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Kathleen DONOVAN & another [FN1] vs. PHILIP MORRIS USA, INC.

SJC-10409

June 9, 2009. - October 19, 2009.

Tobacco Smoke. Negligence, Design, Sale of cigarettes. Damages, Tort. Evidence, Medical expenses. Limitations, Statute of.

CERTIFICATION of questions of law to the Supreme Judicial Court by the United States District Court for the District of Massachusetts.

Steven J. Phillips, of New York (*Christopher Weld, Jr., Edward Foye, & David C. Strouss* with him) for the plaintiffs.

Sheila L. Birnbaum, of New York (*Gary R. Long*, of Missouri, & *Michael K. Murray* with her) for the defendant.

Patricia M. Connally & Stacie B. Lieberman, of the District of Columbia, & *Harry P. Cohen*, for Coalition for Litigation Justice, Inc., & others, amici curiae, submitted a brief.

Present: Marshall, C.J., Ireland, Spina, Cowin, Cordy, Botsford, & Gants, JJ.

SPINA, J.

The United States District Court for the District of Massachusetts, in the context of a motion to dismiss and a motion for summary judgment filed by Philip Morris USA, Inc. (Philip Morris), has certified the following questions to this court, pursuant to S.J.C. Rule 1:03, as appearing in 382 Mass. 700 (1981) [FN2]:

"1. Does the plaintiffs' suit for medical monitoring, based on subclinical effects of exposure to cigarette smoke and increased risk of lung cancer, state a cognizable claim and/or permit a remedy under Massachusetts state law? [FN3]"

"2. If the plaintiffs have successfully stated a claim or claims, has the statute of limitations governing those claims expired?"

The certified questions highlight two problem areas that courts have struggled with when applying general principles of negligence to cases involving toxic torts. We answer the first question, "Yes," to the extent the plaintiffs allege a cause of action in tort for future medical expenses, and we answer the second question, "No." [FN4]

I

The judge submitted a statement of facts and exhibits accompanying the certification order. [FN5] We recite the facts in some detail.

This proposed class action was filed on December 14, 2006. The third amended complaint asserts claims on behalf of a putative class of Massachusetts residents who are fifty years of age or older, have cigarette

smoking histories of twenty pack-years [FN6] or more using Marlboro cigarettes, currently smoke or quit smoking Marlboro cigarettes within one year of the filing of the initial complaint in this action, are not diagnosed with lung cancer or under investigation by a physician for suspected lung cancer, and have smoked Marlboro cigarettes within the Commonwealth.

The plaintiffs allege that Philip Morris wrongfully designed, marketed, and sold Marlboro cigarettes. They assert claims for breach of implied warranty based on design defect, negligent design and testing, and violations of G.L. c. 93A, §§ 2, 9. The plaintiffs do not seek money damages or exemplary damages. They seek to compel Philip Morris to provide them with a court-supervised program of medical surveillance for early detection of lung cancer utilizing a technique known as low-dose computed tomography (LDCT) scans of the chest.

Pursuant to scheduling orders, the parties have conducted and completed pretrial disclosure limited to the question of class certification under Fed.R.Civ.P. 23. There are pending before the District Court three motions that have been fully briefed. The first, filed by Philip Morris, seeks dismissal of this action pursuant to Fed.R.Civ.P. 12(c), arguing that Massachusetts law requires a plaintiff to plead and prove a present physical injury with objective symptoms to recover in tort. On this basis, Philip Morris argues that the plaintiffs' medical monitoring claims are not cognizable under Massachusetts law. The second motion, also filed by Philip Morris, seeks summary judgment pursuant to Fed.R.Civ.P. 56, arguing that the plaintiffs' claims, if cognizable, are untimely because each plaintiff knew that she was at increased risk of lung cancer at least four years prior to the commencement of this action. Pursuant to Rule 56.1 of the Rules of the District Court, Philip Morris filed a statement of undisputed material facts. Pursuant to the same rule, the plaintiffs filed a counterstatement. The third pending motion, filed by the plaintiffs, seeks class certification pursuant to Fed.R.Civ.P. 23. After considering these arguments, pleadings, and exhibits filed by the parties, the judge determined that there exist untested questions of State law that should be certified to the Supreme Judicial Court of Massachusetts.

