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Medical Monitoring Claims—Trends and Defenses

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How Did We Get Here? A Brief History Of Medical Monitoring Claims

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Friends For All Children v. Lockheed Aircraft Corp., 746 F.2d 816 (D.C. Cir. 1984)

- Orphans who survived an airplane crash alleged that the the crash's impact put them at an increased risk of incurring a neurological disorder.
- The court required the defendant to reimburse the 40 surviving orphans who resided in countries that did not provide free health coverage for the cost of examinations to test for the neurological disorder.
- The court's rationale:
  - Allowing recovery for the expense of diagnostic exams "will, in theory, deter misconduct."
  - Recognizing a claim under these circumstances "accords with commonly shared intuitions of normative justice" because the defendant, "through his own negligence, caused the plaintiff to need specific medical services."

Potter v. Firestone Tire & Rubber, 863 P.2d 795 (Cal. 1993)

- Landowners living adjacent to a landfill alleged that toxic waste disposed at the landfill exposed them to harmful carcinogens.
- Although plaintiffs had not suffered physical injuries, the trial court awarded damages to enable plaintiffs to periodically undergo tests for cancer.
- The court's rationale:
  - There is "an important public health interest in fostering access to medical testing for individuals whose exposure to toxic chemicals creates an enhanced risk of disease, particularly in light of the value of early diagnosis and treatment for many cancer patients."
  - Allowing plaintiffs "to recover the costs of [medical monitoring] deters irresponsible discharge of toxic chemicals."
  - Medical monitoring may "have the beneficial effect of preventing or mitigating serious future illnesses and thus reduce the overall costs to the responsible parties."
  - It would be "inequitable for an individual wrongfully exposed to dangerous toxins, but unable to prove that cancer or disease is likely, to have to pay the expense of medical monitoring when such intervention is clearly reasonable and necessary."

Metro-North Commuter R.R. Co. v. Buckley, 521 U.S. 424 (1997)

- An asymptomatic railroad worker exposed to asbestos sought medical monitoring under the Federal Employers' Liability Act. The Court rejected a medical monitoring claim under the Act without proof of physical injury.
- The Court's rationale:
  - Because plaintiff sought "the extra monitoring costs, over and above those otherwise recommended" for non-exposed individuals, "their identification will sometimes pose special difficult[ies] for judges and juries," in part due to "uncertainty among medical professionals about just which tests are most usefully administered and when."
  - Many "millions of individuals may have suffered exposure to substances that might justify some form of substance-exposure-related medical monitoring," which "could threaten both a 'flood' of less important cases (potentially absorbing resources better left available to those more seriously harmed), and the systemic harms that can accompany 'unlimited and unpredictable liability' (for example, vast testing liability adversely affecting the allocation of scarce medical resources)."
  - A "full-blown ordinary tort liability rule would ignore the presence of existing alternative sources of payment, thereby leaving a court uncertain about how much of the potentially large recoveries would pay for otherwise unavailable medical testing and how much would accrue to plaintiffs for whom employers or other sources (say, insurance now or in the future) might provide monitoring in any event."

Henry v. Dow Chem. Co., 701 N.W.2d 684 (Mich. 2005)

- Plaintiffs, who lived or worked near a manufacturing plant owned by Dow Chemical, alleged that they were exposed to dioxin emanating from Dow's plant. Plaintiffs conceded that they did not have physical injuries, but sought a medical monitoring program to screen them for symptoms of dioxin-related disease. The Michigan Supreme Court rejected a medical monitoring claim for uninjured plaintiffs.
- The court's rationale:
  - Requiring physical injury reduces fraudulent claims and provides a clear line allowing fact-finders to distinguish between plaintiffs who have a claim and those who do not.
  - A medical monitoring claim runs afoul of the economic loss doctrine.
  - "Undesirable effects" could flow from a medical monitoring claim, *e.g.*, it could "drain resources needed to compensate those with manifest physical injuries and a more immediate need for medical care," monitoring does not provide "an unmitigated benefit for all concerned," and could "wreak enormous harm" on the economy.
  - Legislatures, not courts, should resolve the type of "far-reaching and complex public policy issues" raised by plaintiffs' request for medical monitoring.

