**IN THE UNITED STATES COURT OF APPEALS**
**FOR THE THIRD CIRCUIT**

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**Nos. 09-1426, 09-3598 & 09-4120**

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**M.G., by and through her parents and natural guardians, K.G. and J.G.**

***Appellant/Cross-Appellee,***

**v.**

**A.I. DUPONT HOSPITAL FOR CHILDREN, THE NEMOURS FOUNDATION, NEMOURS CARDIAC CENTER, NEMOURS DE INSTITUTIONAL REVIEW BOARD, WILLIAM I. NORWOOD, M.D., Ph.D., JOHN MURPHY, M.D., NUMED, INC. and ALLEN TOWER,**

***Appellees/Cross-Appellants.***

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**Appeal and Cross-Appeal (by permission) from the Orders of the United States District Court, for the Eastern District of Pennsylvania, Honorable R. Barclay Surrick, C.A. No. 2:08-cv-00228**

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# COALITION FOR LITIGATION JUSTICE, INC., CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, NATIONAL ASSOCIATION OF MANUFACTURERS, NFIB SMALL BUSINESS LEGAL CENTER, AMERICAN TORT REFORM ASSOCIATION, PROPERTY CASUALTY INSURERS ASSOCIATION OF AMERICA, AMERICAN INSURANCE ASSOCIATION, AMERICAN PETROLEUM INSTITUTE, AMERICAN COATINGS ASSOCIATION, AMERICAN CHEMISTRY COUNCIL, AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA'S *AMICI CURIAE* BRIEF IN SUPPORT OF DEFENDANTS-APPELLEES

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## DISCLOSURE STATEMENT PURSUANT TO RULE 26.1 OF THE FEDERAL RULES OF APPELLATE PROCEDURE

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, counsel for *amici curiae* hereby states that the associations represented on this brief have no parent corporations and have issued no stock.

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## QUESTION PRESENTED

*Amici* submit this brief to address the following certified questions: (1) would the Delaware Supreme Court recognize a cause of action for medical monitoring if presented with the record in this case, and (2) would Plaintiff be able to state a claim for medical monitoring in Delaware?

## IDENTITY AND INTEREST OF *AMICI CURIAE* AND SOURCE OF AUTHORITY TO FILE

As organizations representing companies doing business in Delaware and their insurers, *amici* have a substantial interest in ensuring that Delaware law follows traditional legal principles and reflects sound public policy. *Amici*'s members would be adversely affected by a holding that Delaware would recognize a medical monitoring cause of action in the absence of a proven physical injury. *Amici* submit this brief with an accompanying Motion for Leave to File.

## STATEMENT OF THE CASE

*Amici* adopt Defendants-Appellees's Statement of the Case.

## INTRODUCTION

For more than 200 years, a basic tenet of recovery in tort has been that liability should be imposed only when an individual has sustained a physical injury. *See* William Prosser, *Handbook on the Law of Torts* § 54, at 330-33 (4th ed. 1971). At times, this bright line rule may seem harsh, but it is the best filter courts have been able to develop to prevent a flood of claims, provide faster access

to courts for those with "reliable and serious" claims, *Metro-North Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 444 (1997), and ensure that defendants are held liable only for objectively verifiable, genuine harm. Medical monitoring cases brought by asymptomatic plaintiffs cannot be reconciled with the traditional rule. Such a cause of action would eliminate the long-established injury requirement by permitting plaintiffs to recover based on the mere *possibility* of a future injury.

The Supreme Court of the United States and a "super majority" of state supreme courts to consider the issue over the past decade— the Alabama, Nevada, Kentucky, Michigan, Mississippi, Oregon, and New Jersey Supreme Courts — as well as numerous other state and federal courts have rejected medical monitoring absent a proven physical injury.

The Delaware Supreme Court would follow the guidance of these courts and reject a cause of action for medical monitoring in the absence of a proven physical injury. First and foremost, adoption of such a cause of action would mark a major substantive change in Delaware law. The Delaware Supreme Court has repeatedly affirmed the need for a physical injury in tort cases, *see, e.g.*, *Mergenthaler v. Asbestos Corp. of Am.*, 480 A.2d 647, 651 (Del. 1984); *E.I. DuPont de Nemours and Co. v. Pressman*, 679 A.2d 436, 44-445 (Del. 1996), unless otherwise permitted by statute, *see Spencer v. Goodill*, 2009 WL 3823217 (Del. Super. Nov. 13, 2009). Second, medical monitoring claims raise serious public policy

concerns. *See* Victor E. Schwartz *et al.*, *Medical Monitoring—Should Tort Law Say Yes?*, 34 Wake Forest L. Rev. 1057 (1999); Victor E. Schwartz *et al.*, *Medical Monitoring: The Right Way and the Wrong Way*, 70 Mo. L. Rev. 349 (2005). Such radical and widespread changes in tort law are best left to the Legislature.

