## Court of Appeals

STATE OF NEW YORK

MARCIA L. CARONIA, LINDA MCAULEY, and ARLENE FELDMAN,

Plaintiffs-Appellants,

against

PHILIP MORRIS USA, INC.,

Defendant-Respondent.

On Questions Certified by the United States Court of Appeals for the Second Circuit (USCOA Docket No. 11-0316-cv)

#### **BRIEF FOR PLAINTIFFS-APPELLANTS**

PHILLIPS & PAOLICELLI LLP *Attorneys for Plaintiffs-Appellants* 380 Madison Avenue, 24th Floor New York, New York 10017 212-388-5100

Of Counsel:

Steven J. Phillips Victoria E. Phillips Aryeh L. Taub Lisa W. Davis

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#### **QUESTIONS CERTIFIED**

The United States Court of Appeals for the Second Circuit certified the following questions to this Court:

- (1) Under New York law, may a current or former longtime heavy smoker who has not been diagnosed with a smoking-related disease, and who is not under investigation by a physician for such a suspected disease, pursue an independent equitable cause of action for medical monitoring for such a disease?
- (2) If New York recognizes such an independent cause of action for medical monitoring,
- (A) What are the elements of that cause of action?
- (B) What is the applicable statute of limitations, and when does that cause of action accrue?

In framing these questions, the Second Circuit expressly stated that it did not intend to limit the scope of this Court's analysis, and instead invited this Court "to expand upon or alter these questions as it deems appropriate." A746.<sup>1</sup>

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<sup>&</sup>lt;sup>1</sup> This Court accepted the Second Circuit's certification of questions pursuant to section 500.27 of its Rules of Practice.

#### THE NATURE OF THE CASE

#### **Preliminary Statement**

Lung cancer is the leading cause of cancer death the United States. It is responsible for approximately 160,000 deaths each year, including over 9,000 deaths in New York State alone. A159 ¶4(b); A373 ¶4; A696.

Since 1955, Defendant-Appellee Philip Morris USA, Inc. ("Philip Morris") has manufactured and sold Marlboro cigarettes. A28 ¶34; A30 ¶53. Over eighty percent of lung cancers are caused by cigarette smoking. A373 ¶5. Philip Morris' prolonged and gross misconduct in the manufacture and marketing of cigarettes is well established, and has been the subject of intense judicial scrutiny. *See, e.g., United States v. Philip Morris*, 449 F. Supp.2d 1 (D.D.C. 2006) ("*U.S. v. PMUSA*") *aff'd in part, rev'd in part on other grounds*, 566 F.3d 1095 (D.C. Cir. 2009).

The smoke generated by Marlboro cigarettes is a toxic mixture of more than 4,000 chemicals, over 50 of which are known carcinogens. A260-261; A378-379 ¶42-51. Most smokers are also dependent on the nicotine in Marlboro cigarettes, which research suggests is as addictive as heroin, cocaine, or alcohol.<sup>2</sup>

When used in their normal, foreseeable, and intended manner, Marlboro cigarettes invariably harm and frequently kill their consumers. A36-38 ¶¶83-91,

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<sup>&</sup>lt;sup>2</sup> http://www.cdc.gov/tobacco/quit\_smoking/how\_to\_quit/you\_can\_quit/nicotine/ (last visited July 25, 2013). *See also Evans v. Lorillard Tobacco Co.*, 465 Mass. 411, 420 (2013)("Nicotine is as or more addictive than any other drug of abuse, including heroin and cocaine.").

99-100. For decades, Philip Morris has designed Marlboros to maximize their lethal and addictive propensities, while engaging in a concerted effort to mislead the public about those very properties. A258-275.

Sadly, most of the lung cancers resulting from Philip Morris' misconduct have been detected after a tumor has grown and spread, and successful treatment is no longer possible. Virtually all individuals with late-stage lung cancer experience profound suffering, and a lingering death. A143-145; A174-175; A187-199.

These statistics have remained constant for decades, as there was no effective method to diagnose early-stage lung cancer. Lung cancers have normally been detected when a patient experiences symptoms such as severe weight loss, shortness of breath, and coughing up blood. By then, primary tumors are typically the size of a grapefruit, and successful surgical intervention is impossible. A57 ¶¶62-63; A145-146 ¶¶35-37; A205-206; A207-208; A374 ¶¶9-10; A384-385 ¶¶77-78.

A new imaging technique, utilizing low-dose computerized tomography ("LDCT"), promises to change this tragic reality. LDCT imaging can visualize lung cancer at the earliest stages without undue risk, when a tumor is roughly the size of a grain of rice. At that stage, chances of survival are dramatically improved. A173-180; A196-200; A394-397. However, individuals at high-risk for lung cancer are ill-advised to simply attempt to purchase this procedure on the free

market. Proper medical surveillance for lung cancer requires a program with well-organized algorithms, quality control, outreach, follow-up, informed consent, and a centralized administration. A159-164; A178-179. *See Donovan v. Philip Morris USA, Inc.*, 2012 U.S. Dist. LEXIS 37974, \*51-56 (D. Mass. Mar. 21, 2012)("*Donovan III*"); *Donovan v. Philip Morris USA, Inc.*, 268 F.R.D. 1, 22-28 (D. Mass. 2010)("*Donovan II*").

Against this background, the instant case was commenced as a class action in the United States District Court for the Eastern District of New York in 2006. It sought to compel Philip Morris to establish a program providing LDCT lung cancer surveillance. The class Plaintiffs seek to represent consists of New Yorkers 50 years of age or older, with at least a 20 pack-year<sup>3</sup> history of smoking Marlboro cigarettes, who smoke Marlboros or quit within one year of the action's commencement, and neither suffer from lung cancer, nor are under investigation by a physician for suspected lung cancer. A23 ¶1.

Plaintiffs initially pleaded claims sounding in negligence, strict liability, and breach of implied warranty. A23-40. The sole remedy they sought was injunctive or equitable in nature. Specifically, Plaintiffs sought establishment of an LDCT lung cancer surveillance program available to all class members. A34-36; A39-40.

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<sup>&</sup>lt;sup>3</sup> A pack-year is smoking a pack of cigarettes per day for 1 year, or the equivalent. To illustrate, a 20 pack-year Marlboro smoker may have smoked 1 pack per day for 20 years, 2 packs per day for 10 years, or half a pack per day for 40 years. A27 ¶28, n.2.

Plaintiffs pleaded claims focusing on the defective design of Marlboro cigarettes, which contain excessive and unnecessary quantities of cancer-causing tar. A23-40; A258-275. Plaintiffs were prepared to prove that it was feasible to design cigarettes with markedly reduced carcinogens, without disturbing either flavor or the delivery of nicotine that motivates smoking. A32; A258-275; A378-384.

Faced with motions to dismiss, the District Court ruled that Plaintiffs' negligence and strict product liability claims were time-barred. A357-A364. It so ruled despite the fact that a) Plaintiffs were the victims of ongoing misconduct, which continued to inflict new harm until the filing of this lawsuit, and b) the sole efficacious surveillance remedy which they might seek did not exist until the time of the suit's commencement. However, the District Court denied Philip Morris' summary judgment motion as to Plaintiffs' breach of implied warranty cause of action, rightly recognizing that it was timely, and that evidence supported proximate causation as to that claim. A365-368 (citing N.Y. U.C.C. § 2-725).

The District Court then invited Plaintiffs to amend their Complaint to allege a stand-alone equitable medical surveillance claim. A368-370. Plaintiffs complied. A372-392. After additional briefing, the District Court held that Plaintiffs' equitable claim for medical monitoring was cognizable under New York law and timely. A398-415. Nonetheless, it dismissed that claim, based on a legally incorrect belief that New York requires "but for" causation, and factually mistaken

view that Plaintiffs would have required medical monitoring if they had smoked a feasible alternative design. It also granted summary judgment on the breach of warranty claim, asserting that Plaintiffs' knowledge that cigarettes posed health risks meant that the substantial additional hidden defects, rendering Marlboros far more dangerous than they needed to be, were not actionable. A398-422.

On appeal, the Second Circuit (incorrectly in Plaintiffs' view) affirmed the dismissal of the negligence, strict product liability, and warranty claims. However, it certified to this Court questions of whether an equitable claim for medical monitoring is cognizable, what its elements are, and when such a claim accrues for timeliness purposes. The Second Circuit also invited this Court to expand its analysis and alter the questions posed as it deems appropriate. A746. Accordingly, Point II-III *infra* address the misreading of New York law which informed the dismissal of Plaintiffs' negligence, strict liability, and warranty claims.

Finally, this Court should also be aware that an essentially identical medical surveillance case, involving the same misconduct and seeking the same remedy, was filed in Massachusetts. In that case, the United States District Court for the District of Massachusetts certified to the Supreme Judicial Court of Massachusetts ("SJC") comparable questions respecting the cognizability and timeliness of medical surveillance claims. In a thoughtful and well-reasoned decision, the SJC held *inter alia* that: 1) Plaintiffs' claims for medical surveillance were cognizable,

Donovan v. Philip Morris USA, Inc., 914 N.E.2d 891, 894-902 (Mass. 2009)("Donovan  $\Gamma$ "), 2) the statute of limitations governing those claims had not yet expired, id. at 894-895, 903-904, and 3) the creation of a fund sufficient to pay for the remedy, with unused funds reverting back to the tortfeasor, was proper, id. at 902 n.12.<sup>4</sup>

#### **Statement of Facts**

#### a. Philip Morris' Misconduct

Philip Morris has designed, manufactured, and sold Marlboro cigarettes since 1955. A28 ¶34; A30 ¶53. "Cigarette smoking is by far the most important risk factor for lung cancer." It "accounts for more deaths than any other cancer" with "[a]n estimated 160,340 deaths" expected in 2012 alone. When used in their normal, foreseeable, and intended manner, Marlboros inflict harm on all consumers, and grave illness and death on many of them. A167-172; A260-275.

By way of background, epidemiological studies established an increased risk of lung cancer among cigarette smokers.<sup>6</sup> In 1959, the Surgeon General wrote that

<sup>&</sup>lt;sup>4</sup> Following the SJC's decision, the *Donovan* class was certified pursuant to Fed. R. Civ. P. 23, *Donovan II*, 268 F.R.D. at 1. The First Circuit denied an interlocutory appeal, and a subsequent motion to decertify the class was likewise denied. *Donovan III*, 2012 U.S. Dist. LEXIS 37974. *Donovan* is presently awaiting trial.

<sup>&</sup>lt;sup>5</sup> American Cancer Society, Cancer Facts and Figures, 2012, at p.15, available at http://www.cancer.org/research/cancerfactsfigures/cancerfactsfigures/cancer-facts-figures-2012 (last visited July 25, 2013).

<sup>&</sup>lt;sup>6</sup> Smoking and Tobacco Control Monograph 13: Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Nicotine, U.S. Department of Health and Human Services ("Monograph 13"), at p.1, available at http://cancercontrol.cancer.gov/tcrb/monographs/13/ (last visited July 25, 2013).

the weight of evidence "implicate[d] smoking as the principal factor in the increased incidence of lung cancer." After carefully evaluating clinical and autopsy studies, animal experiments, and population studies, the Surgeon General declared in 1964 that "[t]he risk of developing lung cancer increases with duration of smoking and the number of cigarettes smoked per day, and is diminished by discontinuing smoking."

In the federal government's action against cigarette manufacturers, including Philip Morris, the Honorable Gladys Kessler found, after considering extensive proofs, that "there was a consensus in the scientific community that smoking caused lung cancer and other diseases," by the issuance of the 1964 Surgeon General's Report at the very latest. *U.S. v. PMUSA*, 449 F. Supp. 2d at 180. Philip Morris' Vice-President of Research and Development acknowledged internally that there was "little basis for disputing the findings" of the 1964 Surgeon General's Report. *Id.* Nonetheless, Philip Morris continued to maintain its public position that the causal link between smoking and health was an "open question" for another *thirty-five years*. *Id.* Indeed, Philip Morris did not admit that smoking causes lung cancer until 1999. A272.

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<sup>&</sup>lt;sup>7</sup> Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service, at p.7 (1964)("1964 Surgeon General Report"), available at http://www.surgeongeneral.gov/library/reports/ (last visited July 25, 2013).

<sup>&</sup>lt;sup>8</sup> Id. at pp. 25-31.

In addition to carcinogenic tars, Marlboros contain nicotine. The Centers for Disease Control and Prevention reports that "[n]icotine is the psychoactive drug in tobacco products that produces dependence[,]" and "[m]ost smokers are dependent on nicotine." That surely includes the class Plaintiffs seek to represent, which consists of smokers aged fifty or older, with at least a twenty pack-year history of smoking Marlboros. A372 ¶1.

Overcoming nicotine dependency, even when urged to do so for health reasons, is extremely difficult. Even Philip Morris now "agrees with the overwhelming medical and scientific consensus that cigarette smoking is addictive[.]" That is consistent with the Surgeon General's declaration that:

- 1. Cigarettes and other forms of tobacco are addicting.
- 2. Nicotine is the drug in tobacco that causes addiction.
- 3. The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine.<sup>11</sup>

Philip Morris has well understood these facts for decades, and utilized its knowledge to design cigarettes capable of maintaining addiction. After reviewing

<sup>&</sup>lt;sup>9</sup> http://www.cdc.gov/tobacco/data\_statistics/fact\_sheets/cessation/quitting/ (last visited July 25, 2013).

<sup>&</sup>lt;sup>10</sup>http://www.philipmorrisusa.com/en/cms/Products/Cigarettes/Health\_Issues/default.aspx?src=h ome (last visited July 25, 2013).

