In The

Court of Appeals of Maryland

September Term, 2012
No. 82

BERNARD DIXON, *et al., Petitioners / Cross-Respondents*,
v.
FORD MOTOR COMPANY, *Respondent / Cross-Petitioner.*

BRIEF OF *AMICUS CURIAE* PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF RESPONDENT / CROSS-PETITIONER FORD MOTOR COMPANY

On Appeal from the Circuit Court for Baltimore City (Hon. John M Glynn, J., presiding) on a Writ of *Certiorari* to the Court of Special Appeals

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STATEMENT OF INTEREST

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit association with 102 corporate members from a broad cross-section of American and international product manufacturers. PLAC's corporate members are listed at Tab "A". In addition, several hundred leading product liability defense attorneys are sustaining (non-voting) members of PLAC. On April 13, 2012, the Court of Special Appeals granted PLAC's motion to participate as *amicus curiae* in these proceedings.

PLAC seeks to contribute to the improvement and reform of the law affecting product liability in the United States and elsewhere. PLAC's point of view reflects the experience of corporate members in diverse manufacturing industries. Since 1983, PLAC has filed over 975 briefs as *amicus curiae* in state and federal courts, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of product liability law.

How courts scrutinize expert testimony is of utmost interest to PLAC's members, which frequently confront questionable expert opinions in product liability cases. A generic opinion lacking factual support and merely parroting the legal causation standard – "substantial contributing factor" – is manifestly insufficient. Standards for admissibility of causation opinions are likewise of great and recurring importance. To meet generally accepted scientific and medical methodologies, expert causation opinions in toxic substance cases should address: (1) dose and duration of exposure; (2) general causation, including the exposures required to cause the condition at issue in humans generally; and (3) specific causation comparing a plaintiff's exposure to that minimally required and considering potential alternative causes. These criteria are well within the legal and scientific mainstream.

This *amicus curiae* brief is respectfully submitted to the Court to address the public importance of this issue apart from and beyond the immediate interests of the parties to this case.[1]

[1] Pursuant to Md. Rule 8-511(b), *amicus curiae* PLAC, states that no person or entity, other than it, its members, and its counsel, has made any monetary or other contribution to the preparation or submission of the brief.

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BRIEF OF *AMICUS CURIAE* PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF RESPONDENT / CROSS-PETITIONER FORD MOTOR COMPANY

I. STATEMENT OF THE CASE

PLAC accepts the Statement of the Case of Respondent / Cross-Petitioner Ford Motor Co. (hereafter "Respondent / Cross-Petitioner Ford").

II. STATEMENT OF THE QUESTION PRESENTED

A. Question Presented

PLAC addresses the first question posed by Petitioners / Cross-Respondents Bernard Dixon, *et al.* (hereafter "Petitioners / Cross-Respondents"):

> Did the Court of Special Appeals err in concluding that the trial court abused its discretion by admitting under Maryland Rule 5-702 the opinion of Plaintiff's [*sic*] medical expert, Dr. Welch, because Dr. Welch's testimony did not satisfy the Court of Appeals' newly articulated model of "probabilistic causation"?

PLAC also addresses the second question presented by Respondent / Cross-Petitioner Ford:

> Whether the trial court erred by failing to exclude under Frye-Reed and/or Balbos the general causation opinion of Dr. Laura Welch that every exposure to asbestos, irrespective of dose, regularity, and frequency of exposure, is a substantial contributing factor in causing mesothelioma in anyone?

Both questions provide alternative and independent grounds for affirmance.

B. Applicable Standard of Review

To the extent that the Court of Special Appeals considered the admissibility of Dr. Welch purely as a Md. Rule 5-702 issue, the applicable standard of review is "that the trial court's determination is reviewable on appeal, and may be reversed if founded on an error of law or some serious mistake, or if the trial court has clearly abused its discretion." Gutierrez v. State, 423 Md. 476, 486, 32 A.3d 2, 8 (2011); *accord* Blackwell v. Wyeth, 408 Md. 575, 618, 971 A.2d 235, 261 (2009); Rollins v. State, 392 Md. 455, 500, 897 A.2d 821, 847 (2006).

However, to the extent that admissibility turns on the general acceptance of an expert's methodology and conclusions, the standard of review is *de novo*. Blackwell, 408 Md. At 580 n.9, 971 A.2d at 238 n.9; Wilson v. State, 370 Md. 191, 201 n.5, 803 A.2d 1034, 1040 n.5 (2002). "[E]xpert medical testimony, such as that offered by [a physician], is the proper subject of a Frye-Reed hearing." Montgomery Mutual Insurance Co. v. Chesson, 399 Md. 314, 331, 923 A.2d 939, 948 (2007).

III. STATEMENT OF MATERIAL FACTS

PLAC accepts the statement of material facts of Respondent / Cross-Petitioner Ford. Most critically to PLAC's arguments, the Petitioners / Cross-Respondents' expert, Dr. Laura Welch, opined that "each" or "every" asbestos exposure, no matter how small is a "substantial contributing factor" to mesothelioma:

> Q. Now, with regard to your opinions about asbestos and causation which you have given this jury, it's your opinion, Doctor, that each and every exposure contributes to the development of mesothelioma no matter where it comes from in asbestos exposure; is that right?
>
> A. Right. When somebody has got mesothelioma, all the exposures they have were contributing factors, that's my opinion.

(E.904); see also E.834 ("every exposure contributes to the development of mesothelioma"); E.835 ("each of the exposures contributes to development of the disease"); E.849 ("Is there any safe exposure to asbestos, Doctor? No."); E.854 ("It's my opinion that every exposure to asbestos is a substantial contributing cause"); E.905 ("substantial contributing cause . . . could be one day of work").

Dr. Welch told the jury that asbestos exposure was a contributing factor whether or not that exposure was "frequent" or "regular":

> Q. And it doesn't matter to you whether the exposure is on a frequent basis, correct?
>
> A. No. I mean, an exposure can be like one event. On a frequent basis, you would be talking about a task or something like that. But I think each one of those discrete exposures is a contributing factor.

(E.904).

> Q. So it doesn't have to be a regular course of work? It doesn't have to be something they do occupationally for a period of time; is that true?
>
> A. No, not necessarily. Because we are talking about somebody who has already got the disease. And I think every one of the exposures that go into making their sum total of exposure to asbestos is a contributing factor.

(E.905).

As discussed in Respondent / Cross-Petitioner Ford's papers, and admitted by Dr. Welch, automobile mechanic asbestos exposure has been extensively studied, and no increased risk found (E.1239-51).

> Q. Doctor, are you aware of any prospective or retrospective cohort study of brake mechanics which shows them to be at an increased risk of developing mesothelioma?
>
> A. I don't think there has been such a study.

(E.895).

Despite contrary epidemiologic evidence, Dr. Welch opined, based on downward extrapolation, that because epidemiologic data showed a risk of **other diseases** at **high doses**, there was a smaller risk of mesothelioma at lower doses (E.834, E.851-52, E.855-557, E.911-12, E.986) (relying on non-cancer study).[2] She also relied on: (1) anecdotal case reports of mesothelioma in persons with only low-dose exposure (E.847-49), and (2) administrative regulation of low-dose asbestos exposure (E.835). Dr. Welch selected her data so that it only "included references to support specific statements [she] was making" during her testimony (E.903). She invited the jury to ignore all the studies because one of them was funded by asbestos defendants (E.832, E.872-73).[3]

Dr. Welch gave her opinions without any plaintiff-specific exposure data. She never estimated, let alone calculated, how much asbestos the decedent, Joan Dixon, in-

[2] Dr. Welch discussed one British "case-control" study of fifteen wives. Only two had husbands who worked at all, and then only incidentially, with brake linings, and those two anecdotal cases were not analyzed separately (E.876-78).

[3] Had Respondent / Cross-Petitioner Ford not studied its products, Petitioners / Cross-Respondents would undoubtedly criticize it for that "failure."

haled from Respondent / Cross-Petitioner Ford's products.[4] Her opinions reference hypothetical "individuals" (E.870-71), but not this decedent's work history. "Commercial garage" work is not even mentioned in Dr. Welch's report (E.908), and at trial she had no evidence that the decedent ever set foot in the garage (E.908-09). Dr. Welch offered only a bald "yes" to a hypothetical exposure question that was as lengthy as it was lacking any quantifiable estimates of asbestos exposure (E.883-84).

Whatever the other minimum criteria for expert testimony may be, the most basic scientific requirement – that of empirical data – is absent here.

- There is no evidence, not even an estimate, of **this decedent**'s overall exposure to asbestos.
- There is no evidence, not even an estimate, of the level of intensity of **this decedent**'s exposure to any Ford asbestos-containing products.
- There is no evidence, not even an estimate, of the length of **this decedent**'s exposure to any asbestos fiber-emitting use of a Ford product.
- There is no evidence, not even an estimate, of how proximate **this decedent** was to any asbestos fiber-emitting use of a Ford product.
- There was no evidence that **this decedent**'s asbestos exposure from Ford products even exceeded her asbestos exposure from the ambient air.

The only evidence is that any alleged asbestos exposure from the products of Respondent / Cross-Petitioner Ford is "exceedingly low" – far lower than asbestos exposure levels found to increase risk in the abundant epidemiological literature (E.903).

IV. SUMMARY OF ARGUMENT

An expert opinion that any exposure to an alleged toxin – no matter how low the dose, how brief the period, or how long ago – is a "substantial contributing factor" to an injury is not based upon generally accepted scientific methodology. Such opinions are neither objective nor scientific. Instead, they improperly assert a subjective satisfaction

[4] Dr. Welch did not treat the decedent (E.830), conducted no tests to determine her asbestos load (E.839, E.904), and never contacted the decedent's doctors (E.898).

of the legal causation standard upon which a court charges a jury. Expert legal opinions that usurp the judicial function in this fashion are improper.

The non-scientific opinion here is devoid of empirical data documenting, or even reasonably estimating, the amount of the decedent's asbestos exposure from Respondent / Cross-Petitioner Ford's brake products. Neither the relevant scientific community nor the courts recognize "evidence-free" causation opinions as scientifically valid. Expert opinions must have sufficient factual basis to be admissible. With precisely zero information concerning the decedent's exposure, Petitioners / Cross-Respondents' expert could not possibly opine upon "cumulative" or "dose-related" grounds.

Part and parcel of Petitioners / Cross-Respondents' expert's any-exposure opinion is an invalid scientific technique – downward extrapolation – which assumes that, because something is harmful at high exposure levels, it must also cause harm at any lower level. This assumption is contrary to the most basic notion of science; almost anything, including essential substances like oxygen or water, is harmful at some extreme level.

Lacking statistically valid epidemiologic evidence of actual harm at low doses, or at "any" dose, Petitioners / Cross-Respondents' expert's opinion instead is based largely upon individual case reports. Case reports are anecdotal, offer no comparison to a control group, and are thus subject to many biases and confounding problems. Such reports are not generally recognized as support for causation opinions, and are entirely insufficient where, as here, they fly in the face of contrary epidemiological evidence that is controlled and not anecdotal.

