

FOR PUBLICATION

In the
United States Court of Appeals
For the Eleventh Circuit

No. 24-10080

MICHAEL DAVIS,

on behalf of himself and as personal
representative of Carol Davis,

Plaintiff-Appellant,

THE ESTATE OF CAROL DAVIS,

Plaintiff,

versus

LOCKHEED MARTIN CORPORATION,

Defendant-Appellee.

Appeals from the United States District Court
for the Middle District of Florida
D.C. Docket No. 6:22-cv-00081-RBD-DCI

2

Opinion of the Court

24-10080

No. 24-10416

VERVICIA HENDERSON,
on behalf of herself and as personal
representative of Craig Henderson, et al.,

Plaintiffs,

DONNA DEMILT,
ERIC RUTLEDGE,
EMILIO SAN MARTIN,
BRIAN SLUSARZ,
MICHAEL MCGARRY, et al.,

Plaintiffs-Appellants,

versus

LOCKHEED MARTIN CORPORATION,
UNIVERSAL CITY PROPERTY MANAGEMENT III, LLC,

Defendants-Appellees,

NBCUNIVERSAL MEDIA, LLC, et al.,

Defendants.

Appeals from the United States District Court
for the Middle District of Florida
D.C. Docket No. 6:21-cv-01363-RBD-DCI

Before JILL PRYOR, LUCK, and BRASHER, Circuit Judges.

BRASHER, Circuit Judge:

24-10080

Opinion of the Court

3

This appeal arises from two cases alleging that Lockheed Martin permitted toxic waste to leach into the area surrounding its manufacturing facility, inflicting neurological harm on workers and nearby residents. The plaintiffs submitted testimony from two experts to prove that the toxic waste could have caused their neurological conditions. In response, Lockheed Martin moved to exclude the experts as unreliable and moved for summary judgment based on a lack of general causation evidence. The district court granted Lockheed's motions to exclude, explaining that one expert had not reliably explained or applied his "weight of the evidence" methodology and that the second expert relied on the first expert's report. The court then granted Lockheed's motions for summary judgment, explaining that the plaintiffs lacked reliable general causation testimony.

The question in this appeal is whether the district court abused its discretion when it excluded these two experts as unreliable and granted summary judgment based on this exclusion. Because the experts did not reliably apply their methodologies and without those experts the plaintiffs lacked general causation evidence, the district court did not abuse its discretion in determining that their testimony was unreliable and granting summary judgment. Accordingly, we affirm.

I.

This appeal comes to us from decisions in two related district court cases: *Davis v. Lockheed Martin* and *DeMilt v. Lockheed Martin*. Because the cases are based on substantially the same

claims, the same district judge managed and coordinated discovery in both. He also entered essentially the same order on review in both cases.

The plaintiffs allege that Lockheed Martin¹ mishandled toxins, called volatile organic compounds, at its Sand Lake Road Facility in Orlando. The *DeMilt* plaintiffs are a subset of a larger group of plaintiffs who allege that these compounds leached into the surrounding soil, groundwater, and air, causing them or their close relatives to develop serious health conditions. The *DeMilt* plaintiffs allege that these compounds caused their multiple sclerosis, Parkinson's, or other neurodegenerative diseases. Similarly, Davis alleges that his wife was exposed to these compounds while she worked for Lockheed, and that this exposure caused her to develop multiple sclerosis and pass away. Collectively, the appellants say that five compounds caused their injuries: TCE, PCE, toluene, xylene, and styrene.

Toxic tort claims like these ordinarily require a plaintiff to prove general causation—that a substance *can* cause a given disease. RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL AND EMOTIONAL HARM § 28 cmt. c(3) (A.L.I. 2010). Experts establish

¹ The plaintiffs in *DeMilt* also sued Universal City Property Management, alleging that the company had engaged in a joint venture with Lockheed to contaminate the area. The addition of this defendant in *DeMilt* does not meaningfully change our analysis, so for brevity, we refer only to Lockheed in the remainder of this opinion.

24-10080

Opinion of the Court

5

general causation through three primary methodologies: epidemiological evidence, dose-response relationship, and background risk of disease. *Chapman v. Procter & Gamble Distrib., LLC*, 766 F.3d 1296, 1308 (11th Cir. 2014).

