testify consistently with such asserted consensus view. It is her position that any assessment concerning the substantiality of any particular subset of the exposure history is solely for the jury. See Brief for Appellee at 28; accord N.T., Aug. 17, 2005, at 120 (reflecting the argument of a plaintiff's counsel that "[w]e just have to say he breathed some fibers").

III. Discussion

A. The Decision to Conduct a Frye Hearing

At the outset, we find Judge Colville's decision to conduct a Frye hearing concerning the any-exposure opinion to be appropriate.

There is inherent tension among the various measures for admissibility of expert testimony. The threshold common law test requires merely some reasonable pretension to specialized knowledge. See, e.g., Miller v. Brass Rail Tavern, Inc., 541 Pa. 474, 480, 664 A.2d 525, 528 (1995). Our evidentiary rules, on the other hand, suggest trial courts may take a greater role in assessing whether the testimony will assist the trier of fact to understand the evidence or determine a fact in issue, see Pa.R.E. 702, and in screening evidence to avoid unfair prejudice, confusion of the issues, or misleading of the jury, see Pa.R.E. 403. For better or for worse, however, in the context of the more conventional realms of science, the Pennsylvania decisions tend to downplay the courts' screening function. See, e.g, Commonwealth v. Nazarovitch, 496 Pa. 97, 101, 436 A.2d 170, 172 (1981) ("'[C]ourts will go a long way in

admitting expert testimony deduced from a well-recognized scientific principle or discovery[.]" (quoting Frye, 293 F. at 1014)). A manifestation of this trend is that challenges generally are vetted through the Frye litmus, which winnows the field of the attacks by application of the threshold requirement of novelty. See Grady, 576 Pa. at 555, 839 A.2d at 1043-44.[32]

Various reasons underlie the preference to limit the courts' involvement in determining the admissibility of scientific evidence. There is the concern that liberality in allowing challenges would substantially increase the number of challenges (and cases in which lengthy pre-trial proceedings would ensue). The competency of trial judges to accept or reject scientific theories remains a legitimate subject of controversy. Additionally, a claim or defense in many cases may rise or fall based upon expert testimony and, therefore, there is some reluctance on the part of courts to deprive litigants of their day in court.

On the other hand, this Court has recognized the influential nature of expert testimony on complex subjects, and the potential that distortions have to mislead laypersons. See id. at 558, 839 A.2d at 1045; Topa, 471 Pa. at 231-33, 369 A.2d at 1281-82. It would be naïve, in this regard, to assume that the possibility for distortion is limited to the very newest realms of science. Cf. Grady, 576 Pa. at 557, 839 A.2d at 1045 (explaining that Frye applies not only to novel science, but also where scientific methods are utilized in a novel way).

We therefore agree with Appellants that a reasonably broad meaning should be ascribed to the term "novel." Furthermore, we conclude that a Frye hearing is warranted when a trial judge has articulable grounds to believe that an expert witness

[32] This case was not selected as a vehicle to assess what force Rules 702 and 403 have, in the arena of scientific evidence, apart from Frye. Our only point here is that many of the challenges currently are being channeled through Frye.

has not applied accepted scientific methodology in a conventional fashion in reaching his or her conclusions. Accord id. We believe a narrower approach would unduly constrain trial courts in the appropriate exercise of their discretion in determining the admissibility of evidence. See id. at 559, 839 A.2d at 1046.

In the present case, Judge Colville was right to be circumspect about the scientific methodology underlying the any-exposure opinion. He spent considerable time listening to the attorneys' arguments but was unable to discern a coherent methodology supporting the notion that every single fiber from among, potentially, millions is substantially causative of disease. Moreover, he appreciated the considerable tension between the any-exposure opinion and the axiom (manifested in myriad ways both in science and daily human experience) that the dose makes the poison. Contrary to the perspective of the Superior Court majority, Judge Colville was not misguided in his desire to probe how Dr. Maddox could simultaneously maintain that mesothelioma is dose-responsive and that each and every fiber among millions is substantially causative.[33]

As is also reflected above, the any-exposure opinion is also very significant, in that it obviates the necessity for plaintiffs to purse the more conventional route of establishing specific causation (for example, by presenting a reasonably complete

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[33] As the United States Supreme Court has explained:

> A dose-response curve shows the relationship between different exposure levels and the risk of cancer [or any other disease] associated with those exposure levels. Generally, exposure to higher levels carries with it a higher risk, and exposure to lower levels is accompanied by a reduced risk.

