

Massachusetts Recognizes a Claim for Medical Monitoring Absent Symptoms of Physical Harm

In a recent decision of importance to the life sciences industry, the Massachusetts Supreme Judicial Court ruled that smokers who sued a cigarette manufacturer “for medical monitoring, based on subclinical effects of exposure to cigarette smoke and increased risk of lung cancer, state a cognizable claim.” *Donovan v. Philip Morris USA, Inc.*, 2009 WL 3321445, Mass., Oct. 19, 2009 (SJC-10409). The ruling was issued in response to a question that had been certified by the United States District Court for the District of Massachusetts in the context of a summary judgment motion by Philip Morris seeking dismissal of a putative class action.

The decision is noteworthy because it rejected the manufacturer’s argument that “proof of physical harm manifested by objective symptomology” was a required element of plaintiffs’ claim. Insofar as the Court permitted a medical monitoring claim to proceed absent symptoms of physical harm, the opinion expands the scope of tort liability. However, the decision hinges on the allegation that plaintiffs had sustained “objectively observable and identifiable damage to the tissues and structures of their lungs.” The Court expressly declined to rule on whether subcellular effects that could not be objectively detected would be cognizable: “We leave for another day consideration of cases that involve exposure to levels of chemicals or radiation known to cause cancer, for which immediate medical monitoring may be medically necessary although no symptoms or subclinical changes have occurred.”

The opinion uses sweeping language to advance the proposition that traditional tort law doctrines need to be liberalized to address potential latent injuries arising from exposure to toxic substances:

“Our tort law developed in the late Nineteenth and early Twentieth centuries, when the vast majority of tortious injuries were caused by blunt trauma and mechanical forces. We must adapt to the growing recognition that exposure to toxic substances and radiation may cause substantial injury which should be compensable even if the full effects are not immediately apparent.”

On the other hand, the Court specified a list of seven elements that plaintiffs must establish to prevail on a medical monitoring claim:

“(1) The defendant’s negligence (2) caused (3) the 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 (4) for which an effective medical test for reliable early detection exists, (5) and early detection, combined with prompt and effective treatment, will significantly decrease the risk of death or the severity of the disease, illness or injury, and (6) such diagnostic medical examinations are reasonably (and periodically) necessary, conformably with the standard of care, and (7) the present value of the reasonable cost of such tests and care, as of the date of the filing of the complaint.”

Many of these elements may be fertile ground to resist a medical monitoring claim. Thus, element (1) requires plaintiff to prove negligence; strict liability would be insufficient. Element (3) reiterates plaintiff's obligation to prove the existence of subcellular changes. Allegations of subcellular effects that are undetectable by medical technology should be insufficient. Element (5) requires proof that early detection will result in a better outcome, a proposition that may be difficult to establish because cancer screening programs are often of dubious value.

Also noteworthy, the opinion did not address class certification. Many courts have denied certification of putative medical monitoring classes, holding that individual issues predominate. *E.g.*, *In Re Prempro Products Liability Litigation*, 230 F.R.D. 555 (E.D. Ark. 2005); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61 (S.D.N.Y. 2002). Absent a prospect of classwide relief, plaintiffs often find medical monitoring claims not worth pursuing.

While *Donovan* concerns cigarette smoke — an inherently toxic exposure — and may be distinguished from cases involving a medication or medical device that is prescribed by an expert physician to treat a patient's medical condition, *e.g.*, *Sinclair v. Merck & Co., Inc.*, 195 N.J. 51, 61-65 (N.J. 2008), the opinion potentially expands the scope of tort liability by relaxing proof of injury required for a medical monitoring claim.

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