The plaintiffs proceed on the premise that Marlboro cigarettes are defectively designed. They contend that it was and continues to be wrongful conduct by Philip Morris to design, manufacture, market, and sell its Marlboro cigarettes because they deliver an excessive and unreasonably dangerous quantity of carcinogens when smoked by humans. The plaintiffs further contend that, at all relevant times, Philip Morris had available to it commercially acceptable and feasible alternative designs that would have drastically reduced the cancer-causing content of Marlboro cigarettes and, thus, the risk of developing lung cancer as a result of the prolonged and heavy use of Marlboro cigarettes. Philip Morris, it is alleged, concealed the specific product defect here at issue and kept from the public and the plaintiffs the fact that its Marlboro cigarettes contained excessive, improper, and unnecessarily high levels of carcinogens.

The plaintiffs allege that cigarette smoke from Marlboro cigarettes has caused them damage and injury to the tissues and structures of their lungs. The pulmonary tissue and structures that are alleged damaged include bronchial passageways, the cilia, alveoli, and changes in cell structure throughout the lung. In particular, the plaintiffs' experts aver that the particles and gases inhaled as cigarette smoke cause an inflammatory reaction in the bronchi and bronchioles leading to an accumulation of inflammatory cells and secretions, impairments of mucociliary clearance, and hyperactivity of the smooth muscle causing bronchoconstriction. Further, they state that cigarette smoke shifts the balance of cellular protein synthesis and degradation in the lung, resulting in the over-distention and destruction of functional airspaces. Finally, the inhaled carcinogens allegedly damage the genes of the airway cells and impair the repair mechanisms that protect against genetic damage, resulting in increased carcinogenic genetic mutations and loss of protective repair processes.

The plaintiffs claim that cigarette smoke from Marlboro cigarettes continues to cause damage with each puff, inflicting new and additional bodily harm and substantially contributing to the risk of developing lung cancer. They further claim that the cumulative impact of smoking Marlboro cigarettes increases the alleged injury to each smoker in a dose response fashion, based on both the duration and intensity of exposure. The plaintiffs do not allege, however, any manifest smoking-related disease resulting from their use of Marlboro cigarettes at the present time. Rather, they claim that they are at a high and significantly increased risk of developing lung cancer as a consequence of their prolonged and continuing use of Marlboro cigarettes (twenty pack-years or more) and their age (fifty years old or more).

The plaintiffs contend that the Marlboro cigarettes smoked by each plaintiff within three or four years [FN7] prior to their filing of this lawsuit, and continuing up to the present moment, is a substantial factor and proximate cause of the bodily harm and increased risk of lung cancer alleged. The plaintiffs allege that Philip Morris's conduct in selling its defective and improperly designed Marlboro cigarettes during the three

or four years prior to the filing of this lawsuit and continuing to the present constitutes independent wrongful acts that have proximately caused the harm for which the plaintiffs seek redress.

The sole remedy that the plaintiffs seek in this action is a medical surveillance program that utilizes a specific technology, LDCT screening, which will advise them, at an early stage, whether they have developed lung cancer. They allege that the LDCT lung cancer screening program they seek is based on a newly developed technology that has only become accepted and available in the medical community as an effective screen for lung cancer within the past three years.

Prior to the time that LDCT screening was developed and approbated, the plaintiffs claim that there existed no accepted or efficacious method of lung cancer screening or surveillance. Accordingly, the plaintiffs allege that in past years individuals at high risk of developing lung cancer did not have any meaningful screening or surveillance options available to them, even if they were aware of that risk. For this reason, the plaintiffs claim, they and their counsel could not have brought a medical surveillance action against tobacco companies. Prior to the medical acceptance and adoption of LDCT screening for lung cancer, such a suit would not have been consistent with the plaintiffs' obligations under Fed.R.Civ.P. 11 or equivalent Massachusetts rules that require that plaintiffs truthfully allege all elements of the claim being asserted.

