

Court of Appeals
STATE OF NEW YORK

MARCIA L. CARONIA, LINDA MCAULEY, and ARLENE FELDMEN,

Plaintiffs-Appellants,

—against—

PHILIP MORRIS USA, INC.,

Defendant-Respondent.

*On Questions Certified by the United States Court of Appeals for
the Second Circuit (USCOA Docket No. 11-0316-cv)*

**BRIEF OF AMICI CURIAE THE BUSINESS COUNCIL
OF NEW YORK STATE, INC., THE CHAMBER OF COMMERCE
OF THE UNITED STATES OF AMERICA, AMERICAN COATINGS
ASSOCIATION, NATIONAL ASSOCIATION OF MANUFACTURERS,
AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS
OF AMERICA IN SUPPORT OF DEFENDANT-RESPONDENT**

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DISCLOSURE STATEMENT

Pursuant to 22 N.Y.C.R.R. § 500.1(c), *Amici Curiae* make the following disclosure:

The Business Council of New York State, Inc., Chamber of Commerce of the United States of America, American Coatings Association, National Association of Manufacturers, and Pharmaceutical Research and Manufacturers of America are not-for-profit business federations with no parents, subsidiaries, or affiliates.

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The Business Council of New York State, Inc., the Chamber of Commerce of the United States of America, the American Coatings Association, the National Association of Manufacturers, and the Pharmaceutical Research and Manufacturers of America respectfully submit this brief, accompanied by their motion for *amicus curiae* relief under 22 NYCRR §§ 500.12(e) and 500.23, in support of Defendant-Respondent Philip Morris USA, Inc. in the above-captioned action.

STATEMENT OF INTEREST

The Business Council of New York State, Inc. (“Business Council”) is a statewide organization dedicated to advancing the interests of both large and small businesses in New York. The Business Council works for a healthier business climate, economic growth, and jobs.

The Chamber of Commerce of the United States of America (“Chamber”) is the world’s largest business federation. The Chamber directly represents 300,000 members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before the courts. To that end, the Chamber regularly files *amicus* briefs in cases that raise issues of vital concern to the nation’s business community. This case is of particular importance to the Chamber given the broad range of perspectives and experiences of its members.

The American Coatings Association (“ACA”) is a voluntary, nonprofit trade association representing some 300 manufacturers of paints, coatings, adhesives, sealants and caulks, raw materials suppliers to the industry, and product distributors. Collectively, ACA represents companies with greater than 95% of the country’s annual production of paints and coatings, which are an essential component to virtually every product manufactured in the United States. ACA is actively involved in supporting its members’ interests through *amicus curiae* briefing in courts across the country.

The National Association of Manufacturers (“NAM”) is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs nearly 12 million men and women, contributes more than \$1.8 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for two-thirds of private-sector research and development. The NAM is the powerful voice of the manufacturing community, and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States.

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is a voluntary, nonprofit association representing the nation’s leading research-based pharmaceutical and biotechnology companies. PhRMA’s member companies are

dedicated to discovering medicines that enable patients to lead longer, healthier, and more productive lives. During 2012 alone, PhRMA members invested an estimated \$48.5 billion in efforts to research and develop new medicines.

PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA has frequently filed *amicus curiae* briefs in cases raising matters of significance to its members.

The Business Council, Chamber, ACA, NAM, and PhRMA are filing this brief as *amici curiae* because Plaintiffs' proposed cause of action has no basis in New York law, and the courts are ill-equipped to grapple with the complex social, medical, and scientific issues presented by such claims. Although this case arises in the tobacco context, Plaintiffs' proposed equitable medical monitoring cause of action would impact numerous companies and industries, creating a wide scope of potentially limitless and unpredictable medical monitoring liability. Indeed, because the crux of Plaintiffs' proposed medical monitoring claim is increased risk, such actions could be brought in a wide variety of contexts against companies that manufacture, use, store, sell, or transport substances that could have a potential health effect.

Accordingly, *amici* respectfully submit this brief as friends of this Court, and urge the Court to answer the first certified question "no," and hold that settled New

York law precludes an equitable medical monitoring cause of action absent a present injury.

SUMMARY OF ARGUMENT

Plaintiffs ask this Court to create a new cause of action that would open the courthouse to millions of potential plaintiffs who have no current injury. The policy justifications for adopting such a sweeping change to centuries-old tort law are, at best, hotly disputed and, at worst, deeply flawed. The U.S. Supreme Court and the majority of state high courts considering the issue have rejected pleas to recognize “no injury” medical monitoring claims, either as equitable causes of action or as a remedy under traditional tort theories, because to do so would generate a massive and unpredictable expansion of tort liability, overwhelm the courts, and divert resources that should be devoted to those who suffer actual injuries.

This Court should do the same. Balancing the complex social, legal, and medical policy decisions underlying these claims is the domain of the legislature, not the courts. And the experience of those states in which courts have opted to create new liabilities for medical monitoring proves why: the vague and ill-defined standards that these courts have articulated are so unworkable, and so susceptible to manipulation by plaintiffs’ experts, that they provide no limits at all. If a “no injury” cause of action were combined with an infinitely renewing statute

of limitations, as Plaintiffs here seek, the consequences would be staggering, not only for corporations with current ties to New York but for those who did business here decades ago. This Court should reject Plaintiffs' invitation to create a new medical monitoring cause of action, and should reaffirm New York's long-standing requirement that tort plaintiffs have an actual injury, which does not encompass increased risk or economic loss without underlying injury.

Implicitly conceding that their case is inconsistent with New York law, Plaintiffs claim in their Reply brief that they have suffered an *actual* injury—namely, “physical injury to the tissues and structures of his and her lungs.” (Reply Br. 2). But Plaintiffs' cited evidence largely proves the opposite, stating that Plaintiffs have no currently detectable or symptomatic condition but are at an increased risk of developing lung cancer. (*See* A109 ¶ 194, A137-38 ¶ 16-18, A172-73 ¶ 18-20). The remaining cited evidence merely asserts that smoking can cause lung damage (not that any Plaintiff actually has it), that any damage is not currently detectable (A109 ¶ 195, A137 ¶ 16), and that tissue damage *can be reversed* by the body before it develops into disease, because “cells are replaced and repair can take place” (A171 ¶ 12). Thus, far from proving a current injury that merits monitoring, Plaintiffs have asserted the speculative potential for non-detectable tissue damage that may, or may not, result in disease. This is no different from asserting increased risk of disease.