A Report of the Surgeon General: How Tobacco Smoke Causes Disease, at p.iii (2010) ("2010 Surgeon General Report"), available at http://www.surgeongeneral.gov/library/reports/tobaccosmoke/report-index.html (last visited July 25, 2013), p.105

extensive documentation in *U.S. v. PMUSA*, Judge Kessler found that "Philip Morris intensively studied nicotine and both its pharmacological and physiological effects on smokers ... in an effort to increase its market share within the industry[,]" but "withheld from the public its internal knowledge and acceptance that smoking, because of nicotine, was addictive." *U.S. v. PMUSA*, 449 F. Supp. 2d at 290. Philip Morris "suppressed, and in some cases terminated" research demonstrating the "addictive impact of nicotine on the bodies of animals and humans." *Id.* As early as 1969, Principal Philip Morris Scientist William L. Dunn wrote in a confidential memorandum to Research & Development Vice President Helmut Wakeham: "[D]o we really want to tout cigarette smoke as a drug? It is, of course, but there are dangerous F.D.A. implications to having such a conceptualization go beyond these walls." *Id.* (emphasis added).

Other examples abound. For instance, in 1980, Mr. Dunn wrote another memorandum to Robert Seligman, Vice President of Research & Development at Philip Morris, describing Philip Morris' "Nicotine Receptor Program," a research program on the psychopharmacology of nicotine. That research:

was 'aimed at understanding that specific action of nicotine which causes the smoker to repeatedly introduce nicotine into his body.' While Dunn stated that the nicotine research would likely produce 'significant scientific developments,' he noted that it was 'a highly vexatious topic' that company lawyers did not want to become public because nicotine's drug properties, if known, would support regulation of tobacco by the FDA.

Dunn wrote, 'Yet this is where our attorneys least want us to be.' Moreover, lawyers were concerned that new 'knowledge of nicotine' might permit 'therapeutic breakthroughs to reduce the incidence of smoking.'

Consequently, Dunn observed that while Philip Morris would continue its research program 'to study the drug nicotine, we must not be visible about it[,' adding that] 'our attorneys ... will likely continue to insist on a clandestine effort in order to keep nicotine the drug in low profile.'

*U.S.* v. *PMUSA*, 449 F. Supp. 2d at 292 (emphasis added).

Consistent with Dunn's memorandum, Philip Morris continued to deny that its cigarettes are addictive until quite recently. In a July 18, 1973 "60 Minutes" interview, its Chairman compared "the choice to stop smoking to the choice to eat eggs or not." *Id.* In 1994, Philip Morris' Chief Executive Officer testified under penalty of perjury before the House of Representatives in a nationally televised hearing that he "believe[d that] nicotine is not addictive[.]" *Id.* His prepared statement also claimed that "cigarette smoking is not addictive' and 'Philip Morris has not hidden research which says that it is." *Id.* Philip Morris likewise placed an advertisement in national magazines, as a letter to smokers and nonsmokers entitled "FACTS YOU SHOULD KNOW." One "fact" was that "Philip Morris does not believe cigarette smoking is addictive." *Id.* at 273. <sup>12</sup>

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<sup>&</sup>lt;sup>12</sup> Although Plaintiffs' design defect claims focused on the inclusion of excessive tars in Malboro cigarettes, the habit-forming propensities of Marlboros and the nicotine they contain were undisputed below. Indeed, Philip Morris proffered expert evidence on the subject of addiction,

Philip Morris' false public statements have been reinforced by extraordinary expenditures. Cigarette manufacturers have long viewed marketing efforts as vital to how consumers perceived their products. As the Surgeon General reports, "[t]obacco companies spend more than a million dollars an hour in this country alone to market their products." In 2008 alone, the five major U.S. cigarette companies, which include Altria Group, Inc., Philip Morris' ultimate parent company, spent \$9.94 billion on marketing cigarettes in the United States. 15

By expending extraordinary sums, the industry perpetuated a false controversy about the carcinogenic and addictive properties of cigarettes, allowing consumers to rationalize the decision to commence or continue smoking. Over time, industry health claims evolved from advertisements touting products as the "lowest in nicotine" and "throat-irritating tars and resins[,]" *see*, *e.g.*, *In the Matter of P. Lorillard Co.*, 46 F.T.C. 735 (1950), into more subtle messages, as "[m]otivation researchers and other trade analysts advised the industry to shift

A276-291, and elicited testimony from Plaintiffs concerning their nicotine dependence. A308; A316; A346. Because the Second Circuit certified questions of law in general terms, Plaintiffs discuss nicotine herein by referencing authoritative government publications and judicial findings, in order to provide relevant background respecting Philip Morris' misconduct, which bears on its equitable obligation to provide consumers with the life-saving surveillance sought herein.

<sup>&</sup>lt;sup>13</sup> Monograph 13, p.222.

<sup>&</sup>lt;sup>14</sup> Preventing Tobacco Use Among Youth and Young Adults Fact Sheet (2012) ("2012 Surgeon General's Report"), available at http://www.surgeongeneral.gov/library/reports/preventing-youth-tobacco-use/factsheet.html (last visited July 25, 2013).

<sup>&</sup>lt;sup>15</sup> 2012 Surgeon General's Report at p.488.

from explicit verbal assertions of health toward implied healthfulness, an approach that incorporated the use of visual imagery."<sup>16</sup>

As the Reports of the Surgeon General document, "at least by the mid-1970s the tobacco industry well understood the importance of creating health reassurance messages in order to alleviate health concerns[.]"17 Nonetheless "deceptive practices have been employed over the years (some continue to this date) that foster and perpetuate the illusion that various cigarette brands ... are relatively healthy."18

Unfortunately, these tactics have proven extremely effective. Outside of the cigarette industry, "the various ways that cigarettes were physically modified and the nature and level of compensation in response to design changes were not well understood." Public health officials also failed "to anticipate the degree to which manufacturers could design cigarettes to allow smokers to draw more smoke and nicotine from cigarettes than was represented by machine-measured yields of tar and nicotine." See A381 ¶58-59; A384 ¶74. That tremendous asymmetry of information between the industry and its consumers, aided by extraordinarily well-

Monograph 13, p.199.2010 Surgeon General's Report, p.16.

<sup>&</sup>lt;sup>18</sup> Monograph 13, p.231.

<sup>&</sup>lt;sup>19</sup> 2010 Surgeon General's Report, p.16.

funded marketing campaigns, has perpetuated an epidemic which is responsible for approximately 1 in every 5 deaths each year in the United States.<sup>20</sup>

As Judge Kessler wrote in *U.S. v. PMUSA*, for decades the cigarette "industry has employed a single strategy to defend itself," which consists of "creating doubt about the health charge without actually denying it, advocating the public's right to smoke without actually urging them to take up the practice . . . [and] encouraging objective scientific research as the only way to resolve the question of health hazard." 449 F. Supp. 2d at 73 (quoting Fred Panzer, public relations specialist with the Tobacco Institute). By now the public health community's debate is over, but Philip Morris continues to play the same game in court, suggesting the question of whether Marlboros are dangerous remains an open question.

With that background in mind, Plaintiffs have alleged, and are prepared to prove, that at all relevant times, Marlboro cigarettes have been unreasonably dangerous by virtue of their inclusion of excessive levels of cancer-causing tars. A378-384 ¶42-74; A261-265. Philip Morris had the ability to design, manufacture, and market cigarettes with comparable taste and addictive propensities to Marlboros, and a tiny fraction of the carcinogens present. A375 ¶18; A380-382 ¶¶53-65; A260-272; A220-223; A236-237; A238-239. Feasible

 $^{20}$  Id. at Message from Kathleen Sebelius, Secretary of Health and Human Services.

alternative designs could have reduced carcinogenicity by at least as much as sixty-fold as compared to the least carcinogenic Marlboro. A380 ¶53; A382 ¶62; A258-272; A224-235. Indeed, Philip Morris and others actually designed such cigarettes. A375-383 ¶¶18, 53-68; A260-272; A220-226, A236-237, A238-239. Philip Morris also possessed the ability to manufacture and market cigarettes that would reduce the tar content while retaining the nicotine necessary to maintain addiction (or as Philip Morris calls it, "satisfaction"). A375-383 ¶¶18, 53-68; A220-226; A236-237; A238-239; A260-272. Philip Morris wrongfully concealed this reality from Plaintiffs and from the general public. A272-275. <sup>21</sup>

Plaintiffs initially characterized this misconduct as negligence, strict liability, and breach of the implied warranty of merchantability. A36-39. Later, when the District Court suggested that Plaintiffs might be advised to plead an independent equitable medical monitoring claim, they did so. However, the misconduct underlying this equitable claim essentially mirrored that in the original negligence, warranty, and strict liability claims. A369; A389-391 ¶109-118.

Notably, Philip Morris' misconduct was continuing in nature. Each pack of cigarettes sold is a new wrongful act, particularly in light of new information that is continually being amassed about this hazardous product. A258-275; A377 ¶35.

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<sup>&</sup>lt;sup>21</sup> Indeed, the so-called "e-cigarette" which is now commercially available professes to deliver nicotine and flavor without delivering tars to the consumer.

Finally, it is worth underscoring that the manufacture and sale of Marlboro cigarettes is enormously lucrative. A272-274. Each day in the United States, over 3,800 children under age 18 smoke their first cigarette, and over 1,000 children become daily smokers.<sup>22</sup> Philip Morris has a compelling motive to design a cigarette with strong addictive propensities, while downplaying its health effects.<sup>23</sup>

In sum, Philip Morris wrongfully designed, marketed, and sold an excessively carcinogenic product. It was feasible to design a cigarette that was far less carcinogenic (or entirely non-carcinogenic), while retaining any "utility" cigarettes might be said to possess. The reduced carcinogenicity of alternative designs was sufficiently lower than Marlboros that it would have been impossible for a user to reach the risk-equivalent of 20 pack-years of smoking Marlboros.<sup>24</sup>

#### **b.** Proximate Causation

Smoking Marlboros is harmful to the lungs in a dose-response fashion. A dose-response relationship is one in which increases in the duration or intensity of exposure elevates the incidence or severity of an adverse outcome. A170-171; A262-263; A379 ¶51. Each puff of each Marlboro increases the risk that a smoker will develop lung cancer. A170-171 ¶¶9-14; A262-263.

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<sup>&</sup>lt;sup>22</sup> 2012 Surgeon General's Report, at "Message from Kathleen Sebelius."

<sup>&</sup>lt;sup>23</sup> See 2012 Surgeon General's Report, p.541 ("for a tobacco company to be profitable over the long term, it must compete successfully for a share of the youth market.")

<sup>&</sup>lt;sup>24</sup> A 60-fold decrease in carcinogenicity means that one would have to smoke 60 packs per day for 20 years in order to reach the carcinogenic dose delivered by 1 pack per day of Marlboros.

Advancing age and continued use, measured in increasing pack-year histories, both combine to increase lung cancer risk. A172. As risk elevates, a threshold is reached at which, as a matter of good medical practice, monitoring becomes justifiable. A172-A176. Plaintiffs' experts opined that this occurs when a person both reaches age 50 and has a 20 pack-year smoking history, continuing to the present (or within 1 year of the present). A137-A138 ¶16-18; A172 ¶18-20.

Importantly, Plaintiffs never asserted that a 50-year-old who smoked 20 pack-years of the feasible alternatives they propose would require surveillance, a point that the District Court misapprehended. A416-419. To the contrary, an individual who smoked a cigarette with less than half the carcinogens in a Marlboro would, after 20 pack-years, only have the equivalent of less than a 10 pack-year Marlboro history by the age of 50. The same individual, smoking cigarettes with only one-sixth the carcinogens, would have a three and one-third pack year history. Such individuals would not be proper candidates for surveillance. A170-171 ¶¶9-14.

Another aspect of proximate causation (which the District Court did appreciate) was that the harm inflicted from their most recent 3 years of Marlboro use was a substantial factor in causing the elevated risk of lung cancer necessitating the surveillance remedy. A365-366. In that regard, Plaintiffs' experts, Drs. Miller and Morabia, both opined that the last 3 years of smoking substantially

contribute to the risk of lung cancer, by increasing the dose and duration of harmful particles and gases, and maintaining the destructive and pro-carcinogenic processes. A139-143; A170-171.<sup>25</sup>

#### c. The Harm Inflicted by Marlboro Cigarettes

Plaintiffs do not allege, nor do they seek to recover damages for, any form of cognizable bodily injury which would give rise to a personal injury claim. A109 ¶195; A375 ¶19. By definition, the proposed class' members do not have lung cancer. A372-373 ¶1. Plaintiffs do not claim to be suffering from, nor do they seek to recover for, any smoking-related symptoms or disease. They do not claim to have suffered physically or mentally, and make no demand for such damages. Nor have they experienced disability, lost wages, or economic damages. A375 ¶19. The likelihood that any class member will experience these damages is speculative, although numbers of them unquestionably will. A143-145 ¶¶28-33.

That is not to say that Plaintiffs and the proposed class have not suffered bodily harm from prolonged Marlboro use. Each cigarette smoked, and the ongoing effect of continued cigarette use, causes harm to the cells and tissues of the respiratory system. A109 ¶194; A170-171 ¶¶9-14; A384 ¶73. However, such microscopic harm does not produce pain, disability, or economic loss which would

<sup>25</sup> Moreover, since this action was initially filed on January 19, 2006 -- over seven years ago -- many, if not most, class members continue to smoke, and Philip Morris continues to misbehave, the majority of class members now have experienced as many as eleven years of wrongful

exposures which are unquestionably timely from a breach of warranty perspective.