Finally, expert opinions in civil litigation may not be justified on the basis of actions taken or conclusions reached by governmental administrative agencies. Importation of regulatory standards into civil litigation is improper – and certainly not scientific – because governmental actors are not bound by the rigorous standards of scientific certainty that the law requires of civil litigants. Magic words and anecdotal evidence are no substitute for scientifically reliable data in resolving issues that are within the realm of science.

V. ARGUMENT

A. Petitioners / Cross-Respondents' Expert Opinions Purporting To Define "Substantial Contributing Factor" Differently Than This Court Has Done Were Properly Excluded.

In an asbestos case, the applicable legal causation standard requires a plaintiff to prove that exposure to the products made or sold by each defendant was a "substantial factor" in causing the injury.

> The actor's negligent conduct is a legal cause of harm to another if (a) his conduct is a substantial factor in bringing about the harm, and (b) there is no rule of law relieving the actor from liability because of the manner in which his negligence has resulted in the harm.

Eagle-Picher Industries, Inc. v. Balbos, 326 Md. 179, 208-09, 604 A.2d 445, 459 (1992), *quoting* Restatement (Second) of Torts §431 (1965). "Causation-in-fact may be found if it is 'more likely than not' that the defendant's conduct was a substantial factor in producing the plaintiff's injuries." Pittway Corp. v. Collins, 409 Md. 218, 244, 973 A.2d 771, 787 (2009).

> There are frequently a number of events each of which is not only a necessary antecedent to the other's harm, but is also recognizable as having an appreciable effect in bringing it about. Of these the actor's conduct is only one. 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. So too, although no one of the contributing factors may have such a predominant effect, their combined effect may, as it were, so dilute the effects of the actor's negligence as to prevent it from being a substantial factor.

AC&S, Inc. v. Asner, 344 Md. 155, 176, 686 A.2d 250, 260 (1996), *quoting* Restatement (Second) of Torts §433 (1965). Thus, a defense "may be based on the negligible effect of a claimant's exposure to the defendant's product, or on the negligible effect of the asbestos content of a defendant's product, or both." *Id.* at 176-77, 686 A.2d at 260.

In Balbos, the Court adopted a three-pronged test for determining "substantial factor" in asbestos exposure cases that examines the "frequency, proximity, and regularity" of the plaintiff's claimed contact with the defendant's asbestos-containing product.

> Neither decedent . . . worked directly with asbestos products; rather, they were bystanders. Whether the exposure of any given bystander to any particular supplier's product will be legally sufficient to permit a finding of substantial-factor causation . . . involves the interrelationship between the use of a defendant's product at the workplace and the activities of the plaintiff. . . . Within that context, the factors to be evaluated include the nature of the product, the frequency of its use, the proximity, in distance and in time, of a plaintiff to the use of a product, and the regularity of the exposure of that plaintiff to the use of that product.

326 Md. at 210, 604 A.2d at 460 (citations omitted). The Balbos test applies in "non-occupational settings," such as here. Georgia-Pacific v. Pransky, 369 Md. 360, 366, 800 A.2d 722, 725 (2002). An asbestos exposure cannot be a substantial factor in causing a disease if it had no effect on the person or had only a "negligible effect." Asner, *supra*. Dr. Welch's opinions directly contradicted Balbos – asserting that asbestos exposure could be a "substantial factor" without being either regular or frequent (E.904-05).

The Court of Special Appeals described the Balbos test as "captur[ing] what philosophers of science call 'probabilistic causation.'" Dixon v. Ford Motor Co., 206 Md. App. 180, 191-92, 47 A.3d 1038, 1045 (2012).[5] Eager to shift the focus from Dr. Welch's legally, factually, and scientifically baseless "substantial factor" testimony, Petitioners / Cross-Respondents argue as if some great legal departure has occurred. They are wrong. "Probabilistic causation" is simply another way of describing the "substantial factor" analysis that this Court employed in Balbos and elsewhere. Dixon, 206 Md. App. at 193, 47 A.3d at 1045 ("both doctrines rest on the premise that empirical inquiry can only ever give a certain **degree** of certainty") (emphasis original).

This Court and the Court of Special Appeals repeatedly have recognized probability as an essential aspect of substantial factor causation. In Gourdine v. Crews, 405 Md. 722, 955 A.2d 769 (2008), this Court stated in a product liability case:

> Whether any such unreasonable risk exists in a given situation depends on **balancing the probability and seriousness of harm**, if care is not exer-

[5] *Quoting* Christopher Hitchcock, Probabilistic Causation, The Stanford Encyclopedia of Philosophy (Winter 2011 Edition).

> cised, against the costs of taking appropriate precautions. . . . Based on this negligence law we think that in the products liability domain a duty to warn is imposed on a manufacturer if the item it produces has an inherent and hidden danger about which the producer knows, or should know, could be a substantial factor in bringing injury to an individual.

Id. at 739-40, 955 A.2d at 779-80 (citations and quotation marks omitted) (emphasis added).[6] A failure to warn "could be a substantial factor in bringing injury to an individual . . . [i]f there is some probability of harm sufficiently serious that ordinary men would take precautions to avoid it." Moran v. Faberge, Inc., 273 Md. 538, 552-52, 332 A.2d 11, 20 (1975) (citation and quotation marks omitted).

Probability has always been a major aspect of "substantial factor" causation in asbestos cases. In asbestos litigation "the proposition that the defendant's product is not a substantial cause may be made more probable by evidence tending to prove that the claimant's disease was caused by the products of one or more non-parties." Asner, 344 Md. at 176-77, 686 A.2d at 260. Probability was expressly tied to the Balbos test in Reiter v. ACandS, Inc.:

> [The evidence] is not enough to create a genuine issue of material fact as to whether [defendant's] products were a substantial factor cause. . . . The most that can be shown is that there is some probability that [defendant's product] was located somewhere in the [same facility] at the same time that [defendant] was also [there]. To infer from that information . . . the proximity, regularity, and frequency required by Balbos would be speculation, at best.

179 Md. App. 645, 665, 947 A.2d 570, 582 (2008), *aff'd*, 417 Md. 57, 76, 8 A.3d 725, 736 (2010) (evidence "insufficient" as to use of defendant's products "at the specific site"). Petitioners / Cross-Respondents' focus on "probabilistic causation" as something unknown to the law is thus a smokescreen, a convenient diversion from Dr. Welch's patently inadequate opinions.

In stark contrast to Dr. Welch's conclusory assertion that any exposure to asbestos-contaminated air constitutes a separate "substantial contributing factor," the Balbos

[6] Lengthy quotation from Restatement (Second) of Torts §388 (1965) omitted.

substantial factor test is explicitly based on Restatement (Second) of Torts §431 (1965). Balbos, 326 Md. at 208-09, 604 A.2d at 459.[7] The Restatement provides:

> The word "substantial" is used to denote the fact that the defendant's conduct has such an affect in producing the harm as to **lead reasonable men to regard it as a cause, using that word in the popular sense**, in which there always lurks the idea of responsibility, rather than in the so-called **"philosophic sense," which includes every one of the great number of events without which any happening would not have occurred**. Each of these events is a cause in the so-called "philosophic sense," yet the effect of many of them is so insignificant that no ordinary mind would think of them as causes.

Restatement (Second) of Torts §431, comment a (1965) (emphasis added). Thus, the Court of Special Appeals here is not alone in viewing substantial factor causation as reflecting what is ultimately a "philosophic" problem. The drafters of Restatement §431 – a longstanding part of Maryland law − likewise did so.

Establishing causation is supposed to be "fact specific to each case." Balbos, 326 Md. at 210, 604 A.2d at 460. Dr. Welch did not even attempt to estimate the decedent's amount of exposure to asbestos from Respondent / Cross-Petitioner Ford's products, or to compare that exposure to others established by the evidence. She offered only her any-exposure opinion. Thus, in the "popular sense" of causation that Maryland law follows, any single exposure to asbestos is precisely the sort of "insignificant" or "negligible" cause contemplated by Restatement §431, as adopted by this Court. As to "each and every" exposure, Dr. Welch at best asserted causation in the "philosophic sense," precisely what the law rejects.

This Court in Asner, 344 Md. 155, 686 A.2d 250, also relied upon the Restatement. It referenced the criteria of Restatement (Second) of Torts §433 (1965) for separating causative factors that are "substantial" from those that are insufficient:

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[7] This Court has repeatedly relied upon Restatement §431 as accurately reflecting Maryland law. *E.g.*, Pittway, 409 Md. at 244-45, 973 A.2d at 787; Pittman v. Atlantic Realty Co., 359 Md. 513, 521 n.4, 754 A.2d 1030, 1034 n.4 (2000); Asner, 344 Md. at 171; 686 A.2d at 257-58.

> The following considerations are in themselves or in combination with one another important in determining whether the actor's conduct is a substantial factor in bringing about harm to another:
>
> (a) the number of other factors which contribute in producing the harm and the extent of the effect which they have in producing it;
>
> (b) whether the actor's conduct has created a force or series of forces which are in continuous and active operation up to the time of the harm, or has created a situation harmless unless acted upon by other forces for which the actor is not responsible;
>
> (c) lapse of time.

Restatement (Second) of Torts §433 (1965); *see* Asner, 344 Md. at 176, 686 A.2d at 260 ("other" contributing factors "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"). Far from considering these other factors, Dr. Welch's any-exposure opinion rejected them.

As this Court has held, "[l]egal causation is a policy-oriented doctrine designed to be a method for limiting liability after cause-in-fact has been established." Pittway, 409 Md. at 245, 973 A.2d at 787. Petitioners / Cross-Respondents' argument here – that controlling weight must be given to a conclusory expert "opinion" that any exposure to asbestos is *ipso facto* a separate "substantial factor" – flies in the face of decades of Maryland precedent.

However, in Georgia-Pacific, LLC v. Farrar, 207 Md. App. 520, 53 A.3d 424 (Md. App. 2012) (hereafter "Farrar"), *cert granted*, No. 505, Sept. Term 2012 (Md. Jan. 18, 2013), the Court of Special Appeals declined to find error in the admission of any-exposure expert testimony ("exposure to asbestos above the background level of ambient air") by allowing "sufficient" exposure to be "inferred circumstantially" from certain lay testimony.[8] *Id.* at 555-56, 53 A.3d at 444-15. Thus the Court of Special Appeals in Farrar

[8] That lay testimony primarily concerned "considerable visible dust" allegedly created by sanding joint compound. Farrar, 207 Md. App. at 555, 53 A.3d at 445. *Cf.* Dix-

avoided the foundational question presented here − whether such expert testimony is properly admissible in the first instance. In a footnote, Farrar distinguished Dixon because "the trial court in Ms. Farrar's case did not allow her expert to testify that her exposure to [defendant's] product was a **substantial** cause of her illness" *Id.* at 558 n.5, 53 A.3d at 446 n.5 (emphasis original). Thus, Farrar also declined to address the fundamental inconsistency of any-exposure expert testimony with the legal requirement of "substantial factor" causation. For the reasons stated herein, to the extent that Farrar actually decided any issue relevant to the appeal in Dixon, PLAC respectfully submits that Farrar was wrongly decided and should be reversed.