I. THE PROPOSED CAUSE OF ACTION IS CONTRARY TO NEW YORK TORT LAW.

A. Plaintiffs' Proposed Cause Of Action Cannot Be Reconciled With New York's Injury Requirement.

Under well-established New York law, a plaintiff can recover in tort only for an actual, physical injury, and only for an injury that is separate from the asserted damages. Over 70 years ago, this Court clarified this rule, holding in *Schmidt v. Merchants Despatch Transportation Co.*, 270 N.Y. 287, 300 (1936), that even where negligence is present, “no actionable wrong is committed if the danger is averted. It is only the *injury* to person or property arising from negligence which constitutes an invasion of a personal right, protected by law, and therefore, an actionable wrong.”¹

Applying these principles, courts in New York have long held that increased risk of disease is not a tort injury. *See, e.g., Strohm v. N.Y., Lake Erie & W. R.R. Co.*, 96 N.Y. 305, 306 (1884) (expert testimony that plaintiff may develop future disease inadmissible because “the door was opened for the jury in estimating damages, to include compensation for the mere hazard to which the plaintiff was

¹ *See also Blanco v. Am. Tel. & Tel. Co.*, 90 N.Y.2d 757, 772 (1997) (“[I]njury is necessary for the accrual of a cause of action.”); *Kronos, Inc. v. AVX Corp.*, 81 N.Y.2d 90, 94 (1993) (“[A]s a general proposition, a tort cause of action cannot accrue until an injury is sustained.”); *Barrell v. Glen Oaks Vill. Owners, Inc.*, 29 A.D.3d 612, 613 (2d Dep’t 2006) (a cause of action does not exist until defendant’s alleged conduct causes injury that produces loss or damage); 103 N.Y. Jur. 2d Torts § 9 (2d ed. 2010) (“The mere existence of a wrong, without some identifiable damage, provides no basis for a cause of action.”).

claimed to be exposed”); *Sharma v. Udwadia*, 309 A.D.2d 1250, 1250-51 (4th Dep’t 2003) (“The threat of future harm, not yet realized, is not enough to support an award of damages”) (citation and quotation marks omitted).² Indeed, a black-letter principle of tort law is that “[t]he threat of future harm, not yet realized, is not enough.” W. Page Keeton *et al.*, PROSSER & KEETON ON TORTS, § 30 at 165 (5th ed. 1984).

Plaintiffs’ medical monitoring claim fails under these traditional principles of New York tort law. Plaintiffs admit that they have never “asserted nor conceded that they suffered an injury at all.” (Pl. Br. 62). They disavow “any form of cognizable bodily injury which would give rise to a personal injury claim.” (*Id.* at 18). Rather, Plaintiffs’ proposed equitable cause of action is “premised on an enhanced risk of developing lung cancer” at some undefined point in the future, a risk that they candidly describe as “speculative.” (*Id.*). Such threats of future harm are not an injury.

Likely realizing the inconsistency between their position and New York law, Plaintiffs claim in their Reply brief that they are suffering a present injury. (*See*

² *See also Cillo v. Resjefal Corp.*, 16 A.D.3d 339, 341 (1st Dep’t 2005) (the “possibility of damage in the future ... is too tenuous and speculative to present a material issue of triable fact”); *Frank v. Daimler Chrysler Corp.*, 292 A.D.2d 118, 127 (1st Dep’t 2002) (rejecting “no injury” or “peace of mind” actions on policy grounds); *Ivory v. Int’l Bus. Machs. Corp.*, No. 2012-0768, 37 Misc. 3d 1221(A), 2012 WL 5680180, at *11 (Sup. Ct. Broome Cnty. Nov. 15, 2012) (“There is no doubt but that New York law requires an injury to sustain a tort cause of action, rather than the possibility of some future injury”).

Reply Br. 2, 23). But the cited evidence merely states that Plaintiffs are at an increased risk of cancer because smoking is capable of causing genetic changes, which if not repaired by the body's natural mechanisms, might turn into cancer. (See A109 ¶¶ 194-195, A137-38 ¶¶ 16-18, A170-71 ¶¶ 9-14, A172-73 ¶¶ 18-20, A384 ¶ 73). There is no evidence that any particular Plaintiff in fact has such genetic damage. Plaintiffs' claim that every puff of smoke causes inflammatory damage to lung tissue is a red herring; they have produced no evidence that such inflammation is causally related to the cancer for which they seek screening. Plaintiffs' attempted sleight-of-hand on this issue demonstrates the dangers of allowing medical monitoring claims to be founded on speculative claims about subcellular injury.

Plaintiffs' newly minted "injury" is in all events too speculative to satisfy New York's injury requirement. Indeed, where, as here, the asserted injury is undetectable, uncertain, and not an inevitable cause of disease or injury, there is no meaningful distinction between the injury of increased risk of disease from exposure and presumed tissue damage. Like the former, the latter is a hypothetical impact unless and until it becomes manifest and thus lacks a guarantee of genuineness.

Plaintiffs' alternative argument (Pl. Br. 62)—that their alleged injury is future screening costs—is equally inconsistent with New York law. Economic loss

is not recoverable in New York absent direct injury to person or property. *See, e.g.*, 16 N.Y. Prac., New York Law of Torts § 21:13.10 (no recovery in tort where “a plaintiff [] has sustained an economic loss, but has not sustained any injury to person or property”); *accord Schiavone Constr. Co. v. Elgood Mayo Corp.*, 56 N.Y.2d 667, 669 (1982), *adopting* 81 A.D.2d 221, 227-234 (1st Dep’t 1981) (Silverman, J., dissenting); *Cedar & Washington Assocs., LLC v. Bovis Lend Lease LMB, Inc.*, 95 A.D.3d 448, 449 (1st Dep’t 2012) (“Plaintiff’s tort claims ... also fail since plaintiff merely alleges economic loss, not personal injury or property damages.”). To hold otherwise would improperly conflate injury and damages, which are separate and distinct elements of a tort action.³

Despite this Court’s clear precedent, the Second Circuit erroneously concluded that medical monitoring costs could be recovered as consequential damages based solely on increased risk of disease and the need to incur future costs. *See Caronia v. Philip Morris USA, Inc.*, 715 F.3d 417, 434-36 (2d Cir. 2013). This is wrong. Three New York appellate courts have described medical monitoring as a potential consequential damage in traditional tort actions, but none dispensed with the requirement of an actual physical injury. Rather, these courts

³ *See, e.g., Seril v. Bureau of Highway Operations of Dep’t of Transp., City of New York*, 245 A.D.2d 233, 238 (1st Dep’t 1997) (“An award of damages must be premised upon some injury, and plaintiff has not proven any.”); *Lindor v. Palisades Collection, LLC*, 30 Misc. 3d 754, 758 (Sup. Ct. Kings Cnty. 2010) (“Plaintiff had to have actually been injured to be able to state her claim; without an injury, there is no basis upon which to seek relief.”).

required clinical evidence of an exposure-related condition, such as physical signs or symptoms of disease, and a probability of future disease.⁴ Thus, authorizing any recovery based on mere increased risk of disease would require a radical departure from traditional New York tort law.

B. *Askey* Provides No Support For The Proposed New Cause Of Action.

Plaintiffs' proposed equitable cause of action not only would mark a fundamental departure from traditional New York law but is unsupported by Plaintiffs' primary New York authority, *Askey v. Occidental Chemical Corp.*, 102 A.D.2d 130, 135-36 (4th Dep't 1984). In *Askey*, the Fourth Department affirmed the denial of a motion to certify a class action of individuals claiming chemical exposures from a landfill. The court expressly rejected the notion of a "no injury" tort claim premised only on increased risk, holding that "damages resulting from