The plaintiffs assert that lung cancer is the leading cause of cancer death in the United States and in the Commonwealth. On a nationwide basis, more than 160,000 Americans die annually from this disease. The plaintiffs state that over eighty per cent of these lung cancer deaths are caused by cigarette smoke. They claim that lung cancer when diagnosed in its early stage is usually curable. By contrast, the plaintiffs claim that when lung cancer has progressed, the prospect for successful treatment and cure are reduced. As a result, the plaintiffs allege that prospects for cure and survival are highly dependent upon the ability to diagnose this disease as early as possible. The plaintiffs allege that LDCT can identify and lead to the early diagnosis of lung cancers that heretofore would have remained undiagnosed until the cancer had already progressed to an advanced stage. As a consequence, the prospects for cure and survival of those individuals who obtain LDCT screening are dramatically improved. The plaintiffs believe that they and the proposed class would benefit from LDCT surveillance because it would provide them with an effective means of discovering the existence of tumors at a much earlier stage than is otherwise possible, and thus would provide them with an earlier diagnosis of cancerous growths and earlier treatment of such tumors.

The remedy that the plaintiffs seek is a program and not a procedure. The plaintiffs state that this program requires the hiring of personnel, the establishment of notification and informed consent procedures, the purchase of equipment, quality control practices, the rendering of medical advice, record-keeping and follow-up policies, as well as other steps that can only be achieved through an injunction and ongoing court supervision. The plaintiffs allege that neither they, nor the proposed class, would be provided with meaningful relief solely through an award of monetary damages.

Neither plaintiff was aware or could, with exercise of reasonable diligence, have been aware of the existence of an efficacious form of lung cancer screening until immediately prior to the commencement of this lawsuit.

II

With respect to the first certified question the plaintiffs allege and argue that they seek not a remedy, but a court-ordered, court-supervised *program* of medical surveillance for early detection of lung cancer utilizing LDCT scans. They further contend that without this program they have no adequate remedy at law, and that injunctive relief establishing such a program is necessary. No class has been certified, and the first certified question asks only if the complaint states a cognizable claim under Massachusetts law. We therefore consider the question in the context of a dispute between two individuals, and leave the idea of a "program" to consideration of the question of class certification. See *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 977- 978 (Utah 1993), quoting *Friends For All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 825 (D.C.Cir.1984) (when deciding "whether tort law should encompass a cause of action for diagnostic examinations without proof of actual injury, it is useful to step back from the complex, multi-party setting of the present case and hypothesize a simple, everyday accident involving two individuals"). We address only the named plaintiffs and their individual claims. We conclude that the plaintiffs have stated a claim under Massachusetts law for future medical expenses that may be satisfied by an adequate remedy at law.

The plaintiffs argue that they have sustained a present injury in the form of objectively observable and identifiable damage to the tissues and structures of their lungs resulting in a substantially increased risk of

cancer, and that this injury was caused by Philip Morris's negligence in the design and manufacture of Marlboro cigarettes. They further argue that, under traditional tort principles, this injury entitles them to present and future medical expenses, which they have styled "medical monitoring," to ascertain whether they have in fact contracted cancer. Philip Morris contends that the plaintiffs have not established the essential element of a manifest physical injury, that is, physical harm manifested by objective symptomology.

The elements of a claim of negligence, generally, are (1) negligence, [FN8] that is, "the failure of a responsible person, either by omission or by action, to exercise that degree of care, vigilance and forethought which, in the discharge of the duty then resting on him, the person of ordinary caution and prudence ought to exercise under the particular circumstances," *Altman v. Aronson*, 231 Mass. 588, 591 (1919); (2) the causal connection between the defendant's negligence and the plaintiff's injury or damage, see *Cannon v. Sears, Roebuck & Co.*, 374 Mass. 739, 742 (1978); *Baggs v. Hirschfield*, 293 Mass. 1, 3 (1935); *Sullivan v. Old Colony St. Ry.*, 200 Mass. 303, 307-308 (1908); see also W.L. Prosser & W.P. Keeton, Torts § 30, at 165 & n. 5 (5th ed.1984), citing *Cannon v. Sears, Roebuck & Co.*, *supra* ("Actual loss or damage resulting to the interests of another" is required); and (3) damages. See *Jupin v. Kask*, 447 Mass. 141, 146 (2006). " 'Damages' is the word which expresses in dollars and cents the injury sustained by a plaintiff." *Turcotte v. DeWitt*, 333 Mass. 389, 392 (1955). Injury and damages are the focus of the parties' briefs.

