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### This Week's Feature

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## Money for Nothing: Recent Developments in Medical Monitoring

by Frank Leone and Jennifer H. Gans

Plaintiffs bringing product liability or toxic tort lawsuits must typically show that use of a defendant's product or exposure to a defendant's chemical caused them to suffer an injury. Some courts, however, have allowed plaintiffs without a present physical injury to recover costs for future "medical monitoring" for a latent disease related to an exposure to a defendant's product or chemical. These courts have found that medical monitoring is either a cause of action or a remedy for an existing tort.

In either case, once a plaintiff meets the necessary threshold showing, he or she must demonstrate that a medical monitoring program is an appropriate remedy. Defendants have had recent success challenging plaintiff proof of each element with expert testimony, including whether a medical monitoring program would indeed assist a plaintiff in discovering—and treating—a latent disease linked to his or her exposure.

In this article, we first provide a brief overview of medical monitoring issues. Then, we discuss recent state decisions from New York's and Maryland's highest courts, which came to opposing conclusions when confronted with plaintiffs without a present injury: New York rejected a separate medical monitoring cause of action while Maryland allowed medical monitoring recovery based on "significant risk" of injury. Finally, we review case law and new scientific developments that challenge plaintiffs' ability to demonstrate that medical monitoring is necessary and beneficial, which are key elements of a medical monitoring recovery.

### Overview of Medical Monitoring

Plaintiffs without present injuries have sought medical monitoring in both product liability and toxic tort cases. In a product liability action, plaintiffs may allege exposure to a hazardous substance such as asbestos, a consumer product such as cigarettes, or a pharmaceutical drug, and they claim that such exposure may give rise to a latent future injury. In toxic tort cases, plaintiffs typically allege that they have been exposed to chemicals in drinking water or toxic fumes that likewise may give rise to future injuries. Plaintiffs generally seek medical monitoring purporting to diagnose and to treat various diseases, such as cancer, allegedly triggered by exposure to defendants' products, under the theory that early detection will improve health outcomes.

The cases are often brought as class actions, in which the plaintiffs' counsel seek a large sum of money as present compensation for alleged future medical monitoring costs, or a medical monitoring fund to provide such compensation going forward, and attorney's fees, payable up front. *See, e.g., In re Aredia and Zometa Prod. Liab. Litig.*, No. 3:06-MD-1760, 2007 WL 3012972 (M.D. Tenn. Oct. 10, 2007) (denying motion to certify medical monitoring class in pharmaceutical case where individualized legal and factual issues preclude precise class definition and findings of typicality and adequacy). Thus, these cases are often seen as a vehicle for large recoveries that benefit plaintiffs' counsel, rather than the plaintiffs involved, who may never manifest a disease related to the exposure and in fact may be subjected to unnecessary testing that may lead to harmful interventions.

The viability of medical monitoring claims or damages are determined by state law, and there are a number of variations among the states and among federal courts attempting to interpret state law. Many states simply do not recognize a separate cause of action for medical monitoring. See, e.g., *Norwood v. Raytheon Co.*, 414 F. Supp. 2d 659 (W.D. Tex. 2006) (Texas does not recognize action for medical monitoring absent present physical injury). Federal courts interpreting federal common law have similarly rejected medical monitoring by following the lead of the U.S. Supreme Court's key decision in *Metro-N. Commuter R.R. Co. v. Buckley*, 521 U.S. 424, 443–44 (1997) (finding medical monitoring damages unavailable under Federal Employers' Liability Act). Other states allow plaintiffs to seek medical monitoring. See, e.g., *Bower v. Westinghouse Elec. Corp.*, 522 S.E.2d 424 (W. Va. 1999) (permitting medical monitoring claim, despite absence of any present manifest physical injury).

Whether the state recognizes medical monitoring as a separate cause of action or as a component of consequential damages, courts typically limit the recovery of such damages by requiring a plaintiff to show the following elements:

- Significant exposure through a defendant's negligence to a proven hazardous substance;
- A significantly increased risk of contracting a serious latent disease as a proximate result;
- A reasonable necessity for periodical medical examinations due to the increased risk;
- The existence of monitoring and testing procedures that make early detection possible and beneficial; and
- The existence of a medical monitoring regime that a reasonable physician would prescribe for a plaintiff that differs from the monitoring that would have been prescribed in the absence of that particular exposure.