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create a good faith basis for claiming money damages for personal injury. Nor did Plaintiffs allege (nor do the proofs indicate) that they were proper candidates for monitoring when they first suffered harm to the cells and tissues of the respiratory system, namely, the moment they smoked their first cigarette.

#### d. Plaintiffs' Ages and Facts Bearing on Timeliness

This lawsuit was commenced on January 19, 2006. A23. Plaintiffs, and, by definition, all potential class members, are New Yorkers, 50 years of age or older, at high risk for developing lung cancer by virtue of their age and their prolonged and heavy use of Marlboro cigarettes. A372-373 ¶1.

Lung cancer is a progressive disease, which passes through stages as the malignancy comes into existence, grows, spreads, and ultimately kills. The earlier the stage at which one diagnoses and begins to treats lung cancer, the better the prospects for cure. A174-175 ¶¶22-29; A187-199. As noted, Plaintiffs' experts opine that the risk threshold which medically triggers the need for lung cancer surveillance is a combination of *both* 20 pack-years of Marlboro use *and* reaching the age of 50. A137-138 ¶¶16-18; A172-173 ¶¶18-20.

Plaintiffs did not allege that a person who smokes 20 pack-years of Marlboros would require surveillance for lung cancer prior to her fiftieth birthday. Nor did Philip Morris so argue, or offer proofs supporting such a claim. To the contrary, the proofs demonstrated that risk of cancer increases with age, and

"accelerates at age 50," rendering smokers proper candidates for LDCT monitoring when they amass a 20 pack-year history and are 50 years of age or older. A172 ¶18-20.

This point is noteworthy because Plaintiff Marcia Caronia turned 50 in 2005, less than one year before this action was filed. A297. The same is surely true of hundreds if not thousands of other members of the proposed class. No expert opined that they should have sought monitoring prior to their fiftieth birthdays.

Both sides also agreed below that, prior to the time when this action was commenced, no accepted programs or procedures existed which were deemed medically accepted or efficacious methods for the early detection of lung cancer. Neither conventional chest x-rays nor sputum cytology was considered efficacious. A57 ¶¶62-63; A145-146 ¶¶35-37; A205-206; A207-208; A374 ¶¶9-10; A384-385 ¶¶77-78.

Then, just at the time this suit was filed, a major peer-reviewed study was published in the New England Journal of Medicine, announcing that LDCT screening had extraordinary potential to save lives. Claudia I. Henschke *et al.*, *Survival of Patients with Stage I Lung Cancer Detected on CT Screening*, 355 New Eng. J. Med. 1763 (2006). Accordingly, this action was commenced at the earliest possible moment. Any lung cancer medical surveillance lawsuit commenced prior to 2006 could not have proceeded in good faith, and would have violated the

requirements of Fed. R. Civ. P. 11, since there was no efficacious form of surveillance available to be sought consistent with standards of good medical practice.

During the early years of this action, Philip Morris steadfastly took the position that there was no proper form of lung cancer surveillance available. Without disputing that LDCT could identify tumors early and at small sizes, Philip Morris challenged the efficacy of the technique, claiming that any programs using it were untested, and likely to prove a disappointment. A242-243. Philip Morris pointed to an ongoing federally funded study, the National Lung Cancer Screening Trial ("NLST"), as the study that would provide the gold standard answer on the question of LDCT surveillance's efficacy. See A254.

No doubt expecting that study to drag on for many years while these cases came to a conclusion, Philip Morris was likely disappointed in 2010 when, after preliminary results in the NLST study became available, its principal investigators found the data extraordinarily compelling. In fact, it was so strong that the researchers felt constrained on ethical grounds to halt the study, because it would be unfair to offer chest x-rays to a control group when they could benefit from LDCT surveillance. A395-396. Subsequent publications have confirmed that "[s]creening with the use of low-dose CT reduces mortality from lung cancer." The National Lung Screening Trial Research Team, *Reduced Lung-Cancer Mortality* 

with Low-Dose Computed Tomographic Screening, 365 New Eng. J. Med. 395 (2011)(noting that there was "a relative reduction in mortality from lung cancer with low-dose CT screening of 20.0%" and that "[t]he rate of death from any cause was reduced in the low-dose CT group, as compared with the [control] radiography group, by 6.7%").

With respect to the warranty claim, Plaintiffs, and by definition, all prospective class members, continued to smoke Marlboro cigarettes until at least one year prior to the suit's commencement. A373 ¶1(c). Statistically, it is likely that most have continued to smoke to this day. Since all sales within four years of the Complaint's filing would give rise to timely warranty claims under N.Y.U.C.C. § 2-725, it is clear that all warranty claims occasioned by the sale of Marlboros after January 19, 2002 were timely commenced.<sup>26</sup>

By definition, Plaintiffs and members of the proposed class were neither diagnosed with lung cancer, nor under investigation for suspected lung cancer. A374 ¶1(e). Although many surely had some general awareness that smoking was harmful to their health, none was aware of the fact that Philip Morris had improperly designed the cigarettes they smoked to maximize their carcinogenic content.

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<sup>&</sup>lt;sup>26</sup> Plaintiffs also presented expert proofs that the quantum of injurious exposure occurring after 2002 was sufficient to serve as a proximate cause for the need for lung cancer surveillance. A139-143 ¶19-27; A171 ¶13.

#### e. The Nature of Plaintiffs' Remedy

As the District Court recognized, the relief sought in this action is a program and not money damages. A66 ¶33; A354; A372 ¶2; A375 ¶19; A384-386 ¶¶75-82. Simple payment of money to class members would not enable them to "purchase" the surveillance sought, and only the establishment of a proper LDCT surveillance program would be an adequate remedy. A119 ¶223; A159-160; A181; A209-A215.

Necessary elements of this program would include outreach to inform class members of the availability of the program and its potential benefits. A66 ¶34. Physicians also must examine class members who lack primary care physicians, or wish to have the program write the prescription, to evaluate whether or not there are contraindications for the imaging. A67 ¶35; A159-160; A178-180; A212.<sup>27</sup>

Next, a proper informed consent procedure must be put in place. A66 ¶33; A69 ¶47. With respect to the imaging itself and the interpretation of the images obtained, it is essential that a well-thought-out algorithm be developed. This would include judgments about what might be the criteria for determining that films reveal abnormalities or suspicious findings, and procedures for follow-up (e.g.,

Once within the program, the course of each class member will inevitably vary. A small number of class members due to severe comorbidities (*e.g.*, another diagnosed terminal disease or morbid obesity), may be ineligible for the imaging at the time of the program's commencement. A67 n.4; A178. It is possible that some, when informed, may elect not to go forward. Of course, those who are imaged will also have varying outcomes, since some will have lung cancer and others will not. However, the common remedy sought is notice of and access to the program.

when to order repeat images and to refer participants for further testing). A154-164; A177-178.

Quality control, with respect to both the maintenance and calibration of the equipment, and the uniform interpretation of the films obtained, is also critical. Implicated in this requirement is the need for proper administration and recordkeeping. A160; A209-211.

Also, as related, for those whose images reveal cancer (or other conditions that might be serendipitously revealed), the program would require a proper list of qualified specialists (*e.g.*, pulmonologists, oncologists, interventional radiologists, and thoracic surgeons) to provide to class members seeking such information. Similarly, the program would have an obligation to explain to all class members the meaning of their imaging results. A154-164; A177-178; A213.

Both Plaintiffs' (A159-160) and Philip Morris' experts (A209-215) agreed that only a well designed and executed program of LDCT lung cancer screening would be proper. There was agreement that simply giving class members a monetary recovery and sending them forth to purchase surveillance on their own would not be efficacious. A155-156; A159-160; A162-163; A177-181; A211-215. This is especially important since medicine in this area is rapidly developing, and can be expected to do so in the future.

#### <u>ARGUMENT</u>

# I. PLAINTIFFS' CAUSE OF ACTION SEEKING MEDICAL SURVEILLANCE IS COGNIZABLE AND TIMELY UNDER NEW YORK LAW

It is an ancient maxim that "equity will not suffer a wrong without a remedy." *McKenna v. Levy*, 182 A.D. 678, 689 (2d Dept. 1918); *Williams v. Supreme Council American Legion of Honor*, 80 A.D. 402, 406 (2d Dept. 1903) (quotations and citation omitted). A wrong without a remedy is "an absolute failure of justice," compelling equity to step in and fashion relief. *See Strusburgh v. New York*, 87 N.Y. 452, 456 (1882). *See also generally Rozell v. Rozell*, 281 N.Y. 106 (1939) (reaffirming that "[t]he unquestioned principle of jurisprudence from very early times that there can be no wrong without a remedy is still in force with all its ancient vigor.") (citation and quotations omitted).

In this case, a wrong clearly occurred. Philip Morris endeavored for years to dispute the indisputable – that Marlboro cigarettes dramatically increase a consumer's risk of developing lung cancer. All the while, motivated by greed, it made billions of dollars selling a defective and deadly product. Now, even Philip Morris agrees "with the overwhelming medical and scientific consensus that cigarette smoking causes lung cancer[.]" However, that admission does not undo the damage caused by its decades of selling Marlboro cigarettes.

<sup>&</sup>lt;sup>28</sup>http://www.philipmorrisusa.com/en/cms/Products/Cigarettes/Health\_Issues/default.aspx?src=to p\_nav (last visited July 25, 2013).

Fortunately, technology finally exists with the capacity to detect lung cancer at its earliest stages, saving human lives and alleviating some of the terrible suffering Philip Morris' product causes. Plaintiffs commenced the instant action seeking establishment of an LDCT medical monitoring program at the earliest possible moment when they could assert a prayer for relief in good faith. Nonetheless, the federal courts dismissed their claims as untimely, penalizing Plaintiffs for failure to bring suit at a time when no LDCT expenses could have been incurred, and no meaningful relief was available.

Accordingly, as matters now stand, this case presents a situation where a wronged population is being denied any relief. Faced with mirror image pleadings and proofs, Massachusetts' high court recognized the inherent injustice in Philip Morris' bid for dismissal. Consequently, it recognized a cause of action for medical monitoring, which accrued only when efficacious surveillance existed for which Plaintiffs could make a prayer for relief. *Donovan I*, 914 N.E.2d at 894-904.

That ruling is in harmony with law of this State, and the great weight of authority nationwide. Equity mandates that the wrongdoer, rather than the injured party or the State, bear the costs of medical surveillance. The cause of action for medical monitoring in Massachusetts also recognizes the senselessness of forcing parties to wait until they are symptomatic to bring suit, at which point no meaningful prospect for cure exists. As demonstrated below, the record evidence,

law, and policy considerations all overwhelmingly support recognition of a cause of action for medical monitoring, as Massachusetts' SJC did.

### a. Philip Morris' Decades of Wrongdoing, Inflicting Profound Harm on Plaintiffs and the Class they Seek to Represent, Supports Plaintiffs' Prayer for Equitable Relief

New York's courts have long held that equity will not suffer a wrong without a remedy. *Strusburgh*, 87 N.Y. at 456; *Williams*, 80 A.D. at 406; *McKenna*, 182 A.D. at 689. The allegations concerning Philip Morris' wrongdoing went unchallenged below, and with good reason. As detailed *supra*, at pp. 7-16, Philip Morris has known for decades that Marlboro cigarettes expose consumers to excessive levels of tars which cause lung cancer, terrible suffering, and frequently death. It also has known for decades that because smoking inflicts harm in a doseresponse fashion, the risk of developing lung cancer could be substantially reduced if cigarettes contained fewer inflammatory and carcinogenic particles, and did not encourage consumers to draw smoke more deeply into the lungs. *See*, *e.g.*, *U.S. v. PMUSA*, 449 F. Supp. 2d at 180; A167-172; A257-275.

Philip Morris' former Director of Applied Research, Dr. William Farone,<sup>29</sup> addressed these points in a detailed report. Dr. Farone explained that there existed

<sup>&</sup>lt;sup>29</sup> Dr. Farone is a highly credentialed scientist with a background in chemistry, product design, and engineering. He worked at Philip Morris between the 1970's and 1980's, supervising 5 divisions with approximately 150 employees, which sought to develop cigarettes with the potential to be less hazardous. Since then, Dr. Farone has served as a reviewer and consultant to the National Institutes of Health on smoking issues. He also has sat on the Scientific Advisory Board of the University of California's Transdisciplinary Tobacco Use Research Center with a

a multitude of ways in which Marlboro cigarettes could have been designed to reduce their excessive carcinogenicity. They include, but are not limited to, increasing the cigarettes' "resistance to draw," utilizing a less carcinogenic "filler" tobacco than Burley tobacco, reducing the protein content of tobacco, avoiding its over-fertilization, reducing or eliminating the use of flue curing, and reducing the use of sugars in Marlboro cigarettes. A260-275.

Far from taking those steps, Philip Morris made conscious design choices which unnecessarily and dramatically increased consumers' risk of developing lung cancer. It reduced Marlboros' filler cut size, and utilized a host of additives and flavorings, including licorice and chocolate, to "facilitate deep inhalation of cigarette smoke[,]" "a key factor in the epidemic of lung cancer in the 20th Century." A270-272. Philip Morris also used Burley tobacco in Marlboros, despite knowledge that such tobacco contains relatively high amounts of tobacco-specific nitrosamines, known to be carcinogenic. A265-266. It likewise declined to employ feasible technologies to reduce nitrosamines in cigarette smoke, including reducing protein content, avoiding over-fertilization and use of nitrate fertilizer, reducing alkaloids in tobacco, and reducing or eliminating use of flue-curing. <sup>30</sup> A260-275.

focus on youth smoking, and was engaged by the United Nations World Health Organization to make recommendations for regulation of tobacco products as part of the global tobacco initiative. A258-259. Dr. Farone's testimony were praised by the Honorable Gladys Kessler in U.S. v. *PMUSA*, 449 F. Supp. 2d at 186.