Indus. Union Dep't, AFL-CIO, 448 U.S. at 632 n.33, 100 S. Ct. at 2859 n.33 (quoting Am. Petrolium Inst. v. OSHA, 581 F.2d 493, 504 n.24 (5th Cir. 1978)).

occupational history and providing some reasonable address of potential sources of exposure other than a particular defendant's product). Given both the controversial nature of the any-exposure opinion and its potency in asbestos litigation, Judge Colville pursued the sensible course of permitting evidentiary development so that he could make an informed assessment. Indeed, the Superior Court majority appeared to recognize that "the attempt to link low-level exposure to toxic [substances] with human disease . . . stand at the frontier of current medical and epidemiological inquiry." Betz, 998 A.2d at 982 (quoting Ferebee, 736 F.2d at 1534). It also should have appreciated, then, that the any-exposure opinion is precisely the sort of evidence that merits thoughtful inquiry, as undertaken by Judge Colville.

B. The Appellate Standard of Review

While the orders before the Superior Court awarded summary judgment, an appeal of a final order subsumes challenges to previous interlocutory decisions such as Judge Colville's Frye ruling. See K.H. v. J.R., 573 Pa. 481, 493-94, 826 A.2d 863, 870-71 (2003). Generally, the appropriate appellate standard of review is the one pertaining to the underlying ruling. See Gallagher v. PLCB, 584 Pa. 362, 377 n.11, 883 A.2d 550, 559 n.11 (2005). In the context of Judge Colville's Frye ruling, therefore, the abuse of discretion standard applies. See Grady, 576 Pa. at 559, 839 A.2d at 1046. We also observe that the plaintiffs, as the proponents of expert scientific evidence, bore the burden of establishing all of the elements supporting its admission. See id. at 558, 839 A.2d at 1045.

C. The Relevant Field of Science

As discussed previously, Appellee takes the position that the defendants could not address the methodology of a pathologist, Dr. Maddox, through the testimony of risk assessors, toxicologists, and epidemiologists. We disagree.

Dr. Maddox identified himself as a community hospital pathologist "try[ing] to present the medical literature as I understand it." N.T., Oct. 17, 2005 (p.m.), at 89-90. He did not indicate, however, that his opinion was based on a particular clinical diagnosis; indeed, he expressed no familiarity whatsoever with Mr. Simikian's individual circumstances. Instead, Dr. Maddox offered a broad-scale opinion on causation applicable to anyone inhaling a single asbestos fiber above background exposure levels. In doing so, he took it upon himself to address (and discount) the range of the scientific literature, including pertinent epidemiological studies.

Dr. Maddox's any-exposure opinion simply was not couched in terms of a methodology or standard peculiar to the field of pathology. Accord Brief for Amici Scientists at 47 ("Physicians do not assign causation every day. That is not part of clinical practice."). Rather, he explained that it was based on the interpretation of "dose response curves in terms of pharmacology and toxicology." N.T., Oct. 17, 2005 (p.m.), at 90; see also id. at 153 (articulating the pathologist's risk-related perspective as "a standard principle with toxic exposures to tobacco, to asbestos, any of these materials."). Indeed, the pathologist acknowledged that the rendition of a broad and generally applicable opinion concerning specific causation was outside the range of his usual professional activities. See id. at 79-80 ("[M]ost of my day-to-day work deals with individual patients, not with groups of patients that epidemiologic concepts will be used upon. So, . . . most of the time the material on the patient is brought to me with a question of do you see a mesothelioma in this shipyard worker.").

