

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

LEE ANN SOMMERVILLE, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:19-cv-00878

UNION CARBIDE CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER

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 Surveillance: 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

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.

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 (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 principle 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. Standing²

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

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).

(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.”).

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, *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*

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.*, 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.

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.* 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 damages⁴ 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 exposure

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).

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 unreliable data and methods in creating the air model used to determine the alleged estimated

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.

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 proposed 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. Sumnum*, 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 standing 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 law, the injury

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.*

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 ensure 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 one at a higher risk to *maybe* develop certain cancers at some uncertain

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.*

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

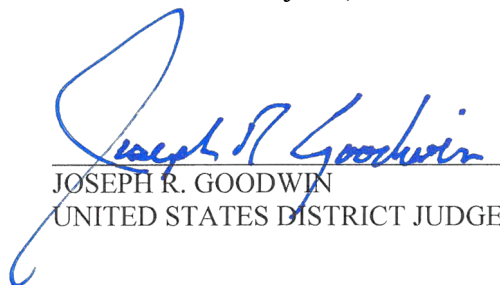
primarily with issues of policy in state government. These same concerns, when applied to federal courts, affect justiciability.

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

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party. The court further **DIRECTS** the Clerk to post a copy of this published opinion on the court’s website, www.wvwd.uscourts.gov.

ENTER: May 13, 2024


JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

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*.