No. _____

IN THE

Supreme Court of the United States

UNION CARBIDE CORPORATION; COVESTRO LLC,
Petitioners.

v.

LEE ANN SOMMERVILLE, individually, and on behalf of all others similarly situated,
Respondent.

On Petition for a Writ of Certiorari to the U.S. Court of Appeals for the Fourth Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether, under Federal Rule of Evidence 702, challenges to the factual basis of an expert witness's testimony always go to the weight of the evidence rather than to admissibility, as the First and Fourth Circuits hold, or whether such challenges go to weight only if a court first finds it more likely than not that an expert has a sufficient basis to support the testimony, as the Fifth, Sixth, Eighth, Ninth, and Federal Circuits hold.

PARTIES TO THE PROCEEDINGS

Petitioners Union Carbide Corporation and Covestro LLC were defendants in the district court and appellees in the court of appeals.

Respondent Lee Ann Sommerville, individually, and on behalf of all others similarly situated, was the plaintiff in the district court and appellant in the court of appeals.

RULE 29.6 STATEMENT

Petitioner Union Carbide Corporation is a wholly owned subsidiary of The Dow Chemical Company, which is a wholly owned subsidiary of Dow Inc. Dow Inc. is a publicly held company. The Vanguard Group owns more than 10% of the stock of Dow Inc.

Petitioner Covestro LLC is a wholly owned subsidiary of Covestro (Netherlands) B.V., and that entity is a wholly owned subsidiary of Covestro Deutschland AG. Covestro Deutschland AG is a wholly owned subsidiary of Covestro AG, a publicly traded company. Covestro AG owns more than 10% of Covestro LLC. ADNOC International Germany Holding AG owns more than 10% of the stock of Covestro AG. ADNOC International Germany Holding AG is a wholly owned subsidiary of ADNOC International UK Limited, which is a wholly owned subsidiary of XRG P.J.S.C., which is a wholly owned subsidiary of Abu Dhabi National Oil Company (ADNOC) P.J.S.C.

RELATED PROCEEDINGS

The proceedings directly related to this petition are:

- *Sommerville* v. *Union Carbide Corporation; Covestro LLC*, No. 24-1491 (4th Cir. Aug. 18, 2025)
- *Sommerville* v. *Union Carbide Corporation*, No. 2:19-cv-00878 (S.D. W. Va. March 20, 2024)
- *Sommerville* v. *Union Carbide Corporation*, No. 2:19-cv-00878 (S.D. W. Va. May 13, 2024)

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Petitioners respectfully petition for a writ of certiorari to review the judgment of the U.S. Court of Appeals for the Fourth Circuit.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, at 1a) is reported at 149 F.4th 408. The order denying rehearing en banc (App., *infra*, at 116a) is unpublished. The district court's order excluding expert testimony (App., *infra*, at 42a) is available at 2024 WL 1204094. The district court's order dismissing the case (App., *infra*, at 89a) is available at 2024 WL 2139394.

JURISDICTION

The judgment of the court of appeals was entered on August 18, 2025. App., *infra*, at 1a. A timely petition for rehearing en banc was denied on November 4, 2025. *Id.* at 116a. This Court's jurisdiction is invoked under 28 U.S.C. 1254(1).

PROVISIONS INVOLVED

The relevant provisions are reproduced in the appendix to this petition. App., *infra*, at 117a.

INTRODUCTION

Federal Rule of Evidence 702 imposes an obligation on federal district judges to ensure that expert testimony meets threshold criteria of reliability before juries may consider that evidence. Faithful discharge of that obligation is essential. "[E]xpertise that is *fausse* and science that is junky" threaten the credibility of the adjudicatory process. *Kumho Tire* v. *Carmichael*, 526 U.S. 137, 158-159 (1999) (Scalia, J., concurring). Jurors seldom possess the knowledge and experience necessary to assess the scientific and technical expert testimony that has come to play such an outsized role in complex civil litigation. At the same time, jurors

are prone to give considerable deference to such expert testimony. See *Daubert* v. *Merrell Dow Pharmaceuticals*, 509 U.S. 579, 595 (1993).

Rule 702's requirement that "the [expert's] testimony is based on sufficient facts or data" addresses those very risks. Fed. R. Evid. 702(b). For years after this Court's decision in *Daubert*, many courts of appeals held that district courts applying this criterion must determine by a preponderance of the evidence that sufficient facts or data support an expert's opinion to render it reliable enough for the jury to consider. But courts like the First and Fourth Circuits applied a different rule. Those circuits held that doubts about the factual underpinnings of an expert's opinion categorically go to the weight jurors should give to that evidence, not to the threshold question of its admissibility. Needless to say, that approach materially increased the risks that jury verdicts will be the product of junk science or other misconceived faux expertise.

In 2023, Rule 702 was amended for the express purpose of repudiating the approach of the First and Fourth Circuits and clarifying that district courts should not admit expert testimony unless they first determine by a preponderance of the evidence that an expert's opinion is based on sufficient facts and data to establish its reliability. Judge Schroeder, the Chair of the Subcommittee that drafted the amendments, specifically pointed to the Fourth Circuit's decision in *Bresler* v. *Wilmington Trust*, 855 F.3d 178, 195 (4th Cir. 2017)—which held that questions about an expert's "factual underpinnings" do not "affect * * * admissibility"—as an exemplar of the error the amendment was trying to correct.

Unfortunately, the Fourth Circuit did not get the message. In the decision below, a sharply divided

panel held that the district court had abused its discretion when it concluded that plaintiff's proposed expert had not established by a preponderance of the evidence that the factual underpinnings of his analysis were sufficiently reliable to justify admission of the testimony.

This case—a putative class action in which the plaintiff alleges a medical-monitoring claim based on allegations that the plaintiff breathed in a contaminant allegedly generated by defendants' operations—is precisely the kind of case in which faithful application of Rule 702 is particularly important. The plaintiff's proposed expert attempted to demonstrate community exposure to the contaminant by extrapolating data from a single year over a 36-year period, using data relating to a facility that has nothing to do with plaintiff's lawsuit, relying on projected emissions for a single year that were inexplicably more than 100 times greater than for any other year, and using multiple contradictory sets of weather information from non-representative locations.

Expressly relying on *Bresler*, one of the very decisions taking the approach that the Advisory Committee repudiated, the court of appeals held that the inadequacy of the factual basis for the expert's testimony was a matter for the jury to consider in deciding how much weight to give that testimony—not a reason to refuse to admit the evidence in the first place. As Chief Judge Diaz observed in dissent, the court's ruling is irreconcilable with Rule 702 and the rule that most circuits apply. App., *infra*, at 35a ("an expert who constructs a model based on faulty assumptions and irrelevant data shouldn't be handed a 'get-out-of-*Daubert*-free card,'" regardless of whether "he uses an otherwise reliable modeling system").

At this point, it is clear that the 2023 amendments have failed to bring the Fourth Circuit into alignment with the correct understanding of Rule 702 that most circuits apply. And the First Circuit has taken the same obdurate approach as the Fourth Circuit.[1] Given how frequently the question arises and how serious the consequences of mistaken admission of expert scientific testimony can be in a wide variety of cases, including putative tort class actions like this one, this Court's immediate intervention is urgently needed.

STATEMENT OF CASE

1. Federal Rule of Evidence 702 states that an expert witness "may testify in the form of an opinion" only "if the proponent demonstrates to the [district] court that it is more likely than not" that several reliability-related requirements are satisfied. Fed. R. Evid. 702; see Fed. R. Evid. 104(a). The proponent must persuade the court that "the [expert's] testimony is based on sufficient facts or data." Fed. R. Evid. 702(b). The proponent also must persuade the court that "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"; "the testimony is the product of reliable principles and methods"; and "the expert's opinion reflects a reliable application of the principles and methods to the facts of the case." Fed. R. Evid. 702(a), (c)-(d).

The current version of Rule 702 is the product of two sets of amendments that occurred after this Court's landmark decision in *Daubert* v. *Merrell Dow*

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[1] See *Rodriguez* v. *Hosp. San Cristobal*, 91 F.4th 59, 70 (1st Cir. 2024) (applying rule from decision that Judge Schroeder identified as emblematic of the incorrect approach); *Doucette* v. *Jacobs*, 106 F.4th 156, 169 (1st Cir. 2024) (same).

Pharmaceuticals, 509 U.S. 579 (1993). *Daubert* requires trial courts to take on a "gatekeeping role" to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Id.* at 589, 597.

In 2000, Rule 702 was amended to "affirm[] the trial court's role as gatekeeper." Fed. R. Evid. 702 advisory committee's notes to 2000 amendments.[2] The 2000 amendments added reliability requirements now found in Rule 702(a)-(d), including the requirement in Rule 702(b) that an expert's testimony be based on sufficient facts or data. *Ibid.* At the time, Rule 702 did not expressly state that the proponent of evidence must demonstrate to the district court by a preponderance of the evidence that those requirements are satisfied. But the Advisory Committee Notes to the 2000 amendments explained that Rule 104(a) separately required that more-likely-than-not showing. Rule 104(a) governs the "admissibility of all expert testimony" and gives the "proponent" of such testimony "the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence." *Ibid.*; see Fed. R. Evid. 104(a) ("The court must decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible.").

In 2023, Rule 702 was amended again to "clarify and emphasize that expert testimony may not be admitted unless the proponent demonstrates to the court

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[2] This Court has long "relied on th[e] well-considered [Advisory Committee] Notes as a useful guide in ascertaining the meaning of the Rules" of Evidence. *Tome* v. *United States*, 513 U.S. 150, 160 (1995).

that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule." Fed. R. Evid. 702 advisory committee's notes to 2023 amendments. The amendments added the phrase "the proponent demonstrates to the court that it is more likely than not that" before the list of reliability criteria in Rule 702(a)-(d). *Ibid.* The Advisory Committee explained that "many courts have held that the critical question[] of the sufficiency of an expert's basis" is a "question[] of weight and not admissibility"—and that those holdings "are an incorrect application of Rules 702 and 104(a)" that "made [it] necessary" to "emphasiz[e] the preponderance standard in Rule 702" itself. *Ibid.*; see *ibid.* (criticizing court rulings that "arguments about the sufficiency of an expert's basis always go to weight and not admissibility").

The 2023 amendments did not change the substantive or procedural requirements imposed by Rule 702. "Rather, the amendment is simply intended to clarify that Rule 104(a)'s requirement applies to expert opinions under Rule 702." Fed. R. Evid. 702 advisory committee's notes to 2023 amendments; accord *EcoFactor* v. *Google*, 137 F.4th 1333, 1339 n.8 (Fed. Cir. 2025) (en banc) ("The 2023 amendment did not substantively change the relevant standard.").

2. In this putative class action, respondent Lee Ann Sommerville sued petitioners as operators of two separate manufacturing facilities located in South Charleston, West Virginia (collectively, "the Plant"). App., *infra*, at 1a-2a. Respondent, who did not work at or have any special connection to the Plant, asserted a single claim for medical monitoring under West Virginia common law. She alleged that Plant operations between 1984 and 2019 emitted ethylene oxide ("EtO")

into the atmosphere, that she breathed in the EtO in the course of her daily life, and that she faced an increased risk of future harm as a result. *Ibid.*

Respondent acknowledged that she could not establish liability without admissible expert testimony showing that she had significant exposure to a "proven hazardous substance" and that her exposure was greater than that of the population at large. App., *infra*, at 19a (quoting *Bower* v. *Westinghouse Elec.*, 522 S.E.2d 424, 432-433 (W. Va. 1999)). In an effort to meet that requirement, respondent offered Dr. Ranajit Sahu as an expert on petitioners' EtO emissions during the relevant period, including where emissions traveled geographically, and the "potential exposure levels of [respondent] and the proposed class members." *Ibid.*

Dr. Sahu claimed that he could model EtO emissions and determine an individual's cumulative EtO exposure based on a residential address and information about the years the individual lived there. App., *infra*, at 33a. But to run the model, he first "had to select the inputs" that the model would use, which "included source data, receptor data, and meteorological data." *Id.* at 19a. Dr. Sahu conceded that the "accuracy of the model bears a strong positive relationship to the correct inputs being used * * * that represent the actual condition" of the Plant and "its emissions sources." *Id.* at 35a.

Dr. Sahu submitted an expert report setting forth his methodology and findings. App., *infra*, at 44a. The report explained that he did not try to assess emissions from the Plant alone—instead, he commingled "results from both" the Plant and Union Carbide's separate facility in Institute, West Virginia, even though that separate facility is not at issue in this case. *Id.* at

44a, 56a. He also listed the emissions sources, emissions data, meteorological data, and data regarding background levels of EtO that he inputted into his model. *Id.* at 45a-49a, 61a-62a. Relying on those inputs, he opined that "persons in the surrounding community were exposed to significant concentrations of EtO." *Id.* at 48a.

3. a. After discovery closed, the district court granted petitioners' motions to exclude Dr. Sahu's testimony. App., *infra*, at 42a-88a. The court first rejected respondent's "contention that the instant motions raise questions affecting the *weight and credibility* of Dr. Sahu's opinions rather than their *admissibility*." *Id.* at 54a. The court explained that, "[u]pon detailed review of the expert reports, I find that the opinions of Dr. Sahu are not based upon sufficient facts or data because the inputs he uses in the air model are speculative and are premised on assumptions that do not accurately represent [petitioners'] operations." *Id.* at 42a.

The district court identified a number of independent "substantive issues" that cast serious doubt on the "reliability" of the data that Dr. Sahu used and rendered his testimony inadmissible. App., *infra*, at 60a. For instance, Dr. Sahu treated data from a single year as representative of emissions levels over the entire 36-year period from 1984 to 2019, without any justification for such an assumption and in the face of official warnings that the data should not be used that way. *Id.* at 62a-63a, 67a-75a. He did the same thing with the "meteorological data" that he used to assess "emissions dispersion characteristics," while also using "three different, contradictory sets of meteorological data taken from different locations" that were not "representative" of the Plant. *Id.* at 76a-78a; see *id.* at

62a (explaining that Dr. Sahu relied on data relating to both the Plant and the separate Union Carbide facility in Institute, even though the latter has nothing to do with respondent's suit). And he used emissions estimates that resulted in projections of "EtO concentrations for the year 1984" that are inexplicably "'over *100 times greater*' than the estimates for some of the other years in the potential class period," without validating his data or adequately explaining the disparity. *Id.* at 70a.

b. In May 2024, the district court granted petitioners' motion for summary judgment. App., *infra*, at 89a-115a. The court explained that respondent "relie[d] entirely" on the expert "to prove her alleged increased risk of cancer development due to the alleged EtO emissions." *Id.* at 104a. But the court had already "excluded * * * Dr. Sahu, because he used patently unreliable data and methods in creating the air model used to determine the alleged estimated EtO emissions—and therefore the increased risk of disease." *Id.* at 104a-105a. Accordingly, the court concluded, respondent could not establish any injury and lacked standing to proceed.

4. The Fourth Circuit reversed in a divided opinion. App., *infra*, at 1a-41a. While agreeing that respondent can pursue her medical-monitoring claim only if she "put[s] forth admissible expert testimony to establish" that "she was * * * 'significantly exposed' to a proven hazardous substance," the majority (Ben-

jamin, J.) ruled that the district court abused its discretion in excluding Dr. Sahu's expert testimony. *Id.* at 18a-21a (quoting *Bower*, 522 S.E.2d at 432-433).[3]

The majority identified the district court's error as "[e]xcluding Dr. Sahu" for his "choice of source [data] and meteorological data." App., *infra*, at 20a. That was wrong, the majority held, because "questions regarding the factual underpinnings of the [expert witness'] opinion affect the weight and credibility of the witness' assessment, not its admissibility." *Id.* at 20a-21a (citation omitted). In a footnote, the majority purported to acknowledge that "a district court can decide that an expert's opinion lacks sufficient support in the record." *Id.* at 27a n.7 (citation omitted). But in the same breath, the majority reemphasized that a court cannot exclude expert testimony based on "disagreement with an expert's choice of data" or "its own assessment of the correctness of an expert's opinions," and quoted *Bresler* v. *Wilmington Trust*, 855 F.3d 178, 195 (4th Cir. 2017), for the unqualified proposition that questions about an expert's "factual underpinnings" do not "affect * * * admissibility." *Ibid.* (emphasis omitted).

The majority repeatedly relied on that principle of law, referring to *Bresler* multiple times throughout its opinion. *E.g.*, App., *infra*, at 21a, 22a, 27a. For example, the court of appeals deemed the district court's critique of Dr. Sahu's "choice of meteorological inputs" improper on the ground that the court "conflated admissibility with the weight a factfinder might attribute Dr. Sahu's testimony based on his choice of data."

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[3] The majority also concluded that respondent has Article III standing because of her alleged "need" to pay "for medical testing *today* to mitigate an increased risk of illness." App., *infra*, at 16a.

Id. at 24a-25a. The court of appeals said the same thing about the district court's analysis of Dr. Sahu's "choice of source parameters" and "emissions data selections," deeming that analysis a "violat[ion of] *Bresler*'s holding that 'questions regarding the factual underpinnings of the [expert witness'] opinion" go only to "weight and credibility," not "admissibility.'" *Id.* at 20a-22a (quoting 855 F.3d at 195). And the court of appeals ruled that "[e]xcluding Dr. Sahu for failing to 'validate' his data" impermissibly rested on "disagree[ment] with Dr. Sahu's choice of data," which *Bresler* "forbids." *Id.* at 21a-22a (citing 855 F.3d at 196).

In dissent, Chief Judge Diaz explained why the district court "correctly excluded" Dr. Sahu's testimony and, at minimum, did not abuse its discretion. App., *infra*, at 33a. He emphasized that the majority was mistaken in holding that district courts may not consider questions about the factual underpinnings of an expert's testimony in deciding admissibility. *Id.* at 36a (citing Fed. R. Evid. 702(b), and *Gen. Elec.* v. *Joiner*, 522 U.S. 136, 146 (1997)).

Under the proper Rule 702 standard, Chief Judge Diaz reasoned, it is clear that Dr. Sahu's testimony "wasn't well-grounded in the facts and data available" and that the district court "had good reason to be concerned about Dr. Sahu's failure to justify the assumptions he made in creating the inputs for the dispersion model." App., *infra*, at 34a, 37a; see *id.* at 35a ("an expert who constructs a model based on faulty assumptions and irrelevant data shouldn't be handed a 'get-out-of-*Daubert*-free card,'" regardless of whether "he uses an otherwise reliable modeling system"). For instance, Chief Judge Diaz explained, Dr. Sahu "relied

on values that *expressly* didn't represent actual emissions"; "ignored telltale signs that there might be a problem with the emissions values he used"; "combined meteorological data from three locations," including locations "some distance away" from the Plant; and "held a value (e.g., emissions, operations) from one year constant over several years (or, for the meteorological data, for the entire thirty-year period at issue)" without explaining how doing so could possibly make sense. *Id.* at 38a-39a.

In Chief Judge Diaz's view, those type of "concerns" fall "squarely within the district court's purview" because they are an important part of fulfilling its "gatekeeping responsibility." App., *infra*, at 34a-37a. Because he would have upheld the exclusion of the expert's testimony, he also would have affirmed the district court's grant of summary judgment to petitioners on the ground that respondent failed to "meet her burden * * * to demonstrate an injury in fact." *Id.* at 33a.[4]

REASONS FOR GRANTING THE PETITION

I. The Courts of Appeals Are Divided Over Whether Challenges to the Factual Basis of an Expert's Opinion Always Go to Weight, Not Admissibility

The Fourth Circuit's decision in this case entrenched a conflict between the First and Fourth Circuits on one side and the Fifth, Sixth, Eighth, Ninth, and Federal Circuits on the other. Circuits in the for-

[4] Chief Judge Diaz also would have held that "medical monitoring costs (incurred or anticipated), without more, can't confer standing to seek damages in federal court." App., *infra*, at 30a.

mer category hold—in the words of the decision below—that challenges to the factual basis of an expert's testimony "affect the weight and credibility" of an expert's testimony and "not its admissibility," App., *infra*, at 20a-21a, while circuits in the latter category hold that such challenges go to the weight of the evidence *only* if a court first finds it more likely than not that an expert's testimony has a sufficient factual basis to render it reliable.

A. That split has been brewing for a number of years—but recent developments make it intolerable. In 2023, Rule 702 was amended to address the decisions of "courts" that had "incorrect[ly]" "held[] that arguments about the sufficiency of an expert's basis *always* go to weight and not admissibility." Fed. R. Evid. 702 advisory committee's notes to 2023 amendments. That amendment was intended to "clarify," not to change, the existing requirements of the Rules of Evidence. *Ibid.*; see *EcoFactor* v. *Google*, 137 F.4th 1333, 1339 n.8 (Fed. Cir. 2025) (en banc) ("The 2023 amendment did not substantively change the relevant standard."). It did so by adding an express reference in Rule 702 to the separate requirement in Rule 104(a) that the proponent of evidence establish admissibility by a preponderance of the evidence. See Fed. R. Evid. 104(a). As of December 1, 2023, therefore, the amended Rule 702 provides that expert testimony is admissible "if the proponent demonstrates *to the court* that it is more likely than not that * * * the testimony is based on sufficient facts or data." Fed. R. Evid. 702 (emphasis added).

After that amendment, courts of appeals that had previously required district courts to determine that expert testimony more likely than not has a sufficient factual basis before admitting it continued to enforce

that requirement. And some courts of appeals that had not consistently approached admissibility that way fell into line. But two courts of appeals—the Fourth Circuit, which issued the decision below, and the First Circuit—continued to hold fast to their position that questions about an expert's factual basis go only to the weight of the expert's testimony and therefore must be decided by a jury. See *Federal Rules of Evidence—Expert Testimony—Judicial Conference Amends Rule 702—Federal Rule of Evidence 702*, 138 Harv. L. Rev. 899, 903 (2025).

Thus, despite the amendments to Rule 702, there remains an intractable circuit split over whether a district court must determine whether it is more likely than not that an expert has a sufficient factual basis to support an opinion before allowing that opinion to be admitted as evidence.

B. The Fifth, Sixth, Eighth, Ninth, and Federal Circuits have hewed to the approach prescribed in the Rule 702 advisory committee notes.

The Ninth Circuit's decision in *Engilis* v. *Monsanto*, 151 F.4th 1040 (9th Cir. 2025), is illustrative. That decision traces Rule 702's history, including the clarifying 2023 amendments, and holds that, "[p]roperly applied, Rule 702 requires that challenges to an expert's opinion go to the weight of the evidence *only* if a court *first* finds it more likely than not that an expert has a sufficient basis to support an opinion." *Id.* at 1049 (emphasis added); see *id.* at 1051 (explaining that Rule 702 requires district courts "to screen expert testimony" to ensure, among other things, that it is "'based on sufficient facts or data'" (quoting Fed. R.

Evid. 702(b))).[5] Applying the more-likely-than-not test reaffirmed in the 2023 amendments, the court of appeals upheld the district court's decision to exclude the expert testimony because the expert had insufficient facts to conclude that the plaintiff was not obese, which was a key premise of the expert's opinion on the causes of a medical condition. See *ibid.* The court of appeals recognized that some evidence—a medical "fact sheet" stating that the plaintiff was "negative" for obesity—supported the expert's premise, but nonetheless upheld the district court's conclusion that the plaintiff had not shown a sufficient factual basis by a "preponderance of the evidence." *Id.* at 1051-1052.

The other circuits' decisions are of a piece. In *In re Onglyza (Saxagliptin) & Kombiglyze (Saxagliptin & Metformin) Products Liability Litigation*, 93 F.4th 339 (6th Cir. 2024), the Sixth Circuit affirmed the district court's exclusion of an expert's testimony, holding that, "[b]efore admitting expert testimony, the district court needed to ensure that" the expert's testimony was "'based on sufficient facts or data.'" 93 F.4th at 345 (quoting Fed. R. Evid. 702); see *id.* at 348 ("competing expert opinions present the classic battle of the experts and it is up to a jury to evaluate what weight and credibility each expert opinion deserves," but "district courts may allow juries to evaluate and weigh *only* relevant and reliable expert testimony" (citation omitted)). The Sixth Circuit noted the clarifying 2023 amendments but explained that its decision "would be the same under either version of the Rule." *Id.* at 345 n.4. The court of appeals concluded that the district court had not abused its discretion in finding that the

[5] The Ninth Circuit noted that the applicable "version of the Rule" did not make a difference, consistent with the fact that the 2023 amendments were merely clarifying. 151 F.4th at 1049 n.9.

expert's testimony lacked sufficient factual support, as his attempt to link defendants' diabetes drug to patients' heart failure relied on a single trial but set aside "without an adequate explanation" subsequent studies reaching the opposite conclusion. *Id.* at 346. Notably, the court of appeals upheld the exclusion of the testimony even though the expert had made some effort to explain away the later studies, because the preponderance of the evidence did not establish a sufficient basis for the expert's opinion. *Id.* at 345.

The Sixth Circuit later applied the same rule in *Baker* v. *Blackhawk Mining*, 141 F.4th 760 (6th Cir. 2025), which is factually similar to this case. The Sixth Circuit held that the district court had not erred in concluding that a causation expert's report was "not based upon sufficient facts or data" about the "specific mining sites" that supposedly caused the plaintiffs' injury, rendering it unreliable under Rule 702. *Id.* at 770 (citation omitted). The court of appeals was not swayed by the fact that the expert looked to studies about other mining sites nearby; that was not enough to send the case to a jury to decide how heavily to weigh the expert's testimony. See *id.* at 763-765, 770.

The law is the same in the Federal Circuit. Most recently, in *EcoFactor* v. *Google*, 137 F.4th 1333 (Fed. Cir. 2025) (en banc), the en banc court concluded that a lack of support for an expert's damages opinion meant that the expert's testimony should have been excluded, as there was not "a sufficient factual basis for [the expert] to provide a reliable opinion" on an estimated reasonable royalty. *Id.* at 1344. The Federal Circuit explained that it was not "usurp[ing] the province of the jury"; it was simply exercising "the gatekeeping function of the court to ensure that there are

sufficient facts or data" for the expert's opinion, consistent with the 2023 amendments clarifying Rule 702. *Id.* at 1339, 1343; see *id.* at 1339-1340 (noting the advisory committee's statement that it is incorrect to hold that "the critical question[] of the sufficiency of an expert's basis" is a "question[] of weight and not admissibility" and emphasizing that "[d]istinguishing 'the gatekeeping role of the judge' * * * from the fact finder's role" is "essential" (citation omitted)). Again, the court reached that conclusion even though there was *some* factual basis for the expert's opinion, see *id.* at 1343—because the evidence on which the expert relied did not satisfy Rule 702's "more likely than not" standard. *Id.* at 1341-1342, 1344-1346.

The Fifth Circuit similarly recognizes that Rule 702 requires district courts to evaluate whether an expert's data is sufficiently sound before a jury may consider it. For example, in *Nairne* v. *Landry*, 151 F.4th 666 (5th Cir. 2025), the court of appeals affirmed a district court's exclusion of an expert on the ground that his testimony regarding voting patterns was not "based on sufficient data," as the expert had considered only some elections and inexplicably excluded others. *Id.* at 698. In doing so, the Fifth Circuit cited the 2023 amendments, on which the district court had relied. See *id.* at 697-698; see also, *e.g.*, *Harris* v. *FedEx Corp. Servs.*, 92 F.4th 286, 303-304 (5th Cir. 2024) (reversing a district court's refusal to exclude expert testimony because the court "abdicated its role as gatekeeper" by admitting testimony that was not "based on sufficient facts or data").

Finally, in *Sprafka* v. *Medical Device Business Services*, 139 F.4th 656 (8th Cir. 2025), the Eighth Circuit applied the same rule in a design-defect case. See *id.* at 661. "After Rule 702's recent amendment," the

Eighth Circuit stated, "courts continue to have a gatekeeping role" to "discern expert opinion evidence based on 'good grounds' from subjective speculation." *Ibid.* (citation omitted). Applying that rule, the court of appeals concluded that the district court had not abused its discretion in refusing to admit expert testimony that a medical-device manufacturer was responsible for a common side effect of a medical procedure that the plaintiff had undergone. See *id.* at 659-661. That conclusion was based on an examination of the expert's factual basis, including the expert's reliance on only a few small studies and some anecdotal observations. Although those provided *some* basis for the expert's opinion, that was not enough to justify putting the expert's testimony before a jury to determine its weight. See *id.* at 661-662; see also, *e.g.*, *Bliv* v. *Charter Oak Fire Ins.*, 159 F.4th 539, 544 (8th Cir. 2025) (affirming district court's exclusion of expert testimony where there was "a reasoned basis to find" that the expert "failed to consider or account for critical information when forming his opinions").

C. The Fourth Circuit, along with the First Circuit, applies a legal rule that is irreconcilable with the rule applied by the circuits above. Despite the clear direction provided by the 2023 amendments to Rule 702, those two circuits continue to treat questions about the sufficiency of the factual basis for an expert's testimony as going only to the weight of that evidence—and thus, invariably, as a jury question rather than as a threshold admissibility question that courts must decide.

1. In the decision below, the Fourth Circuit categorically held that "'questions regarding the factual underpinnings of [an expert's] opinion affect the weight and credibility of the witness' assessment, not

its admissibility.'" App., *infra*, at 20a-21a (quoting *Bresler* v. *Wilmington Tr. Co.*, 855 F.3d 178, 195 (4th Cir. 2017)). On that basis, the court of appeals rejected the district court's many criticisms of the data on which the expert relied—which included air-quality data from locations and time periods that are not at issue in this case—and ruled that the expert's testimony was admissible. See *id.* at 20a-27a. But the court of appeals did not determine whether it was more likely than not that the expert's testimony was supported by sufficient facts or data. See *ibid.* The court below thus took exactly the approach that the advisory committee notes to the 2023 amendments roundly criticize and that the circuits on the other side of the split have firmly rejected.

The specific reasoning that the Fourth Circuit employed highlights that split in authority. For example, the Fourth Circuit ruled that the district court abused its discretion in holding that the expert used "unreliable" data, stating that the expert "provided reasons for why" he "believe[d]" the data was accurate that a jury should "weigh[]." App., *infra*, at 22a. But the circuits on the other side of the split have repeatedly recognized that the existence of *some* factual basis for expert testimony is not enough to satisfy Rule 702; rather, the question is whether the *preponderance of the evidence* establishes the likelihood that a sufficient basis exists. See, *e.g.*, *Engilis*, 151 F.4th at 1050-1051 (Ninth Circuit deeming expert testimony inadmissible for lack of sufficient factual basis even though expert had a medical "fact sheet" supporting his factual assertion); *Onglyza*, 93 F.4th at 345 (Sixth Circuit deeming expert testimony inadmissible for lack of sufficient factual basis even though the expert "provided reasons" for relying on one clinical trial and discounting

others). The decision below is peppered with such conflicts in reasoning, driven by the stark differences between the circuits' legal rules.[6]

2. The First Circuit has long taken the same approach as the Fourth Circuit. See *Judicial Conference Amends Rule 702*, 138 Harv. L. Rev. at 903 ("The First Circuit provides an example of a court that has not acknowledged the impact the amendments ought to have had on its approach to Rule 702 inquiries.").

