

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

| | | |
|---------------------------------------------------|---|--------------------------------------|
| |) | |
| |) | |
| KATHLEEN DONOVAN and PATRICIA |) | |
| CAWLEY, on behalf of themselves and others |) | |
| similarly situated, |) | |
| |) | |
| Plaintiff, |) | |
| |) | |
| v. |) | Civil Action No. 06-12234-DJC |
| |) | |
| |) | |
| PHILIP MORRIS USA, INC., |) | |
| |) | |
| Defendant. |) | |
| |) | |
| |) | |

MEMORANDUM AND ORDER

CASPER, J.

December 12, 2014

I. Introduction

Kathleen Donovan (“Donovan”) and Patricia Cawley (“Cawley”) (collectively, the “Plaintiffs”) bring this class action against Defendant Philip Morris USA, Inc. (“Philip Morris”).

D. 29. Plaintiffs have moved to strike a number of affirmative defenses asserted by Philip Morris. D. 243; D. 245; D. 247; D. 249; D. 251; D. 254; D. 257. Plaintiffs have also moved for partial summary judgment on the breach of warranty claim and “proximate causation” (regarding issues of injury and risk). D. 259. After extensive briefing and oral argument on these motions and for the reasons stated below, the Court GRANTS Plaintiffs’ motion to strike Philip Morris’s thirty-sixth affirmative defense respecting the adequacy of a legal remedy, D. 247; DENIES IN PART and GRANTS IN PART Plaintiffs’ motion for partial summary judgment, D. 259; DENIES Plaintiffs’ motion to strike Philip Morris’s thirty-third affirmative defense regarding an

alternative safer design, D. 251; GRANTS IN PART and DENIES IN PART Plaintiffs' motion to strike all defenses based upon class members' conduct, D. 257; DENIES Plaintiffs' motion to strike Philip Morris's twenty-fourth affirmative defense regarding superseding and intervening cause, D. 249; GRANTS IN PART Plaintiffs' motions to strike Philip Morris's fourteenth, sixteenth and thirty-eighth affirmative defenses respecting damages, D. 245 and D. 243; and GRANTS IN PART and DENIES IN PART Plaintiffs' motion to strike Philip Morris's second and seventeenth affirmative defenses respecting timeliness, D. 254.

II. Standard of Review

The Court grants summary judgment where there is no genuine dispute as to any material fact and the undisputed facts demonstrate that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). "A fact is material if it carries with it the potential to affect the outcome of the suit under applicable law." Santiago-Ramos v. Centennial P.R. Wireless Corp., 217 F.3d 46, 52 (1st Cir. 2000). The movant bears the burden of demonstrating the absence of a genuine issue of material fact. Carmona v. Toledo, 215 F.3d 124, 132 (1st Cir. 2000); see Celotex v. Catrett, 477 U.S. 317, 323 (1986). If the movant meets its burden, the non-moving party may not rest on the allegations or denials in its pleadings, Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986), but must come forward with specific admissible facts showing that there is a genuine issue for trial. Borges ex rel. S.M.B.W. v. Serrano-Isern, 605 F.3d 1, 5 (1st Cir. 2010). The Court "view[s] the record in the light most favorable to the nonmovant, drawing reasonable inferences in his favor." Noonan v. Staples, Inc., 556 F.3d 20, 25 (1st Cir. 2009).¹

¹Plaintiffs have characterized seven of their pending motions as motions to strike pursuant to Fed. R. Civ. P. 56. D. 243; D. 245; D. 247; D. 249; D. 251; D. 254; D. 257. Philip Morris has challenged whether Plaintiffs' motions, as characterized as motions to strike, were timely under Fed. R. Civ. P 12(f) (allowing a limit to "strike from a pleading an insufficient

III. Procedural History

This case has had a long, somewhat complicated history since Donovan and Cawley filed this action on December 14, 2006. D. 1. The Court shall not repeat that full history, but instead refers to the recitation of same in Donovan v. Philip Morris USA, Inc., 455 Mass. 215 (2009) (“Donovan I”), Donovan v. Philip Morris USA, Inc., 268 F.R.D. 1 (D. Mass. 2010) (“Donovan II”) and Donovan v. Philip Morris USA, Inc., No. 06-12234-DJC, 2012 WL 957633 (D. Mass. Mar. 21, 2012) (“Donovan III”). In a nutshell, Plaintiffs have brought claims for breach of the implied warranty of merchantability for the marketing of cigarettes that were allegedly defectively designed and unreasonably dangerous and claims under Mass. Gen. L. c. 93A. D. 29. The relief sought by Plaintiffs is a court-supervised medical surveillance program for the early detection of lung cancer, known as low-dose computed tomography (“LDCT”), which Plaintiffs allege will provide a means to identify and diagnose lung cancer at an early stage, when the cancer is still curable. Id. at ¶¶ 3-13, 70-76.

The Court only recounts the procedural history relevant to the pending motions. On March 21, 2012, the Court issued Donovan III, D. 351, denying Philip Morris’s motion for decertification to the class, and notified the parties that due to ongoing litigation regarding the procedure for disseminating class notice, the Court would deny Plaintiffs’ pending motions to

defense or any redundant, immaterial, impertinent, or scandalous matter”), as well as what standard should apply to the motions. D. 286 at 7-8, 8 n.1. This Court, however, shall consider the motions to strike as timely filed since they were entered pursuant to a stipulated Case Management Order, which established a schedule for merits discovery and dispositive motions. D. 135. As to the standard of review, the Court has applied the summary judgment standard (i.e., whether Plaintiffs have shown that they are entitled to judgment as a matter of law based on a record of undisputed material facts, bearing in mind that a defendant’s defense should only be struck to “eliminate redundant, immaterial, impertinent or scandalous matter from the pleadings...[and] that motions of this nature are not favored.” Gilbert v. Eli Lilly Co., Inc., 56 F.R.D. 116, 120-21 (D.P.R. 1972) (internal quotation marks omitted)).

strike and their motion for partial summary judgment without prejudice to renew once the Court had decided the outstanding notice issues. 3/21/2012 docket entry.

On September 25, 2013, Plaintiffs notified the Court that they had completed the Court-approved notice plan. D. 407. In response, the Court ordered the parties to confer and file a joint status report and proposed scheduling order for the remainder of the case through trial. D. 410. The parties subsequently submitted a proposed schedule and notified the Court that Plaintiffs wished to revive their pending motions to strike and their motion for partial summary judgment. D. 412. The parties also requested an opportunity to submit supplemental briefings on the pending motions to address recent changes in the law and other factual developments. Id. Over a course of months, the parties submitted a number of supplementary briefs on the pending motions.² The Court heard argument on Plaintiffs' pending motions on June 26, 2014 and took the matters under advisement. D. 443.

IV. Factual Background

This class action lawsuit was filed against Philip Morris on December 14, 2006. D. 1. The complaint – filed on behalf of individuals who, as of February 26, 2013: (a) are residents of Massachusetts, (b) are fifty years of age or older, (c) have cigarette smoking histories of twenty pack-years³ or more using Marlboro cigarettes, (d) smoke Marlboro cigarettes, or quit smoking Marlboro cigarettes on or after December 14, 2005, (e) are not diagnosed as suffering from lung cancer or under investigation by a physician for suspected lung cancer as of the date of any judgment being entered, or relief obtained, in this action, (f) have smoked Marlboro cigarettes

²D. 415; D. 416; D. 422; D. 423; D. 424; D. 425; D.426; D. 427; D. 428; D. 437; D.438; D. 439; D. 440; D. 441.

³As noted previously in this litigation, a “pack-year” is the average number of packs of cigarettes smoked per day multiplied by the number of years the person has smoked. One pack a day for twenty years, for example, equals twenty pack-years. Donovan II, 268 F.R.D. at 5 n.1.

within the Commonwealth of Massachusetts – alleges that Philip Morris designed, marketed and sold Marlboro cigarettes that delivered an excessive and dangerous level of carcinogens. D.1; D. 29; D. 403 (adopting D. 400 and amending the class definition). Plaintiffs accuse Philip Morris of breaching the implied warranty of merchantability by marketing cigarettes that were defectively designed and unreasonably dangerous and of violating Mass. Gen. L. c. 93A, §§ 2, 9, which prohibits “unfair and deceptive” trade practices. D. 29 at ¶¶ 78-110.

Plaintiffs do not seek money damages or exemplary damages. *Id.* ¶ 2. Instead, Plaintiffs seek to compel Philip Morris to provide them with a court-supervised program of medical surveillance for early detection of lung cancer utilizing a technique known as LDCT scans of the chest. *Id.* ¶ 3.

V. Discussion

The Court will address each of Plaintiffs’ motions in turn. However, where possible, discussion of related issues has been grouped together.

A. Adequacy of a Legal Remedy (D. 247)

Plaintiffs have moved to strike Philip Morris’s thirty-sixth affirmative defense, which asserts that the claims for relief are barred because Plaintiffs and class members have an adequate remedy at law. D. 247; D. 30 at 28. Philip Morris argues that there remains a genuine issue of material fact as to whether each member of the class would be unable to obtain the features of the LDCT remedy through existing programs at local hospitals if they were awarded money damages. D. 290 at 4.

Plaintiffs contend that this Court, in the context of class certification (and later denial of the motion to decertify the class), has already rejected Philip Morris’s argument that an adequate legal remedy exists and has concluded that no amount of money damages could provide a

remedy as complete, certain and efficient as the programmatic injunctive relief they seek. D. 248 at 1-2. Plaintiffs argue that Philip Morris has offered nothing new in the law or in the factual record that should change the Court's conclusion. *Id.* The Court agrees. For the reasons discussed below, the Court GRANTS Plaintiffs' motion to strike Philip Morris's thirty-sixth affirmative defense, D. 247.