As even the Court of Special Appeals in Farrar suggested, Dr. Welch's any-exposure opinions are an explicit attempt to define for the jury what a "substantial factor" is – and to do so in a manner directly contrary to law. *See* Farrar, 207 Md. App. at 558 n.5, 53 A.3d at 446 n.5 ("[t]he expert testimony in Dixon effectively equated any exposure with legal liability"). Dr. Welch's further testimony that a "substantial factor" can exist without the exposure being "frequent" or "regular" (E.904-05) is nothing less than a frontal assault on the holding in Balbos. She essentially invited the jury to disregard the regularity, frequency, and proximity test adopted in that case. Further, her assertions that "one breath" or "one day" of exposure is a "substantial factor" seeks jury nullification of the *de minimis* defense recognized in Asner. Such testimony could not possibly be "helpful" to the jury.

There is no evidence in this record that "substantial factor" has any inherent scientific meaning; rather it "is a legal standard." McCoy v. Hatmaker, 135 Md. App. 693, 722, 763 A.2d 1233, 1249 (2000) (proper to exclude expert testimony that defendant acted with "reckless disregard"), *cert. denied*, 364 Md. 141, 771 A.2d 1070 (2001). Thus, the Court of Special Appeals was correct in holding that "Dr. Welch's conclusion that the exposure and risk . . . were 'substantial' simply was not a scientific conclusion." Dixon,

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on, 206 Md. App. at 184 & n.2, 47 A.3d at 1040 & n.2 (describing dustiness of joint compound).

206 Md. App. at 197, 47 A.3d at 1048. Her "substantial factor" opinions go not to the facts of this case (she had no evidence of the decedent's actual exposure to asbestos in Ford brakes), but rather to the legal standards that the jury was to apply. Petitioners / Cross-Respondents cannot "ask[] their experts to make a legal conclusion and not a factual one." McCoy, 135 Md. App. at 723, 763 A.2d at 1249.

A legal conclusion such as "substantial contributing factor" is a classic example of improper expert testimony. On questions of law "the tribunal does not need the witness' judgment and hence will insist on dispensing with it." VII Wigmore on Evidence §1952, at 103 (Chadbourne rev. ed. 1978 & Supp. 1991). In Maryland, "expert witnesses may not give opinions on questions of law except for those concerning the law of another jurisdiction." Franch v. Ankney, 341 Md. 350, 361, 670 A.2d 951, 956 (1996). "[I]t is the general rule that an expert witness may not opine on questions of law." Solomon v. State Board of Physician Quality Assurance, 155 Md. App. 687, 706, 845 A.2d 47, 58 (2003), *cert. denied*, 381 Md. 676, 851 A.2d 595 (2004). "When a standard or a measure . . . has been fixed by law, no witness whether expert or nonexpert, nor however qualified, is permitted to express an opinion as to whether or not the person or conduct in question measures up to that standard." Franceschina v. Hope, 267 Md. 632, 643, 298 A.2d 400, 406 (1973) (citation and quotation marks omitted).

It is a trial judge's job to instruct on the law. By allowing Dr. Welch to define "substantial factor" for the jury, the trial court "abandoned its duty as expert in the law and [took] from any potential jury . . . the role of sifting through the facts of [defendant's] actions in this case and applying the law to those facts. McCoy, 135 Md. App. at 723, 763 A.2d at 1249. "Each courtroom comes equipped with a 'legal expert,' called a judge, and it is his or her province alone to instruct the jury on the relevant legal standards." Burkhart v. WMATA, 112 F.3d 1207, 1213 (D.C. Cir. 1997) (citation omitted). "It is black letter law that it is not for witnesses to instruct the jury as to applicable principles of law, but for the judge." Nieves-Villanueva v. Soto-Rivera, 133 F.3d 92, 99 (1st Cir. 1997) (citations omitted). An expert "giving his expert opinion on the governing law . . .

flies squarely in the face of the precedent." Adalman v. Baker, Watts & Co., 807 F.2d 359, 368 (4th Cir. 1986).[9]

The role of an expert witness is to "assist the trier of fact to understand the evidence." Md. Rule 5-702. Dr. Welch's bare assertion that the legal standard the jury will apply was satisfied, without any factual explanation why, or how the jury should apply the standard, is both unhelpful to the jury and a usurpation of the trial judge's exclusive function to charge the jury on the law. "[S]uch testimony invades not only the province of the jury but the province of the court to determine the applicable law and instruct the jury as to that law." McCoy, 135 Md. App. at 723 n.10, 763 A.2d at 1249 n.10 (citation and quotation marks omitted). Because a "substantial factor" opinion is merely a legal conclusion, it was error for the trial court to admit it.[10]

B. Standards for Admissibility of Scientific Expert Testimony

Dr. Welch's opinions also violate the standards for admissibility of scientifically based expert testimony. "[B]efore a scientific opinion will be received as evidence at trial, the basis of that opinion must be shown to be generally accepted as reliable within the expert's particular scientific field." Reed v. State, 283 Md. 374, 381, 391 A.2d 364,

[9] Other federal courts faced with experts purporting to draw legal conclusions likewise ignore such opinions. *See*, *e.g.*, Berckeley Investment Group, Ltd. v. Colkitt, 455 F.3d 195, 218 (3d Cir. 2006) ("any testimony as to the legal effect of the various [administrative] pronouncements . . . are inadmissible as improper legal opinions"); Burkhart, 112 F.3d at 1212 ("[e]xpert testimony that consists of legal conclusions cannot properly assist the trier of fact"); United States v. Bilzerian, 926 F.2d 1285, 1294 (2d Cir.), *cert. denied*, 502 U.S. 813 (1991) (expert testimony "must be carefully circumscribed to assure that the expert does not usurp either the role of the trial judge in instructing the jury . . . or the role of the jury in applying that law to the facts"); Farmland Industries v. Frazier-Parrott Commodities, Inc., 871 F.2d 1402, 1409 (8th Cir. 1989) ("the [expert] witness' testimony [is] superfluous. . . . The admission of such testimony would give the appearance that the court was shifting to [expert] witnesses the responsibility to decide the case") (citation and quotation marks omitted).

[10] While experts are allowed to opine on "ultimate" issues, Md. Rule 5-704, this Rule does not permit testimony on improper legal conclusions. McCoy, 135 Md. App. at 723 n.10, 763 A.2d at 1249 n.10.

368 (1978), "[U]nder Reed, the proponent of an expert witness bears the burden of proving . . . general[] accept[ance]." Blackwell, 408 Md. at 596, 971 A.2d at 248. The scientific community that must accept the theory is broadly defined:

> [T]he "relevant scientific community" includes the full community of scientists with sufficient training and expertise to permit them to comprehend novel scientific methods, and may not properly be restricted to those who practice or otherwise adhere to the methods at issue.

Id. at 603 971 A.2d at 252 (citation omitted).

Maryland "jurisprudence engages trial judges in a serious gate-keeping function, to differentiate serious science from 'junk science'." *Id.* at 591, 971 A.2d at 245. Rigorous gate-keeping is required because "attorneys can seek expert witnesses who will parrot the attorneys' line, and, indeed, implicitly 'bribe' them to do so." *Id.* at 592, 971 A.2d at 245.

General acceptance requires, first and foremost, generally accepted scientific methodology. As discussed in Blackwell, that method is a multi-step process that begins with data and ends with conclusions – not the other way around:

- **Observations**: Here, scientists review the characteristics of persons with mesothelioma.
- **Explanations**: Here, a relationship between bystander asbestos exposure and mesothelioma has been proposed to account for the observed incidence.
- **Hypotheses**: Here, the proposed relationship between bystander asbestos exposure and mesothelioma is evaluated to decide what asbestos exposures would or would not fit the observed data – leading to a methodology for testing the hypothesis.
- **Studies**: Here, principles of epidemiology are employed to confirm or falsify the hypothesis that given types and levels of bystander asbestos exposure are capable of causing mesothelioma. "Critical experiments" that most closely approximate the "relevant phenomena" involve the results of exposure to asbestos brake dust in concentrations similar to the decedent's claimed "take home"[11] exposure.

[11] "Take home" refers to indirect, non-workplace asbestos exposure from, typically, the clothing of someone else who worked with asbestos at another location.

- **Conformity**: Here, proffered theories must be revised or abandoned in accordance with test results. Have available studies confirmed or denied that the sort of asbestos exposure alleged here could cause mesothelioma?

- **Repetition**: Here, results of additional epidemiologic studies either confer general acceptance upon the hypothesis, or do not.

Blackwell, 408 Md. at 581-82, 971 A.2d at 239. No hypothesis is ever entirely proven. *Id.* at 583, 971 A.2d at 240. However, the repetitive process of constant testing eventually yields, in the case of successful hypotheses, "general scientific acceptance."

> [T]heories that withstand such attempts at falsification better and longer become accepted, at least until something better comes along. . . . It is the diligent search for inconsistencies, for falsification, that really puts a theory to the test. A theory that can withstand such scrutiny is one that deserves credence.

Id. A generally accepted scientific theory thus has two primary qualities: (1) it employs a set, repeatable methodology to generate conclusions; and (2) its conclusions produce results that agree with real-world observations. *Id.* at 583-84, 971 A.2d at 240-41. Where a "genuine controversy exists within the relevant scientific community" as to a particular theory, leading to "widespread disagreement," that theory is not generally accepted and thus is inadmissible. Wilson, 370 Md. at 210-11, 803 A.2d at 1045.

Under Maryland law, only generally accepted scientific opinions are admissible. Blackwell, 408 Md. at 584-86, 971 A.2d at 242; Reed, 283 Md. at 399-400, 391 A.2d at 377 (adopting Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923)). Maryland courts follow this rule out of "fairness to litigants" to ensure the conservative and reliable application of science in the courtroom. The Frye-Reed test:

> was **deliberately intended** to interpose a **substantial obstacle** to the unrestrained admission of evidence based upon new scientific principles because lay jurors tend to give considerable weight to "scientific" evidence when presented by "experts" with impressive credentials. . . . [A]s long as the scientific community remains significantly divided, results of controversial techniques will not be admitted, and all litigants will face the same burden.

Blackwell, 408 Md. at 586-87, 971 A.2d at 242 (citations and quotation marks omitted) (emphasis added).

Furthermore, Md. Rule 5-702(3), requires "a sufficient factual basis . . . to support the expert's testimony." Blackwell, 408 Md. at 618, 971 A.2d at 261, *quoting* the Rule. Where an expert fails to provide the basis of an opinion, beyond testimony that "is extremely general, vague, and inconclusive," then a court is "well within the realm of its discretion in excluding this testimony" under Rule 5-702(3). Bomas v. State, 412 Md. 392, 420, 987 A.2d 98, 114 (2010). An expert's "failure to disclose any specific scientific or factual underpinnings for [her] knowledge about the material risks" that are the subject of the opinion is a proper ground for exclusion. University of Maryland Medical System Corp. v. Waldt, 411 Md. 207, 237, 983 A.2d 112, 130 (2009).