Milward v. *Acuity Specialty Products Group*, 639 F.3d 11 (1st Cir. 2011), exemplifies the First Circuit's approach. There, the court of appeals held that the district court's "challenge[s] [to] the factual underpinnings of [the expert's] opinion" that exposure to a chemical substance caused cancer "overstepped the authorized bounds of its role as gatekeeper" because "[t]he soundness of the factual underpinnings of the expert's analysis" is a "factual matter[] to be determined by the trier of fact." *Id.* at 22 (citation omitted). In the First Circuit's view, even if—as the district court had concluded—"the factual underpinning of [the] expert's opinion is weak," that weakness affects

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[6] Compare App., *infra*, at 20a-21a (stating that the expert's "choice of which data to input into his model" goes only to "weight and credibility" and that whether expert failed to validate data is not relevant to admissibility), with *Nairne*, 151 F.4th at 698 (expert testimony properly excluded where expert failed to include relevant data in his model); *Harris*, 92 F.4th at 303 (same); *Onglyza*, 93 F.4th at 346 (same); *Baker*, 141 F.4th at 770 (expert testimony properly excluded where expert relied on improper data); *EcoFactor*, 137 F.4th at 1344 (expert testimony properly excluded where expert did not validate his data but rather relied on only a fact witness's unsupported say-so); *Engilis*, 151 F.4th at 1052 (expert testimony properly excluded where expert relied on data that the expert failed to validate by "undertak[ing] any evaluation" of the underlying facts).

only "the weight and credibility of the testimony" and is therefore "a question to be resolved by the jury." *Ibid.* (citation omitted); see *id.* at 23 ("The questions that the [district] court posed were sensible ones, but ones for the jury to resolve."). In deeming the expert's testimony admissible, the First Circuit—like the Fourth Circuit in this case—never asked the critical question on which the other circuits' admissibility analysis rests: whether the plaintiff had established that it was more likely than not that the expert's testimony was based on sufficient facts or data. See *ibid.* And the First Circuit has repeatedly applied *Milward*'s rule even after the 2023 amendments to Rule 702. See *Rodriguez* v. *Hosp. San Cristobal*, 91 F.4th 59, 70 (1st Cir. 2024); *Doucette* v. *Jacobs*, 106 F.4th 156, 169 (1st Cir. 2024).

In short, there is no way to square the rule applied by the court below and the First Circuit with the rule applied by the Fifth, Sixth, Eighth, Ninth, and Federal Circuits. Action by this Court is urgently needed to bring uniformity to this important area of the law.

II. The Fourth Circuit's Decision Is Incorrect

A. The rule that the Fourth Circuit applied below is at odds with the plain text of Rule 702. Rule 702 assigns to trial court judges "a gatekeeping role" to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589, 597. The rule expressly provides that "[a] witness who is qualified as an expert * * * may testify in the form of an opinion or otherwise if the proponent demonstrates to the court that it is more likely than not that * * * the testimony is based on sufficient facts or data" and that various other reliability requirements are satisfied. Fed. R. Evid. 702(b).

Accordingly, where a party challenges an expert's opinion as not "based on sufficient facts or data," the court must address such a challenge before it can admit the testimony. Fed. R. Evid. 702(b); see *Daubert*, 509 U.S. at 590. If the court concludes by a preponderance of the evidence that the testimony is not based on sufficient facts or data—for example, because the expert's predicate facts are wrong, the expert failed to account for important data, or the expert included irrelevant data—then the court must exclude the testimony. And if the court concludes by a preponderance of the evidence that the expert's testimony has a sufficient factual basis, then the court should admit the testimony so that the jury can hear it and decide how much weight to give it. That is the same preponderance-of-the-evidence test that courts apply when evaluating the other reliability factors listed in Rule 702, such as whether "the testimony is the product of reliable principles and methods" and whether "the expert's opinion reflects a reliable application of the principles and methods to the facts of the case." Fed. R. Evid. 702(c)-(d); see generally *Daubert*, 509 U.S. at 592-593.

The Fourth Circuit's approach is irreconcilable with Rule 702 and with this Court's explication of it. The district court in this case excluded the expert's testimony after identifying a host of reasons why his opinion was not "based on sufficient facts or data." Fed. R. Evid. 702(b). Under Rule 702, reversal would be appropriate only if the Fourth Circuit concluded that respondent had "demonstrate[d] * * * that it is more likely than not that" the expert's report was "based on sufficient facts or data." *Ibid.* But the Fourth Circuit never asked that question. To the contrary, it concluded that the district court abused its discretion for having done so, holding that challenges to the "factual underpinnings" of an expert's testimony

are always for the jury, not the court, to resolve. App., *infra*, at 20a. And when the dissent challenged that approach, the majority responded by quoting from the Fourth Circuit's earlier decision in *Bresler* v. *Wilmington Trust*, 855 F.3d 178 (4th Cir. 2017), articulating the very same rule that the majority adopted: "questions regarding the factual underpinnings of the [expert witness'] opinion affect the weight and credibility of the witness' assessment, not its admissibility." *Id.* at 195 (citation omitted), *quoted in* App., *infra*, at 27a n.7.

That approach is deeply problematic. It inexplicably treats one of the reliability factors in Rule 702—whether "the testimony is based on sufficient facts or data"—differently than the others, even though the Rule uses exactly the same language as to each to describe how a court should conduct its admissibility analysis. See *Clark* v. *Martinez*, 543 U.S. 371, 378 (2005) ("[t]o give these same [statutory] words a different meaning" when applied in different contexts "would be to invent a statute rather than interpret one").

Even more to the point, that approach renders Rule 702's intended "gatekeeping role" a nullity as to the factual basis for expert testimony. *Daubert*, 509 U.S. at 589, 597. The Fourth Circuit's approach fails to screen out expert testimony that lacks adequate rigor because it is premised on insufficient facts or data, and thereby creates exactly the risk that Rule 702 exists to eliminate: that juries may well be swayed by such testimony because of the inherent force of any testimony that is labeled "expert." See, *e.g.*, Peter Huber, *Junk Science and the Jury*, 1990 U. Chi. Legal F. 273, 276-277 (1990).

B. The 2023 amendments and accompanying Advisory Committee notes eliminate all doubt that the decision below is fatally flawed. Those amendments sought to "clarify and emphasize that expert testimony *may not be admitted*" unless its proponent can show, by a preponderance of the evidence, that it satisfies each of the Rule's admissibility requirements. Fed. R. Evid. 702 advisory committee's notes to 2023 amendments (emphasis added). As discussed, that "clarif[ication]" was necessary because "many courts" had "incorrect[ly]" "held that the critical question[] of the sufficiency of an expert's basis" is "always" a "question[] of weight and not admissibility." *Ibid.* The Committee recognized that *sometimes* such questions could go to the weight of evidence—but they could do so *only* "once the court has found it more likely than not that the admissibility requirement has been met." *Ibid.*

There is no question that the Committee was referring to decisions like the one below. And to the extent there were any doubt, Judge Schroeder, the Chair of the Judicial Conference's Subcommittee on Rule 702 that drafted the 2023 amendments, stated that the amendments were directed at *Bresler*, the Fourth Circuit decision from 2017 that articulated the rule that the court below applied to overturn the district court in this case, and similar decisions. In cataloging decisions that "appear to be abdicating their charge under the Federal Rules of Evidence and *Daubert* and its progeny to make the hard call on admissibility," Judge Schroeder focused specifically on *Bresler* as "effectively vitiat[ing] the application of" the preponderance test "to Rule 702(b)." Thomas D. Schroeder, *Toward A More Apparent Approach to Considering the Admission of Expert Testimony*, 95 Notre Dame L. Rev. 2039, 2043, 2049-2050 (2020) (discussing *Bresler*'s holding that "questions regarding the factual underpinnings"

affect "weight and credibility" and not "admissibility"); see App., *infra*, at 21a-22a (repeatedly relying on and quoting *Bresler*). And Judge Schroeder identified the First Circuit's opinion in *Milward* as "a prime example" of the same error. 95 Notre Dame L. Rev. at 2044.

C. Had the court of appeals properly applied Rule 702, it would have affirmed the district court's exclusion of respondent's expert—and that exclusion would have ended the case, as it is indisputable that respondent's claims cannot proceed without such expert testimony. See p. 7, *supra*. As Chief Judge Diaz's dissent explains, the district court's many concerns with the reliability of the expert's data were not only well grounded, but also "squarely within the district court's purview" in enforcing its "gatekeeping responsibility"—and the farthest thing from an abuse of discretion. App., *infra*, at 34a-37a (Diaz, C.J., dissenting).[7]

III. The Question Presented Is Exceptionally Important and Warrants Review in This Case

A. Resolution of the Question Presented Is of Overriding Importance

1. Establishing that trial courts must determine whether it is more likely than not that an expert's testimony is supported by sufficient facts or data before deeming that testimony admissible is a matter of pressing importance. The issue recurs frequently. It also is often outcome-determinative—or, at a minimum, powerfully influences how cases progress, what

[7] In no event could the court of appeals properly have concluded that the expert's testimony was *admissible* without even considering whether it was more likely than not that the testimony had a sufficient factual basis.

juries decide, and the parties' incentives for settlement.

Expert testimony is of course ubiquitous in all types of matters. It plays a particularly important role in product-liability cases, patent cases, environmental cases, and other cases in which science is central to liability determinations. As jurists have observed, "science in all its forms—hard science, soft science, even so-called 'junk' science—has * * * invaded the courtroom to an unparalleled extent." Jed S. Rakoff, *Science and the Law: Uncomfortable Bedfellows*, 38 Seton Hall L. Rev. 1379, 1379 (2008); see Stephen G. Breyer, *Introduction*, in Federal Judicial Center, Reference Manual on Scientific Evidence 3 (3d ed. 2011) (explaining that "[s]cientific issues" now "permeate the law"); see also *Joiner*, 522 U.S. at 148-149 (Breyer, J., concurring) ("modern life * * * depends upon the use of artificial or manufactured substances," making it "particularly important * * * that judges fulfill their *Daubert* gatekeeping function, so that they help assure that the powerful engine of tort liability * * * points toward the right substances and does not destroy the wrong ones").

Expert testimony also is likely to have an outsized impact, especially when it addresses complex scientific issues. Often, as here, a plaintiff's case rests entirely on expert testimony. See App., *infra*, at 40a (expert's "model is the only evidence that, for example, indicates that [respondent] was exposed to EtO emitted by [petitioners'] operations"). And even when that is not true, expert testimony is likely to have a major effect on a factfinder's determination. As this Court previously put it, "[e]xpert evidence can be both powerful and quite misleading." *Daubert*, 509 U.S. at 595 (citation omitted). "[E]xpertise that is *fausse* and science

that is junky" is a very real problem. *Kumho Tire* v. *Carmichael*, 526 U.S. 137, 158-159 (1999) (Scalia, J., concurring); see Victor E. Schwartz & Cary Silverman, *The Draining of Daubert and the Recidivism of Junk Science in Federal and State Courts*, 35 Hofstra L. Rev. 217, 224 (2006) (discussing "misleading junk science"). The Rules "grant expert witnesses testimonial latitude unavailable to other witnesses." *Kumho*, 526 U.S. at 148-149. And expert "testimony often will rest upon an experience confessedly foreign in kind to" a jury's "own," *ibid.* (citation modified)—which means that jurors may well have difficulty, "due to lack of specialized knowledge," in "evaluat[ing] meaningfully the reliability" of the expert's data and methodology, Fed. R. Evid. 702 advisory committee's notes to 2023 amendments. Thus, even junk science, resting on purported facts that are incorrect, misleadingly incomplete, or simply irrelevant, may appear to jurors to "compellingly support[]" an "otherwise unsupportable claim." Huber, *supra*, 1990 U. Chi. Legal F. at 276-277.

Precisely because expert testimony can have such a powerful effect, whether a court decides to admit an expert's testimony not only shapes the substantive decisions made within the litigation itself but also a defendant's decision whether to settle. And when there are serious doubts about the factual underpinnings of an expert's testimony but a court admits that testimony anyway on the ground that any such doubts go only to the testimony's weight, the defendant is often pressured into a settlement to which it would not otherwise have agreed. See Margaret A. Berger, *The Admissibility of Expert Testimony*, in Federal Judicial Center, Reference Manual on Scientific Evidence 19 (3d ed. 2011) ("[A]n inability by the defendant to exclude plaintiffs' experts undoubtedly affects the willingness of the defendant to negotiate a settlement.");

Rakoff, *supra*, at 1391 (noting that "shortly after" decision permitting plaintiffs to offer some expert testimony, "most of the 800 cases [in an MDL] settled"). That problem is most acute in class actions and other mass actions, where a court's decision to admit the testimony of the plaintiffs' expert often exerts "irresistible pressure" on a defendant "to settle the action rather than risk a battle of the experts at trial that, if the defendant loses, can cost exponentially more than the settlement." Christopher R.J. Pace, *Admitting and Excluding General Expert Testimony: The Eleventh Circuit Construct*, 37 Am. J. Trial Advoc. 47, 48 (2013).

2. The question presented arises with great frequency, as the many court of appeals decisions from just the past few years demonstrate. See pp. 12-25, *supra*. And scores of district-court decisions addressing that question never result in published appellate decisions—often because an adverse ruling drives settlement.

In fact, the decision below has already influenced district courts in the Fourth Circuit to admit expert testimony without deciding whether it has a sufficient factual basis, on the ground that *any* challenge to the factual basis of an expert's opinion goes only to weight and therefore should be decided by a jury. For instance, immediately after the decision below, a Maryland district court invoked it to deny a motion to exclude a plaintiff's expert testimony because "[q]uestions regarding the factual underpinnings of the [expert witness'] opinion, which are what Defendant raises here, affect the weight and credibility of the witness' assessment, not its admissibility." *Michael's Fabrics* v. *Donegal Mut. Ins.*, 2025 WL 2624280, at *4 (D. Md. Sept. 11, 2025) (citation modified). District

courts in North Carolina and South Carolina have recently done the same. *In re Camp Lejeune Water Litig.*, 2025 WL 3565850, at *15 (E.D.N.C. Dec. 12, 2025); *Mincey* v. *Se. Farm Equip.*, 2025 WL 2450913, at *10 (D.S.C. Aug. 26, 2025).

3. At this point, it is clear that this Court's intervention is necessary to ensure that the courts of appeals uniformly apply Rule 702 correctly.

The 2023 amendments to Rule 702 were intended to "clarify and emphasize that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony" is supported by sufficient facts or data. Fed. R. Evid. 702 advisory committee's notes to 2023 amendments. Many courts of appeals have taken that clarification to heart. See pp. 14-18, *supra*. But the court below and the First Circuit have defiantly "doubl[ed] down on" their insistence that factual-basis questions about expert testimony are not part of the admissibility analysis—"a sign that the challenge of achieving consistency is greater than something that clarifying amendments can fix." *Judicial Conference Amends Rule 702*, 138 Harv. L. Rev. at 899; see Lee Mickus, *Amended Rule 702 in 2025*, Wash. Legal Found. (Oct. 7, 2025), https://www.wlf.org/2025/10/07/publishing/amended-rule-702-in-2025-circuit-courts-embrace-the-changed-standard/.

The decision below exemplifies that troubling development. As noted, in the run-up to the 2023 amendments, Judge Schroeder specifically critiqued the Fourth Circuit's holding in *Bresler* that "questions regarding the factual underpinnings of the [expert witness'] opinion affect the weight and credibility of the witness' assessment, not its admissibility," explaining

that such an approach "effectively vitiated the application of [the preponderance test] to Rule 702(b)." Schroeder, 95 Notre Dame L. Rev. at 2049-2050 (citation modified). Yet despite that criticism and the clarity of the 2023 amendments, the decision below continued to hew to *Bresler*'s erroneous holding, App., *infra*, at 20a-21a—and, in doing so, rebuffed the arguments in petitioners' merits brief about the significance of those amendments, see Defendants-Appellees' Br. 17, 19-20, 23 n.7 (4th Cir.). The Fourth Circuit then refused to grant rehearing en banc to revisit that holding, even though it quite obviously conflicts with the rule applied in multiple other circuits.

It is thus plain that this deep fissure in the law over a critical aspect of Rule 702 will not close on its own. There is only one way to ensure uniformity and correct the misapplication of Rule 702: action by this Court. The secondary literature has recognized as much—for instance, explaining that "more than twenty years after *Daubert*, the Supreme Court will need to take up the issue directly if it wishes for lower courts to coalesce around one approach" to the role that challenges to an expert's underlying facts or data play in the admissibility analysis. *Judicial Conference Amends Rule 702*, 138 Harv. L. Rev. at 906. That guidance is especially necessary given that the Court has not decided on the merits any issue relating to *Daubert* in more than 25 years.

B. This Case Is an Ideal Vehicle

1. This case squarely presents the legal question whether challenges to the factual basis of expert testimony always go to the weight of the evidence and never go to admissibility. The decision below emphatically holds that the district court's decision was an "abuse of discretion because questions regarding the

factual underpinnings of the [expert witness'] opinion affect the weight and credibility of the witness' assessment, not its admissibility." App., *infra*, at 20a-21a (citation omitted). The district-court decision in question carefully and thoroughly explains why, under the correct legal rule, the expert's testimony does not have a sufficient factual basis to be admitted. And the majority and dissenting opinions in the court of appeals thoroughly ventilated the question presented.

2. A ruling in petitioners' favor also would end this case—making it an unusually compelling vehicle to consider the question presented.

As Chief Judge Diaz explained, "[w]ithout [the expert's] opinion, [respondent] can't carry her burden to present evidence sufficient to demonstrate" that she was injured in any way by petitioners' alleged actions. App., *infra*, at 40a. That conclusion does not turn on disagreements below about whether medical-monitoring costs constitute a sufficient injury for Article III standing. Rather, without the challenged expert opinion, respondent simply "can't establish [an] injury in fact," whether based on alleged monitoring costs or any other alleged harm. *Ibid.* That is because the expert's "model is the only evidence that * * * indicates that [respondent] was exposed to EtO emitted by [petitioners'] operations." *Ibid.*; see *id.* at 103a-105a.

The Fourth Circuit's mistaken understanding of Rule 702 was the only basis it gave for displacing the district court's careful decision about the flaws in the facts and data underlying the expert's opinion. The Fourth Circuit gave no other reason to conclude that the district court exceeded its wide latitude under the abuse-of-discretion standard to assess whether it is

likely that the expert's opinion has a sufficient basis—and no such reason exists.[8]

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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February 2, 2026

[8] Regardless, once the Fourth Circuit's legal error about the scope of Rule 702 is corrected, the court of appeals' decision that the expert's testimony is *admissible* cannot survive, because that court neither concluded itself "that it is more likely than not that * * * the testimony is based on sufficient facts or data," Fed. R. Evid. 702(b), nor remanded to the district court to conduct that analysis anew in light of some identified flaw. See n.7, *supra*.

APPENDICES

APPENDICES

Appendix A: Opinion of the United States Court of Appeals for the Fourth Circuit (August 18, 2025) 1a

Appendix B: Opinion of the United States District Court for the Southern District of West Virginia (March 20, 2024) 42a

Appendix C: Opinion of the United States District Court for the Southern District of West Virginia (May 13, 2024) 89a

Appendix D: Order of the United States Court of Appeals for the Fourth Circuit Denying Rehearing (November 4, 2025) 116a

Appendix E: Provisions Involved 117a

APPENDIX A

No. 24-1491

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

Lee Ann SOMMERVILLE, individually, and on behalf of all others similarly situated,
Plaintiff – Appellant,

v.

UNION CARBIDE CORPORATION; Covestro LLC,
Defendants – Appellees.

American Tort Reform Association; Chamber of Commerce of the United States of America,
Amici Supporting Appellee.

Argued: January 29, 2025

Decided: August 18, 2025

Opinion

Reversed and remanded by published opinion. Judge Benjamin wrote the opinion in which Judge Wynn joined. Chief Judge Diaz wrote a dissenting opinion.

DEANDREA GIST BENJAMIN, Circuit Judge:

Plaintiff Lee Ann Sommerville appeals the district court's exclusion of her proposed expert, Dr. Ranajit Sahu, and its grant of summary judgment to Defendants Union Carbide Corporation and Covestro LLC for lack of standing. We now reverse.

I.

Sommerville, on behalf of herself and others similarly situated, sued Defendants Union Carbide Corporation and Covestro LLC (collectively "the Plant Owners") for alleged exposure to ethylene oxide ("EtO"), a gas that causes cancer. Sommerville's law-

suit concerns a plant in South Charleston, West Virginia ("the Plant"), which Union Carbide, and then Covestro, operated between 1978 and 2019. Sommerville alleges that the Plant emitted EtO into the atmosphere, that she breathed this EtO, and that this exposure increased her risk of developing specific diseases. Sommerville alleges that she has a present need to manage this increased risk of illness through medical monitoring and diagnostic testing, and that the Plant Owners should foot the bill. Sommerville brought a single claim for medical monitoring under West Virginia common law.

Sommerville challenges two orders the district court issued. The first is an order excluding the opinions of her proffered expert, Dr. Sahu. The second is an order granting the Plant Owners summary judgment. Sommerville timely appealed and we have jurisdiction. 28 U.S.C. § 1291.

II.

The district court acknowledged that West Virginia law recognizes medical monitoring claims. Nevertheless, it held that because Sommerville lacked a "manifest" physical injury, she did not have Article III standing. If the district court is correct, then whether Dr. Sahu's testimony was erroneously excluded is beside the point. So we begin with standing. Our review is *de novo. White Tail Park, Inc. v. Stroube*, 413 F.3d 451, 459 (4th Cir. 2005).

A.

In *Bower v. Westinghouse Electric Corp.*, 206 W.Va. 133, 522 S.E.2d 424 (1999), the Supreme Court of Appeals of West Virginia recognized common law claims for medical monitoring. *Id.* at 431. Plaintiffs bringing medical monitoring claims seek "to recover the anticipated costs of long-term diagnostic testing

necessary to detect latent diseases that may develop as a result of tortious exposure to toxic substances." *Id.* at 429. The tort is a "well-grounded extension of traditional common-law tort principles." *See id.*; *see also id*. (collecting cases).[1]

Medical monitoring claims originate from the traditional common law principle that individuals have "legally protected interest[s] in avoiding physical injury." *See Bourgeois v. A.P. Green Indus., Inc.*, 716 So. 2d 355, 359 (La. 1998); *Bower*, 522 S.E.2d at 429–30. Medical monitoring claims apply this principle to injuries where there is no visible "impact." *Bourgeois*, 716 So. 2d at 358 (noting that "modern environmental toxins[ ] affect[ ] the body in ways that often do not become manifest for many years") (citing *Hansen v. Mountain Fuel Supply*, 858 P.2d 970, 977 (Utah 1993)). "[T]he exposure *itself* and the concomitant *need* for medical testing constitute the injury." *Bower*, 522 S.E.2d at 430 (cleaned up and emphasis added) (citing *Hansen*, 858 P.2d at 977).

Medical monitoring claims concern exposure to "hazardous substance[s]" like "asbestos" or, in this case, EtO and, by their nature, occur "without impact." *See Bourgeois*, 716 So. 2d at 358 ("Unlike a car crash, asbestos exposure is an accident almost always without impact."). The fact that exposure to a contaminant happens invisibly—so to speak—does not sever the tort from its common law roots. The exposure "is still an accident that can have consequences every bit as real as those sustained in a head-on colli-

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[1] Because *Bower v. Westinghouse Electric Corp.*, 206 W.Va. 133, 522 S.E.2d 424 (1999), does not articulate explicitly the common law principles from which West Virginia's medical monitoring claim grew, we rely on *Bourgeois v. A.P. Green Industries., Inc.*, 716 So. 2d 355 (La. 1998), one of the cases which *Bower* cited.

sion. In fact, it is precisely because asbestos"—or EtO—"can have such deadly consequences that plaintiffs, regardless of whether or not they are currently suffering from a disease, are often encouraged to submit to regular diagnostic testing." *See id.* at 358–59.

Put simply, "an individual has an interest in avoiding expensive diagnostic examinations just as he or she has an interest in avoiding physical injury." *Friends for All Child., Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 826 (D.C. Cir. 1984). "When a defendant negligently invades this interest, the injury to which is neither speculative nor resistant to proof, it is elementary that the defendant should make the plaintiff whole by paying for the examinations." *Id.*; *Bower*, 522 S.E.2d at 430 (quoting *Friends for All Child.*, 746 F.2d at 826, for this proposition). Or in *Bower*'s own words, "[a]lthough the physical manifestations of an injury may not appear for years, the reality is that many of those exposed have suffered [a] legal detriment; the exposure itself and the concomitant need for medical testing constitute the injury." 522 S.E.2d at 430 (quoting *Hansen*, 858 P.2d at 977).

Given the injury's nature—tortious exposure to a known hazardous substance whose effects won't appear for years but for which expensive medical testing is required today—*Bower* "reject[ed] the contention that a claim for future medical expenses must rest upon the existence of present physical harm." *Id.* *Bower* quoted at length from *Friends for All Children* to support this conclusion. *See* 522 S.E.2d at 430–31. We do too:

> Jones is knocked down by a motorbike which Smith is riding through a red light. Jones lands on his head with some force. Understandably shaken, Jones enters a hospital

> where doctors recommend that he undergo a battery of tests to determine whether he has suffered any internal head injuries. The tests prove negative, but Jones sues Smith solely for what turns out to be the substantial cost of the diagnostic examinations.
>
> ...
>
> [In such circumstances] it is clear that even in the absence of physical injury Jones ought to be able to recover the cost for the various diagnostic examinations proximately caused by Smith's negligent action. A cause of action allowing recovery for the expense of diagnostic examinations recommended by competent physicians will, in theory, deter misconduct, whether it be negligent motorbike riding or negligent aircraft manufacture. The cause of action also accords with commonly shared intuitions of normative justice which underlie the common law of tort. The motorbike rider, through his negligence, caused the plaintiff, in the opinion of medical experts, to need specific medical services—a cost that is neither inconsequential nor of a kind the community generally accepts as part of the wear and tear of daily life. Under these principles of tort law, the motorbiker should pay.

Friends for All Child., 746 F.2d at 825. *Bower* explicitly adopted this logic. 522 S.E.2d at 430–31.

Last, *Bower* articulated the elements required to state a medical monitoring claim. To succeed on a medical monitoring claim, a plaintiff must prove

> (1) he or she has, relative to the general population, been significantly exposed; (2) to a proven hazardous substance; (3) through the

> tortious conduct of the defendant; (4) as a proximate result of the exposure, plaintiff has suffered an increased risk of contracting a serious latent disease; (5) the increased risk of disease makes it reasonably necessary for the plaintiff to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of the exposure; and (6) monitoring procedures exist that make the early detection of a disease possible.

Id. at 432–33.

B.

We turn to the district court's standing decision. The district court correctly recognized that Sommerville sought monetary relief to pay for the future cost of medical monitoring. And because Sommerville sought damages—not injunctive relief—the district court also correctly concluded that Sommerville must show a "present injury." *See Sommerville v. Union Carbide Corp.*, No. 2:19-CV-00878, 2024 WL 2139394, at *6 (S.D.W. Va. May 13, 2024) (hereinafter *Sommerville II*); *TransUnion LLC v. Ramirez*, 594 U.S. 413, 441, 141 S.Ct. 2190, 210 L.Ed.2d 568 (2021) ("[T]he risk of future harm on its own does not support Article III standing for the plaintiffs' damages claim.").

At this point, however, and as we explain later, the district court's analysis went off course. It framed Sommerville's injury as an increased risk of "eventually getting cancer." *Sommerville II*, 2024 WL 2139394, at *7 ("Here, [Sommerville] seeks monetary damages based on the premise that because [the Plant Owners] emit EtO into the air and she, in turn, breathes that air, [the Plant Owners] have put her and proposed class members at higher risk of eventu-

ally getting cancer."); *id.* at *8 ("[H]er claim is based entirely on the unsubstantiated possibility of a future cancer diagnosis."). Then, relying on *TransUnion LLC v. Ramirez*, 594 U.S. 413, 141 S.Ct. 2190, 210 L.Ed.2d 568 (2021), the district court concluded that because the "possibility of [a] future cancer diagnosis" was not "concrete," and because Sommerville did not have a present physical injury, Sommerville lacked Article III standing. *See id.* at *7–8 ("The Supreme Court's holding in *TransUnion* makes clear to me that claims for medical monitoring seeking damages without a manifest injury do not satisfy the injury-in-fact requirement for Article III standing.") (footnote omitted). The district court likewise held that Sommerville's claim was not "ripe" because "not one of [her] experts can say with any level of certainty that [Sommerville] ... *will* develop cancer from [the Plant Owners'] actions." *Id.* at *11.

C.

Article III of the Constitution limits the jurisdiction of federal courts to actual "cases" or "controversies." U.S. Const. art. III, § 2. Thus, it is a jurisdictional requirement that litigants be parties to a live case or controversy. This standing requirement "is an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992) (citing *Allen v. Wright*, 468 U.S. 737, 751, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984)).

To establish standing, a party must establish, as "the irreducible constitutional minimum," three elements: (1) that it has suffered an "injury in fact" that is both "concrete and particularized" and "actual or imminent, not conjectural or hypothetical"; (2) that there is "a causal connection between the injury and the conduct complained of," i.e., the injury is "fairly

traceable" to the challenged action; and (3) that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Id.* at 560–61, 112 S.Ct. 2130 (internal quotation marks and citations omitted); *Burke v. City of Charleston*, 139 F.3d 401, 405 (4th Cir. 1998). As to ripeness, "[t]he doctrine ... prevents judicial consideration of issues until a controversy is presented in clean-cut and concrete form." *Scoggins v. Lee's Crossing Homeowners Ass'n*, 718 F.3d 262, 270 (4th Cir. 2013) (noting a case is ripe "when the action in controversy is final and not dependent on future uncertainties") (quoting *Miller v. Brown*, 462 F.3d 312, 319 (4th Cir. 2006)).

TransUnion addressed "the Article III requirement that the plaintiff's injury in fact be concrete" in the context of a class action. 594 U.S. at 424, 141 S.Ct. 2190 (cleaned up). The named plaintiff in that case brought a class action, alleging that TransUnion, a credit reporting agency, had violated the Fair Credit Reporting Act by failing to use reasonable procedures before placing a misleading alert in his credit file that labeled him as a potential terrorist, drug trafficker, or serious criminal. *Id.* at 419–21, 141 S.Ct. 2190. He also asserted two claims based on TransUnion's having sent him two mailings that did not comply with certain formatting requirements imposed by the statute. *Id.* at 421–22, 141 S.Ct. 2190.

The district court certified a class of more than 8,000 people who had the same misleading alert added to their credit files and who had also received similar mailings during a certain time period. A jury then awarded each class member statutory and punitive damages, and the Ninth Circuit largely affirmed the judgment. *Id.* at 422, 141 S.Ct. 2190.

The Supreme Court reversed and remanded, holding that only a subset of the class had established Ar-

ticle III standing to sue TransUnion for its failure to use reasonable procedures to ensure the accuracy of their credit files—namely, the 1,853 class members whose credit reports had been provided to third-party businesses and who had suffered "concrete reputational harm" as a result. *Id.* at 417, 141 S.Ct. 2190. With respect to the two claims relating to the formatting defects in the mailings, the Court held that no class member other than the named plaintiff had demonstrated any concrete harm caused by the formatting errors, such that only he had standing to recover on those claims. *Id.* at 418, 141 S.Ct. 2190.

In explaining its decision, the Court emphasized that, "under Article III, an injury in law is not an injury in fact" and that "[o]nly those plaintiffs who have been *concretely harmed* by a defendant's statutory violation may sue that private defendant over that violation in federal court." *Id.* at 427, 141 S.Ct. 2190. Put simply, "[n]o concrete harm, no standing." *Id.* at 417, 141 S.Ct. 2190. The Court explained that while "[t]he most obvious" concrete injuries are "tangible harms, such as physical harms and monetary harms," "[v]arious intangible harms can also be concrete," depending on whether they have "a close relationship to harms traditionally recognized as providing a basis for lawsuits in American courts." *Id.* at 425, 141 S.Ct. 2190.