*I. Analysis in Donovan III*⁴

In Donovan III, the Court considered whether changes in the law or in the factual record merited the conclusion that the relief sought by Plaintiffs was monetary and that the class should be decertified under Fed. R. Civ. P. 23(b)(2). Donovan III, 2012 WL 957633 at *5-16; D. 351 at 10-30. The Court concluded that there had been no change in the law to merit decertification under Fed. R. Civ. P. 23(b)(2). Donovan III, 2012 WL 957633 at *12; D. 351 at 20.

The Court then considered the factual record post-certification, specifically new information about the LDCT scans. Donovan III, 2012 WL 957633 at *12-16; D. 351 at 20-30.

The Court explained that:

for the purposes of an adequacy of remedy analysis, the narrow questions of whether the cost of the plaintiffs' proposed relief can be estimated with precision or whether LDCT tests are readily available for purchase are less important than the larger question of whether any amount of money damages could provide a remedy to the plaintiffs that is as complete, certain and efficient as the programmatic injunctive relief they seek. Put another way, even if it were possible both to anticipate accurately the precise cost of the plaintiffs' proposed programmatic remedy and for members of the class to divide up a damages award equal to that precise cost and use the proceeds to purchase individual LDCT tests, the plaintiffs' proposed remedy would not be precluded unless purchasing individual LDCT tests provided them relief that was as certain, complete and efficient as the proposed programmatic remedy.

⁴Although the Court relies, in part, on its analysis in prior class certification decisions, the Court recognizes that the standard of proof for this motion, under Fed. R. Civ. P. 56, is different, but that analysis remains instructive here. Accordingly, the Court applies the familiar summary judgment standard.

Donovan III, 2012 WL 957633 at *14; D. 351 at 26.

Applying this standard, the Court reviewed new discovery, including an expert report – the Epstein/Oster Report, D. 313-2 – that discussed the estimated cost of the LDCT lung cancer screening program. Donovan III, 2012 WL 957633 at *13; D. 351 at 22-24. Philip Morris argued that the report showed that Plaintiffs’ remedy could “be monetized with pinpoint precision.” Id. (quoting Defendant’s Memo, D. 313 at 14); D. 351 at 22. The Court concluded, however, that the “report reinforce[d], rather than undermin[ed], the Court’s earlier conclusion that the LDCT screening program is . . . difficult to monetize.” Donovan III, 2012 WL 957633 at *13 (quoting Donovan II, 268 F.R.D. at 26) (internal quotations omitted). Philip Morris also pointed to post-certification discovery that it claimed disproved the Court’s earlier assertion that LDCT scans were not generally available to class members throughout Massachusetts.⁵ Donovan III, 2012 WL 957633 at *14; D. 351 at 24. The Court found that nothing in the post-certification discovery undermined the Court’s earlier conclusion that “LDCT screening is not yet generally available in Massachusetts.” Id. at *14; D. 351 at 25. Furthermore, the Court found that even if, hypothetically, the remedy could be monetized and the LDCT scans were generally available, the discovery materials provided “by the parties make clear that . . . damages would be inadequate compared to programmatic injunctive relief.” Id. at *14; D. 351 at 26-27.

Examining the factual record, the Court held that:

the parties have not alerted the Court to any facts or expert opinion, discovered either before or after the Court’s June 24, 2010 certification order, that stand for the proposition that a simple money damages award could fashion relief that is as certain, complete and efficient as the injunctive programmatic remedy sought by the Plaintiffs.

⁵Post-certification discovery that the Court considered included: the Oliver Deposition (excerpts provided by Philip Morris), D. 313-3 at 4-8; the Dr. Robert M. Schick Affidavit, D. 313-4 at ¶¶ 8, 32; the Donovan Deposition (excerpts provided by Philip Morris), D. 313-5 at 6-7; and the Cawley Deposition (excerpts provided by Philip Morris), D. 313-6 at 3-4.

Donovan III, 2012 WL 957633 at *16; D. 351 at 30.

2. *There is No Adequate Remedy at Law*

Reviewing Plaintiffs' motion, the Court must consider whether there is any genuine issue of material fact in the record to suggest that individual LDCT tests will provide the class members with relief that is as complete, certain and efficient as the programmatic injunctive relief they seek, i.e., whether Plaintiffs have an adequate remedy at law.

In its original briefing on this issue, Philip Morris highlighted evidence that it contended confirms that LDCT scans are now generally available throughout Massachusetts, including the fact that the class representatives – Donovan and Cawley – have obtained scans on the open market. D. 290 at 6-7. Philip Morris also pointed the Court to the June 9, 2011 Deposition of Christine Oliver, where Dr. Oliver testified that “[i]f patients are interested in having” an LDCT scan, “then [various facilities in Massachusetts] are happy to perform the service, and, in fact, they are advertising the service.” D. 290 at 6; Oliver Deposition (excerpts provided by Philip Morris), D. 291-1 at 3. Philip Morris argues that this evidence shows that there is a genuine issue of fact as to whether Plaintiffs have an adequate legal remedy. However, as the Court explained in Donovan III, even if the Court assumes that LDCT scans are generally available, that fact alone does not address whether individual LDCT tests would provide the class with relief as complete as the programmatic remedy they seek. Donovan III, 2012 WL 957633 at *14. For example, Dr. Oliver also testified that “it’s my understanding from the MGH – certainly, the practice at the MGH is it is not part of a program, per se.” Oliver Deposition (excerpts provided by Philip Morris), D. 291-1 at 3. In other portions of her deposition, Dr. Oliver suggests that merely purchasing an LDCT scan would be inferior to a fully developed program. Oliver Deposition (excerpts provided by Plaintiffs), D. 316-8 at 9-12. Dr. Oliver explains that, although

LDCT scans are available at Massachusetts General Hospital (“MGH”), she would not describe MGH as having a program because the hospital lacks the organization, training, infrastructure, education and staff to run a fully functioning program. *Id.* Plaintiffs agree that there exists in Massachusetts enough radiologists, technicians, and equipment to provide scans to 40,000 class members. D. 322 at 3. That does not mean that radiologists, technicians, and equipment available throughout the Commonwealth will provide the class with the outreach, specialized training, algorithms, infrastructure, and follow-up contemplated by the programmatic remedy that the class here seeks.

Moreover, recent changes in health insurance coverage do not merit a different result. Philip Morris contends that “nearly all Massachusetts residents are insured” and that “92 percent of Massachusetts residents reported that they have a person they think of as their primary health provider.” Schick Affidavit (7/11/2011), D. 291-2 at ¶ 6; Schick Affidavit (10/31/2011), D. 313-4 at ¶ 34. As a threshold matter, even if the Court assumes that Philip Morris is correct and that all class members will have the insurance and the primary care physicians necessary to ensure that they will receive scans that does not address whether the individual scans will provide the relief that the proposed program would provide. Furthermore, Philip Morris’s own cited evidence suggests that the program would be necessary to provide “complete” relief. That is, even viewed in the light most favorable to Philip Morris, Dr. Schnick’s figures about health insurance suggest that at least eight percent of Massachusetts residents would not know where to turn to receive testing, and even the ninety-two percent who would have access to a scan, would not have access to the programmatic relief.

In its original briefing, Philip Morris also countered Plaintiffs’ position that a program is necessary to ensure outreach, quality control and the use of proper algorithms. D. 290 at 9-12.

Addressing the perceived need for programmatic quality control, Philip Morris points to Dr. Oliver's testimony that MGH and Brigham & Women's Hospital had affiliated with community hospitals throughout the Commonwealth of Massachusetts, which, according to Philip Morris, showed that "class members can be screened and receive follow-ups without the need for the massive program that Plaintiffs envision and without being required to travel great distances." D. 290 at 10; Oliver Deposition (excerpts provided by Philip Morris), D. 291-1 at 10-12. But, in fact, Dr. Oliver only testified that the affiliations would make it more convenient for the class to receive scans. Id. Dr. Oliver did not address whether simply receiving the scans – even conveniently – would offer as complete a remedy as the program envisioned by Plaintiffs. Id.

Moving for summary judgment, Plaintiffs have the burden of showing that there is no genuine issue of material fact as to whether money damages would be as certain, complete and efficient a remedy as the program sought. The Court finds that Plaintiffs have met this burden. Therefore, the burden shifts to Philip Morris "to show with admissible evidence the existence of a dispute as to material facts." Kourouvacilis v. Gen. Motors Corp., 410 Mass. 706, 711 (1991) (quoting Godbout v. Cousens, 396 Mass. 254, 261 (1985)). The Court recognizes the difficulty of addressing this issue over the course of years where the landscape continues to change. Nevertheless, the Court finds that Philip Morris has not satisfied that burden.

In its supplemental briefing, Philip Morris argues that new "evidence shows that (1) LDCT screening is already available throughout Massachusetts and is rapidly becoming ubiquitous; (2) screening services can readily be monetized; and (3) screening is being provided in full-blown programs that give patients all the supposed benefits of Plaintiffs' preferred programmatic remedy." D. 422 at 14. To the first point, Philip Morris offers evidence that more screening centers have opened, that these centers can be found on the internet and that at least

one center – University of Massachusetts Memorial – allows patients to refer themselves for the screening. D. 423 at ¶¶ 8-21. The Court cannot conclude that the ready availability of individual scans will provide the class with the outreach, specialized training, algorithms, infrastructure and follow-up contemplated by the programmatic remedy. To the second point, as the Court explained in Donovan III, even if the Court assumes that screening services may be easily monetized that does not mean that a damages award could necessarily fashion relief that is “as certain, complete and efficient” as the injunctive programmatic remedy sought by Plaintiffs. Donovan III, 2012 WL 957633 at *14.