⁴ See, e.g., *Allen v. Gen. Elec. Co.*, 32 A.D.3d 1163, 1165-66 (4th Dep't 2006) (plaintiffs bear ultimate burden of proving demonstrable presence of toxins in their body or indication of toxin-induced disease); *Atkins v. Exxon Mobil Corp.*, 9 A.D.3d 758, 759 (3d Dep't 2004) (affirming dismissal of claims for medical monitoring damages, where plaintiffs "failed to supply any evidence of physical harm sufficient to guarantee the genuineness of their claims"); *Abusio v. Consol. Ed.*, 238 A.D.2d 454, 455 (2d Dep't 1997) (absent evidence of "some indication of PCB-induced disease," plaintiffs had "failed to set forth valid causes of action for emotional distress and future medical monitoring costs"); *Askey v. Occidental Chem. Corp.*, 102 A.D.2d 130, 135-36 (4th Dep't 1984) (affirming denial of class certification of medical monitoring claims, but noting in *dicta* that medical monitoring damages could be recoverable if there were evidence of present genetic damage and "a reasonable certainty" of future illness). Although the Fourth Department in *Baity v. General Electric Co.*, 86 A.D.3d 948, 949 (4th Dep't 2011) distanced itself from the holding in *Allen*, it adopted the reasoning in *Askey*, which as shown *infra*, does not permit "no injury" actions based on increased risk. To the extent the vague language in *Baity* can be interpreted otherwise, it is wrong.

the enhanced risk of cancer and the threat of future harm not yet realized are not compensable in a tort action.” *Id.* at 135. For support, the *Askey* court cited this Court’s opinion in *Schwartz v. Heyden Newport Chemical Corp.*, 12 N.Y.2d 212, 217 (1963), which in turn held that an action “accrues only when there is some actual deterioration of a plaintiff’s bodily structure.” *Id.*

In *dicta*, the *Askey* court discussed the theoretical possibility of medical monitoring, observing that “there is a basis in law to sustain a claim for medical monitoring as an element of consequential damage.” 102 A.D.2d at 135. But the authority on which the Court relied, *Schmidt*, 270 N.Y. 287, proves that it was not eliminating the injury requirement. In *Schmidt*, a statute of limitations case, the plaintiff had a manifest lung disease from exposure to dust many years earlier. The issue was not *whether* the plaintiff had been injured but *when* he had first been injured. Seeking to protect defendants against stale claims, the *Schmidt* Court applied a bright-line rule that the claim accrued upon first exposure, noting in *dicta* that the plaintiff could theoretically have sued at that time for the condition actually created in the plaintiff’s body which “naturally, if not inevitably” resulted in his manifest disease.⁵ *Id.* at 300–01. The Court made clear, however, that

⁵ Despite numerous entreaties, the Court of Appeals steadfastly refused to alter this bright line “first exposure” rule for accrual of latent disease claims, holding that it was up to the legislature to adopt a discovery rule. *Infra* Part III.A; see *Jensen v. Gen. Elec. Co.*, 82 N.Y.2d 77, 84 (1993). Two years after *Askey* was decided, CPLR 214-c was enacted, effectively overruling *Schmidt* insofar as it relates to claims for a manifest latent disease. The “first exposure” accrual

“[t]hough negligence may endanger the person or property of another, no actionable wrong is committed if the danger is averted.” *Id.* Thus, neither exposure nor mere risk of disease constituted a legal “injury” under *Schmidt*.

Recognizing these constraints, the *Askey* court noted that “[t]he proof problems” associated with a claim for medical monitoring damages “are, of course, formidable. In order to recover for apprehended consequences not presently manifest, there must be such a degree of probability of their occurrence as to amount to a reasonable certainty that they will result.”⁶ *See* 102 A.D.2d at 135-37. Demonstrating the formidable proof problems, the *Askey* court held that plaintiffs were not entitled to class certification because their evidence, which included testimony about the potential for invisible genetic damage, “[did] not identify with any degree of specificity those persons within that area whose bodies have been invaded by a toxic substance and who as a result need medical monitoring.” *See id.* at 138. The court emphasized that “[n]ot everyone who ... believes or claims that he has been exposed to toxic chemicals is entitled to future medical expenses.” *Id.*

(continued...)

rule established in *Schmidt* remains good law for claims, such as Plaintiffs’ here, that do not involve actual disease and are not covered by CPLR 214-c. *See infra* Part III.C.

⁶ Although the *Askey* court also held that future medical expenses must be reasonably certain to occur, it did not, as some plaintiffs have argued, limit the “reasonable certainty” test to expenses. *See Baity*, 86 A.D.3d at 950. Indeed, the phrase “apprehended consequences not presently manifest” makes no sense except as a reference to future disease.

Thus, *Askey* undermines Plaintiffs’ proposed “no injury” cause of action. The court rejected increased risk as a basis for suit, and required proof of both an actual present bodily injury and a reasonable certainty of future disease. Although the opinion is not a model of clarity and has often been misconstrued, when read in the context of the Court of Appeals precedents on which it relies, it neither supports an independent cause of action for medical monitoring nor purports to eliminate the present injury requirement of traditional tort law.

Moreover, a single appellate division decision is not the kind of binding statewide precedent that requires legislative action to correct. Nor is there any basis for Plaintiffs’ claim that the New York courts have reached a “broad consensus” regarding *Askey* and the validity of medical monitoring (Reply Br. 14); to the contrary, as a cursory review of Shepards demonstrates, *Askey* has rarely been mentioned, much less followed, on medical monitoring issues decided by New York appellate courts outside the Fourth Department.

II. AUTHORIZING MEDICAL MONITORING CLAIMS BASED ON INCREASED RISK WOULD MASSIVELY EXPAND POTENTIAL LIABILITY IN NEW YORK.

Plaintiffs’ proposed medical monitoring cause of action should be rejected. It would create a flood of litigation, greatly expand potential tort liability, and turn New York into a magnet jurisdiction for medical monitoring claims given that the

majority of other State high courts have rejected such claims. (See Phillip Morris Br. 27-31 & n.6).

A. Characterizing Increased Risk As A Tort Injury Would Dramatically Expand The Scope Of Liability.

Recognizing increased risk of disease and future medical costs as cognizable tort injuries would drastically expand tort law and would have significant implications far beyond this case, as demonstrated by the wide range of medical monitoring cases commenced over the past few decades. Although often ultimately defeated, medical monitoring cases have been commenced against: airlines due to alleged second hand smoke impacts,⁷ medical device manufacturers,⁸ homebuilders,⁹ pharmaceutical companies,¹⁰ the U.S. Army,¹¹ light

⁷ *Duncan v. Northwest Airlines, Inc.*, 203 F.R.D. 601 (W.D. Wash. 2001) (declining to create medical monitoring cause of action due to absence of present injury).

⁸ *In re St. Jude Medical, Inc., Silzone Heart Valve Prod. Liab. Litig.*, 425 F.3d 1116, 1121-23 (8th Cir. 2005) (denying class certification of medical monitoring claim).

⁹ *State ex rel. Richmond Am. Homes of W. Va., Inc. v. Sanders*, 717 S.E.2d 909, 914-16 (W.Va. 2011) (radon exposure).

¹⁰ *Sinclair v. Merck & Co.*, 948 A.2d 587, 589 (N.J. 2008) (refusing to recognize medical monitoring claim absent a manifest injury in Vioxx litigation); *Jensen v. Bayer AG*, 862 N.E.2d 1091, 1100 (Ill. App. Ct. 2007) (refusing to recognize medical monitoring due to the absence of a present injury in case involving the drug Baycol); *Wood v. Wyeth-Ayerst Labs.*, 82 S.W.3d 849, 856-59 (Ky. 2002) (rejecting medical monitoring in Fen-Phen case where there was no present injury).