Finally, while the Plaintiff here is sympathetic and this case is atypical of most medical monitoring claims — because the case involves an implanted medical device (stent) that did not have Food and Drug Administration pre-market approval, and it has been suggested that Plaintiff should receive follow-up care, *see Guinan v. A.I. duPont Hosp. for Children*, 597 F. Supp. 517, 537, 539 (E.D. Pa. 2009), *motion to certify appeal granted*, -- F. Supp. 2d --, 2009 WL 2877595 (E.D. Pa. Aug. 28, 2009) — such facts would not result in a recovery even if this Court were to conclude that the Delaware Supreme Court would find "special recovery circumstances" to exist. *Id.* at 540 n.11 (quoting *Buckley*, 521 U.S. at 440). Plaintiff would be unable to meet the criteria that are applied where medical monitoring claims have been allowed. Thus, a holding that the Delaware Supreme Court would find this case to be a "special recovery-permitting circumstance" would not further Plaintiff's pursuit of a recovery. Furthermore, because the Institutional Defendants have established a registry to monitor persons implanted with the stent, *see id.* at 537, there is no reason to twist tort law for a remedy that is available outside the tort system.

## ARGUMENT

### I. DELAWARE LAW DOES NOT SUPPORT RECOGNITION OF A CAUSE OF ACTION FOR MEDICAL MONITORING IN THE ABSENCE OF A PROVEN PHYSICAL INJURY

The Delaware Supreme Court has never recognized a cause of action for medical monitoring in the absence of a proven physical injury. The court has repeatedly adhered to the traditional requirement that a plaintiff must prove a physical injury to recover in tort. For example, in *Mergenthaler v. Asbestos Corporation of America, supra,* the court held that asymptomatic spouses of workers exposed to asbestos were not entitled to recover for medical surveillance and related mental anguish due to alleged contact with asbestos from handling the workers' clothes. The court explained, "In any claim for mental anguish . . . an essential element of the claim is that the claimant have a present physical injury." *Id.* at 651. The court found plaintiffs' concession that they "suffered no physical injury" to be "dispositive." *Id.* The court also rejected their medical surveillance claim on causation grounds.

Similarly, in *Brzoska v. Olsen*, 688 A.2d 1355 (Del. 1995), the Delaware Supreme Court applied the physical injury rule to dismiss fear of disease claims from a putative class of patients of a dentist who did not inform his patients of his HIV status. Because none of the patients could show actual exposure to HIV, and thus some form of present injury, the court denied recovery for their "fear of

AIDS." *Id.* at 1362; *see also Pressman*, 679 A.2d at 444-45 (Del. 1996) (requiring physical injury to recover for mental distress relating to alleged wrongful termination of employment); *McKnight v. Voshell*, 513 A.2d 1319, 1986 WL 17360, at *3 (Del. Aug. 6, 1986) ("The law of Delaware is well settled that a claim of negligent infliction of emotional distress or mental anguish may not be maintained in the absence of evidence of a present physical injury."); *Lupo v. Medical Ctr. of Del., Inc.*, 1996 WL 111132, at *2 (Del. Super. Feb. 7, 1996); *Rea v. Midway Realty Corp.*, 1989 WL 100452, at *5 (Del. Super. Aug. 23, 1989).

These holdings are consistent with the Delaware Supreme Court's earlier opinion in *Robb v. Pennsylvania Railroad Co.*, 210 A.2d 709 (Del. 1965), where the court ruled that a plaintiff whose automobile stalled on tracks at a railroad crossing and who fled from the automobile seconds before a collision with a train could recover for physical injuries allegedly resulting from fright proximately caused by the railroad's negligence. The court held, "where negligence proximately caused fright, in one within the immediate area of physical danger from that negligence, which in turn produced physical consequences such as would be elements of damage if a bodily injury had been suffered, the injured party is entitled to recover under an application of the prevailing principles of law as to negligence and proximate causation." *Id.* at 464. The court was careful to point out that the plaintiff claimed "physical injuries resulting from fright proximately

caused by the negligence of the defendant." *Id.* at 465; *see also Hamilton v. Wrang*, 221 A.2d 605, 606 (Del. 1966) ("no actionable wrong for personal injury exists absent injury to the person").

In addition, Delaware lower courts have required a proven physical injury in cases presenting novel claims such as the one at issue. *See In re Asbestos Litig. Leary Trial Group,* 1994 Del Super. LEXIS 685, at *5 (Del. Super. Aug. 5, 1994), ("Because the Court has determined that plaintiffs do not have a compensable physical injury, plaintiffs may not recover for the expenses of medical surveillance."), *rev'd on other grounds sub nom. Mancari v. A.C.& S, Inc.,* 670 A.2d 1339 (Del. Super. 1995).