Philip Morris also places great weight on the fact that several medical and public health organizations have recently recommended LDCT screening for lung cancer to certain high-risk groups. D. 422 at 5. Philip Morris argues that these recent recommendations evidence the “rapid evolution of the medical establishment’s view on screening,” which raises genuine issues of fact regarding whether programmatic relief is superior to the provision of damages. D. 422 at 5-6. Plaintiffs acknowledge that LDCT guidelines and algorithms exist as an element of medical practice, however, they argue that the mere existence of standards – standards that are being updated continuously – does not guarantee that the forty-thousand class members “will find their way to practitioners who are either aware of, or even inclined to, follow these guidelines.” D. 323 at 3. The Court agrees that the mere availability of guidelines and algorithms does not guarantee that all the class members will be provided with relief as certain, complete and efficient as the program sought. Moreover, in its’ own brief Philip Morris notes that the United States Preventative Services Task Force (“USPSTF”) now recommends “annual screening for lung cancer with [LDCT] in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years.” D. 422 at 8 (quoting D. 416-3 at 1).

Philip Morris argues that these new recommendations will lead to expanded insurance coverage under the Affordable Care Act, Medicare and Medicaid. D. 422 at 8-9. However, these recommendations do not cover all members of the current class. As Philip Morris acknowledges, “[t]he USPSTF’s recommendation does not extend to class members who are between 50 and 55 or who are over 80, and/or those who have a smoking history of at least 20 but fewer than 30 pack-years.” D. 422 at 8 n.4. Therefore, even if the Court assumes that these recommendations will lead to expanded insurance coverage and treatment, the recommendations do not create a dispute of material fact about whether all class members will be able to obtain the relief sought by Plaintiffs through an award of damages.

Philip Morris also argues that “many health-care providers throughout Massachusetts are now actively promoting comprehensive lung-cancer screening programs” that may make a court-ordered program unnecessary and contends that some existing screening programs may provide the programmatic features that Plaintiffs seek. D. 422 at 6, 16. For example, Philip Morris points the Court to the University of Massachusetts Lung Screening webpage as creating a factual issue about whether programmatic relief is available to Plaintiffs. D. 423 at ¶ 20 (citing D. 424-13 at 2-4). The webpage proffered by Philip Morris does refer to a “clinical coordinator” as well as a “team of lung cancer experts,” including “radiolog[ists], pulmonologists, thoracic surgeons, and medical and radiation oncologists.” D. 424-13 at 2, 3. But none of the features of this website amount to the remedy that Plaintiffs seek, including a specialized medical director, a staff dedicated to outreach, and a robust compliance and follow-up program. D. 248-1 at ¶ 50.

Advocating for programmatic relief, Plaintiffs argue that a class of approximately forty-thousand persons requires systematic outreach and continuing communication between the class members and the program administrators to be effective. Plaintiffs’ experts have acknowledged

that examining LDCT scans for lung cancer – and for the nodules that may represent lung cancer – is now a routine task for many radiology departments. D. 248-2 at 4. The program requested by Plaintiffs, however, is to be run by a central administration that will provide consistent “program design and governance, training, communication, medical oversight, budget/finance, quality control, health care provider recruitment and retention, participant outreach and communication, quality assessment and control and data aggregation, analysis, and dissemination.” D. 248-2 at 5. Key elements of this program include the development and refinement of the program’s standards and protocols, as well as a program information system to address the “flow of medical data, billing, finances, provider and patient participation and other issues” and ongoing assessment of the program through “defined evaluation metrics and quality checks.” D. 248-2 at 5. A class-wide program is also likely to help refine the algorithms to distinguish suspicious, indeterminate, and non-suspicious scans and will be more cost effective and efficient than an individualized system.

The Court is mindful that the LDCT environment continues to evolve. However, this Court has examined the remedy issue in this case three times over the course of several years and is not persuaded that the landscape is changing rapidly enough to warrant a denial of Plaintiffs’ motion to strike, D. 247. Accordingly, the Court GRANTS Plaintiffs’ motion, D. 247.

B. Partial Summary Judgment and Related Defenses (D. 259; D. 251; D. 257)

Plaintiffs have moved for partial summary judgment on the issue of the breach of the implied warranty of merchantability and on the issue of proximate cause regarding alleged “subcellular injury” and risk. D. 259; D. 260 at 1. The issues raised by Plaintiffs’ motion for partial summary judgment on breach of warranty also implicate Plaintiffs’ motions to strike Philip Morris’s thirty-third affirmative defense regarding alternative safer design, D. 251, and

Philip Morris's defenses based on class member conduct, D. 257. For the reasons stated below, the Court DENIES IN PART and GRANTS IN PART Plaintiffs' motion for summary judgment, D. 259; DENIES Plaintiffs' motion regarding alternative safer design, D. 251; and DENIES IN PART and GRANTS IN PART Plaintiffs' motion regarding class conduct, D. 257.

1. Breach of Warranty

Under Massachusetts law, “[a] seller breaches its warranty obligation when a product that is ‘defective and unreasonably dangerous’ . . . for the ‘[o]rdinary purposes’ for which it is ‘fit’ causes injury.” Haglund v. Philip Morris, Inc., 446 Mass. 741, 746 (2006) (citations omitted) (affirming denial of a motion to strike and reversing the judgment of dismissal in a wrongful death action against a cigarette manufacturer predicated on claim of breach of implied warranty of merchantability). Liability for breach of warranty of merchantability is governed by Mass. Gen. L. c. 106, §§ 2-314-2-318, and is consistent with “the [Restatement (Second) of Torts § 402A] definition of a seller’s strict liability for harm suffered by a user or consumer of a seller’s product.” Colter v. Barber-Greene Co., 403 Mass. 50, 61 (1988) (citing Correia v. Firestone Tire & Rubber Co., 388 Mass. 342, 353 (1983)). “Unlike negligence liability, warranty liability focuses on whether the product was defective and unreasonably dangerous and not on the conduct of the user or the seller.” Colter, 403 Mass. at 61-62 (1988) (quoting Correia, 388 Mass. at 355) (internal quotation mark omitted). A defendant, therefore, “may be liable on a theory of breach of warranty of merchantability even though he or she properly designed, manufactured, and sold his or her product.” Id.

Plaintiffs have brought claims for breach of the implied warranty of merchantability for the marketing of cigarettes that were allegedly defectively designed and unreasonably dangerous. As part of its *prima facie* case, a plaintiff must prove the availability of “a technologically

feasible and practical alternative design that would have reduced or prevented the plaintiff's harm." Evans v. Lorillard Tobacco Co., 465 Mass. 411, 428 (2013) (quoting Restatement (Third) of Torts: Products Liability § 2 comment f, at 24 (1998)); see also Uloth v. City Tank Corp., 376 Mass. 874, 881 (1978) (noting that "there is a case for the jury if the plaintiff can show an available design modification which would reduce the risk without undue cost or interference with the performance of the machinery"). "Ordinary purposes refers to the product's intended and foreseeable uses" and "fitness" principally – but not exclusively – implicates the consumers' reasonable expectations. Haglund, 446 Mass. at 746-747 (quoting Back v. Wickes Corp., 375 Mass. 633, 640 (1978)) (internal quotation marks omitted). The plaintiff "must prove that, at the time he was injured, he was using the product in a manner that the defendant seller, manufacturer, or distributor reasonably could have foreseen." Haglund, 446 Mass. at 747 (quoting Allen v. Chance Mfg. Co., 398 Mass. 32, 34 (1986)) (internal quotation marks omitted).

When analyzing "fitness," consumer expectations should not be considered as a sole factor in determining liability but may be considered as part of a risk-utility balancing test to determine if the design is defective. Evans, 465 Mass. at 427-428. The risk-utility factors include: (1) the magnitude and probability of the foreseeable risks of harm; (2) the instructions and warnings accompanying the product; (3) the nature and strength of consumer expectations regarding the product; (4) the relative advantages and disadvantages of the product as designed and as it alternatively could have been designed; and (5) the likely effects of the alternative design on production costs. Evans, 465 Mass. at 425 (quoting Restatement (Third) of Torts: Products Liability § 2 comment f, at 23 (1998)).

a) Defective and Unreasonably Dangerous

To succeed on a breach of warranty claim, Plaintiffs must show that the product is defective and unreasonably dangerous. The determination of whether a product design is defective and unreasonably dangerous depends on a number of factors, including “the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design.” Haglund, 446 Mass. at 748 (quoting Back, 375 Mass. at 633) (internal quotation marks omitted). Here, the parties dispute the last factor – whether the alternative safer design “would result in undue interference with the cost or performance of the product, thereby making the alternative design unreasonable.” Evans, 465 Mass. at 433 (citing Colter, 403 Mass. at 57).

Plaintiffs argue that the gravity of the dangers posed by Marlboro cigarettes cannot be questioned, that the likelihood that the danger would occur is plain, that Philip Morris has conceded the feasibility of a safer alternative design, that there were no excessive costs associated with a safer alternative design and that the consequences to the consumer would have been only favorable. D. 260 at 9-10. Philip Morris contends that low-tar cigarettes – the safer alternative design upon which Plaintiffs rely – were soundly rejected by consumers and do not constitute a feasible alternative. D. 426 at 14.

In Evans, the Supreme Judicial Court addressed a similar issue.⁶ There, the cigarette company argued that the safer cigarette offered by consumers was not a reasonable alternative because “ordinary smokers” would not smoke cigarettes with lower nicotine levels. Evans, 465

⁶Both parties requested, and were granted, the opportunity to submit supplemental briefs addressing this 2013 decision by the Supreme Judicial Court.

Mass. at 433. The Evans court determined that if cigarette company's argument was taken to its natural conclusion that "addictive chemicals would be the only substance whose presence in a product could not, as a matter of law, be found to constitute a defect in the product's design, because there could be no reasonable alternative design that did not include them." Id. at 435. Rejecting this argument, the Court concluded that the appropriate inquiry in cigarette product liability litigation is "whether the design alternative unduly interfered with the performance of the product from the perspective of a rational, informed consumer, whose freedom of choice is not substantially impaired by addiction." Id. at 436.