Finally, to the extent that Dr. Welch's methodologies and lack of underlying data would be inadmissible under the "more liberal" federal Daubert[12] test, they should *a fortiori* be excluded under Frye-Reed. Owens Corning v. Bauman, 125 Md. App. 454, 497, 726 A.2d 745, 766, *cert. denied*, 354 Md. 572, 731 A.2d 970 (1999).[13] Frye-Reed is more restrictive than Daubert because the federal test permits admission of evidence not based on generally accepted theories or methodology under certain circumstances. Burral v. State, 352 Md. 707, 737-38, 724 A.2d 65, 80, *cert. denied*, 528 U.S. 832 (1999); Montgomery Mutual Insurance Co. v. Chesson, 206 Md. App. 569, 607-08, 51 A.3d 18, 41 (Md. App.), *cert. granted*, 429 Md. 528, 56 A.3d 1241 (2012).[14]

[12] Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

[13] *Abrogated on other grounds*, John Crane, Inc. v. Scribner, 369 Md. 369, 800 A.2d 727 (2002) (application of damages cap).

[14] The Court of Special Appeals in Farrar, *supra*, did not have a Frye-Reed challenge before it. Thus Farrar has no bearing on the remaining issues PLAC addresses in this brief.

C. Opinions That Any Asbestos Exposure Is a Legal Cause of Injury Are Not Generally Accepted.

1. Downward Extrapolation Unsupported by Empirical Data Concerning the Decedent Is Scientifically Invalid.

As in Blackwell, Petitioners / Cross-Respondents' expert did not rely on any epidemiologic studies suggesting that "take home" exposure to automotive brake dust causes mesothelioma. There are none. Rather Dr. Welch disregarded the results of many epidemiologic studies (detailed in other briefs) that reach precisely the opposite conclusion – that no statistically significant relationship exists between the greater exposure of actual brake mechanics and mesothelioma (E.830, E.834). She asserted that she disregarded those studies based upon supposed "limitations" or "problems" (E.843-46). To the extent Dr. Welch relied upon any epidemiology at all, she extrapolated from studies involving the incidence of lung cancer or asbestosis at far higher asbestos exposure levels (E.851-52, E.855-557, E.911-12).

The fundamental requirement that "the expert's conclusions must be based upon a legally sufficient factual foundation" is one of the three prerequisites of Rule 5-702. Blackwell, 408 Md. at 696, 971 A.2d at 307.

> An expert opinion derives its probative force from the facts on which it is predicated, and these must be legally sufficient to sustain the opinion. . . . [N]o matter how highly qualified the expert may be in his field, his opinion has no probative force unless a sufficient factual basis to support a rational conclusion is shown. **The opinion of an expert, therefore, must be based on facts, proved or assumed**, sufficient to form a basis for an opinion, and cannot be invoked to supply the substantial facts necessary to support such conclusion.

Jones v. State, 343 Md. 448, 461-62, 682 A.2d 248, 255 (1996) (citations and quotation marks omitted) (emphasis original). Thus, "[i]t is well settled that the trial judge – not the expert witness – determines whether there exists an adequate factual basis for the opinion at issue." Wood v. Toyota Motor Corp., 134 Md. App. 512, 523, 760 A.2d 315, 321, *cert. denied*, 362 Md. 189, 763 A.2d 735 (2000).

An expert opinion must be supported by evidence of record, otherwise it is incompetent. "[O]pinion evidence that is connected to existing data only by the *ipse dixit* of the expert" is inadmissible because "there is simply too great an analytical gap between the data and the opinion proffered." Blackwell, 408 Md. at 606, 971 A.2d at 254, *quoting* General Electric Co. v. Joiner, 522 U.S. 136, 146 (1997). Expert opinion testimony that is "nothing more than a conclusion" is inadmissible – "[i]nstead, the conclusion must flow logically from the facts." Jones, 343 Md. at 463-64, 682 A.2d at 256. Dr. Welch cited no case-specific facts to support her any-exposure opinion. "[A]n expert's opinion is of no greater probative value than the soundness of his [her] reasons given therefor will warrant." Smith v. Dodge Plaza Ltd. Partnership, 148 Md. App. 335, 354, 811 A.2d 881, 892 (2002) (citation and quotation marks omitted), *cert. denied*, 374 Md. 84, 821 A.2d 371 (2003). Dr. Welch's opinions were also inadmissible due to their lack of adequate factual basis to establish any causal exposure.

This general rule mandates reliance upon actual data in extrapolation cases. Extrapolation is only allowed where a reasonably precise basis supports it. *See* CSX Transportation, Inc. v. Pitts, 203 Md. App. 343, 394 n.21, 38 A.3d 445, 475 n.21 (extrapolation of economic losses permissible where expert testimony provided dollar-specific "guideposts"), *cert. granted*, 427 Md. 62, 46 A.3d 404 (2012); Keene Corp., Inc. v. Hall, 96 Md. App. 644, 660-61, 626 A.2d 997, 1006 (permissible to extrapolate causation in asbestos case based upon eleven studies showing a combined relative risk of 2.32), *cert. granted*, 332 Md. 741, 633 A.2d 102 (1993). But in Blackwell, the Court of Appeals rejected an expert's extrapolated causation opinion as "*ipse dixit*." 408 Md. at 608, 971 A.2d at 255. That expert's extrapolated conclusion was "ethereal because the bases of the expert's opinion, including the theory of causation, and the methodologies, are not 'generally accepted'," and because the underlying data "was not tested nor gathered for the purpose of testing the [expert's causation] hypothesis." *Id.* at 608-09, 971 A.2d at 255.

All the flaws that demanded exclusion of the expert causation testimony in Blackwell are present here, and then some. There is no factual basis for the causation opinion here, as there was no evidence of the decedent's level of exposure to asbestos from Re-

spondent / Cross-Petitioner Ford's products. Dr. Welch ignored numerous epidemiological studies demonstrating no increased risk of mesothelioma from exposure to brake dust – no risk to **mechanics**, let alone from the indirect "take home" exposure claimed here. In stark contrast to Keene, none of the on-point epidemiology here established a statistically significant increased risk of this disease from this type of exposure. Finally, the studies from which Dr. Welch purported to extrapolate did not even address mesothelioma. Thus those studies' data were "not tested nor gathered for the purpose" that Dr. Welch used them. Blackwell, *supra*. As a matter of science, logic, and law there is no starting point in this case from which to "extrapolate" any causal risk.

Similarly, cases from other jurisdictions allow extrapolation only when it is grounded in exposure evidence existing in the record. For example, in Betz v. Pneumo Abex LLC, 44 A.3d 27 (Pa. 2012), the court rejected any-exposure extrapolation in an asbestos case under identical circumstances, "agree[ing] with [defendants] that the breadth and character of an expert's extrapolations are relevant to the scientific acceptance of his methodology" concerning the cause of mesothelioma. *Id*. at 58. "The alternative," Betz observed, "is to permit experts to evade a reasoned Frye inquiry merely by making references to accepted methods in the abstract." *Id.*[15]

In Donaldson v. Central Illinois Public Service Co., 767 N.E.2d 314 (Ill. 2002), considerable exposure data existed since for much of the relevant period. The alleged dose was established through "equipment . . . to monitor emissions 24 hours a day, while technicians also performed spot testing several times a day." *Id.* at 320. At other times,

[15] The defense arguments with which Betz agreed were: "an opinion based on extrapolation can be sound only to the degree that it is supported by a sufficiently strong logical inference" and that "no rational inference justifies large-scale downward toxicological extrapolations." 44 A.3d at 47-48 (citing, *inter alia* Blackwell, supra).

there were "weekly emission measurements around the perimeter of the Site." *Id.* at 321. The critical variable – the plaintiff's exposure dosage – was thus well established.[16]

The pre-Daubert federal decision, Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C. Cir.), *cert. denied*, 469 U.S. 1062 (1984), also involved reasonably precise evidence of the length, frequency, and proximity of the relevant dosage. The plaintiff, a crop sprayer, physically handled the chemical at issue and used it "six or seven times a month for between one and three hours . . . during the outdoor growing seasons of 1977, 1978, and 1979." 736 F.2d at 1532. Again, dosage parameters in Ferebee were calculable from the evidence.

Likewise, in Trach v. Fellin, 817 A.2d 1102 (Pa. Super. 2003) (en banc), *appeal denied*, 847 A.2d 1288 (Pa. 2004), the court tied "methodology" firmly to "data":

> [T]he scientific method is a method of research in which a problem is identified, relevant data are gathered, a hypothesis is formulated from these data, and the hypothesis is empirically tested.

817 A.2d at 1113 (citation and quotation marks omitted). For any extrapolation to be valid there must first be an "observed range" of dosage within which a particular "variable . . . is known." *Id.* at 1114. In Trach the "dose" (a massive overdose of a drug) was clearly and precisely known.[17] Trach, moreover, was a case of **upward** extrapolation. Extrapolation to higher doses was "more compelling" because of "[a] strong[] logical inference that a substance known to cause adverse side effects in its recommended dose is likely to cause a heightened level of the same or similar adverse effects when taken in a massive overdose." *Id.* at 1117.

Conversely, in Bland v. Verizon Wireless, L.L.C., 538 F.3d 893 (8th Cir. 2008), discussed with approval in Blackwell, the court affirmed exclusion of an expert causation

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[16] Donaldson has since been "abrogated" in Illinois with respect to "whether the scientific technique at issue is generally accepted." In re Commitment of Simons, 821 N.E.2d 1184, 1189 (Ill. 2004).

[17] In Trach the plaintiff took 4,800 mg. of a drug over five days, where the maximum recommended daily dosage was 300 mg. *Id.* at 1105.

opinion where, as here, the plaintiff's expert "lacked knowledge regarding what level of exposure . . . constitutes an appreciable risk of causing [the plaintiff's injury] and the specific concentration and degree of [plaintiff's] exposure. *Id.* at 898. As Blackwell noted, in Bland "there was "simply too great an analytical gap" between "the data identified and [the expert's] proffered opinion." Blackwell, 408 Md. at 607, 971 A.2d at 254, *quoting* Bland, 538 F.3d at 898. A plaintiff's level of exposure to a claimed toxin must be established. It is "too great a leap to get from mere exposure of an unquantified amount of [a substance] to [drawing] conclusions about appellants' illnesses." *Id.* (citation and quotation marks omitted). "Generally accepted methodology, therefore, must be coupled with generally accepted analysis in order to avoid the pitfalls of an 'analytical gap'." *Id.* at 608, 971 A.2d at 255.

Thus, causation analysis in a heavily studied field must address and account for extensive prior science. In rejecting an expert's "theoretical explanation" in Blackwell, the Court pointed out that numerous studies had been conducted and "reliable epidemiological studies have not found any association." 408 Md. at 612, 971 A.2d at 257. *Accord* Allen v. Pennsylvania Engineering Corp., 102 F.3d 194, 197 (5th Cir. 1996) (when after "many years" of study, "not a single scientific study has revealed a link," opinions contrary to the epidemiology "must be rejected"). "[W]here epidemiology is available, it cannot be ignored." Norris v. Baxter Healthcare Corp., 397 F.3d 878, 882 (10th Cir. 2005). The same is true here.