See, e.g., *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 852 (3d Cir. 1990), *cert. denied*, 499 U.S. 961 (1991). See also *Hoyte v. Stauffer Chem. Co.*, No. 98-3024-CI-7, 2002 WL 31892830, at \*37 (Fla. Cir. Ct. Nov. 6, 2002) (listing elements).

### **Medical Monitoring as Damages Only When Personal Injury or Property Damage Alleged**

In *Caronia v. Philip Morris USA, Inc.*, --- N.E. 2d ---, 22 N.Y.3d 439 (N.Y. 2013), the New York Court of Appeals, in response to a certified question from the Second Circuit, held that New York law does not recognize an independent cause of action for medical monitoring. The plaintiffs were former and current Marlboro cigarette smokers who were over the age of 50 with smoking histories of at least 20 pack-years (1 pack per day, for 20 years), but they had not yet developed lung cancer. *Caronia*, 22 N.Y.3d at 445. The plaintiffs alleged that they had an increased risk of developing lung cancer and would benefit from Low Dose CT scanning of the chest that would allow for earlier detection and treatment of lung cancer.

The court rejected the independent medical monitoring claim because “a threat of future harm is insufficient to impose liability against a defendant in a tort context” and “[t]he requirement that a plaintiff sustain physical harm is a fundamental principle of our state's tort system.” *Id.* at 446. The court repeatedly stated, however, that allegations of “present physical injury or damage to property” would provide a basis for recovery of medical monitoring as consequential damages. See, e.g., *id.* at 452.

The New York court, thus, declined to follow the Massachusetts Supreme Court ruling in *Donovan v. Philip Morris USA, Inc.*, 914 N.E. 2d 891 (Mass. 2009), which permitted a medical monitoring cause of action brought by plaintiffs with similarly extensive smoking histories. *Caronia*, 22 N.Y.3d at 450–52. In *Donovan*, the Massachusetts court answered a certified question from the local federal district court and allowed plaintiffs who alleged “exposure to a hazardous substance that produced, at least, subcellular changes that substantially increased the risk of serious disease, illness, or injury” to seek a medical monitoring fund, even in the absence of outward manifestations of physical harm. *Donovan*, 914 N.E.2d at 902.

The New York court, in contrast, concluded that recognizing a new claim for medical monitoring without “physical injury” would permit “tens of millions” of potential plaintiffs to recover monitoring costs, flooding the courtroom, while depleting the purported tortfeasor's resources. *Caronia*, 22 N.Y.3d at 451 (quoting *Metro-North Commuter RR v. Buckley*, 521 U.S. 243, 442–44 (1997)). The court concluded that “it is speculative, at best, whether asymptomatic plaintiffs will ever contract a disease; allowing them to recover medical monitoring costs without first establishing physical injury would lead to the inequitable diversion of money away from those who have actually sustained an injury as a result of the exposure.” *Caronia*, 22 N.Y.3d at 451. The court recognized that “from a practical standpoint,” there is no context for construction and administration of a medical monitoring program and deferred to the legislature to determine the appropriateness of such a cause of action. *Id.* at 451.

While there is precedent for the *Caronia* court's decision to allow medical monitoring as a potential remedy for current personal injuries, the court did not provide support for recognizing the unobvious nexus between a property damage claim, such as trespass and nuisance, and medical monitoring. Following the New York Court of Appeals holding in *Caronia*, the New York Appellate Division recently concluded that assertion of a personal injury or a property damage claim was a sufficient basis for recovering medical monitoring damages. *Ivory v. International Business Machines, Corp.*, --- N.Y.S. 2d ---, 2014 WL 641883 (N.Y. App. Div. Jan. 15, 2014).