¹¹ *Redland Soccer Club, Inc. v. Dep't of the Army*, 696 A.2d 137 (Pa. 1997) (holding that Pennsylvania would recognize medical monitoring cause of action in connection with hazardous waste disposal at former New Cumberland Army Depot).

bulb manufacturers,¹² window manufacturers,¹³ railroad companies,¹⁴ mining companies,¹⁵ lead smelters,¹⁶ coal preparation plants,¹⁷ agriculture companies,¹⁸ pesticide companies,¹⁹ maritime shipping companies,²⁰ and radar equipment manufacturers²¹—to name a few. If increased risk sufficed as the present injury, any company that uses, transports, stores, manufactures, or sells a product—or even hosts an activity—that could cause a potential health effect would face liability, not just for injuries actually caused but for the mere increased risk of

¹² *Bower v. Westinghouse Elec. Corp.*, 522 S.E.2d 424, 427 (W. Va. 1999) (chemical exposure from light bulb debris).

¹³ *Alsteen v. Wauleco, Inc.*, 802 N.W.2d 212, 214 (Wis. Ct. App. 2011) (no medical monitoring absent present injury for chemical exposure from window manufacturing plant).

¹⁴ *Hirsch v. CSX Transp., Inc.*, 656 F.3d 359, 360 (6th Cir. 2011) (granting summary judgment to defendant due to insufficient evidence of injury for medical monitoring).

¹⁵ *June v. Union Carbide Corp.*, 577 F.3d 1234, 1249-50 (10th Cir. 2009) (holding no medical monitoring under the Price-Anderson Act absent a bodily or physical injury).

¹⁶ *Meyer v. Fluor Corp.*, 220 S.W.3d 712, 714, 719-20 (Mo. 2007) (holding medical monitoring class appropriate due to absence of individual injury requirement).

¹⁷ *Stern v. Chemtall Inc.*, 617 S.E.2d 876, 879 (W.Va. 2005) (medical monitoring for chemical exposure to an industrial water cleaner).

¹⁸ *Hinton v. Monsanto Co.*, 813 So. 2d 827, 828-30 (Ala. 2001) (rejecting medical monitoring in light of absence of a present injury).

¹⁹ *Laxton v. Orkin Exterminating Co.*, 639 S.W.2d 431, 431-32 (Tenn. 1982) (recognizing medical monitoring but only where symptoms manifest and medical costs incurred).

²⁰ *Marine Asbestos Cases v. American Hawaii Cruises, Inc.*, 265 F.3d 861, 865 (9th Cir. 2001) (rejecting medical monitoring claim for alleged asbestos exposure under Jones Act).

²¹ *Norwood v. Raytheon Co.*, 414 F. Supp. 2d 659, 661-62 (W.D. Tex. 2006) (rejecting medical monitoring claim for x-ray radiation).

injury. Under Plaintiffs’ theory, instead of hearing one complex case when 10,000 people claim exposure but one falls ill, the courts would have to deal with 10,000 complex cases, and administer a trust fund potentially for decades.

Moreover, the floodgates would open for other kinds of monitoring-based claims because Plaintiffs’ proposed cause of action would unlimit the injury concept. The logical extension of Plaintiffs’ approach would be medical monitoring liability for schools and youth recreation leagues where athletes have a risk of future injury due to historic sports injuries. In addition, if mere economic loss is a sufficient tort injury, there would be no way to limit other kinds of “monitoring” claims for non-health risks. Indeed, courts have looked to medical-monitoring cases to determine whether a State would recognize “credit monitoring” in cases involving unauthorized disclosure of financial information, and a “product recall” cause of action for latent product defects. *Pisciotta v. Old Nat’l Bancorp.*, 499 F.3d 629, 638 (7th Cir. 2007) (holding Indiana would not create a cause of action for credit monitoring because it had not approved medical monitoring); *see also Grant v. Bridgestone Firestone Inc.*, 55 Pa. D. & C.4th 438, 446 (Ct. Com. Pl. 2001) (examining argument that the logic underlying medical monitoring supports a “products recall” cause of action). One court has also recognized “environmental monitoring”—inspections of groundwater and well water—based on the risk of future contamination and future treatment costs, citing medical monitoring

precedent. *See In re Methyl Tertiary Butyl Ether (MTBE) Prods. Liab. Litig.*, 476 F. Supp. 2d 275, 280 (S.D.N.Y. 2007) (denying motion to dismiss claims seeking “‘investigation,’ and ‘testing and monitoring’ ... to protect against future MTBE intrusions” into plaintiff’s wells).

Though most of these monitoring claims have failed, it has often been only after long, expensive litigation in an area where ill-defined rules encourage mischief. The problem has been exacerbated by courts’ inability to define meaningful standards for these new causes of action. For example, some courts recognizing medical monitoring have held that a claim can be grounded on an exposure “above background levels.” *Redland Soccer Club, Inc. v. Dep’t of the Army*, 696 A.2d 137, 145-46 (Pa. 1997). But “background levels” differ widely in Manhattan, Albany, and the Adirondacks, and from year to year. *See* <http://www.dec.ny.gov/chemical/23786.html> (Manhattan); <http://www.dec.ny.gov/chemical/23787.html> (Albany); <http://www.dec.ny.gov/chemical/23788.html> (Adirondacks). Moreover, there is no scientific or medical basis for assuming that exposures above variable “background” levels have any legal significance.

A few of the jurisdictions recognizing medical monitoring have held that monitoring is available when the exposure creates a “significant” or “substantial” increase in risk, but they have declined to provide any guidance on what those terms mean. *See Donovan v. Philip Morris USA, Inc.*, 455 Mass. 215, 226 (2009);

Hansen v. Mtn. Fuel Supply Co., 858 P.2d 970, 979 (Utah 1993) (“No particular level of quantification is necessary.”); *Bower v. Westinghouse Elec. Corp.*, 206 W. Va. 133, 142 (1999) (same). And in too many cases, courts have refused to dismiss claims where plaintiffs submitted conclusory expert testimony that exposures justify monitoring. *See, e.g., Ayers v. Twp. of Jackson*, 525 A.2d 287, 309 (N.J. 1987) (denying summary judgment on medical monitoring claim even though risks were unquantified and speculative).

Indeed, it is the cases in which plaintiffs purport to quantify risk that the potential for a flood of cases is most evident. The U.S. Supreme Court, for example, rejected medical monitoring in a case involving New York transportation workers where the increase in risk was estimated at between 1-5%. *See Metro-North Commuter R.R. v. Buckley*, 521 U.S. 424, 427 (1997). A New York trial court recently granted summary judgment in a case where plaintiffs’ own expert estimated the increased risk at no more than .006%. *See Ivory v. IBM Corp.*, 37 Misc. 3d 1221, 2012 NY Slip Op 52123, at *6 (Sup. Ct. Broome Cnty. Nov. 15, 2012), *appeal pending*, No. 516276 (3d Dep’t). The U.S. Court of Appeals for the Sixth Circuit rejected a medical monitoring claim based on a “proverbially small” increase in risk of one in a million, explaining:

For some perspective, the National Safety Council estimates a person's lifetime risk of dying in a motor vehicle accident as 1 in 88. The lifetime risk of dying in 'air and space transport accidents' is roughly 1 in 7,000. The risk of being killed by lightning is roughly 1 in 84,000, while the risk of being killed in a 'fireworks discharge' stands at around 1 in 386,000.