Experts who use epidemiological evidence to establish general causation must show that there is an association between a substance and a disease and that the association is causal. *See In re Deepwater Horizon BELO Cases*, 119 F.4th 937, 941 (11th Cir. 2024) (citing Michael D. Green et al., *Reference Guide on Epidemiology*, in *REFERENCE MANUAL ON SCIENTIFIC EVIDENCE* 549, 554, 597 (Fed. Jud. Ctr., 3d ed. 2011)). Because it is difficult to conclusively prove causation in epidemiology, experts often use a methodology called the “weight of the evidence” methodology, by which they infer the best explanation for an association. *See In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 858 F.3d 787, 795 (3rd Cir. 2017). Either as part of the weight of the evidence methodology or as part of a separate methodology, experts can also evaluate the strength of associations they find by using nine metrics called the Bradford Hill factors. *See Green, supra*, at 599–600.

The plaintiffs’ two general causation experts applied a mix of these methodologies. Dr. Daniel Kantor applied an epidemiological evidence approach. And Dr. Ronald Kendall applied both an epidemiological evidence approach and a background risk approach. Dr. Charles Cowan provided a statistical analysis that informed Kendall’s background risk approach.

Kantor's opinion stated that "[b]ased on the weight of the evidence," the compounds that Lockheed emitted, "both individually and in chemical mixtures, are capable of causing the diseases and injuries that have been suffered by Plaintiffs." Doc. 58-1 at 29 (*Davis*); Doc. 138-1 at 29 (*DeMilt*). Lockheed filed rebuttal reports asserting that Kantor failed to explain his methodology and failed to evaluate the Bradford Hill factors. In response, Kantor described the search criteria he used to find studies and stated that his review "did in fact satisfy the Bradford Hill criteria." Doc. 58-2 at 3–4 (*Davis*); Doc. 138-2 at 3–4 (*DeMilt*). He also briefly explained how he might apply the Bradford Hill criteria to one of the studies that he cited. *Id.* at 7.

Kendall's expert opinion stated that he had reviewed other experts' reports, including Kantor's and Cowan's, and concluded that: (1) volatile organic compound exposure could have caused the plaintiffs' illnesses; and (2) the zip codes near Lockheed posed a higher risk of mortality from the plaintiffs' illnesses than the zip codes farther from Lockheed. The relevant part of Cowan's expert opinion compared mortality rates in zip codes surrounding the Lockheed facility with mortality rates in Orange County, Florida. He found statistically significant results showing that the Lockheed zip code had higher mortality rates related to "Diseases of Central Nervous System" and Parkinson's.

Lockheed moved to exclude the expert opinions of Kantor and Kendall and moved for summary judgment based on a failure to establish general causation.

24-10080

Opinion of the Court

7

The district court granted Lockheed's motions (in *DeMilt*, granting partial summary judgment for only the appellants). The court held that Kantor's methodology was unreliable because he did not explain his criteria for pulling or categorizing studies, nor did he evaluate the Bradford Hill factors. The court held that Kendall's methodology was unreliable because his report largely adopted other experts' opinions. And the court held that summary judgment was due against Davis and the *DeMilt* appellants because, without Kantor and Kendall's testimony, they had no general causation evidence.

The district court's ruling in *Davis* ended the case, but the district court's ruling in *DeMilt* did not because it was only a partial summary judgment. Accordingly, the district court certified the partial summary judgment under Federal Rule of Civil Procedure 54(b) for the *DeMilt* appellants to appeal.

All plaintiffs timely appealed.

II.

Before addressing the parties' argument, we resolve two preliminary matters.

First, we have appellate jurisdiction over the *DeMilt* appeal because the district court did not abuse its discretion in certifying its *DeMilt* judgment under Rule 54(b). That judgment disposed of all the *DeMilt* appellants' claims, so it is a final judgment as to those plaintiffs, even though other plaintiffs have claims remaining. Because the remaining plaintiffs suffer from other illnesses, their

claims are not related to the admissibility of this general causation evidence.

We also believe there is “no just reason for delay.” Fed. R. Civ. P. 54(b). The *DeMilt* appellants raise the same issues as Davis based on a materially identical district court order in a jointly managed case. If the *DeMilt* appellants had to wait until a final disposition of the other plaintiffs’ claims, we would need to hear identical appeals about the same district court order twice—Davis’s appeal now and the *DeMilt* plaintiffs’ appeal at some later date. See *Ebrahimi v. City of Huntsville Bd. of Educ.*, 114 F.3d 162, 166 (11th Cir. 1997) (explaining that a Rule 54(b) certification requires weighing the costs and risks of piecemeal appeals).