In *Ivory*, eight test plaintiff-residents alleged that a neighboring industrial facility released chlorinated solvents that contaminated their soil, groundwater, and air. The plaintiffs brought negligence, trespass, nuisance, and strict liability claims for personal injury and property damage, and the decision analyzed each claim by each plaintiff. For plaintiffs demanding the medical monitoring damages, the court used *Caronia* to guide its rulings. The court allowed a claim for medical monitoring damages for one plaintiff who alleged an actual injury related to his exposure (kidney cancer) but appropriately rejected medical monitoring claims from other plaintiffs who only alleged the potential of latent injuries. *Id.* at 8.

Then, the court had to analyze medical monitoring claims under *Caronia*, applying it to those plaintiffs with trespass claims alleging only property damage. *Id.* at 9. By focusing on property damage claims as the basis for medical monitoring, the *Ivory* court had to ignore *Caronia*'s requirement of a present injury, creating a large loophole for future plaintiffs to exploit. Although the court applied the language of the *Caronia* court, it made no attempt to explain why a claim alleging injury to property should give rise to medical monitoring, which by definition addresses injury to a person.

### **Medical Monitoring as a Remedy with No Physical Injury but Requiring Significant Risk**

The Maryland Court of Appeals recently concluded that Maryland did not recognize an independent cause of action for medical monitoring but did recognize that medical monitoring costs are a compensable element of damages under traditional tort theories. *Exxon Mobil Corp. v. Albright*, 433 Md. 303, 389, 71 A.3d 30, 82, *on reconsideration in part*, 433 Md. 502, 71 A.3d 150 (concerning certain plaintiffs' non-medical-monitoring claims), *cert. denied*, 134 S. Ct. 648 (U.S. 2013). Property owners sued the owner of a service station whose leaking underground tank released gasoline to the groundwater. Despite the lack of allegations of any current physical injury, the jury awarded nearly \$500 million in compensatory damages for property damage, emotional distress, and medical monitoring, and over \$1 billion in punitive damages, most of which the highest court overturned.

As to medical monitoring, the *Albright* court held for the first time that Maryland law recognizes "that 'exposure itself, and the concomitant need for medical testing' is the compensable injury for which recovery of damages for medical monitoring is permitted, because such exposure constitutes an 'invasion of a legally protected interest.'" 71 A.3d at 75–76 (citations omitted). The court noted that problems may arise in limiting the potentially expansive class of plaintiffs, but it concluded that "permitting only proven necessary medical costs helps prevent the danger of awarding medical monitoring for speculative injuries, a risk inherent in the area of other common law torts, such as emotional distress." *Id.* at 76. The court then cited with approval opinions that recognized medical monitoring only as a remedy and stated that "we hold that a remedy for medical monitoring is a compensable element of damage under traditional tort theories of recovery." *Id.*

The Maryland court set out standards for recovery of medical monitoring costs, including the requirements that (1) plaintiffs must show that the necessity for medical monitoring is reasonably certain, (2) exposure to toxic substances resulted in a significantly increased risk of contracting a latent disease, and (3) the disease is a direct and proximate result of a defendant's tortious conduct. *Id.* at 77–79. Plaintiffs must also show that this increased risk makes periodic diagnostic medical examinations reasonably necessary and that monitoring procedures exist that make early detection and treatment of the latent disease possible and beneficial. *Id.* at 81–82. Plaintiffs, however, need not demonstrate current physical injury. *Id.* at 80.

Applying those standards to the *Albright* case, the court held that the plaintiffs could not recover medical monitoring damages because some plaintiffs had no evidence of contamination in their water and thus could not show significant exposure to a proven hazardous substance. *Id.* at 82. The plaintiffs with contamination below regulatory action levels could not show a risk of latent disease higher than the average person, much less a significantly increased risk of developing disease. *Id.* at 83. For the remaining plaintiffs, whose wells tested above relevant state action levels for benzene and methyl tertiary butyl ether (MTBE), the court found that each plaintiff was required to offer expert testimony indicating a particularized, significantly increased risk of developing a disease compared to the general public. *Id.* at 84. The plaintiffs' experts testified only that any exposure to benzene or MTBE posed an additional risk of cancer, and the court properly found that such generalized testimony was insufficient. Thus, while the court permitted medical monitoring

damages, not one plaintiff in this case met the standards for recovery. The court reached a similar conclusion in the companion case of *Exxon Mobil Corp. v. Ford*, 433 Md. 426, 71 A.3d 105 (2013).

