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IN THE SUPREME COURT OF THE STATE OF DELAWARE

CATHERINE BAKER,	) No. 393, 2022
	)
Plaintiff-Appellant,	) Certification of Question of Law
	) from the United States Court of
v.	) Appeals for the Third Circuit
	) Appeal Nos. 21-3360 & 22-1333
CRODA INC., f/k/a Croda, Inc.,	)
	) **Court below:**
Defendant-Appellee.	) U.S. District Court, D. Del.
	) Civil Action No. 1:20-cv-01108-SB

APPELLEE'S [CORRECTED] ANSWERING BRIEF

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NATURE OF PROCEEDINGS

Plaintiff Catherine Baker filed suit against Defendant Croda Inc. in the District of Delaware, on behalf of a putative class, alleging that ethylene oxide emissions from Croda's New Castle facility caused an increased risk of illness in the future for the alleged class, even though they had not yet suffered any harm. The district court (Judge Bibas, sitting by designation) dismissed the complaint, holding that a claim for medical monitoring damages based on increased risk, without physical injury, was not cognizable under Delaware law. On Plaintiff's appeal the Third Circuit certified a question for review, which this Court accepted: "Whether an increased risk of illness, without present manifestation of a physical harm, is a cognizable injury under Delaware law? Or put another way, does an increased risk of harm only constitute a cognizable injury once it manifests in a physical disease?"

SUMMARY OF ARGUMENT

1. Denied. Delaware courts have consistently held that there is no claim for injury based on an increased risk of future harm, absent a present, physical injury.

(a). Denied. Delaware Courts have recognized the need for medical monitoring as a cognizable injury only where it is accompanied by a separate physical injury. This Court stated that "[t]he requirement of a preceding physical injury prohibits plaintiffs from claiming that exposure to toxic substances . . . has created an increased risk of harm not yet manifested in a physical disease." *United States v. Anderson*, 669 A.2d 73, 78 (Del. 1995). This Court has also held that "a claim for the expenses of medically required surveillance and related mental anguish . . . fails to state a claim upon which relief can be granted where there is no present physical injury." *Mergenthaler v. Asbestos Corp. of Am.*, 480 A.2d 647, 649 (Del. 1984). While Plaintiff attempts to minimize or factually distinguish these cases, Plaintiff cites no Delaware case ever accepting a claim based on increased risk of future harm without a physical injury. Nor does Plaintiff explain why this case should be an exception to the well-established rule that a tort requires a present injury, not just the possibility of some unknown injury at some uncertain point in the future.

(b). Denied. Delaware Court decisions recognizing the need for medical monitoring as a compensable injury in the workers' compensation context have done

so where there was a present, physical injury separate from the claimed need for medical monitoring. The only case Plaintiff cites in support of this argument is *McCracken v. Wilson Beverage*, No. 91A-10-004, 1992 WL 301985, at *1 (Del. Super. Ct. Oct. 15, 1992), which is clearly inapposite, as it involved neck and back injuries from a car accident in addition to medical monitoring.

(c). Denied. Although Delaware follows the Restatement (Second) of Torts, the Restatement does not permit claims for medical monitoring absent manifest injury. Section 7 states that an injury is "the invasion of any legally protected interest of another," but does not explain what legally protected interest under Delaware law is invaded based only on an allegedly increased risk of future disease.

(d). Denied. The majority of courts to consider the issue require a physical injury to state a claim, and the experience of the minority of courts to the contrary only confirms the wisdom of that requirement. In particular, the U.S. Supreme Court held that a requirement of physical injury is necessary because of the morass that courts would fall into by allowing claims based only on increased risk. As the Court explained, tens of millions of people (or more) are exposed to chemicals and materials that increase the risk of disease, and allowing such claims would thus cause limitless litigation with unknowable liability, and ultimately leave less for the plaintiffs who actually *are* injured. *Metro-North Commuter Railroad Co. v. Buckley*,

521 U.S. 424, 442 (1997). As argued below, numerous state courts (and federal courts applying state law) have taken the same approach, recognizing the need for a present-injury requirement to ensure some constraint on what would otherwise represent limitless claims arising from every person's every-day exposure to countless chemicals.

While some courts have allowed a claim without present, physical injury, the result has been exactly the flood of litigation that the U.S. Supreme Court predicted. To stem the tide, those courts have been forced to impose new barriers to such claims, inventing legal rules on the fly, requiring everything from court-monitored funds to heightened standards of proof to evidence of subcellular changes. In short, the courts have taken on a legislative role in attempting to counter the policy harms caused by their creation of a new claim previously unknown in common law. Plaintiff presents no means for this Court to do so in a principled manner, and indeed, appears to argue that any increased risk suffices to state a claim. This Court should not accept this invitation to turn the Delaware courts into the preferred forum for specious damages claims from healthy persons claiming risk from exposure to just about anything. Rather, this Court should confirm what it has long stated: there is no cognizable claim absent present, physical injury.

Herer, Plaintiff filed a class action on behalf of people who have, by Plaintiff's own definition, *not* suffered any harm from the alleged conduct at issue, but rather

alleged that they *might* be so harmed in the future from inhaling unspecified amounts of a potentially dangerous chemical. Plaintiff's claim for medical monitoring without any present physical injury would require a radical departure from this Court's precedents and would create the kind of limitless liability that has led the majority of courts, including the U.S. Supreme Court, to reject such a claim. The district court correctly dismissed Plaintiff's claim based on a straight-forward application of Delaware law. The Third Circuit believed it could not be certain how this Court would resolve the question, and therefore certified it to this Court. But the law is clear: there must be an injury to state a tort claim, and a possibility of *future* injury—which is both inherently speculative and could be alleged for just about everyone based on countless exposures to potential carcinogens in the modern world—does not suffice to state a claim.