Moreover, as is clear from various passages of Dr. Maddox's testimony set forth in our discussion of the background, his opinion was plainly grounded on risk assessment. In this regard, the following comment of Dr. Paustenbach's carries a fair amount of resonance:

> I don't think [risk assessment] is in the realm of pathologists anyway. I think it is in the realm of toxicologists and risk assessors. Our training is in that.

N.T., Oct. 17, 2005 (p.m.), at 179. Dr. Teta also testified that scientific methodology with respect to disease causation is her core discipline as an epidemiologist. See N.T., Oct. 18, 2005 (p.m.), at 11. Judge Colville did not err in entertaining the testimony of these witnesses on subjects which are not within the particular expertise of a pathologist, but, rather, are interdisciplinary in character.

D. The Any-Exposure Opinion

The understanding that Dr. Maddox's any-exposure opinion is fundamentally risk-based undergirds the primary conceptual concern of the common pleas court. Judge Colville reasonably questioned how it was -- if all Dr. Maddox could say is that a risk attaches to a single asbestos fiber -- that he could also say that such risk is substantial when the test plaintiffs may have been (and likely were) exposed to millions of other fibers from other sources including background exposure.

Appellee attempts to answer this question by shifting the focus back to Mr. Simikian's particular instance, arguing that -- in light of his more than four-decade history as an automotive mechanic -- his is not a case of de minimus occupational exposure. The difficulty, however, is that this case was selected among test cases for the any-exposure opinion as a means, in and of itself, to establish substantial-factor causation. In this regard, the plaintiffs repeatedly advised Judge Colville that there was

no need for them to discuss individual exposure histories, so long as they could establish exposure to at least a single fiber from each defendant's product. See N.T., Aug. 17, 2005, at 76 ("As a matter of law, you just say, hey, you breathed asbestos from a product, oh, you are going to the jury."); id. at 120 ("We don't have to show the amount of fibers. We just have to say he breathed some fibers."). Moreover, Dr. Maddox rendered his opinion without being prepared to discuss the circumstances of any individual's exposure. At this late juncture in the litigation, Appellee cannot redirect the focus of the Frye hearing, which is the subject of our present review.[34]

Appellee's efforts to invoke case reports, animal studies, and regulatory standards are also ineffectual in terms of substantial-factor causation, since the most these can do is suggest that there is underlying risk from the defendants' products, a proposition with which Judge Colville did not disagree.[35] Judge Colville was more concerned with the assessment of substantiality.

In this regard, Dr. Maddox's any-exposure opinion is in irreconcilable conflict with itself. Simply put, one cannot simultaneously maintain that a single fiber among millions is substantially causative, while also conceding that a disease is dose responsive. Cf. supra note 25 (citing cases). Indeed, it is worth repeating the following excerpt from the pathologist's own testimony making the point:

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[34] This is not to say that there may not have been other evidence upon which Appellee might have relied to avoid the summary judgment ruling which ensued in her case after the more generic Frye determination covering all of the test cases. In light of the limited grant of our review, see Betz v. Pneumo Abex LLC, 607 Pa. 620, 9 A.3d 1134 (2010) (per curiam), we refrain from comment on this separate question.

[35] As to the Helsinki criteria, Appellants correctly observe that these do not embody the any-exposure theory. In any event, Dr. Maddox's explanation that "I know that in medic[o]legal circles you will find that it is fairly widely known and fairly widely used," see N.T., Oct. 17, 2005 (p.m.), at 32-33, is unpersuasive in terms of general acceptance in the scientific community pertaining to risk assessment and substantiality of causation.

> Now, individual exposures differ in the potency of the fiber to which an individual is exposed, to the concentration or intensity of the fibers to which one is exposed, and to the duration of the exposure to that particular material. So those are the three factors that need to be considered in trying to estimate the relative effects of different exposures. But all exposures have some effect.