Then, the Court applied those principles to class actions, observing that "standing is not dispensed in gross." *Id.* at 431, 141 S.Ct. 2190. It emphasized that federal courts lack "the power to order relief to any uninjured plaintiff, class action or not." *Id.* (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 466, 136 S.Ct. 1036, 194 L.Ed.2d 124 (2016) (Roberts, C.J., concurring)). As a result, "[e]very class member must have Article III standing in order to recover individu-

al damages." *Id.* Moreover, "plaintiffs must demonstrate standing for each claim that they press and for each form of relief that they seek." *Id.*

Finally, the Court also made clear that the form of relief sought matters when assessing the sufficiency of the alleged harm. Thus, while "a person exposed to a risk of future harm may pursue forward-looking, injunctive relief to prevent the harm from occurring," *id.* at 435, 141 S.Ct. 2190, "the risk of future harm on its own does not support Article III standing for [a] damages claim," *id.* at 441, 141 S.Ct. 2190.

Applying these principles to the facts before it, the Court held that the approximately 6,300 class members who failed to prove that the misleading alerts in their credit reports were ever provided to a third party "did not suffer a concrete harm," as necessary for them to recover damages for the reasonable procedures claim. *Id.* at 439, 141 S.Ct. 2190. The Court rejected the argument that those class members had "suffered a concrete injury for Article III purposes because the existence of misleading ... alerts in their internal credit files exposed them to a *material risk* that the information would be disseminated in the future to third parties and thereby cause them harm." *Id.* at 435, 141 S.Ct. 2190 (emphasis added) (noting plaintiffs, despite seeking damages, tried to demonstrate standing under the standard applicable to injunctive relief).

And it was also unpersuaded by the plaintiffs' argument that it could infer that those class members' credit reports "were likely also sent to third parties ... because all of the class members [had] requested copies of their reports, and consumers usually do not request copies unless they are contemplating a transaction that would trigger a credit check." *Id.* at 438–39, 141 S.Ct. 2190. Rejecting that contention, the Court

reasoned that "[t]he plaintiffs had the burden to prove at trial that their reports were actually sent to third-party businesses" and that "[t]he inferences on which the argument rests are too weak to demonstrate that the reports of any particular [class member were] sent to third-party businesses." *Id.* at 439, 141 S.Ct. 2190.

Finally, the Court concluded that, other than the named plaintiff, none of the class members had "demonstrated that the format of TransUnion's mailings"—even if not in compliance with the statute—caused them "any harm *at all*," let alone "a harm with a close relationship to a harm traditionally recognized as providing a basis for a lawsuit in American courts." *Id.* at 440, 141 S.Ct. 2190.

In sum, *TransUnion* stands for the proposition that "a plaintiff does not 'automatically satisf[y] the injury-in-fact requirement' whenever a statute [or state common law] ... 'grants a person a [ ] right and purports to authorize that person to sue to vindicate that right.' " *See Fernandez v. RentGrow, Inc.*, 116 F.4th 288, 294 (4th Cir. 2024) (quoting *TransUnion*, 594 U.S. at 426, 141 S.Ct. 2190). Article III requires a "concrete injury." *Id.* (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 341, 136 S.Ct. 1540, 194 L.Ed.2d 635 (2016)). "Accordingly, '[o]nly those plaintiffs who have been *concretely harmed* by a defendant's statutory violation [or tortious act] may sue that private defendant over that violation in federal court.' " *See id.* (quoting *TransUnion*, 594 U.S. at 427, 141 S.Ct. 2190).

D.

i.

We reverse the district court's order granting the Plant Owners summary judgment. Sommerville has

Article III standing.

To begin, the district court misstated the harm for which medical monitoring plaintiffs like Sommerville seek recovery. Sommerville's alleged injury is not an "increased risk of cancer development due to the alleged EtO emissions." *Sommerville II*, 2024 WL 2139394, at *7. Sommerville's injury is her "exposure *itself*" to "environmental toxins" tortiously emitted by the Plant Owners, "[which] affect the body in ways that often do not become manifest for several years" and "the concomitant need [to pay] for medical testing" *today* to mitigate an increased risk of illness which Sommerville would not bear but for the Plant Owners' actions. *See Bower*, 522 S.E.2d at 430 (emphasis added); *Bourgeois*, 716 So. 2d at 358 (cleaned up); *Friends for All Child.*, 746 F.2d at 825 ("The [tortfeasor], through his negligence, caused the plaintiff, in the opinion of medical experts, to need specific medical services—a cost that is neither inconsequential nor of a kind the community generally accepts as part of the wear and tear of daily life. Under these principles of tort law, the [tortfeasor] should pay."). Framed properly, Sommerville's injury is concrete and ripe.

Sommerville alleges that the Plant Owners wrongfully exposed her to EtO in such great quantities that her chance of contracting a serious latent disease increased to the point that she must, in a qualified physician's opinion, pay for and undergo periodic diagnostic medical examinations *now*. *See Bower*, 522 S.E.2d at 433. West Virginia law permits Sommerville to seek recovery for this harm, which is grounded in the "traditional common-law principle[ ]" of "avoiding physical injury." *Bourgeois*, 716 So. 2d at 359; *Bower*, 522 S.E.2d at 429–30; *see TransUnion*, 594 U.S. at 424–25, 141 S.Ct. 2190. Sommerville

might not have a visible injury like a broken arm, but this does not make her injury any less actual, concrete, or serious. *See Bourgeois*, 716 So. 2d at 358 (observing that "asbestos exposure is an accident almost always without impact. Nevertheless, it is still an accident that can have consequences every bit as real as those sustained in a head-on collision").

Lest there be any doubt that the injury requisite to bring a medical monitoring claim is not merely "conjectural," *Sommerville II*, 2024 WL 2139394, at *8, the Supreme Court of Appeals of West Virginia has emphasized that the six *Bower* factors "establish[ ] an extremely high bar for a plaintiff to overcome before there can be any recovery for medical monitoring." *In re Tobacco Litig.*, 215 W.Va. 476, 600 S.E.2d 188, 194 (2004). These factors require Sommerville to demonstrate such significant exposure to a hazardous substance as to render monitoring a present medical necessity. This injury is actual and concrete. So, Sommerville has Article III standing.

The Plant Owners' principal argument for affirming the district court's grant of summary judgment is unconvincing. The Plant Owners contend that the district court *didn't* hold that medical monitoring plaintiffs without a manifest physical injury always lack Article III standing. Appellees' Br. (ECF No. 24) at 53 ("[Sommerville] argues against a strawman she puts forth—that the District Court decided that no medical-monitoring plaintiff could ever have Article III standing at any stage of litigation."). Instead, the Plant Owners insist that the district court granted them summary judgment because Sommerville "lacked admissible evidence [of] her exposure." *Id.* at 56 (arguing that the district court's exclusion, by prior order, of Dr. Sahu's testimony left Sommerville without evidence of exposure to EtO). This argument

is counterfactual.[2]

The district court explicitly ruled that Sommerville lacked an actual injury because "[t]he Supreme Court's holding in *TransUnion* ma[d]e[ ] clear to [it] that claims for medical monitoring seeking damages without a manifest injury do not satisfy the ... requirement[s] for Article III standing." *See Sommerville II*, 2024 WL 2139394, at *7. As explained above and as we reiterate here, this conclusion—along with the factual assertions on which it rested—was wrong.

Sommerville's claim is not that the Plant Owners' EtO emissions *may* have harmed her by putting her "at a higher risk of eventually getting cancer." *Sommerville II*, 2024 WL 2139394, at *7; *see TransUnion*, 594 U.S. at 435, 141 S.Ct. 2190 (rejecting argument that roughly 6,300 class members had "suffered a concrete injury for Article III purposes because the existence of misleading ... alerts in their internal credit files exposes them to a material risk that the information w[ill] be disseminated in the future to third parties and thereby cause them harm"). Rather, Sommerville's injury is that the Plant Owners exposed her to EtO in such quantities that she must, in

[2] Having previously excluded Dr. Sahu's testimony, the district court could have granted the Plant Owners summary judgment against Sommerville not for "lack of standing," but for want of necessary evidence. *See Sommerville v. Union Carbide Corp.*, No. 2:19-CV-00878, 2024 WL 2139394, at *12 n.7 (S.D.W. Va. May 13, 2024) (noting that "*if* [the district court] had to proceed to the merits of the action," it would have granted the Plant Owners summary judgment due to Sommerville's failure to meet *Bower*'s first element). The district court, however, granted summary judgment based on standing. Further, even if the district court had granted the Plant Owners summary judgment for failure to meet *Bower*'s first element, that conclusion would have been erroneous—as explained in Section III, Dr. Sahu's testimony was wrongfully excluded.

a qualified physician's opinion, pay for and undergo periodic diagnostic medical examinations *now*. *This* injury is no less concrete than the injury suffered by the 1,853 class members in *TransUnion* whose credit reports had *actually* been provided to third-party businesses and who had suffered "concrete reputational harm." *See TransUnion*, 594 U.S. at 417, 141 S.Ct. 2190.

ii.

The dissent frames Sommerville's injury like the district court—as an increased risk of "develop[ing] cancer." *See* Diss. Op. at 428 ("Sommerville claims that she's at an increased risk of developing cancer and that the risk creates a present need for medical monitoring. ...Though the future harm here—cancer—is serious, it's certainly not impending. The record doesn't show who in the putative class (if anyone) will develop cancer or when (if ever)."). Then, relying on *Beck v. McDonald*, 848 F.3d 262 (4th Cir. 2017), it concludes Sommerville's injury is too speculative to establish Article III standing. Diss. Op. at 427 – 28.

In *Beck*, the plaintiffs sued Department of Veterans Affairs officials after their medical records were stolen from a Veterans Affairs medical center. The plaintiffs sought damages for two injuries: (1) the "increased risk of future identity theft" and (2) "credit monitoring services." *Id.* at 273, 276. The court held that both injuries were "too speculative" to confer Article III standing. *See id.* at 274; *id.* at 276 (holding second injury was "a repackaged version" of the first and that plaintiffs could not establish standing by seeking "costs they incurred in response to a speculative threat") (cleaned up).

In holding that the plaintiffs' claims were too

speculative, *Beck* emphasized the "attenuated chain of possibilities" that the plaintiffs relied on to establish their injury. *Id.* at 275 (quoting *Clapper v. Amnesty Intern. USA*, 568 U.S. 398, 410, 133 S.Ct. 1138, 185 L.Ed.2d 264 (2013)). This chain included "assum[ing] that the thief targeted the stolen items for the personal information they contained. *And* ... [that] the thieves select[ed], from thousands of others, the personal information of the named plaintiffs *and* attempt[ed] successfully to use that information to steal their identifies." *Id.* (emphasis added).

Here, *Beck* is inapposite. Sommerville's alleged injury does not rest on an "attenuated chain of possibilities." Nor does it rest on an unknown third party's actions. It exists *already*. Her injury is a present physical one—"exposure *itself*" to "environmental toxins" the Plant Owners tortiously emitted and "the concomitant need [to submit to and pay] for medical testing" *today* to mitigate an increased risk of illness. *See Bower*, 522 S.E.2d at 430 (emphasis added). Put differently, Sommerville is not suing about a "speculative threat" that depends on a third party's future acts. *Beck*, 848 F.3d at 277 (cleaned up). She is suing about her current need for "specific medical services—a cost that is neither inconsequential nor of a kind the community generally accepts as part of the wear and tear of daily life." *Friends for All Child.*, 746 F.2d at 825. At bottom then, like the district court, the dissent misapprehends both the nature and immediateness of the harm for which Sommerville seeks redress.

* * *

For the reasons stated above, we hold that plaintiffs properly alleging the elements of West Virginia's medical monitoring tort have Article III standing. Sommerville has done so, and we reverse the district

court's order granting the Plant Owners summary judgment for lack of standing.

III.

We now address the district court's exclusion of Sommerville's proposed expert Dr. Sahu.

A.

Under Fed. R. Evid. 702, trial judges act as gatekeepers to "ensure that any and all scientific testimony ... is not only relevant, but reliable." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 588, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). While "Rule 702 was intended to liberalize the introduction of relevant expert evidence ... court[s] must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.' " *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (quoting *Daubert*, 509 U.S. at 595, 113 S.Ct. 2786) (internal citation omitted). Therefore, a trial judge, faced with a proffer of expert scientific testimony, must conduct "a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93, 113 S.Ct. 2786. The proponent of the testimony must establish its admissibility by a preponderance of proof. *See id.* at 592 n. 10, 113 S.Ct. 2786 (citing *Bourjaily v. United States*, 483 U.S. 171, 175–76, 107 S.Ct. 2775, 97 L.Ed.2d 144 (1987)); Fed. R. Evid. 702.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993), the Supreme Court identified several factors that may bear on a judge's determination of the reliability of an expert's testimony. *See* 509 U.S. at 592–94, 113

S.Ct. 2786. Those factors include: (1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community. *See id* at 592–94, 113 S.Ct. 2786.

In *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999), the Supreme Court noted that the factors discussed in *Daubert* were neither definitive, nor exhaustive. *Id.* at 150–51, 119 S.Ct. 1167. The Court explained that particular factors may or may not be pertinent in assessing reliability, "depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *See id.* The Court further emphasized that the objective of *Daubert*'s gatekeeping requirement is to "make certain that an expert ... employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *See id.* at 152, 119 S.Ct. 1167.

Courts of appeals apply an abuse of discretion standard when reviewing a trial court's decision to admit or exclude expert testimony. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 138–39, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). The Supreme Court also has emphasized that "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *See Kumho Tire*, 526 U.S. at 152, 119 S.Ct. 1167.

B.

To establish liability, Sommerville acknowledges

that she must put forth admissible expert testimony to establish *Bower*'s first element—that she was, relevant to the general population, "significantly exposed" to a proven hazardous substance. 522 S.E.2d at 432– 33. Accordingly, Sommerville offered Dr. Sahu to testify about the fate and transport of the Plant's EtO emissions between 1984 and 2019. Dr. Sahu sought to provide "technical expertise, analysis, methodology, and opinions regarding various environmental and pollutant fate and transport issues relating to emissions of [EtO] from [the Plant] ... to ultimately determine the potential exposure levels of [Sommerville] and the proposed class members." *Sommerville v. Union Carbide Corp.*, No. 2:19-CV-00878, 2024 WL 1204094, at *2 (S.D.W. Va. Mar. 20, 2024) (hereinafter *Sommerville I*).

Dr. Sahu modeled EtO emissions using the "AERMOD" dispersion model, a computer program. J.A. 524. Before running AERMOD, however, Dr. Sahu had to select the inputs AERMOD would use to generate his EtO modeling. These inputs included source data[3], receptor data[4], and meteorological data. J.A. 524.

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[3] Source data means EtO "emissions sources" including "specification and locations of source units, historical emissions rates, and source parameters." J.A. 524. "Source parameters" are details describing the locations from which EtO was omitted. *Id.* 525. "Point source" or "stack emissions" are "air releases that occur through identifiable confined air streams, such as stacks, ducts or pipes." *Sommerville v. Union Carbide Corp.*, No. 2:19-CV-00878, 2024 WL 1204094, at *10 n.5 (S.D.W. Va. Mar. 20, 2024) (cleaned up). And "fugitive emissions" are "releases to air that don't occur through a confined air stream" such as via "equipment leaks." *Id.*

[4] "The AERMOD model allows the user to input a set of receptors, which are locations at which the model will predict hourly concentrations due to the input source emissions." J.A. 526.

The district court excluded Dr. Sahu's proposed testimony. For a plethora of supposedly independently-sufficient reasons, the district court found Dr. Sahu's testimony was unreliable. The district court did not question AERMOD itself but took issue with Dr. Sahu's choice of source and meteorological data.

First, the district court found that Dr. Sahu's choice of source parameters rendered his report unreliable. *Sommerville I*, 2024 WL 1204094, at *10. To set his source parameters, Dr. Sahu relied on data the West Virginia Department of Environmental Protection created. Further, for the years 1985–1989, Dr. Sahu modeled all emissions as fugitive. The district court faulted Dr. Sahu for these choices, holding that both decisions were based on "assumptions ... with little to no scientific basis." *Id.* at *11.

Excluding Dr. Sahu for these choices was an abuse of discretion. Dr. Sahu presented detailed reasons for his challenged assumptions. *See, e.g., id.* (acknowledging Dr. Sahu's assertion that the Plant Owners' lack of record keeping limited Dr. Sahu's choice of "site-specific data to base his model on"); J.A. 514 (explaining why Dr. Sahu chose to model all Plant emissions as fugitive for 1985–1989); *id.* 568 (further explaining Dr. Sahu's modeling choices and assumptions as to fugitive emissions). The district court, however, simply ignored or discounted Dr. Sahu's proffered explanations in favor of those that the Plant Owners' expert, Dr. Ranjit Machado, offered. *See Sommerville I*, 2024 WL 1204094, at *10–11.

At bottom, the district court's analysis was not a true critique of Dr. Sahu's "methodology," but a veiled credibility determination based on Dr. Sahu's choice of which data to input into his model. This was an abuse of discretion because "questions regarding the factual underpinnings of the [expert witness'] opinion

affect the weight and credibility of the witness' assessment, not its admissibility." *See Bresler v. Wilmington Tr. Co.*, 855 F.3d 178, 195 (4th Cir. 2017) (cleaned up); *Rappuhn v. Primal Vantage Co.*, No. 23-10050, 2024 WL 2930448, at *4 (11th Cir. June 11, 2024) ("[C]rediting one expert over another ... misapplies *Daubert* and intrudes on the province of the jury.").

Second, the district court found Dr. Sahu's testimony was unreliable because he did not "validate" Union Carbide's self-reported emissions data before inputting them into AERMOD. *Sommerville I*, 2024 WL 1204094, at *12–13 (Union Carbide self-reported 1984 data); *id.* at *13–14 (Union Carbide self-reported data 1990–2019). The district court did not cite controlling case law imposing a "validation" requirement. Nor did it explain, in practical terms, *how* Dr. Sahu was supposed to undertake "validation."

Excluding Dr. Sahu for failing to "validate" his data was a glaring abuse of discretion. Nothing in Rule 702 requires an expert witness to "validate" data. Fed. R. Evid. 702. The district court's requirement that Dr. Sahu do just that, however, was extratextual, an error of law, and thus an abuse of discretion per se. *See New York City Transit Auth. v. Express Scripts, Inc.*, 588 F. Supp. 3d 424, 445 (S.D.N.Y. 2022) (rejecting argument that expert failed to validate data and noting "the [c]ourt has not found[ ] precedent requiring experts to validate the data underlying each source on which they rely in order to satisfy the reliability threshold for admissibility"); *see also Daubert*, 509 U.S. at 596, 113 S.Ct. 2786 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Said differently, the district court again disagreed with Dr. Sahu's choice of data and excluded Dr. Sahu's testimony as a result, even though our caselaw forbids as much. *See Baxter v. Comm'r of I.R.S.*, 910 F.3d 150, 158 (4th Cir. 2018) (affirming admission of expert and rejecting challenge to his selection of certain data finding that "to the extent that Taxpayers[ ] disagree with Kolbe's estimates of the costs of obtaining a 'good' or 'normal' loan, 'such challenges ... affect the weight and credibility of [Kolbe's] assessment, not its admissibility' ") (citing *Bresler*, 855 F.3d at 196).

The district court made further related errors concerning its critique of Dr. Sahu's emissions data selections. For the year 1984, Dr. Sahu relied on data Union Carbide reported to the West Virginia Air Pollution Control Commission. When Union Carbide reported this data to authorities, it included a letter claiming its figures should not be taken at face value because they were "drastically overstated." *Sommerville I*, 2024 WL 1204094, at *12. In the district court's opinion, because Union Carbide had cast doubt on its own data, Dr. Sahu's use of the data rendered his opinion unreliable.

This conclusion was an abuse of discretion for two reasons. First, Dr. Sahu provided reasons for why he did not believe Union Carbide's claim that its 1984 data were inaccurate. Second, and more fundamentally, excluding Dr. Sahu on this basis again violated *Bresler*'s holding that "questions regarding the factual underpinnings of the [expert witness'] opinion affect the weight and credibility of the witness' assessment, not its admissibility." *See Bresler*, 855 F.3d at 195 (cleaned up).

The district court committed a similar error when it held that Dr. Sahu's report was unreliable because of the data Dr. Sahu based emissions on for the years

1985–1989. For this period, Dr. Sahu based EtO emissions on the "Toxic Air Pollutant Facility Registration Summary Sheets" the Plant Owners provided to regulatory authorities. The district court took issue with this choice because it believed that the "values listed [on the summary sheets were] estimates for maximum toxic air pollutant emissions, not *actual* emissions." *Sommerville I*, 2024 WL 1204094, at *13 (cleaned up). The district court, however, ignored Dr. Sahu's testimony justifying his contrary interpretation of the summary sheets.

While Dr. Machado argued that the summary sheets were only potential emissions, Dr. Sahu testified that the "substantial variation" over time in the reported figures led him to infer Union Carbide was reporting actual emissions. J.A. 261–62. Such a "factual dispute is best settled by a battle of the experts before the fact finder, not by judicial fiat." *See City of Pomona v. SQM N. Am. Corp.*, 750 F.3d 1036, 1048–49 (9th Cir. 2014); *see also Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 562 (8th Cir. 2014) ("The district court in the instant case violated these liberal admission standards by resolving doubts in favor of keeping the testimony out and relying upon its own assessment of the correctness of the expert opinions."); *Westberry*, 178 F.3d at 261 ("[T]he court need not determine that the expert testimony a litigant seeks to offer into evidence is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to being tested by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.' ") (quoting *Daubert*, 509 U.S. at 596, 113 S.Ct. 2786) (alteration adopted); *see also McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1044 (2d Cir. 1995) (noting that perceived faults in doctor's differential diagnosis were

matters for cross-examination that did not affect admissibility).

Third, the district court took issue with Dr. Sahu's choice of meteorological inputs for AERMOD. To model dispersion patterns around the Plant, Dr. Sahu had to input wind speed and direction data. Dr. Sahu inputted data from various sites and elevations to create his model. The district court concluded Dr. Sahu's testimony was unreliable because "[w]ind directions are highly variable ... [and] a single location—such as [Sommerville's] residence—cannot have multiple wind speeds coming from various directions at one specific time." *Sommerville I*, 2024 WL 1204094, at *16. The district court further found Dr. Sahu's testimony unreliable because Dr. Sahu used 1985–1986 onsite meteorological data from the Plant for the years 1984–2019.

These conclusions were abuses of discretion. Beyond possibly misstating the science of wind[5]—and unnecessarily attempting to make scientific findings to justify its exclusion of Dr. Sahu[6]—the district court

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[5] Multiple wind speeds from different directions at the same time at a single geographic location is not only possible but widely accepted. *See, e.g., What Causes Tornadoes?*, NOAA (describing how tornadoes are created and noting that "[c]onditions are ripe for tornadoes when the air becomes very unstable, *with winds at different altitudes blowing in different directions or at different speeds*—a condition called wind shear") (emphasis added), https://perma.cc/9MYS-P7CK.

[6] We agree with the dissent that the *district court* should not have fashioned itself as an "amateur scientist[ ]," and excluded Dr. Sahu's testimony on the basis that "a single location ... cannot have multiple wind speeds coming from various directions at one specific time." *Sommerville I*, 2024 WL 1204094, at *16; Diss. Op. at 432 n.9; *cf. Daubert*, 509 U.S. at 601, 113 S.Ct. 2786 (Rehnquist, C.J., concurring in part and dissenting in part) ("[Rule 702] imposes on [courts] [n]either the obligation [n]or the

again conflated admissibility with the weight a fact-finder might attribute Dr. Sahu's testimony based on his choice of data. Simultaneously, the district court ignored Dr. Sahu's testimony as to why using wind data from various altitudes was proper given South Charleston's mountainous geography and why Dr. Sahu chose to use onsite data from 1985–1986 to model 1984–2019. *See* J.A. 532–33 (explaining that because of the "elevated point source[s]" of certain "flare emissions," Dr. Sahu used data from Yeager Airport, roughly 285 meters elevation); *id.* 572 (explaining that the *only* onsite data available at the Plant was from 1985–1986, that the Plant Owners had supplied no other data and, in Dr. Sahu's professional experience, any variation would not be significant); *see also Daubert*, 509 U.S. at 596, 113 S.Ct. 2786 ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

Fourth, the district court faulted Dr. Sahu for how he chose to calculate "background" EtO levels. "Background" refers to exposure levels experienced by the general population as opposed to the levels Sommerville alleges she was exposed to due to the Plant Owners' negligence. The district court found Dr. Sahu's testimony was unreliable because Dr. Sahu used data produced by the United States Environmental Protection Agency (EPA) instead of data from the West Virginia Department of Environmental Protection—data the district court described as being more "local." *Sommerville I*, 2024 WL 1204094, at *19. The

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authority to become amateur scientists"). We include the information in the preceding footnote only to emphasize the danger trial courts run when, as the district court did here, they attempt to exclude expert testimony in this fashion.

district court found Dr. Sahu was "cherry-picking" data. *Id.* at *18–19. This finding was an abuse of discretion.

Dr. Sahu didn't "cherry-pick data." Cherry-picking data means engaging in a "[r]esult-driven analysis" that "undermines principles of the scientific method." *See In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 634 (4th Cir. 2018). In *Lipitor*, this court affirmed the trial court's exclusion of the plaintiffs' expert where he "cho[se] to include in his report the results of some tests he performed (which supported the plaintiffs' argument) but exclude the results of another (which did not)." *Id.* at 634–35.

Dr. Sahu did nothing of the sort. Instead, Dr. Sahu chose to use the EPA's data because he found it more representative of Sommerville's claims. True, the EPA had reservations about aspects of its data set. *See* J.A. 814 (stating that while the EPA was "confident" in EtO data collected "downwind of facilities," the EPA had also detected EtO levels close to the detection limit, implying "greater uncertainty in its measurement and ... less confiden[ce] in [its] accuracy"). But the West Virginia data the district court held Dr. Sahu should have used came with disclaimers too. *Id.* 1786 ("The project involved four (4) 24-hour sampling events. Four days of data cannot be used to calculate risk over a 70-year period."). Put simply, the weight to give Dr. Sahu's choice of EtO background data had nothing to do with the admissibility of his testimony. Though framed as a "reliability" question, the district court again waded into credibility determinations. Excluding Dr. Sahu on this basis was an abuse of discretion.

Last, the district court abused its discretion when it concluded that Dr. Sahu's report was unreliable be-

cause Dr. Sahu had wrongly maintained Covestro's emissions rates constant from 1984–2019 in AERMOD. To so find, the district court ignored Dr. Sahu's testimony that while he had erroneously held Covestro's emissions constant in his initial report, he had corrected this error in his supplemental report. *Id.* 1188–93 ("I ... reran the model using the varying emission rates for the Covestro sources. In this supplemental report I show the results of this revised modeling and also comparisons to the prior constant emission rate results.") (cleaned up). Therefore, the district court's exclusion of Dr. Sahu on this basis was likewise an abuse of discretion.

In sum, none of the reasons for which the district court excluded Dr. Sahu's testimony were proper. And in accordance with Federal Rules of Evidence 104(a) and 702, Sommerville has established by a preponderance of evidence that Dr. Sahu's testimony is admissible. Therefore, Dr. Sahu's exclusion was an abuse of discretion.[7]

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[7] The dissent is unclear "what line" we "intend to draw." Diss. Op. at 431. We do not question that a district court can decide "that an expert's opinion lacks sufficient support in the record" or that "there is simply too great an analytical gap between [an expert's] data and the opinion proffered." *Id.*; *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). Rather, we underscore that a district court may not exclude expert testimony based on (1) its *mere disagreement* with an expert's choice of data or (2) its *own* assessment of the correctness of an expert's opinions. *See Bresler v. Wilmington Tr. Co.*, 855 F.3d 178, 195 (4th Cir. 2017) (noting "questions regarding the factual underpinnings of the [expert witness'] opinion affect the weight and credibility of the witness' assessment, not its admissibility") (cleaned up); *Rappuhn v. Primal Vantage Co.*, No. 23-10050, 2024 WL 2930448, at *4 (11th Cir. June 11, 2024) ("[C]rediting one expert over another ... misapplies *Daubert* and intrudes on the province of the jury."). *These* errors permeate

IV.

For the reasons stated above, we reverse the district court's grant of summary judgment to the Plant Owners and its exclusion of Dr. Sahu.

REVERSED AND REMANDED

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the district court's order excluding Dr. Sahu and dictate reversal.

DIAZ, Chief Judge, dissenting:

West Virginia courts have opened their doors to claims for damages, like Sommerville's, in which the only claimed injury is a present need for medical monitoring. In my view, Article III standing principles prevent us from doing the same. Because my colleagues conclude otherwise, I respectfully dissent.

I.

West Virginia allows plaintiffs to bring medical monitoring claims "to recover the anticipated costs of long-term diagnostic testing necessary to detect latent diseases that may develop as a result of tortious exposure to toxic substances." *Bower v. Westinghouse Elec. Corp.*, 206 W.Va. 133, 522 S.E.2d 424, 429 (1999). Plaintiffs must show—as relevant here—that an exposure to a hazardous substance put them at a "significantly increased risk of contracting a particular disease" that makes diagnostic testing "reasonably necessary." *Id.* at 433. They don't need to show that they've experienced any physical harm, nor any certainty (or even likelihood) that a disease will occur. *Id.*

But to get into federal court, a state law injury isn't enough. As my colleagues agree, Sommerville (who alleges she was exposed to a carcinogen emitted from Defendants' operations at a manufacturing facility in South Charleston, West Virginia near her home) must show that she's suffered an injury in fact sufficient for Article III.

Sommerville doesn't claim that she's been physically harmed. Nor does she claim that her injury in fact is an increased risk of developing cancer. And for good reason, because a "risk of future harm ... cannot, by itself, establish concrete injury to have standing to seek *damages*." *Penegar v. Liberty Mut. Ins. Co.*, 115

F.4th 294, 302 (4th Cir. 2024) (citing *TransUnion LLC v. Ramirez*, 594 U.S. 413, 436, 141 S.Ct. 2190, 210 L.Ed.2d 568 (2021)).

Instead, Sommerville's asserted injury is the "necessary medical monitoring costs resulting from toxic exposure." Appellant's Br at 12. For the majority, that's enough for standing.[1] I disagree and would instead hold that medical monitoring costs (incurred or anticipated), without more, can't confer standing to seek damages in federal court.

Our decision in *Beck v. McDonald*, 848 F.3d 262 (4th Cir. 2017), explains why. There, plaintiffs sued after their medical records were stolen from a Veterans Affairs medical center. *Id.* at 267–68. They brought data privacy claims seeking damages and declaratory and injunctive relief. *Id.* They claimed two injuries in fact: (1) "the increased risk of future identity theft," *id.* at 273, and (2) "the cost of measures to guard against identity theft, including the costs of credit monitoring services," that they had incurred or would incur, *id.* at 276.

But we rejected the first because, under the circumstances of the data breaches, the risk that the plaintiffs' identities would be stolen was too specula-

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[1] Neither the *Bower* court, in its assessment of the common-law principles underlying medical monitoring claims, nor the majority, in its injury-in-fact analysis, disaggregate the exposure from the costs of medical monitoring. Though both mention the exposure, both focus on the economic harm of medical monitoring costs stemming from the exposure. So the asserted injury in fact here appears to be the costs of medical monitoring, not the exposure that creates the need for those costs.

