United States Court of Appeals For the First Circuit

No. 13-2132

BRIAN MILWARD and LINDA J. MILWARD,

Plaintiffs, Appellants,

v.

RUST-OLEUM CORPORATION,

Defendant, Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

[Hon. Douglas P. Woodlock, U.S. District Judge]

Before

Howard, <u>Chief Judge</u>, Thompson, <u>Circuit Judge</u>, and Laplante,* District Judge.

Steve Baughman Jensen, with whom Allen Stewart, P.C., Ian McCallister, and Kreindler & Kreindler, LLP, were on brief, for appellants.

Francis M. Lynch, with whom <u>Cetrulo LLP</u>, was on brief, for appellee.

April 25, 2016

* Of the District of New Hampshire, sitting by designation.

HOWARD, <u>Chief Judge</u>. In this toxic tort case, we previously considered the admissibility of testimony from the plaintiffs' general causation expert. At issue in the present appeal is whether the district court abused its discretion in excluding the testimony of the plaintiffs' specific causation expert. We conclude that the district court's ruling was a supportable exercise of its discretion, and we therefore affirm the grant of summary judgment to the defendant following that evidentiary ruling.

I.

Background

Brian Milward worked as a pipefitter and refrigerator technician for over thirty years. During the course of his employment, Milward was exposed to varying levels of benzene from paints and other products manufactured by (among others) Rust-Oleum Corporation. In 2004, he was diagnosed with Acute Promyelocytic Leukemia ("APL"). Three years later, Milward and his spouse sued a number of defendants on the theory that their negligence caused Milward's disease. The only remaining defendant is Rust-Oleum.

To succeed against Rust-Oleum, the Milwards had the burden of establishing, through expert testimony, general and specific causation. In other words, they needed to show that exposure to benzene can cause APL (general causation), and that

- 2 -

exposure to benzene was, in fact, a substantial factor in the development of Brian's APL (specific causation). The district court bifurcated the proceedings; it planned first to address the admissibility of expert testimony on general causation, and then to consider the specific causation issue.

In a 2009 ruling, the district court excluded the Milwards' general causation expert. Accordingly, it entered judgment in favor of the defendants without proceeding to the second phase of the case. The Milwards appealed that decision and, for reasons specific to their general causation expert, we reversed. <u>See Milward v. Acuity Specialty Prods. Grp., Inc.</u>, 639 F.3d 11 (1st Cir. 2011). We remanded the case to the district court to proceed to the specific causation question.

Under the supervision of a different district court judge, the parties engaged in discovery on the subject of specific causation. Relevant here, the Milwards retained occupational medicine physician Dr. Sheila Butler to serve as their expert witness.¹ The admissibility of her opinion testimony is at the

¹ The Milwards also engaged industrial hygienist Dr. James Stewart. Dr. Stewart evaluated Brian Milward's exposure to benzene at various points in his career and calculated the benzene levels in various products that he used. Based on those considerations, Dr. Stewart estimated that Milward was exposed to benzene at a level of 25.6 parts per million-years (the measurement of the amount of benzene equivalent to what a person would breathe on average each day of the year a person spent at work). The district court found Dr. Stewart's testimony to be admissible, and Rust-

heart of this appeal, and thus additional background on her opinion is in order.

Dr. Butler

Dr. Butler, an employee of the Veterans Administration, specializes in clinical assessments of environmental and occupational exposure in combat-exposed veterans. In her proposed testimony, Dr. Butler presented three theories.

First, she testified that although benzene is naturally occurring, there is no safe level of benzene exposure. This was her predominant theory, and she consistently reiterated her hypothesis. She emphasized that she reached this conclusion by examining "the biology, the pathophysiology, what the substance does to the person and the disease process." And, she noted, she was able to do so without relying on any of the relevant epidemiological studies. Given this no-safe level theory, Dr. Butler maintained that Milward's exposure (as detailed by Dr. Stewart) was likely the cause of his APL. The district court rejected this hypothesis because it could not be properly tested with any known rate of error. The Milwards do not meaningfully challenge the district court's conclusion on appeal. Accordingly, we assume that the ruling was correct and bypass further discussion

Oleum now argues that this decision was erroneous. Given our disposition of the case, we do not reach this argument.

of the issue. <u>See Mills</u> v. <u>U.S. Bank, NA</u>, 753 F.3d 47, 55 (1st Cir. 2014).

Second, Dr. Butler rather cursorily concluded that even beyond the no-safe level hypothesis, certain epidemiological studies have established that an individual's "relative risk" of developing APL increases when exposed to specified amounts of She then compared Milward's exposure levels to those benzene. that had been found to be dangerous in that research. Since Milward's exposure was higher than the amounts found to be hazardous, Dr. Butler reasoned that benzene exposure was likely the cause of his APL. Notably, she did not explain why she chose the studies on which she relied, nor did she address any study with contrary findings. In fact, during Dr. Butler's deposition, defendant's counsel asked her a number of questions about her ability and willingness to engage with the relevant epidemiological research. For instance, counsel asked, "Are you aware of any studies which find that there is no relationship between benzene exposure and APL," to which she answered "Yes . . . the literature [] has support for both." Counsel then asked, "Do you intend in this case to weigh the different epidemiological studies and offer an opinion as to which ones we should rely on and which ones we should discount," to which she replied, "No."