N.T., Oct. 17, 2005 (p.m.), at 37 (emphasis added). The any-exposure opinion, as applied to substantial-factor causation, does not consider the three factors which Dr. Maddox himself explains "need to be considered in trying to estimate the relative effects of different exposures." Id.[36]

Thus, Dr. Maddox's explanations do not undercut, but rather support, what we said in Gregg:

> 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

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[36] Cf. Brief for Appellant Allied Signal, Inc. at 13 ("Simply stated, plaintiff's experts in this case, as well as in other asbestos cases, have never been able to explain the scientific and logical implausibility of agreeing to the premise that a lifetime of breathing asbestos in the ambient air will not harm a person, while on the other hand arguing that every breath of asbestos from a defendant's product, no matter how inconsequential, will." (emphasis deleted)). See generally I.J. Selikoff et al., The Occurrence of Asbestosis Among Insulation Workers in the United States, 132 ANN. N.Y. ACAD. SCI. 139 (1965) ("The different occupations vary widely in important respects; in intimacy, intensity and duration of exposure, in variety and grade of asbestos used, in working conditions, in concomitant exposure to other dusts or inhalants.").

The comments to the Second Restatement of Torts recognize that a proportionate evaluation may be required in a reasoned assessment of substantial-factor causation. RESTATEMENT (SECOND) OF TORTS, §433, cmt. d (1965) ("Some other event which is a contributing factor in producing the harm may have such a predominant effect in bringing it about as to make the effect of the actor's negligence insignificant and, therefore, to prevent it from being a substantial factor."). Notably, this Court has cited Section 433 as consistent with Pennsylvania law. See Vattimo v. Lower Bucks Hosp., Inc., 502 Pa. 241, 246-47, 465 A.2d 1231, 1233-34 (1983).

> 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. See, e.g., Menne v. Celotex Corp., 861 F.2d 1453, 1464-70 (10th Cir. 1988). See generally Comment, The Threshold Level of Proof of Asbestos Causation: The "Frequency, Regularity and Proximity Test" and a Modified Summers v. Tice Theory of Burden-Shifting, 24 CAP. U.L. REV. 735 (1995).[fn]. 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. The result, 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.
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> [*fn*]. Notably, under some of these theories, in recognition of the fact that a defendant may be held liable under less than substantial-factor causation, relief from joint and several liability may be available. See Menne, 861 F.2d at 1468 n.22.

Gregg, 596 Pa. at 291-92, 943 A.2d at 226-27.

In this regard, the analogies offered by Dr. Maddox in support of his position convey that it is fundamentally inconsistent with both science and the governing standard for legal causation. The force of his marbles-in-a-glass illustration changes materially upon the recognition that, to visualize this scenario in terms of even a rough analogy, one must accept that the marbles must be non-uniform in size (as asbestos fibers are in size and potency), microscopic, and million-fold. From this frame of reference, it is very difficult to say that a single one of the smallest of microscopic marbles is a substantial factor in causing a glass of water to overflow.

Next, Dr. Maddox said that his opinion is akin to the sentiment that every soldier in the field has a substantial effect on the outcome of a war. While we agree with the pathologist that this is true in a figurative and honorary fashion, we fail to see that this analogy bears any connection whatsoever to science. The same is true of his Ellis Island comment. N.T., Oct. 17, 2005 (p.m.), at 141 ("Once [a fiber] enters the body through the nose, then it doesn't matter where it came from. Then everything becomes equal. That is Ellis Island. You are an American then."). Dr. Maddox's boxer analogy is as inconsistent with human experience as it is with science, as the difference between a glancing blow to the shoulder and a knockout punch to the jaw is commonly understood. Finally, with regard to the cigarette analogy, Dr. Maddox offered no scientific basis for concluding that a single cigarette of the potentially half-million a person might smoke in a lifetime is substantially causative of such person's lung cancer.