At trial the plaintiffs will have the burden of proving each element of a negligence claim by a preponderance of the evidence. See *Quinby v. Boston & Me. R.R.*, 318 Mass. 438, 443 (1945) (negligence); *Zeuski v. Jenny Mfg. Co.*, 363 Mass. 324, 328-329 (1973) (causation); *Pullen v. Boston Elevated Ry.*, 208 Mass. 356, 357 (1911) (damages); *Soebel v. Boston Elevated Ry.*, 197 Mass. 46, 50 (1907) (same).

"Negligence in the abstract does not support a cause of action." *International Mobiles Corp. v. Corroon & Black/Fairfield & Ellis, Inc.*, 29 Mass.App.Ct. 215, 217 (1990). "A negligence action may not be maintained unless one has suffered injury or damage." *Cannon v. Sears, Roebuck & Co.*, *supra*, citing *Sullivan v. Old Colony St. Ry.*, *supra* at 308. Under our law of negligence injury and damages are integrally related: there can be no invasion of the rights of another unless legal damage is caused, and for that reason nominal damages cannot be recovered. *Sullivan v. Old Colony St. Ry.*, *supra*. [FN9]

Generally, the measure of damages in negligence for personal injury is fair compensation for the resulting injuries, which includes pain and suffering; reasonable expenses incurred for medical care and nursing in the treatment and cure of the injury; diminution in earning capacity; and pain and suffering and such medical expenses and diminution in earning capacity as are shown to be reasonably probable to continue in the future. *Rodgers v. Boynton*, 315 Mass. 279, 280 (1943).

With respect to future damages, "[a] plaintiff is entitled to compensation for all damages that reasonably are to be expected to follow, but not to those that possibly may follow, the injury which he has suffered. He is not restricted to compensation for suffering and expense which by a fair preponderance of the evidence he has proved will inevitably follow. He is entitled to compensation for suffering and expense which by a fair preponderance of the evidence he has satisfied the jury reasonably are to be expected to follow, so far as human knowledge can foretell. There are many cases where the suffering and expense following an injury cannot be foretold with exactness. The fact that suffering and expense cannot always be foretold with exactness is a fact which the jury have to deal with in determining what suffering and expense reasonably will follow as distinguished from what possibly may follow." *Pullen v. Boston Elevated Ry.*, 208 Mass. 356, 357-358 (1911). See *Menard v. Collins*, 298 Mass. 40 (1937); *Anderson v. W.R. Grace & Co.*, 628 F.Supp. 1219, 1230-1231 (D.Mass.1986). Future damages must be reduced to an amount as of the date of the filing of the complaint. [FN10] See *Griffin v. General Motors Corp.*, 380 Mass. 362, 367 (1980).

The plaintiffs are not suing for pain and suffering or diminution of earning capacity. They have not contracted cancer, and they do not allege they are likely to contract cancer in the immediate future as a result of the alleged negligence of Philip Morris. See *Pullen v. Boston Elev. Ry.*, *supra*. The plaintiffs do not ask us to extend the holding in *Matsuyama v. Birnbaum*, 452 Mass. 1, 16-20 (2008), which recognized loss of chance as a theory of injury in a wrongful death action based on medical malpractice, or recognize increased risk of cancer as a basis for rewarding the full range of tort damages. It is important to realize that the plaintiffs are suing only for medical expenses reasonably to be incurred because of the alleged negligence of Philip Morris. In its simplest and most straightforward form, the plaintiffs' complaint seeks only present and future medical expenses for diagnostic LDCT scans to determine the onset of cancer at the earliest practicable time for the purpose of maximizing the effective treatment of the disease. These damages are indeed the only presently provable damages for the impact these plaintiffs have suffered as a

result of the alleged negligence of Philip Morris.

Philip Morris contends that our jurisprudence requires proof of physical harm manifested by objective symptomology as a necessary part of damages. We disagree. This requirement applies to claims of negligent infliction of emotional distress, as a safeguard against false claims. See *Payton v. Abbott Labs*, 386 Mass. 540, 552-555 (1982). The plaintiffs do not seek damages for emotional distress. They are seeking only reasonable medical expenses for diagnostic tests.