STATEMENT OF FACTS

A. The Atlas Point Facility

Croda Inc. has produced various specialty chemicals at the Atlas Point complex in New Castle, Delaware since 2006. Prior to Croda's ownership, the Atlas Point facility was operated by Uniqema. A0017 ¶¶ 33-34. Plaintiff and the members of the putative class seek to recover for alleged exposure to ethylene oxide emitted from the Atlas Point facility from 1988 to the present. A0022-23 ¶¶ 62-64. Over the course of more than three decades, the Atlas Point facility emitted trace levels of ethylene oxide that were within state and federal emissions limits. From 1988 to 2015, the Complaint alleges only minor, technical violations of state regulations, including "failure to record emissions," failure to maintain "best management practices," and "failure to make timely permit applications." A0017 ¶¶ 33-35. The Complaint also notes that a "documented unpermitted release" of ethylene oxide occurred in 2008. *Id*. ¶ 35.

In 2015, Croda—with all the required state and county approvals—started construction on a new bio-ethylene oxide plant that would be the first facility in the United States to produce ethylene oxide using biofuels. Croda uses the ethylene oxide it produces onsite to make other products at the Atlas Point facility. Croda completed construction of its bio-ethylene oxide plant in late 2018, and began operations in compliance with federal, state, and local environmental regulations

relating to emissions. Shortly after the plant opened, a gasket installed by a subcontractor that did not meet the engineering specifications failed, resulting in an ethylene oxide leak. Croda and first responders sprayed thousands of gallons of deluge water into the air to quickly contain the leaked ethylene oxide. A0017-18 ¶ 37.

B. The Complaint

Catherine Baker (a Delaware resident) filed suit against Croda (a Delaware corporation) in the District of Delaware, alleging that the ethylene oxide emitted from Croda's New Castle facility since 1988 caused her and members of the putative class to be at an increased risk of developing cancer or another serious illness in the future. A0022-23¶¶ 62-63. Plaintiff has asserted claims for ultrahazardous activity/strict liability, public nuisance, private nuisance, negligence, willful and wanton conduct, and medical monitoring. A0026-34 ¶¶ 73-123. The purported class members include only persons who have *not* been diagnosed with cancer or an illness, disease, or disease process of the kind caused by ethylene oxide. A0023 ¶ 63. However, Plaintiff asserts that both she and class members—essentially everyone who lived near the plant for one year or more at any time during a period of approximately 35 years (A0022)—are at "an increased risk of illness and disease," and seeks the cost of a medical monitoring program to detect early signs or symptoms of disease as a remedy for each asserted claim. A0025 ¶ 68.

Notably, many of Plaintiff's assertions in her brief go beyond those of the Complaint. For example, Plaintiff asserts (Br. 8) that "[f]rom 2008 through at least 2015, Defendant, at its Atlas Point facility, violated State of Delaware Department of Natural Resources and Environmental Control ('DNREC') regulations." But Plaintiff cites only the allegation concerning the single event in 2008 (A0017 at ¶ 35), and the Complaint cites no evidence of continuous violations. In addition, while Plaintiff suggests (Br. 7) that "Defendant releases and emits substantial and dangerous volumes of ethylene oxide gas every year," the Complaint does not make even a conclusory allegation to support this claim of "dangerous" emissions every year.

C. Decisions Below

After briefing and argument, the district court (Judge Bibas, sitting by designation) dismissed Plaintiff's Complaint for failure to state a claim. Ex. B to Appellant's Br., *Baker v. Croda Inc.*, 2021 WL 7209363 (D. Del. Nov. 23, 2021). The court held that all of Plaintiff's claims require the existence of an injury, but the Complaint's allegation of injury based solely on increased risk of future disease is not cognizable under Delaware law.

In particular, allowing Plaintiff's claims "would fly in the face of clear signals in Delaware tort law." *Id*. at *2. As the district court explained, "the Delaware Supreme Court has said as much in dicta" in *United States v. Anderson*, 669 A.2d

73, 77 (Del. 1995), and "Delaware tort law presupposes that plaintiffs will bring suits after they suffer physical symptoms, not before." *Id*. Moreover, "[m]ost courts reject increased-risk claims," and "[u]nderstandably so" to prevent "limitless and endless litigation," *id*. (quotation marks omitted). The court concluded: "Without a contrary directive from the Delaware Supreme Court, I will not open those floodgates here." *Id.* The court further noted that Plaintiff "may amend to show that the class has suffered physical injury." *Id*. Plaintiff chose not to do so. *See* A0102 (requesting "a Final Order of dismissal with prejudice") and A0104 (dismissing the Complaint with prejudice). Finally, the court stated it would "not certify this question to the Delaware Supreme Court" because "Delaware law already points to my holding today, so certification would not be efficient." Ex. B, *Baker*, 2021 WL 7209363, at *3.