Hirsch v. CSX Transp., Inc., 656 F.3d 359, 364 (6th Cir. 2011) (quoting National Safety Council, INJURY FACTS 37 (2011 ed.), http://www.nsc.org/NSC%20Picture%20Library/News/web_graphics/Injury_Facts_37.pdf).

While these claims were properly dismissed, it took years of expensive litigation and appeals to reach these common sense results. And too often in jurisdictions recognizing monitoring, plaintiffs have avoided summary judgment by finding an expert to characterize such miniscule risks—or any increase in risk—as “significant.” *See, e.g., Ayers*, 525 A.2d at 309.

Courts have even affirmed jury verdicts awarding medical monitoring based on expert testimony that contradicts the findings of the government agencies charged by law with determining whether a hazard exists or medical monitoring is required. For example, in *Perrine v. E. I. du Pont de Nemours & Co.*, 694 S.E.2d 815, 874-75 (W.Va. 2010), the court affirmed a \$130 million jury verdict creating a 40-year medical monitoring program notwithstanding a government regulator's finding that the levels of lead exposure plaintiffs claimed were not hazardous. *Id.*; *see also, e.g., Ayers*, 525 A.2d at 309 (denying summary judgment on medical

monitoring claim based on expert testimony, even though risks were unquantified and speculative).

The purported need for particular medical screening tests is similarly susceptible to expert conjecture and manipulation. Because plaintiffs in medical monitoring cases exhibit no physical injury or symptoms of disease, the issue is not the *objective* question whether a certain exposure caused harm, but the *subjective* question whether it is *advisable* to undertake medical screening tests in a particular case. That, in turn, depends on how one balances the costs and risks of the screening against the potential benefits of early detection of disease. As Plaintiffs acknowledge (Reply Br. 46), there is often no consensus in the medical community on whether to recommend certain screening tests, how often to test (if at all), and who should be tested (if anyone). *See Metro-North*, 521 U.S. at 441 (noting “uncertainty among medical professionals about just which tests are most usefully administered and when”); *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 147 (E.D. La. 2002) (denying class certification where “[n]either the FDA, nor any medical organization or institution, nor anyone else for that matter, except the plaintiff’s expert, has recommended or suggested that a program of medical monitoring ... be undertaken”).

Indeed, Plaintiffs’ proposed medical monitoring claim is marked by so many subjective inquiries and elements that it is essentially standardless. To be sure,

every mass tort case involves questions of scientific complexity and expert battles. But those disagreements are generally limited to objective facts, such as the scope of a concretely identified injury and causation. In jurisdictions that have defined the injury in a medical monitoring case as the need for future monitoring, the very existence of an injury—the *sine qua non* of a cause of action—turns on nuanced, subjective, and often-evolving judgments about where a particular medical test falls on the spectrum from required to beneficial to acceptable to inadvisable. The risk of baseless claims getting to a jury is high, indeed, is particularly acute in New York, where depositions are rarely available to flesh out the basis (or lack thereof) for an expert’s opinion, and “no evidence” summary judgment motions are precluded. *See* CPLR § 3101(d)(1)(iii) (expert depositions permitted “only by court order upon a showing of special circumstances”).

B. The Purported Limitations On The Scope Of Medical Monitoring Claims Are Not Tenable.

Other courts’ attempts to draw lines for medical monitoring claims between environmental exposures and those for product use—or between so-called “voluntary” exposures and those that are “involuntary”—fix none of the problems of recognizing medical monitoring claims. These approaches would do little to stem the tide of litigation that would flood the New York courts, because in the modern world exposures to risk-enhancing substances and activities are so

commonplace—indeed, universal—that every individual would become a potential plaintiff.

Hundreds of millions of Americans could claim a theoretical increase in risk from previous exposure to air or water pollution, second-hand smoke,²² or even noise pollution. As the U.S. Supreme Court recognized in rejecting medical monitoring under federal law, exposure to established carcinogens is common. *See Metro-North*, 521 U.S. at 434-35 (citing Nicholson, Perkel, & Selikoff, *Occupational Exposure to Asbestos: Population at Risk and Projected Mortality—1980-2030*, 3 AM. J. INDUST. MED. 259 (1982) (estimating that 21 million Americans have been exposed to work-related asbestos); U.S. Dep’t of Health and Human Services, 1 SEVENTH ANNUAL REPORT ON CARCINOGENS 71 (1994) (the majority of Americans have been exposed to benzene outside the workplace, and 3 million workers have had occupational exposure to benzene); Pirkle *et al.*, *Exposure of the U S Population to Environmental Tobacco Smoke*, 275 JAMA 1233, 1237 (1996) (reporting that 43% of American children and 37% of adult nonsmokers were exposed to environmental tobacco smoke at home or at work)).

Nor is any line between voluntary and involuntary exposure likely to withstand the pressures of the plaintiffs’ bar. Plaintiffs are certain to argue that

²² *Duncan*, 203 F.R.D. 601.

there is no legal justification for allowing medical monitoring solely for involuntary exposures. Indeed, whether a plaintiff voluntarily exposes himself to a substance bears only on affirmative defenses in New York; it is irrelevant to whether a defendant's conduct gives rise to a cause of action. *See, e.g., Van Wert v. Randall*, 35 Misc. 3d 1202(A), 950 N.Y.S.2d 726 (Sup. Ct. 2012) (distinguishing affirmative defense of assumption of risk from stand-alone "counterclaim for contribution").²³ Determining whether an exposure was truly involuntary would clog the courts with collateral disputes that would exacerbate the unpredictable scope of the proposed new liability. For example, if a plaintiff moved in the late 1960's to a home one block from a massive industrial facility, was his exposure to air pollution voluntary or involuntary? If a plaintiff lives in a home with a spouse who is a smoker, is her exposure to second-hand smoke voluntary or involuntary? If a plaintiff applies for a job with a lawn service that involves use of pesticides, is his exposure voluntary or involuntary?

In addition, there is no real deterrent value to allowing medical monitoring claims for environmental exposures that arise from conduct that ended decades ago and was lawful at the time. Plaintiffs have, for example, brought suits in the past

²³ *See also, e.g., Baker v. Westinghouse Elec. Corp.*, 70 F.3d 951, 953, 955 (7th Cir. 1995) (affirming summary judgment dismissing plaintiff homeowners' nuisance claims in the absence of any alleged "concrete harm," without regard to fact that employer allowed plaintiff to take scrap PCB-contaminated insulation home for personal use).

five years seeking medical monitoring for air pollution exposures in the 1960's and 1970's.²⁴ In these cases, there is no current conduct to deter and the past conduct at issue was lawful at the time. Moreover, modern CERCLA liability should provide adequate deterrence against ongoing misconduct. *See, e.g., United States v. Gen. Elec. Co.*, 670 F.3d 377, 382 (1st Cir. 2012) (discussing deterrent effect of CERCLA liability); *Bocre Leasing Corp. v. Gen. Motors Corp.*, 84 N.Y.2d 685, 693 (1995) (concluding that traditional tort principles provide “ample deterrents to manufacturers injecting unsafe products into the commerce stream,” and declining to permit recovery of “contractually based economic loss” in the absence of any physical injury).