Finally, Dr. Butler engaged in a "differential diagnosis" to conclude that benzene exposure likely caused

- 5 -

Milward's APL. Through this method (essentially a process of elimination) Dr. Butler "ruled out" some of the more common factors associated with APL, among them obesity and smoking. She then determined that since benzene exposure was a potential cause, she could also "rule out" an idiopathic diagnosis (or, a diagnosis without a known cause). Thus, since benzene exposure was the only significant potential cause remaining, she concluded that it was likely the culprit.

Procedural History

Back in court, Rust-Oleum moved both to exclude Dr. Butler's testimony and for summary judgment. The district court evaluated, and rejected, each of the theories that Dr. Butler put forward to establish specific causation. For reasons discussed below, the judge ultimately ruled that Dr. Butler's testimony was inadmissible under Federal Rule of Evidence 702. Since the Milwards could not establish specific causation without Dr. Butler's testimony, the district court granted summary judgment in favor of Rust-Oleum. Fed. R. Civ. P. 56. This timely appeal followed.

II.

We review the district court's decision to admit or exclude expert testimony for abuse of discretion. <u>See United</u> <u>States</u> v. <u>Shay</u>, 57 F.3d 126, 132 (1st Cir. 1995) (noting that we will only "reverse a decision . . . if (1) the district court based

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the decision on an incorrect legal standard . . . or (2) we have a definite and firm conviction that the court made a clear error of judgment. . . ."). Predicate factual findings are reviewed for clear error, while pure questions of law engender de novo review. <u>Milward</u>, 639 F.3d at 13-14. As for the district court's ultimate decision to grant Rust-Oleum summary judgment, because the Milwards are proceeding under state-law theories of liability, we apply Massachusetts law, <u>see Philibotte</u> v. <u>Nisource Corp. Servs.</u> <u>Co.</u>, 793 F.3d 159, 165 (1st Cir. 2015), and review the decision de novo, <u>see Samaan</u> v. <u>St. Joseph Hosp.</u>, 670 F.3d 21, 38 (1st Cir. 2012).

As in the district court, our admissibility inquiry is guided by Federal Rule of Evidence 702, which provides that:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

(a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
(b) the testimony is based on sufficient facts or data;
(c) the testimony is the product of reliable principles and methods; and
(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. In applying Rule 702, the district court serves as the gatekeeper for expert testimony by "ensuring that [it] . .

. both rests on a reliable foundation and is relevant to the task at hand." <u>Daubert</u> v. <u>Merrell Dow Pharm.</u>, 509 U.S. 579, 597 (1993). The party seeking to introduce the evidence has the burden of establishing both its reliability and its relevance. <u>See id.</u> at 593 n.10; see also Fed. R. Evid. 702, advisory committee's note.

As noted above, the district court rejected each theory that Dr. Butler put forward to establish specific causation. We now focus on the two theories that the Milwards press on appeal: Dr. Butler's relative risk conclusion and her differential diagnosis.²

Relative Risk

The district court rejected Dr. Butler's relative risk testimony because she had expressly disavowed her intent, and minimized her ability, to analyze conflicting epidemiological studies. The district court reasoned that without such analysis,

² The Milwards broadly allege that the district court applied the wrong legal standard when evaluating Dr. Butler's fitness to serve as an expert witness. They note that the court "held that Dr. Butler is unqualified because she cannot 'evaluate the relevant studies' with the 'rigor' of an epidemiologist." This argument misconstrues the district court's action. The court did not, in a vacuum, conclude that Dr. Butler was unqualified to provide expert testimony in this case because she was not an epidemiologist. Instead, the court stated that since Dr. Butler was unwilling to provide testimony respecting the epidemiological literature in the context of the "relative risk" approach, the Milwards could not rely on that method to prove specific causation. While we provide more detail about that conclusion below, it suffices here to say that the district court did not err as the Milwards allege.

it was impossible to ensure that the studies she cited were actually based on a reliable methodology. The Milwards challenge this decision in three ways.

First, they assert that in rejecting the testimony, the district court relied on an incorrect premise: that conflicting epidemiological studies existed. They note that there were studies establishing an increased risk of APL after a certain level of exposure, such as 8 ppm-years. <u>See, e.g.</u>, Deborah C. Glass et al., <u>The Health Watch Case -- Control Study of Leukemia and Benzene</u>, 1076 Ann. N.Y. Acad. Sci. 80, 85 (2006); Richard B. Hayes et al., <u>Benzene and Lymphohematopoietic Malignancies in Humans</u>, 40 Am. J. Indus. Med. 117, 120. The Milwards also acknowledge that other studies found no increased risk of leukemia with exposure at any level less than 40 ppm-years. <u>See, e.g.</u>, Robert A. Rinsky et al., <u>Benzene and Leukemia: An Epidemiologic Risk Assessment</u>, 316 New England J. Med. 1044 (1987). They argue, however, that since the Rinsky study did not affirmatively find the absence of a relationship, the studies were not actually in conflict.