On appeal, the Third Circuit issued an order certifying the question to this Court. The court stated: "The limits of what may constitute an 'injury-in-fact' vary among states. Some recognize an increased risk of illness as a cognizable injury warranting recovery, while others do not." Ex. C to Appellant's Br. at 2 (footnotes omitted). It noted that this Court "broached the question when it issued its decision in *United States v. Anderson*, writing, in *dicta*, that plaintiffs could not recover by 'claiming that exposure to toxic substances . . . has created an increased risk of harm not yet manifested in a physical disease.'" *Id*. at 2-3. Nonetheless, the Third Circuit

found that "[t]here remains an unsettled issue . . . whether an increased risk of illness, without present manifestation of a physical harm, is a cognizable injury under Delaware law." *Id*. at 3. And it further found that "the decision to recognize an increased risk of disease as a cognizable injury is significant, and its implications are far-reaching," and "we believe that the State's high court is the most appropriate forum to weigh competing public policy interests." *Id*. at 6.

ARGUMENT

THIS COURT SHOULD REJECT PLAINTIFF'S ATTEMPT TO EXPAND DELAWARE LAW TO RECOGNIZE A TORT CLAIM BASED SOLELY ON AN INCREASED RISK OF HARM IN THE FUTURE, WITH NO CURRENT PHYSICAL INJURY

A. Question Presented

The Court of Appeals for the Third Circuit certified the following question for review: "Whether an increased risk of illness, without present manifestation of a physical harm, is a cognizable injury under Delaware law? Or put another way, does an increased risk of harm only constitute a cognizable injury once it manifests in a physical disease?" *Id*. at 8.

B. Scope Of Review

As Plaintiff recognizes (Br. 13), the certified question is a question of law reviewed *de novo*.

C. Merits Of Argument

As district court recognized, all of Plaintiff's claims require the existence of an injury under Delaware law. *See* Ex. B, *Baker*, 2021 WL 7209363 at *2 ("All tort claims require an injury.") (citing Restatement (Second) of Torts § 7 (1965)). Plaintiff does not dispute this point. Nor does Plaintiff dispute that she and the proposed class members have alleged no physical injury as a result of living near the Atlas Point facility. In fact, all class members by definition cannot be ill or have any disease process associated with the alleged exposure because the putative class

excludes "all persons who have been currently diagnosed with cancer or illness, disease or disease process of the kind caused by EtO[.]" A0023 ¶ 63.

Given the undisputed absence of any physical injury, Plaintiff's Complaint and her brief rely solely on the theory that an increased *risk* of developing disease in the future is a cognizable injury. However, as the district court correctly held, this theory conflicts with well-established Delaware law. Even if this Court were to examine the issue anew, it should follow the majority of courts, including the U.S. Supreme Court, in rejecting the claim.

1. Plaintiff's Allegedly Increased Risk Of Future Disease Does Not Constitute A Cognizable Injury Under Delaware Law

Plaintiff's theory of injury—based solely on an increased possibility of illness in the future, without any present, physical injury—is inconsistent with Delaware law. This Court stated the point unequivocally: "The requirement of a preceding physical injury prohibits plaintiffs from claiming that exposure to toxic substances, for instance, has created an increased risk of harm not yet manifested in a physical disease." *Anderson*, 669 A.2d at 77. The Third Circuit recognized this Court's language, but concluded that it could be set aside as dicta. Ex. C at 5-6. However, this Court's statement of law, which has been followed for almost three decades, should not be so lightly ignored.

The sentence is just a specific application of *Anderson*'s more general holding that increased risk is not a substitute for injury and that physical injury is required to

ensure claims about future harm are not too speculative. The Court ruled that "increased risk of harm *accompanied by physical injury* is a compensable element of damages under Delaware law," and that physical injury is required to "address[] concerns about speculative claims for future harm." *Id.* at 74, 77 (emphasis added). *Anderson* also held that "[i]ncreased risk" is "merely one element of damages"—not injury—and can provide those damages only "when negligence has caused harm." *Id.* at 78. There is no question that this language is not dicta, as it was a critical part of this Court's reasoning for its disposition that Plaintiff had a claim only *because* he "has suffered present physical injuries caused by the defendant's negligence." *Id.* at 79. That holding is dispositive here, just as this Court recognized when it said—dicta or not—that the very same "physical injury" limitation applies to a claim based on exposure to toxic substances. *Id.* at 77.

Plaintiff cannot evade the dispositive language in *Anderson* by burying its discussion of the case in a single paragraph at the back of its brief (Br. 32-33). According to Plaintiff, *Anderson*'s sentence on toxic torts was simply describing Connecticut law. But that sentence was not descriptive; rather it was explaining why "[t]his approach" is correct: because it "addresses concerns about speculative claims for future harm." *Id.* at 77. Regardless, Plaintiff ignores the rest of *Anderson*, which unequivocally describes a requirement of "physical injury." Nor does Plaintiff argue for some special exception to this rule for toxic tort cases. Rather, Plaintiff argues

that physical injury simply is not required to state a tort claim—an argument directly in conflict with *Anderson*.