The Current Status Of Medical Monitoring Claims

- In addition to the California Supreme Court in *Potter*, the highest courts in Massachusetts, Missouri, New Jersey, Pennsylvania, Utah, and West Virginia have adopted claims for medical monitoring. *Donovan v. Philip Morris USA*, 914 N.E.2d 891 (Mass. 2009); *Meyer v. Fluor Corp.*, 220 S.W.3d 712 (Mo. 2007); *Ayers v. Twp. of Jackson*, 525 A.2d 287 (N.J. 1987); *Redland Soccer Club v. Dep't of the Army*, 696 A.2d 137 (Pa. 1997); *Hansen v. Mountain Fuel Supply*, 858 P.2d 970 (Utah 1993); *Bower v. Westinghouse Elec. Corp.*, 522 S.E.2d 424 (W. Va. 1999).
- In addition to the Michigan Supreme Court in *Henry*, the highest courts in several other states, as well as the legislature in Louisiana, have rejected claims for medical monitoring. *Hinton v. Monsanto Co.*, 813 So. 2d 827 (Ala. 2001); *Wood v. Wyeth-Ayerst Labs.*, 82 S.W.3d 849 (Ky. 2002); La. Civ. Code art. 2315; *Paz v. Brush Engineered Materials*, 949 So. 2d 1 (Miss. 2007); *Badillo v. Am. Brands, Inc.,* 16 P.3d 435 (Nev. 2001); *Lowe v. Philip Morris USA*, 183 P.3d 181 (Or. 2008).
- In just about every other state, lower state courts or federal courts predicting state law have opined on medical monitoring claims, sometimes in conflict with other courts from the same state.

Arguing Against The Adoption Of A Medical Monitoring Claim

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Defenses Against The Adoption Of Medical Monitoring Claims

- Monitoring claims require courts to abdicate the traditional tort rule requiring proof of injury:
  - Requiring physical injury reduces the risk of fraudulent claims.
  - Plaintiffs could be barred from suing later if they incur actual injuries.
  - Monitoring claims may run afoul of the economic loss rule.
- Monitoring claims endanger claims of future plaintiffs who incur actual injuries.
- Monitoring claims diminish medical resources and may reduce the accessibility of beneficial products.
- Medically-necessary monitoring is usually paid for by insurance.
- Monitoring claims consume substantial judicial resources.
- Legislatures are better suited to devising and administering a medical monitoring regime.

Responses To Courts That Have Adopted Medical Monitoring Claims

- The key case that courts have cited in adopting medical monitoring claims—*Friends For All Children*—does not support such a claim outside its particularized factual context.
- The "compensation" rationale is inadequate because insurance provides access to medically-necessary monitoring for most Americans, and monitoring does not provide the unmitigated benefit suggested by plaintiffs' lawyers.
- The "deterrence" rationale does not account for the deterrence provided by requiring defendants to compensate plaintiffs who incur actual injuries.
- The "justice" rationale also ignores the existence of insurance and overlooks the injustice of consuming resources that may be needed later to compensate plaintiffs who incur physical injuries.

Open Questions About Medical Monitoring

- Is medical monitoring a stand-alone cause of action or must it be tied to a traditional claim?
  - Some courts have characterized medical monitoring as "a common law claim." *Redland Soccer Club v. Dep't of the Army*, 696 A.2d 137 (Pa. 1997).
  - Other courts have said that "medical monitoring does not create a new tort. It is simply a compensable item of damage when liability is established under traditional theories of recovery.'" *Bower v. Westinghouse Elec. Corp.*, 522 S.E.2d 424 (W. Va. 1999).
  - This conflict may have little practical import because courts requiring plaintiffs to establish liability under a traditional tort have explained that "[t]his is not to say that a plaintiff may not, as a matter of pleading, assert a separate cause of action based upon medical monitoring." *Bower v. Westinghouse Elec. Corp.*, 522 S.E.2d 424 (W. Va. 1999).