There can be no doubt that an infant negligently and violently shaken by someone may recover expenses for diagnostic tests determined to be medically necessary under the standard of care to ascertain whether the child suffered a brain injury, even if those test results are negative. Similarly, a pedestrian negligently struck by a (non "no-fault") motorist may recover expenses for diagnostic tests determined to be medically necessary under the standard of care to ascertain the existence of internal injuries absent any external injuries, even if those tests produce negative results. In those instances outward manifestations of physical harm would not be required. Cf. *Metro-North Commuter R.R. v. Buckley*, 521 U.S. 424 (1997); *Friends For All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 825 (D.C.Cir.1984). In the instant case the plaintiffs have produced sufficient proof of "impact," *Payton v. Abbott Labs*, *supra* at 553, to safeguard against false claims: they have proffered evidence of physiological changes caused by smoking, and they have proffered expert medical testimony that, because of these physiological changes, they are at a substantially greater risk of cancer due to the negligence of Philip Morris.

Modern living has exposed people to a variety of toxic substances. Illness and disease from exposure to these substances are often latent, not manifesting themselves for years or even decades after the exposure. Some people so exposed may never develop an illness or disease, but some will. Subcellular or other physiological changes may occur which, in themselves, are not symptoms of any illness or disease, but are warning signs to a trained physician that the patient has developed a condition that indicates a substantial increase in risk of contracting a serious illness or disease and thus the patient will require periodic monitoring. Not all cases will involve physiological change manifesting a known illness, but such cases should be allowed to proceed when a plaintiff's reasonable medical expenses have increased (or are likely to increase, in the exercise of due care) as a result of these physiological changes. 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. Here, the physiological changes with the attendant substantial increase in risk of cancer, and the medical necessity of monitoring with its attendant cost, may adequately establish the elements of injury and damages.

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. See *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 977 (Utah 1993). When competent medical testimony establishes that medical monitoring is necessary to detect the potential onset of a serious illness or disease due to physiological changes indicating a substantial increase in risk of harm from exposure to a known hazardous substance, the element of injury and damage will have been satisfied and the cost of that monitoring is recoverable in tort. No particular level or quantification of increase in risk of harm is necessary, so long as it is substantial and so long as there has been at least a corresponding subcellular change. *Id.* at 979-980. This should address any concern over false claims, see *Payton v. Abbott Labs*, *supra* at 552-555, yet permit a genuinely injured person to recover legitimate expenses without having to overcome insurmountable problems of proof in this difficult and complex area. In this respect, medical expenses are recoverable not only for direct treatment and diagnosis of a present injury or an injury likely to occur, but for diagnostic tests needed to monitor medically a person who has been substantially exposed to a toxic substance that has created physiological changes indicating a substantial increase in risk that the person will contract a serious illness or disease. The expense of medical monitoring is thus a form of future medical expense and should be treated as such.

In conclusion, each plaintiff must prove the following [FN11]:

(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. [FN12] See *Sullivan v. Old Colony St. Ry.*, 197 Mass. 512, 516 (1908).

Proof of these elements usually will require competent expert testimony. See *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 852 (3d Cir.1990), cert. denied sub nom. *General Elec. Co. v. Knight*, 499 U.S. 961 (1991); *Ayers v. Jackson*, 106 N.J. 557, 606 (1987); *Hansen v. Mountain Fuel Supply Co.*, *supra* at 980.

We address a related issue. The very nature of this type of action raises the question whether the "single controversy rule," which requires a party to include in the action all related claims against the opposing party, would bar a future action for damages in the event a plaintiff subsequently contracts cancer. See *Dwight v. Dwight*, 371 Mass. 424, 427 (1976); *Liberty Mut. Ins. Co. v. National Consol. Warehouses, Inc.*, 34 Mass.App.Ct. 293, 297 (1993). This rule was never intended to address the problem of toxic torts, where a disease may be manifested years after the exposure. In this context, the rule acts as a deterrent to persons seeking early detection of catastrophic disease, and it would expose both plaintiffs and defendants to far more serious consequences should the disease later manifest itself in an advanced stage. Such a result makes no sense.