The argument also conflicts with several other Delaware cases that have made the same point. For instance, the Delaware Superior Court held that a claim based on "fear of future asbestos related harm without a demonstrable physical change in bodily condition . . . is not compensable." *Nutt v. A.C. & S., Inc.*, 466 A.2d 18, 26 (Del. Super. Ct. 1983), *aff'd sub nom. Mergenthaler*, 480 A.2d 647 (Del. 1984). This Court affirmed, holding that "a claim for the expenses of medically required surveillance and related mental anguish . . . fails to state a claim upon which relief can be granted *where there is no present physical injury*." *Mergenthaler*, 480 A.2d at 649 (emphasis added). Where, as here, plaintiffs "concede that they have suffered no physical injury due to wrongful [toxin] exposure . . . *that concession is dispositive*[.]" *Id.* at 651 (emphasis added). Plaintiff erroneously attempts (Br. 15) to limit *Mergenthaler* to "claims for mental anguish." But the claim there was not simply for "mental anguish," but also for "fear of contracting cancer in the future as a result of the wives' contact with asbestos-fibers in the laundering of their husbands' work clothes" and "the expenses of medically required surveillance" therefrom. *Id.* at 649. There, as here, "an essential element of the claim is that the claimant have a present physical injury." *Id*. at 651. While the Third Circuit suggested some ambiguity over whether "fear" of cancer was different than "increased risk,"

Mergenthaler's specific claim was for "medically required surveillance," not just damages based upon subjective fear. *Id.*; *see also In re Asbestos Litig.*, 1994 WL 16805917, at *2 (Del. Super. Ct. Aug. 5, 1994) (holding that where "plaintiffs do not have a compensable physical injury, plaintiffs may not recover for the expenses of medical surveillance").[1]

Similarly, in *Brzoska v. Olson*, 668 A.2d 1355 (Del. 1995), this Court affirmed the dismissal of a claim for the cost of medical testing and monitoring because "[i]n this case, plaintiffs have sustained no physical injury, and, therefore, they could not recover under a negligence theory." *Id.* at 1362. *Brzoska* further held that "damages for claims of . . . fear of contracting a disease [] are recoverable only if the underlying physical injury is shown." *Id.* Plaintiff attempts (Br. 19-20) to distinguish *Brzoska* because there was no actual exposure there. But this Court relied on lack of actual exposure only in holding that the battery claim must fail, *see* 668 A.2d at 1363-65; it held the negligence claim (including recovery for medical monitoring) failed for lack of a present, physical injury, *id.* at 1362. Moreover, regardless of the particular factual context, the rule is clear across the board: to bring a tort claim, there must be a *present* injury, not the possibility of *future* injury.

[1] Plaintiff notes (Br. 16-18) that *Mergenthaler* mentioned *Ayers v. Jackson Tp.*, 461 A.2d 184 (N.J. 1983), but the citation to *Ayers* did not suggest a disregard of the physical injury requirement, and regardless, *Ayers* is inapposite, as discussed *infra* at 25-26.

Furthermore, as the district court explained, the way that this Court has approached other legal questions regarding toxic tort claims confirms the present-injury rule. *Baker,* 2021 WL 7209363 at *2. In particular, "the statute of limitations for toxic-tort claims starts to run when a plaintiff begins to feel physical effects, suggesting that they are needed in every toxic-tort case." *Id*. (citing *Brown v. E.I. duPont de Nemours & Co.*, 820 A.2d 362, 368 (Del. 2003)). In addition, "Delaware lets toxic tort plaintiffs bring separate claims for different diseases caused by one exposure," and "states that do so generally allow recovery only for manifested disease." *Id*. Plaintiff offers no response to the district court's reasoning.

In the face of the clear and repeated precedent discussed above, Plaintiff does not cite a single Delaware case ever accepting a claim based on an alleged increased risk of harm without any physical injury. No such case exists. Plaintiff cites (Br. 18) *Garrison v. Medical Center of Delaware Inc.*, 581 A.2d 288 (Del. 1989), but *Garrison* said nothing at all about allowing a tort claim for risk of future harm, and no Delaware case has ever cited it for that proposition. In short, *Garrison* was a negligence case in which plaintiffs alleged that defendants improperly performed a medical procedure (amniocentesis), a procedure that, if it had been performed in a timely manner, would have informed plaintiffs of certain genetic abnormalities in time to allow plaintiffs to consider whether to terminate a pregnancy. *Id*. at 290. The injury alleged was not risk of future harm, but actual payments parents were

making to address present harms from their child's genetic abnormality. *Id.* at 290 ("The resulting injury to the plaintiff parents lies in their being deprived of the opportunity to make an informed decision to terminate the pregnancy, requiring them to incur extraordinary expenses in the care and education of their child afflicted with a genetic abnormality."). Thus, there was a physical harm to the child that was non-speculative, and the parents had a claim for recovery of the payments made due to that harm. Plaintiff also cites (Br. 21-22) *McCracken v. Wilson Beverage*, No. 91A-10-004, 1992 WL 301985, at *1 (Del. Super. Ct. Oct. 15, 1992), which is clearly inapposite, as it involved neck and back injuries from a car accident in addition to medical monitoring.

In addition, while Plaintiff notes (Br. 15 n.36) that "one federal court has predicted Delaware law recognizes Plaintiff's claims as compensable" (citing *Guinan v. A.I. duPont Hosp. for Children*, 597 F. Supp. 2d 517 (E.D. Pa. 2009)), Plaintiff fails to mention that this decision was reversed on appeal *on this very point* in *M.G. ex rel. K.G. v. A.I. Dupont Hosp. for Children*, 393 F. App'x 884 (3d Cir. 2010). While the Third Circuit "declin[ed] to predict whether the Delaware Supreme Court might acknowledge some variant of a medical monitoring claim," it stated plainly that "[t]he Delaware Supreme Court has not recognized a cause of action for medical monitoring[.]" *Id.* at 892 & n.6; *see also id.* at 892 ("Neither the District Court nor Plaintiff points to any case in this Circuit, let alone in Delaware, in which

a free-standing medical monitoring claim has been allowed to proceed although the plaintiff has not demonstrated significant exposure to a toxic (poisonous) or proven hazardous substance."). Thus, "the District Court's prediction that the Delaware Supreme Court would permit a claim for medical monitoring on this record requires several 'leaps' from the current state of the law, generally, let alone Delaware law." *Id*.