It is undisputed that Plaintiffs in this case have identified cigarette designs capable of delivering less tar to the consumer. D. 253 at ¶¶ 3, 5-11; Bonhomme Report, D. 223-1 at ¶¶ 37, 35, 47, 56; D. 252-2 at 2; Jupe Report, D. 252-3 at ¶¶ 20, 26; D. 296 at ¶¶ 2-3; D. 30 at ¶ 60 (noting that "Philip Morris USA admits that in 1980 it introduced an ultra low tar cigarette, Cambridge, with a 0.1 mg FTC machine-test measured tar yield"). Nor is it disputed that these low-tar cigarettes were capable of being substantially less carcinogenic. Jupe Report, D. 260-6 at ¶ 26. Therefore, Plaintiffs contend that the "decision of a non-addicted smoker to select a more dangerous cigarette is *per se* unreasonable," and Evans effectively removed the consumer acceptability inquiry completely. D. 415 at 11. The Court does not agree. The Evans decision narrowed, but did not remove, the consumer acceptability calculus. Even after Evans, Plaintiffs must show that the alternative design would have been acceptable to a rational, informed, non-addicted consumer.

Philip Morris has offered evidence that low-tar cigarettes have been rejected by consumers for decades for reasons unrelated to addiction. In particular, Philip Morris points to consumers who complained they did not like the taste and the "flavor intensity" of low-tar

cigarettes. Bonhomme Report, D. 260-18 at ¶¶ 42, 54-55; Jupe Report, D. 260-6 at ¶ 26. Other smokers have complained that the low-tar cigarettes are “very difficult to light.” Jupe Report, D. 260-6 at ¶ 26; see also, Bonhomme Report, D. 260-18 at ¶ 42 (noting that “[a]dult smokers reported that the 0.1 mg. cigarette was hard to draw or keep lit . . .”). In light of this evidence, the Court cannot conclude that a rational, informed, non-addicted smoker would, as a matter of law, find that the design alternative in no way interfered with the performance of the product. Plaintiffs will be free to argue at trial that this dissatisfaction with the taste of the proposed alternative design is not rational and/or that these comments were made by insufficiently informed consumers and a jury would be free to agree or disagree. Accordingly, as discussed further below, Plaintiffs’ motion to strike the defense relating to alternative safer design, D. 251, is DENIED.

b) Ordinary Purposes and Fitness

Philip Morris also argues that a product cannot be unreasonably dangerous, and therefore defective, if the product “met consumers’ reasonable expectations as to safety.” D. 426 at 21 (quoting Haglund, 446 Mass. at 428). As noted above, the breach of warranty analysis requires a determination that the product at issue was used for the “ordinary purposes,” for which it was “fit.” Haglund, 446 Mass. at 746. “Ordinary purposes” concerns the product’s intended and foreseeable use, while the product’s “fitness” implicates the consumers’ reasonable expectations. Id. at 746-747.

In Evans, the cigarette manufacturer argued that the judge had erred by instructing the jury that they “may” consider consumer expectations, rather than instructing them that they “must” consider consumer expectations. Id. at 423. Concluding that the cigarette manufacturer was effectively asking the court “to adopt the reasonable consumer expectations standard for

design defect in comment i to § 402A of the Restatement (Second) of Torts . . . rather than the risk-utility balancing standard in § 2 of the Third Restatement,” the Supreme Judicial Court rejected this argument and adopted the Third Restatement’s risk-utility balancing test. Id. at 423-424. Under the risk-utility test, a consumer’s expectations may be considered in a defective design case, but they do not play a determinative role. Therefore, “[t]he mere fact that a risk presented by a product design is open and obvious, or generally known, and that the product thus satisfies expectations, does not prevent a finding that the design is defective.” Id. at 425 (quoting Restatement (Third) of Torts: Products Liability § 2 comment g, at 28 (1998)). In other words, a product may be defective even when consumers “expect the product to be no safer than it is.” Id.

Nevertheless, in determining liability in a breach of warranty action, the factfinder may still consider the risk-utility factors discussed above to determine whether the proposed alternative design is “reasonable” and whether, therefore, its omission renders the product “unreasonably dangerous.” Plaintiffs argue that there is no requirement under Massachusetts law that obligates them to prove that Philip Morris’s cigarettes were more dangerous than consumer expectations. D. 415 at 8. The Court agrees. Evans, 465 Mass. at 428 (noting that “because reasonable consumer expectations are simply one of many factors that may be considered and not necessarily the determinative factor, the plaintiff was not obligated to prove that [the] cigarettes were more dangerous than consumers reasonably expected”). However, although Plaintiffs do not have to prove that Marlboro cigarettes were more dangerous than consumer expectations, that does not mean, as a matter of law, the jury is not entitled to consider consumer expectations. Reasonable consumer expectations are one of the risk-utility factors explicitly adopted in Evans and may aid the jury’s determination of Marlboro’s “fitness.” Evans, 465 Mass. at 428. If the jury believes that rational, informed consumers would have expected

Marlboro cigarettes to be dangerous, then the jury may (but is not required) to conclude that the product's design, though dangerous, is not defective. Accordingly, Plaintiffs' motion for partial summary judgment, D. 259, is DENIED IN PART as to breach of the implied warranty of merchantability.

c) Injury and Risk

As this Court noted in Donovan II, Plaintiffs must prove that the design defect – Marlboro cigarettes' excessive carcinogenicity – caused their injury, meaning both the proximate cause and the actual cause of their subcellular harm. Donovan II, 268 F.R.D. at 14 (citing Wasylow v. Glock, Inc., 975 F. Supp. 370, 377 (D. Mass. 1996); Ulwick v. DeChristopher, 411 Mass. 401, 408 (1991)); D. 119 at 21. Under Massachusetts law, proximate cause requires proof that a product defect is a substantial factor in bringing about the injury. Actual causation requires proof that the defect was the but-for cause of the injury.⁷

Plaintiffs argue that the undisputed factual record shows that twenty pack-years of smoking Marlboro cigarettes necessarily damage the lungs. D. 260 at 2; Miller Report (8/23/2006), D. 260-5 at ¶¶ 9-15. They contend that there is no dispute between the parties that twenty pack-years of Marlboro use is a substantial factor in elevating any individual's risk of developing lung cancer and that the excess harm – caused by the differential between Marlboros and the feasible alternative – would similarly be a substantial factor. D. 260 at 10-11. Plaintiffs argue, therefore, that there are no outstanding issues of material fact on the issues of injury and risk and seek summary judgment on those issues. D. 259; D. 260 at 11.

⁷ Massachusetts courts use a substantial factor test, instead of a but-for cause test, in cases in which there were two or more causal events sufficient to bring about the plaintiffs' harm. However, cases in which one defendant's conduct is alleged to have caused the harm, a but-for cause test is appropriate. Matsuyama, 452 Mass. 1, 30 & 30 n.47.

Philip Morris argues that Plaintiffs have not provided sufficient evidence to prove, as a matter of law, that they have satisfied “either the but-for or the substantial factor test” required under Massachusetts law for injury and risk. D. 426 at 34. In making this argument, Philip Morris focuses on Plaintiffs’ need for medical monitoring as being essential to the very definition of the injury. Id.

Philip Morris posits that if there is “an individual who is over 50 years old and has smoked for 20 pack years” who would still require medical monitoring even having smoked the alternative design, then Marlboro cigarettes cannot be considered the but-for or a substantial factor causing the injury. D. 426 at 34. In the alternative, Philip Morris argues that even if all Plaintiffs must show is a reduction in risk – without completely removing the need for monitoring – that there are factual questions about whether the proposed design would have reduced the need for medical monitoring at all. D. 426 at 27; D. 295 at 32-36.

(1) Necessary Level of Risk Reduction

In Donovan I, the Supreme Judicial Court held that a plaintiff seeking medical monitoring must prove 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 effective medical test for reliable early detection exists, (5) and early detection, combined with prompt and effective treatment, will significantly decrease the risk of death or the severity of the disease, illness, or injury, and (6) such diagnostic medical examinations are reasonably (and periodically) necessary, conformably with the standard of care, and (7) the present value of the reasonable cost of such tests and care, as of the date of the filing of the complaint.” Donovan I, 455 Mass. at 226.

Philip Morris claims that Donovan I established that the only actionable “injury” is the need for medical monitoring and the attendant increase in reasonable medical expenses. D. 426 at 29-30. In the alternative, Philip Morris argues that, at a minimum, Donovan I defined the injury as a level of harm that triggers a need for medical monitoring. Donovan Hearing Transcript 6/26/2014, D. 444 at 58-59. It argues that Donovan I required Plaintiffs to show that they “have suffered a sufficient amount of damage to necessitate medical monitoring,” and that Plaintiffs “must further show that the damage that necessitates monitoring was caused by the defendant’s tortious conduct.” D. 426 at 29. Philip Morris, therefore, argues that the jury must find that Plaintiffs’ need for medical monitoring would have been reduced had Plaintiffs used the alternative design, and that since “the need for medical monitoring cannot be reduced” because Plaintiffs “either need[] such monitoring, or [they do] not,” Plaintiffs cannot recover without a showing that the alternative design would have removed the need for medical monitoring entirely. Id. at 30. The Court disagrees. The “injury” detailed in Donovan I is the “subcellular change[] that substantially increased the risk of serious disease, illness, or injury . . .” Donovan I at 226. To sustain its medical monitoring claim, a plaintiff must ultimately show that “an effective medical test for reliable early detection” of the injury (of the “subcellular change”) exists that “will significantly decrease the risk of death or the severity of the disease . . . ,” id., but this does not change the underlying nature of the injury that Plaintiffs must show.