Finally, as the Supreme Court of New Jersey noted, the single controversy rule would not apply because the subsequent cause of action would not accrue until the disease is manifested. See *Ayers v. Jackson*, *supra* at 583-584. For these reasons we conclude that, in the context of toxic torts, the single controversy rule does not bar a subsequent action for negligence if one of these plaintiffs actually contracts cancer.

We answer the first certified question in the affirmative, [FN13] although for the reasons stated, the cause of action is in tort, not equity.

III

The second certified question asks whether the applicable statutes of limitations governing the plaintiffs' claims have expired. Application of a statute of limitations usually involves a question of fact to be decided by a jury. See *Vinci v. Byers*, 65 Mass.App.Ct. 135, 139 (2005). To the extent this case involves a question of law for which there is no precedent, we address that question. S.J.C. Rule 1:03.

The plaintiffs argue that their claims could not have accrued until the remedy they seek became available, because until it became available they could not have commenced this action. Philip Morris contends that the discovery rule controls a determination when the plaintiffs' claims accrue.

Under the discovery rule, a cause of action accrues when "an event or events have occurred that were reasonably likely to put the plaintiff on notice that someone may have caused her injury." *Bowen v. Eli Lilly & Co.*, 408 Mass. 204, 207 (1990). "Massachusetts does not require discovery of each of the elements of the cause of action--duty, breach, causation, and damages before the limitation clock in G.L. c. 260, § 4, starts ticking.... Rather, the three-year limitations period commences to run when a reasonably prudent person (in the tort claimant's position), reacting to any suspicious circumstances of which he might have been aware (what the Court of Appeals in *Fidler v. Eastman Kodak Co.*, 714 F.2d 192, 199 (1st Cir.1983), called 'likely cause'), should have discovered that he had been harmed by his physician's treatment." (Citations and footnote omitted.) *Malapanis v. Shirazi*, 21 Mass.App.Ct. 378, 382-383 (1986). "We do not require that a plaintiff have notice of a breach of duty before a cause of action may accrue, but we do require that a plaintiff have (1) knowledge or sufficient notice that she was harmed and (2) knowledge or sufficient notice of what the cause of harm was." *Bowen v. Eli Lilly & Co.*, *supra* at 208. In the context of toxic torts, where the harm may not have been manifested by the onset of disease, notice of harm and cause in many cases may not occur until the plaintiff is so advised by a physician.

In this case, it is not merely the risk of cancer of which the plaintiffs have notice, but the substantial increase in the risk of cancer, as reflected in their complaint. Because the harm involves subclinical changes that only will be discovered by a physician, notice most likely will take the form of advice by a physician, together with a recommendation for diagnostic testing conformably with the medical standard of care. In short, the statute begins to run when (1) there is a physiological change resulting in a substantial increase in the risk of cancer, and (2) that increase, under the standard of care, triggers the need for available diagnostic testing that has been accepted in the medical community as an efficacious method of lung cancer screening or surveillance.

As previously discussed, medical monitoring expense is the plaintiffs' only arguably provable damages.

They could not have sued for pain and suffering or lost earning capacity. This is not a case where plaintiffs recovered damages for pain and suffering, lost earning capacity, but only some medical expenses based on existing medical technology. These plaintiffs, or so they allege, had absolutely no remedy until LDCT technology appeared. If they can establish these circumstances, which are unusual and perhaps unique to medical monitoring claims, then their claims are timely. This is a question that cannot be resolved on the record before us; it must be resolved on a motion for summary judgment or, if genuine issues of material fact remain, by a jury. The plaintiffs also must show that the standard of care of the reasonable physician did not call for monitoring of any precancerous condition prior to the statute of limitations period, not just that the technology at that time was less effective for monitoring.

We answer the second certified question in the negative, subject to determination as we have outlined it.

The Reporter of Decisions is to furnish attested copies of this opinion to the clerk of this court. The clerk, in turn, will transmit one copy under the seal of this court to the clerk of the United States District Court, District of Massachusetts, in answer to the questions certified, and will also transmit a copy to each party.

So ordered.

FN1. Patricia Cawley.