Plaintiff's reliance (Br. 23-24) on the Restatement (Second) of Torts is also misplaced. Plaintiff does not identify any Restatement provision suggesting that increased risk suffices for an injury. Section 7 states that injury is "the invasion of any legally protected interest of another," but Plaintiff does not explain what legally protected interest under Delaware law is invaded based only on an allegedly increased risk of future disease. And while Plaintiff notes (Br. 24) that the Restatement defines harm differently than injury, Plaintiff fails to mention that the Restatement explains this difference in terms of unwanted touching or an injury to property, not an increased risk of future harm. *See* Restatement (Second) of Torts § 7 cmt. a ("The most usual form of injury is the infliction of some harm; but there may be an injury although no harm is done. Thus, any intrusion upon land in the possession of another is an injury . . . . So too, the mere apprehension of an intentional and immediate bodily contact, whether harmful or merely offensive, is as much an 'injury' as a blow which breaks an arm."). Indeed, many of the courts

rejecting increased-risk claims (discussed below) applied the Restatement. *See, e.g.*, *Berry v. City of Chicago*, 181 N.E.3d 679, 689 (Ill. 2020) (citing Restatement and ruling that "in a negligence action, an increased risk of harm is not an injury"); *Wood v. Wyeth-Ayerst Lab'ys, Div. of Am. Home Prod.*, 82 S.W.3d 849, 859 (Ky. 2002) (citing Restatement and finding that "[t]raditional tort law militates against recognition of such" fear of future harm claims "without a showing of present physical injury").

In sum, adopting Plaintiff's position would require a revolution in Delaware law, undermining decades of precedent and creating a previously unknown exception to the requirement of a *present* injury. As set forth below, the reasoning and experiences of other courts strongly weigh against Plaintiff's proposed revolution.

2. The Reasoning Of The Majority Of Courts And The Troubling Experience Of The Minority Confirm That This Court Should Not Expand Delaware Law To Permit Claims For Increased Risk Absent Physical Injury

The majority of courts to consider the issue do not permit recovery of medical monitoring damages unless actual injury—such as symptoms or disease—already has been established. As the district court explained, "[m]ost courts reject increased-risk claims." Ex. B, *Baker*, 2021 WL 7209363 at *2 (citing 1 Toxic Torts Litig. Guide § 4:12 (2020)). A full canvass of all 50 states comes to the same conclusion. *See* Mark A. Behrens & Christopher E. Appel, American Law Institute Proposes

Controversial Medical Monitoring Rule in Final Part of Torts Restatement at 10-17 (Oct. 2020), at https://www.iadclaw.org/assets/1/17/American_Law_Institute_Proposes_Controversial_Medical_Monitoring_Rule_in_Final_Part_of_Torts_Restatement.pdf (providing a chart with footnotes of cases describing the rule in every state). Specifically, "there are only ten states in which a state appellate court has adopted medical monitoring absent present physical injury," and "[a]t least as many states reject medical monitoring absent present injury." *Id.* at 5. And of the ten not requiring physical injury, "[o]nly five states have adopted medical monitoring absent present injury as an independent cause of action," as opposed to as an item of recoverable damages. *Id.* at 6 (listing Florida, Massachusetts, Pennsylvania, Utah, and West Virginia). But far more important than head-counting, the reasoning and experience of other courts shows precisely why Plaintiff's theory should be rejected.

To begin with, the traditional consensus has long been that actual loss or harm is required to award damages, and "the threat of future harm, not yet realized, is not enough." W. Page Keeton, et al., Prosser and Keeton on the Law of Torts § 30 at 165 (West 5th ed. 1984); *see also, e.g.*, Victor E. Schwartz et al., *Medical Monitoring: Should Tort Law Say Yes?*, 34 Wake Forest L. Rev. 1057, 1059 (1999) ("[O]ne of the fundamental principles of tort law has been that a plaintiff cannot recover without proof of a physical injury.").

The U.S. Supreme Court recognized and followed this traditional approach in rejecting a medical monitoring cause of action under federal law for lack of a present, physical injury. *See Metro-North Commuter Railroad Co. v. Buckley*, 521 U.S. 424 (1997). As Justice Breyer's opinion for the Court explained, "contacts, even extensive contacts, with serious carcinogens are common." *Id.* at 434 (noting "21 million Americans have been exposed to work-related asbestos," "3 million workers exposed to benzene, a majority of Americans exposed outside the work place," and "43% American children lived in a home with at least one smoker"). "The large number of those exposed and the uncertainties that may surround recovery" lead to "the problem of unlimited and unpredictable liability." *Id.* at 435 (quotation marks omitted). In short, "tens of millions of individuals may have suffered exposure to substances that might justify some form of substance-exposure-related medical monitoring." *Id.* at 442. "[T]hat fact, along with uncertainty as to the amount of liability, could threaten both a flood of less important cases (potentially absorbing resources better left available to those more seriously harmed) and the systemic harms that can accompany unlimited and unpredictable liability." *Id.* (internal punctuation and citations omitted).