### **No Recovery if No Benefit from Medical Monitoring**

Even if a court rejects medical monitoring as a separate claim, plaintiffs may seek the establishment of a medical monitoring fund as a remedy. In either case, among the elements in a standard medical monitoring action that plaintiffs must prove are the existence of a medical test that makes early detection of a disease possible, a reasonably necessary monitoring regime according to contemporary scientific principles, and a method of early detection that will result in treatment that is beneficial to a plaintiff. *Hoyte v. Stauffer Chem. Co.*, No. 98-3024-CI-7, 2002 WL 31892830, at \*37 (Fla. Cir. Ct. Nov. 6, 2002). To resolve these issues, courts may refer to reliable sources of scientific information, such as the United States Preventive Services Task Force (USPSTF), to understand better whether a medical monitoring program would be useful to individual plaintiffs in these types of cases.

In *Hoyte*, the defendant's medical monitoring expert and the court looked to published medical guidance about the necessity and the benefits of medical monitoring. The court rejected the plaintiffs' proposed medical monitoring class when it found that diagnostic testing was not necessary and beneficial for each individual plaintiff. This case featured former employees of a phosphorus plant who brought a class action seeking damages for personal injury and medical monitoring arising from exposure to a variety of substances. The court heard testimony from each side, including medical monitoring expert witnesses, and ultimately refused to certify the class because individual issues predominated, class representatives were not adequate or typical, the class was overbroad and not ascertainable, and the class lacked cohesiveness.

As to the medical monitoring claim, the court accepted testimony from the defendant's expert that the current medical standard of care did not (and does not) favor across-the-board testing. The standard of care, instead, requires examinations targeted to specific medical conditions that depend on an individual's risk factors. *Id.* at 29 (citing the USPSTF 1996 Guide to Preventive Services). The court further cited defense expert testimony that medical monitoring must be beneficial to the individual, and to benefit the individual

(1) it has to be for a condition that will have a significant impact on quality of life or longevity; (2) the condition must have an asymptomatic period during which detection and treatment can significantly reduce morbidity or mortality; (3) effective tests and treatments must be available that are acceptable to the individual; and (4) treatment in the asymptomatic stage must result in improved clinical outcome compared with treatment after symptoms appear.

*Id.* at 31.

Medical monitoring was thus inappropriate because, even assuming that exposure, dose, and increased risk of latent disease were uniform and significant for all plaintiffs, (1) the plaintiffs' expert failed to show that there were treatments that would significantly reduce the morbidity or mortality of class members if they received them in the asymptomatic period; (2) the recommended tests were not effective and might lead to a cascade of additional, more invasive tests for certain workers; and (3) medical monitoring would not, for all members of the proposed class, improve the clinical outcome of the relevant latent diseases. *Id.*

Over time, scientific concerns have grown about unnecessary and potentially harmful diagnostic testing in the absence of symptoms, and courts such as the one in *Hoyte* often lean on the recommendations of the USPSTF, which is an independent panel of private sector experts in prevention and primary care sponsored by the U.S. Agency for Healthcare Research and Quality. As stated in its most recent Guide to Clinical Preventive Services (2012) (guide), the USPSTF's charge is "to conduct rigorous reviews of scientific evidence to create evidence-based recommendations that should be provided in the primary care setting." *Id.* at 2, available at <http://www.ahrq.gov/professionals/clinicians-providers/guidelines-recommendations/guide/abstract.html>. The guide contains specific recommendations evaluating the benefits and risks of specific types of monitoring for specific diseases. The USPSTF acknowledges that the "suggestion that it is not beneficial to provide all the services available for prevention was nearly a heretical concept in US medical practice when the first USPSTF started its work." *Id.* The USPSTF recommendations are now widely accepted, and the medical community recognizes that testing of people with no signs or symptoms of a specific disease may result in early identification of disease and improvement in health, but it may also include adverse effects due to the test itself or inaccurate test results that may lead to additional testing, additional risks, or unneeded invasive treatment. *Id.* at 96.