I don't read the majority opinion to hold that exposure alone is an injury in fact. Nor could I join such a novel holding without substantially more analysis than what the majority offers.

tive.[2] *Id.* at 274. And the second was "merely a repackaged version" of the first. *Id.* at 276 (cleaned up). It too failed because "costs ... incurred in response to a speculative threat" can't confer standing.[3] *Beck*, 848 F.3d at 276–77 (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 416, 133 S.Ct. 1138, 185 L.Ed.2d 264 (2013)); *see also Remijas v. Neiman Marcus Grp., LLC*, 794 F.3d 688, 694 (7th Cir. 2015) ("Mitigation expenses do not qualify as actual injuries where the harm is not imminent.").

So too here. Sommerville claims that she's at an increased risk of developing cancer and that the risk creates a present need for medical monitoring—the costs of which are her injury in fact. But to confer Article III standing, these costs must be based on a future harm that is "certainly impending." *Clapper*, 568 U.S. at 409, 416, 133 S.Ct. 1138.

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[2] Recall that Sommerville doesn't press that her injury in fact is an increased risk of developing cancer.

[3] The plaintiffs in *Clapper v. Amnesty International USA*, 568 U.S. 398, 133 S.Ct. 1138, 185 L.Ed.2d 264 (2013), sought injunctive relief, and Sommerville seeks damages. Still, *Clapper*'s reasoning with respect to the mitigation injury asserted there applies here. *Id.* at 415, 133 S.Ct. 1138 (costs incurred to protect confidentiality of communications based on risk of surveillance).

In each case, plaintiffs claimed to be suffering "present injury" because the risk of a harm in the future created the need to incur certain costs now and in the future (and, in *Clapper*, it had forced them to incur such costs already). *Id.* at 401, 133 S.Ct. 1138. That type of injury can be addressed by eliminating the risk that the future harm will occur (via injunction) or by shifting the costs to the defendant (via damages). A plaintiff who lacks standing to seek an injunction because the underlying "future harm ... is not impending" shouldn't have standing to seek damages for costs incurred based on that same speculative harm. *Id.*

Though the future harm here—cancer—is serious, it's not certainly impending. The record doesn't show who in the putative class (if anyone) will develop cancer or when (if ever). Because the risk of this harm coming to pass, even if heightened, is uncertain, monitoring costs based on such a risk aren't enough for Article III standing.

According to the majority, I "misapprehend[ ]" the injury it recognizes. Majority Opinion at 421. I think not.

I don't rely on *Beck* because I see here a similarly "attenuated chain of possibilities." *Id.* (quoting *Beck*, 848 F.3d at 275). Nor is that alone what *Beck* relied on to decide the case. And I would know—I wrote it!

Beck instructs that for *costs* stemming from a potential future harm to be an injury in fact, the underlying *future harm* must be a non-speculative one. The future harm underlying the credit-monitoring-cost injury asserted in *Beck* was not that the plaintiffs' medical records had been stolen—it was the risk of identity theft. Similarly, the future harm underlying the medical-monitoring-cost injury asserted here is not the EtO exposure—it's the risk of developing cancer. In each case, plaintiffs seek to "monitor" something that may occur, not the event that's already occurred.

Here and in *Beck*, the future harm underlying the monitoring-cost injury is speculative. It doesn't matter that the future harm in *Beck* isn't speculative in precisely the same manner as here. Because the underlying future harm is speculative, costs needed or incurred based on that harm can't be an injury in fact.

II.

There's yet another reason Sommerville lacks standing. The district court, in my view, correctly excluded Dr. Ranajit Sahu's expert testimony. And without Sahu's testimony, Sommerville can't meet her burden at summary judgment to demonstrate an injury in fact.

A.

Sommerville hired Dr. Sahu to reconstruct ethylene oxide, or "EtO,"[4] emissions from the Defendants' South Charleston industrial facility between 1984 and 2019 and to create an air dispersion model[5] to estimate cumulative EtO exposure levels at points near the facility.

According to Sahu, this model could estimate an individual's cumulative EtO exposure based on where they lived and the years they lived there. Sommerville's other experts would use these cumulative exposure estimates and background EtO levels—which Dr. Sahu also estimated—to calculate each class

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[4] EtO is a human carcinogen. *Our Current Understanding of Ethylene Oxide (EtO)*, EPA, https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto [https://perma.cc/F53C-JPUV]. Long-term exposure to EtO increases the risk of certain cancers, while "[s]hort-term inhalation exposure to high amounts of EtO can cause headache, dizziness, nausea, fatigue, respiratory irritation[,] ... and, in some cases, ... gastrointestinal distress." *Id.*

[5] Air dispersion modeling uses mathematical formulas to simulate "the atmospheric processes that disperse [an air] pollutant emitted by a source." *Air Quality Dispersion Modeling*, EPA (Nov. 21, 2024), https://www.epa.gov/scram/air-quality-dispersion-modeling [https://perma.cc/F7C6-L6C6]. An air dispersion model "can be used to predict concentrations" of an air pollutant at locations around the source. *Id.*

member's relative risk of developing certain cancers.

When faced with expert testimony, the district court's gatekeeping responsibility is to "ensur[e] that [the] testimony both rests on a *reliable* foundation and is *relevant* to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) (emphases added). To be reliable, an expert's opinion must be "based on scientific, technical, or other specialized knowledge and not on belief or speculation," and any "inferences must be derived using scientific or other valid methods." *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (emphasis omitted) (quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999)).

The question isn't whether we would have admitted Dr. Sahu's testimony in the first instance, but whether the district court abused its discretion in excluding it. The Supreme Court has cautioned us against being "overly stringent" in answering this question. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). After all, "[i]t is very much a matter of discretion with the court whether to receive or exclude the evidence," so we should not reverse "unless the ruling is manifestly erroneous." *McKiver v. Murphy-Brown, LLC*, 980 F.3d 937, 962 (4th Cir. 2020) (quoting *Gen. Elec. Co.*, 522 U.S. at 142, 118 S.Ct. 512).

Here, the district court concluded that Sahu's expert testimony wasn't well-grounded in the facts and data available and was thus unreliable. *Sommerville v. Union Carbide Corp.*, No. 19-CV-00878, 2024 WL 1204094, at *1 (S.D. W. Va. Mar. 20, 2024). The district court didn't abuse its discretion. In fact, the court was right.

1.

The majority faults the district court for focusing on Dr. Sahu's justifications for his inputs into the "AERMOD" modeling system, rather than on the system itself. According to the majority, this flouts *Daubert*, which directs courts to focus on methodology. Not so.

The AERMOD modeling system and Sahu's model aren't the same. The fact that the AERMOD modeling system could (in theory) produce *a* sufficiently reliable dispersion model[6] doesn't settle whether *Sahu's* dispersion model was sufficiently reliable. Instead, the reliability of Sahu's model depends on the reliability of the inputs, as Dr. Sahu himself agreed.[7] *E.g.*, J.A. 219 (agreeing that "the accuracy of the model bears a strong positive relationship to the correct inputs being used ... that represent the actual condition in the facilities in its emissions sources").

True, *Daubert* directs us to focus on "principles and methodology, not on the conclusions that they generate." 509 U.S. at 595, 113 S.Ct. 2786. But an expert who constructs a model based on faulty assumptions and irrelevant data shouldn't be handed a "get-out-of-*Daubert*-free card" simply because he uses an otherwise reliable modeling system. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 641 (4th Cir. 2018); *see also id.* at 643–44.

A modeling expert's methodology doesn't end with selecting a modeling system. The expert must also develop the inputs and assumptions used to create

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[6] The Defendants don't challenge the reliability of the AERMOD modeling system. So I assume that the system doesn't introduce any separate *Daubert* concerns here.

[7] Put more bluntly, garbage in, garbage out.

the model.[8] Here, the district court had to consider whether those inputs and assumptions are supported by "scientifically valid" "reasoning or methodology," *Daubert*, 509 U.S. at 592–93, 113 S.Ct. 2786, such that the resulting model is "based on sufficient facts or data," Fed. R. Evid. 702(b). And that's precisely what the district court did.

But, says the majority, "questions regarding the factual underpinnings of the expert witness'[s] opinion affect the weight and credibility of the witness'[s] assessment, not its admissibility." Majority Opinion at 423, 424 (cleaned up) (quoting *Bresler v. Wilmington Tr. Co.*, 855 F.3d 178, 195 (4th Cir. 2017)).

I can't tell what line my colleagues intend to draw here, especially because *Daubert* inquiries are inherently "tied to the facts of a particular case." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999) (cleaned up). Yet they can't possibly mean that district courts may not decide that an expert's opinion lacks sufficient support in the record, *cf.* Fed. R. Evid. 702(b), or conclude "that there is simply too great an analytical gap between [an expert's] data and the opinion proffered," *Gen. Elec. Co.*, 522 U.S. at 146, 118 S.Ct. 512.

We've faulted district courts for "abdicat[ing] [their] responsibility" with respect to expert testimony based on the belief "that the question of whether an expert's opinion had an adequate basis in fact should be handled by opposing counsel through cross examination and in jury argument." *Tyger Constr. Co.*

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[8] Even Dr. Sahu considered developing these inputs to be his methodology. The "Methodology" section of his expert report focuses exclusively on how he "reconstruct[ed] operations and identif[ied] emission and waste sources." J.A. 467–68; *see also* J.A. 494.

v. Pensacola Constr. Co., 29 F.3d 137, 143 (4th Cir. 1994); *see also Sardis v. Overhead Door Corp.*, 10 F.4th 268, 281–82 (4th Cir. 2021).

The district court recognized its duty here and honored it. We should commend the court, not reverse its ruling.

2.

Nor can I agree with the majority that the district court's concern about a lack of validation was misplaced. *See Sommerville*, 2024 WL 1204094, at *12, *14. Validation (as in "data validation") can refer to specific protocols used to confirm data quality. But I take the district court to have used "validate" in a more colloquial sense—as in "substantiate" or "support."

The district court had good reason to be concerned about Dr. Sahu's failure to justify the assumptions he made in creating the inputs for the dispersion model. *See Daubert*, 509 U.S. at 590, 113 S.Ct. 2786 ("Proposed testimony must be supported by appropriate *validation*—i.e., '*good grounds*,' based on what is known." (emphases added)). Here again, the district court was simply doing its job as the "gatekeeper[ ] of expert testimony." *Sardis*, 10 F.4th at 275 (cleaned up).

3.

What's left are a series of concerns squarely within the district court's purview—that the inputs were "speculative" and "premised on assumptions that [did] not accurately represent the Defendants' operations in South Charleston." *Sommerville*, 2024 WL 1204094, at *1; *see, e.g., In re Lipitor*, 892 F.3d at 633–35 (unrepresentative data set, flawed logic, unsound assumptions); *EEOC v. Freeman*, 778 F.3d 463,

466–67 (4th Cir. 2015) (unexplained discrepancies in data set, analytical fallacies); *Belville v. Ford Motor Co.*, 919 F.3d 224, 229 (4th Cir. 2019) (unsupported assumptions). I can't agree with the majority's attempt to recast these problems as a "mere disagreement with [Sahu's] choice of data" or an "assessment of the correctness" of his ultimate opinions. Majority Opinion at 427 n.7 (emphases omitted).

Sahu's model purports to estimate actual emissions. Yet he relied on values that *expressly* didn't represent actual emissions. *Sommerville*, 2024 WL 1204094, at *13. Sahu himself "identified inconsistencies in [the] reported EtO emissions," J.A. 1188, but he "[n]onetheless ... used [those] emissions for ... various years in updating [his] modeling," J.A. 1190.

And Sahu ignored telltale signs that there might be a problem with the emissions values he used. For example, his model shows that in 1984 the cumulative EtO exposure at a point a half mile from the South Charleston facility was 100 times greater than in other years, J.A. 535, yet that outlier raised no red flags for Sahu—at least none that warranted an explanation.

The model also required meteorological inputs. To develop them, Sahu combined meteorological data from three locations—one year of hourly wind speed and wind direction data from near the South Charleston facility (which he supplemented with data from an airport five miles away); twice-daily upper air data from a town fifty miles away; and other meteorological parameters also from the airport. But Sahu never explained why the data from some distance away was representative of the conditions near the

facility.[9] *See Tyger Constr. Co.*, 29 F.3d at 143.

Sahu filled in gaps in the emissions and meteorological data with assumptions. That isn't problematic on its own. "Trained experts commonly extrapolate from existing data." *Gen. Elec. Co.*, 522 U.S. at 146, 118 S.Ct. 512. But those assumptions must be "connected to existing data" by more than just "the *ipse dixit* of the expert." *Id.*

Sahu justified some of his assumptions in his initial report, but he simply identified others. And his rebuttal report and deposition testimony provided little support beyond his say-so.

In many instances, Sahu held a value (e.g., emissions, operations) from one year constant over several years (or, for the meteorological data, for the entire thirty-year period at issue). But as the district court correctly recognized, he failed to explain why such values were unlikely to change significantly from year to year.

The district court "identified and articulated clear ... concerns it had about the manner in which [Dr. Sahu] reached his conclusions." *In re Lipitor*, 892 F.3d at 638. I'm not left with "a definite and firm con-

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[9] It strikes me as unwise for courts to opine on "the science of wind"—whatever that entails—unless absolutely necessary. Majority Opinion at 425 & n.5; *cf. Daubert*, 509 U.S. at 601, 113 S.Ct. 2786 (Rehnquist, C.J., concurring in part and dissenting in part) ("[Rule 702] imposes on [courts] [n]either the obligation [n]or the authority to become amateur scientists."). That's especially true here, where we're unaided by briefing or record evidence. Whatever direction the science of wind blows, Dr. Sahu failed to support his meteorological assumptions. And whatever the district court's "scientific finding[s]," Majority Opinion at 425, it acted well within its discretion to conclude as much, *Sommerville*, 2024 WL 1204094, at *17.

viction that the [district] court ... committed a clear error of judgment" in carrying out its gatekeeping responsibility. *Freeman*, 778 F.3d at 466. To the contrary, the district court's decision to exclude Dr. Sahu's opinion is right on the merits.

In holding otherwise, the majority wrongly invites district courts to "delegate [their] gatekeeping responsibility to the jury." *Nease*, 848 F.3d at 231.

B.

Without Dr. Sahu's opinion, Sommerville can't carry her burden to present evidence sufficient to demonstrate Article III standing.

At summary judgment, Sommerville "cannot rest on mere allegations but must set forth evidence which ... would establish the elements of Article III standing." *Fernandez v. RentGrow, Inc.*, 116 F.4th 288, 295 (4th Cir. 2024). Though we view the evidence in Sommerville's favor, *id.*, we "may not consider inadmissible evidence" at summary judgment, *Giles v. Nat'l R.R. Passenger Corp.*, 59 F.4th 696, 704 (4th Cir. 2023).

So even if the need for and costs of medical monitoring is an injury in fact, Sommerville can't establish that injury in fact without Dr. Sahu's opinion. His model is the only evidence that, for example, indicates that Sommerville was exposed to EtO emitted by the Defendants' operations. And without Sahu's estimates of her cumulative exposure, Sommerville's other experts couldn't calculate her relative risk of developing certain cancers, or opine on the significance of that risk, or her need for medical monitoring.

III.

I have no quarrel with the West Virginia Supreme Court of Appeals' reasons for recognizing a medical

monitoring cause of action, which the majority aptly recounts. But the need for and costs of medical monitoring—without more—isn't an injury in fact sufficient for Article III standing. Even if it were, Sommerville can't demonstrate such an injury without Dr. Sahu's expert testimony, which the district court properly excluded.

Because the majority holds otherwise, I dissent.

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF
WEST VIRGINIA
CHARLESTON DIVISION.

Lee Ann SOMMERVILLE, et al., Plaintiffs,

v.

UNION CARBIDE CORPORATION, Defendant.

CIVIL ACTION NO. 2:19-cv-00878

Signed March 20, 2024

MEMORANDUM OPINION AND ORDER

JOSEPH R. GOODWIN, UNITED STATES DISTRICT JUDGE

Pending before the court are two motions to limit the opinions and testimony of Dr. Ranajit (Ron) Sahu filed by Defendants Union Carbide Corporation ("UCC"), [ECF No. 309], and Covestro LLC ("Covestro"), [ECF No. 327], respectively. Plaintiff Lee Ann Sommerville ("Plaintiff") filed a response to UCC's motion, [ECF No. 343], and a response to Covestro's motion, [ECF No. 342], on July 10, 2023. For the reasons discussed below, I **GRANT** both motions, [ECF Nos. 309, 327], and **ORDER** that the testimony and reports of Dr. Ranajit Sahu be excluded as unreliable.

Upon detailed review of the expert reports, I find that the opinions of Dr. Sahu are not based upon sufficient facts or data because the inputs he uses in the air model are speculative and are premised on assumptions that do not accurately represent the Defendants' operations in South Charleston. As such, there are serious doubts about whether such opinions

are the product of reliable principles and methods, which have also not been reliably applied to the facts of this case. For these reasons, which I discuss in greater detail below, I **GRANT** both motions, [ECF Nos. 309, 327], and **ORDER** that the testimony and reports of Dr. Ranajit Sahu be excluded as unreliable.

I. Background

The named Plaintiff brought this proposed medical monitoring class action against Defendants UCC and Covestro, as owners and operators of a manufacturing facility located in South Charleston, West Virginia, for their alleged "dangerous and reckless emission of ethylene oxide ("EtO")," a known human carcinogen, between 1984 and 2019. [ECF No. 85, ¶¶ 1–2].

A. Ethylene Oxide Exposure

EtO is a colorless, odorless gas produced in large volumes at some chemical manufacturing facilities. *See Our Current Understanding of Ethylene Oxide (EtO)*, U.S. Env't Prot. Agency, https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto#what (last visited Mar. 11, 2024). According to the Environmental Protection Agency ("EPA"), EtO is a known human carcinogen, and regular, long-term exposure to EtO can cause certain cancers of the white blood cells, including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia. *Id.* Because the primary way EtO enters the environment is by release into the air, individuals who live near facilities that release EtO into the outdoor air may be exposed to EtO. *Id.*

According to Plaintiff, UCC is "the world's leading producer of EtO," and "the South Charleston Plant is one of the only facilities in the [United States] that manufactures EtO." [ECF No. 85, ¶ 28]. UCC has

"owned and operated the South Charleston Plant since at least 1978," and in 2015, Covestro began "operat[ing] polyols facilities" at the South Charleston plant. *Id.* ¶¶ 41, 44. Plaintiff claims that UCC and Covestro "operated without sufficient pollution controls to limit and/or eliminate the emissions of toxic EtO and, as a result, exposed thousands of residents in neighboring areas" to the carcinogen "for at least 41 years." *Id.* ¶¶ 48, 53. As a result of the allegedly "negligent and tortious" emissions of EtO, Plaintiff claims that she and the proposed class members "have suffered significant exposure to hazardous EtO gases relative to the general population in the [United States]," *id.* ¶ 59, and are, therefore, "at an increased risk of developing cancer," making "periodic diagnostic medical examinations [ ] reasonably necessary," *id.* ¶ 62. Plaintiff seeks an award of "the quantifiable costs" of medical monitoring for the benefit of all proposed class members due to their alleged exposure. *Id.* ¶¶ 84–86.

B. Expert Opinion of Dr. Ranajit Sahu

Plaintiff relies upon a number of expert opinions in seeking to establish the elements of her claim. One such opinion is offered by Dr. Ranajit Sahu, a mechanical engineer, who was engaged to provide "technical expertise, analysis, methodology, and opinions regarding various environmental and pollutant fate and transport issues relating to emissions of [EtO] from Union Carbide's Institute and [the] South Charleston facilities" (collectively, the "Facilities") to ultimately determine the potential exposure levels of Plaintiff and the proposed class members. [ECF No. 309-3, at 6]. Dr. Sahu provided his Expert Report on February 17, 2023. [ECF No. 309-3]. Defendants seek to exclude the opinions in this report, as well as Dr. Sahu's related testimony.

1. Dr. Sahu's Background and Experience

Dr. Sahu is "a mechanical engineer with over thirty years of experience in the fields of environmental, mechanical, and chemical engineering." *Id.* After obtaining a Bachelor of Technology in mechanical engineering from the Indian Institute of Technology in Kharagpur, India in 1983, Dr. Sahu attended the California Institute of Technology in Pasadena, California from 1984 to 1988, where he received a Master of Science and Doctorate degree in mechanical engineering. *Id.* at 7. Dr. Sahu also has over twenty-seven years of "project management experience" and has "provided consulting services to numerous private sector, public sector, and public interest group clients" over the past twenty-five years. *Id.* His experiences include "design and specification of pollution control equipment for a wide range of emissions sources," "multimedia environmental regulatory compliance," "transportation air quality impact analysis," "air quality ... permitting," "multimedia/multipathway human health risk assessment for toxics," and "air dispersion modeling." *Id.* at 6–7. Dr. Sahu has also taught numerous university courses in air pollution, process hazard analysis, air pollution controls, transportation and air quality, and engineering. *Id.* at 7.

2. Dr. Sahu's Summary of Opinions

In his February 17, 2023, report, Dr. Sahu outlines his findings related to the EtO emissions from operations at the Facilities. His summary of opinions is listed below:

> (i) There were numerous sources of EtO air emissions from Union Carbide's West Virginia Operations (WVO). EtO was used extensively in various production processes. EtO was

brought into the [Facilities] from elsewhere, and subsequently distributed, stored, and processed. This handling and use of EtO created significant opportunities for EtO releases into the ambient air. Examples include: EtO emissions from various storage tanks, where EtO was present in the materials being stored, and therefore emitted from such tanks; EtO emissions from various fugitive components—such as valves, pump seals, connectors, flanges, and others—which were present throughout the [Facilities], including in all handling, storage, distribution, and processing areas; EtO emissions from so-called extended cookout operations at the reactors; and EtO emissions from flaring of waste gases containing EtO.

(ii) In spite of the many sources of EtO at the [Facilities], there was no direct testing of EtO mass emissions to the ambient air from any of the sources under representative conditions over the many years of EtO-related operations.

While direct monitoring of the open-flame stack flares at the [Facilities] would have been problematic, no efforts were made to use other types of thermal combustion devices (such as enclosed stack flares, thermal oxidizers, etc.) for waste gas disposal, which could have been tested and monitored.

There was no direct testing of the many fugitive components that emitted EtO. The Leak Detection and Repair (LDAR) program that was used for some period of time relied on assumed emission factors and effectiveness of the program with no verification.

There was no testing of EtO emissions from any of the tanks that stored EtO containing materials.

There was little direct testing of EtO from extended cookout operations, which were claimed to be appropriate regulatory controls for various hazardous air pollutants, including EtO.

(iii) Since there was no direct testing of EtO emissions from the many sources of EtO, and certainly therefore no testing under representative conditions, all emissions of EtO developed and/or reported by Defendants used engineering estimates. However, for engineering estimates to be proper, they needed to be grounded by site specific data.

Site specific data is not constant at chemical manufacturing operations such as at the operations in question. Union Carbide's estimates of EtO emissions relied on sporadic and unsupported assumptions; and, crucially, in the case of flares, on "surrogate" parameters that bore no relation to actual operating conditions or actual emissions.

As such it is my opinion that EtO emissions were underestimated significantly from all sources. In this report, I have highlighted the example of underestimation of the EtO emissions from the flares, via the use of an unrealistically high flare control efficiency, which did not and could not have represented every-day operations of the flares.

(iv) The few verification tests that were conducted at the facilities in order to meet regulatory requirements showed that actual opera-

tions deviated considerably from regulatory requirements. In the case of the flares, preliminary tests conducted prior to the required compliance tests, showed significant failures. Due to the lack of prior testing at the facilities, these significant failures indicate that inadequate conditions existed for persistent periods of time prior to the failed tests. This is supported by internal discussions among Union Carbide managers explicitly acknowledging that the control efficiencies they reported to regulators rarely matched reality.

(v) Failed tests were remedied for regulatory compliance demonstrations in order to make them "pass." However, the failed tests were never reported to regulators as required. Once a "passing" test was obtained, there is no record that Union Carbide monitored subsequent flare operating conditions, or had any policies or procedures to ensure that necessary passing conditions were maintained. Thus, the compliance tests were unrepresentative of usual or normal operations and were meaningless. Worse, it is my opinion, that by conducting sham compliance tests, Defendants were in violation of applicable regulatory requirements, such as the need to conduct testing under representative conditions and to keep proper records demonstrating continuous compliance.

(vi) Based on conservative (i.e., still likely underestimated emissions) recalculation of emissions and by modeling such emissions using appropriate and standard air dispersion modeling, it is my opinion that persons in the surrounding community were exposed to significant concentrations of EtO.

> (vii) Collectively, it is my opinion that Defendants' conduct relating to the emissions of EtO was irresponsible and exhibited a knowing and willful disregard of both their regulatory requirements and the health and safety of persons in the surrounding community.

Id. at 8–10.

C. Defendant UCC's Motion to Exclude [ECF No. 309]

UCC asserts that Dr. Sahu should be excluded as a witness for four primary reasons. First, UCC argues that Dr. Sahu's air modeling opinions do not "fit" the facts of the case. [ECF No. 310, at 3–4].[1] Second, UCC asserts that Dr. Sahu's air modeling opinions suffer from "serious methodological flaws" which render them unreliable because they do not rely on an accurate historical reconstruction and were formulated using "patently unreliable emissions data" that Dr. Sahu failed to validate. *Id.* at 11, 13, 15. Third, UCC contends that Dr. Sahu's source configurations do not reliably represent historical conditions. *Id.* at 19. Finally, UCC claims that Dr. Sahu did not employ a reliable method to estimate background levels of EtO in the community and combined contradictory meteorological data that leads to impossible results. *Id.* at 20. For these reasons, UCC argues that "Dr. Sahu's work ... falls far short of the standard set by this [c]ourt," *id.* at 3, and should be excluded pursuant to Rule 702 of the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

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[1] Unless otherwise stated, the page numbers cited correspond to CM/ECF page numbers.

Plaintiff rebuts these arguments, arguing that UCC "does not mount a true *Daubert* challenge." [ECF No. 343, at 3 (quoting *TWFS, Inc. v. Shaefer*, 325 F.3d 234, 240 (4th Cir. 2003))]. Rather, Plaintiff claims that UCC "mounts an attack on the data inputs to Dr. Sahu's air model by disputing the accuracy of the data and the assumptions that are required to fill gaps in the data, while failing to offer any different conclusions that might be reached with different data." *Id.* She argues that the court should deny UCC's motion because "questions regarding the factual underpinnings of an expert's opinion affect the weight and credibility of the opinion, not admissibility." *Id.* (citing *Bresler v. Wilmington Tr. Co.*, 855 F.3d 178, 195 (4th Cir. 2017)).

D. Defendant Covestro's Motion to Exclude [ECF No. 327]

Likewise, Defendant Covestro asserts that the court should exclude the testimony and reports of Dr. Sahu because they are irrelevant to Plaintiff's claims against Covestro and are also fatally unreliable. [ECF No. 327, at 1]. Specifically, Covestro contends that (1) the opinions are "irrelevant as to Covestro" because Dr. Sahu is "unfamiliar" with Covestro's operations in South Charleston; (2) the air model is "irrelevant and unreliable as to Covestro because its inputs do not reflect the reality" of its operations in South Charleston; (3) the figures produced by Dr. Sahu's air model are "irrelevant and unreliable because they do not represent exposure or dose;" and (4) the opinions "regarding the exposure of the general population" are "irrelevant and unreliable because Dr. Sahu does not know the background levels of [EtO] in the air." *Id.*

In response, Plaintiff argues that Covestro, too, fails to "mount a true *Daubert* challenge," but instead, "challenges the factual underpinnings, data

inputs, and relevancy of Dr. Sahu's opinions." [ECF No. 342, at 3]. She claims that Dr. Sahu had properly considered Covestro's South Charleston operations and that his opinions are based on those operations. *Id.* She also argues that Dr. Sahu's opinions on "significant EtO exposure are relevant," that the "meteorological inputs are reliable," and that the EPA's National Air Toxics Assessment ("NATA") database—which Dr. Sahu used as a data source—"provides the most appropriate background level." *Id.* Further, while Plaintiff concedes that there was a "minor error with a data input" related to Covestro's operations, she asserts that "Dr. Sahu properly updated his expert report" to correct the issue,[2] and that regardless, the "minor error" was not sufficient grounds to exclude his opinions. *Id.* For these reasons, Plaintiff asks the court to deny Covestro's motion. *Id.* at 12.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it (1) will "help the trier of fact to understand the evidence or to determine a fact in issue" (2) is "based upon sufficient facts or data," and (3) is "the product of reliable principles and methods," which (4) have been "reliably appli[ed] ... to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony: evidence is admissible if "it rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. He must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admis-

[2] There is currently pending a motion filed by Covestro to strike this supplemental expert report as untimely under Federal Rule of Civil Procedure 26(e). *See* [ECF No. 300].

sible." *Md. Cas. Co. v. Therm-O-Disc., Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court has an important role as the gatekeeper of expert opinions and testimony. Because "expert witnesses have the potential to be both powerful and quite misleading," the court must "ensure that any and all scientific testimony ... is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (internal markings omitted) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.' " *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596) (alteration in original); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable ... and helpful").

Daubert outlines specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include "(1) whether the particular scientific theory can 'be (and has been) tested'; (2) whether the theory 'has been subjected to peer review and publication'; (3) the 'known or potential rate of error'; (4) the 'existence and maintenance of standards controlling the technique's operation'; and (5) whether the technique has achieved 'general acceptance' in the relevant scientific or expert community." *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

With respect to relevancy, *Daubert* explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes....Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Id. at 591–92 (internal citations omitted).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.' ") (citation omitted); *see also Crisp*, 324 F.3d at 266 (citing *Kumho* for the proposition "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert"). However, "conclusions and methodology are not entirely distinct from one another." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

Additionally, some scholars have opined that "[*Daubert*] has proven especially inappropriate and inadequate in evaluating model reliability. The problems that plague all models—namely uncertainty and a lack of transparency—are exacerbated in environmental-tort litigation." Matthew W. Swinehart, *Remedying* Daubert*'s Inadequacy in Evaluating the Ad-*

missibility of Scientific Models Used in Environmental-Tort Litigation, 86 Tex. L. Rev. 1281, 1283 (2008) [hereinafter *Remedying* Daubert*'s Inadequacy*]; *see also* Wendy Wagner et al., *Misunderstanding Models in Environmental and Public Health Regulation*, 18 N.Y.U. Envt'l L.J. 293, 324 (2010) [hereinafter *Misunderstanding Models*] ("There are significant conflicts between the Supreme Court's deterministic test for admissibility of expert testimony (embodied in *Daubert v. Merrell Dow Pharmaceuticals*) and the true nature of models."). Ultimately, a district court has broad discretion in determining whether to admit or exclude expert testimony, and "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152); *see also United States v. Hankey*, 203 F.3d 1160, 1167 (9th Cir. 2000) ("A trial court not only has broad latitude in determining whether an expert's testimony is reliable, but also in deciding *how* to determine the testimony's reliability.") (internal quotation marks and citations omitted).

III. Discussion

Before reaching the analysis of Dr. Sahu's expert opinions, I will first address Plaintiff's contention that the instant motions raise questions affecting *the weight and credibility* of Dr. Sahu's opinions rather than their *admissibility* and the inference that the issues are, thus, a matter for the jury, not the court. *See* [ECF No. 343, at 3].