To support its reading of Donovan I, Philip Morris points the Court to Hansen v. Mountain Fuel Supply Co., 858 P.2d 970 (Utah 1993), which the Donovan I court cites in a footnote immediately after detailing the elements of the medical monitoring claim. Donovan I, 455 Mass. at 226. The footnote reads in full:

Because the nature of these medical expenses is diagnostic, in contrast to responsive treatment costs, they are somewhat akin to what we customarily have

seen as medical expenses that have already been incurred. In this respect, the lump sum usually awarded for future medical expenses, see Griffin v. General Motors Corp., 380 Mass. 362, 367, 403 N.E.2d 402 (1980); Sullivan v. Old Colony St. Ry., 197 Mass. 512, 516, 83 N.E. 1091 (1908), may, in cases such as this, be ordered paid into an appropriate account and drawn down as the expenses are actually incurred. If they are not used, the award, or balance thereof, may be returned to the defendant who was obligated to make such payment. See Hansen v. Mountain Fuel Supply Co., 858 P.2d 970, 982 (Utah 1993). A plaintiff's reasonable attorney's fees and costs may be paid out of such award.

Donovan I, 455 Mass. at 226 n.12.

The Court reads the Donovan I court to be relying on Hansen regarding the remedy – specifically the remedy of medical monitoring – not to clarify the definition of the injury. The cited section of Hansen is entitled “Remedy,” and begins, “[w]e add a final note on remedy.” Hansen, 858 P.2d at 982. The discussion that follows provides that plaintiffs should only be allowed to recover for the cost of medical monitoring actually received, not for damages. Id. Explaining this limit to the remedy, the Hansen court does state that “if monitoring is not actually provided to the plaintiff, then a significant theoretical element of his or her injury is missing...” Id. This analysis, however, is included in a section explicitly intended to address the remedy, not the injury, and the Court does not otherwise read the Hansen court as requiring the definition of injury sought by the defendant.⁸ Importantly, the Hansen court’s examination of the medical monitoring cause of action arises in the context of toxic-tort plaintiffs who had not established any physical injury from exposure to asbestos. Id. at 973. Because the Hansen plaintiffs had not established any physical injury, their compensable injury was limited to “the exposure itself and the concomitant need for medical testing.” Id. at 977. Here, the Court need not address the need for medical monitoring in the absence of any physical injury since in the

⁸Even if Philip Morris’s definition of “injury” could be fairly construed as the holding of Hansen, such an out-of-circuit holding is not binding on this Court. United States v. Lang, 672 F.3d 17, 26 n.15 (1st Cir. 2012).

present case Plaintiffs concede that they must prove subcellular injury. See D. 260 at 10.

Establishing the medical monitoring remedy, the Hansen court relies on an analogy, comparing the medical monitoring tort to “a simple, everyday accident involving two individuals,” in part, to justify the remedy in the absence of any injury at all. Hansen, 858 P.2d at 977 (quoting Friends For All Children, Inc. v. Lockheed Aircraft Corp., 746 F.2d 816, 826 (D.C. Cir. 1984)). In the example:

Jones is knocked down by a motorbike which Smith is riding through a red light. Jones lands on his head with some force. Understandably shaken, Jones enters a hospital where doctors recommend that he undergo a battery of tests to determine whether he has suffered any internal head injuries. The tests prove negative, but Jones sues Smith solely for what turns out to be the substantial cost of the diagnostic examinations.

Id. at 977-978. Pointing to this example, the Hansen court concluded “a plaintiff forced to incur the cost of medical monitoring as a result of a defendant’s negligent conduct should be entitled to compensation for those expenses.” Id. at 978. And it is clear that in the Hansen court’s own example, the injury is not the “battery of tests” recommended by the doctors. Hansen, 858 P.2d at 978. The injury is “land[ing] on his head with some force.” Id. It is true that the Hansen court requires the plaintiff to “prove that a test exists for detecting the onset of the illness before it would be apparent to the layperson” because if no monitoring exists, then the “potential plaintiff is not harmed until the onset of the actual illness.” Id. at 979. In this scenario, the plaintiff has not yet accrued any costs, not because the plaintiff has not suffered any injury at all, but because the plaintiff has not yet suffered a detectable – and therefore compensable – injury. Returning to the example used by the Hansen court, if “Jones lands on his head with some force” and sustains damage that will likely lead to a brain bleed but there is, in this example, no diagnostic test available to detect this damage, Jones is not harmed by being denied a test that

does not exist. That does not mean that he is not injured. It means that there is no way to detect that he is injured, and that he has not incurred costs – i.e., damages – to detect the injury.

The Donovan I court cites Hansen several other times; however, the Donovan I court does not do so in the context of defining the “injury.” Rather, the Supreme Judicial Court relies on Hansen as support for “the growing recognition that exposure to toxic substances and radiation may cause substantial injury which should be compensable” and to support the statement that proof of the medical monitoring elements “will usually require competent expert testimony.” Donovan I, 455 Mass. at 225-226. For all of these reasons, the Court rejects Philip Morris’s argument as to the nature of the “injury.”

(2) Factual Record Regarding Any Risk Reduction

In the alternative, Philip Morris argues that even if all Plaintiffs must show is that an alternative design would have lessened their risk of the subcellular changes that increase the risk of lung cancer, disputed facts remain about whether the proposed design would have reduced the risk in any meaningful way. D. 426 at 26-27; D. 295 at 32-36. It points to the fact that “scientific and public health communities have not yet determined that any cigarettes warrant a claimed reduction in risk.” D. 426 at 37 (emphasis in original); D. 295 at 36 (citing Farone Deposition, D. 298-19 at 8) (acknowledging that the Surgeon General has not endorsed a Cambridge-type design as reduced risk). In other words, Philip Morris argues that because no cigarette is safe, a low-tar cigarette might not have prevented Plaintiffs’ alleged injury.

This is not the first time that this Court has considered and rejected this argument. In Donovan II, this Court considered Philip Morris’s arguments that Plaintiffs would have to show that the alternative design would have completely prevented their injury. Donovan II, 268 F.R.D. at 14-15. The Court rejected that argument and concluded that “[t]he best plaintiffs can

ask for is a safer cigarette.” Id. (emphasis in original). Quoting from Haglund at some length, the Court concluded that “plaintiffs need only show that the less carcinogenic cigarette design would have reduced their risk of lung cancer, not that it would have prevented the injury.” Donovan II, 268 F.R.D. at 14 (emphasis in original). The Supreme Judicial Court has subsequently confirmed this interpretation of Massachusetts law in Evans. There, the court concluded that a plaintiff only need show that the nicotine and tar consumed by smokers was a substantial factor in bringing about her injury and that the injury would have been reduced with the reasonable alternative design. Evans, 465 Mass. at 438-439. As discussed above, the plaintiff in Evans did not have to prove that she would have used a reasonable alternative design if available. Id. at 438. To establish causation, then, Plaintiffs need only show that the less carcinogenic cigarette design would have reduced their risk of subcellular changes that increased their risk of lung cancer. Plaintiffs do not have to show that the alternative design would have completely prevented the injury. Nor do they have to show that the alternative design would have meaningfully prevented their injury. All that Plaintiffs have to show is reduction in risk of harm.

Plaintiffs claim that there is no dispute in the record that smoking Marlboros for 20 pack-years causes subcellular harm and thus increases the risk that a smoker will develop lung cancer. D. 260 at 2. Philip Morris does not dispute that several studies indicate and certain experts contend that use of lower tar cigarettes is associated with decreased risk for lung cancer. D. 30 at ¶ 49. Rather, it argues that there is, at a minimum, some factual debate as to whether smoking the proposed alternative design for 20 pack-years would have reduced Plaintiffs’ risk of lung cancer. D. 426 at 35 (noting that “Plaintiffs’ own experts have repeatedly testified that even an ultra-low-tar cigarette would have exposed a long-time smoker to a significantly increased risk

of lung cancer”). It may be true that at even an ultra-low-tar cigarette would have exposed a long-time smoker to an increased risk of lung cancer. However, the injury is the “subcellular changes” that increase the risk of cancer. The question, then, is whether there is a material issue as to whether the proposed alternative design would have reduced – at all – Plaintiffs’ risk of the subcellular changes that increased their risk of lung cancer. Accordingly, Plaintiffs’ motion for partial summary judgment, D. 259, is ALLOWED IN PART only as to the issues of injury and risk, but otherwise DENIED as to the breach of the implied warranty of merchantability claim.

2. *Related Defenses (D. 251; D. 257)*

The issues raised by Plaintiffs’ motion for partial summary judgment on breach of warranty, discussed above, also implicate Plaintiffs’ motions to strike Philip Morris’s thirty-third affirmative defense regarding alternative safer design, D. 251, and Philip Morris’s defenses based on class member conduct. D. 257. The Court will address those motions here.

a) Alternative Safer Design (D. 251)

Plaintiffs have moved to strike Philip Morris’s thirty-third affirmative defense regarding an alternative safer design. D. 251. In this affirmative defense, Philip Morris claims that it did not know, and could not have known, of the design characteristics that allegedly caused the injuries, the alleged danger of such design characteristics, or of the alternative design referred to by Plaintiffs. D. 30 at 28. Philip Morris also claims that any alternative design referred to by Plaintiffs was not feasible. Id.

As discussed above, to prevail on their breach of warranty claim, Plaintiffs must prove that “a product that is ‘defective and unreasonably dangerous’ . . . for the ‘[o]rdinary purposes’ for which it is ‘fit’ causes injury.” Haglund, 446 Mass. at 746 (quoting Colter, 403 Mass. at 62). And, as noted above, a number of factors must be considered to determine whether a product

design is defective and unreasonably dangerous, including “the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design.” Haglund, 446 Mass. at 748 (quoting Back, 375 Mass. at 633) (internal quotation marks omitted). Generally, “[i]t is the province of the jury to determine whether the relevant factors, properly balanced, suggest that a product’s design is unreasonable.” Osorio v. One World Technologies Inc., 659 F.3d 81, 85 (1st Cir. 2011)(citing Back, 375 Mass. at 641-42).