Furthermore, abandoning the physical injury rule would have consequences for other legal rules as well. First, it is difficult to reconcile a medical monitoring claim with the Delaware Supreme Court's decision in *United States v. Anderson*, 669 A.2d 73 (Del. 1995), which allowed a claim for increased risk of future harm where the plaintiff suffered a serious physical injury (cancer) which spread because of a late diagnosis. In *Anderson*, the court voiced concern about the potentially "speculative" nature of increased risk theories of negligence. *Id.* at 77. A Delaware Superior Court in *Kern ex rel. Kern v. Alfred I. duPont Institute of Nemours Foundation,* 2004 WL 2191036 (Del. Super. July 30, 2004), also noted that absent medical expert testimony detailing a patient's increased risks in

percentages articulated with "reasonable probability and precision," increased risk theories were too speculative to go before a jury." *Id.* at *4. "Medical monitoring claims are . . . just as speculative as increased risk of future harm because they both base liability on speculation about the likelihood that the plaintiff may someday contract a particular disease." Herbert L. Zarov *et al.*, *A Medical Monitoring Claim for Asymptomatic Plaintiffs: Should Illinois Take the Plunge?*, 12 DePaul J. Heath Care L. 1, 20 (2009).

Second, recognition of a medical monitoring claim may run afoul of the economic loss rule. *See Danforth v. Acorn Structures, Inc.*, 608 A.2d 1194, 1195 (Del. 1992) ("The economic loss doctrine is a judicially created doctrine that prohibits recovery in tort where a product has damaged only itself (*i.e.*, has not caused personal injury or damage to other property) and, the only losses suffered are economic in nature."). "The costs of medical monitoring are, of course, mere economic loss." Herbert L. Zarov *et al.*, 12 DePaul J. Heath Care L. at 20. "Therefore, a clear tension exists between the rule barring recovery of mere economic loss in tort and the abandonment of the physical injury rule in order to allow medical monitoring claims." *Id.* at 20-21.

Where recovery has been permitted in Delaware without a showing of physical injury, it has been due to legislative action. *See Spencer v. Goodill*, 2009

WL 3823217 (Del. Super. Nov. 13, 2009) (Delaware's Wrongful Death Statute explicitly provides for recovery of "mental anguish" without physical injury).

Against this weight of authority, the district court suggested that *Merganthaler* may permit medical monitoring "if the evidence established direct contact with the hazardous substance." *Guinan*, 597 F. Supp. 2d at 539. We disagree. First, the language in *Mergenthaler* "is dictum in which the Supreme Court was distinguishing a New Jersey case which had been cited by plaintiffs in that case." *In re Asbestos Litig. Leary Trial Group,* 1994 WL 721763, at *6 (Del. Super. June 14, 1994), *rev'd on other grounds sub nom. Mancari v. A.C.& S, Inc.,* 670 A.2d 1339 (Del. Super. 1995). Second, as discussed, other case law suggests that the Delaware Supreme Court would apply the physical injury rule even in this circumstance. Third, there is no evidence here that the stent at issue is, in fact, "hazardous." Finally, the early New Jersey case cited by the court in *Merganthaler* as providing support for a medical monitoring claim, *Ayers v. Township of Jackson*, 525 A.2d 287 (N.J. 1987), has since been limited, *see Theer v. Philip Carey Co.*, 628 A.2d 724, 733 (N.J. 1993) (mentioning that *Ayers* was special because it was a public entity that was required to pay medical monitoring costs), and very recently found *not* to be the law in product-related actions such as this one. *See Sinclair v. Merck & Co., Inc.,* 948 A.2d 587, 588-589 (N.J. 2008).

## II. THE DELAWARE SUPREME COURT WOULD FOLLOW THE UNITED STATES SUPREME COURT AND THE GREAT WEIGHT OF AUTHORITY OVER THE LAST DECADE

### A. The United States Supreme Court Has Rejected Medical Monitoring Absent a Present Injury

1997 was a landmark year for medical monitoring litigation. Earlier, courts were divided as to whether to allow medical monitoring for plaintiffs with no present physical injury. Such claims were viewed as having "emotional and political appeal" because our society has developed a "heightened sensitivity to environmental issues." Susan L. Martin & Jonathan D. Martin, *Tort Actions for Medical Monitoring: Warranted or Wasteful?*, 20 Colum. J. Envtl. L. 121, 121 (1995).

Then, in *Metro-North Commuter R.R. Co. v. Buckley*, 521 U.S. 424 (1997), the United States Supreme Court ruled 7-2 against allowing a medical monitoring claim brought under the Federal Employers' Liability Act, a statute that has often been construed in favor of plaintiffs. The Court closely considered the policy concerns militating against adoption of a medical monitoring cause of action, including the difficulty in identifying which medical monitoring costs are over and above the preventative medicine ordinarily recommended for everyone, conflicting testimony from medical professionals as to the benefit and appropriate timing of particular tests or treatments, and each plaintiff's unique medical needs. *See id.* at 441-42. The Court appreciated that medical monitoring would permit literally "tens of millions of individuals" to justify "some form of substance-exposure-related medical

monitoring." *Id.* at 442. [1] The Court rejected the argument that medical monitoring awards are not costly and feared that allowing such claims could create double recoveries because alternative sources of monitoring are often available, such as through employer-provided health insurance plans. *See id.* at 443-44.[2]

### B. Almost All State Supreme Courts over the Past Decade Have Rejected Medical Monitoring Claims

Since the *Buckley* decision, "[t]he clear trend in most U.S. jurisdictions has been to reject medical monitoring claims where there is no present physical injury." I.W. Hamer, *Medical Monitoring in North America: Does This Horse Have Legs?*, 77 Def. Couns. J. 50, 55-56 (Jan. 2010); *Norwood v. Raytheon Co.*, 414 F. Supp. 2d 659, 666 (W.D. Tex. 2006) ("The majority of states considering medical monitoring as a cause of action since *Metro-North* have rejected the claims.").