In toxic tort cases, expert testimony on causation is rooted in scientific principles established through toxicology and epidemiology. In order for proffered expert testimony on medical causation to constitute "good science," it must follow the standards and methods generally established and followed by scientists in these relevant communities. Extrapolation in the absence of any exposure data entirely ignores one of the foundations of toxicology – that to determine the cause of a particular condition reliably, the dose-response relationship between a substance and a particular condition must be ascertained. Trach, 817 A.2d at 1113; Bernard D. Goldstein & Mary Sue Henifin, "Reference Guide on Toxicology," Reference Manual on Scientific Evidence, at 646-47 (Fed. Judicial Cen-

ter 3d ed. 2011) (hereafter "Toxicology Guide"). "[A] risk estimate from a study that involved a greater exposure is not applicable to an individual exposed to a lower dose." Michael D. Green, D. Michal Freedman & Leon Gordis, "Reference Guide on Epidemiology," Reference Manual on Scientific Evidence, at 613 (Fed. Judicial Center 3d ed. 2011) (hereafter Epidemiology Guide").[18]

Downward extrapolation to low exposures also ignores that nothing is free of toxins. Every time a chemical is washed down a sink, that chemical is released into the water, and each time a car is driven or a shirt is dry-cleaned, chemicals are released into the air. Air and water will never be toxin-free. Ronald E. Gots, Toxic Risks: Science, Regulation, & Perception, at 108 (CRC Press 1993). Carcinogens are found in everyday items such as "wine, beer, lettuce, root beer, apples, mushrooms, pears, plums, peanut butter, tea, celery, carrots, bread, and chlorinated water." Richard J. Pierce, Jr., "Causation in Government Regulation & Toxic Torts," 76 Wash. U.L.Q. 1307, 1315-16 (1998).[19] Thus, the relevant question is not "Is any [toxin] present?" but "Is any meaningful amount [of toxin] present?" Gots, Toxic Risks, at 108-09.

It follows that a "central tenet" of toxicology – the study of adverse effects of chemical substances on life – is that "the dose makes the poison." Toxicology Guide, at 636. This principle recognizes that all chemical substances, "[e]ven water," can cause harm, but only when a person is exposed to a sufficient dose of the substance. *Id.* Since

[18] Following the Daubert decision, the Federal Judicial Center produced a series of authoritative references for judges faced with determining the validity of various types of expert testimony, the most recent being the 2011 third edition of the Reference Manual on Scientific Evidence.

[19] Specifically, "[b]oth orange juice and coffee each contain known animal carcinogens. Orange juice contains d-limonene, while coffee contains nineteen known animal carcinogens, the most powerful of which is caffeic acid." Pierce, 76 Wash. U.L.Q. at 1313. The specific carcinogens in orange juice and coffee are more potent, by more than an order of magnitude, than the pesticide Alar and are "more carcinogenic by six to eight orders of magnitude than three of the synthetic substances that the National Research Council ('NRC') has identified as posing relatively high potential risks to humans." *Id.*

"depending upon dose, all chemical and physical agents are harmful," *id.* at 660, the dose must be, if not known, at least reasonably estimated.

Some things, while helpful or even necessary to sustain life, are harmful in large doses. Oxygen is toxic when breathed in 100% concentrations over several days, and aspirin, while alleviating headaches with two tablets, can be fatal if an entire bottle is ingested. Gots, Toxic Risks, at 42. Thus, the foundation of toxicology is the dose-response relationship, which "describes the relationship between the magnitude or severity of the effects [of a substance] and the dose." David L. Eaton, "Scientific Judgment & Toxic Torts – A Primer in Toxicology for Judges & Lawyers," 12 J.L. & Pol'y 5, 15 (2003).

"Evidence of exposure is essential in determining the effects of harmful substances." Toxicology Guide, at 666. "Ultimately the dose incurred by populations or individuals is the measure needed by health experts to quantify risk of toxicity." Establishing the degree of exposure to a substance is "[c]ritical to the determination of causation." Joseph V. Rodricks, "Reference Guide on Exposure Science," Reference Manual on Scientific Evidence, at 507 (Fed. Judicial Center 3d ed. 2011) ("Exposure Science Guide"). "Dose is a central concept in the field of toxicology, and an expert toxicologist will consider the extent of a plaintiff's dose in making an opinion." Toxicology Guide, at 638.

Likewise, determining the dose-response relationship is "essential in evaluating a causal connection between an alleged exposure and a particular disease." Eaton, "Scientific Judgment," 12 J.L. & Pol'y, at 18. For an opinion on causation to be reliable, it must be premised on three criteria, each of which depends on a dose-response relationship:

> First, the expert should analyze whether the disease can be related to chemical exposure by a biologically plausible theory. Second, the expert should examine if the plaintiff was exposed to the chemical in a manner that can lead to absorption into the body. Third, the expert should offer an opinion as to whether the dose to which the plaintiff was exposed is sufficient to cause the disease.

Toxicology Guide, at 661. The dose-response relationship of a given substance is "relatively consistent" and "predictable from person to person." Gots, Toxic Risks, at 44

(observing "[i]f this were not so, there would be no safe medications; two tablets might help one patient, but kill another").[20]

The necessity of measuring dose-response relationship is reiterated in the Exposure Science Guide. "Understanding the dose is the necessary first step" in "toxicology, epidemiology, and medicine." *Id.* at 518. Further, "information on concentrations in the media through which people are exposed is the necessary first step in estimating doses." *Id.* at 529. Thus, "[w]hatever the case, the exposure scientist must be careful to ensure accurate description of the exposure concentration (and resulting dose)." *Id.* at 534. *See also* Gots, Toxic Risks, at 163 ("When an exposure to a chemical is less than that known to produce a toxic response, scientific data cannot, as a rule, support a claim of a causal connection."); Toxicology Guide, at 665 (causation "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.").

When an expert is proffered to testify that exposure to a particular substance was the cause of a plaintiff's condition, the expert must be able to demonstrate reliably both that the substance is capable of causing the condition and that it in fact did so in that case. "General causation is established by demonstrating, usually through scientific evidence,

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[20] Like toxicology, epidemiology also recognizes that set criteria must be met before experts may make valid causation determinations. Epidemiology concerns "disease causation and [how] to prevent disease in groups of individuals." Epidemiology Guide, at 551. When diagnosing causes of disease, physicians/scientists first look to epidemiology to determine if there is, at least, an association. Only if one exists, do they then resort to formulae such as the Bradford Hill criteria to evaluate whether an epidemiologic association is causal in a particular individual. Those criteria are: (1) consistency; (2) strength of association; (3) dose response; (4) biological plausibility; (5) coherence; (6) temporality; (7) specificity; (8) analogy; and (9) experimentation. Douglas L. Weed, "Causation: An Epidemiologic Perspective (In Five Parts)," 12 J.L. & Pol'y 43, 43 (2003-04), *citing* Austin Bradford Hill, "The Environment & Disease: Association or Causation?" 58 Royal Soc'y Med. 295, 295-300 (1965). The Epidemiology Guide lists these as factors to be used in determining causation. *See* Epidemiology Guide, at 600.

that a defendant's action or product causes (or is capable of causing) disease." John B. Wong, Lawrence O. Gostin & Oscar A. Cabrera, "Reference Guide on Medical Testimony," Reference Manual on Scientific Evidence, at 743 (Fed. Judicial Center 3d ed. 2011). "Specific causation," by contrast, "is established by demonstrating that a defendant's action or product is the cause of a particular plaintiff's disease." Id at 744. See Aventis Pasteur v. Skevofilax, 396 Md. 405, 414, 914 A.2d 113, 118 (2007) (distinguishing the two concepts). The opinion here went solely to general causation, as it ignored dose-response, and specific causation was not addressed in any meaningful fashion. Dr. Welch strayed far from what is "generally accepted" by scientists in the relevant field.

Thus, an important function of toxicology is to determine the "no observable effect level" – the "threshold . . . below which no toxicity is observed." Toxicology Guide, at 641; Eaton, "Scientific Judgment," 12 J.L. & Pol'y, at 16, Gots, Toxic Risks, at 47. Below this level "a relationship between the exposure and disease **cannot be established**." Toxicology Guide, at 669 (emphasis added). That a particular substance could conceivably be harmful in small doses (without evidence that it is) is not an excuse for abandoning fundamental scientific principles. As one scientist observed about chemical carcinogens, "To deny the existence of dose response [is] clearly an insupportable concept." Paul Kotin, "Dose-Response Relationship & Threshold Concepts," 271 Annals N.Y. Acad. Sci. 22, 24 (1976).

Both science and precedent are clear. Extrapolation – especially downward extrapolation – cannot be reliably performed in the absence of exposure/dose data. "[E]xtrapolation requires more than mere conjecture to pass reliability scrutiny." Blackwell, 408 Md. at 606, 971 A.2d at 253 (excluding unreliable extrapolation under Frye-Reed).[21] Dr. Welch relied upon no such facts here, the decedent's level of exposure asbestos dust from

[21] Nor can downward extrapolation be pursued to the point of absurdity – with purported evidence of exposure more than an order of magnitude below the lowest observed statistical association – as such risks, if they exist, are "very slight and [do] not achieve medical probability." Toxicology Guide, at 679 (footnote omitted).

Respondent / Cross-Petitioner Ford's products is entirely lacking. It was error to admit her opinions. "The purpose of the Frye test is defeated by an approach which allows a court to ignore the informed opinions of a substantial segment of the scientific community which stands in opposition to the process in question." Reed, 283 Md. at 399, 391 A.2d at 377.

2. Other Courts Do Not Accept Causation Opinions Unsupported by Exposure Data And Reject Any-Exposure Opinions for This Reason.

Courts recognize the importance of the dose-response relationship in reliably establishing causation. "[S]cientific knowledge of the harmful level of exposure to a chemical, and knowledge that the plaintiff was exposed to such quantities are minimal facts necessary to sustain the plaintiffs' burden." Burleson v. Texas Dep't of Criminal Justice, 393 F.3d 577, 586 (5th Cir. 2004) (citation and quotation marks omitted). "'[S]cientific knowledge' implies the opinion is based on more than unsupported speculation." Ranes v. Adams Laboratories, Inc., 778 N.W.2d 677, 697 (Iowa 2010) (citation omitted).

These principles are established throughout the country. For example, in Parker v. Mobil Oil Corp., 857 N.E.2d 1114 (N.Y. 2006), New York's highest court applied the Frye test to require that causation opinions in toxic exposure cases have adequate scientific support. In litigation involving toxic exposure, Parker held that the scientific consensus rejects causation opinions made without regard for dose-response relationships and without quantification of the plaintiff's exposure to the product. It is "well-established that an opinion on causation should set forth a plaintiff's exposure to a toxin, that the toxin is capable of causing the particular illness (general causation) and that plaintiff was exposed to sufficient levels of the toxin to cause the illness (specific causation)." *Id.* at 1120 (citations omitted).