Since *Metro-North*, there has been "a clear trend against the recognition of medical monitoring claims." Herbert L. Zarov et al., *A Medical Monitoring Claim for Asymptomatic Plaintiffs: Should Illinois Take the Plunge?*, 12 DePaul J. Health

Care L. 1, 2-3 (2009). To provide just a few examples of courts that have examined the issue: The New York Court of Appeals refused to recognize tort recovery for medical monitoring by "asymptomatic plaintiffs" who have not contracted (and may never contract) a disease. *Caronia v. Philip Morris USA, Inc.*, 22 N.Y.3d 439 (2013). The court explained that "dispensing with the physical injury requirement could permit tens of millions of potential plaintiffs to recover monitoring costs, effectively flooding the courts while concomitantly depleting the purported tortfeasor's resources for those who have actually sustained damage." *Id.* at 451 (cleaned up).

Similarly, in *Henry v. Dow Chem. Co.*, 701 N.W.2d 684, 694 (Mich. 2005), the Michigan Supreme Court refused to permit an award of medical monitoring damages for a class of plaintiffs who had not "suffered any present physical harm," *id*. at 689, as a result of exposure to dioxin, holding: "Plaintiffs have asked us to recognize a cause of action that departs drastically from our traditional notions of a valid negligence claim" and "recognizing a cause of action based solely on exposure—one without a requirement of a present injury—would create a potentially limitless pool of plaintiffs." *Id*. at 694. "We would be unwise, to say the least, to alter the common law in the manner requested by plaintiffs when it is unclear what the consequences of such a decision may be and when we have strong suspicions, shared by our nation's highest court, that they may well be disastrous." *Id.* at 697.

The Supreme Court of Kentucky likewise rejected a claim for medical monitoring for a plaintiff who had been exposed to asbestos, but had not developed symptoms of a related disease, because "having weighed the few potential benefits against the many almost-certain problems of medical monitoring, we are convinced that this Court has little reason to allow such a remedy without a showing of present physical injury." *Wood v. Wyeth-Ayerst Lab'ys, Div. of Am. Home Prod.*, 82 S.W.3d 849, 859 (Ky. 2002). "Traditional tort law militates against recognition of such claims, and we are not prepared to step into the legislative role and mutate otherwise sound legal principles." *Id.* Many other courts are in accord.[2]

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[2] *See, e.g.*, *Ball v. Joy Techs., Inc.*, 958 F.2d 36, 39 (4th Cir. 1991) (applying Virginia law); *Pisciotta v. Old Nat'l Bancorp*, 499 F.3d 629, 638-39 (7th Cir. 2007) (applying Indiana law); *Lowe v. Philip Morris USA, Inc.*, 344 Or. 403(2008); *Paz v. Brush Engineered Materials, Inc.*, 949 So. 2d 1, 3 (Miss. 2007); *Hinton ex rel. Hinton v. Monsanto Co.*, 813 So. 2d 827, 831-32 (Ala. 2001); *Berry v. City of Chicago*, 181 N.E.3d 679, 688-89 (Ill. 2020); *Baker v. Atl. Richfield Co.*, 2022 WL 4396333, at *4-5 (N.D. Ind. Sept. 23, 2022); *DuRocher v. Riddell, Inc.*, 97 F. Supp. 3d 1006, 1015-16 (S.D. Ind. 2015) (applying Washington law); *Alsteen v. Wauleco, Inc.*, 802 N.W.2d 212, 218-19 (App. 2011); *In re All Pending Chinese Drywall Cases*, 80 Va. Cir. 69, 2010 WL 7378659, at *9-10 (Va. Cir. Ct. 2010); *Cole v. ASARCO, Inc.*, 256 F.R.D. 690, 695 (N.D. Okla. 2009); *Miranda v. DaCruz*, 2009 WL 3515196, at *7-8 (R.I. Super. 2009); *Curl v. Am. Multimedia, Inc.*, 187 N.C. App. 649, 657 (2007); *Norwood v. Raytheon Co.*, 414 F. Supp. 2d 659, 664-68 (W.D. Tex. 2006); *Parker v. Brush Wellman, Inc.,* 377 F. Supp. 2d 1290, 1302 (N.D. Ga. 2005), *aff'd sub nom. Parker v. Wellman*, 230 F. App'x 878, 883 (11th Cir. 2007); *Rosmer v. Pfizer, Inc.*, 2001 WL 34010613, at *5 (D.S.C. 2001); *Jones v. Brush Wellman, Inc.*, 2000 WL 33727733, at *8 (N.D. Ohio 2000) (applying Tennessee law); *see also* La. Civ. Code Ann. Art. 2315(B).

The reasoning of these courts is persuasive. Requiring a present injury is a reasonable and necessary limitation on recovery for the possibility of future harm in light of the widespread exposure and use of potentially hazardous substances in everyday life.[3] And, of course, if any class member has developed or later develops a disease of any kind caused by the exposure alleged here, that individual can bring a claim at that time. *See, e.g.*, *In re Asbestos Litig.*, 2017 WL 3600418, at *1 (Del. Super. Ct. Aug. 18, 2017) (a person who *develops an injury* as a result of exposure to a toxic substance can bring a claim "when the plaintiff is chargeable with knowledge that his condition is attributable to [toxic] exposure").