While it is certainly true that, at least in some cases, the "absence of evidence" is not the same as "evidence of absence," it is not similarly true that the studies must present diametrically opposing conclusions to be in tension with one another. Here, a number of studies have been identified that show a correlation between APL and benzene exposure at a specific level,

- 9 -

while other studies do not show that correlation. In order to establish specific causation by the relative risk method, Dr. Butler was required to choose a study, or studies, to serve as a baseline to which she could then compare Brian Milward's case. There can be no serious question that choosing a study that showed a correlation above a specific level (e.g., the 8 ppm-years in the Glass study), rather than one that did not exhibit any such correlation (e.g., the 40 ppm-years in the Rinsky study), yields a vastly different comparison. The district court did not clearly err in finding that the studies were sufficiently distinct from one another such that utilizing one, rather than another, would necessarily lead to different testimony.

The Milwards next argue, albeit summarily, that Dr. Butler did not actually disavow her willingness to consider the divergent studies. Instead, they allege that the district court took her statements out of context.

We make quick work of this argument given the clarity of the record. Dr. Butler anchored her testimony to her no-safe threshold hypothesis, a theory that did not turn on the validity of any of the epidemiological studies. Indeed, given that she acknowledged that she based that theory on "the biology, the pathophysiology, [and] what the substance does to the person and the disease process," it was consistent for her to then state that she had neither the need nor the intent to compare the competing epidemiological literature.³ There was no error in the district court's decision to give her statements their plain meaning.

Finally, the Milwards argue that even if the district court did not err in these respects, Dr. Butler's testimony was nevertheless still based on reliable evidence, and it was therefore admissible. In support of this contention, the Milwards defend the studies that Dr. Butler invoked in her testimony. They also cite <u>Schultz</u> v. <u>Akzo Novel Paints, LLC</u>, 721 F.3d 426 (7th Cir. 2013), which they maintain is closely analogous to this case.

Generally, where an expert's medical opinion is grounded exclusively on scientific literature, a district court acts within its discretion to require the expert to explain why she relied on the studies that she did and, similarly, why she disregarded other, incompatible research. <u>See, e.g.</u>, <u>Kuhn</u> v. <u>Wyeth, Inc.</u>, 686 F.3d 618, 623-24 & 633 (8th Cir. 2012) (permitting testimony where the expert witness relied on methodologically reliable studies <u>and</u> provided an explanation for why those studies were chosen); <u>Norris</u> v. <u>Baxter Healthcare Corp.</u>, 397 F.3d 878, 886 (10th Cir. 2005) (noting in the context of a general causation finding that the expert witness's inability to address contrary views made the

³ Likewise, in discussing the statistical significance of the reports, Dr. Butler seemingly minimized her ability to analyze the studies when she said "and I'm not an epidemiologist if you're going to go there. I'm just saying that to me that's fairly -that's fairly significant."

opinion unreliable). It is self-evident that, when an expert engages in a relative risk analysis in the manner that Dr. Butler did here, the district court is on firm ground in requiring such an explanation, since the validity of the approach depends on the reliability of the studies chosen. <u>See</u> 3 Mod. Sci. Evidence § 23:27 (2014-2015 Ed.) (discussing the use of the relative risk approach in establishing specific causation). That is, if the expert is comparing the plaintiff's condition to a study, and the study is based on an unreliable methodology, then the comparison itself is futile.

Schultz, the case on which the Milwards rely, is consistent with this view. In that case, the Seventh Circuit reversed a district court's decision to exclude specific causation expert testimony about an individual's exposure level to benzene. 721 F.3d at 428. The Seventh Circuit found that the testimony was reliable because the expert "focused specifically on the amount of benzene to which [the plaintiff] had been exposed and related this amount to the scientific literature." Id. at 432. Importantly, the expert in Schultz did not simply point to favorable studies showing an increased risk of leukemia at low levels of exposure. Instead, the expert in that case explained why he believed that a conflicting study was unreliable and why, based on his knowledge of the literature, he chose to rely on the studies that he did. Id. at 432-33.

- 12 -

Here, the relevant studies were not only in tension with one another, but expressly cast each other into doubt. See, e.g., EPA Office of Research and Development, Carcinogenic Effects of Benzene: An Update, at 14 (April 1998). Given that, the district court reasonably ruled that there needed to be some indication of why Dr. Butler utilized the studies that she did. Indeed, her complete unwillingness to engage with the conflicting studies (irrespective of whether she was able to or not) made it impossible for the district court to ensure that her opinion was actually based scientifically reliable evidence on and, correspondingly, that it comported with Rule 702. Not only does this render this case readily distinguishable from Schultz, but it also justifies the district court's decision.⁴

Differential Diagnosis

The district court also rejected Dr. Butler's "differential diagnosis." Although the judge did not question Dr.