As part of its "gatekeeping function," the court must "ensure[ ] that expert evidence is sufficiently relevant and reliable when it is submitted to the jury." *Nease v. Ford Motor Co.*, 848 F.3d 219, 231 (4th Cir. 2017) (emphasis in original). "Thus, the trial

court must probe the reliability and relevance of expert testimony any time 'such testimony's factual basis, data, principles, methods, or their application are sufficiently called into question.' " *EEOC v. Freeman*, 778 F.3d 463, 472 (4th Cir. 2015) (Agee, J., concurring) (quoting *Kumho*, 526 U.S. at 149). "[T]he fact that an expert witness [is] 'subject to a thorough and extensive examination' does not ensure the *reliability* of the expert's testimony; such testimony must still be assessed *before* it is presented to the jury." *Nease*, 848 F.3d at 231 (quoting *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1238 (11th Cir. 2005) (emphasis added)). Therefore, "[a]lthough the jury ultimately decides the 'weight' of the evidence, the judge ensures there is sufficient probative value ... to justify submitting the issue in the first instance." Daniel D. Blinka, *Expert Testimony and the Relevancy Rule in the Age of Daubert*, 90 Marq. L. Rev. 173, 191 (2006). Here, the issues presented to the court deal not only with the validity of the underlying data used by Dr. Sahu but also with Dr. Sahu's methods in applying that data to the facts of the case. I will now proceed to Defendants' arguments regarding relevance and reliability.

A. Relevance Challenge: The "Fit" of Dr. Sahu's Opinions to the Facts of the Case

First, both UCC and Covestro argue that Dr. Sahu's opinions are irrelevant or do not "fit" the facts of the case, because this case deals solely with EtO emissions from the Defendants' operations at South Charleston, and Dr. Sahu's model consists of combined emissions sources from operations at both Institute *and* South Charleston. *See* [ECF No. 310, at 12]; [ECF No. 328, at 4]. According to UCC, this failure to disaggregate the emissions sources and resulting exposure estimates makes it "impossible to dis-

cern the impacts of EtO emissions" from just the South Charleston facility. [ECF No. 310, at 3]. And Defendants argue that this same issue plagues the jury's ability to discern the alleged impacts from each of their separate operations at that facility. As a result, Defendants claim that Dr. Sahu's model and opinions are irrelevant and should be excluded. *Id.* at 12; *see* [ECF No. 328 at 13 ("Dr. Sahu's opinions are irrelevant and unreliable because he does not ... separate alleged impacts between the defendants.")].

Plaintiff, conversely, argues that while Dr. Sahu's model presents combined results from both Institute and South Charleston, it is "entirely capable of predicting, at each desired receptor, the impacts from not just one plant but from specific sources within each plant." [ECF No. 342, at 9 (quoting [ECF No. 327-13, at 17])]. Further, Plaintiff contends that Dr. Sahu's opinions are relevant because his model shows that proposed class members "were 'significantly exposed' to a hazardous substance relative to the general population." *Id.* (quoting *In re W. Va. Rezulin Litig.*, 585 S.E.2d 52, 73 (W. Va. 2003)). These facts, Plaintiff argues, defeat Defendants' relevancy challenges.[3]

Under *Daubert*, expert testimony should be "sufficiently tied to the facts of the case that it will aid the

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[3] Plaintiff also argues that because West Virginia law allows plaintiffs to sue "only one of several joint tortfeasors," *Bradley v. Appalachian Power Co.*, 256 S.E.2d 879, 886 (W. Va. 1979), and does not require plaintiffs to "prove that the negligence of one of the defendants is the sole proximate cause of the injury," *Kodym v. Frazier*, 412 S.E.2d 219, 224 (W. Va. 1991), the Defendants here cannot avoid liability by "blaming the emissions from its other plant." [ECF No. 343, at 6]. However, because that argument deals with liability, rather than the *relevance* of Dr. Sahu's report, I need not address it here.

jury in resolving a factual dispute." *Daubert*, 509 U.S. at 591 (quoting *United States v. Downing*, 753 F.2d 1224, 1242 (3d Cir. 1985)); *see also United States v. Chapman*, 209 F. App'x 253, 269 (4th Cir. 2006) (noting that expert testimony is "excludable under Rule 702 if it does not aid the jury"). While I agree that Dr. Sahu's failure to disaggregate the sources of EtO emissions in his report creates issues of reliability, I cannot agree that this renders the report or Dr. Sahu's opinions entirely irrelevant. Dr. Sahu's opinions are inarguably related to the issues in this case even if the report contains superfluous information. Therefore, I find that the opinions of Dr. Sahu are relevant and decline to exclude his opinions on this ground.

B. Reliability Challenges: Dr. Sahu's "Serious Methodological Flaws"

Next, Defendants UCC and Covestro argue that Dr. Sahu's opinions suffer from "serious methodological flaws" and are, therefore, unreliable. [ECF Nos. 310, at 4]; *see also* [ECF No. 328, at 3–4]. I agree. The issues plaguing Dr. Sahu's opinions stem not only from concerns about the validity of the underlying data but also with the methodology used by Dr. Sahu's in *applying* that data.

"Evidence is admissible only if 'it rests on a reliable foundation.' " *Freeman*, 778 F.3d at 471 (quoting *Daubert*, 509 U.S. at 597). Courts must, therefore, verify that expert testimony is "based on sufficient facts or data." *See* Fed. R. Evid. 702(b). And courts widely agree that "trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable." *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 15 (1st Cir. 2011) (cleaned up); *accord Blunt v. Lower Merion Sch. Dist.*, 767 F.3d 247, 276 (3d Cir. 2014); *In*

re TMI Litig., 193 F.3d 613, 697 (3d Cir. 1999); *United States v. City of Miami*, 115 F.3d 870, 873 (11th Cir. 1997).

"Dispersion modeling is considered to be both an art and a science. There are numerous variables to consider in any such analysis, each of which may be open to careful scrutiny and analysis during the litigation process." Andrew C. Wilson et al., *Tracking Spills and Releases: High-Tech in the Courtroom*, 10 Tul. Env't L.J. 371, 390 (1997) [hereinafter Wilson et al., *Tracking Spills and Releases*].

> While the "troubled marriage between science and law" is now a familiar phenomenon, models may best be thought of as the unhappy couple's inconsolable child. All of the challenges that afflict science used for policy also afflict models: significant uncertainties and subjective judgments loom in model design, in interpretation of the data, and in communicating that data to other scientists as well as lay persons.

Wagner et al., *Misunderstanding Models, supra*, at 308; *see also* Swinehart, *Remedying* Daubert*'s Inadequacy, supra*, at 1288–89 ("Model development is plagued by uncertainties regarding (A) which components of a system to include in the model; [and] (B) whether one has gathered accurate, precise, and representative data about the system ....") (internal quotation marks and citations omitted). Additionally,

> ... models used in environmental-tort litigation present two additional issues. First, the adversarial process creates unfortunate incentives to misuse models in "unscientific" ways, perhaps taking advantage of their uncertain and impervious nature. Second, because models

> are particularly complex and enigmatic applications of science, they are even less accessible to judges ....

Swinehart, *Remedying* Daubert*'s Inadequacy, supra*, at 1288. Air models, by their nature, have "many moving parts." *Coleman v. Union Carbide Corp.*, No. 2:11-0366, 2013 WL 5461855, at *23 (S.D. W. Va. Sept. 30, 2013). "Modeling involves synthesizing disparate data, assumptions, uncertainties, and theories in the most robust way possible." Wagner et al., *Misunderstanding Models, supra*, at 310. "The accuracy of the model bears a strong positive relationship to the correct inputs being used—inputs that represent the actual conditions at the facility and its emission sources." *Coleman*, 2013 WL 5461855, at *23; *see also* Swinehart, *Remedying* Daubert*'s Inadequacy, supra*, at 1294–95 ("A model is only as good as its underlying data; even the best models cannot make up for faulty data."); Charles D. Case, *Problems in Judicial Review Arising from the Use of Computer Models and Other Quantitative Methodologies in Environmental Decisionmaking*, 10 Bos. Coll. Env't Aff. L. Rev. 251, 275 (1982) ("[A] lack of data can hamper the accurate application of a model."); Thomas O. McGarity & Wendy E. Wagner, *Legal Aspects of the Regulatory Use of Environmental Modeling*, 33 ELR 10751, 10770 (2003) ("[T]he empirical data upon which models are based and the input data from which models extrapolate to make predictions are critical to the accuracy of those predictions.").

UCC argues that Dr. Sahu's air model does not accurately represent "the actual conditions" at the South Charleston plant or the "emission sources over the 36-year period" at issue in this case. [ECF No. 310, at 5]. Specifically, UCC takes issue with Dr. Sahu's (1) use of "maximum possible emissions figures

from permit applications" in lieu of actual emissions data; (2) "cherry-picking" of Institute plant flare emissions from one year and "counter-factually assuming that the emissions from that sources remained constant over an 18-year period;" and (3) "making the ahistorical assumption that current-day operations existed unchanged over the 36-year period." *Id.* Additionally, UCC contends that "Dr. Sahu use[s] three different sets of meteorological data from different locations with different wind directions and speeds, and then added the concentrations together to reach an impossible model result." *Id.* Due to "the lack of reliability of his model inputs, including source configuration, emissions characterization, and meteorological conditions, and no attempt to validate his model results," UCC argues that "Sahu's modeling results are unreliable and not scientifically defensible." [ECF No. 309-1, at 8].

Likewise, Covestro seeks to exclude Dr. Sahu's opinions and testimony as unreliable. Specifically, Covestro contends that Dr. Sahu's "constant emission rates *overstate[ ] ethylene oxide emissions by 30%* compared to Covestro's reported emissions, which themselves are overestimates." [ECF No. 328, at 4 (emphasis in original)]. Additionally, Covestro argues that "Dr. Sahu also model[s] emissions from Covestro sources going back to 1984, when Covestro did not begin its South Charleston operations until April 1, 2000." *Id.* Finally, Covestro claims that Dr. Sahu's background concentration level is unreliable and that his modeled results "do not represent exposure or dose." *Id.* As such, Covestro asks the court to exclude Dr. Sahu's opinions and testimony.

Because both Defendants' motions deal with the same substantive issues concerning reliability, I will address them together.

1. Failure to Represent Actual Emissions at South Charleston

i. Inapplicable Emissions Sources

UCC employed its own expert, Ranajit J. Machado, P.E. ("Machado"), to examine Dr. Sahu's report.[4] According to Machado, Dr. Sahu models four groups of sources in this case: (1) UCC's and Covestro's South Charleston facility sources, not including tanks; (2) UCC storage tanks; (3) Institute facility sources, not including flares; and (4) Institute facility flares, "each with their own set of meteorology." [ECF No. 309-1, at 38]. UCC claims that "Dr. Sahu's results do not differentiate impacts from each of these source groups but instead only present the final combined concentrations, meaning it is impossible to discern the impacts from the individual source groups from Dr. Sahu's presented results." [ECF No. 310, at 9]. This is important, UCC alleges, because in this lawsuit, "Plaintiff has only alleged exposure to emissions from the South Charleston facility, not the Institute facility." *Id.* For instance, Dr. Sahu uses flare emission data from the Institute facility, which "account[s] for the overwhelming majority of modeled air concentrations" and has a "significant impact" on Dr. Sahu's exposure conclusions. *Id.* at 9, 12. But that emissions data does not apply to the South Charleston facility, as it has never used flares. *Id.* UCC argues that this methodology makes "it is impossible to draw conclusions about exposure from South Charleston alone from Dr. Sahu's results since Institute dis-

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[4] Although I discuss Machado's report while explaining the challenges made to Dr. Sahu's model, my decision to exclude the opinions of Dr. Sahu rests solely on the law and research detailed above as applied in this case.

proportionately impacts concentrations across the domain." *Id.* at 13.

In Dr. Sahu's expert rebuttal report, he argues that "[w]hile [he] has presented the results from both plants, the model is entirely capable of predicting, at each desired receptor, the impacts from not just one plant but from specific sources within each plant." [ECF No. 309-6, at 20]. Thus, he claims, "there is no issue about predicting impacts from Institute, impacts from [UCC's] operations at South Charleston[,] and Covestro's impacts from its operations at South Charleston separately." *Id.*

Dr. Sahu's model and expert report, as provided to Defendants—and, in turn, the court—do not disaggregate the impacts between facilities or separate operations at the South Charleston facility. The court cannot, therefore, determine the reliability of the estimated exposure from the Defendants' operations based on the information provided. Furthermore, the model and report suffer from additional methodological flaws that further merit exclusion.

ii. Assumptions in Historical Data

The next challenge to the Dr. Sahu's methodology is that he assumes historical data—rather than using records that reflect actual conditions at the Facilities—and fails to verify that data.

Experts identify emissions sources "by reviewing plot plans, process diagrams, and operational information for the specific time period involved." *Coleman*, 2013 WL 5461855, at *23. After collecting this data, "one then determines the amount of targeted pollutants produced from each source." *Id.* The process requires "[a]n in-depth data investigation, a searching historical analysis, an excruciating attention to detail, and a methodology designed to wring

error out of the process" because with the model, "one is attempting to recreate decades of emissions, plume movements, and particle depositions." *Id.* at *24. Dr. Sahu did not complete this process and instead makes assumptions regarding historical data at the Facilities with little to no basis for doing so.

(a) Source Parameters

First, in defining source parameters and configurations for the full period of 1984 to 2019, Dr. Sahu uses modeling conducted in 2019 by the West Virginia Department of Environmental Protection ("WVDEP") and, according to UCC, "assume[s] that during that 36-year period, there were no relevant changes in those source characteristics or other plant operations." [ECF No. 310, at 11]. For areas not covered by this WVDEP model, UCC contends that Dr. Sahu "invent[s] volume sources 'covering the general area' at the plants where that process area had previously operated." *Id.* (citing [ECF No. 309-3, at 63 (noting that where the 2019 WVDEP modeling could not be used, "a volume source was used for modeling purposes covering the general area")]); *see* [ECF No. 309-1, at 8 (arguing that Dr. Sahu "does not account for changes in source characteristics over time and artificially creates source parameters for historical sources that were not modeled by WVDEP, rather than providing factual model parameters as model inputs")]. For example, for areas "where WVDEP/UCC prepared fugitive emission estimates," UCC argues that Dr. Sahu "took an average" of those estimates "and applie[s] this same distribution" to all of the source areas for "all years where ... fugitive emissions were estimated." [ECF No. 309-3, at 63].

Additionally, for the period from 1985 to 1989, Dr. Sahu models all South Charleston emissions as fugitive emissions, which UCC contends was incorrect

because there is "no reason to believe that no point sources existed during that time frame."[5] [ECF No. 310, at 11 (citing [ECF No. 309-3, at 58]; [ECF No. 309-2, at 36–37 (admitting he modeled all of the sources for 1985 to 1988 as fugitive emission sources)])]. UCC asserts that Dr. Sahu "assume[s] without support that emissions were apportioned between fugitive and point sources in the exact same proportion [for the years 1990 to 1995] as they were in 1996." *Id.* (citing [ECF No. 309-3, at 62]). Finally, UCC's expert, Machado, asserts that "[a]lgorithms in air dispersion models depend on accurate source parameter information to reliably simulate dispersion." [ECF No. 309-1, at 8]. "These parameters, including temperature, exit velocity, stack/release height, and diameter, are used with the model's pre-defined algorithms that calculate emission plume dispersion, and in turn, modeled concentrations." *Id.* at 11. Machado suggests that it is crucial to apply a "rigorous methodology to accurately represent each emission source" when producing air dispersion modeling predictions.[6] *Id.*

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[5] Point source emissions, "also called 'stack emissions,' " are defined as "[a]ir releases that occur through [identifiable] confined air streams, such as stacks, ducts or pipes," whereas fugitive emissions are those "[r]eleases to air that don't occur through a confined air stream" and includes "equipment leaks, releases from building ventilation systems and evaporative losses from surface impoundments and spills." *Toxics Release Inventory (TRI) Program: Common TRI Terms*, U.S. Env't Prot. Agency, https://www.epa.gov/toxics-release-inventory-tri-program/common-tri-terms (last visited Mar. 14, 2024).

[6] Machado provides the following reasoning for his assertion:

> The high temperature of flare stacks will cause emission plumes to have buoyancy, which gives way to "plume rise" that disperses emissions vertically. Conversely, fugitive emissions are often released at ambient

Dr. Sahu disagrees with these sentiments, stating that "[f]or modeling purposes" certain sources "can be modeled in a variety of ways." [ECF No. 309-6, at 13]. He claims that "[t]here is nothing extraordinary or 'contrived' about this." *Id.* Instead, he blames the Defendants for his need for assumptions and any lack of precision in determining source parameters. *See id.* ("Such sources may have been capable of being modeled with greater precision had defendants taken efforts to describe these sources more precisely in the ordinary course of business—but they did not."). He goes on to claim that "even if these sources were capable of being modeled more precisely, it is unlikely this would have materially changed the results of the analysis." *Id.* When asked for the basis for his assertion that more precise source parameters would not have a material effect on the results of his analysis, Dr. Sahu states that it is simply "[his] judgment." [ECF No. 309-2, at 27]. He goes on to argue that "the easiest way to prove [him] wrong would have been to show[ ] and correct all the criticisms with an alternate set of analyses."[7] *Id.* Further, he states that it is his "judgment" that "even if [the source parameters]

> temperature, leading to less buoyancy, less vertical dispersion, and higher modeled ground concentrations near the emission source.... Two sources with equal emissions rates, but with different source configurations, ... can result in orders of magnitude differences in offsite concentrations.

[ECF No. 309-1, at 11].

[7] Because it is the proffered expert's duty to illustrate that his assumptions are "more than subjective belief or unsupported speculation," I find Dr. Sahu's argument that Defendants failed to prove him wrong or provide alternative analyses to be unconvincing. *See Daubert*, 509 U.S. at 590 (stating that "the word 'knowledge' connotes more than subjective belief or unsupported speculation").

were 'corrected' in some fashion with a whole bunch of unsupported *alternative assumptions*, they would not have changed the conclusions" that Dr. Sahu reached. *Id.* (emphasis added). He concedes, however, that despite Machado's criticisms, he "ha[s] not done any additional analysis" or new modeling to rebut Machado's assertions. *Id.*

"The accuracy of the model depends upon the rigor applied in the input gathering process." *Coleman*, 2013 WL 5461855, at *24; *see also* Wilson et al., *Tracking Spills and Releases, supra*, at 390 ("The method of application of the data is as important to the modeling process as the integrity of the data being used."). Although Dr. Sahu attempts to blame Defendants for the lack of reliable, site-specific data to base his model on, it is clear that he made assumptions in determining the source parameters for his model with little to no scientific basis for doing so. Simply put, the data Dr. Sahu used for the air model is based on nothing but Dr. Sahu's own assertions, and the court will not presume such opinions to be reliable. *See Gen. Elec. Co.*, 522 U.S. at 146 ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert."); *see also Coleman*, 2013 WL 5461855, at *31 (stating that "emission rates from actual facility records are far superior to hypothesized extrapolations").

Despite Dr. Sahu's contention that more precise source parameters would not have a material effect on the results of his analysis, this court has previously made clear that "the location and configuration of emissions sources if *of critical importance* in producing an accurate air dispersion model." *Coleman*, 2013 WL 5461855, at *25 (emphasis added). Indeed, "it is

critical in the air modeling process to *accurately* estimate (1) emissions, (2) their sources and the dispersion characteristics of the sources, and (3) the location, size, and physical characteristics of the sources." *Id.* at *28 (emphasis added); *see also Gulf S. Insulation v. U.S. Consumer Prod. Safety Comm'n*, 701 F.2d 1137, 1146 (5th Cir. 1983) ("To make precise estimates, precise data [is] required."). Dr. Sahu has not done that.

(b) Emissions Data by Period

Next, in addition to such assumptions, Defendants argue that Dr. Sahu also uses unreliable or unvalidated emissions data "for different years throughout the period he models" and makes several assumptions in applying that data to relevant periods. [ECF No. 310, at 10–11]. Covestro argues that "unburdened by information contained in Covestro's timely produced documents or known by Covestro's witnesses, Dr. Sahu model[s] Covestro's [EtO] emissions by applying emission rates that he [holds] constant for 1984 to 2019." [ECF No. 328, at 10].

"[I]t is methodologically unsound to assume [a manufacturing plant] operated historically in a static sense." *Coleman*, 2013 WL 5461855, at *30. But that is precisely what Dr. Sahu does here, despite the fact that Covestro did not begin operating at the South Charleston facility until 2000. *See* [ECF No. 328, at 11]. In short, Dr. Sahu chooses "the far simpler, but inherently unreliable, approach of assuming" that operations at the Facilities remained "essentially unchanged historically" rather than examining their actual operations histories. *See Coleman*, 2013 WL 5461855, at *29. This, along with his unsubstantiated assumptions outlined below, undermines the reliability of Dr. Sahu's findings.

a. 1984

According to Dr. Sahu, "[t]wo sets of records[8] were relied on to reconstruct EtO emissions to air for 1984, both prepared by UCC for the Institute and South Charleston plants as part of [the West Virginia Air Pollution Control Commission's ('WVAPCC')] 1984 Emission Inventory." [ECF No. 309-3, at 56]. But when reporting this 1984 data, UCC stressed to the regulatory agency that the figures represented on the report were "drastically overstated" and did not reflect reality. [ECF No. 309-4, at 2 (February 1986 letter from UCC's Environmental Protection Coordinator stating that UCC was "extremely skeptical of the validity" of the information provided and "convinced that the numbers generated drastically overstate actual fugitive losses")]. UCC has consistently argued since that these estimates are unreliable. *See* [ECF Nos. 309-1, at 31 (excerpt from UCC's 1984 Fugitive Emissions Inventory Summary for the South Charleston plant in which UCC states that it believes that its fugitive losses were "at the worst, no more than ten per cent of the total losses reported")]. Yet, Dr. Sahu ignores UCC's reliability concerns and uses the estimates in preparing his model, claiming at his deposition that UCC's explanations were "unfounded conclusionary statements" despite performing no exercises to prove the validity of his assertions. [ECF No. 310, at 17 (quoting [ECF No. 309-2, at 41])].

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[8] Dr. Sahu also used a 1984 statewide Air Facility System ("AFS") emissions inventory located and produced by the WVDEP. But he concedes that these reports "contain emissions inventories ... not specific to any one facility in the state" but instead combine data from all facilities within the state into one file per annum. [ECF No. 309-3, at 56]. These reports are, therefore, not capable of reliably estimating emissions from only the South Charleston facility.

Dr. Sahu's use of patently unreliable estimates is troublesome because, as noted in *TMI Litigation*, "if the data underlying the expert's opinion [is] so unreliable that no reasonable expert could base an opinion on them, the opinion resting on that data must be excluded." 193 F.3d at 697; *see also* Langley R. Shook & James A. Tartal, *Unreliable Speculation or Sound Science Under Daubert?-Use of Expert Testimony to Model Contaminant Release and Transport*, SE55 ALI-ABA 525, 541 (2000) ("Regardless of its basis, testimony founded on critical facts that are plainly untrustworthy may be excluded because it cannot be helpful to the trier of fact."). Here, UCC has expressed concerns for almost 40 years about the validity of the 1984 reported data. Despite this, Dr. Sahu "freely admitted that he performed no validation of that 1984 data." [ECF No. 310, at 10 (citing [ECF No. 309-2, at 38 (responding to question about validation of 1984 data by stating he "made the assumption that the company would not provide misleading data to its regulator")])]; *see also* [ECF No. 309-2, at 42 (stating that he did not "do any sort of validation for the 1984 data")]. But the mere fact that UCC reported the data does not permit Dr. Sahu to use it in estimating exposures without any scientific underpinnings to support his decision, especially in light of UCC's reliability concerns at the time of submitting the reports. *See Colon v. BIC USA, Inc.*, 199 F. Supp. 2d 53, 79 n.18 (S.D.N.Y. 2001) ("Some courts have stated that an opinion based solely on the defendant's data is not reliable.") (citing *Pestel v. Vermeer Mfg. Co.*, 64 F.3d 382, 384 (8th Cir. 1995) (refusing to allow expert to rely on testing done by manufacturer because he had not developed, participated in, nor supervised the testing)); *see also Clay v. Ford Motor Co.*, 215 F.3d 663, 676 (6th Cir. 2000) ("While there is a certain logical appeal to the notion that [an expert's] opinion

must be reliable if it rests upon data produced by the defendant, the notion does not withstand close consideration.") (Ryan, C.J., dissenting); *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 473 (4th Cir. 2013) (stating that the proponent of data "need not have analyzed or explicitly rejected every data source presented, but it surely was required to 'cogently explain why it ha[d] exercised its discretion' in relying on a data set that was so highly criticized") (internal citation omitted).

In addition to failing to take any steps to validate the estimates from the 1984 reports, Dr. Sahu concludes—"without citing to any counter-vailing site-specific data"—that UCC had *underestimated* the fugitive emissions estimates provided to the WVAPCC. *Id.* at 10 (citing [ECF No. 309-2, at 23 (replying "no" when asked whether there was any site-specific information he had relied on for his conclusion that UCC had underestimated its fugitive emissions numbers)]); *see* [ECF No. 309-2, at 24]. Sahu's unsupported speculation as to the validity of UCC's reported figures does not lend to his opinions' admissibility. *See* Fed. R. Evid. 702 advisory committee's note (2000 amends.) ("The trial judge ... must find that [the proffered testimony] is properly grounded, well-reasoned, and *not speculative* before it can be admitted.") (emphasis added); *see also* Itzchak E. Kornfeld, *A Postscript on Groundwater Modelling:* Daubert*, "Good Grounds," and the Central Role of Cross-Examination*, 29 Tort & Ins. L.J. 646, 646 (1994) ("When the model is speculative, show it for what it is. Defective.").

Ultimately, Dr. Sahu's modeled EtO concentrations for the year 1984 are "over *100 times greater*" than the estimates for some of the other years in the potential class period. [ECF No. 310, at 16 (emphasis

in original)]; *see* [ECF No. 390-3, at 78–79 (Tables 10–12)]. This prodigious inconsistency should prompt most experts to re-evaluate the validity of their underlying data. Dr. Sahu, however, stands by his position in his rebuttal report, claiming that because Defendants failed "to refine and create their own and better inventory," his use of "reported emissions, along with engineering [judgment] when no data was available and where gaps had to be filled" renders his analysis "reliable, robust, and a likely under-prediction of actual emissions." [ECF No. 309-6, at 15]. But this statement is contrary to logic, for an estimate cannot be both "a likely *under-prediction*" and a *reliable* estimate of total exposure based on those emissions.

b. 1985–1989

Next, for the period of 1985 through 1989, Dr. Sahu relies on the Toxic Air Pollutant Facility Registration Summary Sheets for both Facilities, which he "interpret[s] as emissions for year 1989." *See* [ECF No. 390-3, at 58]. He then assumes that emissions for 1985 through 1988 "were the same as 1989." *Id.* But this approach also drastically affects the reliability of Dr. Sahu's estimates because the reported data on which Dr. Sahu relies did not reflect reality.

The summary sheets used by Dr. Sahu clearly indicate that the values listed are "estimates for maximum toxic air pollutant emissions," not *actual* emissions. *See* [ECF No. 309-1, at 27 (Figure 5)]; *id.* at 26 ("These Registration Summary Sheets reported *potential*, or maximum possible emissions of these facilities to WVDEP, not actual emissions.") (emphasis in original). This was also echoed in a July 1990 office memorandum from an operator at the Institute facility. [ECF No. 309-8, at 2 (describing the emissions to be reported on the registration sheets as "*maximum*

emissions based on *unit design capacity*, not on *actual* production rates and hours") (emphasis in original)]. When confronted with this information, Dr. Sahu stated that it was his understanding that the figures represented on the summary sheets "were the estimates for actual emissions." [ECF No. 309-2, at 35]. He further stated that he had reached this conclusion solely because the values listed on the summary sheets changed over time, and in his opinion, if those values were "based on maximum production capacity," then they "would not change over time." *Id.*

Dr. Sahu addresses the issue of data stagnation in his rebuttal report, stating that he had "been able to locate little data in the historical record which [spoke] to the mass of EtO emissions from either facility from 1985–1988." [ECF No. 309-6, at 28]. He argues, however, that "EtO emissions were not zero in this period" and that he fills the data gap "consistent with standard practice" by using "data from the years proximate (in this instance, 1989)." *Id.* He further claims that "[t]here were no process changes [he] could identify in the record between 1989 and the gap years," which would make his assumption reasonable. *Id.* However, he makes no mention of the true issue here: that the data he uses for these years was based on the potential maximum emission rates, not actual emissions.

Dr. Sahu's reliance on these "worst-case emissions rates," [ECF No. 310, at 17], damages the reliability of Dr. Sahu's report because his estimates do not "reflect site-specific data on operating scenarios" for the South Charleston facility for 1989, let alone for the entire period from 1985 to 1989. [ECF No. 309-1, at 26].

c. 1990–2019

Finally, for the 29-year period from 1990 to 2019, UCC claims that Dr. Sahu "relie[s] on emissions estimates reported by UCC pursuant to regulatory requirements and accepted all reported emissions without analysis." [ECF No. 310, at 10–11]; *see also* [ECF No. 309-1, at 27 ("From 1990–2019, Sahu relies on 'self-reported data' submitted under [Toxic Release Inventory ('TRI')] and WVDEP annual emissions inventory requirements for [UCC's] operations at the South Charleston facility.")]. Dr. Sahu states in his report that "[f]or the period 1990–1995, emissions of EtO were estimated based on TRI reporting by UCC since no other sources of data were identified which documented the amount of EtO released by emission point." [ECF No. 309-3, at 62]. The emissions for "each individual fugitive and point source" for this period "were assumed to be in the same proportion as 1996." *Id.*

In his responsive report, Machado argues that these regulatory reports "were not intended or designed for exposure reconstruction," and Dr. Sahu's use of them for that purpose presents serious methodological issues. [ECF No. 309-1, at 8].

> Regulatory submittals are not always specific as to the source of emissions. For example, TRI reports "stack" and "fugitive" emissions but does not specify which stacks or which fugitive emissions. Sahu attempts to allocate emissions from regulatory submittals to various sources. For example, he states, "*Emissions from 1990–1995 for each individual fugitive and point source were assumed to be in the same proportions as 1996.*" ... This would only be true if each emission source was used in the same proportion to each other each year,

> which is not the case since different sources are related to different product manufacturing, and the amount of each type of product produced depends on customer demand.... accurate year-by-year estimates are critical, and Sahu's model results that use average emission allocation factors rather than year-specific allocation factors misconstrue actual exposure. In conclusion, it is evident that Sahu's wholesale adoption of regulatory submittals without any rigorous review of intent and purpose resulted in the improper application of emission inventories for purposes of exposure reconstruction.

Id. at 34. (emphasis in original).

In response to this criticism, Dr. Sahu attacks Machado's findings, claiming that Machado "attempts to clumsily discredit the emissions that his own client reported" and used particular evidence to make "purposefully misleading" arguments. [ECF No. 309-6, at 14]. According to Dr. Sahu, "all [Machado] presents is an illogical phobia of anything that may have some contact with regulatory agencies, and an impossible standard that plaintiffs in litigation must somehow go back in time and force companies to collect better contemporaneous data." *Id.* He claims that Machado is "off base when he claims that inventories reported to agencies have no use in estimating exposures," because "WVDEP believes [required annual emissions] inventories are reliable for modeling toxic exposures and eliminating risks." *Id.* at 15–16 (internal citation omitted).