Recognizing that it is not always possible to quantify exposure levels precisely or to utilize an exact dose-response relationship, the Parker court discussed several generally accepted scientific alternative bases for causation testimony:

- Actual dosage levels – which are, of course, preferred where they exist.

- Reliance upon "intensity of exposure" where the science suggests that intensity "may be more important than a cumulative dose for determining the risk."
- Estimation of exposure "through the use of mathematical modeling by taking a plaintiff's work history into account."
- "[Q]ualitative" comparison of the plaintiff's exposure "to the exposure levels of subjects of other studies" where an expert makes "a specific comparison sufficient to show how the plaintiff's exposure level related to those of the other subjects."

Id. at 1121.

The plaintiff in Parker, like Petitioners / Cross-Respondents here, utilized none of these methods and did not attempt to estimate his exposure to the substance (benzene) at issue. The Parker court affirmed summary judgment. A "general, subjective and conclusory assertion-based" causation opinion based solely on the plaintiff's self-interested testimony was outside the pale of general scientific acceptance. *Id.* Such an opinion "neither states the level of [studied] exposure, nor specifies how [plaintiff's] exposure exceeded it, thus [it] lack[s] epidemiologic evidence to support the claim." *Id.* at 1121-22. A second expert opinion couched in vague and unquantifiable terms – "frequent," "extensive," "excessive" – also failed because: (1) "even given that an expert is not required to pinpoint exposure with complete precision [that] cannot be characterized as a scientific expression of [plaintiff's] exposure level"; (2) exposure to the concentrated substance could not be analogized to exposure to the substance in dilute form; (3) the opinion lacked epidemiological support; and (4) "standards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation." *Id.* at 1122.

The same is true in asbestos cases. The Pennsylvania Supreme Court in Gregg v. V-J Auto Parts Co., 943 A.2d 216 (Pa. 2007), made the same point in another automotive brake mesothelioma case:

> 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, [plaintiffs' 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. [Plaintiffs' ex-**

> **pert'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 . . . [but] it can hardly be said that the one whiff of the asbestos from the brakes is a "substantial" factor in causing disease.

Id. at 223 (citation and quotation marks omitted) (emphasis added).

The rationale of Gregg was reiterated and reaffirmed in Betz, 44 A.3d 27, in which the same court held that: (1) "the scientific methodology underlying the any-exposure opinion" constituted "novel" expert testimony subject to Pennsylvania's Frye-based regimen, *id.* at 53, and (2) rejected such opinions as inherently unscientific because:

- The expert "rendered his opinion without being prepared to discuss the circumstances of any individual's exposure." *Id.* at 55.
- "[E]fforts 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." *Id.*
- An "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." *Id.* at 56.
- "The comments to the Second Restatement of Torts recognize that a proportionate evaluation may be required in a reasoned assessment of substantial-factor causation." *Id.* at 56 n.36.
- The expert "discount[ed]" epidemiologic studies and "was not really prepared to discuss epidemiology." *Id.* at 57.
- The expert's extrapolations sought "to evade a reasoned Frye inquiry merely by making references to accepted methods in the abstract." *Id.* at 58.

Similarly, the unanimous Nevada Supreme Court agreed that both evidence of actual exposure to each defendant's asbestos-containing products, and sufficient proof of "frequency, regularity, and proximity" is necessary to establish "substantial factor" causation. Holcomb v. Georgia Pacific LLC, 289 P.3d 188, 197 (Nev. 2012). Expert testimony based on *de minimis* exposure was not enough:

> [W]e first address the standard for finding that a respondent's product caused [decedent's] mesothelioma. . . . [T]he courts that adopt the three-factor test of frequency, regularity, and proximity regularly reject the "any"

> exposure argument. Thus, more than any exposure must be shown . . . [and] *de minimis* exposures are insufficient to prove that the exposure was a substantial factor in causing mesothelioma.

Id. (citing precedent from Maryland and Pennsylvania). Nor could causation be based on vague, unquantified references to possible exposure to a defendant's products. *Id*. at 200 ("[w]ithout knowing the specific products that [decedent] used at a particular time, [plaintiffs] cannot show that [defendant's] asbestos was in the products used by [him]").

Another any-exposure opinion in Smith v. Kelly-Moore Paint Co., 307 S.W.3d 829 (Tex. App. 2010), purporting to find causation in a mesothelioma case without any evidence of dose or exposure levels, was likewise rejected as fundamentally unsupported:

> [Plaintiff's expert] further relies on the results of "molecular biological studies, animal experiments, epidemiological studies, case reports, and asbestos tissue burden studies" . . . [but] there is no evidence of any attempt to correlate the dosages . . . and none of the epidemiological studies show a minimum threshold . . . from which to measure whether [plaintiff] had an elevated risk of mesothelioma. . . . **[W]ithout scientific evidence of the minimum exposure level leading to an increased risk of development of mesothelioma . . . [the expert's] opinion lacks [] factual and scientific foundation . . . and, thus, is insufficient to raise a fact issue.**

Id. at 839 (citation and quotation marks omitted) (emphasis added). Other state appellate courts have likewise excluded any-exposure opinions. *E.g.*, Borg-Warner Corp. v. Flores, 232 S.W.3d 765, 773-74 (Tex. 2007); Butler v. Union Carbide Corp., 712 S.E.2d 537, 543-44 (Ga. App. 2011), *cert. denied* (Ga. Oct. 17, 2011); Georgia-Pacific Corp. v. Stephens, 239 S.W.3d 304, 320-21 (Tex. App. 2007), *review denied* (Tex. Feb. 22, 2008); Brooks v. Stone Architecture, P.A., 934 So.2d 350, 354-55 (Miss. App. 2006); McPhee v. Ford Motor Co., 2006 WL 2988891, at *4 (Wash. App. Oct. 16, 2006); Johnson v. Triangle Insulation, 2003 WL 21769867, at *3 (Ky. App. Aug. 1, 2003).

Federal courts have also ruled any-exposure causation opinions inadmissible under their looser Daubert-based analysis of the scientific bases of expert testimony:

> The [causation] requirement, however, is that the plaintiff make a showing with respect to each defendant that the defendant's product was a substantial factor in plaintiff's injury. As a matter of law, [the expert's] affidavit does not provide a basis for a causation finding as to any particular defen-

> dant. **A holding to the contrary would permit imposition of liability on the manufacturer of any product with which a worker had the briefest of encounters on a single occasion.**

Lindstrom v. A-C Product Liability Trust, 424 F.3d 488, 493 (6th Cir. 2005) (applying maritime law) (citation omitted) (emphasis added); *accord* Moeller v. Garlock Sealing Technologies, LLC, 660 F.3d 950, 955 (6th Cir. 2011) (applying Kentucky law); Chism v. W.R. Grace & Co., 158 F.3d 988, 992 (8th Cir. 1998) (applying Missouri law).

Most recently in Smith v. Ford Motor Co., 2013 WL 214378 (D. Utah Jan. 18, 2013), the court found it "questionable" whether the any-exposure proposition "can even properly be called a theory" because it was not "a coherent collection of general propositions used to describe a conclusion." *Id.* at *2. An any-exposure opinion "asks too much from too little evidence":

> [The expert] wants to be allowed to tell a jury that all of the plaintiff's possible exposures to asbestos during his entire life were contributing causes . . . without regard to dosage or how long ago the exposure occurred. Just because we cannot rule anything out does not mean we can rule everything in.

Id. at *3; *accord* In re W.R. Grace & Co., 355 B.R. 462, 476 (Bankr. D. Del. 2006).

Courts in non-asbestos toxic exposure cases agree. In Pluck v. BP Oil Pipeline Co., 640 F.3d 671 (6th Cir. 2011) (applying Ohio law), the court held that "a plaintiff must show that she was exposed to the toxic substance and that the level of exposure was sufficient to induce the complained-of medical condition." *Id.* at 677 (citation and quotation marks omitted). A "differential diagnosis" failed because plaintiff could not "rule in" exposure to a substance when her expert "did not ascertain [her] level of . . . exposure." *Id.* at 679.

In Burleson, 393 F.3d 577, the plaintiff argued against dose assessment, claiming that the only important measurement was "the total dose of radiation to the one cell that was transformed into a cancer cell." That dose, of course, could not be determined, but was allegedly "high." *Id.* at 587. With the plaintiff's exposure level undetermined, the court rejected the opinion as mere "*ipse dixit* of the expert." *Id., quoting* General Electric v. Joiner, 522 U.S. at 146. Extrapolated data, where the expert "failed to conduct a dose

assessment" produces "too great an analytical gap between the data and the opinion proffered." 393 F.3d at 587 (citation and quotation marks omitted).

In Hannan v. Pest Control Services, Inc., 734 N.E.2d 674 (Ind. App. 2000), *transfer denied*, 753 N.E.2d 17 (Ind. 2001), the plaintiffs offered an expert whose "protocol for determining whether a chemical has caused a particular illness did not include an analysis of the exposure levels or the dose of the chemical received by the plaintiffs." *Id.* at 680. This failure alone warranted exclusion.

> [M]ere temporal coincidence of the pesticide application and [plaintiff's] alleged and self-reported illness . . . is insufficient to establish a prima facie case on the element of causation. . . . [T]he trial court properly excluded the testimony of the purported experts because. . . their methods and opinions: (1) were unreliable; (2) were not grounded in scientific knowledge; (3) were not generally accepted in the relevant scientific community, and (4) failed to negate other possible causes of the plaintiffs' illnesses[.]

Id. at 682-83 (citations omitted).

In Guinn v. AstraZeneca Pharmaceuticals LP, 602 F.3d 1245 (11th Cir. 2010), the plaintiff's expert sought to avoid quantification by claiming that every risk factor was *ipso facto* a "substantial cause." The court affirmed exclusion of that opinion:

> An expert, however, cannot merely conclude that all risk factors for a disease are substantial contributing factors in its development. The fact that exposure to [a substance] may be a risk factor for a disease does not make it an actual cause simply because the disease developed.

Id. at 1255. (applying Florida law).

Guinn relied upon Cano v. Everest Minerals Corp., 362 F. Supp.2d 814, 824 (W.D. Tex. 2005), where the plaintiff's "linear no-threshold model," as here, amounted to an opinion that any exposure to radiation, however minute, was a substantial factor in causing cancer. That opinion was inadmissible as contrary to fundamental science.

> [The expert] repeatedly testified that dose did not matter, and that any exposure above background (apparently no matter how small or remote) was a substantial contributing factor. . . . [The law] require[s] more of an expert witness than simply saying that [a minuscule dose] of radiation was a substantial contributing factor because. . .we are all exposed to radiation daily, yet most people do not get cancer. . . .