The Alabama Supreme Court in *Hinton v. Monsanto Co.*, 813 So. 2d 827 (Ala. 2001), rejected a medical monitoring claim brought by a claimant exposed to

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1 "Some 40 million persons—nearly 20 percent of the U.S. population—live within four miles of a hazardous waste site on the EPA's National Priority List, and eight out of ten Americans live near some type of hazardous waste site." Paul J. Komyatte, *Medical Monitoring Damages: An Evolution of Environmental Tort Law*, 23 Colo. Law. 1533, 1533 (1994).

2 Medical monitoring "may be an extremely redundant remedy for those who already have health insurance." *See* Arvin Maskin et al., *Medical Monitoring: A Viable Remedy for Deserving Plaintiffs or Tort Law's Most Expensive Consolation Prize?*, 27 Wm. Mitchell L. Rev. 521, 528 (2000). Approximately 80 percent of standard medical testing is paid for by third party insurance. *See* Am. Law Inst., 2 *Enterprise Responsibility for Personal Injury – Reporters' Study* 379 (1991).

a toxin allegedly released into the environment because of the absence of a "manifest, present injury." *Id.* at 829. The court stated, "To recognize medical monitoring as a distinct cause of action . . . would require this court to completely rewrite Alabama's tort-law system, a task akin to traveling in uncharted waters, without the benefit of a seasoned guide" – a voyage on which the court was "unprepared to embark." *Id.* at 830. The court concluded: "we find it inappropriate . . . to stand Alabama tort law on its head in an attempt to alleviate [plaintiff's] concerns about what *might* occur in the future. . . . That law provides no redress for a plaintiff who has no present injury or illness." *Id.* at 831-32; *see also Houston County Health Care Auth. v. Williams*, 961 So. 2d 795, 811 (Ala. 2006) (medical monitoring claims require "present physical injury.,").

The Nevada Supreme Court in *Badillo v. American Brands, Inc.*, 16 P.3d 435 (Nev. 2001), rejected claims by smokers and casino workers who brought class actions seeking the establishment of a court-supervised medical monitoring program to aid in the early diagnosis and treatment of alleged tobacco-related illnesses. The court held, "Nevada common law does not recognize a cause of action for medical monitoring," *id.* at 438, observing that medical monitoring is "a novel, non-traditional tort and remedy." *Id.* at 441. The court concluded that "[a]ltering common law rights, creating new causes of action, and providing new remedies, for wrongs is generally a legislative, not a judicial function." *Id.* at 440.

The Kentucky Supreme Court rejected medical monitoring in *Wood v. Wyeth-Ayerst Laboratories*, 82 S.W.3d 849 (Ky. 2002), where plaintiffs sought a court-supervised medical monitoring fund to detect the possible onset of primary pulmonary hypertension from ingesting the "Fen-Phen" diet drug combination. "To find otherwise," the court stated, "would force us to stretch the limits of logic and ignore a long line of legal precedent." *Id.* at 853-54. The court concluded: "[t]raditional 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.* at 859. The court also noted that its decision was supported "by both the United States Supreme Court and a persuasive cadre of authors from academia." *Id.* at 857.

Additionally, the Supreme Court of Michigan rejected a request to establish a medical screening program for possible negative effects from dioxin exposure. In *Henry v. Dow Chemical Co.*, 701 N.W.2d 684 (Mich. 2005), the court concluded that a medical monitoring cause of action would "depart[] drastically from [the] traditional notions of a valid negligence claim" and that "judicial recognition of plaintiffs' claim may also have undesirable effects that neither [the court] nor the parties can satisfactorily predict." *Id.* at 694. The court further opined that this type of claim would "drain resources need to compensate those

with manifest physical injuries and a more immediate need for medical care," and that this change "ought to be made, if at all, by the Legislature." *Id.* at 686, 694.

Mississippi's highest court rejected medical monitoring in *Paz v. Brush Engineered Materials, Inc.*, 949 So. 2d 1 (Miss. 2007), where a class of workers exposed to beryllium sought the establishment of a medical monitoring fund. The court held that "[t]he possibility of a future injury is insufficient to maintain a tort claim," and "it would be contrary to current Mississippi law to recognize a claim for medical monitoring costs for mere exposure to a harmful substance without proof of current physical or emotional injury from that exposure." *Id.* at 5.

More recently, in *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181 (Or. 2008), the Oregon Supreme Court held that a smoker's allegation that her accumulated exposure to cigarette smoke required her to undergo periodic medical monitoring was insufficient to give rise to a claim. The court held that "negligent conduct that results only in a significantly increased risk of future injury that requires medical monitoring does not give rise to a claim for negligence." *Id.* at 187.