Overall, this issue comes down to a lack of validation. "Generally, scientific methodology involves 'generating hypotheses and testing them to see if they can be falsified.' " *Nease*, 848 F.3d at 232 (quoting

Daubert, 509 U.S. at 593). As noted in *Coleman*, "the accuracy of [a] model depends upon the rigor applied in the input gathering process." 2013 WL 5461855, at *24. It is troubling that Dr. Sahu has repeatedly failed to make any attempt to validate the available data or the assumptions he makes in determining his estimated exposure, despite agreeing that it is "an important part" of his role in this case to determine whether the data presented "is, in fact, valid and appropriate" for its used purpose. [ECF No. 309-2, at 97]. Not only that, but Dr. Sahu has also repeatedly failed to validate the data he used in *forming* his hypotheses. *See id.* at 74–75 (Dr. Sahu responding that he "stuck pretty much to reported information" in response to being asked whether he "under[took] any sort of validation process with any of the emissions data that ended up as inputs" in his model); *id.* at 150–51 (confirming that he did not do "any kind of verification or validation of the 1984 numbers" because he "trusted the emission reporting by UCC in 1984"); *id.* at 160 (again confirming he did no "sort of validation for the 1984 data"); *id.* at 201 (admitting that he did not test the validity of his conclusion that nationwide NATA concentrations were "more conservative" than statewide concentrations). And while trained experts can, and often do, extrapolate from existing data, the court is not required to automatically treat such data as reliable or accurate. *See Gen. Elec. Co.*, 522 U.S. at 146. As such, it is nondeterminative that Dr. Sahu appeared to have used data from UCC's emissions estimates because he failed to validate it. The use of this unvalidated input data—which Dr. Sahu assumes remained unchanged throughout multi-year periods—evidences that there are serious flaws not only in his methodology but also in the conclusions that he has reached. *See id.* (stating that "conclusions and methodology are not entire-

ly distinct from one another"). This continued failure to validate, again, casts doubt on the reliability of Dr. Sahu's model.

2. Emission Dispersion Characteristics/Meteorological Data

Next, the court has grave concerns about the meteorological data that Dr. Sahu relies on in determining emissions dispersion characteristics.

> Once a substance is released into the atmosphere, downwind dispersion of it is largely driven by meteorological considerations. In reality, dispersion of the material takes place on both a very small (micro) scale and on a larger (macro) scale. On the microscale, small areas of turbulence, referred to as eddies, are generated by nearby structures (trees, buildings, etc.), thermals, and split-second variations in wind speed and direction.... A majority of air dispersion models predict downwind concentrations using mathematical algorithms that describe macroscale effects. Wind speed, wind direction, ambient temperature, and stability are the most-common inputs to these simplified Gaussian models. Wind speed drives the rate of transport, degree of shearing, and instantaneous concentrations. Wind direction determines which geographical areas are exposed; ambient temperature influences the rise of the material above the ground; stability dictates the level of mixing of the material with the ambient air.

Wilson et al., *Tracking Spills and Releases, supra*, at 390.

According to Dr. Sahu's report, "[f]or modeling of emissions from the South Charleston facility source

units for all years between 1984 and 2019, hourly on-site wind speed and wind direction data collected between December 5, 1985[,] and December 5, 1986[,] were combined with twice-daily upper air radiosonde data[9] from Huntington, [West Virginia][10] to create a single annual meteorological dataset for input." [ECF No. 309-3, at 76]. For the 39 non-flare Institute sources, Dr. Sahu models emissions for all years between 1984 and 2019 by using "a similar annual dataset" that "was created using hourly on-site wind data collected between December 6, 1985[,] and December 6, 1986[,] at a site adjacent to the Institute facility," which was also combined with the same upper-air radiosonde data from Huntington. *Id.* "Hourly wind data from Yeager Airport (located 7 km east of the [South] Charleston facility) were used for hours in which the on-site data for either [South] Charleston or Institute were missing and for other required meteorological parameters such as atmospheric pressure, relative humidity, cloud cover, and precipitation." *Id.* at 76 n.85. Surface characteristics, also referred to by Dr. Sahu as "land-use" characteristics, "were developed for the areas surrounding each of the

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[9] According to the National Oceanic & Atmospheric Administration, a radiosonde is "a small instrument package that is suspended below [a] balloon filled with either hydrogen or helium," and "[a]s the radiosonde is carried aloft, it measures pressure, temperature, and relative humidity." *Radiosondes*, Nat'l Oceanic & Atmospheric Admin., https://www.noaa.gov/jetstream/upperair/radiosondes (last visited Mar. 12, 2024). Additionally, "[b]y tracking the position of the radiosonde in flight via GPS (Global Positioning System), measurements of wind speed and direction aloft is also obtained." *Id.*

[10] The straight-line distance between Huntington and South Charleston is approximately 41 miles, while the straight-line distance between Huntington and Institute is approximately 37 miles.

three locations where hourly wind data were collected (South Charleston, Institute, and Yeager Airport)." *Id.* Additionally, for "the two elevated Institute flares," Dr. Sahu collected hourly meteorological data from the Yeager Airport "for each year between 1990 and 2019," which was then "combined with twice-daily upper air radiosonde data collected at Huntington, [West Virginia] for 1990 through 1994, at Dulles Airport, [Virginia][11] for 1995, and at Roanoke, [Virginia][12] for 1996 through 2019." *Id.* at 77. This information was then used to model emissions for these flares for 1984 through 2019. "Surface (land-use) characteristics ... were developed for the area surrounding the Yeager Airport met tower," and because "[c]omplete hourly surface meteorological data were not available at the Yeager Airport for 1984 through 1989," Dr. Sahu uses meteorological data from 1990 for those years. *Id.*

The Defendants argue that Dr. Sahu's methodology is flawed because he "applie[s] three different, contradictory sets of meteorological data taken from different locations in a single year (1986) to model emissions and add[s] the results together." *Id.*; *see also* [ECF No. 328, at 16 (stating that "the model Dr. Sahu elected to use, AERMOD, is only capable of modeling one set of meteorological data at a time.... So, Dr. Sahu ran a separate model for each set of meteorological data he chose to use[ ] and added them on top of each other.")]. "Specifically, he use[s] data from outside Kanawha Valley to model flare emissions and data from inside the valley to model non-flare emissions

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[11] The straight-line distance from Dulles Airport, Va. to Institute, W. Va. is approximately 239 miles.

[12] The straight-line distance from Roanoke, Va. to Institute, W. Va. is approximately 126 miles.

and sum[s] them together—assuming that the non-flare and flare meteorological data sets impacted all modeled locations across the modeling domain equally, even if the modeled receptors differ in terms of whether they are inside or outside of the valley." *Id.* (citing [ECF No. 309-3, at 76–77]). Additionally, Defendants assert that Dr. Sahu has done "nothing to ensure that the meteorological data was consistent." [ECF No. 328, at 16]. I agree.

Dr. Sahu's method was to use three different sets of meteorological data from surrounding geographic locations, which is ultimately not representative of the South Charleston facility. The EPA promulgated guidelines for its own air quality modeling, which can help provide guidance in this case. It provides that "meteorological data used as input to a dispersion model should be selected on the basis of spatial and climatological (temporal) representativeness." 40 C.F.R. Pt. 51, App. W § 8.4(b); *see also Marias v. EPA*, 906 F.3d 1069, 1077 (D.C. Cir. 2018) (explaining how the EPA's air quality modeling guidelines assess representativeness in response to a challenge to the EPA's designation of an area as having high levels of sulfur dioxide) *order clarified*, No. 16-1314, 2019 WL 1096761 (D.C. Cir. Feb. 22, 2019). The EPA looks at numerous factors to determine whether the input data is representative; these factors include "(1) the proximity of the meteorological monitoring site to the are under consideration; (2) the complexity of the terrain; (3) the exposure of the meteorological monitoring site; and (4) the period of time during which data are collected." *Marias*, 906 F.3d at 1077 (*quoting* 40 C.F.R. pt. 51, App. § 8.4(b)).

Applying this reasoning to this case, I do not find that the meteorological data Dr. Sahu uses when determining emissions dispersion characteristics is rep-

resentative of the South Charleston facility, rendering it unreliable. First, the three different locations have various wind patterns and directions, which were then combined to create cumulative exposure levels. Wind directions are highly variable; however, a single location—such as Plaintiff's residence—cannot have multiple wind speeds coming from various directions at one specific time. This in turn, renders the methods Dr. Sahu uses as unreliable because the model results in elevated cumulative exposure levels. This approach regarding meteorological data does not "tie with reality." *Coleman*, 2013 WL 5461855, at *26.

This issue is compounded when considering the geographical terrain of the area. West Virginia is a mountainous state, and the South Charleston facility is located in the Kanawha Valley. Ignoring the topographical characteristics of the region and using data from outside the valley without considering such terrain further indicates flaws in Dr. Sahu's use of such meteorological data as input to his dispersion model.

Finally, Dr. Sahu failed to assess year-to-year variability in wind speed or wind direction within the Valley, as he consistently applies the meteorological data for South Charleston from 1985–1986 to all of 1984 through 2019. As such, the period of time upon which his data was collected presumes that there have been no changes to the meteorological conditions near the South Charleston facility in the past 33 years. Ultimately, it fails to accurately explain or predict the concentrations, and it leads to further uncertainty in his models.

Dr. Sahu responds to the criticism of his model by arguing that "[i]t is entirely appropriate to use two different met data sets to disperse emissions from two sources when using a single met data set would

be inappropriate to disperse emissions from one of the sources." [ECF No. 309-6, at 37]. He claims that "[t]here is nothing inherently incorrect about adding the contributions from all the modeled sources to determine the total impact" and paints Machado's dissenting opinions as "speculative and unsupported rhetoric." *Id.* And while he concedes that Kanawha Valley "may have some differences" in wind direction and speed at different heights—"especially close to the ground"—he argues that "the data from 'outside' the valley will typically be a reasonable representation of the flow in the wider area." *Id.* Dr. Sahu also argues that "[i]t is highly unlikely that modeled annual averages will vary much using 'other' data, even if such additional on-site data was available." *Id.* at 36.

I find Dr. Sahu's response unpersuasive, especially in light of his failure to perform any additional testing to rebut or otherwise respond to Machado's assertions. One cannot reliably determine that potential variances would be minimal without having a legitimate basis for that determination. Ultimately, it does nothing to quell the court's concerns as to the reliability of Dr. Sahu's model and opinions.

3. Background EtO Levels

Finally, the Defendants argue that Dr. Sahu lacks a reliable method to estimate background levels[13] of EtO in the community. *See* [ECF No. 328, at 17 ("Dr. Sahu's opinions concerning background levels of [EtO] are ... unreliable because he selected a surrogate figure for background that was developed by the [EPA] that does not even attempt to represent back-

[13] "Background" refers to exposure levels experienced by the general population. *See Rhodes v. E.I. du Pont de Nemours and Co.*, 253 F.R.D. 365, 374–75 (S.D. W. Va. 2008) (Goodwin, J.).

ground, and Dr. Sahu ignored numerous, relevant alternative sources.")].

In his report, Dr. Sahu admits that although he is "aware of some recent ambient monitoring at a few locations designated as background," he feels that "the measured concentrations at these locations do not represent background" because (1) "the designated locations were selected with no underlying analysis or basis for their suitability to represent background concentrations," and (2) "even at these locations[,] monitoring has not been done for an extended time period[,] and therefore[,] annual average monitoring data are simply not available." [ECF No. 309-3, at 80]. However, he fails to indicate the source of this information or offer any additional details that would invalidate such data. Instead, he states that in determining a background level, he "relied on EPA's NATA database to obtain annual average concentrations of EtO," which showed an "annual average concentration for all U.S. exposures" of 0.000216 ug/m^3. *Id.* (citation omitted). He then compared that figure "against predicted model concentrations" to determine that "the class representatives were chronically exposed to levels far higher than national background levels." *Id.* "In fact," he claims, "in all years of their residency except 2019, the Class Representatives were exposed to levels that were more than 100x higher [than] national annual average background exposures." *Id.*

UCC argues that despite the EPA's statements that they "don't know what background levels for EtO are" and "can't put an exact number on it," Dr. Sahu "used one cherrypicked figure from the EPA to approximate the background concentration of EtO." *Id.* at 18–19 (citing [ECF No. 309-12, at 3]). According to UCC, this "surrogate figure" fails to "consider 'eth-

ylene oxide in the outdoor air that is not clearly linked to a particular industrial facility,' " and cannot, then, be considered a background level. *Id.* at 19 (citing [ECF No. 309-12, at 2 (defining the term "background ethylene oxide" as EtO "in the outdoor air that is not clearly linked to a particular industrial facility")]). UCC also claims that Dr. Sahu's figure "has nothing to do with the proposed class area" because Dr. Sahu used a national annual average instead of one specifically linked to the South Charleston area. *Id.* (citing *Dodge v. Cotter Corp.*, 328 F.3d 1212, 1225–26 (10th Cir. 2003) (stating that background concentration measurements should be "tied" to the proposed class area)).

Next, UCC disagrees with Dr. Sahu's contention that the locations designated as background in recent ambient air monitoring were "selected with no underlying analysis or basis for their suitability to represent background concentrations." [ECF No. 309-1, at 47 (citing [ECF No. 309-3, at 80])]. Instead, Machado asserts that the WVDEP, who completed that monitoring, "clearly explains" in their monitoring report that "[t]he background sites were chosen in areas where there were no known sources of EtO." *Id.* (citing *Ethylene Oxide (EtO)*), W. Va. Dept. of Env't Prot., https://dep.wv.gov/key-issues/Pages/EtO.aspx (last visited Mar. 18, 2024). The WVDEP's background measurements "ranged from 0.06 ug/m^3 to 1.71 ug/m^3, with several of the background samples indicating concentrations higher than those taken onsite or around the [F]acilities." *Id.* In fact, "[t]he highest measured background concentration, 1.71 ug/m^3, is higher than a *majority* of [Dr.] Sahu's modeled concentrations at the class representative location." *Id.* While Machado states that he "recognize[s] that WVDEP monitoring consists of snapshots in

time, not an annual average, and concentrations can fluctuate in a year," he proposes that WVDEP's data suggests that background EtO concentrations not linked to a particular facility "cannot be ignored." *Id.*

Machado also takes issue with Dr. Sahu's decision to use NATA annual average concentrations for all U.S. exposures as his EtO background level. *Id.* at 48. He argues that "NATA provides screening estimates of concentrations from modeling of emission sources and does not incorporate measured concentrations of background EtO in model results." *Id.* Further, "NATA modeling extends to the far reaches of the continental US, in areas remote from anthropogenic sources of EtO rather than the populated area represented in [Dr.] Sahu's modeled domain." *Id.*

In response to these criticisms, Dr. Sahu argues claims that "[b]ackground, *as relevant for this matter*, is the concentration of ethylene oxide at the locations of interest, *but for* the contributions from Defendants' plants and activities." [ECF No. 309-6, at 17]. "Background is not, as Mr. Machado (and others) presume, some measurement (or questionable quality) conducted by an agency for some other unknown purpose." *Id.* at 17–18. Because "no agency[—]or anyone else for that matter[—]has collected continuous measurements for one year or more in any location relevant to Plaintiffs' background," Dr. Sahu contends that his use of the NATA data is "appropriate and common." *Id.* at 18. He claims that he "looked at AirToxScreen results for the nationwide average across the entire US, consistent with its purpose" and not "to assess what any Plaintiff or Class Members' exposures are." *Id.* Additionally, Dr. Sahu argues that "[l]ike his other non-material and trivial criticisms," Machado's assertion that Dr. Sahu's use of a single year of NATA data in determining background

concentration levels for additional years is indicative of Machado's misunderstanding of "the relevant issue." *Id.* at 18–19. He claims that he is "not aware of any EPA guidance that contradicts" his approach. *Id.* at 19. I disagree.

The EPA has expressly indicated important limitations to user applications of its NATA data sets:

> EPA suggests that the results of this assessment be used cautiously, as *the overall quality and uncertainties of the assessment will vary* from location to location as well as from pollutant to pollutant. *In many cases more localized assessments, including monitoring and modeling, may be needed to better characterize local-level risk*....

The following are important specific limitations to recognize:

- The results apply to geographic areas, *not specific locations*....
- The results apply to groups*, not to specific individuals.*
- The *results are restricted to the year of the analysis* since emissions for that year were used....
- *The results do not fully reflect variation in background ambient air concentrations.*
- The *results might systematically underestimate ambient air concentration for some compounds.*

National Air Toxics Assessment: NATA Limitations, U.S. Env't Prot. Agency, https://19january2017snapshot.epa.gov/national-air-toxics-assessment/nata-limitations_.html (last visited Mar. 12, 2024) (emphasis added) [hereinafter NATA Limitations]. Moreover, "courts have consistently excluded expert

testimony that 'cherry-picks' relevant data." *Lipitor (Atorvastatin Calcium) Mktg. v. Pfizer, Inc.*, 892 F.3d 624, 634 (4th Cir. 2018) (quoting *EEOC v. Freeman*, 778 F.3d 463, 469 (4th Cir. 2015) (collecting cases)). This is because expert testimony based on cherry-picked data "does not reflect scientific knowledge, is not derived by the scientific method, and is not 'good science.' " *Id.* (quoting *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176 (N.D. Cal. 2007)).

In conflict with the EPA's statements that "the results are restricted to the year of the analysis," *see NATA Limitations, supra*, Dr. Sahu cites to only the 2019 AirToxScreen results and seems to compare these 2019 results to each year from 1984 to 2019. *See* [ECF No. 309-3, at 80]. Moreover, it is clear from the EPA's numerous statements that the background concentration levels of EtO are not known with any level of certainty. And despite there being a local monitoring report replete with information that Dr. Sahu could have potentially used in calculating a reasonable background level, Dr. Sahu chooses instead to ignore local data in lieu of using a national average from a single year—the validity of which is questioned even by the very entity that compiled the data. Although Dr. Sahu believes that the nationwide estimate is much more "rubust and representative," he provides no evidence to back up that statement aside from asserting that the "locations designated as background were not selected using any criteria designed to ensure that they are robust or representative estimates." Such self-serving statements do little to alleviate the court's concerns about his methodology.

"In the absence of individualized personal monitoring data, toxic tort litigants [attempt] to use air-

modeling techniques as evidence of a plaintiff's actual exposure." Jose A. Berlanga & Nancy J. Brown, *Establishing Tort Liability with Regulatory Tools? The Utility of Air Modeling as a Surrogate for Monitoring Data*, 3 Env't & Energy L. & Pol'y J. 1, 27 (2008). However, "while models are most reliable for estimating the highest concentration occurring within an area, they lack the fundamental capacity to show actual exposure to an individual at a precise location." *Id.* at 29. Further, "the sheer complexity of [the] mathematical computations [involved] suggests that those looking to air modeling data should proceed with caution, especially when applying models to ambient individual exposures." *Id.* at 30.

> In resolving challenges to models, most courts perpetuate the pervasive misunderstanding and assume that since the model is mathematical, it is correct. As a result, they pass the model through the system without much, if any, scrutiny. The dominant trend in the courts follows this deferential, deterministic path, even in cases when there are reasons to suspect that the model may have significant problems.

Wagner et al., *Misunderstanding Models, supra*, at 320; *see also* Swinehart, *Remedying* Daubert*'s Inadequacy, supra*, at 1296 (arguing that models "are not precise, and their remarkable value should not obscure the judicial inquity into model reliability."). I decline to take that path and find instead that where, as here, a plaintiff's claim rests in large part on one expert's determination of exposure, "[a]n in-depth data investigation, a searching historical analysis, an excruciating attention to detail, and a methodology designed to wring error out of the process seems especially *apropos.*" *Coleman*, 2013 WL 5461855, at

*24. Despite these methodological principles, Dr. Sahu has presented us with a model that is "a speculative conglomeration of data that is unreliable on the question of exposure" surrounding the South Charleston facility. *See id.* at *25. "This basic methodological flaw infects his entire analysis" and "makes for a patently unreliable measure of significant exposure to harmful substances, which is the central issue" in this case. *Id.*

I find that the opinions of Dr. Sahu are not based upon sufficient facts or data. However, even if that underlying data were sufficient, Dr. Sahu *application* of the data to the facts of this case was methodologically flawed, full of unsubstantiated assumptions, and not scientifically sound. Therefore, I find that his opinions are not the product of reliable principles and methods, and these methods have not been reliably applied to the facts of this case. As such, his opinions should be excluded for a lack of reliability under *Daubert.*

IV. Conclusion

Having considered the entirety of the challenge to Dr. Sahu, I **GRANT** the Defendants' Motions to Exclude his testimony and opinions. [ECF Nos. 309, 327].

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF
WEST VIRGINIA
CHARLESTON DIVISION.

Lee Ann SOMMERVILLE, et al., Plaintiffs,

v.

UNION CARBIDE CORPORATION, Defendant.

CIVIL ACTION NO. 2:19-cv-00878

Signed May 13, 2024

MEMORANDUM OPINION AND ORDER

JOSEPH R. GOODWIN, UNITED STATES DISTRICT JUDGE

This case involves a proposed medical monitoring class action against Defendants Union Carbide Corporation and Covestro, LLC, as the owners and operators of a manufacturing facility (the "Plant") in South Charleston, West Virginia, for alleged emissions of ethylene oxide ("EtO"), a known carcinogen. Plaintiff and proposed class members reside in neighborhoods surrounding the Plant, and their lawsuit is based on an alleged significant increase in their risk of developing cancer as a result of the Defendants' alleged EtO emissions.

The question before the court is whether Plaintiff's claim is justiciable in federal courts. The answer is no. I **FIND** that Plaintiff lacks standing to bring this claim in federal court and that it fails to meet ripeness requirements. This case is **DISMISSED**.

I. Procedural History

Plaintiff brought this action on December 6, 2019, [ECF No. 1], alleging five causes of action against UCC. After UCC moved to dismiss the Complaint, [ECF No. 13], and to strike the Complaint, [ECF No. 15], the court granted Plaintiff leave to file a First Amended Complaint, *see* [ECF Nos. 26, 27]. Plaintiff did so. On May 14, 2020, I granted in part UCC's Motion to Dismiss that First Amended Complaint, leaving only Plaintiff's medical monitoring claim pending. *See* [ECF Nos. 37, 47]. Plaintiff was then given leave to amend again, and on January 15, 2021, filed a Second Amended Class Action Complaint, maintaining a medical monitoring claim and adding eight new defendants. [ECF No. 85]. All Defendants, except UCC and Covestro, have since been dismissed from this action. *See* [ECF Nos. 170, 171, 174, 175, 185, 190, 193, 195, 196].

In her Second Amended Complaint, Plaintiff alleges that Defendants negligently and tortiously emitted EtO, causing her and the proposed class members to "have suffered significant exposure to hazardous EtO gases" as compared to the average person in the country, *id.* ¶ 59, and that Plaintiff and the class are, therefore, "at an increased risk of developing cancer," *id.* ¶ 62. She claims that the Defendants' wrongful conduct makes "periodic diagnostic medical examinations [ ] reasonably necessary," *id.*, and seeks "the quantifiable costs" of a medical monitoring regime, *id.* ¶ 86. Plaintiff specifically asks "[f]or damages in an amount determined just and reasonable to fund a medical monitoring program." *Id.* at 22.

EtO is a colorless, odorless gas produced in large volumes at some chemical manufacturing facilities. *See Our Current Understanding of Ethylene Oxide*

(EtO), U.S. Env't Prot. Agency, https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/our-current-understanding-ethylene-oxide-eto#what (last visited May 6, 2024). According to the United States Environmental Protection Agency ("EPA"), EtO is a known human carcinogen, and regular, long-term exposure to EtO can cause certain cancers of the white blood cells, including non-Hodgkin lymphoma, myeloma, and lymphocytic leukemia. *Id.* The primary way EtO enters the environment is by release into the air, and because of this, individuals who live near facilities that release EtO into the outdoor air may be exposed to EtO. *Id.*

Plaintiff alleges that companies in the United States became broadly aware of EtO's carcinogenic effects in 1977, and since that time, the National Institute of Occupational Safety and Health ("NIOSH"), the United States Department of Health and Human Services ("HHS"), the World Health Organization ("WHO"), and the EPA have continued to confirm EtO's carcinogenic and mutagenic properties. [ECF No. 85, ¶¶ 31–39]. Plaintiff contends that UCC is "the world's leading producer of EtO," and "the South Charleston Plant is one of the only facilities in the [United States] that manufactures EtO." *Id.* ¶ 28. UCC has allegedly owned and operated the South Charleston Plant since at least 1978, and in 2015, Covestro began operating polyols facilities at the Plant. *Id.* ¶¶ 41, 44. Plaintiff asserts that UCC and Covestro "operated without sufficient pollution controls to limit and/or eliminate the emissions of toxic EtO and, as a result, exposed thousands of residents in neighboring areas" to the carcinogen "for at least 41 years." *Id.* ¶¶ 48, 53.

Both Defendants have moved for summary judgment, arguing that Plaintiff has failed to satisfy the

required elements for her claim. Further, Defendant Covestro argues that Plaintiff lacks standing to bring this action, and that the relief requested is outside this court's equitable authority. *See* [ECF No. 380].

II. A History of Medical Monitoring

The origin of medical monitoring claims in federal courts is generally traced to *Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816 (D.C. Cir. 1984). In that case, the Court of Appeals for the D.C. Circuit permitted an award for medical monitoring after a plane transporting Vietnamese orphans decompressed and crashed, killing about half of the occupants and creating an increased risk that the surviving orphans would develop a neurological development disorder. Herbert L. Zarov et al., *A Medical Monitoring Claim for Asymptomatic Plaintiffs: Should Illinois Take the Plunge?*, 12 DePaul J. Health Care L. 1, 34 (2009); *Friends for All Children*, 746 F.2d at 822–23. The D.C. Circuit found that there had already been a present insult to a cognizable right caused by the force of impact—i.e., an injury—and medical monitoring was simply awarded to determine the *extent* of that injury. *See* Victor E. Schwartz & Cary Silverman, *The Rise of "Empty Suit" Litigation: Where Should Tort Law Draw the Line?*, 80 Brook. L. Rev. 599, 612 n.53 (2015) ("Unlike the situation in modern medical monitoring cases in which a plaintiff with no present physical injury seeks recovery for exposure to a harmful substance, the orphans had suffered an objective, verifiable physical injury in an airplane crash."). The court reasoned that if a defendant negligently invades an individual's interest in avoiding expensive diagnostic examinations, "the injury to which is neither speculative nor resistant to proof, it is elementary that the defendant should make the plaintiff whole by paying

for the examinations." *Friends for All Children*, 746 F.2d at 826. The court, in "[f]inding that the equitable remedy of in-kind provision of diagnostic examinations now was preferable to legal damages proved later at trial," ordered the manufacturer of the aircraft to pay into a court registry to reimburse the plaintiffs' expenses incurred from diagnostic examinations. George W.C. McCarter, *Medical Sue-Veillance: A History and Critique of the Medical Monitoring Remedy in Toxic Tort Litigation*, 45 Rutgers L. Rev. 227, 234 (1993) (internal quotations omitted).

Shortly after the D.C. Circuit affirmed the district court's holding in *Friends for All Children*, two other federal appellate courts—the Fifth and the Third Circuits—also grappled with the concept of medical monitoring. *See Hagerty v. L & L Marine Servs.*, 788 F.2d 315, 319 (5th Cir. 1986), *reh'g denied*, 797 F.2d 256 (5th Cir. 1986) (holding that a plaintiff can recover damages for an increased risk of contracting cancer "only where he can show that [his] toxic exposure more probably than not *will* lead to cancer") (emphasis in original); *Herber v. Johns-Manville Corp.*, 785 F.2d 79, 82 (3d Cir. 1986) (outlining "the proposition that a future injury, to be compensable, must be shown to be a reasonable medical probability" and stating that "[t]he objective of this approach is not only to provide compensation for harm that is likely to occur but also to ensure that an award of damages is not made for an injury that probably will not be suffered").

The Supreme Court has considered medical monitoring only once—in 1997—when the Court rejected the cause of action as a cognizable tort under the Federal Employee's Liability Act ("FELA"). *See Metro-North Commuter R.R. Co. v. Buckley*, 521 U.S. 424 (1997). In *Buckley*, a plaintiff brought a lawsuit after

being exposed to asbestos at work but before developing any symptoms of an asbestos-related disease. *See id.* The Court expressed doubts about the cause of action, stating it was troubled "by the potential systemic effects of creating a new, full-blown, tort law cause of action" for medical monitoring under FELA. *Id.* at 443. After examining various cases from state supreme courts as well as federal courts interpreting state law, the Court noted that the cases which authorized recovery "in the absence of physical injury [did] not endorse a full-blown, traditional tort law cause of action for lump-sum damages." *Id.* at 440.

After *Buckley*, many states followed the Supreme Court's reasoning and rejected medical monitoring as a "non-traditional tort and remedy" for toxic tort exposure cases where the plaintiff did not experience a present physical injury. Schwartz & Silverman, *supra*, at 619 (explaining how "a flurry of state supreme courts" recognized that allowing medical monitoring due to mere exposure would constitute an unprecedented departure from the traditional elements of a tort action) (internal footnotes omitted).

III. Medical Monitoring in West Virginia

In West Virginia, the tort was wholly constructed by the Supreme Court of Appeals in *Bower v. Westinghouse Elec. Corp.*, 522 S.E.2d 424 (W. Va. 1999). That is, there was no statutory authority nor settled common law predicate for a claim for medical monitoring. Rather, the court created a state cause of action for medical monitoring allowing for unrestricted relief absent present physical injury. *See Bower*, 522 S.E.2d at 431 (holding that "a plaintiff asserting a claim for medical monitoring costs is not required to prove present physical harm resulting from tortious exposure to toxic substances"). Rather than a remedy based on traditional tort law, the *Bower* court created

a broad cause of action allowing for a wide range of relief based upon an "increased risk" of future harm. *Id.* at 433.

To prevail on a medical monitoring claim under West Virginia law, a plaintiff must prove only that:

> (1) [s]he ... has, relative to the general population, been significantly exposed; (2) to a proven hazardous substance; (3) through the tortious conduct of the defendant; (4) as a proximate result of the exposure, plaintiff has suffered an increased risk of contracting a serious latent disease; (5) the increased risk of disease makes it reasonably necessary for the plaintiff to undergo periodic diagnostic medical examinations different from what would be prescribed in the absence of exposure; and (6) monitoring procedures exist that make the early detection of a disease possible.

Rhodes v. E.I. du Pont de Nemours & Co., 253 F.R.D. 365, 372–73 (S.D. W. Va. 2008) ("*Rhodes I*") (quoting *Bower*, 522 S.E.2d at 432–33).