Open Questions About Medical Monitoring

- Does medical monitoring apply beyond toxic tort suits to products liability cases, *e.g.*, medical device and pharmaceutical litigation?
  - Some courts have said "no." *E.g.*, *M.G. v. A.I. DuPont Hosp. for Children*, 2010 WL 3310720 (3d Cir. Aug. 24, 2010). Individuals who take prescription drugs or have implanted medical devices are necessarily already being monitored by a doctor.
  - The New Jersey Supreme Court, which has adopted medical monitoring in the toxic tort setting, refused to apply it to a prescription drug case on the ground that the suit was governed by the State's products liability statute, which required physical injury. *Sinclair v. Merck & Co.*, 948 A.2d 587 (N.J. 2008).
  - Other courts have simply assumed that medical monitoring applies in the products liability context. *E.g.*, *Sutton v. St. Jude Med. S.C.*, 419 F.3d 568 (6th Cir. 2005); *Petito v. A.H. Robins Co.*, 750 So. 2d 103 (Fla. Dist. Ct. App. 1999).

Open Questions About Medical Monitoring

- Should medical monitoring be awarded in the form of lump-sum damages or *via* a court-supervised fund?
  - The majority rule favors "the use of court-supervised funds to pay medical-surveillance claims as they accrue, rather than lump-sum verdicts." *Ayers v. T'ship of Jackson*, 525 A.2d 287 (N.J. 1987).
  - Other courts have suggested that lump-sum damages may be an acceptable remedy in medical monitoring suits. *E.g.*, *Bower v. Westinghouse Elec. Corp.*, 522 S.E.2d 424 (W. Va. 1999).

Open Questions About Medical Monitoring

- Can medical monitoring plaintiffs recover punitive damages?
  - Few courts have addressed the question; a divided West Virginia Supreme Court recently answered "no." *Perrine v. E.I. Du Pont Nemours & Co.*, 694 S.E.2d 815 (W. Va. 2010).

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Defending Against Medical Monitoring Claims In Jurisdictions That Have Adopted the Claim

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The Elements Of A Medical Monitoring Claim

- Courts have identified different factors as relevant in deciding whether to award medical monitoring.
  - The Pennsylvania Supreme Court identified the following requirements: "(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 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." *Redland Soccer Club v. Dep't of the Army*, 696 A.2d 137, 145-46 (Pa. 1997).
  - Other courts have also required that "early detection" of the monitored disease be "beneficial, meaning that a treatment exists that can alter the course of the illness." *Hansen v. Mountain Fuel Supply*, 858 P.2d 970, 979 (Utah 1993). Although "a monitoring regime might be of theoretical value in detecting and treating a particular illness, … if a reasonable physician would not prescribe it because the benefits of the monitoring would be outweighed by the costs, which may include, among other things, the burdensome frequency of the monitoring procedure, its excessive price, or its risk of harm to the patient, then recovery would not be allowed." *Id.* at 980.

Substantive Defenses to Medical Monitoring Claims

- The underlying conduct of the defendant was not tortious.
- The plaintiff cannot establish that he is at a significant increased risk of injury. *E.g.*, *Sheridan v. NGK Metals Corp.*, 609 F.3d 239 (3d Cir. 2010) (affirming summary judgment for manufacturer of beryllium-based products because plaintiff failed to show that he was "sensitized" to beryllium).
- The proposed monitoring is not capable of detecting the condition earlier than without monitoring.
- The proposed monitoring is not reasonably necessary.
  - Would a reasonable physician prescribe the proposed monitoring? *E.g.*, *In re Propulsid Prods. Liab. Litig.,* 208 F.R.D. 133 (E.D. La. 2002) (denying certification of medical monitoring class action in pharmaceutical case because "[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 or a group study of all former Propulsid users be undertaken").

Substantive Defenses to Medical Monitoring Claims

- The proposed monitoring is not reasonably necessary (con't).
  - Would a reasonable plaintiff sue only for monitoring?
  - Do the benefits of early detection outweigh the risks of monitoring?
    - Are the risks from the procedure themselves substantial? (mammograms, PSA tests, false positives)
    - Will early detection matter?
- The proposed monitoring is recommended/provided even without the claimed increased risk of injury. *E.g.*, *Wyeth, Inc. v. Gottlieb*, 930 So. 2d 635 (Fla. Dist. Ct. App. 2007) (rejecting medical monitoring claim because "the monitoring program for detecting breast cancer would involve essentially the same medical examinations that menopausal and post-menopausal women are advised to complete regardless of whether they used Prempro").

Defending Against Class Certification In Medical Monitoring Suits

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Rule 23(b)(2) or (b)(3)?