Plaintiffs contend that, as a factual matter, the alternative design was not only available but that Philip Morris sold the safer product before removing it from the market. It is undisputed that Plaintiffs in this case have identified cigarette designs capable of delivering dramatically less tar to the consumer, including Philip Morris’s Cambridge brand. D. 253 at ¶¶ 3, 5-11; Bonhomme Report, D. 223-1 at ¶¶ 37, 35, 47, 56; D. 252-2 at 2; Jupe Report, D. 252-3 at ¶¶ 20, 26; D. 296 at ¶¶ 2-3. It is also undisputed that Philip Morris, at least temporarily, sold the alternative design (again, the Cambridge brand). D. 30 at ¶ 60. Philip Morris has also acknowledged that it was possible to make cigarettes with less than 0.1 mg tar. Id. Philip Morris, however, argues that there is still a genuine dispute as to whether the alternative designs offered by Plaintiffs were feasible or whether the safer design interfered with the product’s performance. D. 426 at 10-16.

Philip Morris contends that the proposed safer design was not sufficiently similar to satisfy consumers. D. 426 at 12-14. As discussed in some detail above, the Supreme Judicial Court has held that plaintiffs need only show that the design alternative did not unduly interfere with the performance of the product from the perspective of a “rational, informed consumer,

whose freedom of choice is not substantially impaired by addiction.” Evans, 465 Mass. at 436. Plaintiffs argue that there is no way “that a rational, informed, non-addicted potential consumer would prefer a product that would continuously damage his or her body, and subject him or her to high risk of heart disease, emphysema, lung cancer, and a host of other grave ailments.” D. 415 at 10. Plaintiffs believe that such a choice would be “inescapably irrational.” Id. (emphasis in original). However, for the reasons stated above, the Court believes that a reasonable jury could conclude that a rational, informed, non-addicted smoker would have found that the design alternative interfered with the performance of the product and thus was not a “feasible” alternative design under Massachusetts law. Accordingly, Plaintiffs’ motion to strike Philip Morris’s thirty-third affirmative defense, D. 251, is DENIED.

b) Class Member Conduct (D. 257)

Plaintiffs have moved to strike all of Philip Morris’s affirmative defenses respecting the conduct of class members, including Philip Morris’s twenty-fourth affirmative defense, which is the subject of a separate motion to strike and is discussed *infra*.⁹ In addition, Plaintiffs have moved to strike all defenses relating to the fact that Philip Morris sold a legal product.¹⁰ For the

⁹Plaintiffs have moved to strike Philip Morris’s Eighteenth Affirmative Defense (failure to mitigate); Nineteenth Affirmative Defense (that risks of smoking are common knowledge); Twenty-fourth Affirmative Defense (superseding/intervening cause); Twenty-fifth Affirmative Defense (conditions, forces and/or things over which Philip Morris lacked control); Twenty-sixth Affirmative Defense (comparative fault or contributory negligence); Twenty-seventh Affirmative Defense (consent); Twenty-eighth Affirmative Defense (assumption of risk); Twenty-ninth Affirmative Defense (awareness of risk); Thirtieth Affirmative Defense (information in public domain); Thirty-first Affirmative Defense (open and obvious dangers); Thirty-fourth Affirmative Defense (unclean hands and *in pari delicto*); Forty-first Affirmative Defense (failure to satisfy Restatement (2d) of Torts 402A, cmt. i); Forty-second Affirmative Defense (Philip Morris’s misconduct unlikely to affect Plaintiffs in light of adequacy of information available); Forty-sixth Affirmative Defense (lack of privity); and Forty-seventh and Forty-eighth Affirmative Defense (disclaimer/waiver of warranties of merchantability).

¹⁰Plaintiffs have moved to strike Philip Morris’s Fifth Affirmative Defense (sale of cigarettes is lawful in Massachusetts); Twenty-first Affirmative Defense (conflict with federal

reasons stated below, the Court GRANTS IN PART and DENIES IN PART Plaintiffs' motion to strike, D. 257.

Philip Morris concedes that five of these defenses “appear to be inapplicable to this case,” and that Philip Morris “has no plans to press them.” D. 281 at 8. Accordingly, the Court GRANTS Plaintiffs' motion to strike, D. 257, as to Philip Morris's twenty-sixth affirmative defense (Comparative Fault/Contributory Negligence); twenty-seventh affirmative defense (Consent); forty-sixth affirmative defense (Lack of Privity) and forty-seventh and forty-eighth affirmative defenses (Disclaimer/Waiver of Warranties of Merchantability).

In addition, failure to mitigate, like contributory negligence, is not a defense recognized in a Massachusetts breach of warranty action. Nascimento v. Ford Motor Co., No. 905460, 1993 WL 818646, at *1 (Mass. Super. Apr. 12, 1993) (striking “failure to mitigate damages” defense and “avoidable consequences” defense because “[n]either of these defenses are recognized in Massachusetts”); see Correia, 388 Mass. at 357 (explaining that “[n]o recovery by the plaintiff shall be diminished on account of any other conduct which might be deemed contributorily negligent”); Haglund, 446 Mass. at 749–753 (concluding that a cigarette smoker's negligence in smoking does not bar him from recovery); 37 Mass. Prac., Tort Law § 17.6 (3d ed.) (noting that “in breach of warranty cases, the plaintiff's damages are not decreased by his proportionate share of fault”). In Correia, the Supreme Judicial Court considered whether the “underlying principles” of comparative negligence should apply as a full, or partial, defense in Massachusetts breach of warranty actions, and concluded that they do not. Correia, 388 Mass. at 354. The

and state regulatory schemes); Thirty-second Affirmative Defense (Marlboros were consistent with government regulations and industry standards); Fortieth Affirmative Defense (sale of cigarettes was in good faith and for valid business purpose); and any other affirmative defense that concerns class members' conduct, the lawfulness of Philip Morris's conduct or its conformity with industry standards.

court explained that, in Massachusetts breach of warranty actions, the seller is held strictly liable for “physical harm to a user or consumer of the seller’s product.” Id. at 353 (citing Back, 375 Mass. at 640). “Recognizing that the seller is in the best position to ensure product safety, the law of strict liability imposes on the seller a duty to prevent the release of any product in a defective condition unreasonably dangerous to the user or consumer, into the stream of commerce.” Id. at 355 (quoting Restatement (Second) of Torts § 402A) (internal quotations omitted). The focus in a breach of warranty action, therefore, is solely whether the product was defective and unreasonably dangerous, “and not on the conduct of the user or the seller.” Id. “Given this focus, the only duty imposed on the user is to act reasonably with respect to a product which he knows to be defective and dangerous.” Id. As such, Massachusetts courts likewise do not recognize the defense of failure to mitigate because “the only plaintiff-conduct defense to a breach of warranty claim recognized in this state” is “the defense set forth in Correia.” Nascimento, 1993 WL 818646, at *1.

Nor are Plaintiffs required to satisfy the reasonable consumer expectations standard for design defect in comment i to § 402A of the Restatement (Second) of Torts. Evans, 465 Mass. at 424-428 (adopting the risk-utility balancing standard in § 2 of the Third Restatement). Accordingly, the Court GRANTS Plaintiffs’ motion, D. 257, as to Philip Morris’s eighteenth affirmative defense (failure to mitigate) and forty-first affirmative defense (failure to satisfy Restatement (2d) of Torts 402A, cmt. i). The Court now turns to the remaining affirmative defenses.

(1) Defenses Related to Class Conduct

Plaintiffs contend that the only plaintiff-conduct defense available in Massachusetts for a breach of warranty claim is “that the user unreasonably proceeds to use a product which he

knows to be defective and dangerous,” (unreasonable use defense), which Plaintiffs argue was precluded as a defense in the context of cigarettes by Haglund, 446 Mass. 741. D. 258 at 4 (quoting Nascimento, 1993 WL 818646, at *1-2). Philip Morris counters that these myriad affirmative defenses raise legitimate questions that are fundamental to Plaintiffs’ breach of warranty claims and that the jury should be entitled to consider, for example: “whether Marlboro cigarettes are more dangerous than an ordinary consumer would expect; whether they were fit for their intended use; whether Plaintiffs’ proposed alternative design would be viewed by consumers as a reasonable substitute for Marlboro cigarettes; and whether PM USA’s allegedly tortious conduct caused Plaintiffs’ injuries.”¹¹ D. 281 at 7. Philip Morris argues, further, that even the defenses that explicitly implicate Plaintiffs’ conduct should be preserved for trial because, as this Court has recognized, the Supreme Judicial Court has declined to foreclose the Correia defense “as a matter of law in every cigarette-related product liability action.” D. 281 at 7-8 (quoting Haglund, 446 Mass. at 734); see also Donovan II, 268 F.R.D. at 20.

(a) *Jury Entitled to Consider Consumer Expectations
as Part of Risk-Utility Balancing Test*

Plaintiffs move to strike several of Philip Morris’s affirmative defenses that touch on consumer expectations, including, for example, Philip Morris’s nineteenth affirmative defense (that risks of smoking are common knowledge). As discussed above, in a Massachusetts breach of warranty case, consumer expectations are not the sole factor determining liability but may be considered as part of the risk-utility balancing test to determine if the design is defective. Evans, 465 Mass. at 428. The jury is, therefore, entitled (but is not required) to consider Philip Morris’s arguments regarding consumer expectations. Accordingly, Plaintiffs’ motion to strike, D. 257, is

¹¹As discussed above, these are also questions that would be implicated in the risk-utility balancing test that the jury should be allowed to consider.

DENIED as to Philip Morris's affirmative defenses that concern consumer expectations.

(b) *The Correia Defense*

Plaintiffs have also moved to strike several of Philip Morris's affirmative defenses relating to Plaintiffs' unreasonable use of the product, including Philip Morris's twenty-eighth affirmative defense (assumption of risk), twenty-ninth affirmative defense (awareness of risk), and thirty-first affirmative defense (open and obvious dangers). For the reasons discussed below, the Court DENIES Plaintiffs' motion to strike, D. 257, as to the Correia defense.