⁴ We also note that the Milwards' position yields a further problem. Absent Dr. Butler's testimony weighing the studies, the only support for their reliability is the fact that they were peerreviewed, published works. As we have noted though, "an article does not reach the dignity of a 'reliable authority' merely because some editor, even a most reputable one, sees fit to circulate it . . [and] [m]ere publication cannot make them automatically reliable authority." <u>Meschino v. N. Am. Drager, Inc.</u>, 841 F.2d 429, 434 (1st Cir. 1988). Given the need for some evidence establishing the reliability of the studies invoked, the court likewise did not err in refusing to take judicial notice of their reliability.

Butler's decision to "rule out" obesity and smoking as causes of Brian Milward's APL, the court was concerned about the utility of the approach given the high percentage of APL cases that are idiopathic (according to the record, roughly 70-80% of all APL diagnoses). The judge also stated that Dr. Butler's reasoning was circular; she "ruled out" an idiopathic APL by "ruling in" benzene as a cause, but she had failed to provide a scientifically reliable method of "ruling in" benzene in the first instance. The Milwards contend that in making this decision, the district court ignored our case law that has blessed an expert's use of a differential diagnosis to establish causation.

Even if the Milwards' scanty argument in their opening brief were sufficiently developed as to avoid a waiver finding, <u>see United States</u> v. <u>Oladosu</u>, 744 F.3d 36, 39 (1st Cir. 2014) ("[b]ecause the argument is underdeveloped, it is waived"), we nonetheless see no abuse of discretion in the district court's decision. The Milwards are certainly correct that a "differential diagnosis" can be a "reliable method of medical diagnosis." <u>Milward</u>, 639 F.3d at 18; <u>see also Granfield</u> v. <u>CSX Transp., Inc.</u>, 597 F.3d 474, 486 (1st Cir. 2010). But, they still must show that the steps taken as part of that analysis -- the "ruling out" and the "ruling in" of causes -- were accomplished utilizing scientifically valid methods. <u>See Ruggiero</u> v. <u>Warner-Lambert Co.</u>, 424 F.3d 249, 254 (2d Cir. 2005).

- 14 -

Since Dr. Butler was only able to "rule out" an idiopathic APL because she had "ruled in" benzene as a cause, the validity of her differential diagnosis turns on the reliability of that latter conclusion. <u>See Ruggiero</u>, 424 F.3d at 254 (noting that an expert must use reliable scientific methods to "rule in" causes); <u>see also Best</u> v. <u>Lowe's Home Ctrs., Inc.</u>, 563 F.3d 171, 179 (6th Cir. 2009); <u>Glastetter</u> v. <u>Novartis Pharm. Corp.</u>, 252 F.3d 986, 989 (8th Cir. 2001). Indeed, the reliability of that decision is particularly critical here given the extensive number of APL cases that are idiopathic. Under such circumstances, eliminating a number of potential causes -- without properly and explicitly "ruling in" a cause -- is simply "of little assistance." Restatement (Third) of Torts; Phys. & Emot. Harm § 28, cmt. c(4)(2010).

Dr. Butler appears to have "ruled in" benzene exposure solely by relying on her two other theories. But, as explained above, the district court found both of these theories to be unreliable. As we agree with the district court's conclusion regarding the relative risk methodology, and since the Milwards have not challenged the district court's no-safe threshold determination, they have failed to show how Dr. Butler could have reliably utilized either method to "rule in" benzene exposure. Nor, we note, have they pointed to other evidence in the record that Dr. Butler could have conceivably used to "rule in" benzene. Given that the record does not contain a scientifically reliable basis to "rule in" benzene, Dr. Butler needed some other method to "rule out" an idiopathic diagnosis. She did not provide one. As such, the district court acted within its discretion to conclude that the extraordinary number of idiopathic APL cases, coupled with the lack of a reliable means to rule out an idiopathic diagnosis here, muted Dr. Butler's ability to reliably apply this methodology.⁵

III.

Once the district court excluded Dr. Butler's testimony, it then correctly granted Rust-Oleum's motion for summary judgment. As is well-established under Massachusetts law, "expert testimony is required to establish medical causation." <u>Reckis</u> v. <u>Johnson & Johnson</u>, 28 N.E.3d 445, 461 (Mass. 2015). This applies to both general and specific causation. <u>Id.</u> at 461 n.33. Without any other medical expert evidence in the record probative on specific causation, judgment as a matter of law was necessarily required. Fed. R. Civ. P. 56.

⁵ In their brief, the Milwards also argue that Dr. Butler's position on specific causation is consistent with the latency period in Brian Milward's case. The district court did not rest its decision on that proposition (instead, it just noted a concern about the issue), and we therefore need not reach the argument.