- Rule 23(b)(2)
  - Applies when the party opposing class certification acted or refused to act on grounds that apply generally to the class so that injunctive or declaratory relief is appropriate respecting the class as a whole.
  - Most courts have interpreted certification under this subsection as requiring "cohesion" among class members.
- Rule 23(b)(3)
  - **Predominance –** common issues among class members predominate over individual ones; and
  - **Superiority** – class treatment is superior to other methods of adjudicating the issues.

Rule 23(b)(2) or (b)(3)?

- The Manual for Complex Litigation observes that "[c]ourts are divided over whether Rule 23(b)2) or Rule 23(b)(3) is the appropriate vehicle for certifying a mass tort class for medical monitoring." Manual for Complex Litigation, § 22.74 (2004).
- The Manual states that "Rule 23(b)(2) generally applies when the relief sought is a court-supervised program for periodic medical examinations and research to detect diseases attributable to the products in question," rather than a request for money damages.
- However, where plaintiffs seek a medical monitoring "fund," as opposed to a medical monitoring "program," some courts have held that this "is in essence a request for monetary relief" and thus the more demanding predominance and superiority requirements of Rule 23(b)(3) must be satisfied. *Zinser v. Accufix Research Inst. Inc.,* 253 F.3d 1180 (9th Cir. 2001).
- As noted, even under Rule 23(b)(2), courts generally demand that plaintiffs establish class "cohesion," a requirement that is often difficult to satisfy in medical monitoring cases.

Class Certification In Products Liability Cases

- Courts have increasingly denied certification of medical monitoring classes in the products liability context.
  - *In re St. Jude Med., Inc.*, 425 F.3d 1116 (8th Cir. 2005). Individuals implanted with recalled heart valves sought certification of a multi-state medical monitoring class. The Eighth Circuit reversed Rule 23(b)(2) certification of a class of patients who resided in states that recognize medical monitoring as an independent cause of action:
    - Each class member's need for medical monitoring "is highly individualized" because the need for additional monitoring over and above what all patients with implanted heart valves receive depends on "that patient's medical history, the condition of the patient's heart valves at the time of implantation, the patient's risk factors for heart valve complications, the patient's general health, the patient's personal choices, and other factors."
    - States that recognize medical monitoring "have different elements triggering culpability."
    - No independent medical society or public health agency recommended special monitoring.
- However, courts have continued to certify medical monitoring classes in the products liability context under certain circumstances. *E.g.*, *Donovan v. Philip Morris USA*, 268 F.R.D. 1 (D. Mass. 2010) (certifying medical monitoring class of Massachusetts residents who smoked Marlboros for at least 20 pack-years under Rules 23(b)(2) and (b)(3)).

Class Certification In Toxic Tort Cases

- *Perrine v. E.I. Du Pont Nemours & Co.*, 694 S.E.2d 815 (W. Va. 2010).
  - Plaintiffs who lived near a zinc smelter facility sued the current and former owners of the facility, alleging that it released hazardous substances such as arsenic, cadmium, and lead. Plaintiffs alleged that their exposure increased the risk that they would contract various diseases. The trial court certified a medical monitoring class, and a jury found in favor of the class. The trial court concluded that the 8,500 class members should be screened for various diseases every two years for a total of forty years and estimated that the cost of the program would be $130 million.
  - The West Virginia Supreme Court affirmed class certification. In a cursory analysis, the court stated that "each plaintiff would rely upon the same evidence to show" negligence and the owners' "knowledge of the dangers posed by the waste."

Class Certification In Toxic Tort Cases

- *Gates v. Rohm & Haas Co.*, 265 F.R.D. 208 (E.D. Pa. 2010).
  - Plaintiffs alleged that the defendant's chemicals manufacturing facility contaminated the surrounding air with vinyl chloride, resulting in an increased risk of brain cancer. Plaintiffs sought certification of a medical monitoring class of asymptomatic individuals who lived near the facility. The court denied certification under Rules 23(b)(2) and (b)(3):
    - Plaintiffs could not prove on a classwide basis that all class members were exposed to vinyl chloride at a level greater than normal background levels.
    - Plaintiffs could not show using common proof that all class members were at a significantly increased risk of contracting brain cancer.
    - Plaintiffs did not show that "serial MRIs" were reasonably necessary for all class members.