<sup>&</sup>lt;sup>30</sup> Significantly, these design decisions relate to Marlboros, the only brand at issue in this suit. A268. Marlboro cigarettes have been shown to possess significantly higher levels of tobacco-

As detailed *supra*, this misconduct was accompanied by decades of false public statements, and untold billions in marketing expenditures, to perpetuate a false controversy about the health effects of smoking. *See, e.g., U.S. v. PMUSA*, 449 F. Supp. 2d at 180, 272, 290, 292. In fact, Philip Morris refused to admit that smoking causes lung cancer until 1999. A272. As Dr. Farone explained, Philip Morris was motivated by fear that marketing a safer cigarette would draw attention to the hazards of its top-selling Marlboro brand. Philip Morris thus entered into a "Gentlemen's Agreement" with other manufacturers not to compete on health issues, or conduct biological research on its "as-sold" cigarettes. This agreement served a common interest of all tobacco companies of maintaining the large market of cigarette smokers. In short, Philip Morris placed profit over human life in making cigarette design decisions. A272-273.

It is equally clear that Philip Morris' wrongdoing harmed the Plaintiffs and the class they seek to represent. In addition to Dr. Farone, who possesses expertise in chemistry (A258-259), Plaintiffs presented proofs from experts highly qualified in fields including epidemiology (A132-150), pulmonary and internal medicine (A166-183), occupational and environmental medicine (A154-165), and thoracic

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specific nitrosamines than cigarettes sold by other manufacturers. Id. Marlboros also expose consumers to approximately 3 times higher levels of tobacco-specific nitrosamines than Carlton and Merit (one of Philip Morris' own brands). Id. In other words, Plaintiffs are *not* seeking to impose categorical liability on all cigarette manufacturers, as Philip Morris has sometimes incorrectly claimed. Plaintiffs are challenging the specific design decisions made by one company respecting the Marlboro brand.

surgery and oncology (A184-201). They attest to the proposition that smoking is harmful to the lungs in a dose-response fashion, a well-established principle in the scientific community. *See, e.g.*, A137-138; A170-171; A262-263; A379 ¶51. They likewise explain that Marlboro cigarettes expose smokers to excessive levels of carcinogenic tar, which could have been reduced by one hundred fold, a reduction which would have proportionally reduced the Plaintiffs' risk of developing lung cancer. A260-272; A171-172. Philip Morris' failure to take those steps placed Plaintiffs at substantially elevated risk of developing lung cancer. Id.; A137-138.

The proposed class members are especially vulnerable to lung cancer on account of their ages and smoking histories. A172. Lung cancer is a lethal disease. Without proper surveillance, of 10 victims, 6 will die within 5 years, and 9 will die within 10 years of diagnosis. A143-144. Duration of survival is heavily influenced by whether the cancer is detected early, and lung cancers discovered late do not ordinarily lend themselves to curative treatment. A141-144; A174. Philip Morris' misconduct has placed the members of the proposed class at serious risk of contracting a fatal disease.

Nonetheless, the District Court held that Plaintiffs have no remedy at law. It held that Plaintiffs' claims were untimely even though uncontroverted proofs were that a) Philip Morris' misconduct was ongoing in nature, continuing to inflict new harm up to and including date on which action was commenced, A109 ¶194;

A170- A171 ¶¶9-14; A384 ¶73, and b) no efficacious remedy existed before action was commenced in 2006, A57 ¶¶62-63; A145-146 ¶¶35-37; A205-A206; A207-A208; A374 ¶¶9-10; A384-A385 ¶¶77-78.

As discussed *infra* at Point II, Plaintiffs believe that federal court ruling reflects a misapprehension of New York law which warrants correction by this Court. However, insofar as the federal courts were applying existing New York law, this case now presents a classic example of a wrong without a remedy. Defendant's misbehavior is uncontroverted, egregious, and ongoing. Philip Morris now admits that its product causes grave harm to consumers. On account of that harm, Plaintiffs and the class they seek to represent are all proper candidates for LDCT monitoring, which has the dramatic potential to save human life. A145-150; A173-180; A184-201. Plaintiffs brought suit at the earliest moment they could possibly have done so in good faith, supported by affirmations of highly qualified and credible physicians and scientists.

On that record, to penalize Plaintiffs for perceived 'untimeliness' by dismissing their actions would constitute a serious injustice. Moreover, asking Plaintiffs to wait until they become symptomatic for lung cancer to bring suit hardly constitutes an adequate remedy. Chances of cure at that stage are remarkably slim. Personal injury litigation against a legal giant like Philip Morris also invariably takes years to run its course, by which point the injured party is

usually deceased. Beyond that, wrongful death damages, however justified and generous, cannot restore the decedent to life and health.

In short, there is a compelling case for equity to step in and right an injustice.

## b. The Supreme Judicial Court of Massachusetts Rightly Permitted a Cause of Action for Medical Monitoring Based on Mirror Image Proofs and Pleadings

Donovan v. Philip Morris USA, Inc., 06-12234-DJC, was filed in the United States District Court for the District of Massachusetts, shortly after the commencement of this action. It is a companion to this case, brought on behalf of class of Massachusetts residents, aged 50 or older, with at least 20 pack-year histories of Marlboro use, who smoke Marlboro cigarettes or quit smoking within one year of the complaint's filing, and are were not diagnosed with or under investigation by a physician for suspected lung cancer. The *Donovan* plaintiffs also sought establishment of an LDCT surveillance program. Their pleadings and proofs parallel those in the instant action in all material respects. *See Donovan I*, 914 N.E.2d at 895-898. Discovery proceeded simultaneously in the two cases.

As in this case, Philip Morris attempted to argue in *Donovan* that the claims were not cognizable and/or were untimely. *Id.* at 895-896. The Honorable Nancy Gertner certified to the SJC the question of whether "plaintiffs' suit for medical monitoring, based on subclinical effects of exposure to cigarette smoke and

increased risk of lung cancer, state[d] a cognizable claim and/or permit a remedy under Massachusetts state law[.]" She also asked the SJC whether "the statute of limitations governing those claims [had] expired[.]" *Donovan I*, 914 N.E.2d at 894-895.

In essence, those are the same questions certified to this Court by the Second Circuit. Accordingly, *Donovan I* provides this Court with the benefit of detailed analysis from a sister court, presented with the same pleadings and proofs. Plaintiffs respectfully submit that the SJC's analysis of the cognizability and timeliness of the very same medical monitoring claims are well-reasoned, and that this Court should reach a similar conclusion.

Turning to the first certified question in *Donovan I*, the SJC answered it in the affirmative, holding that Plaintiffs had stated a cognizable claim which permitted a remedy under Massachusetts law. 914 N.E.2d at 895. The SJC rejected Philip Morris' argument that the Plaintiffs must offer proof of physical harm manifested by objective symptoms to state a claim, sensibly recognizing that the purpose of LDCT surveillance is to detect lung cancer at early stages, when treatment is far more likely to be effective. *Id.* at 898-900. Instead of requiring Plaintiffs to wait for the onset of symptoms – by which time lung cancer has generally progressed beyond the point of treatment – the SJC allowed Plaintiffs to

bring a claim where they can show "subclinical" or "subcellular" changes triggered by smoking. *Id.* at 898-902.<sup>31</sup>

In reaching that conclusion, the SJC aptly observed that "[t]here 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." Id. at 900. As it recognized, a pedestrian negligently struck by a motorist may also "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." Id. This is consistent with New York law. See New York Pattern Jury Instructions (Civil) (3d Ed. 2012) ("P.J.I.") 2:2865 (discussing plaintiff's entitlement "to recover the amount of reasonable expenditures for medical ... services" including "diagnostic expenses"; adding that if plaintiff will require such expenses "in the future[,]" jurors should include such an award in verdict). See also generally Gallagher v. Samples, 6 A.D.3d 659 (2d Dept. 2004)(denying ability to seek future medical expenses was "fundamental" error).

Notably, numerous other courts have recognized that "a present physical injury" standard, which might require Plaintiffs to establish symptoms of a disease in order to seek surveillance, is inconsistent with the medical monitoring] theory of recovery. *See, e.g., Friends for All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 825 (D.C. Cir. 1984); *Meyer v. Fluor Corp.*, 220 S.W.3d 712, 717 (Mo. 2007); *Ayers v. Township of Jackson*, 525 A.2d 287, 315 (N.J. 1987).

Thus, the SJC rejected the irrational approach requiring Plaintiffs to display present physical injury manifested in "objective symptoms" before seeking relief, which would defeat the utility of monitoring. *Id.* at 900. It found that Plaintiffs had "produced sufficient proof of 'impact,' to safeguard against false claims" by proffering "evidence of physiological changes caused by smoking" and "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." *Id.* at 900-901 (citations omitted).

Significantly, the very same proof concerning physiological changes caused by smoking Marlboros was offered in this case. In fact, the expert report of pulmonologist, Albert Miller M.D., FACP, FCCP, which formed the basis of the SJC's findings, was offered in *Donovan* and *Caronia*. *Compare Donovan* 1, 914 N.E.2d at 896-897 (discussing how smoking Marlboros causes damage "to the tissues and structures of their lungs[,]" damages "the genes of the airway cells and impair[s] the repair mechanisms that protect against genetic damage, resulting in increased carcinogenic genetic mutations and loss of protective repair processes"), *with* A165-182 (Dr. Miller's Report). The SJC's finding that these physiological changes place asymptomatic twenty-pack year smokers "at a substantially greater risk of cancer," *Donovan* 1, 914 N.E.2d at 901, is plainly correct, as detailed *supra*.

The SJC continued by observing that "[m]odern living has exposed people to a variety of toxic substances" and "[i]llness and disease from exposure to these substances are often latent, not manifesting themselves for years or even decades after the exposure." *Donovan I*, 914 N.E.2d at 901. It recognized that "[s]ubcellular or other physiological changes" may not be symptoms of an illness, but nonetheless offer warning signs to a trained physician that "indicate[] a substantial increase in risk of contracting a serious illness[.]" *Id.* Accordingly, it held that "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." *Id.* 

Recognizing that "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[,]" the SJC Court wrote, "[w]e must adapt to the growing recognition that to toxic substances and radiation may cause substantial injury which should be compensable even if the full effects are not immediately apparent." Id. at 901 (citation omitted, emphasis added). Thus, "[w]hen 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." *Id.* It further held that "[n]o 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[,]" a rule intended to "address any concern over false claims, yet permit a genuinely injured person to recover legitimate expenses without having to overcome insurmountable problems of proof in this difficult and complex area." *Id.* (citation omitted).<sup>32</sup>

The SJC then articulated the elements in a medical monitoring cause of action. It held that a plaintiff must establish that:

(1) [t]he 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)

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<sup>&</sup>lt;sup>32</sup> Consistent with the ruling in *Donovan I*, California's Supreme Court has written that "[i]t bears emphasizing that allowing compensation for medical monitoring costs 'does not require courts to speculate about the probability of future injury. It merely requires courts to ascertain the probability that the far less costly remedy of medical supervision is appropriate." Potter v. Firestone Tire & Rubber Co., 863 P.2d 795, 824 (Cal. 1993)(emphasis added)(quoting Paoli I, supra, 916 F.2d at 852). That ruling makes perfect sense. "[S]cience may well counsel medical intervention with respect to a known health risk long before it reaches the point where the law would regard its occurrence as reasonably certain." *Id.* (citation omitted). Accordingly, "recovery of medical monitoring damages should not be dependent upon a showing that a particular cancer or disease is reasonably certain to occur in the future." *Id. See also Ayers*, 525 A.2d at 312. The same ruling should be reached here.

the present value of the reasonable cost of such tests and care, as of the date of the filing of the complaint.

*Id.* at 902. Plaintiffs respectfully request that this Court reach essentially the same ruling.<sup>33</sup>

In *Donovan*, the SJC also addressed the form that medical monitoring awards should take, albeit in the context of a dispute between two individuals. *Id.* at 989, 902 n.12. As it wrote, "[b]ecause 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." *Id.* at 902, n.12. Thus, the SJC favored creation of a fund, wherein "the lump sum usually awarded for future medical expenses may ... be ordered paid into an appropriate account and drawn down as the expenses are actually incurred." *Id.* (citations omitted). It explained that if the lump sum is "not used, the award, or

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<sup>&</sup>lt;sup>33</sup> In three respects, clarifications might improve upon the *Donovan I* ruling. First, this Court should clarify that the "negligence" concept embraces any theory of fault properly supported by evidence (e.g., strict liability). Second, it should be made explicit that New York's black letter "substantial factor" causation standard applies to the second element. See, e.g., Voss v. Black & Decker Mfg. Co., 59 N.Y.2d 102, 109-110 (1983); Derdiarian v. Felix Contracting Corp., 51 N.Y.2d 308, 315 (1980); Nallan v. Helmsley-Spear, Inc., 50 N.Y.2d 507, 520 (1980); Dunham v. Canisteo, 303 N.Y. 498, 505-506 (1952). That clarification is important, as this point was misapprehended by the District Court, which mistakenly applied a 'but for' causation standard (A418), inconsistent with New York law. Id. See also P.J.I. 2:70; Commentary on P.J.I., 2:70; Pavlou v. City of New York, 21 A.D.3d 74, 82-83 (1st Dept. 2005) ("The defense's argument that the accident would have occurred even without this negligence amounts to the use of a 'but for' analysis . . . this type of 'but for' approach to tort liability has been rejected as the test of proximate cause.")(citations omitted), aff'd, 8 N.Y.3d 961 (2007). Third, although in this case, it is manifest that subcellular harm exists, this Court should not resolve on this record whether surveillance will be permitted in the absence of such damage. That issue should await a case and developed record concerning such circumstances.

balance thereof, may be returned to the defendant who was obligated to make such payment[,]" and that "[a] plaintiff's reasonable attorney's fees and costs may be paid out of such award." *Id.* (*citing Hansen v. Mountain Fuel Supply Co.*, 858 P.2d 970, 982 (Utah 1993)).