Second, we review a district court’s *Daubert* rulings for abuse of discretion. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 141–43 (1997). The district court has “broad discretion.” *Montgomery v. Aetna Cas. & Sur. Co.*, 898 F.2d 1537, 1541 (11th Cir. 1990). “We defer to the district court unless its ruling was manifestly erroneous.” *Adams v. Lab’y Corp. of Am.*, 760 F.3d 1322, 1327 (11th Cir. 2014) (citation modified). This deference includes giving the district court “considerable leeway” to decide “how to go about determining” whether expert testimony is reliable. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999) (emphasis added).

III.

The plaintiffs argue that the district court abused its discretion by excluding two general causation experts and, for that reason, should not have granted summary judgment on their claims.

24-10080

Opinion of the Court

9

We disagree. We cannot say that the district court abused its discretion in excluding either expert. The district court reasonably determined that Kantor did not reliably apply his methodology. And Kendall’s general causation opinion merely relied on the opinions of other experts like Kantor and did not reliably apply any methodology. Because Kantor and Kendall provided the only general causation testimony relevant to the plaintiffs, the district court did not err in granting summary judgment.

We address the district court’s reasoning as to each expert in turn.

A.

We begin with Kantor. In epidemiology, a general causation opinion must do two things. It must reliably assess whether there is an association between a substance and a disease and, if there is an association, whether the association is causal. *In re Deepwater Horizon*, 119 F.4th at 941 (citing *Green*, *supra*, at 623); *see* FED. R. EVID. 702(d) (requiring an expert’s opinion to be a “reliable application of the principles and methods to the facts”).

We assume without deciding that Kantor reliably concluded that there was some association between the compounds and the relevant neurological conditions.

Moving to the second part of a general causation opinion, Kantor did not reliably apply his methodology to find a causal relationship. Kantor wrote that he applied the weight of the evidence methodology. And in his rebuttal report, Kantor elaborated that his

methodology satisfied the Bradford Hill criteria. But the district court held that, although the weight of the evidence methodology can be reliable, Kantor did not apply it reliably. The district court highlighted that Kantor’s initial report did not analyze the Bradford Hill factors and his rebuttal report did not properly analyze them. Because this holding is reasonable, we cannot say the district court abused its discretion in excluding Kantor’s general causation opinion.

We believe that the district court reasonably concluded that Kantor’s testimony was unreliable because of the cumulative effect of two reasons: first, he did not explain his methodology; and second, he did not adequately evaluate the Bradford Hill factors.

1.

We begin with the first reason. Although Kantor applied a common methodology for discerning a causal relationship, he did not adequately explain it. The weight of the evidence methodology “involves a series of logical steps used to infer to the best explanation.” *In re Zolof*, 858 F.3d at 795 (citation modified). These steps require an expert to consider a broad range of evidence and alternative explanations before concluding what the “best explanation” for an association is. *See Milward v. Acuity Specialty Prods. Grp.*, 639 F.3d 11, 17–18 (1st Cir. 2011). Because it is such a “flexible” methodology, it is susceptible of being “a mere conclusion-oriented selection process.” *In re Zolof*, 858 F.3d at 795–96 (citation modified). But the Supreme Court has held that a district court may exclude evidence that “is connected to existing data only by the *ipse dixit* of

24-10080

Opinion of the Court

11

the expert.” *Joiner*, 522 U.S. at 146. With this instruction in mind, we join with our sister circuits in holding that an expert must explain how he weighed the evidence for this methodology to be reliable. *See Milward*, 639 F.3d at 18–20, 22–23 (writing that this methodology “requires judgment and interpretation” and admitting the opinion of an expert who “carefully explained” his weight of the evidence analysis); *In re Zoloft*, 858 F.3d at 796.