Accordingly, we **<u>affirm</u>** the district court's decision to exclude Dr. Butler's testimony and its concomitant grant of summary judgment in favor of Rust-Oleum.

--Dissenting Opinion Follows--

THOMPSON, Circuit Judge, dissenting.

Setting the Stage

Dr. Butler has quite the CV. A graduate of Wellesley College, she has a medical degree from Howard University and a masters of public health from Columbia University. Specializing in occupational medicine, she is board-certified in preventive medicine and general public health (by the American Board of Preventive Medicine) and in anatomic pathology, clinical pathology, and hematology (by the American Board of Pathology).⁶ This means (according to the American Board of Preventive Medicine) she has "core competencies" in, among other things, that "epidemiology" and "research into causes of disease and injury in population groups."⁷ She has a pretty impressive job too, working full time as a physician at a VA medical center that deals with veterans ravaged by diseases after being exposed to toxins during their service. Figuring out the causes of chronic illnesses in patients exposed to toxic substances is what she does day in and day out. All told, she has (in the district judge's words) over a decade's worth of experience "as a practicing diagnostic

⁶ Pathology is a medical specialty focusing on the nature and causes of diseases. <u>See Stedman's Medical Dictionary</u> 1332 (27th ed. 2000) ("<u>Stedman's</u>," from here on). And hematology is the study of blood-related diseases. <u>See id.</u> at 796.

⁷ Epidemiology is the study of the incidence, distribution, and control of disease in a population. See <u>id.</u> at 604.

hematopathologist and as a consultant on occupationally-related malignancies."

As the Milwards' specific-causation expert, Dr. Butler testified by report, deposition, and affidavit that — based on her review of the scientific evidence — there is no "safe" level of benzene exposure.⁸ In other words, every benzene exposure increases a person's risk of leukemia. But, she added, given our different genetic makeups, what might be a safe exposure level for some could be a lethal one for others. Anyway, using two accepted causation methodologies — "relative risk" and "differential diagnosis" — and zeroing in on Brian's benzene-exposure level (set by Dr. Stewart at 25.6 ppm-years) Dr. Butler concluded that Brian's "excessive" exposure to benzene caused his leukemia.⁹

On a different note, because there are two Milwards - Brian and Linda - it makes sense to use a first name where necessary to avoid confusion. Obviously I intend no disrespect.

⁸ Remember — the Milwards had to show that benzene exposure can cause leukemia (general causation) and that Brian's exposure was a substantial factor contributing to his leukemia (specific causation). A different district judge excluded the Milwards' general-causation expert as unreliable under Rule 702. Noting (among other things) that the judge had taken "sides on questions that are currently the focus of extensive scientific research and debate — and on which reasonable scientists can clearly disagree" — we concluded that the exclusion edict constituted an abuse of discretion. See Milward, 639 F.3d at 22, 26.

⁹ As my friends in the majority note, the Milwards hired Dr. Stewart (an industrial hygienist) to assess Brian's benzene exposures.

A quick word about how she applied these methodologies. Starting with relative risk, Dr. Butler said that even if there were some threshold level of benzene exposure needed to cause leukemia, that threshold was exceeded here - and by a considerable amount. With Brian's 25.6 ppm-years exposure level firmly in mind, she pointed to a peer-reviewed epidemiology study finding that workers exposed to benzene at or above 8 ppm-years were 7 times more likely than controls to develop leukemia. And she did not stop there. Rather, she went on to spotlight other studies of the same caliber showing a statistically significant increased risk of leukemia among workers cumulatively exposed to benzene at levels below Brian's 25.6 ppm-years.¹⁰ In a deposition she said that she is neither an epidemiologist nor a researcher. She also agreed that some studies found no relationship between benzene exposure and leukemia. Asked by defense counsel if she "intend[ed] in this case to weigh the different epidemiological studies" and comment on "which ones we should rely on and which ones we should discount," she replied, "No" - and then added:

> I'm relying on what I know about the biology, the pathophysiology, what the substance does to the person and the disease process. Now,

¹⁰ <u>See</u> Deborah R. Glass et al., <u>The Health Watch Case - Control</u> <u>Study of Leukemia and Benzene: The Story So Far</u>, 1076 Ann. N.Y. Acad. Sci. 80 (2006); Dusica Lazarov et al., <u>Acute Myeloid Leukemia</u> <u>and Exposure to Organic Solvents: A Case-Control Study</u>, 16 Eur. J. of Epidemiology 295 (2000); Richard B. Hayes et al., <u>Benzene</u> <u>and the Dose-Related Incidence of Hematologic Neoplasms in China</u>, 89 J. of the Nat'l Cancer Inst. 1065 (1997).

if there are studies that support it then that's even better, but without the studies based on what I know there is a very - it's more likely than not that benzene contributes to the development of [the type of leukemia Brian suffers from].¹¹

And she later said that "one doesn't just rely on literature" in formulating a specific-causation opinion.