Most recently, the New Jersey Supreme Court rejected medical monitoring for a proposed national class of individuals who ingested the prescription drug Vioxx. *See Sinclair v. Merck & Co.*, 948 A.2d 587 (N.J. 2008). The court held that the definition of "harm" under New Jersey's Products Liability Act (PLA) did not include the remedy of medical monitoring when no manifest injury is alleged.

*See id.* at 588-589; *see also Vitanza v. Wyeth, Inc.*, 2006 WL 462470, at *9 (N.J. Super. Jan. 24, 2006).

Many other courts have rejected medical monitoring absent a present injury.[3]

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[3] *See Goodall v. United Illuminating*, 1998 WL 914274, at *7-10 (Conn. Super. Ct. Dec. 15, 1998); *Johnson v. Abbott Labs.*, 2004 WL 3245947, at *6 (Ind. Cir. Ct. Dec. 31, 2004) ("Indiana does not recognize medical monitoring as a cause of action."); *Hunt v. American Wood Preservers Inst.*, 2002 WL 34447541, at *1 (S.D. Ind. July 31, 2002) (a medical monitoring claim "is not cognizable in the State of Indiana."); *Abusio v. Consol. Edison Co. of N.Y., Inc.*, 656 N.Y.S.2d 371, 372 (N.Y. App. Div.) (requiring a showing of clinically demonstrable presence of toxins in the plaintiff's body or some indication of exposure-related disease to establish "reasonable basis" for recovery of future medical monitoring costs), *leave to appeal denied*, 686 N.E.2d 1363 (N.Y. 1997); *Parker v. Brush Wellman, Inc.*, 377 F. Supp. 2d 1290 (N.D. Ga. 2005) ("[N]o Georgia court has ever indicated an inclination to recognize such a remedy."), *aff'd*, 230 Fed. Appx. 878 (11th Cir. 2007); *Carroll v. Litton Sys., Inc.*, 1990 WL 312969, *87 (W.D.N.C. Oct. 29, 1990) (refusing to allow medical monitoring claim in absence of clear direction of the North Carolina legislature, and noting that even if North Carolina courts recognized medical monitoring, they would require a present physical injury); *Curl v. Am. Multimedia, Inc.*, 654 S.E.2d 76, 81 (N.C. Ct. App. 2007) (refusing to create a "new cause of action" for medical monitoring and stating that it "is a policy decision which falls within the province of the legislature"); *Norwood*, 414 F. Supp. 2d at 667 ("it appears likely that the Texas Supreme Court would follow the recent trend of rejecting medical monitoring as a cause of action"); *Ball v. Joy Tech., Inc.*, 958 F.2d 36, 39 (4th Cir. 1991) (dismissing claim for medical monitoring damages because Virginia law requires a present, physical injury prior to recovery for negligence), *cert. denied*, 502 U.S. 1033 (1992); *Thompson v. American Tobacco Co., Inc.*, 189 F.R.D. 544, 552 (D. Minn. 1999) ("Given the novelty of the tort of medical monitoring and that the Minnesota Supreme Court has yet to recognize it as an independent theory of recovery, this Court is not inclined at this time to find that such a tort exists under Minnesota law."); *Trimble v. Asarco, Inc.*, 232 F.3d 946, 963 (8th Cir. 2000) (holding Nebraska law has not recognized a cause of action or damages for medical monitoring and predicting that Nebraska courts would not judicially adopt such a right or remedy), *abrogated on other grounds by Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546 (2005); *Avila v. CNH Am. LLC*, 2007 WL 2688613, at *1 (D. Neb. Sep. 10, 2007)

Massachusetts and Missouri are the only recent states to permit medical monitoring in some circumstances, but those cases are distinguishable. In *Meyer ex rel. Coplin v. Fluor Corp.*, 220 S.W.3d 712, 717 (Mo. 2007), the Missouri Supreme Court held that plaintiffs may recover medical monitoring as an item of damages when liability is established under a traditional theory of recovery. *Meyer* involved a class action filed by children allegedly exposed to lead released into the

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("Nebraska law does not recognize a claim for medical monitoring when no present physical injury is alleged."); *Schwan v. Cargill Inc.*, 2007 WL 4570421, at *1 (D. Neb. Dec. 21, 2007) (same); *Mehl v. Canadian Pac. Ry.*, 227 F.R.D. 505, 518 (D.N.D. 2005) ("a plaintiff [in North Dakota] would be required to demonstrate a legally cognizable injury to recover any type of damages in a newly recognized tort, including a medical monitoring claim."); *Rosmer v. Pfizer*, 2001 WL 34010613, at *5 (D.S.C. Mar. 30, 2001) (noting that South Carolina has not recognized such a claim); *Jones v. Brush Wellman, Inc.*, 2000 WL 33727733, at *8 (N.D. Ohio 2000) ("It is clear that under Tennessee law, a plaintiff must allege a present injury or loss to maintain an action in tort. No Tennessee cases support a cause of action for medical monitoring in the absence of a present injury."); *Bostick v. St. Jude Med., Inc.*, 2004 WL 3313614, *14 (W.D. Tenn. Aug. 17, 2004) ("[A] review of the applicable case law reveals that Tennessee does require a present injury."); *Duncan v. Northwest Airlines, Inc.*, 203 F.R.D. 601, 606 (W.D. Wash. 2001) (anticipating that Washington courts would not recognize a cause of action for medical monitoring because Washington law requires existing injury in order to pursue a negligence claim); *Purjet v. Hess Oil Virgin Islands Corp.*, 1986 WL 1200, at *4 (D.V.I. Jan. 8, 1986) (rejecting medical monitoring claim absent physical injury under Virgin Islands law); *Louis v. Caneel Bay, Inc.*, 2008 WL 4372941, at *5 (V.I. Super. Ct. July 21, 2008) ("A fundamental requirement for any Plaintiff in a negligence action . . . is 'physical injury.'"); *In re Pempro*, 230 F.R.D. 555, 569 (E.D. Ark. 2005) ("Arkansas has rejected medical monitoring as a cause of action, and questions its availability as a remedy."); *Cole v. Asarco Inc.*, 2009 WL 920581, at *4 (N.D. Okla. Apr. 2, 2009) ("Oklahoma law requires plaintiffs to demonstrate an existing disease or physical injury before they can recover the costs of future medical treatment that is deemed medically necessary."); *cf.* La. Civ. Code Ann. art. 2315.