In all events, the dangers of recognizing claims based only on increased risk are the same for both environmental exposure and product-based medical monitoring claims. And, as Philip Morris has explained, medical screening is readily available, without the creation of new causes of action, for any exposure—voluntary or not—that the medical community has, by consensus, determined requires it. (*See Philip Morris Br. 21-24*).

²⁴ *See, e.g., Ivory*, 2012 N.Y. Slip Op. 52124(U), at *6 (alleging exposure to air pollution in the 1960s); *Alsteen*, 802 N.W.2d at 214 (rejecting plaintiffs’ medical monitoring claim in the absence of present injury, based on alleged exposures to “air, soil, surface water, and groundwater” contaminated “[f]rom approximately 1946 to 1986”); *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 258 (3d Cir. 2011) (affirming denial of class certification of “a class seeking medical monitoring for village residents exposed to the airborne vinyl chloride between 1968 and 2002”).

III. THE LEGISLATURE SHOULD DECIDE WHETHER TO CREATE A NEW EQUITABLE MEDICAL MONITORING CAUSE OF ACTION.

A. Only The Legislature Should Create A New Cause Of Action.

As this Court has long recognized, it is a legislative, not judicial, function to create new causes of action. Since at least the 1800s, this Court has declined to create novel common law claims in the absence of an express statutory mandate. *See Whitford v. Panama R.R. Co.*, 23 N.Y. 465, 467 (1861); *George v. Mt. Sinai Hosp.*, 47 N.Y.2d 170, 176 (1979) (“The cause of action for wrongful death was originally deemed completely a child of statute, as it had no counterpart in the common law.”); *Liff v. Schildkrout*, 49 N.Y.2d 622, 633 (1980) (“declin[ing] the invitation to recognize a common-law cause of action ... [for] wrongful death,” and insisting that “[a]ny cause of action or, indeed, remedy” for this wrong “must be founded in statutory authority”).

When this rule came under attack in the latter half of the 20th century, the Court remained steadfast and refused to recognize new causes of action, for example, for “wrongful life,” *Becker v. Schwartz*, 46 N.Y.2d 401, 408-09 (1978); “educational malpractice,” *Donohue v. Copiague Union Free Sch. Dist.*, 47 N.Y.2d 440, 442, 444 (1979); “abusive or wrongful discharge of an employee,” *Murphy v. American Home Products Corp.*, 58 N.Y.2d 293, 297, 300 (1983); negligent operation of a polygraph, *Hall v. UPS of America*, 76 N.Y.2d 27, 33-34 (1990); and third-party interference with attorney-client privilege, *Madden v. Creative*

Services, Inc., 84 N.Y.2d 738, 746 (1995). More recently, this Court declined to adopt a new common law cause of action for negligent spoliation of evidence, citing the need for legislative action. *See, e.g., Ortega v. City of New York*, 9 N.Y.3d 69, 80 (2007) (refusing to create a new cause of action where the plaintiffs “c[ould not] meet the traditional proximate cause and actual damages standards at the foundation of our common-law tort jurisprudence”).

This Court’s refusal to usurp the legislative function is well illustrated by New York’s discovery accrual rule for certain latent injuries. For decades, exposure-based tort claims that later resulted in an actual physical injury accrued at the time of first exposure—not when the injury was discovered. Despite the potentially harsh consequences of the first-exposure rule, this Court refused to alter the rule and “repeatedly importuned the Legislature to make the desired policy change, as a matter more appropriately within its province.” *Jensen v. Gen. Elec. Co.*, 82 N.Y.2d 77, 84 (1993); *see also Schwartz*, 12 N.Y.2d at 219 (“It is not without reason that change in this area has been thought by us to be the responsibility of the Legislature.”); *Thornton v. Roosevelt Hosp.*, 47 N.Y.2d 780, 781-82 (1979) (“We decline the invitation to extend judicially the discovery rule to strict products liability actions. Such matter is best reserved for the Legislature, and not the courts.”); *Matter of Steinhardt*, 54 N.Y.2d 1008, 1010-11 (1981) (“[F]urther extension of the [limitations period] was a matter best reserved for the

Legislature, and not for the courts. We believe it to be inappropriate and injudicious to intrude into an area best suited for legislative scrutiny.”) The legislature eventually answered the call, enacting CPLR § 214-c. Notably, CPLR § 214-c was not the rule proposed by toxic tort plaintiffs, but a “balanced, new rule” that reflected legislative priority and democratic accountability. *See Jensen*, 82 N.Y.2d at 83-87. So too here, any decision to overturn centuries of New York law and in a manner that vastly expands potential tort liability is one that should be made by the legislature, not by the courts.

B. The Legislature Is Best Suited To Resolve The Complex Policy Decisions Underlying Medical Monitoring.

Any decision to permit medical monitoring claims requires a balancing of complex social, medical, and legal policies that are more appropriately evaluated by the legislature. This Court has long recognized that analysis of the social or economic effects of a new cause of action cannot “safely be made without the kind of factual investigation which the Legislature[,] and not the courts, is equipped for.” *Woods v. Lancet*, 303 N.Y. 349, 355 (1951). “The Legislature has infinitely greater resources and procedural means ... to examine the variety of pertinent considerations ... and to investigate and anticipate the impact of imposition of such liability.” *Murphy*, 58 N.Y.2d at 302.

Moreover, “[b]road policy choices, which involve the ordering of priorities and the allocation of finite resources” are “matters for the executive and legislative

branches of government.” *Jiggetts v. Grinker*, 75 N.Y.2d 411, 415 (1990); *Snyder v. Town Insulation, Inc.*, 81 N.Y.2d 429, 435-36 (1993) (balancing of policy considerations “lies with the Legislature”); *Liff*, 49 N.Y.2d at 632 (“The courts have deferred to the wisdom of the Legislature in striking the sensitive balance as to the causes of action which should be permitted to be maintained due to the wrongful death of another ...”).

Those issues are particularly weighty here. The costs of monitoring include not just the social opportunity costs associated with diverting medical resources away from other socially necessary uses and towards mere monitoring, but also the dangers of medical testing, which is not without its own added risks. *See* James E. Henderson, Jr. & Aaron D. Twerski, *Asbestos Litigation Gone Mad: Exposure-Based Recovery for Increased Risk, Mental Distress, and Medical Monitoring*, 53 S.C. L. Rev. 815, 844 (2002) (hereinafter “Henderson & Twerski, *supra*”) (“[M]onitoring—especially excessive monitoring—is not only wasteful of scarce resources, but often places those being monitored at risk of surveillance-related harm.”). In addition, recognizing a new cause of action always implies, and in this case would certainly imply, the expenditure of additional judicial resources to handle the new influx of cases, which the Legislature is charged with allocating. *See, e.g., Trombetta v. Conkling*, 82 N.Y.2d 549, 554 (1993) (refusing to extend tort liability in light of potential for “unmanageable proliferation of such claims”);

Madden, 84 N.Y.2d at 746 (refusing to expand liability due to “potential for vast, uncircumscribed liability”).

Courts that have adopted medical monitoring causes of action have often done so based on the unsupported assumption, widely repeated in the 1980s, that testing is always beneficial if it might lead to early detection of disease. *See, e.g., Ayers*, 525 A.2d at 311 (“[t]he value of early diagnosis and treatment for cancer patients is well-documented”; “it is universally agreed within the medical community that delay in cancer diagnosis and treatment usually increases the risk of metastasis.” (quoting *Evers v. Dollinger*, 471 A.2d 405, 419 (N.J. 1984) (Handler, J., concurring))); *see also Askey*, 102 A.D.2d at 137 (“There is no doubt that [medical monitoring] would permit the early detection and treatment of maladies.”).