Turning, then, to differential diagnosis (aptly described by the majority as "essentially a process of elimination"), Dr. Butler "ruled out" possible causes of Brian's leukemia, like smoking and obesity, leaving only benzene. She talked about "'idiopathic' leukemia" too - "idiopathic" being another way of saying medical professionals do not know why a given person has the disease. "[E]very case of leukemia has <u>some</u> cause[]," she explained, and only "[t]hose cases with unidentified causes" get hit with the "'idiopathic'" tag. But given her conclusion that Brian's "benzene exposures were a substantial factor causing his [leukemia]," she could "also 'rule[] out' that his [leukemia] was . . . 'idiopathic.'"

The district judge, however, would have none of Dr. Butler's talk about benzene being the specific cause of Brian's leukemia. Given her concession that she is "'not an epidemiologist'" and "'not a researcher,'" and given her

¹¹ Pathophysiology is the study of the functional changes that accompany a particular disease. See Stedman's 1333.

"professed inability to engage with conflicting epidemiological literature" (these are quotes from the judge's rescript), the judge excluded her relative-risk analysis as unreliable under Rule 702.¹² That meant that Dr. Butler's differential-diagnosis analysis – through which she "'ruled out' an idiopathic origin of [Brian's] leukemia by 'ruling in' benzene" (these too are quotes from the judge's order) – was unreliable too (because she is, the judge concluded, not qualified to say whether benzene exposure at Brian's level could have caused his leukemia). And with the Milwards' specific-causation expert out of the picture, all that was left for the judge to do was enter summary judgment against them – which the judge did.

Fast-forward to the present, with the majority spying no abused discretion here because Dr. Butler's "complete unwillingness to engage with the conflicting studies (irrespective of whether she was able to or not) made it impossible for the [judge] to ensure that her opinion was actually based on scientifically reliable evidence" as required by Rule 702. Call me unpersuaded. As I see things, the complaints about Dr. Butler's

¹² The "conflicting" study that everyone focuses on is Robert A. Rinsky et al., <u>Benzene and Leukemia: An Epidemiologic Risk</u> <u>Assessment</u>, 316 New Eng. J. of Med. 1044 (1987), which found no increased risk of leukemia in workers exposed to less than 40 ppmyears of benzene.

specific-causation opinion go to weight, not admissibility - as I now explain.¹³

My Take on the Matter

(a) The Standard of Review Explained

Abuse-of-discretion review is "respectful," certainly. <u>Corp. Techs.</u> v. <u>Harnett</u>, 731 F.3d 6, 10 (1st Cir. 2013). But "respectful" does not mean we must throw up our hands and simply affirm every discretionary call. <u>See</u>, <u>e.g.</u>, <u>Negron-Almeda</u> v. <u>Santiago</u>, 528 F.3d 15, 21 (1st Cir. 2008). Review under this standard does involve <u>review</u>, after all. <u>See</u>, <u>e.g.</u>, <u>Dopp</u> v. <u>Pritzker</u>, 38 F.3d 1239, 1253 (1st Cir. 1994). And we will not hesitate to find abuse where, for example, the district judge based his decision on clearly erroneous facts, made a serious legal error, or suffered a significant lapse of judgment, <u>see</u>, <u>e.g.</u>, <u>Cent. Pension Fund of the Int'l Union of Operating Eng'rs &</u> <u>Participating Emp'rs</u> v. <u>Ray Haluch Gravel Co.</u>, 745 F.3d 1, 5 (1st Cir. 2014); <u>Riva</u> v. <u>Ficco</u>, 615 F.3d 35, 43 (1st Cir. 2010); <u>Ruiz-</u> <u>Troche</u> v. <u>Pepsi Cola of P.R. Bottling Co.</u>, 161 F.3d 77, 83 (1st Cir. 1998) – a point made each time we have reversed the exclusion

¹³ Because the majority jettisons the case by upholding the judge's decision to exclude Dr. Butler's testimony, I (obviously) focus my energy on that issue. So, like the majority, I make no comment on Rust-Oleum's other arguments - <u>i.e.</u>, that the judge should have excluded Dr. Stewart's testimony and that the Milwards cannot show that the failure to provide certain warnings about benzene proximately caused Brian's injuries.

of expert testimony, <u>see</u>, <u>e.g.</u>, <u>Milward</u>, 639 F.3d at 13-14, 23-25; Ruiz-Troche, 161 F.3d at 79, 83-86.

(b)

A Short Primer on Expert Opinion

Rule 702 governs the admission of expert-opinion testimony, with the offering party required to show that such testimony is relevant and reliable. <u>See</u>, <u>e.g.</u>, <u>Kumho Tire Co.</u> v. <u>Carmichael</u>, 526 U.S. 137, 149 (1999) (relying on <u>Daubert</u>, 509 U.S. at 592); <u>Ruiz-Troche</u>, 161 F.3d at 80 (same). Expert-opinion testimony is relevant if it will assist the factfinder in understanding and deciding a fact. <u>See</u>, <u>e.g.</u>, <u>Daubert</u>, 509 U.S. at 592. And it is reliable if it has "a reliable basis in the knowledge and experience of [the pertinent] discipline."¹⁴ Id.