environment by defendant's smelter. The court's opinion relied upon pre-*Buckley* authority and does not address any of the concerns identified by the Supreme Court and other states that have rejected medical monitoring. The Missouri Supreme Court also declined to establish any parameters for the new tort it created, leaving litigants and lower courts unguided to find their way in the tangle of medical, scientific, and policy issues involved in implementing the court's vague directive. *See* Mark A. Behrens & Christopher E. Appel, *Medical Monitoring in Missouri After Meyer Ex Rel. Coplin v. Fluor Corp.: Sound Policy Should be Restored to a Vague and Unsound Directive*, 27 St. Louis U. Pub. L. Rev. 135 (2007). Perhaps most importantly for this appeal, a federal court recently concluded that *Meyer* "does not apply to potential latent injuries resulting from anything other than exposure to toxic substances," and "does not support medical monitoring claims in garden variety products liability cases." *Ratliff v. Mentor Corp.*, 569 F. Supp. 2d 926, 928-29 (W.D. Mo. 2008).

The Massachusetts case, *Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891, 902 (Mass. 2009), presented the narrow question whether the subclinical effects of exposure to cigarette smoke would support an equitable remedy. *See id.* at 894. The court held that injunctive relief establishing medical monitoring is available if the defendant's negligence caused plaintiff to become exposed to a hazardous substance that produced, at least, subcellular changes that substantially

increased the risk of serious disease, illness, or injury. . . ." *Id.* at 902. The circumstances here are fundamentally different.

### C. The Experience of States That Have Adopted Medical Monitoring Shows Why Delaware Would Reject It

The negative experience of some states that have adopted medical monitoring also demonstrates why the Delaware Supreme Court would be unwilling to adopt such a cause of action.

West Virginia provides a good example. In *Bower v. Westinghouse Electric Corp.*, 522 S.E.2d 424, 432-33 (W. Va. 1999), West Virginia's highest court established a cause of action for medical monitoring, even when testing is not medically necessary or beneficial, and does not require plaintiffs to spend any of the award on actual monitoring. *See id.* at 433-34. As a result, thousands of uninjured people from other states have sought to have their claims adjudicated in West Virginia.[4] *See, e.g.*, Robert D. Mauk, *McGraw Ruling Harms State's Reputation in Law, Medical Monitoring*, Charleston Gazette, Mar. 1, 2003, at 5A

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[4] *See Stern v. Chemtall, Inc.*, 617 S.E.2d 876, 887 (W. Va. 2005) (Starcher, J., concurring) ("[W]e have dumped an additional pile of medical monitoring cases into the circuit judge's lap."); *In re Tobacco Litig. (Medical Monitoring Cases)*, 600 S.E.2d 188 (W. Va. 2004) (affirming verdict denying medical monitoring claim in class involving some 270,000 present and former smokers); *In re W. Va. Rezulin Litig.*, 585 S.E.2d 52 (W. Va. 2003) (medical monitoring class of approximately 5,000 users of drug); *State ex rel. E.I. DuPont de Nemours and Co. v. Hill*, 591 S.E.2d 318 (W. Va. 2003) (blood tests to approximately 50,000 individuals possibly exposed to material used to make fluoropolymers).

("[T]he *Bower* medical monitoring ruling has cast a shadow over our state's reputation in the legal field. It affects West Virginia's jobs, taxes, health care and the public credibility of our courts.").

Louisiana provides another example. In *Bourgeouis v. A.P. Green Industries, Inc.*, 716 So. 2d 355 (La. 1998), the Louisiana Supreme Court recognized medical monitoring as a cause of action. Such claims soon flooded in.[5] In response, the legislature swiftly reversed *Bourgeouis*, requiring a manifest injury to support medical monitoring claims. La. Civ. Code Ann. § 2315 (1999).

These experiences suggest that the Delaware Supreme Court would be likely to adhere to traditional principles or leave the issue to the legislature to be decided.