The concept that medical testing of asymptomatic individuals may do more harm than good is illustrated in the current controversy concerning mammography screening for breast cancer. In some cases, a mammogram may detect a tumor early and lead to appropriate treatment. But a recent study involving 90,000 women observed for 25 years found that annual mammograms did not reduce breast cancer-specific mortality for women. A. Miller et al., *Twenty-Five Year Follow-Up for Breast Cancer Incidence and Mortality of the Canadian National Breast Screening Study: Randomized Screening Trial*, *BMJ* 2014; 348: g366. doi: <http://dx.doi.org/10.1136/bmj.g366> (published Feb. 11, 2014). This and other studies have found that breast cancer cases may be “over diagnosed”—meaning screening detection of tumors that would never have led to clinical symptoms. See, e.g., A. Bleyer and H.G. Welch, *Effects of Three Decades of Screening Mammography on Breast-Cancer Incidence*, *N. Engl. J. Med.* 2012; 367:1998–2005. Such over diagnosis can lead to unnecessary surgery, radiation, hormone therapy, and chemotherapy with their associated health risks. For these reasons, the USPSTF has recommended breast cancer screening every two years, but only for women between the ages of 50 and 74. USPSTF Guide, *supra*, at 15.

Thus, defendants should retain experts well versed in the latest approaches to diagnostic testing and medical monitoring to evaluate plaintiffs’ claims regarding whether medical monitoring is appropriate for an individual exposed to a hazardous substance. This expert should take into account the particulars of each individual’s situation, such as the nature of the exposure, dose, toxicology of substance, reliability of the monitoring tests in early detection, whether early detection will assist treatment, whether treatment will reduce morbidity and mortality, and the risks of such monitoring. If plaintiffs, through their expert’s testimony, cannot make a sufficient showing that monitoring is necessary and beneficial, a court should reject their claims. *Hoyte v. Stauffer Chem.*, No. 98-3024-CI-7, 2002 WL 31892830, at \*37 (Fla. Cir. Ct. Nov. 6, 2002). See also *Allgood v. Gen. Motors Corp.*, No. 102CV 1077 DFHTAB, 2006 WL 2669337, at \*31 (S.D. Ind. Sept. 18, 2006) (excluding plaintiff’s medical monitoring expert on *Daubert* grounds, among other things, for failure to consider USPSTF and similar guidelines and granting summary judgment on medical monitoring claim).

## Conclusion

Plaintiffs in toxic tort and products liability cases continue to seek medical monitoring in various forms, but courts have become more cautious about allowing such recoveries in cases with no current injury and little scientific support for the alleged potential for latent injuries. Defendants would be wise to retain qualified medical monitoring experts and stay up to date with scientific research, similar to that performed by entities such as the USPSTF, to challenge plaintiffs’ assertions of medical monitoring needs.



**Frank Leone**, a partner of **Hollingsworth LLP** in the firm’s Washington, D.C., office, has a broad litigation practice that includes litigating parallel tort actions seeking personal injury, property damage and/medical monitoring damages. He has special expertise in environmental litigation and counseling, including issues relating to Superfund, natural resource damages, hazardous waste, hazard communication, groundwater, surface water, wetlands, clean air, state environmental laws, and environmental auditing. His experience includes representing a large manufacturer in multiple state CERCLA enforcement actions and related personal injury/property damage cases, litigating a Consumer Product Safety Act case, and defending asbestos personal injury and property damage claims. Mr. Leone is a member of the DRI Toxic Torts and Environmental Law Committee.



**Jennifer H. Gans**, an associate practicing in the **Hollingsworth LLP** Washington, D.C., office, specializes in product liability and toxic tort cases, commercial and private banking matters, and environmental litigation. In her product liability work, she has defended various pharmaceutical and medical device manufacturers in state and federal courts across the country. In environmental litigation and counseling, she has experience in the defense of private and public nuisance, trespass, RCRA, CERCLA, and related statutory and common law claims. Additionally, her work includes the successful litigation at the state and federal levels of commercial transactions, bank collections, and disputes governed by the Uniform Commercial Code for financial institutions. Ms. Gans also belongs to the DRI Toxic Torts and Environmental Law Committee.

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