Basically then, district judges are supposed to weed out nonsense opinions by junk scientists. But in doing so, they must keep a bunch of things in mind - including the following:

 The rule on expert-opinion testimony is notably "liberal," with the evidence considered presumptively admissible. <u>See</u>
 4 Jack B. Weinstein & Margaret A. Berger, Weinstein's

¹⁴ Because everyone focuses on whether Dr. Butler's testimony is reliable, I will do likewise.

Federal Evidence § 702.02[1], at 702-5 (Joseph M. McLaughlin ed., 2d ed. 2013) ("Weinstein's," to save some keystrokes).

- Proponents of expert testimony must show that the proposed witness is able – through her education, training, or experience – to offer a meaningful opinion on the issue in play. Id. § 702.04[1][c], at 702-57.
- An expert can rely, then, on "clinical instinct" <u>i.e.</u>, "what experience adds to scientific knowledge and training" - which is a well-known and accepted part of today's medical practice. <u>Mueller</u> v. <u>Auker</u>, 700 F.3d 1180, 1191 (9th Cir. 2012) (quoted approvingly in <u>Weinstein's</u> § 702.05[2][c], at 702-103 n.46).
- Judges abuse their discretion if they "exclude testimony that would otherwise" help the factfinder "understand a fact in issue, simply because the expert does not have the specialization" that the judges think "most appropriate." <u>Pagés-Ramírez v. Ramírez-González</u>, 605 F.3d 109, 114 (1st Cir. 2010) (internal quotation marks omitted); <u>see also Ralston v. Smith & Nephew Richards, Inc.</u>, 275 F.3d 965, 970 (10th Cir. 2001) (explaining that so long as the expert keeps "within the reasonable confines of [her] subject area, . . . a lack of specialization does not affect the

admissibility of [her] opinion, but only its weight" (internal quotation marks omitted)).

- Also, an expert need not have epidemiological studies at the ready to get her opinion in. <u>See Milward</u>, 639 F.3d at 24 (holding that "[e]pidemiological studies are not per se required as a condition of admissibility regardless of context"); <u>see also Daubert</u>, 509 U.S. at 593 (explaining that "[p]ublication . . . is not a <u>sine qua non</u> of admissibility").
- And an opinion, by the way, does not have to conclusively prove causation to be admissible. "[M]edical knowledge," we can all agree, "is often uncertain. The human body is complex, etiology is often uncertain, and ethical concerns often prevent double-blind studies calculated to establish statistical proof." <u>United States</u> v. <u>Sandoval-Mendoza</u>, 472 F.3d 645, 655 (9th Cir. 2006). But that "does not preclude the introduction of medical expert opinion testimony when medical knowledge permits the assertion of a reasonable opinion." Id. (internal quotation marks omitted).
- Critically too, deciding "which of several competing scientific theories has the best provenance" is none of the judges' business – which is just another way of saying that

judges must focus on the expert opinion's admissibility, not its correctness. Ruiz-Troche, 161 F.3d at 85.

- Here's a biggie: That the parties' experts disagree (they often do, unsurprisingly) goes to weight, not admissibility. <u>See</u>, <u>e.g.</u>, <u>Feliciano-Hill</u> v. <u>Principi</u>, 439
 F.3d 18, 25 (1st Cir. 2006); <u>see also Weinstein's</u>
 § 702.05[3], at 702-112 n.58 (collecting a cornucopia of additional cases).
- Here's another biggie: An expert's backers "do not necessarily have the burden" of disproving a study championed by the other side that is what a case the majority relies on says. See Kuhn, 686 F.3d at 626. Again, the proponents must "show that [their expert] arrived at [her] contrary opinion in a scientifically sound and methodological fashion." Id. And if they do, "the question becomes one for the jury to decide." Id.

(c) The Instances of Abused Discretion

The ruling my colleagues affirm — that Dr. Butler "is 'not an epidemiologist' and 'not a researcher'" who "professed" an "inability to engage with conflicting epidemiological literature" and "thus" is "unqualified" to say whether Brian's level of benzene exposure could cause his leukemia (quotes lifted from the district judge's order) - is filled with errors. And these errors rise to the level of an abuse of discretion.