## III. THE DELAWARE SUPREME COURT WOULD REJECT MEDICAL MONITORING ON PUBLIC POLICY GROUNDS

Judicial adoption of medical monitoring would likely foster litigation. *See* James A. 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 (2002). Almost everyone comes into contact with a potentially limitless number of products or materials that could be argued to warrant medical monitoring relief. *See* Arvin Maskin *et al., Medical Monitoring:*

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[5] *See, e.g., Dragon v. Cooper/T. Smith Stevedoring Co., Inc.*, 726 So. 2d 1006 (La. App. 1999) (permitting a class action for medical monitoring for seamen exposed to asbestos); *Scott v. American Tobacco Co.*, 725 So. 2d 10 (La. App. 1998) (certifying as a medical monitoring class all Louisiana residents who were cigarette smokers on or before May 24, 1996, provided that each claimant started smoking on or before Sep. 1, 1988), *writ denied*, 731 So. 2d 189 (La. 1999).

*A Viable Remedy for Deserving Plaintiffs or Tort Law's Most Expensive Consolation Prize*?, 27 Wm. Mitchell L. Rev. 521 (2000). As the Texas Supreme Court wisely observed, "[i]f recovery were allowed in the absence of present disease, individuals might feel obliged to bring suit for such recovery prophylactically, against the possibility of future consequences from what is now an inchoate risk." *Temple-Inland Forest Prods. Corp. v. Carter*, 993 S.W.2d 88, 93 (Tex. 1999).

Courts would be forced to decide claims that are premature (because there is not yet any physical injury) or actually meritless (because there never will be). The truly injured would be adversely impacted by the unsound diversion of resources to the non-sick.[6] Courts would face the difficult and time-consuming task of developing a system for the administration of medical monitoring claims. Delaware has not shown any inclination to adopt such a system.

In addition, a decision to recognize medical monitoring would necessarily require development of an effective legal scheme for its just application; a task courts are ill-suited to undertake. Courts are designed to adjudicate disputes concerning discrete issues and parties. A medical monitoring system, in contrast, involves a number of complex scientific, medical, and economic questions. A state

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[6] *See Ball*, 755 F. Supp. at 1372 ("There must be a realization that such defendants' pockets or bank accounts do not contain infinite resources. Allowing today's generation of exposed but uninjured plaintiffs to recover may lead to tomorrow's generation of exposed and injured plaintiff's [sic] being remediless.").

legislature, with its information-gathering ability, prospective treatment of new laws, and broad perspective, is better equipped to make far-reaching changes in the law.[7]

Devising a sound medical monitoring system would require, at a minimum, identifying the types of health conditions that may be monitored; the procedures for determining eligibility for monitoring; the likelihood that monitoring will detect the existence of disease; when eligible parties may join the program; the length of time the program should last; the frequency of any periodic monitoring and the circumstances in which the frequency can be changed to allow special monitoring; the content of the monitoring exams; whether the facility testing will be formal or informal; whether the service provider is to be designated by the court or chosen by the claimant; and the potential medical, scientific, and economic downsides to medical monitoring, including the effect of such awards on job growth and the economy. *See* Jesse R. Lee, *Medical Monitoring Damages: Issues Concerning the Administration of Medical Monitoring Programs*, 20 Am. J.L. & Med. 251, 267-72 (1994).

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[7] *See* D. Scott Aberson, Note, *A Fifty-State Survey of Medical Monitoring and the Approach the Minnesota Supreme Court Should Take When Confronted with the Issue*, 32 Wm. Mitchell L. Rev. 1095, 1129 (2006) (urging courts to reject medical monitoring absent injury as issue is best suited for the legislature); Carey C. Jordan, Note, *Medical Monitoring in Toxic Tort Cases: Another Windfall for Texas Plaintiffs?*, 33 Hous. L. Rev. 473, 496 (1996) (same).

When courts make bright-line rules allowing medical monitoring of all types of health conditions, they disregard the crucial medical understanding that medical monitoring is only appropriate for curable or treatable conditions. Such decisions display a critical misunderstanding of the purpose of medical monitoring and illustrate that courts do not have access to all the information that is needed to make sound decisions about appropriate medical monitoring.[8]

Courts that allow medical monitoring claims must make scientific and medical decisions about which treatment is proper for specific plaintiffs. In some cases, plaintiffs' lawyers deluge the court with a battery of diagnostic tests they would like to see the court authorize for their clients.[9] Critics have suggested that "[t]he all-too-transparent method behind this madness is to inflate as much as possible the cost of yearly monitoring per plaintiff so as to maximize plaintiffs' damage award and their attorneys' contingent fees." Thomas M. Goutman,

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[8] *See Henry*, 701 N.W.2d at 699 (courts do not possess the "technical expertise necessary to effectively administer a program heavily dependent on scientific disciplines such as medicine, chemistry and environmental science").