Id. at 847-48 (footnotes omitted). Where "an expert's causation opinion [is] not based on sufficient information of the level of the agent to which Plaintiffs were exposed, his methodology would not be reliable, rendering his causation opinion inadmissible." *Id.* at 848 (citation and quotation marks omitted).[22]

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[22] *Accord* National Bank of Commerce v. Associated Milk Producers, Inc., 191 F.3d 858, 864 (8th Cir. 1999) (that "plaintiffs' experts have no scientific knowledge or information as to the level of [plaintiffs] exposure" supported affirmance of exclusion); Zellars v. NexTech Northeast, LLC, ___ F. Supp.2d ___, 2012 WL 3993674, at *6 (E.D. Va. Sept. 11, 2012) ("the plaintiff in a toxic tort case bears the burden of demonstrating her actual level of exposure to the alleged toxin"); Baker v. Chevron USA, Inc., 680 F. Supp.2d 865, 885 (S.D. Ohio 2010) ("the no threshold or one-hit theory is not an accepted causation theory"); Henricksen v. ConocoPhillips Co., 605 F. Supp.2d 1142, 1162 (E.D. Wash. 2009) (excluding causation opinion that "did not attempt to quantify dose or even estimate [plaintiff's] level of exposure"); Wills v. Amerada Hess Corp., 2002 WL 140542, at *14 (S.D.N.Y. Jan. 31, 2002) (rejecting opinion because "the level of exposure of plaintiff to the toxin in question must be determined," and the expert "admitted" not doing so); Polaino v. Bayer Corp., 122 F. Supp.2d 63, 70 (D. Mass. 2000) (expert's "fundamental error was his failure . . . to estimate through modeling (or any other technique) the dose to which [plaintiff] could have been exposed"); Wynacht v. Beckman Instruments, Inc., 113 F. Supp.2d 1205, 1210 (E.D. Tenn. 2000) ("Key to these investigations is identifying the level of exposure and how it interacts with various organs or body systems ('dose-response'), both in terms of how the chemical is initially distributed through the organism as well as how it ultimately produces a specific ill-effect."); Sutera v. Perrier Group, Inc., 986 F. Supp. 655, 666 (D. Mass. 1997) ("there is no scientific evidence that the linear no-safe threshold analysis is an acceptable scientific technique used by experts in determining causation in an individual"); Mancuso v. Consolidated Edison Co., 967 F. Supp. 1437, 1450 (S.D.N.Y. 1997) ("it is improper for an expert to presume that the plaintiff must have somehow been exposed to a high enough dose to exceed the threshold necessary to cause the illness") (quotation marks omitted); Cuevas v. E.I. DuPont de Nemours & Co., 956 F. Supp. 1306, 1312 (S.D. Miss. 1997) ("requir[ing] a determination of what dose-response relationship exists between the element in question and the harm that has possibly been caused"); Cartwright v. Home Depot U.S.A., Inc., 936 F. Supp. 900, 904 (M.D. Fla. 1996) (excluding causation opinions where "[n]either expert made any effort to ascertain or even approximate what level of exposure" plaintiffs had; experts "did not provide any quantification to substantiate in scientific terms what level of exposure would have been sufficient to cause asthma in Plaintiffs or anyone else"); Whiting v. Boston Edison Co., 891 F. Supp. 12, 23 (D. Mass. 1995) (rejecting causation opinion that "[i]n layman's terms . . . assumes that if a lot of something

In this case Dr. Welch purported to opine on causation without any attempt to quantify the decedent's asbestos exposure from Ford products. Such a methodology is not "generally accepted" either as a matter of science or a matter of law. Because such opinions are infirm under Frye-Reed and Md. Rule 5-702, it would be error to allow the jury to hear them.

3. Opinions Based on Anecdotal Case Reports Are Unreliable under Generally Accepted Scientific Principles.

The Court of Special Appeals agreed that "'case reports' and other anecdotal evidence are not probative of either general or actual causation." Dixon, 206 Md. App. at 198, 47 A.3d at 1048. Thus, Dr. Welch's methodology also fails because of heavy dependence on this sort of non-probative material (E.871-72). Frye-Reed requires courts evaluating scientific methodology to be guided by actual science. "When a scientist claims to rely on a method practiced by most scientists, yet presents conclusions that are shared by no other scientist, the trial court should be wary that the method has not been faithfully applied." Blackwell, 408 Md. at 606, 971 A.2d at 254, *quoting* Lust v. Merrell Dow Pharmaceuticals, Inc., 89 F.3d 594, 598 (9th Cir. 1996). Experts must "follow the procedures established by the scientists." Schultz v. State, 106 Md. App. 145, 154, 664 A.2d 60, 64 (1995).

The Federal Environmental Protection Agency – whose job it is to evaluate the carcinogenicity of asbestos (among other things) – rejects Dr. Welch's use of case reports to support causation opinions:

> Case reports describe a particular effect in an individual or group of individuals who were exposed to a substance. These reports are often anecdotal or highly selective in nature and generally are of limited use for hazard assessment. **Specifically, cancer causality can rarely be inferred from case reports alone**.

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is bad for you, a little of the same thing, while perhaps not equally bad, must be so in some degree").

United States, EPA, "Guidelines for Carcinogen Risk Assessment," at 2-6 (March 2005) (emphasis added).[23] As recognized by this Court in Blackwell, similar caveats preclude reliance upon voluntary adverse reaction reporting to the Food and Drug Administration ("FDA"), another federal agency charged with scientific risk assessment.

> VAERS [FDA's Vaccine Adverse Event Reporting System] cannot be used to calculate incidence rates because the VAERS database does not have complete reporting of all adverse events and because many report events lack a confirmed diagnosis or confirmed attribution to vaccine.

408 Md. at 601, 971 A.2d at 250-51 (quoting official FDA evaluation). The FDA − responsible for drugs and medical devices in addition to the vaccine in Blackwell − continues to hold this view today:

> FDA does not receive reports for every adverse event or medication error that occurs with a product. Many factors can influence whether or not an event will be reported, such as the time a product has been marketed and publicity about an event. Therefore, **FAERS data cannot be used to calculate the incidence of an adverse event** or medication error in the U.S. population.

United States, FDA, "FDA Adverse Event Reporting System (FAERS) (formerly AERS)" (Sept. 10, 2012) (emphasis added).[24]

Not only do the relevant government agencies charged with collecting case reports confirm that these anecdotal submissions are inherently unreliable to establish causation, but more generally:

> Anecdotal reports may be of value, but they are ordinarily more helpful in generating lines of inquiry than in proving causation. . . . Anecdotal evidence usually amounts to reports that events of one kind are followed by events of another kind. **Typically, the reports are not even sufficient to show association, because there is no comparison group**.

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[23] Available online at: < http://www.epa.gov/raf/publications/pdfs/CANCER_GUIDELINES_FINAL_3-25-05.PDF > (last visited Feb. 12, 2013).

[24] Available online at: < http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm > (last visited Feb. 12, 2013).

David H. Kaye & David A. Freedman, "Reference Guide on Statistics," Reference Manual on Scientific Evidence, at 217-18 (Fed. Judicial Center 3d ed. 2011) (footnote omitted) (emphasis added).

Thus, under Frye-Reed, anecdotal case reports are incompetent as evidence of causation because their use for this purpose is not "generally accepted." "Anecdotal evidence and testimonials do not rise to the level of substantial evidence." T-UP, Inc. v. Consumer Protection Division, 145 Md. App. 27, 66 n.8, 801 A.2d 173, 195 n.8, *cert. denied*, 369 Md. 661, 802 A.2d 439 (2002). In Blackwell, the Court condemned an expert's reliance on adverse event reports as a means of proving causation.[25] The opinion was "faulty extrapolation from [adverse event reporting] data" and "[n]one of [the expert's] research aimed at establishing a link between [between the exposure and injury], moreover, is based upon sound methodology." 408 Md. at 608-09, 971 A.2d at 255. The "plural of anecdote" is not "data." United States v. Raymond, 700 F. Supp.2d 142, 147 n.5 (D. Me. 2010) (excluding anecdotally based expert testimony under Daubert).

Many courts recognize that anecdotal material is not a scientifically valid basis for a causation opinion. On virtually identical facts, the Pennsylvania Supreme Court in Betz dismissed "case reports, animal studies, and regulatory standards" as "ineffectual in terms of substantial-factor causation." 44 A.3d at 55. The Third Circuit excluded a causation opinion based upon "purely anecdotal" data in In re TMI Litigation, 193 F.3d 613, 673-74 (3d Cir. 1999) (applying Pennsylvania law), *cert. denied*, 530 U.S. 1225 (2000). The Iowa Supreme Court similarly observed that "case reports are merely accounts of medical events. They reflect only reported data, not scientific methodology." Ranes, 778 N.W.2d at 693 (citation and quotation marks omitted). Ranes held: (1) "the methodology used by the expert becomes suspect when it is only supported by case reports of limited use to the

[25] The excluded expert in Blackwell had prepared six studies of autism based on the FDA's collected vaccine adverse event reports ("VAERS") database. 408 Md. at 602-03, 971 A.2d at 251-52.

medical field," and (2) "a bare analogy from case reports to the injuries alleged in a particular case is unreliable." *Id.*

This issue has frequently arisen under the looser federal Daubert standard. Even under that standard, courts around the country have rejected causation and/or risk opinions based upon anecdotal case reports. "[R]eliance on anecdotal evidence" is one of the "[r]ed flags that caution against certifying an expert." Newell Rubbermaid, Inc. v. Raymond Corp., 676 F.3d 521, 527 (6th Cir. 2012) (applying Ohio law). "The fundamental scientific limitations of anecdotal evidence have led federal courts to consistently reject individual case reports as a reliable basis for medical causation opinions." W.R. Grace, 355 B.R. at 481 (excluding mesothelioma causation opinion based on anecdotal case reports) (citations omitted). Such reports "make little attempt to screen out alternative causes for a patient's condition," and "frequently lack analysis." Glastetter v. Novartis Pharmaceuticals Corp., 252 F.3d 986, 989-90 (8th Cir. 2001) (affirming exclusion of causation/risk opinions) (applying Missouri law). They are also "unreliable because they do not take into account the known background risk of a disease." Soldo v. Sandoz Pharmaceuticals Corp., 244 F. Supp.2d 434, 540 (W.D. Pa. 2003) (citation omitted). Thus, "reliance on the case reports is *per se* unscientific." *Id.* at 537. "[F]or any given report, there is no certainty that the suspect [substance] caused the reaction." Reynolds v. Warthan, 896 S.W.2d 823, 827 (Tex. App. 1995) (applying Daubert standard). "[A] compilation of case reports without any statistical context," cannot support a causation opinion. Kilpatrick v. Breg, Inc., 613 F.3d 1329, 1338 (11th Cir. 2010) (applying Florida law).

"Case reports and case studies are universally regarded as an insufficient basis for a conclusion regarding causation because case reports lack controls." Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1411 (D. Or. 1996) (citations omitted). With "very small sample size and no rigorous scientific assessment," case studies do "not demonstrate anything more than an indeterminate correlation." Rose v. Matrixx Initiatives, Inc., 2009 WL 902311, at *15 (W.D. Tenn. March 31, 2009). Such anecdotal material, and thus expert causation opinions relying on them, do not come close to the "general acceptance" standard for scientific evidence under Frye-Reed. Such methodology is more ap-

propriately described as "generally rejected." Therefore, the Court of Special Appeals properly rejected Dr. Welch's opinions.