Notably, the United States District Court Judge interpreting this ruling in Massachusetts recognized that "the SJC's characterization of the remedy suggests equity," because "[1]egal damages, while intended to compensate the plaintiff for some harm, may be used for anything." *Donovan II*, 268 F.R.D. at 25. "Equity, on the other hand, is specific" and "'aspire[s] to prevent harm, or undo it, rather than let it happen and compensate for it." *Id.* (*citing* Douglas Laycock, The Death of the Irreparable Injury Rule, 103 Harv. L. Rev. 687, 696 (1990)). Thus while "[t]he SJC opinion acknowledged that in some circumstances, legal damages" might be appropriate, such as where "a medical test is easily accessible and can be purchased[,] ... a class presents different issues -- including lack of doctors and access to technology." *Id.* 

The creation of a monitoring fund has found favor outside of Massachusetts. In one of the leading cases concerning the propriety of medical monitoring claims, the Supreme Court of New Jersey characterized a surveillance fund as "a highly appropriate exercise of the Court's equitable powers." Ayers v. Township of Jackson, 525 A.2d 287, 314 (N.J. 1987)(emphasis added). See also Burns v.

Jaquays Mining Corp., 752 P.2d 28, 34 (Ariz. Ct. App. 1987); Potter v. Firestone Tire & Rubber Co., 863 P.2d 795, 825, n.28 (Cal. 1993); Petito v. A.H. Robins Co., 750 So. 2d 103, 106 (Fla. Dist. Ct. App. 1999); Hansen, 858 P.2d at 982. Plaintiffs respectfully request that this Court reach the same conclusion.

Following its discussion of the form of relief available, the SJC clarified that the "single controversy rule," which in Massachusetts ordinarily requires a party to include all related claims against the opposing party, would not bar a future action if a plaintiff subsequently contracts cancer. *Donovan I*, 914 N.E.2d at 902. As it explained, "[t]his rule was never intended to address the problem of toxic torts, where a disease may be manifested years after the exposure." *Id.* The SJC reasoned that, "[i]n 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." *Id.* 

The SJC added that "the single controversy rule would not apply because the subsequent cause of action would not accrue until the disease is manifested." *Id.* (citation omitted). Thus, it held 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." *Id.* This holding is well reasoned, and finds broad national support, including in New York. *See Abbatiello v. Monsanto Co.*,

522 F. Supp. 2d 524, 538 (S.D.N.Y. 2007)("Where the statute of limitations has run on one exposure-related medical problem, a later exposure-related medical problem that is separate and distinct is still actionable under New York's two-injury rule.")(citing Braune v. Abbott Labs., 895 F. Supp. 530, 555 (E.D.N.Y. 1995); Fusaro v. Porter-Hayden Co., 145 Misc. 2d 911 (N.Y. Sup. Ct. 1989), aff'd, 170 A.D.2d 239 (1st Dept. 1991)). See also Burns, 752 P.2d at 31; Petito, 750 So. 2d at 106; Ayers, 525 A.2d at 300-301. It should be adopted in this decision as well.

Finally, the SJC rejected Philip Morris' argument that the *Donovan* plaintiffs' claims were time-barred. *Donovan I*, 914 N.E.2d at 894-895, 903-904. As it explained, in Massachusetts, a cause of action ordinarily 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." *Id.* at 903 (citation and quotations omitted). However, while that state's courts "do not require that a plaintiff have notice of a breach of duty before a cause of action may accrue," they "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." *Id.* (citation and quotations omitted). As the SJC explained "[i]n 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." *Id*.

#### The SJC concluded that:

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.

Id.

Plaintiffs respectfully request that the Court adopt a similar approach, which would put right the inequities created by the federal court's rulings in this case. Based on a mechanical (and Plaintiffs believe, incorrect) application of inapposite precedents, the federal courts held that Plaintiffs' claims accrued at the moment when they reached 20 pack-years of smoking. Thus, they deemed Plaintiffs' claims untimely even if Plaintiffs had no idea that crossing such a threshold rendered them proper candidates for surveillance, and even if no form of efficacious surveillance existed for which they might make a prayer for relief, or incur expenses.

In contrast, the SJC appreciated the reality that at-risk but asymptomatic Plaintiffs may not appreciate that they are proper candidates for medical surveillance without guidance from a physician. *Id.* It likewise recognized the futility of forcing plaintiffs to commence medical monitoring actions when no diagnostic testing is "accepted in the medical community as an efficacious method." *Id.* Such an approach would unfairly penalize persons, like the Plaintiffs, who did not bring suit when there was no efficacious relief available, and might also tend to encourage premature lawsuits destined to fail. The rule the SJC crafted equitably balanced those considerations, ensuring that those wronged are not left without a remedy.<sup>34</sup>

Notably too, by tying accrual to the point at which available diagnostic testing is accepted in the medical community as an efficacious method of lung cancer screening or surveillance, the SJC rendered timeliness a common issue subject to resolution on a class-wide basis. *See Donovan II*, 268 F.R.D. at 19-20 ("Since the statute of limitations determination depends on evidence that is unaffected by individual inquiries – whether and when LDCT screening became the standard of care – the statute of limitations does not prevent class

<sup>&</sup>lt;sup>34</sup> See Abbatiello, supra, 522 F. Supp. 2d at 538 ("If no separate cause of action for medical monitoring were available, [plaintiffs] face a dilemma: either (1) bring a lawsuit, and be denied recovery for the increased risk of contracting serious illnesses; or (2) bear the financial burden of medical monitoring and risk being barred by the statute of limitations from suing later in the unfortunate event that a serious illness were contracted. The Court is not persuaded that the New York Court of Appeals would endorse such a result.")(emphasis added).

certification"). The practical importance of that ruling, which allowed the plaintiffs to proceed forward on a class-wide basis, deserves emphasis. While LDCT monitoring has life-saving potential, litigating against Philip Morris is a daunting endeavor. Both economics involved and the programmatic nature of the remedy require that litigation of a surveillance action such as this case be pursued on a class-wide basis, or not at all.<sup>35</sup>

In sum, on mirror image pleadings and proofs, the SJC recognized that the plaintiffs' claims were cognizable and timely, and expressed approval of the establishment of a medical monitoring fund endowed by Philip Morris to cover LDCT surveillance. As demonstrated below, this outcome is both consistent with New York jurisprudence, and an equitable result strongly supported by widely recognized policy considerations.

# c. An Equitable Medical Monitoring Cause of Action is Consistent With Existing New York Law

As the Second Circuit observed, New York's Appellate Division has permitted claims for medical monitoring since at least 1984. A721. In *Askey v. Occidental Chemical Corp.*, 102 A.D.2d 130 (4th Dept. 1984), the Appellate Division considered plaintiffs who had "an increased risk of cancer, genetic damage and other illnesses by reason of their exposure to the toxic chemicals

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<sup>&</sup>lt;sup>35</sup> Because the relief Plaintiffs are seeking is equitable in nature (A373 ¶2; A384-386 ¶75-82 A391-392), this cause of action is governed by the six-year statute of limitations in C.P.L.R. 213(1). *See Kaufman v. Cohen*, 307 A.D.2d 113, 118 (1st Dept. 2003)(citing cases).

emanating from the landfill, but whose physical injuries [we]re not evident[.]" *Id*. at 131. Like the SJC in Donovan I, Askey held that recovery for medical available, and rejected any "objective symptomology" monitoring was requirement. Instead it wrote that a plaintiff "can recover all damages which he can show resulted or would result therefrom, even though at the time the action is commenced no serious damage to the plaintiff has developed[]," and that "[t]he defendant is liable for reasonably anticipated consequential damages which may flow later from that invasion although the invasion itself is an injury too slight to be noticed at the time it is inflicted." *Id.* at 136 (quotations and citations omitted). Because the record showed that the plaintiffs "exposed to toxic chemicals emanating from the landfill ha[d] an increased risk of invisible genetic damage and a present cause of action for their injury," the Askey court wrote that that they could "recover all 'reasonably anticipated' consequential damages." Id. at 137.

In so holding, the *Askey* Court wrote, "[t]here is no doubt that such a remedy would permit the early detection and treatment of maladies and that as a matter of public policy the tort-feasor should bear its cost." Id. (emphasis added). Of course, like the *Askey* plaintiffs, Plaintiffs in this case were "exposed to toxic chemicals" in Marlboro cigarettes, and have "an increased risk of invisible genetic damage." Id.; A167-172.

Along with Ayers v. Jackson Township, supra, Askey is considered one "of the early cases establishing that traditional tort law principles support recovering medical monitoring damages and both disclaim the notion that present physical injury must be shown." Meyer v. Fluor Corp., 220 S.W.3d 712,718 n.5 (Mo. 2007). Since Askey, New York's intermediate appellate and trial-level courts have recognized that persons tortiously exposed to toxic substances, who can show that they have a rational basis for fear of developing cancer, may pursue legal actions seeking medical monitoring. See, e.g., Baity v General Elec. Co., 86 A.D.3d 948, 950 (4th Dept. 2011)(motion for summary judgment dismissing medical monitoring claims properly denied); Osarczuk v. Associated Universities, Inc., 36 A.D.3d 872, 877 (2d Dept. 2007) ("medical monitoring and other injunctive relief" available as remedies for negligence and gross negligence claims); Dangler v. Town of Whitestown, 241 A.D.2d 290, 294 (4th Dept. 1998)(trial court erred in excluding evidence on need for medical monitoring); Acevedo v. Consolidated Edison Co., 189 A.D.2d 497, 502 (1st Dept. 1993)(discussing compensability of medical monitoring costs under workers' compensation system); Gerardi v. Nuclear Utility Services, Inc., 149 Misc. 2d 657, 657-59 (Sup. Ct. West. Co. 1991)(holding that plaintiffs "stated a cause of action for ... future medical expenses for lifetime medical monitoring and diagnostic treatment as a result of the negligence of defendants"). These rulings led the District Court to predict that this

Court would recognize Plaintiffs' standalone cause of action for medical monitoring. A403-411.

That prediction was also in harmony with numerous federal courts in this State. Indeed, "most of the federal district courts sitting in New York State have ruled that medical monitoring is available as a remedy for tortious exposure to carcinogenic substances even if the plaintiffs have not exhibited symptoms of cancer, concluding that the New York Court of Appeals would recognize such a claim." A724.

That includes *Gibbs v. E.I. DuPont de Nemours & Co.*, which concerned exposure to compounds subjecting the plaintiffs to a risk of developing bladder cancer. 876 F. Supp. 475, 476 (W.D.N.Y. 1995). In *Gibbs*, "[n]one of the named plaintiffs claim[ed] to have any present physical injury." *Id.* at 477. As in the instant case, the plaintiffs had not been diagnosed with cancer, and sought "injunctive relief in the form of a court-administered fund paid for by defendants which would cover the reasonably anticipated costs of a medical monitoring program for bladder cancer for the lifetime of the class members." *Id.* Citing *Askey* and two decisions of the United States Court of Appeals for the Third Circuit, *In re Paoli R.R. Yard PCB Litigation*, 916 F.2d 829 (3d Cir. 1990) ("*Paoli I*"), and 35 F.3d 717 (3d Cir. 1994) ("*Paoli II*"), the District Court rejected the argument that

New York does not recognize a cause of action for medical monitoring without present physical injury. As it wrote:

Although the New York courts have not conclusively ruled on the availability of a claim for medical monitoring in the absence of present injury, *I believe that Askey accurately represents a growing national acceptance of a such a claim* . . . and would be embraced by the New York Court of Appeals. Thus, the medical monitoring claim shall stand.

Gibbs, 876 F. Supp. at 479 (emphasis added, citations omitted).

To the same effect is *Abbatiello v. Monsanto Co.*, 522 F.Supp.2d 524, 536 (S.D.N.Y. 2007). There, the District Court similarly predicted that "in cases involving exposure to toxic materials, the New York Court of Appeals would recognize an independent cause of action for medical monitoring" even "where the present damage is not a physical injury but the financial burden associated with periodic medical monitoring[.]" *Id.* at 538.<sup>36</sup>

In sum, *Askey* declared almost 30 years ago that parties exposed to hazardous substances may pursue medical monitoring, and that as a matter of public policy, the wrongdoer should bear those costs. Since then, New York's courts have overwhelmingly permitted such parties to pursue medical monitoring,

of the exposure.").

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<sup>&</sup>lt;sup>36</sup> See also Sorrentino v. ASN Roosevelt Center, 579 F.Supp.2d 387, 390 (E.D.N.Y. 2008) (concluding that the intermediate appellate courts had "expressly recognized an independent cause of action for medical monitoring"); Beckley v. United States, 1995 U.S. Dist. LEXIS 14599, at \*11 (S.D.N.Y. 1995) ("In New York, courts recognize a separate cause of action, with a relaxed standard of proof, for medical monitoring expenses due to exposure to toxic chemicals when the plaintiff cannot show with reasonable certainty that he will contract a disease as a result

either as a form of relief or an independent cause of action. Decisions of the federal courts sitting in diversity are in accord. Thus, recognizing such a cause of action in this case would allow a remedy for grave wrongdoing, without engendering any unfair surprise. This too counsels strongly in favor of allowing Plaintiffs' claims to proceed.