IV. Justiciability

I have previously expressed my skepticism about the viability of medical monitoring as a tort in light of Article III's justiciability doctrines. *See Rhodes v. E.I. du Pont de Nemours & Co.*, 657 F. Supp. 2d 751, 755 (S.D. W. Va. 2009) ("*Rhodes II*") (explaining how medical monitoring is "a recently recognized and much criticized cause of action"); *Letart v. Union Carbide Corp.*, 461 F. Supp. 3d 391, 397 (S.D. W. Va. 2020) ("I remain skeptical about the injury element of a medical monitoring cause of action."). However, this is the first instance in which a party in my court has raised

a justiciability issue in a toxic exposure medical monitoring claim.[1]

The justiciability doctrines "assure that the functional requisites of adjudication are met," "conserve judicial resources by excluding cases unsuitable for judicial decision-making," and "also allocate power between the branches of the government to maintain the structural integrity outlined in the Constitution." Isil Yildiz, Note, *Standing First: Addressing the Article III Standing Defects of Rule 23(b)(3) Class Actions Composed Wholly of Future Claimants*, 26 Rev. Litig. 773, 779–80 (2007). This case is before this court based on diversity jurisdiction under 28 U.S.C. § 1332(a). Therefore, West Virginia substantive law applies. *See Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 73 (1938) ("[F]ederal courts exercising jurisdiction in diversity of citizenship cases [should] apply as their rules of decision the law of the State."). However, for purposes of Article III justiciability, it is not dispositive that a state judiciary has recognized a cause of action in state courts. *See Hollingsworth v. Perry*, 570 U.S. 693, 715 (2013) (explaining that states cannot give private parties who otherwise lack standing "a ticket to the federal courthouse"). Article III justiciability is a question of federal law. *See Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 804 (1985) ("Standing to sue in any Article III court is, of course, a federal question which does not depend on the party's prior standing in state court."); *Miller v. Redwood Toxicology Lab'y, Inc.*, 688 F.3d 928, 934 (8th Cir. 2012) (quoting *Perry v. Brown*, 671 F.3d 1052, 1074

[1] Although medical monitoring was mentioned in *Chambers v. Actavis Totowa, LLC*, No. 2:08-cv-01175, 2010 WL 2509774 (S.D. W. Va. June 17, 2010), that case dealt with the plaintiff's standing to bring an economic-loss claim based on a recalled medication. I found there was no standing.

(9th Cir. 2012)) (stating that while "[s]tate courts may afford litigants standing to appear where federal courts would not," state conferrals of standing "[have] no bearing on the parties' Article III standing in federal court"). Therefore, a plaintiff seeking to bring a medical monitoring claim under West Virginia law in federal court must go beyond merely proving the elements required by West Virginia law; they must also independently satisfy Article III's requirements. *See Wilding v. DNC Servs. Corp.*, 941 F.3d 1116, 1125 (11th Cir. 2019) ("Article III's standing requirements apply to state-law claims brought in federal court.").

A. Separation of Powers Concerns

Article III of the United States Constitution limits the jurisdiction of federal courts to only "Cases" and "Controversies." U.S. Const. Art. III, § 2. "The case or controversy requirement ... includes more specialized notions of ripeness, mootness, and standing to sue, and prohibits consideration of constitutional issues except as a necessary incident to the resolution of a concrete 'case' or 'controversy.' " Lea Brilmayer, *The Jurisprudence of Article III: Perspectives on the "Case or Controversy" Requirement*, 93 Harv. L. Rev. 297, 297 (1979).

The "primary function" of the case or controversy requirement "is the preservation of the separation of powers." Note, *And Justiciability for All?: Future Injury Plaintiffs and the Separation of Powers*, 109 Harv. L. Rev. 1066, 1072 (1996) [hereinafter *And Justiciability for All?*]; *see also* Jerett Yan, Note, *Standing as a Limitation on Judicial Review of Agency Action*, 39 Ecology L.Q. 593, 596 (2012) (arguing that this limitation exists to ensure that the judiciary's use of its power "does not intrude on the prerogatives of the other branches"); *Hein v. Freedom from Religion Found., Inc.*, 551 U.S. 587, 598 (2007) ("No prin-

ciple is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.") (internal quotation marks and citations omitted). "[U]nder our tripartite system of government, each branch is responsible for various spheres of activity." *And Justiciability for All?, supra*, at 1076. "Stated in its simplest terms, the separation of powers doctrine prohibits each branch of the government from 'intruding upon the central prerogatives of another.' " *United States v. Moussaoui*, 382 F.3d 453, 469 (4th Cir. 2004) (quoting *Loving v. United States*, 517 U.S. 748, 757 (1996)).

B. Standing[2]

1. Purpose and Requirements

"Standing to sue is a doctrine rooted in the traditional understanding of a case or controversy." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). According to the Supreme Court, the "single basic idea" informing the development of the standing doctrine is "the idea of separation of powers." *Raines v. Byrd*, 521 U.S. 811, 820 (1997); *see also Allen v. Wright*, 468 U.S. 737, 752 (1984) ("[T]he law of Art. III standing is built on a single basic idea -- the idea of separation of powers.").

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[2] It should be noted that of the courts of appeals that have discussed the viability of medical monitoring, the majority have done so without an in-depth analysis or discussion of Article III standing. For instance, in *In re Paoli R.R. Yard PCB Litig.*, the Third Circuit failed to even address standing. 916 F.2d 829 (3d Cir. 1990). The Sixth Circuit, meanwhile, reasoned that it need not discuss standing because the Supreme Court, in rejecting medical monitoring, did not address standing. *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568 (6th Cir. 2005).

To establish Article III standing, a plaintiff must show that (1) he suffered an injury-in-fact that is both concrete and particularized, as well as either actual or imminent; (2) the injury was likely caused by the defendant; and (3) the injury is redressable by judicial relief. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992) ("*Lujan I*"). "The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing these elements." *Spokeo*, 578 U.S. at 338 (citing *FW/PBS, Inc. v. Dallas*, 493 U.S. 215, 231 (1990)). These elements must be supported "in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." *Lujan I*, 504 U.S. at 561. At the summary judgment stage—where this case currently stands—a plaintiff must "set forth" specific facts or evidence to be taken as true if he is to survive a standing challenge. *Id.*

Each of the three standing requirements shares a common purpose: "to ensure that the judiciary, and not another branch of government, is the appropriate forum in which to address a plaintiff's complaint." *See Friends of the Earth, Inc. v. Gaston Copper Recycling Corp.*, 204 F.3d 149, 154 (4th Cir. 2000); *see also* F. Andrew Hessick, *The Separation-of-Powers Theory of Standing*, 95 N.C.L. Rev. 673, 680 (2017) ("The role of standing is to ensure that the judiciary does not usurp the role of the legislative and executive branches by limiting the circumstances under which the judiciary can act."). For instance, "Congress has expansive power ... to pass legislation to redress perceived social, economic, and other problems" by effectively "anoint[ing] certain parties to be the beneficiaries of legislation: those who are injured by a violation of the law and for whom a cause of action is expressly

or impliedly created." David A. Logan, *Standing to Sue: A Proposed Separation of Powers Analysis*, 1984 Wis. L. Rev. 37, 59 (1984). This power is conferred upon Congress due to its "ability to inquire into social problems, to identify their causes, and to prescribe remedies." *Id.* at 62.

Regrettably, growing challenges to the executive and legislative branches of our government are resulting in the forced resolution of policy issues through litigation in the judicial arena. "It is in these ... cases that courts have too strong an incentive to overstep their powers and infringe on what properly is the role of Congress." Jeremy Gaston, Note, *Standing on Its Head: The Problem of Future Claimants in Mass Tort Class Actions*, 77 Tex. L. Rev. 215, 244 (1998); *see also Gaston Copper*, 204 F.3d at 164 (Neimeyer, J., concurring) (stating that with the increasing relaxation of standing's injury-in-fact requirement, the "scope of Article III power expands," putting courts in the position of the legislature and requiring the judiciary to "resolve contests over legislation simply because citizens disagree with its interpretation.").

2. Injury-in-Fact

Of special concern in analyzing standing in this case is the requirement that a plaintiff allege a sufficient injury-in-fact. Although some courts have treated injury-in-fact "an elastic concept" that courts "may construe broadly," I disagree, finding instead that separation of powers principles require that the sufficiency of an alleged injury not hinge on judicial whims. Logan, *supra*, at 43–44. Rather, current binding precedent has firm requirements for an injury-in-fact under Article III: an injury-in-fact must be concrete, actual or imminent, and particularized. *TransUnion, LLC v. Ramirez*, 594 U.S. 413, 423

(2021); *Spokeo*, 578 U.S. at 334 (explaining that a plaintiff must allege an injury that is both "concrete *and* particularized") (quoting *Laidlaw*, 528 U.S. at 180–81) (emphasis in original). I will address each of these requirements in turn.

a. Particularization

For an injury to satisfy the particularization requirement, it "must affect the plaintiff in a personal and individual way." *Spokeo*, 578 U.S. at 339. I **FIND** that Plaintiff has sufficiently asserted that her alleged injury has affected her in a personal and individualized way, and therefore, she has satisfied the particularization required to establish an injury-in-fact.

But particularization alone is not enough. *Id.* The injury must also be actual or imminent, as well as concrete. *TransUnion*, 594 U.S. at 423.

b. Actual or Imminent

When an injury is actual, it is a present injury—*i.e.*, it has already occurred or is presently occurring. Of the states that acknowledge medical monitoring as an independent tort, most require that a plaintiff demonstrate a present injury or illness. *See What is Medical Monitoring?*, Mass Tort Inst. (May 28, 2021), https://www.masstortinstitute.com/blog/what-is-medical-monitoring. However, some courts have held that threatened injury may constitute an injury-in-fact sufficient to establish standing under Article III, provided that the threatened injury is imminent. *See Gaston Copper Recycling Corp.*, 204 F.3d at 160 (holding that "[t]hreats or increased risk [] constitutes cognizable harm")[3]; *see also* Diana R. H. Winters,

[3] Relying on the holding by Supreme Court of the United States in *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*,

False Certainty: Judicial Forcing of the Quantification of Risk, 85 Temp. L. Rev. 315, 336 (2013) ("Probabilistic injury is based on the idea that a plaintiff is at an increased risk of harm due to the defendant's actions, and that this increased risk constitutes a harm in and of itself."). When an injury is *imminent*, it is certain or reasonably probable to occur.

Which standard applies—present or imminent—largely depends upon the type of relief requested, and "[a] plaintiff must 'demonstrate standing separately for each form of relief sought.' " *TransUnion*, 594 U.S. at 436 (quoting *Laidlaw*, 528 U.S. at 185). A claim for damages requires present injury, whereas claims for injunctive relief require only imminence. These principles were articulated in the recent Supreme Court case of *TransUnion.* In that case, the Court recognized that a plaintiff seeking *damages* must prove a *present* concrete harm to have Article III standing. *Id.* at 417 ("No concrete harm, no standing."). Meanwhile, "a person exposed to a risk of *future harm* may pursue *forward-looking, injunctive relief* to prevent the harm from occurring, at least so long as the risk of harm is sufficiently imminent and substantial." *Id.*

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528 U.S. 167 (2000), the Fourth Circuit explained that "[t]hreatened environmental injury is by nature probabilistic." *Gaston Copper*, 204 F.3d at 160. *Gaston Copper* was a citizen suit under the Clean Water Act, a strict liability statute that allows citizens to sue based on an unlawful discharge that affects the citizens' interests—in that case, plaintiffs' recreational interests in the polluted waters. Notably, the Clean Water Act, itself, limits citizen suits to injunctive relief and civil penalties. There is no allowance in the Act for damages awards directly to plaintiffs. Therefore, it is reasonable that for a threatened environmental injury, the lesser injury standard be allowed. But where, as here, a plaintiff is seeking monetary damages based on a future personal injury, more is required. *See TransUnion*, 594 U.S. at 417.

at 435 (emphasis added). This aligns with the long line of cases decided by the Supreme Court of the United States and the Court of Appeals for the Fourth Circuit, wherein those courts have found standing based on an injury that is by nature "probabilistic," such as the environmental injury in *Gaston Copper*, when the plaintiffs invariably requested *injunctive relief* to redress their injury. *See Laidlaw*, 528 U.S. 167; *Sierra Club v. Morton*, 405 U.S. 727 (1972); *Lujan II*, 497 U.S. 871; *City of Los Angeles v. Lyons*, 461 U.S. 95 (1983) (finding that the plaintiff lacked standing not due to the structure of the requested relief—injunctive in nature—but rather because the plaintiff could not allege a realistic threat).

I note that *TransUnion* was decided in 2021, after I had issued the opinions in *Rhodes* and *Letart.* The Supreme Court's holding in *TransUnion* makes clear to me that claims for medical monitoring seeking damages[4] without a manifest injury do not satisfy the injury-in-fact requirement for Article III standing.

Under West Virginia law, "a plaintiff asserting a claim for medical monitoring costs is not required to prove present physical harm resulting from tortious

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[4] Whether the remedy of medical monitoring is treated as a claim for damages or injunctive relief depends in part on how the request for medical monitoring is structured. *Easler v. Hoechst Celanese Corp.*, 7:14-00048-TMC, 2014 WL 3868022, at *6 (D.S.C. Aug. 5, 2014); *see also Werlein v. United States*, 746 F. Supp. 887, 895 (D. Minn. 1990), *vacated in part on other grounds, Werlein v. United States*, 793 F. Supp. 898 (D. Minn. 1992). Unless the requested medical monitoring program "goes beyond the payment of the costs of monitoring an individual plaintiff's health to establish pooled resources for the early detection and advances in treatment of the disease," the proposed program is not injunctive in nature and is "predominantly money damages." *Gibbs v. E.I. DuPont De Nemours & Co.*, 876 F. Supp. 475, 481 (W.D.N.Y. 1995) (internal quotation omitted).

exposure to toxic substances," even if he is seeking monetary damages. *Bower*, 522 S.E.2d at 431. Rather, the only " 'injury' required to prove a medical monitoring claim is a 'significantly increased *risk* of contracting a particular disease relative to what would be the case in the absence of exposure.' " *Rhodes v. E.I. du Pont de Nemours and Co.*, 636 F.3d 88, 98 (4th Cir. 2011) ("*Rhodes III*") (quoting *Bower*, 522 S.E.2d at 433) (emphasis added). This distinguishes West Virginia's law from that analyzed in *Hagerty*, 788 F.2d at 319, wherein the Fifth Circuit held that a plaintiff can recover damages for an increased risk of contracting cancer "only where he can show that [his] toxic exposure more probably than not *will* lead to cancer," and in *Herber*, 785 F.2d at 82, which supported "the proposition that a future injury, to be compensable, must be shown to be a reasonable medical probability."

Here, Plaintiff seeks monetary damages based on the premise that because Defendants emit EtO into the air and she, in turn, breathes that air, Defendants have put her and proposed class members at a higher risk of eventually getting cancer. [ECF No. 85, ¶¶ 83–84]. Plaintiff relies entirely upon expert opinions to prove her alleged increased risk of cancer development due to the alleged EtO emissions. But expert opinions are just that—opinions, not facts.[5] And in any event, the court has excluded Plaintiff's emissions expert, Dr. Sahu, because he used patently un-

[5] Courts permit experts to give opinion evidence so that it may help the jury determine or conceptualize certain complex issues. When the expert testimony offers an opinion that is identical to the sole question that the jury must decide, the court must be more careful regarding the reliability of that opinion. The expert testimony is central to the ultimate issue. In such circumstances, the gatekeeping function of the court is more important.

reliable data and methods in creating the air model used to determine the alleged estimated EtO emissions—and therefore the increased risk of disease—in the proposed class area. *See* [ECF No. 410]. This unreliable model was then used to assume that a speculative disease might someday materialize in some unknown person. This does not establish an imminent injury sufficient to survive a standing challenge.

Plaintiff has failed to provide any evidence of present injury beyond the speculative increase in risk. She cannot even accurately demonstrate the level of exposure for each proposed class member. And despite the prolonged period of potential alleged exposure at issue in this case—forty-one years—Plaintiff never claims that she or any proposed class member have experienced symptoms of a disease, let alone that any individual has actually developed cancer. She cannot prove that she or any class member *will* get cancer, or that it's even *more likely than not.* Rather, her claim is based entirely on the unsubstantiated possibility of future cancer diagnoses.

Medical monitoring claims face significant hurdles in establishing federal standing, particularly when, as here, the claim is premised on exposure without current symptomatic illness. "Risk, which is by definition only the possibility of harm, is speculative and amorphous." Winters, *supra*, at 315. As such, "courts grapple with the question of whether probabilistic harm, or harm based on increased risk itself, can ever satisfy injury in fact." *Id.* at 318. Courts do not provide damages to those who only speculate that they could potentially become injured one day if such injury is not imminent or actual. Plaintiff's injury cannot be sufficiently imminent when there is no evidence that the named plaintiff or any individual in the pro-

posed class will or is reasonably likely to develop cancer.

Under Article III, an injury must be more than conjectural. While a West Virginia state court may allow the cause of action to proceed, these allegations are not sufficient to confer federal standing.

c. Concreteness

Next, to be concrete, an injury must be real and not abstract. To be sure, concreteness does not necessarily equate to tangibility. The Supreme Court has repeatedly recognized that intangible harms can be sufficiently concrete. *See, e.g., Spokeo*, 578 U.S. at 340; *Pleasant Grove City v. Summum*, 555 U.S. 460 (2009); *Church of Lukumi Babalu Aye, Inc. v. Hialeah*, 508 U.S. 520 (1993). When evaluating whether an intangible harm is sufficiently concrete to be an injury-in-fact, one must consider whether Congress has spoken on the matter and whether the harm in question is one grounded in traditional common law. *Id.* at 340–41. This requirement ensures that federal courts exercise "their proper function in a limited and separated government." *TransUnion LLC*, 594 U.S. at 423 (quoting John G. Roberts, Jr., *Article III Limits on Statutory Standing*, 42 Duke L.J. 1219, 1224 (1993)).

I offer, first, the preliminary observation that this claim—medical monitoring—does not arise from any congressional act and is inconsistent with traditional common law. Congress may elevate otherwise concrete injuries "to the status of legally cognizable injuries" that were previously inadequate at law. *Lujan I*, 504 U.S. at 578. Similarly, "Congress has the power to define injuries and articulate chains of causation that will give rise to a case or controversy where none existed before." *Id.* at 580 (Kennedy, J., concurring). This power to identify and elevate intangible harms

to the status of actionable claims does *not* mean, however, that "a plaintiff automatically satisfies the injury-in-fact requirement" whenever the legislature creates a statutory right and purports by statute to authorize a person to enforce that right. *Spokeo*, 578 U.S. at 341. While Congress "cannot erase Article III's standing requirement" by granting standing to a plaintiff who would not otherwise have sanding to sue, *Raines*, 521 U.S. at 820 n.3, whether Congress has recognized a cause of action may be instructive of whether a harm meets the requirements of an injury-in-fact. *Spokeo*, 578 U.S. at 341. Medical monitoring is a type of tort claim, and it is widely understood that tort law, absent a few exceptions, is "a matter of state law rather than federal law." Andreas Kuersten, Cong. Rsch. Serv., IF11291, *Introduction to Tort Law* 1 (2023), https://crsreports.congress.gov/product/pdf/IF/IF11291. Here, the United States Congress has not codified a claim for medical monitoring. It has, however, created laws to regulate the emission of toxic chemicals, such as the Clean Air Act.[6]

The concreteness of Plaintiff's alleged injury is also undermined by the vague risk quantification standard imposed in *Bower*. Under West Virginia

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[6] As to EtO, the EPA announced on April 9, 2024, that it had promulgated a set of final rules under the Clean Air Act that "will significantly reduce emissions of toxic air pollution from chemical plants, including EtO." *Actions to Protect Communities and Workers from Ethylene Oxide (EtO) Risk*, U.S. Env't Prot. Agency, https://www.epa.gov/hazardous-air-pollutants-ethylene-oxide/actions-protect-communities-and-workers-ethylene-oxide-eto (last visited May 6, 2024). These rules are expected to "reduce the number of people with elevated air toxics-related cancer risks in communities" near plants that use or produce EtO. *Id.* According to the EPA, "the number of people with a potential risk of greater than or equal to one in one million will be reduced by approximately 92 percent." *Id.*

law, the injury in a medical monitoring cause of action is the significant increased risk of future disease. But what constitutes significance in this context? The *Bower* Court offers little guidance on that standard, merely stating that "[n]o particular level of quantification is necessary to satisfy this requirement." *Bower*, 522 S.E.2d at 433 (internal citation omitted). However, by requiring the increase in risk be significant, the *Bower* Court is, indeed, requiring that plaintiffs meet a certain threshold—which does, in fact, require quantification of risk—without concretely establishing what that threshold is in quantifiable terms.

Plaintiff attempts to address this gap in West Virginia's medical monitoring law by piggybacking on the Third Circuit's adoption of the EPA's one-in-a-million standard in *Redland Soccer Club, Inc. v. Dep't of Army of U.S.*, 55 F.3d 827 (3d Cir. 1995). However, even the Third Circuit was skeptical of the EPA's basis for that standard, stating:

> [n]o one points to any demographic, epidemiologic or any other type of scientific data, nor to any risk-utility analysis that supports EPA's million-fold regulatory factor as demonstrating the presence of a hazard, nor does this threshold appear in the regulatory or statutory history. Nevertheless, the million-fold factor seems ubiquitous in regulatory risk-utility determinations despite its indeterminate pedigree. We will assume that it has some rational basis and thus represents a regulatory determination to which we must defer in deciding plaintiffs' statutory claims. (citations omitted).

Redland Soccer Club, 55 F.3d at 840 n.7; *see also id.* at 847 n.9 ("We ... note again that EPA's basis for its use of the one-in-a-million lifetime ration to judge

significant exposure is not readily apparent. Nevertheless, we will assume a rational basis for EPA's one-in-a-million standard in defining 'significant' risk.").

I, too, am dubious of this standard and I am unwilling to assume it has a rational basis. In nearly every other context, a one-in-a-million risk is seen as a statistical anomaly, not "significant." For instance, if a doctor tells a patient that he has a one-in-a-million risk of a severe complication from a surgery, that risk is not cast as significant but rather the opposite. How, then, is a one-in-a-million increase in risk in contracting certain cancers considered significant?

Unlike the Third Circuit, I choose not to treat deference principles as "synonymous with a rubber stamp." Winters, *supra*, at 327. However, I also recognize that courts should not "put themselves in the business of assessing what constitutes an acceptable amount of increased risk for actual and concrete injury." *Id.* at 347. By forcing parties to quantify increased risk to prove injury, the process also forces courts to decide the acceptable amount of increased risk, *i.e.*, "to act legislatively—exactly the position courts [try] to avoid." *Id.* at 318. Although quantifying risk may appear to make an injury more "definable and assessable[,] ... [b]eneath the veneer of objectivity and certainty" in quantification of risk lies "a messy and subjective process." *Id.* at 317. The result is often an arbitrary—or, in this case, ambiguous—threshold that undermines the concreteness of a plaintiff's alleged injury.

For an injury to be concrete and real, rather than abstract, a plaintiff must prove that an increased risk is more than a mere possibility. And to satisfy *Bower*,

a West Virginia plaintiff must prove that the risk is significant. Plaintiff fails to prove either here.

In short, the alleged increased risk of harm seen in this case and allowed by West Virginia law—where there is a complete lack of evidence that the risk is both concrete and actual or imminent—does not satisfy the injury-in-fact requirements under Article III at the summary judgment stage. Because Plaintiff cannot establish standing to pursue her claim in federal court, it must be dismissed.

C. Ripeness

Finally, I am troubled that ripeness, another justiciability doctrine arising under Article III, also stands at odds with West Virginia's medical monitoring laws. *See Whitaker v. Monroe Staffing Servs., LLC*, 42 F.4th 200, 206 (4th Cir. 2022). While standing involves "the question[ ] of *who* may sue," ripeness involves "*when* they [may] sue." *Wild Va. v. Council on Env't Quality*, 56 F.4th 281, 293 (4th Cir. 2022) (emphases in original) (quoting *South Carolina v. United States*, 912 F.3d 720, 730 (4th Cir. 2019)). Whether a claim is ripe is a legal question governed by federal law. *See Sansotta v. Town of Nags Head*, 724 F.3d 533, 544 (4th Cir. 2013). The core of the ripeness doctrine is ensuring that the issues before the court are definite and concrete, not contingent or hypothetical. *See In re Naranjo*, 768 F.3d 332, 347 (4th Cir. 2014) (internal quotation marks omitted) ("A case is fit for adjudication when the action in controversy is final and not dependent on future uncertainties; conversely, a claim is not ripe when it rests upon contingent future events that may not occur as anticipated.").

For a case to be ripe, the event in question must be likely to occur with its effects felt in a concrete

way. The more speculative or unlikely the event, the less likely the case is ripe for adjudication. "To be sure, ripeness can rest on anticipated future injury," but that future injury cannot be "wholly speculative" or "rest[ ] upon contingent future events that may not occur as anticipated, or indeed may not occur at all." *Wild Va.*, 56 F.4th at 295 (internal quotation marks omitted) (quoting *South Carolina*, 912 F.3d at 730); *accord Clayland Farm Enters., LLC v. Talbot Cnty.*, 672 F. App'x 240, 244 (4th Cir. 2016) ("A claim should be dismissed for lack of ripeness if the plaintiff has not yet suffered injury and any future impact remains wholly speculative.") (internal quotation marks omitted); *A/S J. Ludwig Mowinckles Rederi v. Tidewater Constr. Corp.*, 559 F.2d 928, 932 (4th Cir. 1977) ("An important factor in considering ripeness is whether resolution of the tendered issue is based upon events or determinations which may not occur as anticipated.").

In reviewing whether a claim is ripe, the court must consider "(1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration." *Deal v. Mercer Cnty. Bd. of Educ.*, 911 F.3d 183, 191 (4th Cir. 2018) (internal quotation marks omitted); *see also Ohio Forestry Ass'n v. Sierra Club*, 523 U.S. 726, 733 (1998) (describing the considerations as "(1) whether delayed review would cause hardship to the plaintiffs; (2) whether judicial intervention would inappropriately interfere with further administrative action; and (3) whether the courts would benefit from further factual development of the issues presented"). In essence, the probabilistic nature of a future event demands a nuanced analysis of both how certain and imminent the event is as well as what the consequences of waiting for an event to materialize might be. These tenets en-

sure that the judicial system intervenes at appropriate times, balancing the need to address potential harms with the principle of not engaging in abstract or advisory rulings.

Where a plaintiff has alleged that a hypothetical number of people may become injured at some time in the future to a hypothetical degree and thus will incur hypothetical damages, I do not find that case fit for adjudication. That is precisely what Plaintiff claims here. In this case, Plaintiff contends that that as a result of Defendants' allegedly "negligent and tortious" emissions of EtO, she and the proposed class members "have suffered significant exposure to hazardous EtO gases relative to the general population in the [United States]," and are, therefore, "at an increased risk of developing cancer." [ECF No. 85, ¶¶ 59, 62]. Plaintiff relies entirely on the opinions of three experts to prove that Plaintiff and the proposed Class Members were significantly exposed to EtO in relation to the general population.[7]

However, not one of these experts can say with any level of certainty that Plaintiff or any of the proposed Class Members *will* develop cancer from Defendant's actions. Rather, this entire suit rests on the notion that a theoretical level of exposure *could* place

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[7] First, Plaintiff relies on Dr. Sahu's air model to illustrate "individual Class [M]embers' exposures based on location and duration of time at the location," thereby establishing the significance of each individual's exposure as compared to background levels. *See* [ECF No. 381, at 11–12]. Based upon Dr. Sahu's exposure analysis, "Dr. Wells provides relative risk calculations for lymphoid cancer," claiming "a 340.558-in-a-million increase in relative risk to Plaintiff resulting from exposure to Defendants' EtO emissions." *Id.* at 12. Id. Dr. Stayner, meanwhile, "offers opinions regarding the increased risk of lymphatic and hematopoietic neoplasms as a result of exposure to EtO." *Id.*

one at a higher risk to *maybe* develop certain cancers at some uncertain point in the future. This is exactly the type of "wholly speculative" future injury that the ripeness doctrine prohibits.

On this basis, I conclude that even if I were to find that Plaintiff has alleged a sufficient injury-in-fact to establish Article III standing, Plaintiff's claim would regardless not be justiciable in federal court because the claim for medical monitoring is not ripe.

V. Conclusion

Medical monitoring involves complex decisions requiring scientific and medical judgments. These decisions should not be left to the courts. "When adjudicating claims of probabilistic injury"—like the increased risk of disease alleged here—"courts express anxiety over whether they are overstepping the bounds of their proper authority and infringing on that of the legislative or executive branches." Winters, *supra*, at 351. As such, "[p]robabilistic harm raises the specter of activist judges making law," *id.*, because it "forces courts, by making a determination on the acceptable amount of increased risk, to act legislatively," *id.* at 318; *see also Pub. Citizen, Inc. v. Nat'l Highway Traffic Safety Admin.*, 513 F.3d 234, 242 (D.C. Cir. 2008) (Sentelle, J, concurring) (stating that "if we do not soon abandon this idea of probabilistic harm, we will find ourselves looking more and more like legislatures rather than courts").

In his dissent to *Bower*, Justice Maynard shared these concerns, asserting that, in creating this cause of action, the majority had "exceeded its legitimate [judicial] powers and usurped the function of the legislature" because the legislature alone "has the right to create new causes of action for the recovery of money." *Bower*, 522 S.E.2d at 435 (citing *Norfolk &*

W. Ry. Co. v. Pinnacle Coal Co., 30 S.E. 196, 197 (W. Va. 1898)). He characterized the majority's decision as providing a windfall for plaintiffs because one now may be compensated even when there is no injury. *Id.* Instead, "the practical effect of [the *Bower*] decision is to make almost every West Virginian a potential plaintiff in a medical monitoring cause of action." *Id.* Justice Ketchum mirrored these sentiments in his partial dissent in *Perrine v. E.I. du Pont de Nemours & Co.*, stating that prior to *Bower*, West Virginia law did not provide a cause of action "for the mere possibility of future harm, not yet realized." 694 S.E.2d 815, 918 (W. Va. 2010). He then warned that "[m]edical monitoring class action lawsuits will continue to mount if plaintiffs who are not sick or injured are allowed to pursue benefits for the mere possibility of future harm" and called on the West Virginia Supreme Court of Appeals to modify its law. *Id.* ("We should not allow an asymptomatic plaintiff to recover damages by way of medical monitoring for the possibility of contracting a disease in the unpredictable future."). Specifically, he states that plaintiffs should be required to "prove a present physical injury (or present disease) caused by the manufacturer or business" so as to "provide a clear standard as to when a plaintiff has a meritorious cause of action," thereby "eliminat[ing] damages for a mere possible future harm." *Id.* Finally, Justice Ketchum recognized that "[w]e must rely on government regulation to police the emission of toxic substances, not damage lawsuits of uninjured plaintiffs." *Id.* I note that the concerns of Justice Maynard and Justice Ketchum reflect state separation of powers and deal primarily with issues of policy in state government. These same concerns, when applied to federal courts, affect justiciability.

A grave and persistent concern of this court is the metastasis of the malignant belief that courts are the solution to all problems recognized but unaddressed by the other two branches of government. It is not the province of federal courts to usurp the power of the other branches of government to solve social problems with legislatively phrased directives disguised in judicial language. "[N]o matter how admirable the result may seem[,] unless change occurs through legitimate means, it disparages the image of the judiciary and the principles of our system of government." Gaston, *supra*, at 244.

For the foregoing reasons, I **FIND** that Plaintiff lacks Article III standing to bring this action on behalf of herself or the proposed class, and her claim is not ripe. The court, therefore, lacks jurisdiction to consider Plaintiff's claim. As such, this case is **DISMISSED**.[8]

[8] As a final note, if I had to proceed to the merits of the action, I alternatively would have granted summary judgment for Defendants. With the exclusion of Dr. Sahu's report, Plaintiff fails to meet the first element of the medical monitoring tort as outlined in *Bower*.

APPENDIX D

No. 24-1491

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

Lee Ann SOMMERVILLE, individually, and on behalf of all others similarly situated,
Plaintiff – Appellant,

v.

UNION CARBIDE CORPORATION; Covestro LLC,
Defendants – Appellees.

American Tort Reform Association; Chamber of Commerce of the United States of America,
Amici Supporting Appellee.

FILED: November 4, 2025

ORDER

The petition for rehearing en banc was circulated to the full court. No judge requested a poll under Fed. R. App. P. 40. The court denies the petition for rehearing en banc.