4. Governmental Risk Assessments Do Not Establish Causation in This Case.

Dr. Welch also repeatedly relied on regulatory exposure standards imposed by OSHA, EPA and as many as "a dozen state and national regulatory bodies" in the United States and elsewhere (E.851, E.855, E.869, E.870-71, E.872, E.899). She even "bas[ed] [her] opinion on the [OSHA] regulation itself" (E.871). This, too, was unscientific.

Governments promulgating regulations use much lower standards than common-law courts. Administrative agencies "may make regulatory decisions . . . based on post-marketing evidence that gives rise to only a suspicion of causation." Matrixx Initiatives, Inc. v. Siracuso, ___ U.S. ___, 131 S. Ct. 1309, 1320 (2011) (citation omitted). "The distinction between avoidance of risk through regulation and compensation for injuries after the fact is a fundamental one." In re Agent Orange Product Liability Litigation, 597 F. Supp. 740, 781 (E.D.N.Y. 1984), *aff'd in pertinent part*, 818 F.2d 145 (2d Cir. 1987), *cert denied*, 484 U.S. 1004 (1988). Thus, courts have repeatedly rejected efforts by private plaintiffs to satisfy scientific reliability burdens in civil litigation with reference to looser regulatory risk assessments made by governmental agencies.

Unlike civil litigants, administrative agencies may prophylactically target possible risks suggested by far less than the "more likely than not" proof of actual causation that courts require. As pointed out in a prior asbestos case:

> [p]roof of risk and proof of causation entail somewhat different questions because risk assessment frequently calls for a cost-benefit analysis. The agency assessing risk may decide to bar a substance or product if the potential benefits are outweighed by the possibility of risks that are largely unquantifiable because of presently unknown contingencies. Consequently, risk assessors may pay heed to any evidence that points to a need for caution, rather than assess the likelihood that a causal relationship in a specific case is more likely than not.

Butler, 712 S.E.2d at 552, *quoting* Margaret A. Berger, "The Supreme Court's Trilogy on the Admissibility of Expert Testimony," Reference Manual On Scientific Evidence, at 33

(Fed. Judicial Center 2d ed. 2000); *accord* Matrixx Initiatives, 131 S. Ct. at 1320 n.9 (also quoting Reference Manual). In a toxic tort case, however, the focus is on proving that causation is more likely than not, as opposed to administrative cost-benefit analysis.

In his toxicology "primer," Dr. Eaton likewise explains that public health guidelines cannot be interpreted as setting causation criteria in civil cases involving specific individuals because governmental bodies intentionally "overestimate" risk.

> Because a number of protective, often "worst-case" assumptions . . . are made in estimating allowable exposures for large populations, these criteria and the resulting regulatory levels . . . generally **overestimate potential toxicity levels for nearly all individuals**. Furthermore, because these guidelines are intended to be protective of all individuals in a population, including the very young, the very old, and other potentially "sensitive" individuals, the theoretical risks from exposure at the guideline range level is likely to be substantially over-estimated for the large majority of individuals in the population.

"Scientific Judgment & Toxic Torts," 12 J.L. & Policy at 34-35 (emphasis added). Nothing in the record establishes that any of the governmental exposure criteria relied upon by Dr. Welch adhered to the "more likely than not," "reasonable degree of certainty," and "substantial factor" standards required under Maryland law.

Thus, "standards promulgated by regulatory agencies as protective measures are inadequate to demonstrate legal causation." Parker, 857 N.E.2d at 1122. Recognizing the disparate standards set by administrative bodies responsible for overall public health, courts have repeatedly refused to equate governmental guidelines with the stricter requirements imposed on plaintiffs in civil litigation – and have excluded, as unhelpful and confusing to juries, expert testimony that would ignore these distinctions. The FDA's standards for product approval, for example, are not probative of causation.

> [T]he FDA did not purport to have drawn a conclusion about causation. Instead, the statement merely states that possible risks outweigh the limited benefits of the drug. This risk-utility analysis involves a **much lower standard** than that which is demanded by a court of law. A regulatory agency such as the FDA may choose to err on the side of caution.

Rider v. Sandoz Pharmaceuticals Corp., 295 F.3d 1194, 1201 (11th Cir. 2002) (emphasis added). Administrative "risk-utility analysis" "does not directly focus on the question of

causation" in individuals, and thus "is unreliable proof of medical causation in the present case because the FDA employs a reduced standard (*vis-a-vis* tort liability) for gauging causation." McClain v. Metabolife International, Inc., 401 F.3d 1233, 1250 (11th Cir. 2005) (citation and quotation marks omitted).

Agencies like OSHA and EPA routinely set exposure standards for substances, such as asbestos, that cannot satisfy a plaintiff's burden of proof in a common-law tort case. In Allen, 102 F.3d 194, the court excluded expert opinions that "employ[ed] a "weight of the evidence" analysis used by organizations such as the World Health Organization, OSHA, and the EPA "to rate the carcinogenicity of various substances in humans." *Id.* at 196. Such standards could not be imported into tort litigation because they were based on "much lower" standards of proof:

> We are also unpersuaded that the "weight of the evidence" methodology these experts use is scientifically acceptable for demonstrating a medical link. . . . Regulatory and advisory bodies . . . utilize a "weight of the evidence" method to assess the carcinogenicity of various substances in human beings and suggest or make prophylactic rules governing human exposure. This methodology results from the preventive perspective that the agencies adopt in order to reduce public exposure to harmful substances. The agencies' threshold of proof is reasonably **lower than that appropriate in tort law**, which traditionally makes more particularized inquiries into cause and effect and requires a plaintiff to prove that it is more likely than not that another individual has caused him or her harm.

Id. at 198 (citation and quotation marks omitted) (emphasis added). An Ohio court of appeals, in a decision affirmed by that state's Supreme Court, made the same point:

> [S]ubstances are regulated because of what they might do at given levels, not because of what they will do. . . . The fact of regulation does not imply scientific certainty. It may suggest a decision to err on the side of safety as a matter of regulatory policy rather than the existence of scientific fact or knowledge. . . .

Valentine v. PPG Industries, Inc., 821 N.E.2d 580, 597-98 (Ohio App. 2004) (citations and quotation marks omitted), *aff'd*, 850 N.E.2d 683 (Ohio 2006). "[T]he fact that an agency, *ex ante*, sets a[] standard . . . does not compel, or even necessarily support, the *ex*

post conclusion that [plaintiff's condition] was caused by" an exposure in excess of that standard. Sutera v. Perrier Group, Inc., 986 F. Supp. 655, 664 (D. Mass. 1997).[26]

Both scientific principles and legal precedent establish that Dr. Welch's reliance on administrative asbestos exposure standards, instead of the common-law causation standards applicable to this case, is not "generally accepted" as mandated by Frye-Reed.

* * * *

In Blackwell, the Court warned that, while "fact witnesses may also have their biases," attorneys "cannot normally shop for an ordinary fact witness." 408 Md. at 592,

[26] Accord Johnson v. Arkema, Inc., 685 F.3d 452, 464-65 (5th Cir. 2012) (following Allen; excluding opinion based on agency standards as "irrelevant and unreliable"); Mitchell v. Gencorp Inc., 165 F.3d 778, 783 n.3 (10th Cir. 1999) (state administrative finding of carcinogenicity discounted as based upon lower administrative standard); Baker, 680 F. Supp.2d at 880 ("mere fact that Plaintiffs were exposed to [the product] in excess of mandated limits is insufficient to establish causation"); Junk v. Terminix International Co., 594 F. Supp.2d 1062, 1071 (S.D. Iowa 2008) ("government agency regulatory standards are irrelevant to [plaintiff's] burden of proof in a toxic tort cause of action because of the agency's preventative perspective"); Rhodes v. E.I. du Pont de Nemours & Co., 253 F.R.D. 365, 377 (S.D.W. Va. 2008) ("governmental standards are "of limited utility in a toxic tort case, especially for the issue of causation" because "developed for regulatory purposes and . . . not provide information about actual risk or causation"); Molden v. Georgia Gulf Corp., 465 F. Supp.2d 606, 611 (M.D. La. 2006) ("regulatory and advisory bodies make prophylactic rules governing human exposure based on proof that is reasonably lower than that appropriate in tort law"); Cano, 362 F. Supp.2d at 825 (that the product "has been classified as a carcinogen by agencies responsible for public health regulations is not probative of" common-law specific causation); Burleson v. Glass, 268 F. Supp.2d 699, 717 (W.D. Tex. 2003) ("mere fact that [the product] has been classified by certain regulatory organizations as a carcinogen is not probative on the issue of whether [plaintiff's] exposure . . . caused his . . . cancers"), *aff'd*, 393 F.3d 577 (5th Cir. 2004); Mancuso, 967 F. Supp. at 1448 ("recommended or prescribed precautionary standards cannot provide legal causation"; "[f]ailure to meet regulatory standards is simply not sufficient" to establish liability); O'Neal v. Dep't of the Army, 852 F. Supp. 327, 333 (M.D. Pa. 1994) (administrative risk figures are "appropriate for regulatory purposes in which the goal is to be particularly cautious . . . [but] overstate the actual risk and, so, are inappropriate for use in determining" civil liability); Wade-Greaux v. Whitehall Laboratories, Inc., 874 F. Supp. 1441, 1464 (D.V.I.) ("assumption[s that] may be useful in a regulatory risk-benefit context . . . ha[ve] no applicability to issues of causation-in-fact"), *aff'd*, 46 F.3d 1120 (3d Cir. 1994).

971 A.2d at 245. As to expert witnesses, however, "attorneys can seek expert witnesses who will parrot the attorneys' line, and, indeed, implicitly 'bribe' them to do so." *Id.* Precisely that occurred here, with a witness whose any-exposure opinions ignored extensive epidemiology, and relied instead on unreliable anecdotal case reports and prophylactic governmental standards. Instead of scientific testimony, the expert offered the jury an opinion on legal causation – "substantial factor" – that was fundamentally at odds with established Maryland law. Whether a single breath of asbestos-contaminated air may constitute "substantial factor" causation is a matter of jurisprudence, not science. The trial court therefore erred in admitting those opinions, and the Court of Special Appeals' reversal should also be affirmed under Frye-Reed.

VI. CONCLUSION

For the foregoing reasons, *amicus curiae* Product Liability Advisory Council, Inc. respectfully urges this Court to affirm the Court of Special Appeals and hold that causation opinions such as those offered by Dr. Welch are inadmissible, both as impermissible expert testimony on the legal issue of "substantial factor" causation and under the Frye-Reed "general acceptance" standard for expert testimony.

STATEMENT ON PROPORTIONALLY SPACED TYPE

In compliance with Md. Rules 8-504 and 8-112, this brief was written in 1.5 line spaced Times New Roman font, type size 13.

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Dated: February 25, 2013

CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of February, 2013, I caused two copies of the foregoing Brief Of *Amicus Curiae* Product Liability Advisory Council, Inc. In Support Of Respondent / Cross-Petitioner Ford Motor Company to be served by first class mail upon:

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