FN2. Supreme Judicial Court Rule 1:03, as appearing in 382 Mass. 700 (1981), provides: "This court may answer questions of law certified to it by ... a United States District Court ... when requested by the certifying court if there are involved in any proceeding before it questions of law of this State which may be determinative of the cause then pending in the certifying court and as to which it appears to the certifying court there is no controlling precedent in the decisions of this court."

FN3. "[S]ubclinical--Denoting the presence of a disease without manifest symptoms; may be an early stage in the evolution of a disease." Stedman's Medical Dictionary 1492 (25th ed.1990).

FN4. We acknowledge the amicus curiae brief filed by Coalition for Litigation Justice, Inc.; Chamber of Commerce of the United States of America; National Association of Manufacturers; American Tort Reform Association; American Chemistry Council; American Petroleum Institute; American Insurance Association; and Property Casualty Insurers Association of America.

FN5. In preparing her statement of facts, the District Court judge stated she "construed [the] plaintiffs' allegations and the evidence presented in opposition to summary judgment in accordance with well-settled [F]ederal law governing motions pursuant to Fed.R.Civ.P. 12(b)(6), 12(c), and 56. Thus, in considering whether the plaintiffs have stated a claim, all allegations are taken as true and all reasonable inferences made in their favor; likewise, the evidence presented in opposition to summary judgment has been taken in the light most favorable to the non-moving party, the plaintiffs. See *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir.1993) (motion to dismiss standard); Fed.R.Civ.P. 56 (summary judgment standard)."

FN6. A "pack-year" is the average number of packs of cigarettes smoked per day multiplied by the number of years the person has smoked. For example, two packs of cigarettes smoked per day for one year equals two pack-years.

FN7. The applicable statute of limitations for claims under G.L. c. 260, § 2A, is three years from the date of accrual; claims under G.L. c. 106, § 2- 725, and G.L. c. 93A, §§ 2, 9, must be commenced within four years of accrual.

FN8. Negligence actually consists of two elements: a legal duty and an act or omission in violation of that duty. See *Royal Indem. Co. v. Pittsfield Elec. Co.*, 293 Mass. 4, 6 (1935).

FN9. Contrast Restatement (Third) of Torts § 4 comment c (Tent. Draft No. 5, 2007) ("Given the function of the definition, any level of physical impairment is sufficient for liability; no minimum amount of physical harm is required. Thus, any detrimental change in the physical condition of a person's body or property counts as a harmful impairment.... Under this Restatement's Sections on liability, the problem of minor physical harm will often solve itself: most persons who incur such harm are not inclined to sue only to recover a trivial amount of compensation").

FN10. This requirement is based on the assumption, stated earlier, that this opinion addresses only individual claims, and not a class action. We express no view about the superiority of a class action (the use of a court-supervised medical monitoring program) over an individual adjudication of claims and an award of monetary damages. See *Weld v. Glaxo Wellcome Inc.*, 434 Mass. 81, 94-95 (2001); J.W. Smith & H.B. Zobel, Rules Practice § 23.9 (2d ed.2006); 7B C.A. Wright, A.R. Miller, & M.K. Kane, Federal Practice and Procedure § 1805 (3d ed.2005).

FN11. A plaintiff's claim would, of course, remain subject to all available affirmative defenses, such as contributory negligence.

FN12. Because the nature of these medical expenses is diagnostic, in contrast to responsive treatment costs, they are somewhat akin to what we customarily have seen as medical expenses that have already been incurred. In this respect, the lump sum usually awarded for future medical expenses, see *Griffin v. General Motors Corp.*, 380 Mass. 362, 367 (1980); *Sullivan v. Old Colony St. Ry.*, 197 Mass. 512, 516 (1908), may, in cases such as this, be ordered paid into an appropriate account and drawn down as the expenses are actually incurred. If they are not used, the award, or balance thereof, may be returned to the defendant who was obligated to make such payment. See *Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 982 (Utah 1993). A plaintiff's reasonable attorney's fees and costs may be paid out of such award.

FN13. Our resolution of the negligent design claim similarly resolves the claims for breach of warranty and violations of G.L. c. 93A, all of which are based on the same theory of injury and the same set of alleged facts. For this reason those claims survive or fail under the same analysis as the underlying negligence claim. See *Iannacchino v. Ford Motor Co.*, 451 Mass. 623, 634- 635 (2008).

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