## d. As Courts Nationwide Have Recognized, Sound Public Policy Considerations Support Allowing Plaintiffs to Seek Medical Monitoring

The rulings in *Askey*, *supra*, and *Donovan I*, *supra*, are by no means outliers. In the three decades since *Askey* was written, the concept of medical monitoring has gained wide acceptance. *See*, *e.g.*, *Paoli I*, 916 F.2d at 849-852; *Friends For All Children, Inc. v. Lockheed Aircraft Corp.*, 746 F.2d 816, 826 (D.C. Cir. 1984); *Gibbs*, 876 F. Supp. at 477-489; *Merry v. Westinghouse Electric Corp.*, 684 F. Supp. 847, 849 (M.D. Pa. 1988); *Meyers*, 220 S.W.3d at 718; *Ayers*, 525 A.2d at 312; *Hansen*, 858 P.2d at 970.

The reason for this widespread acceptance is that a host of public policy considerations support allowing parties to seek medical monitoring. First, "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." *Potter*, 863 P.2d at 824 (citations omitted). Plaintiffs and the class they seek to represent were exposed to toxic chemicals in Marlboro smoke, creating an

enhanced risk of developing lung cancer. Early diagnosis plays a critical role in successful treatment. Allowing this action to proceed has the potential to save human lives, increase productivity, and avoid terrible suffering.

Second, allowing parties to recover the cost of this medical monitoring may serve an important role deterring misconduct. *Potter*, 863 P.2d at 824 (citing cases). "The difficulty of proving causation, where the disease is manifested years after exposure, has caused many commentators to suggest that tort law has no capacity to deter polluters, because the costs of proper disposal are often viewed by polluters as exceeding the risk of tort liability." Ayers, 525 A.2d at 311-312 (citing Ginsberg & Weiss, Common Law Liability for Toxic Torts: A Phantom Remedy, 9 Hofstra L. Rev. 859, 903-04 (1981); Rosenberg, The Causal Connection in Mass Exposure Cases: A 'Public Law' Vision of the Tort System, 97 Harv. L. Rev. 851, 862-863 (1984); Trauberman, Statutory Reform of 'Toxic Torts': Relieving Legal, Scientific, and Economic Burdens on the Chemical Victim, 7 Harv. Envtl. L. Rev. 177, 209-210 (1983)). Permitting recovery for reasonable pre-symptom, medicalsurveillance expenses subjects bad actors to "significant liability when proof of the causal connection between the tortious conduct and the plaintiffs' exposure to chemicals is likely to be most readily available." *Id.* at 312.

Third, "[t]he availability of a substantial remedy before the consequences of the plaintiffs' exposure are manifest may also have the beneficial effect of preventing or mitigating serious future illnesses and thus reduce the overall costs to the responsible parties." *Ayers*, 525 A.2d at 312; *Burns*, 752 P.2d at 33. As detailed *supra*, early detection of lung cancer can dramatically improve the prospects for successful. In addition to benefiting the proposed class, reducing lung cancer mortality could have the benefit of reducing Philip Morris' the financial burden in litigating wrongful death actions.

Fourth, "societal notions of fairness and elemental justice are better served by allowing recovery of medical monitoring costs. That is, 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." *Potter*, 863 P.2d at 824 (citations omitted). Nor would it be equitable for the State, as a payer of last resort, to bear the costs of monitoring, while the wrongdoer avoids responsibility. Indeed, diagnosing illness at early stages may even reduce the financial burden on health insurance providers and the State. This too counsels in favor of allowing the instant claims to proceed.

Finally, it is worth underscoring that the relief sought herein is fundamentally different from that at issue in a personal injury action. Plaintiffs are not asking for punitive damages. Nor are they seeking a monetary award to redress lost wages, pain and suffering, or loss of consortium. In fact, the individual

Plaintiffs do not stand to receive a single dollar if they prevail at trial. The relief for which Plaintiffs pray is establishment of a program which would offer at-risk individuals access to a life-saving technology. As discussed *supra*, the SJC and many courts nationwide have favored structuring a medical monitoring fund to endow such programs, recognizing that such activity is "is well within a court's equitable powers," *Petito*, 750 So. 2d at 106, and would help to ensure that the medical surveillance funds are used for their intended purpose. *Ayers*, 525 A.2d at 314; *Hansen*, 858 P.2d at 982; *Potter*, 863 P.2d at 825, n.28. The equities weigh strongly in favor of allowing Plaintiffs to seek such relief.

## e. Public Policy Considerations Support the SJC's Holding that Plaintiffs' Claims are Not Time-Barred

The SJC's ruling that Plaintiffs' claims were not time-barred is also strongly supported by important policy considerations. First, it is the defendant who bears the burden of pleading and proving the affirmative defense of laches. *See Dreikausen v. Zoning Bd. of Appeals*, 98 N.Y.2d 165, 173 n.4 (2002); *Galyn v. Schwartz*, 56 N.Y.2d 969, 972 (1982). No one could plausibly accuse the Plaintiffs of such delay. Indeed, Philip Morris made no serious attempt to establish that Plaintiffs engaged in unreasonable delay before the District Court, nor would such a charge bear scrutiny. As discussed, Plaintiffs brought suit at the earliest possible moment when an efficacious form of surveillance relief was available. Before the publication of the 2006 New England Journal of Medicine article, they could not

have, in good faith, sought LDCT or any lung cancer surveillance. Indeed, Philip Morris' experts maintained that LDCT surveillance remained untested even after this suit's filing. A203-205; A253. They also admitted that no other efficacious form of surveillance to diagnose lung cancer at early stages was available before 2006, which the Plaintiffs could have sought. A203-205.

Second, the concerns typically invoked by defendants invoking a timeliness defense, concerning prejudice and stale evidence, are inapplicable to this action. Far from being lost to time, Philip Morris' misconduct is a matter of public record, memorialized in myriad public documents including detailed Reports of the Surgeon General.<sup>37</sup> Indeed, Philip Morris litigates its misconduct on a daily basis in federal and state courts, having provided in the process scores of depositions, while producing and authenticating thousands of documents. *See, e.g., U.S. v. PMUSA*, 449 F. Supp.2d at 1; *Haglund v. Philip Morris*, Inc., 847 N.E.2d 315 (Mass. 2006);

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<sup>&</sup>lt;sup>37</sup> See, e.g., 2012 Surgeon General's Report at p.535 (detailing cigarette manufacturers' attempts to capture the youth market, illustrated by "[a] 1959 Philip Morris market research analysis which concluded that "people want mildness....We also should win more young nonsmokers with mildness")(emphasis added); p.520 (citing Philip Morris' internal documents, and writing that "[f]rom internal industry documents, depositions, and trial testimony, it is clear that the tobacco industry understands the need to be accepted, particularly among youth, and has attempted to exploit this need through its marketing efforts"); p.536 (noting that a "review of internal documents of the tobacco industry ... recounts how Philip Morris scientists began experimenting with additives in their brands, including ammonia, diammonium phosphate, and various ethanolamines and carbonates"); p.557 (describing how tobacco industry "used its programs on youth access to undermine tobacco control efforts" and referencing "e-mails in 1996 between high-level Philip Morris executives [which] revealed that Philip Morris placed ads ... in locations where legislators would be sure to see them [and] used the[ir] presence ... to argue against the need for government funding of further tobacco control efforts.")(internal citations omitted).

Aspinall v. Philip Morris Co., 813 N.E.2d 476 (Mass. 2004). Philip Morris also appreciates that it has not achieved "finality" vis-à-vis the proposed class members. After all, it continues to market its lethal product to this day, subjecting Plaintiffs and the class they seek to represent to ongoing harm. Philip Morris surely understands that any one of the class members may be diagnosed with lung cancer in the future, at which time a personal injury lawsuit would unquestionably be timely.<sup>38</sup> In short, the traditional policy rationales for holding claims to be timebarred have little, if any, application here, and Philip Morris has not been prejudiced by any undue delay. *Galyn*, 56 N.Y.2d at 972 (laches unavailable where party failed to show prejudice by adversary's alleged undue delay)(citation omitted).

Third, any argument that Plaintiffs' claims are time-barred is belied by the nature of Philip Morris' misconduct. Before the federal courts, Philip Morris did not seriously dispute Plaintiffs' showing that Marlboros have been excessively carcinogenic for decades, relative to safer alternative designs. Nor does it dispute that the years of smoking Marlboros immediately preceding the filing of this action substantially contributed to increased risk of developing cancer. A139-143; A170-171.

<sup>&</sup>lt;sup>38</sup> Of course, the Plaintiffs themselves are also living, which is rarely the case in personal injury claims against Philip Morris.

On that record, Philip Morris has no reasoned basis for challenging the timeliness of this case. New York's "continuing tort" doctrine has long recognized that a defendant does not gain a prescriptive right to continue engaging in misconduct if the plaintiff does not bring suit at the earliest moment when he experiences its harmful effects. Instead, a defendant's continuing misconduct remains subject to suit where, as here, it continues to inflict new and aggravate old harm. *Pieczonka v. Pullman Co.*, 89 F.2d 353, 356 (2d Cir. 1937)(Learned Hand, J.); *Sodowski v. Long Island R.R.*, 292 N.Y. 448, 457-458 (1944).

To be sure, in *Jensen v. Gen. Elec. Co.*, this Court wrote that in personal injury actions seeking money damages, the discovery rule in CPLR 214-c(2) displaced the rationale for continuing tort doctrine. 82 N.Y.2d 77, 86 (1993). Importantly, however, *Jensen* also held that "CPLR 214-c(2) applies by its terms only to actions 'to recover damages,'" and does not "affect or purport to affect the availability to a party of seeking injunctive equitable relief." *Id.* at 89-91. This Court expressly limited its holding to actions seeking money damages, while holding that "the common-law accrual method [remains] applicable" in actions seeking equitable or injunctive relief. *Id. See also Covington v. Walker*, 3 N.Y.3d 287, 292-293 (2004)(applying continuing wrong doctrine in context of divorce case; emphasizing that adopting a contrary rule "would further none of the policy considerations at the heart of our statutes of limitations jurisprudence").

In this action, Plaintiffs seek only injunctive relief. A375-386 ¶¶19, 75-82. Consequently, the continuing tort doctrine remains in effect, rendering Plaintiffs' claims timely. *Jensen*, 82 N.Y.2d at 86-91. *See also, e.g., Syms v. Olin Corp.*, 408 F.3d 95, 110 n.10 (2d Cir. 2005); *Orange Env't v. County of Orange*, 860 F. Supp. 1003, 1030 (S.D.N.Y. 1994)("*Jensen* only applies to damages and does not purport to affect the availability of suits for injunctive relief.").

Fourth, Philip Morris' invocation of timeliness defense represents an attempt to place square pegs into round holes. That argument was based on the mistaken view that all claims accrue at injury, and that Plaintiffs sustained an injury when they amassed a 20 pack-year history. That is incorrect. Amassing 20 pack-years is not an "injury." Subcellular harm occurs from the time a person smokes his first Marlboro, and grow more profound over time in a dose-response fashion. A169-172. Twenty pack-years is simply a threshold at which Plaintiffs' experts opine that medical monitoring becomes advisable for persons over 50 years of age. Id.

Tying accrual to the point at which one crosses the 20 pack-year threshold misapprehends the nature of a medical monitoring claim. In such a case, "[t]he injury for which compensation is sought is not a present physical injury. Instead, medical monitoring damages compensate the plaintiff for the quantifiable costs of periodic medical examinations reasonably necessary for the early detection and treatment of latent injuries caused by the plaintiff's exposure to toxic substances."

Meyer, 220 S.W.3d at 718 (citing Paoli I, 916 F.2d at 850). Philip Morris' experts admit that there was no medical surveillance available for the early detection and treatment of latent injuries caused by the plaintiff's exposure to toxic substances prior to 2006. A204-206. Thus, no costs were incurred, and there was no relief that Plaintiffs could, in good faith, have sought in a prayer for relief. On those peculiar facts, the SJC rightly found that Plaintiffs' claims had not accrued. See also Hansen, 858 P.2d at 979 & n.12 (if no test exists "for detecting the onset of the illness before it would be apparent to the layperson[,]" "then periodic monitoring is pointless and no cause of action for monitoring exists.... Of course, if a test is later developed that will detect the disease, a plaintiff would retain the right to demonstrate at some later date the effectiveness of the test and be compensated for utilizing it, if all other elements of the cause of action are present.").

Finally, the rationale behind the SJC's timeliness ruling deserves emphasis, as it is precisely attuned to the allegations and record presented here. As that Court recognized, "[b]ecause 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." *Donovan I*, 914 N.E.2d at 903. That approach avoids the harsh and irrational result for which Philip Morris advocated below, which would deem Plaintiffs' claims untimely even if they had no idea that crossing such

a threshold rendered them proper candidates for surveillance, and no form of efficacious surveillance existed. The SJC's ruling also takes into account the reality that asymptomatic Plaintiffs may not appreciate that they are proper candidates for medical surveillance – particularly for a novel form not widely in use – without guidance from a physician. *Id. See generally Beckley, supra*, 1995 U.S. Dist. LEXIS 14599, at \*12 (explaining that "plaintiff's cause of action [could] accrue[] due to an advance in medical knowledge")(citation omitted). The SJC further recognized the futility of requiring plaintiffs to commence monitoring actions when no diagnostic testing is "accepted in the medical community as an efficacious method." *Donovan I*, 914 N.E.2d at 903. The rule it announced equitably balanced those considerations to ensure that those wronged are not left without a remedy based on a rigid application of inapposite precedents.