The district court did not abuse its discretion in concluding that Kantor’s insufficient explanation for his methodology contributed to its unreliability. Although Kantor’s rebuttal report disclosed some of the search terms he used to find studies, he never identified all the terms that he used during his research. Although his rebuttal report provided an example of “some of the factors” he used to analyze some studies, Doc. 58-2 at 4 (*Davis*); Doc. 138-2 at 4 (*DeMilt*), he did not explain how he weighed those factors, what other factors he used, or even how these representative factors would apply to all of the studies he evaluated. And although he named the studies that supported his conclusions, he never explained how he sorted those studies, ranked rival explanations, sought out additional evidence to separate the more plausible from the less plausible explanations, or used his professional judgment to derive the best explanation. In sum, because Kantor never adequately explained his weight of the evidence methodology, the district court’s conclusion that his testimony was unreliable was not an abuse of discretion.

2.

The second reason is that Kantor’s Bradford Hill analysis was unreliable. As articulated by Sir Austin Bradford Hill, the Bradford Hill factors are “viewpoints” that can guide epidemiologists as they make judgments about whether an association is causal. *See Green, supra*, at 600 n.148 (citation modified). The factors include: (1) temporal relationship; (2) strength of the association; (3) dose-response relationship; (4) replication of the findings; (5) biological plausibility; (6) consideration of alternative explanations; (7) cessation of exposure; (8) specificity of the association; and (9) consistency with other knowledge. *In re Deepwater Horizon*, 119 F.4th at 941 (quoting *Green, supra*, at 600). Experts frequently, but must not always, use the Bradford Hill factors as part of their weight of the evidence methodology. *Id.* (writing that to determine a causal relationship, “experts consider the nine [Bradford Hill] factors”).

Although the Bradford Hill factors are not always a necessary part of the weight of the evidence methodology, a district court is within its discretion to require an expert who is applying these factors to discuss each factor in some depth. Or, as the district court did here, a district court has the discretion to conclude that an expert is unreliable because he failed to both explain his weight of the evidence methodology and properly address the Bradford Hill factors. District courts have considerable discretion in determining how to evaluate expert reliability. *See Kumho Tire Co.*, 526 U.S. at 152. Thus, a district court may conclude that an expert is unreliable because he failed to evaluate all Bradford Hill factors

with sufficient depth as part of the weight of the evidence methodology. In this vein, we have upheld a district court’s exclusion of experts who failed “to provide more than a hasty discussion of the Bradford Hill factors,” who “addressed only three of the nine factors in a few brief sentences,” or who offered a “ cursory and superficial” analysis in the form of “a sentence or two” per factor. *In re Deepwater Horizon*, 119 F.4th at 946–47.

The Third, Sixth, and Seventh Circuits agree that a district court may consider failure to adequately evaluate the Bradford Hill factors as a reason to exclude expert testimony. *See In re Zolof*, 858 F.3d at 796 (“In discussing the conclusions produced by such techniques in light of the Bradford Hill criteria, an expert must explain 1) how conclusions are drawn for each Bradford Hill criterion and 2) how the criteria are weighed relative to one another.”); *In re Onglyza (Saxagliptin) and Kombiglyze (Saxagliptin and Metformin) Prods. Liab. Litig.*, 93 F.4th 339, 347–48 (6th Cir. 2024) (holding that a district court “had multiple grounds to find that [the expert] had not reliably applied Bradford Hill”); *Gilbert v. Lands’ End, Inc.*, 158 F.4th 839, 851 (7th Cir. 2025) (explaining that “we see no reason to undo the district court’s conclusion that” a shortened Bradford Hill analysis “falls short because it fails to sufficiently account for the established Bradford-Hill criteria”).

Applying these principles, we believe that the district court was within its discretion to conclude that Kantor’s Bradford Hill analysis was inadequate. After Lockheed’s experts criticized Kantor for failing to mention Bradford Hill in his initial report, Kantor’s

rebuttal maintained that his methodology incorporated the Bradford Hill criteria. But his Bradford Hill analysis still had two problems: (1) Kantor provided only a cursory description of how the Bradford Hill factors might apply, and (2) he did so for only one study even though his methodology used numerous studies.

First, Kantor provided too little analysis of each Bradford Hill factor. The only Bradford Hill analysis he offered was a sentence listing his conclusions for the factors with language like: “Applying the Bradford Hill Causality Criteria, the association (with a high odds ratio) was **strong**; **temporality** was satisfied as the exposure preceded the diagnosis of PD” Doc. 58-2 at 7 (*Davis*); Doc. 138-2 at 7 (*DeMilt*). We have upheld a district court’s exclusion of experts even when they did more. For example, we affirmed exclusion of one expert in *Deepwater Horizon* who used a “sentence or two” for most factors and affirmed exclusion of another who addressed several factors “in a few brief sentences.” 119 F.4th at 946–47.