Plaintiffs are correct that under Massachusetts law, the only pure "plaintiff-conduct defense to a breach of warranty claim . . . is the defense that a user unreasonably proceeds to use a product which he knows to be defective and dangerous."¹² Nascimento, 1993 WL 818646, at *1. This defense (the Correia defense) tempers the manufacturer's burden by requiring the consumer to act reasonably when using a product that he or she knows to be defective and dangerous. When the consumer's use of a dangerous and defective product is unreasonable, under Correia, the consumer's conduct has become the proximate cause of her injuries. Correia, 388 Mass. at 356. The defense serves to deter a consumer from knowingly using a product that is in a defective and dangerous condition. However, in Haglund, the Supreme Judicial Court held that the Correia defense for unreasonable use applies to cigarettes only in certain narrow circumstances. Haglund, 446 Mass. at 742-43 (noting that "[b]ecause no cigarette can be safely used for its ordinary purpose, smoking, there can be no nonunreasonable use of cigarettes. Thus the Correia defense, which serves to deter unreasonable use of products in a dangerous and defective state, will, in the usual course, be inapplicable").

The Supreme Judicial Court held that the Correia defense did not presume that the only

¹²The Correia defense is only applicable after Plaintiffs have proven their case-in-chief unlike other of the defenses raised, *supra*, that attack on Plaintiffs' *prima facie* case.

safe use of a product was nonuse, but instead determined that because cigarettes could not be used safely, cigarette merchandising was incompatible with the Correia defense in most circumstances. Id. Nevertheless, the court concluded that “a defendant in a cigarette product liability warranty claim should not be entirely foreclosed from asserting the Correia defense as a matter of law.” Haglund, 446 Mass. at 753. In certain narrow situations, then, the Correia defense may be invoked when a consumer’s behavior is “overwhelmingly unreasonable.” Id. at 753. The example that the Supreme Judicial Court gave of such unreasonable behavior was when a consumer begins smoking cigarettes knowing that she has a medical condition, such as emphysema. Id. at 753-754. Haglund does not suggest this example as the only scenario of “overwhelmingly unreasonable” consumer behavior. Id. at 753. However, when invoked in this circumstance, a defendant must show that the plaintiff knew of her medical condition and the risks smoking added to that specific condition at the time she began smoking. Id. at 753-754.

At this juncture, the Court need not decide the exact dimensions of the Correia defense as applied to cigarette litigation. Instead, it is enough to conclude that the defense is still available to Philip Morris in some fashion at trial. Plaintiffs are correct that this defense, narrowed by Haglund, does not give Philip Morris the right to litigate every aspect of class member conduct; however, to the extent that class conduct touches on the Correia defense, as it is allowed in post-Haglund cigarette product liability actions, Philip Morris will be allowed this defense at trial. Accordingly, the Court DENIES Plaintiffs’ motion to strike, D. 257, as to the Correia defense.

(i) *Waiver*

Plaintiffs also argue that Philip Morris has waived the Correia defense by failing to plead it in its answer. D. 415 at 18. Philip Morris counters that the Correia defense was encompassed in several of its affirmative defenses, including its Twenty-Fourth Affirmative Defense

(superseding/intervening cause); and Twenty-Eighth Affirmative Defense (assumption of risk), which rest on principles of proximate cause and assumption of risk. Regardless, both parties have briefed this issue and argued the issue at the class certification stage – where Plaintiffs did not argue that Philip Morris waived Correia. D. 117 at 17-23; D. 343 at 88-92, 98-102. That is, its answer put Plaintiffs on notice about the nature of Philip Morris’s defenses. Accordingly, under these circumstances, the Court finds no waiver here. See e.g., Palasota v. Hagggar Clothing Co., 499 F.3d 474, 487 n.10 (5th Cir. 2007) (finding no waiver because “both parties spent extensive time discussing the issue of mitigation at trial. . . . The record is clear that no . . . surprise resulted here”).

(2) Defenses Relating to the Lawfulness of Cigarettes

Plaintiffs also move to strike Philip Morris’s fifth, twenty-first and twenty-second affirmative defenses respecting the lawfulness of its conduct and the similar behavior of other cigarette manufacturers. D. 258 at 7-8. Plaintiffs argue that the legality of cigarettes and their conformity with industry standards does not constitute a defense to a breach of warranty action. Id.

Opposing Plaintiffs’ motion to strike, Philip Morris has raised a number of factual questions that it argues will implicate the risk-utility factors, including whether Marlboros can be defective if they share the same properties as all other cigarettes on the market and if they conform to industry standards. D. 426 at 22-23; D. 295 at 19-20. Philip Morris argues that evidence of adherence to industry norms and regulations (thirty-second affirmative defense) and evidence that governments have expressly decided to keep cigarettes on the market (fifth and twenty-first affirmative defenses) is relevant to whether the product is fit for the ordinary

purposes for which such goods are used. D. 426 at 22-23. In Haglund, the Supreme Judicial Court considered this issue and determined that:

warranty liability may be imposed even where the product was properly designed, manufactured, or sold; conformed to industry standards; and passed regulatory muster, and even where the consumer used the product negligently.

Haglund, 446 Mass. at 748 (citing Correia, 388 Mass. at 353). More recently, the Evans decision confirmed that “a product may be defectively designed even if the characteristic that makes the product unreasonably dangerous is shared with every other competitive product on the market.” Evans, 465 Mass. at 432 (citing Haglund, 446 Mass. at 748).

Nevertheless, as discussed above, the case law makes clear that the jury may consider consumer expectations to determine whether Marlboro cigarettes are unreasonably dangerous and that these inherently fact-based balancing tests are best left to a jury. Evans, 465 Mass. at 423-428; Haglund, 446 Mass. at 745-754. Accordingly, the Court DENIES Plaintiffs’ motion to strike, D. 257, to the extent that the legality of cigarettes and Philip Morris’s conformity with industry standards may be considered by the jury as part of the risk-utility balancing test.

(3) Prejudice

Plaintiffs suggest that Philip Morris’s only purpose in calling into question the conduct of the class members is to play into prejudices against smokers in an effort to provoke jury nullification. However, arguments regarding the potential prejudicial effect of evidence are not properly addressed in a motion for summary judgment. The Court can address the parties’ arguments regarding the alleged prejudicial effect that substantially outweighs any probative value, under Fed. R. Evid. 403, of any such evidence at trial.

C. Superseding and Intervening Cause (Proximate Cause) (D. 249)¹³

In its twenty-fourth affirmative defense, Philip Morris asserts that Plaintiffs' claims are barred because the superseding or intervening cause of Plaintiffs' injury is the class members' own conduct, or the conduct of others, for which Philip Morris is not liable. D. 30 at 26. Plaintiffs seek to strike this defense, arguing that it is black-letter law in Massachusetts that a superseding or intervening cause must be unforeseeable to relieve a tortfeasor of liability for his misconduct and that there is no genuine issue of material fact as to whether the class members' smoking was foreseeable to Philip Morris. D. 250 at 1-2.

1. Class Members' Conduct as Superseding or Intervening Cause

Both parties agree that proximate cause is traditionally a jury question in Massachusetts. D. 250 at 2 (citing Solimene v. B. Grauel & Co., 399 Mass. 790, 794 (1987)); D. 274 at 2. Nevertheless, Plaintiffs argue that summary judgment is appropriate in this case because there is no genuine issue of material fact about whether the class members' smoking was foreseeable to Philip Morris. They argue that the class members' smoking cannot be a superseding or intervening cause because it is necessarily foreseeable to Philip Morris that smokers would continue to smoke, even in the face of illness or a family history of lung cancer. Plaintiffs point to Philip Morris's admissions in its Answer that "cigarettes are intended to be smoked by adult smokers of the legal age for purchasing cigarettes," and that Philip Morris "strives to ensure that its cigarettes have specific nicotine yields" as evidence that Philip Morris's business model necessarily counts on the foreseeability of smokers continuing to smoke. D. 30 at ¶¶ 50, 81.

Philip Morris argues that the admissions relied upon by Plaintiffs – who bear the burden of proving causation – do not establish that Philip Morris necessarily foresaw that every class

¹³The issues raised in this motion – to the extent that they touch on the unreasonable use defense (the Correia defense) – have been resolved above.

member would continue to smoke in every circumstance. D. 275 at 3; D. 274 at 2-4. However, Philip Morris does not offer any evidence to counter the proposition that it would be foreseeable that an “ordinary” smoker would smoke and would continue to smoke. Rather, Philip Morris focuses on the fact that a class member could have had special circumstances – e.g., family medical history or exposure to toxic materials – that would have made that class member’s continued smoking unforeseeable. D. 274 at 5. Nevertheless, as the parties point out, causation is an element of Plaintiffs’ *prima facie* case, and is therefore not a true affirmative defense.¹⁴ Therefore, to the extent that Philip Morris intends simply to contest at trial that a smoker continuing to smoke is foreseeable, the Court ALLOWS Plaintiffs’ motion to strike, D. 249, to the extent that it applies as to ordinary smokers in the ordinary course; the motion is otherwise DENIED, but will require a showing at trial (or *in limine* before trial) as to special circumstances.

2. *Acts of Third Persons or Other Forces*

Philip Morris argues that even if it was undisputed that it was foreseeable that every class member would have continued to smoke in every circumstance that should not remove the question of superseding or intervening cause from the jury because the acts of third parties and/or other forces could foreclose its liability. D. 274 at 4. For example, Philip Morris points to the depositions of the named class members, who admitted to smoking other brands of cigarettes, to argue that there could be genuine issues of fact regarding proximate cause. D. 274 at 5; D. 275 at 2; Donovan Deposition (excerpts provided by Philip Morris), D. 276-1 at 4, 6-9; Cawley Deposition (excerpts provided by Philip Morris), D. 276-2 at 3-5. In addition, Philip

¹⁴Plaintiffs still argue, however, that they would be prejudiced by allowing this defense to stand because it would create an opening for Philip Morris to advance improper evidence that will have no bearing on liability.

Morris argues that class members could have strong family histories of lung cancer or that they could have been exposed to some other substance that would increase their risk of lung cancer. D. 274 at 5 (exposure to silica and stone dust); D. 281 at 17 (asbestos, silica, beryllium, chromium, nickel or radon).