[9] For example, the plaintiffs in *In re Paoli R.R. Yard PCB Litig.*, 113 F.3d 444 (3d Cir. 1997), requested the following tests for feared PCB exposure: amniocentesis, developmental and achievement testing, electrocardiography, pulmonary function tests, mammography, sigmoidoscopy, urine cytology, sputum cytology, basic immunotoxicology panel, chromosomal analysis, complete optomologic evaluation, complete cardiovascular evaluation, complete neurological evaluation, complete gastrointestinal evaluation, PCV detoxification, urinalysis, PSA, CBC, urine porphyrin, and male fertility evaluation. *See* Schwartz et al., *The Right Way and the Wrong Way,* at 377 n.171.

*Medical Monitoring: How Bad Science Makes Bad Law* 15 (2001). Courts must then decipher which of these suggested tests to channel the plaintiff toward by "[s]crutiniz[ing] the clinical efficacy of the [suggested diagnostic tests], and in some cases, even the treatments planned to follow identification of disease." David M. Studdert *et al., Medical Monitoring for Pharmaceutical Injuries: Tort Law for the Public's Health?*, JAMA, Feb. 19, 2003, at 890. Adding complexity, this determination may change over time with emerging cures and treatments for current diseases and with the introduction of new types of diseases.

In an attempt to confine claims, courts that have permitted recovery for medical monitoring have established certain threshold criteria for these claims, but they have not demonstrated an ability to articulate consistent eligibility requirements.[10] A review of the different approaches taken by states illustrates the difficulty in developing the novel remedy. *See, e.g., Bower*, 522 S.E.2d at 432-33 (plaintiff only has to show that "he or she has, relative to the general population, been significantly exposed" and "is not required to show that a particular disease is certain or even likely to occur as a result of exposure"); *Redland Soccer Club, Inc. v. Dep't of the Army*, 696 A.2d 137, 145 (Pa. 1997) (plaintiff must show a

[10] *See, e.g., Potter v. Firestone Tire & Rubber Co.*, 863 P.2d 795, 824-25 (Cal. 1993) (five factors for plaintiffs to satisfy); *Bourgeouis*, 716 So. 2d 355, 360-361 (La. 19987) (seven factors); *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 979 (Utah 1993) (eight factors). When courts set forth generalized factors, they often do not specify whether each element must be separately established or whether all factors should be weighed together.

"significantly increased risk of contacting serious latent disease" as a result of "exposure [to] greater than normal background levels"); *Carey v. Kerr-McGee Chem. Corp.*, 999 F. Supp. 1109, 1119 (N.D. Ill. 1998) (plaintiff must demonstrate "a reasonable certainty of contracting a disease in the future").

States also have different standards for what medical basis is required for a medical monitoring claim. *See, e.g., Bower*, 522 S.E.2d at 433 (medical monitoring can be "based, at least in part, on a plaintiff's subjective desires . . . for information concerning the state of his or her health"); *Redland Soccer Club*, 696 A.2d at 146 ("prescribed monitoring regime [must be] reasonably necessary according to contemporary scientific principles"). Legislatures are best equipped to consider these issues.

## IV. PLAINTIFF'S CLAIM WOULD FAIL EVEN IF SPECIAL RECOVERY-PERMITTING CIRCUMSTANCES WERE FOUND TO EXIST

The district court suggested that even if the Delaware Supreme Court would not recognize a broad medical monitoring cause of action the court might find "special recovery circumstances" to exist. There is no reason to adopt such a fiction, however, because Plaintiff would be unable to satisfy the criteria that are routinely applied where medical monitoring claims have been allowed. Furthermore, Plaintiff has a remedy available outside the tort system.

For example, in a pre-*Buckley* case, the Pennsylvania Supreme Court in *Redland Soccer Club,* building on this Court's decision in *In re Paoli Railroad Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994), *cert. denied sub nom. General Electric Co. v. Ingram*, 513 U.S. 1190 (1995), found that plaintiffs must prove the following elements by expert testimony: (1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles. *See Redland Soccer Club,* 696 A.2d at 145-146; *see also Barnes v. American Tobacco Co.*, 161 F.3d 127, 138-139 (3d Cir. 1998), *cert. denied*, 526 U.S. 1114 (1999).

Plaintiff cannot satisfy these criteria because there has been no exposure to a "proven hazardous substance." *See In re Orthopedic Bone Screw Prods. Liab. Litig.,* 1995 WL 273597, at *9 (E.D. Pa. Feb. 22, 1995) ("Medical monitoring is a suitable form of relief in toxic substance exposure types of cases" but not "in products liability cases, where diseases caused by exposure to toxic substances are not the type of injury at issue."); *Ratliff*, 569 F. Supp. 2d at 929 (medical

monitoring in Missouri is not available in "garden variety products liability cases"). This case does not involve exposure to a toxic substance and the stent at issue is not associated with any disease that can be identified by warning signs identified by doctors.

Plaintiff also cannot show "a significantly increased risk of contracting a serious latent disease." Plaintiff has no known increased risk of harm that makes periodic diagnostic medical examinations necessary.

Finally, there is no evidence that Plaintiff requires monitoring that is different from that normally recommended in the absence of the exposure.

## CONCLUSION

For these reasons, this Court should hold that the Delaware Supreme Court would not recognize medical monitoring absent a proven physical injury.

Respectfully submitted,

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## COMBINED CERTIFICATIONS

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