Take the district judge's fixation on her saying that she was "not an epidemiologist" and "not a researcher." Time and again we have said that one "need not be a specialist in a particular medical discipline to render expert testimony relating Gaydar v. Sociedad Instituto Ginecoto that discipline." Quirurgico y Planificacion Familiar, 345 F.3d 15, 24 (1st Cir. 2003); see also Pagés-Ramírez, 605 F.3d at 116-17. And not only have we talked the talk, but we have walked the walk - reversing as an abuse of discretion expert-exclusion rulings premised on an expert's missing the type of specialization the judges think necessary, even though the testimony would have helped the jury understand a disputed issue. See, e.g., Pagés-Ramírez, 605 F.3d at 116-17. And given her training and experience - don't forget, (a) her board certification in preventive medicine shows she has competency in epidemiology and research into causes of disease, and (b) she analyzes specific-causation issues as a routine part of her job - the judge's ruling faulting Dr. Butler for not being able to "evaluate the relevant studies" with the "rigor" of an epidemiologist fits that category of error. The majority tries to downplay the district judge's comments about her not being an epidemiologist by playing up how concerned he was with her "unwilling[ness]" to analyze the "conflicting" literature. But

the fact remains that the judge did add her non-epidemiologist status to his decisional mix, which (for the reasons just discussed) is an abuse of discretion, plain and simple.

Now, as for the judge's belief — shared by the majority — that Dr. Butler "professed [an] inability to engage with the conflicting epidemiological literature," there are problems galore.

For starters, I espy no conflict. To repeat a point I made a few paragraphs ago: The studies Dr. Butler relied on show that benzene-exposure levels below the 25.6 ppm-years endured by Brian can cause leukemia. The Rinsky study - the supposedly "conflicting" study — also shows that benzene exposure at certain levels can cause leukemia, though the authors found no increased risk of leukemia among workers exposed to less than 40 ppm-years of benzene. According to the district judge, because the Rinsky study did not find any increased risk of leukemia at lower exposure is "conflict" levels, there а and "debate within the epidemiological literature" that can only be put to rest by someone with epidemiologist credentials. Not only did the judge get the epidemiologist-credentials part wrong (as I just noted); he got the "conflict" part wrong too. For a true conflict to exist, the Rinsky study would have to show that benzene-exposure levels of 25.6 ppm-years or lower <u>cannot</u> cause leukemia. And the Rinsky study does no such thing.

Anyhow, even assuming there is a conflict, the judge still erred in two important ways. For one thing, despite what the judge said, Dr. Butler hardly copped to being unable to engage with the literature. By my lights, the judge could only say what he said by misreading her deposition. Questioned (recall) by defense counsel about whether she "intended in this case to weigh the different epidemiological studies and offer an opinion as to which ones we should rely on and which ones we should discount," Dr. Butler said, "No." That is because, she stressed, (a) one need not rely just "on literature" and (b) her experience with "biology," "pathophysiology," and "the disease process" provided the specialized knowledge to support her specific-causation testimony. Statements (a) and (b) square with our caselaw. See, e.g., Milward, 639 F.3d at 24 (emphasizing how "[e]pidemiological studies are not per se required as a condition of admissibility"). And just as importantly, nothing she said there intimated even a possible whisper of a hint of a suggestion that she could not take on the relevant literature. Put differently, she did not say that she lacks the know-how to assess Rust-Oleum's preferred studies only that she did not need to in formulating her expert opinion.

The word "intend" - I hope we can all agree - does not imply "can't."

For another thing, despite what the judge indicated, neither Dr. Butler nor the Milwards had any burden to explain why the Rinsky study is wrong. Think back to the primer: The proponents of expert testimony, I noted, are not reflexively obliged to "discredit" a study pushed by their opponents. Kuhn a case highlighted by the majority - says as much. Sure, the plaintiffs' expert there tried to poke holes in a study relied on by the defendants. And, deeming the criticisms insubstantial, the judge excluded the expert from testifying. Significantly for present purposes, though, the circuit court wrote that the expert did not have to debunk the study; he only had to show that he reached his conclusion via a sound methodology.¹⁵ See Kuhn, 686 F.3d at 626. Dr. Butler did that in spades, using two recognized techniques for identifying causes (relative risk and differential diagnosis) and relying in part on studies that (as best I can tell) neither the district judge nor the majority has any problems with.

 $^{^{15}}$ So instead of supporting the majority's position that Dr. Butler had to explain why she disagreed with "incompatible" studies, <u>Kuhn</u> rejects that position. And <u>Norris</u> – another case cited by the majority – is not a difference maker for the majority either. The court there upheld the exclusion of expert testimony because the experts did not confront the reality that their opinions were "flatly contrary to all of the available epidemiological evidence," <u>see</u> 397 F.3d at 885-86 – which is worlds apart from our case.

And having met her burden, a jury should get to decide which studies to believe (hers or Rust-Oleum's), if any, <u>see id.</u> – just like a jury would get to do if faced with dueling experts (instead of dueling studies), see Feliciano-Hill, 439 F.3d at 25.

Summing Up

Because, as discussed, the judge made serious judgment errors in excluding Dr. Butler's expert testimony - a ruling (in my view) inconsistent with the "liberal thrust of the Federal Rules and their general approach of relaxing the traditional barriers to 'opinion' testimony," <u>see Daubert</u>, 509 U.S. at 588 - I would reverse his ruling as an abuse of discretion. And because the majority, though conscientious, has decided otherwise, I respectfully - but unequivocally - dissent.