Second, Kantor’s discussion of how he applied the Bradford Hill factors considered only one study (Goldman 2012) even though he cited numerous studies as informing his analysis. Even if his Bradford Hill analysis as to that one study were sufficient, it could not explain his overall methodology.

Because Kantor never adequately explained his weight of the evidence methodology and insufficiently evaluated the Bradford Hill factors, the district court was within its discretion to conclude that his testimony was unreliable.

B.

We turn now to Kendall. Kendall's expert report expressed two relevant opinions: (1) exposures to volatile organic compounds can cause the plaintiffs' diseases, and (2) people living in zip codes closest to Lockheed's facility have higher risks of developing Central Nervous System Diseases than those in other areas. The district court did not abuse its discretion in excluding the first opinion because Kendall merely adopted the opinions of others, and the court did not abuse its discretion in excluding the second opinion because Kendall did not reliably conduct a background risk assessment.

The district court did not abuse its discretion in excluding Kendall's first opinion because Kendall adopted the opinions of other experts and thus did not explain his methodology. Kendall's expert report baldly asserts that he reviewed reports from other experts (including Kantor) as well as "the science" to reach the conclusion that "chronic exposures to solvent mixtures are capable of causing the diseases suffered by Plaintiffs." Doc. 59-1 at 5 & n.2 (*Davis*); Doc. 150-1 at 5 & n.2 (*DeMilt*). This kind of bald assertion is what *Joiner* warns against: "opinion evidence that is connected to existing data only by the *ipse dixit* of the expert." 522 U.S. at 146. The district court thus did not abuse its discretion in excluding Kendall's first opinion as unreliable.

The district court did not abuse its discretion in excluding Kendall's second opinion because it was not a reliable background risk assessment. A background risk assessment is one of the three

primary methodologies for proving general causation. Background risk is “the risk a plaintiff and other members of the general public have of suffering the disease or injury that plaintiff alleges *without* exposure to the drug or chemical in question.” *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233, 1243 (11th Cir. 2005).

The *DeMilt* briefing characterizes Kendall’s opinion as a background risk assessment, but Lockheed responds that this briefing was the first time that anyone had characterized Kendall’s opinion as a background risk assessment. Lockheed also argues that, in any event, Kendall’s opinion is not a proper background risk assessment.

We agree with Lockheed. A background risk assessment must compare the risk of disease without exposure to the risk with exposure. *See McClain*, 401 F.3d at 1243–44. But Kendall never conducted this comparison. Kendall essentially adopted Cowan’s expert opinion. And Cowan never conducted a proper background risk assessment. Instead, Cowan compared the mortality rates of those in a zip code near Lockheed’s facility to the mortality rates of those in a zip code farther away. A proper background risk assessment would have compared the disease rates of those who have been exposed to volatile organic compounds and the disease rates of those who have not. On top of the fact that Cowan measured mortality rates and not disease rates, Cowan also did not know the exposure levels of the populations that he was comparing. It is not enough to guess that people in a zip code near Lockheed were ex-

24-10080

Opinion of the Court

17

posed and that people in a zip code far from Lockheed weren't exposed. And Kendall's adoption of Cowan's analysis did not add any information about volatile organic compound exposure in the relevant zip codes. Thus, neither Cowan nor Kendall conducted a proper background risk assessment.

In sum, the district court did not abuse its discretion in excluding Kendall's expert report because one of his opinions was a wholesale adoption of other experts' opinions and the second was not a proper background risk assessment.

IV.

For the foregoing reasons, the district court's orders excluding Kantor and Kendall and granting summary judgment to Lockheed based on those exclusions are **AFFIRMED**.