Although that view might have intuitive appeal, it is ultimately a public policy judgment that courts are ill-equipped to make. The benefits of monitoring depend on such technical considerations as: How effective is the screening test at detecting early disease? What is the rate of false positives and false negatives relative to the background level of the disease? Does the test itself (*e.g.*, the radiation from an x-ray) subject the patient to risk? Will the procedures (*e.g.*, biopsy or surgery) conducted as a follow-up to a false positive result expose the patient to risk of serious injury? Does early detection increase the chances of cure?

And how do these answers change based on length of exposure, age of the individual, or other case-specific factors?²⁵ These are all questions that courts and juries are ill-equipped to address.

Indeed, even medical experts frequently disagree about how to strike the balance in medical screening. The very monitoring that Plaintiffs request in this case—a low-dose CT scan (“LDCT”) for long-term smokers—is the subject of extensive debate in the medical community. The American Academy of Family Physicians has concluded that there is insufficient evidence to support LDCT screening. *See* AAFP, *Lung Cancer*, <http://www.aafp.org/patient-care/clinical-recommendations/all/lung-cancer.html>. The U.S. Preventive Services Task Force (“USPSTF”) until recently took the same view. USPSTF, *Lung Cancer Screening: Recommendation Statement*, <http://www.uspreventiveservicestaskforce.org/3rduspstf/lungcancer/lungcanrs.htm>. New USPSTF draft recommendations

²⁵ *See* Schwartz *et al.*, *Medical Monitoring—Should Tort Law Say Yes?*, 34 WAKE FOREST L. REV. 1057, 1073 (1999) (“An appropriate cost-benefit analysis in the context of medical monitoring requires the decision maker to consider a host of detailed and intricately intertwined factors,” like “prevalence (*i.e.*, the proportion of the population with the suspect condition) and the proposed test’s scientific sensitivity, specificity, and predictive value.”); George W.C. McCarter, *Medical Sue-Veillance: A History and Critique of the Medical Monitoring Remedy in Toxic Tort Litigation*, 45 RUTGERS L. REV. 227, 276-77 (1993) (warning that “protocols that pay insufficient heed to predictive value will produce large numbers of false positives in asymptomatic individuals, subjecting them to additional unnecessary procedures that may be painful, stressful, and even risky”).

released this summer recommend annual LDCT screening, but only for adults aged 55-79 who have a *30-pack-year* smoking history and either currently smoke or have smoked in the past 15 years. <http://www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcandraftrec.htm> The American Cancer Society takes a middle ground, recommending that certain 30-pack-year patients be counseled on the risks and benefits and be allowed to make their own choice.²⁶ None of these sources recommends LDCT screening for 20-pack-year smokers—the group Plaintiffs claim to represent.

As these examples illustrate, determining whether a particular asymptomatic person should undergo any particular screening test is subjective and dependent on evolving scientific research that may be subject to interpretation and dispute.²⁷ This creates jurisprudential complications in medical monitoring cases, where the alleged need—or mere desire—to incur the expense of medical screening is the substitute for the long-standing present injury requirement. Under Plaintiffs’ proposed approach, juries would determine whether a plaintiff had suffered an

²⁶ The American Cancer Society advises that, although “screening carries risks that may outweigh the benefits,” doctors should “discuss lung cancer screening” with patients “aged 55 to 74 years” (not 79) who are “in fairly good health,” “have a smoking history equivalent to a pack a day for 30 years, and currently smoke or have quit within the past 15 years.” ACS, New Lung Cancer Screening Guidelines for Heavy Smokers (Jan. 11, 2013), <http://www.cancer.org/cancer/news/news/new-lung-cancer-screening-guidelines-for-heavy-smokers>.

²⁷ See, e.g., Chronological History of ACS Recommendations for the Early Detection of Cancer in Asymptomatic People (May 17, 2013), <http://www.cancer.org/healthy/findcancerearly/cancerscreeningguidelines/chronological-history-of-ac-s-recommendations>.

injury based on a subjective evaluation of the perceived need for medical testing. If a jury concluded that testing is necessary, the plaintiff has been injured; if it concludes that testing is not necessary, the plaintiff has suffered no injury. Yet considerable judicial and defense resources would have been devoted to litigating an issue that, under existing tort law, is a prerequisite for filing suit.

“The courts are not fit to answer all [of these] questions arising with the implementation of a medical monitoring system.” Schwartz *et al.*, *Medical Monitoring: The Right Way and the Wrong Way*, 70 MO. L. REV. 349, 377 (2005). Rather, “courtrooms are the last place where medicine should be practiced, where prescriptions should be written and tests ordered.” Thomas M. Goutman, MEDICAL MONITORING: HOW BAD SCIENCE MAKES BAD LAW 16 (2001); *see Trombetta*, 82 N.Y.2d at 554 (refusing to expand liability due to “the complex responsibility that would be imposed on the courts”).

Indeed, a new medical monitoring cause of action would generate cascading questions that are best examined as part of an overarching legislative scheme. For example, the legislature would have to consider, at a minimum: Should the courts award damages or equitable relief? Awarding an upfront damage award creates the real risk that plaintiffs will squander the money on things other than medical testing, thus eviscerating the theoretical injury—the alleged need for monitoring—underlying the claim. *See also Metro-North*, 521 U.S. at 441-42.

Although a pay-as-you-go fund can prevent such abuse, courts are not equipped to decide the myriad issues that would arise in the course of administering such a fund. Plaintiffs' claim that the U.S. Supreme Court "allowed" an award of funds for "equitable surveillance claims" in *Metro-North* (Reply Br. 3) is simply wrong. In her non-binding opinion dissenting in part and concurring in part, Justice Ginsburg touted the use of equitable funds. *Metro-North*, 521 U.S. at 454. The Court observed that use of funds was evidence of the "policy concerns that have been pointed out to us here" (*id.* at 441), and concluded that it was "more troubled than is Justice Ginsburg by the potential systemic effects" of creating any medical monitoring cause of action. *Id.* at 443.

How much monitoring is enough? Should a monitoring program continue for five years, 30 years, or until the money is gone? Are special stand-alone screening programs required, or should individuals seek testing from their own physicians? If the former, is the defendant liable not only for the cost of tests but also for the infrastructure required to build a new clinic, hire medical staff, and buy equipment and computers? And how would courts supervise any such program? *See, e.g., Donovan v. Philip Morris USA, Inc.*, 268 F.R.D. 1, 22 (D. Mass. 2010) ("The plaintiffs seek a structured program," whereby "plaintiffs would have to hire medical and administrative personnel, purchase equipment, and establish procedures for intake, informed consent, record keeping, and so on.").

If the equitable fund is not spent in 30 years, what happens to the money? This is not a hypothetical problem. In *Klier v. Elf Atochem North America, Inc.*, the Fifth Circuit Court of Appeals struggled with administrative problems arising from the disposition of excess monitoring funds caused by participation rates that were “less than three percent,” and the absence of “significant health problems.” 658 F.3d 468, 472–73 (5th Cir. 2011). Professors Henderson and Twerski, the architects of modern American tort law, predicted this very outcome and the potentially harmful consequences of monitoring, noting:

Available evidence strongly suggests that many, if not most, persons exposed to toxic substances do not want to be monitored [E]ven if it were somehow possible to determine which monitoring costs are attributable to which toxic sources, most monitoring systems established to accomplish marginal improvements would duplicate systems set up for similar purposes Furthermore, such monitoring—especially excessive monitoring—is not only wasteful of scarce resources, but often places those being monitored at risk of surveillance-related harm.