Summary Of Defenses To Class Certification In Medical Monitoring Cases

- In multi-state classes, there will likely be variances in whether states accept medical monitoring and, if they do, the elements that must be proved.
  - *See Zehel-Miller v. Astrazenaca Pharms.*, 223 F.R.D. 659 (M.D. Fla. 2004) (denying certification of nationwide medical monitoring class due to differences in state laws).
  - *But see In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. 279 (N.D. Ohio 2007) ("a court could manage the differences in medical monitoring law among the eight states … by holding separate trials for each state-wide subclass, or perhaps a combined trial for a few statewide subclasses").

Summary Of Defenses To Class Certification In Medical Monitoring Cases

- Determining whether a product is "hazardous" may depend on class members' individual risk factors. *E.g.*, *In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389 (S.D.N.Y. 2008) (denying certification of medical monitoring class of prescription drug users because "a pharmaceutical drug that currently enjoys FDA-approval" is unlikely to be "inherently hazardous to all persons who have taken it"); *Perez v. Metabolife Int'l, Inc.*, 218 F.R.D. 262, 264 (S.D. Fla. 2003) (denying certification of medical monitoring class of dietary supplement users because while supplement "may be dangerous to an individual who is simultaneously taking certain prescription drugs or to one who had already suffered heart palpitations," it may "be safe for individuals on no medication and with no history of medical disorders").
- As *Gates* shows, determining whether each class member was exposed to a toxin at greater than background levels may require individual inquiry.

Summary Of Defenses To Class Certification In Medical Monitoring Cases

- Proving the defendant's negligence often raises individual issues, particularly in the products realm. *E.g.*, *In re Welding Fume Prods. Liab. Litig.*, 245 F.R.D. 279, 310 (N.D. Ohio 2007) (denying certification of medical monitoring class of welders alleging exposure to manganese in welding fume because "whether the defendants were negligent … depends not simply on whether any given plaintiff suffered exposure, but on whether the warning supplied by the defendant sufficiently apprised the plaintiff of the risk of exposure"); *In re Baycol Prods. Liab. Litig.*, 218 F.R.D. 197, 208 (D. Minn. 2003) (denying certification of medical monitoring class of prescription drug users because "negligence claims depend on individual facts – whether there is a breach of duty or the foreseeability of harm will depend on what Defendants knew or should have known at the time Baycol was prescribed and whether Defendants acted reasonably based on the knowledge at the time").

Summary Of Defenses To Class Certification In Medical Monitoring Cases

- Whether class members' exposure to a toxin or use of a product significantly increased their risk of harm often necessitates individual inquiry. *E.g.*, *In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389 (S.D.N.Y. 2008) (denying certification of medical monitoring class of prescription drug users because whether use of drug resulted in increased risk of harm "depends on the dosage taken, how long patients took the drug, how much time has elapsed since patients discontinued using the drug," as well as "the unique medical history of each patient"); *Zehel-Miller v. Astrazenaca Pharms.*, 223 F.R.D. 659 (M.D. Fla. 2004) (denying certification of medical monitoring class of over-the-counter drug users because determining whether use of drug significantly increased risk of incurring injury required inquiry into class members' "risk factors").
- Individual inquiry will usually be necessary to determine whether medical monitoring is reasonably necessary for all class members. *E.g.*, *Barnes v. Am. Tobacco Co.*, 161 F.3d 127 (3d Cir. 1998) (denying certification of medical monitoring class of smokers because "to prove the program he requires, a plaintiff must present evidence about his individual smoking history"); *In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389 (S.D.N.Y. 2008) (denying certification of medical monitoring class of prescription drug users because need for monitoring "varies depending upon [class members'] unique medical history").

Summary Of Defenses To Class Certification In Medical Monitoring Cases

- Affirmative defenses "such as failure to follow directions, assumption of the risk, contributory negligence, and the statute of limitations" often require individual inquiry. *In re Am. Med. Sys., Inc.*, 75 F.3d 1069 (6th Cir. 1996) (decertifying medical monitoring class); *e.g.*, *In re Fosamax Prods. Liab. Litig.*, 248 F.R.D. 389 (S.D.N.Y. 2008) (denying certification of class of prescription drug users because "[c]omparative negligence and assumption of the risk require assessment of what each class member knew of the risks of [the injury allegedly caused by the drug]").

Questions

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