# II. PLAINTIFFS' CLAIMS SOUNDING IN NEGLIGENCE AND STRICT LIABILITY WERE WRONGLY DISMISSED BASED ON A MISREADING OF BOTH BLACK LETTER NEW YORK LAW AND THE EVIDENCE

For the reasons discussed above, Plaintiffs believe that they have stated a cognizable and timely equitable cause of action for medical monitoring relief. Recognizing such a cause of action is consistent with New York law, supported by important policy considerations, and would permit Plaintiffs to go forward and seek establishment of an LDCT surveillance program on a class-wide basis.

However, in the event that this Court views medical monitoring as a form of equitable relief, rather than an independent cause of action, Plaintiffs still have alleged cognizable and timely negligence, strict liability, and breach of warranty claims. In Plaintiffs' view, these claims were wrongly dismissed based on the federal courts' misreading of New York timeliness and warranty law. Plaintiffs respectfully request that this Court correct those misapprehensions, which are set forth in Points II and III, *infra*. Such a ruling would be fully consistent with the Second Circuit's certification order, which expressly stated that it did not intend to limit the scope of this Court's analysis, and invited this Court "to expand upon or alter these questions as it deems appropriate." A746.

### A. The Statutory Scheme

Timeliness is a creature of statute in New York. Article 2 of the CPLR sets forth time periods, and then identifies the type of actions that are subject to each limitation period. Several limitation periods warrant discussion.

C.P.L.R. § 214(5) provides that "except as provided in [C.P.L.R.] sections 214-b, 214-c and 215[,]" "an action to recover damages for a personal injury" must be commenced within 3 years. C.P.L.R. § 214-c(2) provides that "the three-year period [relating to] an action to recover damages for personal injury ... caused by the latent effects of exposure ... shall be computed from the date of the discovery of the injury by the plaintiff or from the date when through the exercise of

reasonable diligence such injury should have been discovered...." Finally C.P.L.R. § 213(1) states that "an action for which no limitation is specifically prescribed by law" must be commenced within 6 years.

C.P.L.R. § 203(a) also addresses the method of computing periods of limitation. It states that such computations "shall be computed from the time the cause of action accrued...."

C.P.L.R. §§ 214(5) and 214-c(2) do not address the limitations period for negligence or strict liability theories of misconduct. Instead, they address a type of harm: "personal injury." However, Plaintiffs do not allege personal injury in this case. They allege an elevated risk of harm and a corresponding need for surveillance, which is quite different.

These two provisions also are also inapposite because they are expressly limited to actions "to recover damages." C.P.L.R. § 214(5); C.P.L.R. § 214-c(2). In this case, Plaintiffs do not seek to recover money damages. They seek equitable or injunctive relief, which is not governed by these provisions. *See Kaufman v. Cohen*, 307 A.D.2d 113, 118 (1st Dept. 2003)("Where the relief sought is equitable in nature, the six-year limitations period of N.Y. C.P.L.R. 213(1) applies")(citing cases); *see also Bano v. Union Carbide Corp.*, 361 F.3d 696, 710 (2d Cir. 2004)(citation omitted). Thus, it is doubtful that either iteration of N.Y. C.P.L.R.

214 applies to the negligence and strict liability claims. Rather, the six-year catch all provision of § C.P.L.R. 213(1) governs these claims.<sup>39</sup>

#### B. Accrual

Identification of the proper limitations period is the beginning of the timeliness analysis. It is also necessary for this Court to determine when a claim accrues. The federal court's dismissal of Plaintiffs' strict liability and negligence claims was premised on its mistaken conclusions that (a) those claims accrued when the Plaintiffs were injured, and (b) reaching a 20 pack-year history constitutes an injury.

<sup>&</sup>lt;sup>39</sup> If the Court were to find that this case is seeking to recover damages for personal injuries, Plaintiffs respectfully submit that such a ruling would be in contravention of the pleadings and proofs. Plaintiffs have sought equitable relief in the form of establishment of a medical monitoring program, rather than money damages. See A372-392. In a case seeking to provide novel technology to a large class, programmatic relief is important, and a simple award of money damages would not constitute an adequate remedy, as the District Court recently reaffirmed in the companion case. Donovan III, 2012 U.S. Dist. LEXIS 37974, at \*38-56. Notably, however, if this Court were to hold that this is a legal personal injury action for money damages, Plaintiffs would be entitled to the benefit of C.P.L.R. 214-c(2), which grants 3 years "from the date of discovery of the injury by the plaintiff or from the date when through the exercise of reasonable diligence such injury should have been discovered by the plaintiff" within which to bring suit. Plaintiffs do not have lung cancer, and could not have discovered what does not exist or is still latent through exercise of reasonable diligence. Moreover, Plaintiffs did not have any basis for incurring surveillance costs or "discovering" entitlement to them prior to the suit's commencement, since no efficacious surveillance remedy existed before 2006. Thus, while Plaintiffs do not believe that this is a legal action governed by CPLR 214-c(2), if this Court were to hold otherwise, there would still be no basis for dismissing Plaintiffs' claims as untimely. See generally Glod v. Morrill Press Div. of Engraph, Inc., 168 A.D.2d 954 (4th Dept. 1990)("A determination of constructive discovery is a mixed question of law and fact[,]" and "[w]here it does not conclusively appear that a plaintiff had knowledge of facts from which the injury could reasonably be inferred, the complaint should not be dismissed on motion and the question should be left to the trier of fact.")(citations omitted); Roman v. Radio Frequency Co., 207 A.D.2d 1012 (4th Dept. 1994)(same).

Here, Plaintiffs neither asserted nor conceded that they suffered an injury at all. All Rather, their claims were premised on an enhanced risk of developing lung cancer resulting from Philip Morris' misconduct, requiring medical surveillance. Insofar as any "injury" may be said to exist in a medical monitoring action, it is the increased costs a person must bear in paying for the surveillance occasioned by the tortfeasor's misdeeds. *See Meyer*, 220 S.W.3d at 718 ("[t]he injury for which compensation is sought is not a present physical injury. Instead, medical monitoring damages compensate the plaintiff for the quantifiable costs of periodic medical examinations reasonably necessary for the early detection and treatment of latent injuries caused by the plaintiff's exposure to toxic substances.")(*citing Paoli I*, 916 F.2d at 850). That is something the Plaintiffs did not and could not have incurred before this suit was filed, as no relief was available to them prior to 2006.

However, assuming *arguendo* that Plaintiffs' increased risk of cancer were held to be an "injury," amassing twenty pack-years still would not trigger the running of the statute of limitations because no meaningful relief was available to

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<sup>&</sup>lt;sup>40</sup> In ruling otherwise, the federal courts took a remark made at oral argument by Plaintiffs' former counsel, Jerome Block, entirely out of context. A361. In the language quoted by the District Court, Mr. Block was not speaking about the statute of limitations at all. Rather, he was discussing one aspect of Plaintiffs' theory of misconduct in the context of the class certification motion. A473-474. Thus, when Mr. Block responded to the Court's question about "injury," issues of proximate causation, rather than accrual, were being addressed. However, when the subject of timeliness was argued, Plaintiffs' counsel could not have been clearer that increased risk was not injury, and that a date of injury analysis had no application in a surveillance context. A589-591 at 166:4-168:10. That point also was expressly briefed and set forth in the power point presentation submitted to the District Court. In short, the federal courts' conclusion that there was a concession regarding what constitutes an 'injury' in a medical monitoring claim is inaccurate.

the Plaintiffs, nor did they incur any surveillance costs, upon crossing that threshold. This Court has repeatedly held that a claim accrues only after "all of the facts necessary to sustain the cause of action have occurred, so that a party could obtain relief in court." Vigilant Ins. Co. of Am. v. Hous. Auth. of City of El Paso, Tex., 87 N.Y.2d 36, 43 (1995)(citation omitted). Put differently, claims do not accrue until meaningful relief can be obtained in court. See, e.g., LaBello v. Albany Med. Ctr. Hosp., 85 N.Y.2d 701, 706 (1995)(the "[s]tatute of Limitations does not run until there is a legal right to relief" and "accrual occurs when the claim becomes enforceable"); id. at 705 ("'A cause of action is the right to prosecute an action with effect ... It is not possible for one at the same time to have a cause of action and not to have the right to sue")(citations omitted)(emphasis in original); Ely-Cruikshank Co., Inc. v. Bank of Montreal, 81 N.Y.2d 399, 406 (1993) ("general rule [is that claims accrue] when all the factual elements necessary to maintain the lawsuit and obtain relief come into existence"); Aetna Life & Cas. Co. v. Nelson, 67 N.Y.2d 169, 175 (1986)("The Statute of Limitations begins to run ... when all of the facts necessary to the cause of action have occurred so that the party would be entitled to obtain relief in court")(citations omitted); City of New York v. State, 40 N.Y.2d 659, 668 (1976)("a claimant's cause of action does not accrue until it possesses the legal right to be paid and to enforce its right to payment in court.").

To be sure, in conventional personal injury actions, the last occurrence necessary to trigger the accrual of a claim is typically the infliction of injury. However, in such actions – except for those governed by the latency provisions of C.P.L.R. 214-c – the fact of injury is immediately apparent. In addition, where the relief sought is money damages, there is nothing to prevent an injured party from uttering a prayer for relief.

At the same time, this Court has likewise recognized that accrual questions require a "balancing of policy considerations" which include the plaintiff's "interest in not being deprived of a claim before a reasonable chance to assert it arises." Vigilant Ins. Co. of Am., 87 N.Y.2d at 43 (citation omitted). That interest is particularly weighty in the instant medical monitoring case, where Plaintiffs seek a form of surveillance that was not available or approbated before the suit's filing. It was undisputed below that, prior to the instant suit's commencement, no efficacious relief was available to Plaintiffs or the class they sought to represent. A80 ¶78; A205-A206, A207-A208; A374 ¶¶9-10; A384-A385 ¶¶77-78. Thus, even if one were to characterize the "elevated risk" of lung cancer as an injury, and posits knowledge of such "injury" as existing more than 6 (or 4, or 3) years prior to suit, Plaintiffs' claims still did not accrue. Knowing that one has been harmed, and even wishing to do something about it, does not mean that a remedy exists or a claim is legally enforceable. See Britt v. Legal Aid Soc., Inc., 95 N.Y.2d 443

(2000)(accrual occurs when a claim becomes enforceable); *LaBello*, 85 N.Y.2d at 706 (statute of limitations cannot run "until there is a legal right to relief"); *Kronos*, *Inc. v. AVX Corp.*, 81 N.Y.2d 90, 94 (1993)(same); *Jacobus v. Colgate*, 217 N.Y. 235, 245 (1916)(Cardozo, J.)("A cause of action does not accrue until its enforcement becomes possible.").

## C. New Misconduct Inflicting New Harm

The federal court also erred in holding untimely Philip Morris' misconduct in selling Marlboros within 6 (or 3) years of the suit's commencement, which continued to inflict new injury. The seminal decision applying New York law, Pieczonka v. Pullman Co., 89 F.2d 353 (2d Cir. 1937), was written by the Honorable Learned Hand. It held that where a continuing course of wrongful conduct inflicts new and continuing injury, or aggravates old injury, the wrongfully inflicted injury or aggravation occurring within the period permitted by the applicable statute of limitations is timely. *Id.* at 356. New York's courts long ago confirmed Judge Hand's pronouncement. See, e.g., Sadowski v. Long Island R. Co., 292 N.Y. 448, 457 (1944); Syms v. Olin Corp., 408 F.3d 95, 110 n.10 (2d Cir. 2005)(noting availability of injunctive relief under a continuing tort theory). See also generally Burt Olney Canning Co. v. State, 230 N.Y. 351, 355 (1921) (Cardozo, J.)("A new claim arises as successive injuries are suffered").

The federal courts mistakenly believed that *Snyder v. Town Insulation, Inc.*, 81 N.Y.2d 429 (1993), eliminated this time-honored rule and the continuing tort doctrine. It did not. In *Snyder*, the defendant committed a single act of misconduct – selling toxic buildings materials which leached into the plaintiffs' residence causing noxious fumes – many years before the action's commencement. *Id.* at 431-32. The plaintiff was aware of this damage, and alleged that defendant's misconduct began causing respiratory problems "about the date of installation," but sat on her hands until long after the applicable limitations period had elapsed. *Id.* Attempting to escape a timeliness dismissal, the Plaintiff tried to cite the continuing harm caused by the materials as a basis for extending the statute of limitations. *Id.* at 432-433. This Court sensibly declined to do so under those circumstances. *Id.* at 436.

The distinctions between *Snyder* and the *Pieckzonka* line of cases are plain. In this case and *Pieckzonka*, the defendants continued to misbehave, inflicting entirely new injury that proximately caused new harm with each cigarette smoked. In *Snyder*, the defendant's misconduct was long past, the plaintiff was aware of the consequences of that misconduct, and the plaintiff specifically alleged that she had been injured "about the date of installation." *Id*.

The District Court's reliance on *Jensen v. Gen. Elec. Co.*, 82 N.Y.2d at 77, was likewise misplaced for reasons discussed *supra* at Point I. Briefly, *Jensen*, held

that in personal injury actions seeking money damages, the discovery rule in C.P.L.R. 214-c(2) displaced the rationale for continuing tort doctrine. 82 N.Y.2d at 86. However, this Court also clearly held in *Jensen* that "CPLR 214-c(2) applies by its terms only to actions 'to recover damages," and does not "affect or purport to affect the availability to a party of seeking injunctive equitable relief." *Id.* at 89-91 (*quoting* C.P.L.R. 214-c(2)). Accordingly, this Court expressly limited its holding to actions seeking money damages, while holding that "the common-law accrual method [remains] applicable" in actions seeking equitable or injunctive relief. *Id.* 

The federal courts' erroneous interpretation of New York's timeliness precedents respecting negligence and strict liability created a troubling and unfounded ruling. In effect, they gave a tortfeasor license to continue its misconduct and inflict new and egregious harm with impunity, so long as the limitations period on its initial wrongful act has expired. Judge Hand and this Court rightly rejected this possibility decades ago. *See Pieczonka*, 89 F.2d at 356 (stressing that the defendant-employer obtained "no prescriptive right to contaminate his workmen's lungs.").