For the Court

/s/ Nwamaka Anowi, Clerk

APPENDIX E

PROVISIONS INVOLVED

Federal Rules of Evidence

Rule 104. Preliminary Questions:

(a) In General. The court must decide any preliminary question about whether a witness is qualified, a privilege exists, or evidence is admissible. In so deciding, the court is not bound by evidence rules, except those on privilege.

(b) Relevance That Depends on a Fact. When the relevance of evidence depends on whether a fact exists, proof must be introduced sufficient to support a finding that the fact does exist. The court may admit the proposed evidence on the condition that the proof be introduced later.

(c) Conducting a Hearing So That the Jury Cannot Hear It. The court must conduct any hearing on a preliminary question so that the jury cannot hear it if:

(1) the hearing involves the admissibility of a confession;

(2) a defendant in a criminal case is a witness and so requests; or

(3) justice so requires.

(d) Cross-Examining a Defendant in a Criminal Case. By testifying on a preliminary question, a defendant in a criminal case does not become subject to cross-examination on other issues in the case.

(e) Evidence Relevant to Weight and Credibility. This rule does not limit a party's right to introduce before the jury evidence that is relevant to the weight or credibility of other evidence.

ADVISORY COMMITTEE NOTES

1972 Proposed Rule

Note to Subdivision (a). The applicability of a particular rule of evidence often depends upon the existence of a condition. Is the alleged expert a qualified physician? Is a witness whose former testimony is offered unavailable? Was a stranger present during a conversation between attorney and client? In each instance the admissibility of evidence will turn upon the answer to the question of the existence of the condition. Accepted practice, incorporated in the rule, places on the judge the responsibility for these determinations. McCormick § 53; Morgan, Basic Problems of Evidence 45-50 (1962).

To the extent that these inquiries are factual, the judge acts as a trier of fact. Often, however, rulings on evidence call for an evaluation in terms of a legally set standard. Thus when a hearsay statement is offered as a declaration against interest, a decision must be made whether it possesses the required against-interest characteristics. These decisions, too, are made by the judge.

In view of these considerations, this subdivision refers to preliminary requirements generally by the broad term "questions," without attempt at specification.

This subdivision is of general application. It must, however, be read as subject to the special provisions for "conditional relevancy" in subdivision (b) and those for confessions in subdivision (d).

If the question is factual in nature, the judge will of necessity receive evidence pro and con on the issue. The rule provides that the rules of evidence in general do not apply to this process. McCormick § 53, p.

123, n. 8, points out that the authorities are "scattered and inconclusive," and observes:

"Should the exclusionary law of evidence, 'the child of the jury system' in Thayer's phrase, be applied to this hearing before the judge? Sound sense backs the view that it should not, and that the judge should be empowered to hear any relevant evidence, such as affidavits or other reliable hearsay."

This view is reinforced by practical necessity in certain situations. An item, offered and objected to, may itself be considered in ruling on admissibility, though not yet admitted in evidence. Thus, the content of an asserted declaration against interest must be considered in ruling whether it is against interest. Again, common practice calls for considering the testimony of a witness, particularly a child, in determining competency. Another example is the requirement of Rule 602 dealing with personal knowledge. In the case of hearsay, it is enough, if the declarant "so far as appears [has] had an opportunity to observe the fact declared." McCormick, § 10, p. 19.

If concern is felt over the use of affidavits by the judge in preliminary hearings on admissibility, attention is directed to the many important judicial determinations made on the basis of affidavits. Rule 47 of the Federal Rules of Criminal Procedure provides:

"An application to the court for an order shall be by motion. * * * It may be supported by affidavit."

The Rules of Civil Procedure are more detailed. Rule 43(e), dealing with motions generally, provides:

"When a motion is based on facts not appearing of record the court may hear the matter on affidavits presented by the respective parties, but the court may direct that the matter be heard wholly or partly

on oral testimony or depositions." Rule 4(g) provides for proof of service by affidavit. Rule 56 provides in detail for the entry of summary judgment based on affidavits. Affidavits may supply the foundation for temporary restraining orders under Rule 65(b).

The study made for the California Law Revision Commission recommended an amendment to Uniform Rule 2 as follows:

"In the determination of the issue aforesaid [preliminary determination], exclusionary rules shall not apply, subject, however, to Rule 45 and any valid claim of privilege." Tentative Recommendation and a Study Relating to the Uniform Rules of Evidence (Article VIII, Hearsay), Cal.Law Revision Comm'n, Rep., Rec. & Studies, 470 (1962). The proposal was not adopted in the California Evidence Code. The Uniform Rules are likewise silent on the subject. However, New Jersey Evidence Rule 8(1), dealing with preliminary inquiry by the judge, provides:

"In his determination the rules of evidence shall not apply except for Rule 4 [exclusion on grounds of confusion, etc.] or a valid claim of privilege."

Note to Subdivision (b). In some situations, the relevancy of an item of evidence, in the large sense, depends upon the existence of a particular preliminary fact. Thus when a spoken statement is relied upon to prove notice to X, it is without probative value unless X heard it. Or if a letter purporting to be from Y is relied upon to establish an admission by him, it has no probative value unless Y wrote or authorized it. Relevance in this sense has been labelled "conditional relevancy." Morgan, Basic Problems of Evidence 45-46 (1962). Problems arising in connection with it are to be distinguished from problems of logical relevancy, e.g., evidence in a murder case that

accused on the day before purchased a weapon of the kind used in the killing, treated in Rule 401.

If preliminary questions of conditional relevancy were determined solely by the judge, as provided in subdivision (a), the functioning of the jury as a trier of fact would be greatly restricted and in some cases virtually destroyed. These are appropriate questions for juries. Accepted treatment, as provided in the rule, is consistent with that given fact questions generally. The judge makes a preliminary determination whether the foundation evidence is sufficient to support a finding of fulfillment of the condition. If so, the item is admitted. If after all the evidence on the issue is in, pro and con, the jury could reasonably conclude that fulfillment of the condition is not established, the issue is for them. If the evidence is not such as to allow a finding, the judge withdraws the matter from their consideration. Morgan, *supra;* California Evidence Code § 403; New Jersey Rule 8(2). See also Uniform Rules 19 and 67.

The order of proof here, as generally, is subject to the control of the judge.

Note to Subdivision (c). Preliminary hearings on the admissibility of confessions must be conducted outside the hearing of the jury. See *Jackson v. Denno,* 378 U.S. 368, 84 S.Ct. 1774, 12 L.Ed.2d 908 (1964). Otherwise, detailed treatment of when preliminary matters should be heard outside the hearing of the jury is not feasible. The procedure is time consuming. Not infrequently the same evidence which is relevant to the issue of establishment of fulfillment of a condition precedent to admissibility is also relevant to weight or credibility, and time is saved by taking foundation proof in the presence of the jury. Much evidence on preliminary questions, though not relevant to jury issues, may be heard by the jury with no ad-

verse effect. A great deal must be left to the discretion of the judge who will act as the interests of justice require.

Note to Subdivision (d). The limitation upon cross-examination is designed to encourage participation by the accused in the determination of preliminary matters. He may testify concerning them without exposing himself to cross-examination generally. The provision is necessary because of the breadth of cross-examination under Rule 611(b).

The rule does not address itself to questions of the subsequent use of testimony given by an accused at a hearing on a preliminary matter. See *Walder v. United States,* 347 U.S. 62 (1954); *Simmons v. United States,* 390 U.S. 377 (1968); *Harris v. New York,* 401 U.S. 222 (1971).

Note to Subdivision (e). For similar provisions see Uniform Rule 8; California Evidence Code § 406; Kansas Code of Civil Procedure § 60-408; New Jersey Evidence Rule 8(1).

1974 Enactment

Rule 104(c) as submitted to the Congress provided that hearings on the admissibility of confessions shall be conducted outside the presence of the jury and hearings on all other preliminary matters should be so conducted when the interests of justice require. The Committee amended the Rule to provide that where an accused is a witness as to a preliminary matter, he has the right, upon his request, to be heard outside the jury's presence. Although recognizing that in some cases duplication of evidence would occur and that the procedure could be subject to abuse, the Committee believed that a proper regard for the right of an accused not to testify generally in the case dictates that he be given an option to testify

out of the presence of the jury on preliminary matters.

The Committee construes the second sentence of subdivision (c) as applying to civil actions and proceedings as well as to criminal cases, and on this assumption has left the sentence unamended. House Report No. 93-650.

Under rule 104(c) the hearing on a preliminary matter may at times be conducted in front of the jury. Should an accused testify in such a hearing, waiving his privilege against self-incrimination as to the preliminary issue, rule 104(d) provides that he will not generally be subject to cross-examination as to any other issue. This rule is not, however, intended to immunize the accused from cross-examination where, in testifying about a preliminary issue, he injects other issues into the hearing. If he could not be cross-examined about any issues gratuitously raised by him beyond the scope of the preliminary matters, injustice might result. Accordingly, in order to prevent any such unjust result, the committee intends the rule to be construed to provide that the accused may subject himself to cross-examination as to issues raised by his own testimony upon a preliminary matter before a jury. Senate Report No. 93-1277.

1987 Amendments

The amendments are technical. No substantive change is intended.

2011 Amendments

The language of Rule 104 has been amended as part of the restyling of the Evidence Rules to make them more easily understood and to make style and terminology consistent throughout the rules. These changes are intended to be stylistic only. There is no intent

to change any result in any ruling on evidence admissibility.

Rule 702. Testimony by Expert Witnesses:

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 the proponent demonstrates to the court that it is more likely than not that:

(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's opinion reflects a reliable application of the principles and methods to the facts of the case.

ADVISORY COMMITTEE NOTES

1972 Proposed Rules

An intelligent evaluation of facts is often difficult or impossible without the application of some scientific, technical, or other specialized knowledge. The most common source of this knowledge is the expert witness, although there are other techniques for supplying it.

Most of the literature assumes that experts testify only in the form of opinions. The assumption is logically unfounded. The rule accordingly recognizes that an expert on the stand may give a dissertation or exposition of scientific or other principles relevant to the case, leaving the trier of fact to apply them to the facts. Since much of the criticism of expert testimony

has centered upon the hypothetical question, it seems wise to recognize that opinions are not indispensable and to encourage the use of expert testimony in non-opinion form when counsel believes the trier can itself draw the requisite inference. The use of opinions is not abolished by the rule, however. It will continue to be permissible for the experts to take the further step of suggesting the inference which should be drawn from applying the specialized knowledge to the facts. See Rules 703 to 705.

Whether the situation is a proper one for the use of expert testimony is to be determined on the basis of assisting the trier. "There is no more certain test for determining when experts may be used than the common sense inquiry whether the untrained layman would be qualified to determine intelligently and to the best possible degree the particular issue without enlightenment from those having a specialized understanding of the subject involved in the dispute." Ladd, Expert Testimony, 5 Vand.L.Rev. 414, 418 (1952). When opinions are excluded, it is because they are unhelpful and therefore superfluous and a waste of time. 7 Wigmore § 1918.

The rule is broadly phrased. The fields of knowledge which may be drawn upon are not limited merely to the "scientific" and "technical" but extend to all "specialized" knowledge. Similarly, the expert is viewed, not in a narrow sense, but as a person qualified by "knowledge, skill, experience, training or education." Thus within the scope of the rule are not only experts in the strictest sense of the word, e.g., physicians, physicists, and architects, but also the large group sometimes called "skilled" witnesses, such as bankers or landowners testifying to land values.

2000 Amendments

Rule 702 has been amended in response to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and to the many cases applying *Daubert*, including *Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167 (1999). In *Daubert* the Court charged trial judges with the responsibility of acting as gatekeepers to exclude unreliable expert testimony, and the Court in *Kumho* clarified that this gatekeeper function applies to all expert testimony, not just testimony based in science. *See also Kumho*, 119 S.Ct. at 1178 (citing the Committee Note to the proposed amendment to Rule 702, which had been released for public comment before the date of the *Kumho* decision). The amendment affirms the trial court's role as gatekeeper and provides some general standards that the trial court must use to assess the reliability and helpfulness of proffered expert testimony. Consistently with *Kumho*, the Rule as amended provides that all types of expert testimony present questions of admissibility for the trial court in deciding whether the evidence is reliable and helpful. Consequently, the admissibility of all expert testimony is governed by the principles of Rule 104(a). Under that Rule, the proponent has the burden of establishing that the pertinent admissibility requirements are met by a preponderance of the evidence. *See Bourjaily v. United States*, 483 U.S. 171 (1987).

Daubert set forth a non-exclusive checklist for trial courts to use in assessing the reliability of scientific expert testimony. The specific factors explicated by the *Daubert* Court are (1) whether the expert's technique or theory can be or has been tested---that is, whether the expert's theory can be challenged in some objective sense, or whether it is instead simply a subjective, conclusory approach that cannot reason-

ably be assessed for reliability; (2) whether the technique or theory has been subject to peer review and publication; (3) the known or potential rate of error of the technique or theory when applied; (4) the existence and maintenance of standards and controls; and (5) whether the technique or theory has been generally accepted in the scientific community. The Court in *Kumho* held that these factors might also be applicable in assessing the reliability of non-scientific expert testimony, depending upon "the particular circumstances of the particular case at issue." 119 S.Ct. at 1175.

No attempt has been made to "codify" these specific factors. *Daubert* itself emphasized that the factors were neither exclusive nor dispositive. Other cases have recognized that not all of the specific *Daubert* factors can apply to every type of expert testimony. In addition to *Kumho*, 119 S.Ct. at 1175, *see Tyus v. Urban Search Management*, 102 F.3d 256 (7th Cir. 1996) (noting that the factors mentioned by the Court in *Daubert* do not neatly apply to expert testimony from a sociologist). *See also Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 809 (3d Cir. 1997) (holding that lack of peer review or publication was not dispositive where the expert's opinion was supported by "widely accepted scientific knowledge"). The standards set forth in the amendment are broad enough to require consideration of any or all of the specific *Daubert* factors where appropriate.

Courts both before and after *Daubert* have found other factors relevant in determining whether expert testimony is sufficiently reliable to be considered by the trier of fact. These factors include:

(1) Whether experts are "proposing to testify about matters growing naturally and directly out of research they have conducted independent of the liti-

gation, or whether they have developed their opinions expressly for purposes of testifying." *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 43 F.3d 1311, 1317 (9th Cir. 1995).

(2) Whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion. *See General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (noting that in some cases a trial court "may conclude that there is simply too great an analytical gap between the data and the opinion proffered").

(3) Whether the expert has adequately accounted for obvious alternative explanations. *See Claar v. Burlington N.R.R*., 29 F.3d 499 (9th Cir. 1994) (testimony excluded where the expert failed to consider other obvious causes for the plaintiff's condition). *Compare Ambrosini v. Labarraque*, 101 F.3d 129 (D.C. Cir. 1996) (the possibility of some uneliminated causes presents a question of weight, so long as the most obvious causes have been considered and reasonably ruled out by the expert).

(4) Whether the expert "is being as careful as he would be in his regular professional work outside his paid litigation consulting." *Sheehan v. Daily Racing Form, Inc*., 104 F.3d 940, 942 (7th Cir. 1997). *See Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167, 1176 (1999) (*Daubert* requires the trial court to assure itself that the expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field").

(5) Whether the field of expertise claimed by the expert is known to reach reliable results for the type of opinion the expert would give. *See Kumho Tire Co. v. Carmichael*, 119 S.Ct.1167, 1175 (1999)

(*Daubert's* general acceptance factor does not "help show that an expert's testimony is reliable where the discipline itself lacks reliability, as for example, do theories grounded in any so-called generally accepted principles of astrology or necromancy."), *Moore v. Ashland Chemical, Inc*., 151 F.3d 269 (5th Cir. 1998) (en banc) (clinical doctor was properly precluded from testifying to the toxicological cause of the plaintiff's respiratory problem, where the opinion was not sufficiently grounded in scientific methodology); *Sterling v. Velsicol Chem. Corp*., 855 F.2d 1188 (6th Cir. 1988) (rejecting testimony based on "clinical ecology" as unfounded and unreliable).

All of these factors remain relevant to the determination of the reliability of expert testimony under the Rule as amended. Other factors may also be relevant. *See Kumho*, 119 S.Ct. 1167, 1176 ("[W]e conclude that the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable."). Yet no single factor is necessarily dispositive of the reliability of a particular expert's testimony. *See, e.g., Heller v. Shaw Industries, Inc*., 167 F.3d 146, 155 (3d Cir. 1999) ("not only must each stage of the expert's testimony be reliable, but each stage must be evaluated practically and flexibly without bright-line exclusionary (or inclusionary) rules."); *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 43 F.3d 1311, 1317, n.5 (9th Cir. 1995) (noting that some expert disciplines "have the courtroom as a principal theatre of operations" and as to these disciplines "the fact that the expert has developed an expertise principally for purposes of litigation will obviously not be a substantial consideration.").

A review of the caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather

than the rule. *Daubert* did not work a "seachange over federal evidence law," and "the trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system." *United States v. 14.38 Acres of Land Situated in Leflore County, Mississippi*, 80 F.3d 1074, 1078 (5th Cir. 1996). As the Court in *Daubert* stated: "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." 509 U.S. at 595. Likewise, this amendment is not intended to provide an excuse for an automatic challenge to the testimony of every expert. *See Kumho Tire Co. v. Carmichael*, 119 S.Ct.1167, 1176 (1999) (noting that the trial judge has the discretion "both to avoid unnecessary 'reliability' proceedings in ordinary cases where the reliability of an expert's methods is properly taken for granted, and to require appropriate proceedings in the less usual or more complex cases where cause for questioning the expert's reliability arises.").

When a trial court, applying this amendment, rules that an expert's testimony is reliable, this does not necessarily mean that contradictory expert testimony is unreliable. The amendment is broad enough to permit testimony that is the product of competing principles or methods in the same field of expertise. *See, e.g., Heller v. Shaw Industries, Inc*., 167 F.3d 146, 160 (3d Cir. 1999) (expert testimony cannot be excluded simply because the expert uses one test rather than another, when both tests are accepted in the field and both reach reliable results). As the court stated in *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 744 (3d Cir. 1994), proponents "do not have to demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are

correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable.... The evidentiary requirement of reliability is lower than the merits standard of correctness." *See also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) (scientific experts might be permitted to testify if they could show that the methods they used were also employed by "a recognized minority of scientists in their field."); *Ruiz-Troche v. Pepsi Cola*, 161 F.3d 77, 85 (1st Cir. 1998) ("*Daubert* neither requires nor empowers trial courts to determine which of several competing scientific theories has the best provenance.").

The Court in *Daubert* declared that the "focus, of course, must be solely on principles and methodology, not on the conclusions they generate." 509 U.S. at 595. Yet as the Court later recognized, "conclusions and methodology are not entirely distinct from one another." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Under the amendment, as under *Daubert*, when an expert purports to apply principles and methods in accordance with professional standards, and yet reaches a conclusion that other experts in the field would not reach, the trial court may fairly suspect that the principles and methods have not been faithfully applied. *See Lust v. Merrell Dow Pharmaceuticals, Inc.*, 89 F.3d 594, 598 (9th Cir. 1996). The amendment specifically provides that the trial court must scrutinize not only the principles and methods used by the expert, but also whether those principles and methods have been properly applied to the facts of the case. As the court noted in *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 745 (3d Cir. 1994), "*any* step that renders the analysis unreliable ... renders the expert's testimony inadmissible. *This is true whether the step completely changes a reliable meth-*

odology or merely misapplies that methodology."

If the expert purports to apply principles and methods to the facts of the case, it is important that this application be conducted reliably. Yet it might also be important in some cases for an expert to educate the factfinder about general principles, without ever attempting to apply these principles to the specific facts of the case. For example, experts might instruct the factfinder on the principles of thermodynamics, or bloodclotting, or on how financial markets respond to corporate reports, without ever knowing about or trying to tie their testimony into the facts of the case. The amendment does not alter the venerable practice of using expert testimony to educate the factfinder on general principles. For this kind of generalized testimony, Rule 702 simply requires that: (1) the expert be qualified; (2) the testimony address a subject matter on which the factfinder can be assisted by an expert; (3) the testimony be reliable; and (4) the testimony "fit" the facts of the case.

As stated earlier, the amendment does not distinguish between scientific and other forms of expert testimony. The trial court's gatekeeping function applies to testimony by any expert. *See Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167, 1171 (1999) ("We conclude that *Daubert's* general holding--setting forth the trial judge's general 'gatekeeping' obligation--applies not only to testimony based on 'scientific' knowledge, but also to testimony based on 'technical' and 'other specialized' knowledge."). While the relevant factors for determining reliability will vary from expertise to expertise, the amendment rejects the premise that an expert's testimony should be treated more permissively simply because it is outside the realm of science. An opinion from an expert who is not a scientist should receive the same degree of scru-

tiny for reliability as an opinion from an expert who purports to be a scientist. *See Watkins v. Telsmith, Inc*., 121 F.3d 984, 991 (5th Cir. 1997) ("[I]t seems exactly backwards that experts who purport to rely on general engineering principles and practical experience might escape screening by the district court simply by stating that their conclusions were not reached by any particular method or technique."). Some types of expert testimony will be more objectively verifiable, and subject to the expectations of falsifiability, peer review, and publication, than others. Some types of expert testimony will not rely on anything like a scientific method, and so will have to be evaluated by reference to other standard principles attendant to the particular area of expertise. The trial judge in all cases of proffered expert testimony must find that it is properly grounded, well-reasoned, and not speculative before it can be admitted. The expert's testimony must be grounded in an accepted body of learning or experience in the expert's field, and the expert must explain how the conclusion is so grounded. *See, e.g*., American College of Trial Lawyers, Standards and Procedures for Determining the Admissibility of Expert Testimony after *Daubert*, 157 F.R.D. 571, 579 (1994) ("[W]hether the testimony concerns economic principles, accounting standards, property valuation or other non-scientific subjects, it should be evaluated by reference to the 'knowledge and experience' of that particular field.").

The amendment requires that the testimony must be the product of reliable principles and methods that are reliably applied to the facts of the case. While the terms "principles" and "methods" may convey a certain impression when applied to scientific knowledge, they remain relevant when applied to testimony based on technical or other specialized knowledge.

For example, when a law enforcement agent testifies regarding the use of code words in a drug transaction, the principle used by the agent is that participants in such transactions regularly use code words to conceal the nature of their activities. The method used by the agent is the application of extensive experience to analyze the meaning of the conversations. So long as the principles and methods are reliable and applied reliably to the facts of the case, this type of testimony should be admitted.

Nothing in this amendment is intended to suggest that experience alone--or experience in conjunction with other knowledge, skill, training or education--may not provide a sufficient foundation for expert testimony. To the contrary, the text of Rule 702 expressly contemplates that an expert may be qualified on the basis of experience. In certain fields, experience is the predominant, if not sole, basis for a great deal of reliable expert testimony. *See, e.g., United States v. Jones*, 107 F.3d 1147 (6th Cir. 1997) (no abuse of discretion in admitting the testimony of a handwriting examiner who had years of practical experience and extensive training, and who explained his methodology in detail); *Tassin v. Sears Roebuck*, 946 F.Supp. 1241, 1248 (M.D.La. 1996) (design engineer's testimony can be admissible when the expert's opinions "are based on facts, a reasonable investigation, and traditional technical/mechanical expertise, and he provides a reasonable link between the information and procedures he uses and the conclusions he reaches"). *See also Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167, 1178 (1999) (stating that "no one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.").

If the witness is relying solely or primarily on experi-

ence, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply "taking the expert's word for it." *See Daubert v. Merrell Dow Pharmaceuticals, Inc*., 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough."). The more subjective and controversial the expert's inquiry, the more likely the testimony should be excluded as unreliable. *See O'Conner v. Commonwealth Edison Co*., 13 F.3d 1090 (7th Cir. 1994) (expert testimony based on a completely subjective methodology held properly excluded). *See also Kumho Tire Co. v. Carmichael*, 119 S.Ct. 1167, 1176 (1999) ("[I]t will at times be useful to ask even of a witness whose expertise is based purely on experience, say, a perfume tester able to distinguish among 140 odors at a sniff, whether his preparation is of a kind that others in the field would recognize as acceptable.").

Subpart (1) of Rule 702 calls for a quantitative rather than qualitative analysis. The amendment requires that expert testimony be based on sufficient underlying "facts or data." The term "data" is intended to encompass the reliable opinions of other experts. See the original Advisory Committee Note to Rule 703. The language "facts or data" is broad enough to allow an expert to rely on hypothetical facts that are supported by the evidence. *Id*.

When facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts. The emphasis in the amendment on " sufficient facts or data" is not intended to authorize a trial court to exclude an expert's testimony on the ground

that the court believes one version of the facts and not the other.

There has been some confusion over the relationship between Rules 702 and 703. The amendment makes clear that the sufficiency of the basis of an expert' s testimony is to be decided under Rule 702. Rule 702 sets forth the overarching requirement of reliability, and an analysis of the sufficiency of the expert's basis cannot be divorced from the ultimate reliability of the expert's opinion. In contrast, the "reasonable reliance" requirement of Rule 703 is a relatively narrow inquiry. When an expert relies on inadmissible information, Rule 703 requires the trial court to determine whether that information is of a type reasonably relied on by other experts in the field. If so, the expert can rely on the information in reaching an opinion. However, the question whether the expert is relying on a *sufficient* basis of information--whether admissible information or not--is governed by the requirements of Rule 702.

The amendment continues the practice of the original Rule in referring to a qualified witness as an "expert." This was done to provide continuity and to minimize change. The use of the term "expert" in the Rule does not, however, mean that a jury should actually be informed that a qualified witness is testifying as an "expert." Indeed, there is much to be said for a practice that prohibits the use of the term "expert" by both the parties and the court at trial. Such a practice "ensures that trial courts do not inadvertently put their stamp of authority" on a witness's opinion, and protects against the jury's being "overwhelmed by the so-called 'experts'." Hon. Charles Richey, *Proposals to Eliminate the Prejudicial Effect of the Use of the Word "Expert" Under the Federal Rules of Evidence in Criminal and Civil Jury Trials*, 154 F.R.D.

537, 559 (1994) (setting forth limiting instructions and a standing order employed to prohibit the use of the term " expert" injury trials).

GAP Report--Proposed Amendment to Rule 702

The Committee made the following changes to the published draft of the proposed amendment to Evidence Rule 702:

1. The word "reliable" was deleted from Subpart (1) of the proposed amendment, in order to avoid an overlap with Evidence Rule 703, and to clarify that an expert opinion need not be excluded simply because it is based on hypothetical facts. The Committee Note was amended to accord with this textual change.

2. The Committee Note was amended throughout to include pertinent references to the Supreme Court's decision in *Kumho Tire Co. v. Carmichael*, which was rendered after the proposed amendment was released for public comment. Other citations were updated as well.

3. The Committee Note was revised to emphasize that the amendment is not intended to limit the right to jury trial, nor to permit a challenge to the testimony of every expert, nor to preclude the testimony of experience-based experts, nor to prohibit testimony based on competing methodologies within a field of expertise.

4. Language was added to the Committee Note to clarify that no single factor is necessarily dispositive of the reliability inquiry mandated by Evidence Rule 702.

2011 Amendments

The language of Rule 702 has been amended as part of the restyling of the Evidence Rules to make them more easily understood and to make style and terminology consistent throughout the rules. These changes are intended to be stylistic only. There is no intent to change any result in any ruling on evidence admissibility.

2023 Amendments

Rule 702 has been amended in two respects:

(1) First, the rule has been amended to clarify and emphasize that expert testimony may not be admitted unless the proponent demonstrates to the court that it is more likely than not that the proffered testimony meets the admissibility requirements set forth in the rule. *See* Rule 104(a). This is the preponderance of the evidence standard that applies to most of the admissibility requirements set forth in the evidence rules. *See Bourjaily v. United States*, 483 U.S. 171, 175 (1987) ("The preponderance standard ensures that before admitting evidence, the court will have found it more likely than not that the technical issues and policy concerns addressed by the Federal Rules of Evidence have been afforded due consideration."); *Huddleston v. United States*, 485 U.S. 681, 687 n.5 (1988) ("preliminary factual findings under Rule 104(a) are subject to the preponderance-of-the-evidence standard"). But many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's methodology, are questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a).

There is no intent to raise any negative inference regarding the applicability of the Rule 104(a) standard

of proof for other rules. The Committee concluded that emphasizing the preponderance standard in Rule 702 specifically was made necessary by the courts that have failed to apply correctly the reliability requirements of that rule. Nor does the amendment require that the court make a finding of reliability in the absence of objection.

The amendment clarifies that the preponderance standard applies to the three reliability-based requirements added in 2000--requirements that many courts have incorrectly determined to be governed by the more permissive Rule 104(b) standard. But it remains the case that other admissibility requirements in the rule (such as that the expert must be qualified and the expert's testimony must help the trier of fact) are governed by the Rule 104(a) standard as well.

Some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard. For example, if the court finds it more likely than not that an expert has a sufficient basis to support an opinion, the fact that the expert has not read every single study that exists will raise a question of weight and not admissibility. But this does not mean, as certain courts have held, that arguments about the sufficiency of an expert's basis always go to weight and not admissibility. Rather it means that once the court has found it more likely than not that the admissibility requirement has been met, any attack by the opponent will go only to the weight of the evidence.

It will often occur that experts come to different conclusions based on contested sets of facts. Where that is so, the Rule 104(a) standard does not necessarily require exclusion of either side's experts. Rather, by deciding the disputed facts, the jury can decide which side's experts to credit. "[P]roponents 'do not have to

demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are correct, they only have to demonstrate by a preponderance of evidence that their opinions are reliable... The evidentiary requirement of reliability is lower than the merits standard of correctness.'" Advisory Committee Note to the 2000 amendment to Rule 702, quoting *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717, 744 (3d Cir. 1994).

Rule 702 requires that the expert's knowledge "help" the trier of fact to understand the evidence or to determine a fact in issue. Unfortunately, some courts have required the expert's testimony to "appreciably help" the trier of fact. Applying a higher standard than helpfulness to otherwise reliable expert testimony is unnecessarily strict.

(2) Rule 702(d) has also been amended to emphasize that each expert opinion must stay within the bounds of what can be concluded from a reliable application of the expert's basis and methodology. Judicial gatekeeping is essential because just as jurors may be unable, due to lack of specialized knowledge, to evaluate meaningfully the reliability of scientific and other methods underlying expert opinion, jurors may also lack the specialized knowledge to determine whether the conclusions of an expert go beyond what the expert's basis and methodology may reliably support.

The amendment is especially pertinent to the testimony of forensic experts in both criminal and civil cases. Forensic experts should avoid assertions of absolute or one hundred percent certainty--or to a reasonable degree of scientific certainty--if the methodology is subjective and thus potentially subject to error. In deciding whether to admit forensic expert testimony, the judge should (where possible) receive an

estimate of the known or potential rate of error of the methodology employed, based (where appropriate) on studies that reflect how often the method produces accurate results. Expert opinion testimony regarding the weight of feature comparison evidence (i.e., evidence that a set of features corresponds between two examined items) must be limited to those inferences that can reasonably be drawn from a reliable application of the principles and methods. This amendment does not, however, bar testimony that comports with substantive law requiring opinions to a particular degree of certainty.

Nothing in the amendment imposes any new, specific procedures. Rather, the amendment is simply intended to clarify that Rule 104(a)'s requirement applies to expert opinions under Rule 702. Similarly, nothing in the amendment requires the court to nitpick an expert's opinion in order to reach a perfect expression of what the basis and methodology can support. The Rule 104(a) standard does not require perfection. On the other hand, it does not permit the expert to make claims that are unsupported by the expert's basis and methodology.