To be sure, a handful of states have allowed medical monitoring claims without physical injury, but the experience in those states only confirms the folly of recognizing this kind of claim. In West Virginia, for example, the state Supreme Court's decision approving medical-monitoring remedies, *see Bower v. Westinghouse Elec. Corp.,* 522 S.E.2d 424, 432-33 (W. Va. 1999), immediately produced a rash of new litigation. Plaintiffs' attorneys quickly moved to bring suit "against major cigarette manufacturers on behalf of approximately 270,000 West

[3] One need only consider the wide array of items that the International Agency for Research on Cancer (IARC) have been listed as "possibly carcinogenic to humans." Among the hundreds of items are "Aloe vera, whole leaf extract" and "carpentry and joinery." *See generally* List of Classifications – IARC Monographs on the Identification of Carcinogenic Hazards to Humans (who.int), available at https://monographs.iarc.who.int/list-of-classifications.

Virginia smokers who had not been diagnosed with any smoking-related diseases." *Henry*, 701 N.W.2d at 694 n.12 (citing *In re Tobacco Litig.* (*Med. Monitoring Cases*), No. 00-C-6000 (W. Va. Ohio Cty. Cir. Ct. 2001)). In a separate action, "healthy plaintiffs from seven states" all sought "medical monitoring on the basis of alleged exposure to toxic materials." *Id.* (citing *Stern v Chemtall, Inc.*, No. 03-C-49M (W. Va., Kanawha Cty. Cir. Ct. 2001)).

Indeed, the case law from around the country reveals the "potentially limitless pool of plaintiffs," *Henry*, 701 N.W.2d at 694, who could in theory generate claims for medical monitoring without physical injury, based on exposure to, e.g., asbestos, cigarettes, industrial chemicals, radiation, drugs, medical devices, building materials, and even cosmetics.[4] And in this state, just recently, a court dismissed a proposed class action for medical monitoring due to groundwater contamination allegedly causing increased risk of disease. *Banks v. E.I. du Pont de Nemours & Co.*, 2022 WL 3139087, at *2 (D. Del. Aug. 4, 2022), (dismissing claims for those

[4] *See, e.g.*, *Hinton ex rel. v. Monsanto Co.*, 813 So. 2d 827 (Ala. 2001) (polychlorinated biphenyls (PCB)); *Norwood v. Raytheon Co.*, 414 F. Supp. 2d 659 (W.D. Tex. 2006) (radar); *Wood v. Wyeth-Ayerst Laboratories*, 82 S.W.3d 849 (Ky. 2002) (appetite suppressants); *In re W. Va. Rezulin Litig.*, 585 S.E.2d 52 (W. Va. 2003) (diabetes medication); *Sutton v. St. Jude Med., Inc.*, 292 F. Supp. 2d 1005 (W.D. Tenn. 2003) (aortic connector), *rev'd*, 419 F.3d 568 (6th Cir. 2005); *In re All Pending Chinese Drywall Cases*, 80 Va. Cir. 69, 2010 WL 7378659 (2010) (drywall); *Stella v. LVMH Perfumes & Cosmetics USA, Inc.*, 564 F. Supp. 2d 833, 836 (N.D. III. 2008) (lipstick).

without physical injury because "[i]n Delaware, an increased risk of illness (without a present physical injury), is not a sufficient injury"), *report and recommendation adopted*, 2022 WL 3577111 (D. Del. Aug. 19, 2022). Thus, the flood of limitless litigation invited by Plaintiff's theory is not merely a theoretical possibility; it is an inevitable consequence of allowing medical monitoring claims for those who have no physical injury, given the pervasiveness of potentially harmful chemicals and materials people encounter in everyday life.

Faced with this inevitability, the courts that permit such claims typically have been forced to invent restraints on such claims to keep them from spinning out of control. As the Supreme Court recognized, and is still true today, "the cases authorizing recovery for medical monitoring in the absence of physical injury do not endorse a full-blown, traditional tort law cause of action for lump-sum damages . . . . Rather, those courts, while recognizing that medical monitoring costs can amount to a harm that justifies a tort remedy, have suggested, or imposed, special limitations on that remedy." *Metro-North*, 521 U.S. at 441 (cleaned up).

For instance, Plaintiff relies (Br. 14-16) on *Ayers*, but the New Jersey Supreme Court subsequently held that *Ayers* involved "a unique damage claim . . . [which] must be understood in its narrow context." *Nieves v. Off. of the Pub. Def.*, 230 A.3d 227, 236 (N.J. 2020). The *Ayers* decision thus "has not been expanded upon since," and the New Jersey Supreme Court "decline[d] the invitation to" expand its holding

to other factual contexts. *Nieves*, 230 A.3d at 236. In particular, the remedy in *Ayers* "is not easily invoked" and "was fashioned to help a class or persons who had been victimized by a public entity." *Theer v. Philip Carey Co.*, 628 A.2d 724, 732 (N.J. 1993). In *Theer*, the court rejected medical surveillance damages for a woman who alleged that she had been exposed to asbestos by handling her husbands' work clothes containing asbestos fibers: "If a plaintiff is exposed to a [toxin] in an indirect manner, *and, further, has not suffered from any injury or condition relating to that exposure*, it becomes increasingly difficult for courts and juries to determine the direct correlation between the indirect exposure and any future risk of injury." *Id.* at 627 (emphasis added). The New Jersey Supreme Court "conclude[d] that medical surveillance damages are not available for plaintiffs who have not experienced direct and hence discrete exposure to a toxic substance *and who have not suffered an injury or condition resulting from that exposure*[.]" *Id.* at 628 (emphasis added).