## D. The Claims of Plaintiff Marcia Caronia, and Other Similarly Situated Class Members Who Turned Fifty Shortly Before the Suit's Commencement, are Timely Under Any Conceivable Reading of New York Law

The federal courts' dismissal of Plaintiffs' negligence and strict liability claims as time-barred was also premised on a simple misreading of the evidence.

Their ruling assumed that Marcia L. Caronia, Arlene Fedman, and Linda McAuley should have brought suit in the 1990s seeking surveillance, when they supposedly sustained the 'injury' of being at increased risk for lung cancer, and warranting medical monitoring. As discussed above, Plaintiffs respectfully disagree both with the legal analysis of the federal courts, and the inequitable result they achieved.

However, the federal courts' accrual analysis was flawed in another important respect which is straightforward and warrants correction. As discussed *supra*, Plaintiffs did *not* allege that a person who smokes 20 pack-years of Marlboros requires surveillance for lung cancer prior to their fiftieth birthday. Nor did Philip Morris argue or offer proofs supporting such a claim.

To the contrary, uncontroverted expert proofs from Dr. Miller described how the risk of cancer increases with age, and "accelerates at age 50." Thus, smokers become proper candidates for LDCT monitoring when they amass a twenty packyear Marlboro history *and* are 50 years of age or older. A172 ¶¶18-20. This is noteworthy because Plaintiff Marcia Caronia turned 50 in 2005, *less than one year before this action was filed*. A297. The same is surely true of hundreds if not thousands of other members of the proposed class. Contrary to the federal courts' misunderstanding, no expert proofs were offered for the proposition that the Plaintiffs should have sought LDCT monitoring – if such relief had even been available – prior to their fiftieth birthdays.

There is simply no basis under New York law for finding the claim of Ms. Caronia (or others like her) untimely. LDCT surveillance was not known to be efficacious prior to this suit's commencement, nor was it generally available outside the context of clinical trials. None of the Plaintiffs had any reasonable basis for learning of its existence, let alone bringing suit to seek such a form of monitoring. However, even assuming a counter-factual universe, wherein LDCT surveillance was well-known and considered efficacious, younger members of the proposed class like Ms. Caronia *still* would not have been proper candidates for this technology until they turned 50. Since Ms. Caronia brought suit within one year of her fiftieth birthday, her claim is timely under any conceivable reading of New York law. The same is true for other Marlboro customers whose fiftieth birthdays were within 6 years of this suit's commencement in January 2006.

## III. PLAINTIFFS' BREACH OF WARRANTY CLAIMS WERE IMPROPERLY DISMISSED

The District Court also dismissed Plaintiffs' breach of implied warranty claim on the basis that Plaintiffs knew that smoking posed some health risks more than 4 years prior to this action's commencement. If this analysis were correct, then any manufacturer of any product whose danger is open, obvious, and a matter of common knowledge (*e.g.*, table saws, explosives, acetylene torches), would be free to manufacture products that were far more dangerous than they

needed to be, secure in the knowledge that their customers' actual (but incomplete) knowledge of some danger gave them license to misbehave.

That is not the state of New York law. In granting summary judgment as to the warranty claims, the District Court ignored jurisprudence recognizing that many products in the market are unavoidably dangerous, such as knives, fireworks, swimming pools, and power tools. The fact that consumers may generally know that these products are dangerous does not eliminate the implied warranty of merchantability, nor does it relieve a manufacturer of the obligation to take necessary and reasonable steps to eliminate avoidable dangers, and place in their customers' hands a safe product. A defendant who sells a product that is unnecessarily and covertly dangerous will be liable for breach of implied warranty despite the consuming public's or plaintiff's general knowledge of the product's dangers. See, e.g., Anderson v. Hedstrom Corp., 76 F. Supp. 2d 422, 445-446, 459 (S.D.N.Y. 1999)(rejecting argument that dangers created by trampoline usage are "obvious as a matter of law" and denying summary judgment as to implied warranty claim); Robinson v. Reed-Prentice Div. of Package Mach. Co., 49 N.Y.2d 471, 479-480 (1980)(recognizing that "some products, for example knives, must by their very nature be dangerous in order to be functional," but nonetheless holding that "[i]t is the manufacturer who must bear the responsibility if its purposeful design choice presents an unreasonable danger to users."). See generally Liriano v.

Hobart Corp., 92 N.Y.2d 232, 242 (1998)(noting that "the open and obvious defense generally should not apply when there are aspects of the hazard which are concealed or not reasonably apparent to the user"); Codling v. Paglia, 32 N.Y.2d 330, 340 (1973)("Manufacturers of articles which may be a source of danger to several people if not properly manufactured should not be immune from liability for breach of implied warranty ... where the manufacturer could reasonably contemplate injury" to the consumer) (citation omitted).

Plaintiffs do not dispute that they had some knowledge that Marlboros were dangerous and carcinogenic in the 4 years prior to commencing this action. What Plaintiffs did not know, and what Philip Morris concealed from them, was that Marlboros were unnecessarily carcinogenic by orders of magnitude. A51 ¶11; A53 ¶32; A258-275. See 2010 Surgeon General's Report, p.16 (explaining that outside of the cigarette industry "the various ways that cigarettes were physically modified and the nature and level of compensation in response to design changes were not well understood[,]" and even public health officials failed "to anticipate the degree to which manufacturers could design cigarettes to allow smokers to draw more smoke and nicotine from cigarettes than was represented by machine-measured yields of tar and nicotine."); A381 ¶58-59; A384 ¶74.

Under New York law, by marketing Marlboros, Philip Morris was impliedly warranting that these cigarettes were "minimally safe" for their expected purpose.

Denny v. Ford Motor Co., 87 N.Y.2d 248, 259 (1995). See also Voss, 59 N.Y.2d at 108 (defining "safe" product as one where "the risks are reduced to the greatest extent possible while retaining the product's inherent usefulness at an acceptable cost."); Codling, 32 N.Y.2d at 341 (the manufacturer "alone has the practical opportunity, as well as a considerable incentive, to turn out useful, attractive, but safe products. To impose this economic burden on the manufacturer should encourage safety in design and production; [which] should be acceptable to the user if thereby he is given added assurance of his own protection").

Philip Morris offered no evidence whatsoever establishing that Marlboros were "minimally safe." Indeed, it did not even challenge Plaintiffs' factual showing as to how Marlboros are highly and unnecessarily carcinogenic in the compelling expert report of Dr. William Farone. A257-275. As discussed *supra*, that report identifies numerous ways in which Marlboros could have been designed to reduce the product's excessive carcinogenicity, and the Plaintiffs' increased likelihood of developing cancer. They include, but are not limited to, increasing the cigarettes' "resistance to draw," utilizing a less carcinogenic "filler" tobacco than Burley tobacco, reducing the protein content of tobacco, avoiding the overfertilization of tobacco, and reducing or eliminating the use of flue curing. A260-275. In short, there is a genuine issue of material fact on the question of whether

Philip Morris sold "minimally safe" cigarettes to class members between January 19, 2002 and the present. *See Denny*, 87 N.Y.2d at 259.

Although such a showing is not legally required under New York law, Plaintiffs also presented proof that, had Philip Morris produced the Marlboros that it was impliedly warranting (minimally safe cigarettes), and had Plaintiffs smoked them, their exposure would have been insufficient to create the need for the remedy they now seek as a matter of good medical practice. A172-173 ¶¶18-20; A372-373 ¶1; A375 ¶18; A376 ¶29; A381-384 ¶¶60-73. Thus, the breach is not only a substantial factor, it is a "but for" cause of the need for medical surveillance.

Notably, in dismissing Plaintiffs' warranty claims, the District Court principally relied on *Inzerilla v. The Am. Tobacco Co., et al.*, INDEX 11754196, 2000 WL 34016364 (N.Y. Sup. Ct. Oct. 27, 2000). However, that unpublished trial court decision provided no analysis in support of its dismissal of a warranty claim, other than citing a non-binding and poorly reasoned Texas decision on which the District Court also relied. *See Inzerilla*, 2000 WL 34016364 at \*14 (*citing Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 435 (Tex. 1997)). Moreover, that court's observation that there were general warnings on cigarette packages in 1969 stating that smoking posed "dangers" to smokers' "health," *id.*, in no way resolves the question of whether Marlboro cigarettes sold after that date carried an implied warranty of merchantability, which Philip Morris breached. To answer that

question, the fact-finder in this case must determine whether the Marlboro cigarettes sold to Plaintiffs during the last four years prior to the commencement of this lawsuit and continuing to the present were "minimally safe," or whether they contained excess and concealed carcinogens, which could have been removed so as to reduce class members' risk of developing cancer. *See Denny*, 87 N.Y.2d at 259. The federal court rulings improperly removed that question from a jury.

Finally, the federal courts made passing reference to this Court's decision Adamo v. Brown & Williamson Tobacco Corp., 11 N.Y.3d 545 (2008), which deserves mention. In that design defect case, this Court, identified cigarettes' "utility" as the satisfaction they provide their customers. Id. at 549-551. Having failed to anticipate the legal standard that would be adopted respecting design defects in cigarettes, the plaintiff in Adamo presented no proof on that subject, id. at 549, let alone the compelling proof in the record below regarding the feasibility of producing cigarettes that were "satisfying," with fractions of the carcinogenic tars. A258-275. Accordingly, while Adamo was a victory for the tobacco industry, premised on an assumption from a different record that cigarettes were unavoidably as dangerous as they are, Plaintiffs here have complied with the

standard announced by that decision. That is further support for the proposition that the Court below erred in dismissing Plaintiffs' claims.<sup>41</sup>

## **CONCLUSION**

For the reasons stated above, Plaintiffs-Appellants respectfully request that this Court hold that under New York law, a current or former longtime heavy smoker who has not been diagnosed with a smoking-related disease, and who is not under investigation by a physician for such a suspected disease, may pursue an independent equitable cause of action for medical monitoring for such a disease.

Plaintiffs-Appellants respectfully request that this Court hold that the elements of a medical monitoring cause of action are that:

- (1) the defendant's negligence (or other actionable misconduct)
- (2) was a substantial factor in causing
- (3) the plaintiff to become exposed to a hazardous substance that substantially increased the risk of serious disease, illness, or injury
- (4) for which an effective medical test for reliable early detection exists,

<sup>&</sup>lt;sup>41</sup> Notably, the District Court's dismissal of Plaintiffs' implied warranty claims is inconsistent with decisions of numerous other courts in the context of tobacco litigation. See, e.g., Mash v. Brown & Williamson Tobacco Corp., 2004 U.S. Dist. LEXIS 28951, \*26-27 (E.D. Mo. 2004) (Missouri law); Little v. Brown & Williamson Tobacco Corp., 243 F. Supp. 2d 480, 504 (D.S.C. 2001) (South Carolina law); Evans v. Lorillard Tobacco Co., 465 Mass. 411, 422-438 (2013)(Massachusetts law); Haglund v. Philip Morris, Inc., 847 N.E.2d 315 (2006)(addressing warranty claim under Massachusetts law in suit against Philip Morris). Furthermore, one of the rulings on which the District Court relied was subsequently reversed, and the plaintiffs' implied warranty claims against Brown & Williamson were found viable under Alabama law. See Spain v. Brown & Williamson Tobacco Corp., 363 F.3d 1183, 1198 (11th Cir. 2004)(holding that plaintiffs "claim for breach of implied warranty of merchantability, to the extent that it is based on injuries that occurred within four years of [her] death, may not be dismissed for failure to state a claim under Alabama law.").

- (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.

Plaintiffs also respectfully request that this Court hold that because Plaintiffs are seeking equitable relief, their cause of action is governed by the six-year statute of limitations in C.P.L.R. 213(1), and that such relief may take the form of creation of a medical monitoring fund sufficient to pay for the remedy, with unused funds reverting back to the tortfeasor.

Plaintiffs also respectfully request that this Court hold that Plaintiffs' cause of action accrues when:

- (1) there is 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.

In the alternative, if this Court views medical monitoring as a form of equitable relief rather than an independent cause of action, Plaintiffs respectfully request that it correct the federal courts' misapprehension of New York law, by holding that:

(1) Plaintiffs' claims sounding in negligence and strict liability were timely commenced under the continuing

tort doctrine, as Philip Morris' misconduct was ongoing in nature, and Plaintiffs are seeking equitable relief,

- (2) Plaintiffs claims sounding in negligence and strict liability were also timely commenced because medical monitoring damages compensate the plaintiff for the quantifiable costs of periodic medical examinations reasonably necessary for the early detection and treatment of latent injuries caused by the Defendant's misconduct, and there was no efficacious remedy which Plaintiffs might have sought until the time of the suit's commencement, and
- (3) Plaintiffs have adequately pleaded and offered proofs supporting a timely breach of warranty claim under New York law.

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Respectfully Submitted

Steven J. Phillips Victoria E. Phillips

Aryeh L. Taub Lisa W. Davis

Attorneys for Plaintiffs Marcia L. Caronia, Linda McAuley, and Arlene Feldman

Phillips & Paolicelli 380 Madison Avenue, 24<sup>th</sup> Floor New York, NY 10017 p. (212) 388-5100 f. (212) 388-5200 sphillips@p2law.com vphillips@p2law.com ataub@p2law.com