24-10080

LUCK, J., Concurring

1

LUCK, Circuit Judge, concurring:

The majority opinion affirms the exclusion of Dr. Kantor’s and Dr. Kendall’s expert general causation opinions because they did not reliably apply their own methodologies. In other words, they didn’t do what they said they were going to do. The majority opinion is surely right about this. But, in addition to explaining why the experts were wrong on their own terms, I thought it would be helpful to highlight, once again, how causation expert testimony works in toxic tort cases like this one. *See, e.g., In re Deepwater Horizon BELO Cases*, 119 F.4th 937 (11th Cir. 2024); *Taylor v. Mentor Worldwide LLC*, 940 F.3d 582 (11th Cir. 2019); *Chapman v. Proctor & Gamble Distrib., LLC*, 776 F.3d 1296 (11th Cir. 2014); *McClain v. Metabolife Int’l, Inc.*, 401 F.3d 1233 (11th Cir. 2005).

There are two kinds of toxic tort actions. “In the first, the medical community already recognizes that a specific ‘agent’—i.e., a substance external to the human body (think drugs, chemicals, minerals)—is toxic and capable of ‘causing the type of harm a plaintiff alleges.’” *In re Deepwater Horizon*, 119 F.4th at 940 (citation modified) (quoting *McClain*, 401 F.3d at 1239). “In these actions, the parties battle over specific causation only: that is, whether the agent caused a specific plaintiff’s disease.” *Id.* “In the second, the medical community does not recognize an agent as both toxic and capable of causing the kind of injury a plaintiff alleges.” *Id.* “Plaintiffs in these actions must establish both general and specific causation.” *Id.*

This case is the second kind of toxic tort action because it involves volatile organic compounds that the medical community does not recognize as both toxic and capable of causing the kind of injuries the plaintiffs alleged. In cases like this one, the “plaintiff ‘must demonstrate the levels of exposure’ to the alleged toxin ‘that are hazardous to human beings generally.’” *Id.* at 945 (quoting *McClain*, 401 F.3d at 1241). That is, “a plaintiff must demonstrate the level of exposure to the allegedly harmful chemical that is hazardous to a human being.” *Id.* (citation modified) (quoting *Taylor*, 940 F.3d at 595). This “‘minimal fact’—‘scientific knowledge of the harmless level of exposure to a chemical’—relates to general causation: ‘whether an agent increases the incidence of a disease in a group.’” *Id.* at 946 (citation modified) (quoting *McClain*, 401 F.3d at 1239, 1241).

There are three ways experts can establish this minimal fact: “through epidemiological evidence, dose-response relationship, and background risk of disease.” *Id.* at 941. Here’s how each one works. For epidemiological evidence:

Epidemiology studies the incidence, distribution, and cause of disease in human populations. Experts who rely on epidemiological evidence to establish general causation assess that evidence in two steps. To start, they ask whether the evidence reveals an association between an agent and a disease. To identify an association, experts must rule out alternative explanations, by asking, for example, whether a potential association resulted from limitations in the study, like

24-10080

LUCK, J., Concurring

3

chance or bias. Experts also ask whether the association reflects a true cause-effect relationship. In this context, causation means something akin to but-for cause: exposure to a toxic agent is a necessary link in the chain of events that led to the disease.

To decide whether a particular study supports a causal inference, experts consider the nine factors developed by Sir Austin Bradford Hill: (1) temporal relationship; (2) strength of the association; (3) dose-response relationship; (4) replication of the findings; (5) biological plausibility; (6) consideration of alternative explanations; (7) cessation of exposure; (8) specificity of the association; and (9) consistency with other knowledge. No factor is dispositive. And no algorithm exists for applying the Hill guidelines. Instead, their application requires judgment.

Id. (citation modified).

For dose-response relationship:

[T]he greater the exposure, the greater the risk of disease. At a more granular level, the term describes a relationship in which a change in amount, intensity, or duration of exposure to a chemical is associated with a change—either an increase or decrease—in risk. This relationship is the hallmark of basic toxicology because all substances potentially can be toxic. Most low dose exposures—even for many years—will have no consequences at all. This fact makes dose the single most important factor to consider in evaluating

whether an alleged exposure caused a specific adverse effect.

Id. (citation modified).

And for background risk of disease:

Background risk of disease simply means the risk the general public has of suffering the disease or injury that a plaintiff alleges *without* exposure to the drug or chemical in question. This risk assessment covers all causes of a disease, whether known or unknown, excluding the drug or chemical in question. The epidemiological and toxicological methods discussed focus on whether an association exists between a specific agent or disease. But without background risk as a baseline, determining whether an association is anything more than a coincidence becomes difficult, if not impossible.

Id. at 941–42 (citation modified).

With these principles in mind, I join the majority opinion.