Similarly, Plaintiff cites (Br. 22) *Friends For All Children v. Lockheed Aircraft Corp.*, 746 F.2d 816, 825 (D.C. Cir. 1984), but that case involved neurological monitoring of children who had been in a plane crash and had suffered extensive physical trauma. In those circumstances, the D.C. Circuit (applying District of Columbia law) allowed a claim injury even though the physical trauma had not yet resulted in physical injury and expressly distinguished increased risk of disease. *See id.* at 826 ("The cases Lockheed cites for the general proposition that

the common law recognizes no action for being put 'at risk' are readily distinguishable on the grounds that the alleged injury to be compensated was speculative without the corroborative presence of physical injury. . . . The 'injury' that stems from having an increased risk of disease is obviously speculative.").

Other courts have set forth a variety of novel limitations. Most require that the medical-monitoring damages be in the form of a court-supervised fund, to ensure the money is appropriately used for such monitoring. *See Metro-North*, 521 U.S. at 441 (citing cases); *see also, e.g.*, *Exxon Mobil Corp. v. Albright*, 71 A.3d 30, 80-81 (Md. App. 2013). Most also have imposed heightened standards or additional elements for such a claim. *See, e.g.*, *Exxon*, 71 A.3d at 81-82 (describing four-part test); *Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215, 226 (2009) (describing seven-part test, including requirement of "subcellular" injury); *Potter v. Firestone Tire & Rubber Co.*, 6 Cal. 4th 965, 1006 (1993) (describing five-part test).

In sum, courts that do not want a flood of litigation imposing limitless liability are forced to take on the quintessentially legislative task of making difficult public policy judgments with new rules, and these amorphous rules often succeed only in creating uncertainty for courts and litigants. As the New York Court of Appeals aptly noted, "there is no framework concerning how such a medical monitoring program would be implemented and administered." *Caronia*, 22 N.Y.3d at 452. "Courts generally lack the technical expertise necessary to effectively administer a

program heavily dependent on scientific disciplines such as medicine, chemistry, and environmental science. The legislature is plainly in the better position to study the impact and consequences of creating such a cause of action, including the costs of implementation and the burden on the courts in adjudicating such claims." *Id.* (quotation omitted); *see also Henry*, 701 N.W.2d at 696 n.15 ("to create a medical monitoring cause of action, in light of both the essentially limitless number of such exposures and the limited resource pool from which such exposures can be compensated, a 'cutoff' line would . . . inevitably need to be drawn" which the legislature is "better suited to draw").

Far from suggesting how this Court should embark on the thorny task of developing needed limitations on this new form of liability, Plaintiff appears to advocate no meaningful limits at all. According to Plaintiff (Br. 21), the claim here is meritorious because "ethylene oxide is a carcinogen . . . unsafe at any level," "Plaintiff was actually exposed to this carcinogen, . . . and this actual inhalation caused present, increased risk of illness and disease." Under this theory, *any* exposure to a carcinogen producing *any* increased risk would suffice. Plaintiff asserts (Br. 32) that this case is different because there is a "demonstrated and scientifically provable objective increased risk of harm and demonstration and proof of necessary medical monitoring and diagnostic testing." But this proposed test still provides no floor for the amount of exposure or increased risk necessary to state a

claim. Rather, it just describes the supposed strength of proof here, which a plaintiff will allege in any case, and which will be the subject of complex, controversial medical evidence in those cases.

Finally, Plaintiff repeatedly mentions the supposed unfairness of not providing a remedy here, but ignores the policy justification the Delaware courts (and many others) have recognized as necessary to constrain otherwise-limitless liability. While Plaintiff makes light of this as a "parade of horribles" (Br. 32), it has been (as discussed above) the very real experience of courts that follow Plaintiff's proposal. Plaintiff also ignores the effect on those that have actual, present, physical injuries. Allowing plaintiffs "to recover medical monitoring costs without first establishing physical injury would lead to the inequitable diversion of money away from those who have actually sustained an injury as a result of the exposure." *Caronia*, 22 N.Y.3d at 442. And by the time the "pre-injury claims" for medical monitoring are litigated and resolved, there may be little left to compensate those who ultimately develop "manifest physical injuries and a more immediate need for medical care." *Henry*, 701 N.W.2d at 695; *see also Metro-North*, 521 U.S. at 444 (noting "the effects upon interests of other potential plaintiffs who are not before the court and who depend on a tort system that can distinguish between reliable and serious claims on the one hand, and unreliable and relatively trivial claims on the other."). "The reality is that competing interests are at stake—and those interests

sometimes can be reconciled in ways other than simply through the creation of a full-blown, traditional, tort law cause of action." *Metro-North*, 521 U.S. at 444. This Court should strike the proper balance, as it has in prior cases, by permitting those with an injury from exposure to file suit but preventing cases (such as this one) from proceeding based on nothing more than alleged exposure that creates some supposedly increased future risk.

CONCLUSION

For the reasons above, this Court should answer the certified question "no," and rule that an increased risk of illness, without present manifestation of a physical harm, is not a cognizable injury under Delaware law.

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