In terms of the epidemiological studies, while Judge Colville declined to squarely address these (thereby narrowing our own review), it is worth noting that Dr. Maddox took the opportunity to discount these studies while avoiding further elaboration upon his explanation that he was "not really prepared to discuss epidemiology with you." N.T., Oct. 17, 2005 (p.m.), at 112. It is very difficult to credit an expert's assessment of studies which he discounts but is unwilling or unprepared to discuss. Compare Blum, 564 Pa. at 7-8 n.5, 764 A.2d at 5 n.5 (criticizing the methodology of a medical doctor who "worked backwards through the science, from the statistical results back to the original mere associations that led to the studies in the first place"), with N.T., Oct. 17, 2005 (p.m.), at 12 (reflecting the testimony of Dr. Maddox that, "in the context of all the other small steps that I have tried to illustrate, I think the case reports to me are more persuasive than are the epidemiologic studies which are really inconclusive."); cf. Norris

v. Baxter Healthcare Corp., 397 F.3d 878, 882 (10th Cir. 2005) (explaining that, "where epidemiology is available, it cannot be ignored.").

While the Superior Court is correct that Judge Colville did not embellish his opinion with specific citations to the record, his findings and conclusions are amply supported throughout that record nonetheless. As reflected above, defense witnesses testified that Dr. Maddox's methodology did not follow any acceptable scientific practice, inter alia, in that it contained large analytical gaps; was in conflict with the dose-response relationship; and was internally inconsistent. In this regard, as well, we agree with Appellants that the breadth and character of an expert's extrapolations are relevant to the scientific acceptance of his methodology. The alternative is to permit experts to evade a reasoned Frye inquiry merely by making references to accepted methods in the abstract.

Finally, in other opinions approving the any-exposure opinion, the Superior Court has relied on a passage from Tragarz v. Keene Corp., 980 F.2d 411, 421 (7th Cir. 1992), for the proposition that "[w]here there is competent evidence that one or a de minimis number of asbestos fibers can cause injury, a jury may conclude the fibers were a substantial factor in causing a plaintiff's injury." Howard v. A.W. Chesterton Co., 31 A.3d 974, 983 (Pa. Super. 2011) (quoting Tragarz, 980 F.2d at 421); Estate of Hicks, 984 A.2d at 957 (same). Tragarz did not elaborate on the difficulties involved in a comparative assessment of impact among differing exposures, something Dr. Maddox has acknowledged is required for causal attribution as a matter of science, as it is under Pennsylvania law. Accord Gregg, 596 Pa. at 291-92, 943 A.2d at 226-27. Moreover, the Seventh Circuit's comment is based on its understanding of Illinois tort law and is drawn from an Illinois court's decision in Wehmeier v. UNR Industries, Inc., 572 N.E.2d 320 (Ill. App. Ct. 1991). See Tragarz, 980 F.2d at 421. Wehmeirer, however,

recognized that the causation inquiry in latent-disease cases is circumstance dependent. See, e.g., Wehmeirer, 572 N.E.2d at 336 (discussing the relevance of factors such as the types of asbestos involved; the tendency of the defendants' products to release fibers into the air; and the character of the workplace in issue). Accordingly, we have no reason to believe that either the Illinois courts or the Seventh Circuit would disregard the comparative weight of differing exposures in what all experts agree is a risk-related inquiry. Certainly a complete discounting of the substantiality in exposure would be fundamentally inconsistent with Pennsylvania law.

For the above reasons, we hold that Judge Colville did not abuse his discretion in his Frye assessment.

The order of the Superior Court is reversed, and the case is remanded for consideration of whether there were remaining, preserved issues on appeal which were obviated by the intermediate court's approach to the common pleas court's ruling.

Mr. Chief Justice Castille, Messrs. Justice Eakin and Baer, Madame Justice Todd, and Mr. Justice McCaffery join the opinion.

Madame Justice Orie Melvin did not participate in the decision of this case.