Henderson & Twerski, *supra* at 844 (observing that plaintiffs “apparently have a lot better ways to spend the money than on monitoring, once they receive it”).

As discussed above, courts have also struggled to define how much risk is enough to justify a claim. Should plaintiffs be required to prove that disease is probable, or as the *Askey* court suggested, “reasonably certain”? Or may a corporation be liable for conduct that allegedly increases a plaintiffs’ risk of disease by 1 in 10,000? 1 in 100,000? 1 in 1,000,000? Although such claims are often unsuccessful, the courts have been burdened with cases in which plaintiffs

have demanded medical monitoring based on all of those scenarios. *See supra* Part II.A.

The failure of courts, in jurisdictions recognizing medical monitoring, to define a standard of actionable risk is in some respects understandable: courts are ill-equipped to make the critical policy judgments required to draw any line other than perhaps “reasonable certainty of disease,” *i.e.*, greater than 50%. But the proper resolution of that dilemma is to leave those judgments to the legislature, not to create nebulous causes of action that abdicate those complex policy judgments to juries. *See, e.g., Henry v. Dow Chem. Co.*, 701 N.W.2d 684, 686 (Mich. 2005) (rejecting medical monitoring cause of action premised on an alleged “increased risk,” in part because “[as] a matter of prudence,” the Legislature and state agencies were best suited to “deal[] with health risks stemming from industrial pollution” and “to undertake the complex task of balancing the competing societal interests at stake”).

C. The Lack Of A Workable Accrual Rule Further Demonstrates The Inherent Flaws In Medical Monitoring Jurisprudence.

Plaintiffs are correct in arguing that the statutes of limitations applicable to personal injuries do not apply. (Pl. Br. 59-60). Specifically, the discovery rule embodied in CPLR § 214-c has no application because that statute is expressly limited to claims for personal injury or property damage caused by the latent

effects of exposure. As is true in virtually all medical monitoring cases, Plaintiffs have no such injury.²⁸ (Pl. Br. 62).

Indeed, the very same reasons that countenance against the application of the personal-injury statute of limitations highlight why medical monitoring claims premised on increased risk do not belong in the courts.

In many medical monitoring cases, the date when an individual has reached the threshold above which monitoring is recommended is objectively unknowable. Indeed, the environmental exposures that have generated medical monitoring claims cannot readily be quantified. The science regarding causation often ranges from murky to non-existent, and particularly so at the low levels of exposure typically at issue. There are few, if any, recommended screening tests for individuals with such environmental exposures, and certainly no published thresholds above which there is a consensus in the medical establishment that screening is required. The problem is exacerbated when courts permit medical monitoring claims to proceed based on an expert's *ipse dixit* that an unquantified—and unquantifiable—exposure created a “significant risk.” When (as here) there is

²⁸ CPLR § 214-c(2) is limited to actions “to recover damages for *personal injury* or injury to property *caused by the latent effects of exposure . . . upon or within the body.*” *Id.* (emphases added). Thus, to fall within CPLR § 214-c(2), a plaintiff must have a diagnosable disease, symptom, or other bodily effect. “Increased risk” is not a disease or even a physical impact “upon or within the body”; it is merely a mathematical expression. “Increased medical monitoring costs” similarly are not an effect “upon or within the body,” but an economic injury.

no objective standard for measuring “significant risk,” and no consensus in the medical community about the level of exposure or risk that warrants medical monitoring, there can be no objective standard for determining when a claim accrues.

The test proposed by Plaintiffs is even more unworkable. Medical technology and the medical community’s views of the value of specific screening tests are constantly evolving. New tests are developed, and tests that were once considered standard cease to be such when long-term studies demonstrate that the risks of screening outweigh the benefits. Thus, for example, in 2011, the USPSTF withdrew its recommendation for prostate cancer screening for certain populations because the serious harms associated with early treatment outweighed the benefits of early detection. *See* <http://www.uspreventiveservicestaskforce.org/prostatecancerscreening.htm>. Consequently, both the existence of an “injury” (the need for screening) and the accrual of the claim would be different today than they were three years ago due to evolving medical knowledge. Legal rights and obligations should not be erected upon such shifting sands.

Furthermore, under Plaintiffs’ theory, causes of action based on conduct that ended decades earlier could be resurrected based on the development of new testing methodologies. Defendants would be forced to litigate over the propriety of business practices long after witnesses are dead and evidence has disappeared.

Although the legislature has determined to impose that burden on defendants in the case of actual latent injuries, it cannot be assumed that it would weigh the balance in the same way for plaintiffs who have no injury. It is for the legislature, not the judiciary, to determine whether the unfairness and unpredictability of open-ended liability outweigh the right of plaintiffs with no actual injury to take advantage of new medical developments, on defendants' nickel, in perpetuity.

This Court has repeatedly held that it is for the legislature, not the courts, to engage in the balancing of policy considerations that underlie the accrual of statutes of limitations. *See Jensen*, 82 N.Y.2d at 84; *see also supra* Part III.A. Moreover, in the absence of legislative input, this Court has consistently opted to apply “bright line accrual rule[s]” in order to protect defendants from fraudulent claims, “provide manufacturers, employers and other economic actors who are potential defendants with a degree of certainty or predictability in assessing the risk of liability and to avoid stale claims which often turn on questions of credibility or disputed medical judgments.” *Consorti v. Owens-Corning Fiberglas Corp.*, 86 N.Y.2d 449, 451-52 (1995); *see, e.g., MRI Broadway Rental, Inc. v. U.S. Mineral Prods. Co.*, 92 N.Y.2d 421, 424, 427 (1998); *Snyder*, 81 N.Y.2d at 433.

If the Court adopts a medical monitoring cause of action, the only “bright line, readily verifiable rule” is the date of first exposure to the product or substance at issue. That rule, which was announced in *Schmidt*, remains the law in New

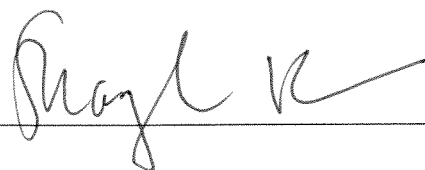
York in toxic exposure cases that are not covered by CPLR 214-c. *Rothstein v. Tenn. Gas Pipeline Co.*, 87 N.Y.2d 90, 93 (1995); *see also Consorti*, 86 N.Y.2d at 452-54 (same); *Snyder*, 81 N.Y.2d at 433 (holding, in the only Court of Appeals case to cite *Askey*, that *Askey* erroneously applied a “last exposure” rule); *MRI Broadway Rental*, 92 N.Y.2d at 424 (cause of action “accrues upon initial exposure to the toxic substance”).

CONCLUSION

For the foregoing reasons, *amici curiae* respectfully urge this Court to answer the first certified question in the negative, declining to create an independent equitable cause of action for medical monitoring, and clarifying that New York tort law requires proof of a present injury, not mere increased risk.

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