Plaintiffs do concede that, under Massachusetts law, either a plaintiff's own conduct or the "act of a third person or other force" can constitute a superseding or intervening cause, but they argue that Philip Morris has not been able to point to one possible superseding or intervening cause that would not have been foreseeable. D. 339 at 1-2. Plaintiffs argue that "there exists no factual scenario in which any subsequent act which might have caused Plaintiffs or class members to develop risk of lung cancer which was not entirely foreseeable to Philip Morris." *Id.* at 1.

On this record, the Court cannot conclude that there is no genuine, material factual issue regarding the existence of any single superseding or intervening cause. The smoking of other cigarette brands may have been foreseeable, but class members very well may have been exposed to other substances that were unusual and unforeseeable. Plaintiffs' medical histories may have made their continued smoking unforeseeable under the circumstances.¹⁵ Plaintiffs have the burden on summary judgment to establish that there is no material fact at issue when viewing the record in the light most favorable to Philip Morris. Their bare statement that "there exists no factual scenario" in which any act that might have caused Plaintiffs' risk of lung cancer "was not entirely foreseeable to Philip Morris" is not sufficient. Accordingly, the Court DENIES Plaintiffs' motion regarding superseding/intervening cause; D. 249.

¹⁵Moreover, as discussed above, the Supreme Judicial Court preserved the Correia defense in circumstances where a plaintiff begins smoking after being diagnosed with emphysema.

D. Damages (D. 245; D. 243)

Plaintiffs press two motions to strike, D. 245 and D. 243, that address damages issues and accordingly, the Court addresses them together.

1. Speculative and Remote Damages (D. 245)

In its sixteenth affirmative defense, Philip Morris asserts that Plaintiffs are not entitled to recovery “because the damages sought are too speculative and remote.” D. 30 at 25. In its thirty-eighth affirmative defense, Philip Morris argues that Plaintiffs are not entitled to the relief requested “because the Court lacks any sufficiently certain, nonspeculative basis for fashioning such relief.” *Id.* at 29. Plaintiffs argue that these defenses fail as a matter of law in light of the Supreme Judicial Court’s opinion in Donovan I, but the parties focused their arguments upon the issue of the participation rates in the relief of medical monitoring program as being too speculative and remote and, accordingly, the Court confines its analysis to this issue. D. 246 at 1-3; D. 286 at 8-16; see also, June 26, 2014 Hearing Transcript, D. 444 at 6-7.

a) Participation Rate

In Donovan I, the Supreme Judicial Court considered whether Plaintiffs’ suit for medical monitoring stated a cognizable claim that permitted for a remedy under Massachusetts state law. Donovan I, 455 Mass. at 215-216. The Supreme Judicial Court concluded that Plaintiffs had stated a claim and that “medical monitoring is a form of future medical expense and should be treated as such.” Donovan I, 455 Mass. at 226. Regarding future damages, the Supreme Judicial Court noted that under Massachusetts law, “[a] plaintiff is entitled to compensation for all damages that reasonably are to be expected to follow, but not to those that possibly may follow, the injury which he has suffered.” Donovan I, 455 Mass. at 223 (quoting Pullen v. Boston Elevated Ry., 208 Mass. 356, 357-358 (1911) (internal quotation mark omitted)).

The Donovan I court held that Plaintiffs will have the burden to prove at trial “the present value of the reasonable cost of [diagnostic] tests and care, as of the date of the filing of the complaint.” Donovan I, 455 Mass. at 226. Likewise, this Court has found that the present value of Plaintiffs’ future medical expenses is a fact question for the jury, that the “plaintiffs will have the burden to prove at trial the present value of the reasonable cost of [diagnostic] test and care” and that “the jury may award damages according to this value.” 5/25/2011 docket entry (citation omitted). The issue, here, is whether the “present value of the reasonable cost of such tests and care” requires the factfinder to determine how many class members will participate in the program.

As a threshold matter, Philip Morris has argued that the participation rate issue goes to the very definition of the injury. June 26, 2014 Hearing Transcript, D. 444 at 34. Relying on footnote twelve in Donovan I and on the Hansen case, discussed in some detail above, Philip Morris argues that if Plaintiffs do not actually receive the LDCT scans then they are not actually injured. Id. at 34-35. Philip Morris draws this conclusion based on a reading of Donovan I that defines the plaintiff’s injury – not as subcellular changes that substantially increase the risk of lung cancer – but as the need for medical monitoring and the attending costs. Id. at 35. To prove any injury at all, therefore, Philip Morris contends that Plaintiffs are required to prove that they will actually receive the scans. However, as discussed above, the Court does not adopt Philip Morris’s definition of “injury.”

Philip Morris also points the Court to numerous facts that show the “only undisputed fact in the record about the participation rate is that it would not be 100 percent,”¹⁶ which Philip Morris argues necessarily precludes summary judgment on the likely participation rate. D. 286

¹⁶A one hundred percent participation rate would mean that each class member actually obtained all annual and follow-up scans each year for 28 years.

at 8. Plaintiffs agree that, if they prevail on the merits, “more than zero and less than one hundred percent of class members will ultimately receive LDCT surveillance.” D. 318 at 1. Plaintiffs, however, argue that any dispute between the parties’ experts regarding the participation rate in any remedy is immaterial at this stage. Id. at 2. Plaintiffs claim that while Donovan I made clear that they must prove “the present value of the reasonable cost of such tests and care” that they do not have an obligation to “offer evidence concerning the likelihood that they will seek or obtain medical surveillance.” D. 318 at 5 (emphasis in original) (quoting Donovan I, 455 Mass. at 226) (citation omitted). In addition, Plaintiffs argue that allowing evidence regarding participation rates would needlessly inject another issue into the case, adding considerable expense and delay. D. 318 at 6.

Philip Morris contends that the participation rate is a key component of the “value of the reasonable cost of [diagnostic] tests and care” because the cost of the program will be determined, in part, by the number of scans – a number that necessarily depends on the proportion of the class that will avail themselves of the remedy. D. 286 at 6-14 (quoting Order Regarding Trial Plan, 5/25/2011 docket entry) (citation omitted). Philip Morris argues further that if the fund is created based on a “concededly false assumption of 100% participation” that it would be forced to overfund the remedy in violation of the Rules Enabling Act and due process. D. 328 at 4, 5-7.

Under Donovan I, Plaintiffs must establish that the LDCT surveillance is reasonably and periodically necessary, and “the present value of the reasonable cost of such tests and care, as of the date of the filing of the complaint.” Donovan I, 455 Mass. at 226. The fundamental issue is whether the class will need monitoring and, then, if necessary, the “reasonable costs of such tests” for the class. The reasonable cost of monitoring on a class-wide basis would inevitably

require some assessment of class size, but it is not clear that an assessment of the reasonable cost of monitoring for the class would require the jury to determine whether the program will be used by any or all individual members of that class. Nevertheless, whether the class will receive medical monitoring is the primary issue, independent of whether an individual plaintiff can or will satisfy that need.¹⁷ Accordingly, the Court GRANTS IN PART Plaintiffs' motion to strike Philip Morris's sixteenth and thirty-eighth affirmative defenses, D. 245, as to the participation rate and Philip Morris is precluded from putting on evidence regarding same in liability phase of the trial. If necessary, the Court will return to this issue at the damages phase.

2. *Collateral Source (D. 243)*

Plaintiffs have moved to strike Philip Morris's fourteenth affirmative defense, D. 243, in which Philip Morris contends that it is "entitled to set-off, should any damages be awarded against it, in the amount of damages or settlement amounts recovered by Plaintiffs . . . with respect to the same alleged injuries" and (2) that Philip Morris is "entitled to have any damages that may be awarded to Plaintiffs . . . reduced by the value of any benefit or payment . . . from any collateral source." D. 30 at 24.

The Court will reserve issues of set-off unless and until Plaintiffs establish liability during the liability phase at trial. However, as to collateral source, it is well settled under Massachusetts law – and the parties do not contest – that Philip Morris is not entitled to set-off, should any damages be awarded against them, in the amount of any benefit or payment to Plaintiffs from any collateral source. D. 244 at 1-3; D. 277 at 2 ("Philip Morris . . .

¹⁷Similarly, in Donovan III, the Court responded to Philip Morris's argument that Plaintiffs would not be able to succeed on their medical monitoring claim without proving medical necessity. This Court found that "individual plaintiff's medical inability to satisfy his or her need for diagnostic examination does not alter the fact that she has undergone physiological change that increases a risk of cancer and triggers the need for diagnostic surveillance in the first place." Donovan III, 2012 WL 957633 at *24.

acknowledges that in personal injury actions Massachusetts law precludes the reduction of medical-expense damages based on payments received from health insurance providers”); see also Goldstein v. Gontarz, 364 Mass. 800, 808-9 (1974) (noting that “a defendant may not show that the plaintiff has received other compensation for his injury, whether from an accident insurance policy, from workmen’s compensation, from an employer, or from other sources”) (internal citations omitted); Law v. Griffith, 457 Mass. 349, 354-55 (2010) (noting that “[u]nder the common-law collateral source rule, the value of reasonable medical expenses that an injured plaintiff would be entitled to recover from the tortfeasor as a component of her compensatory damages is not to be reduced by any insurance payments or other compensation received from third parties by or on behalf of the injured person”) (internal citation omitted).

Philip Morris does argue, however, that evidence of insurance coverage could be relevant and admissible for other defenses that they may arise during trial and disputes Plaintiffs’ motion to strike “[t]o the extent that [it] is a disguised motion *in limine* seeking to bar all evidence relating to insurance coverage for LDCT scans.” D. 277 at 2. Whether evidence of insurance coverage will be admissible for another purpose at trial is an evidentiary question that the Court may address upon a motion *in limine* or an objection at trial. England v. Reinauer Transp. Cos., 194 F.3d 265, 273-74 (1st Cir. 1999) (explaining that when evidence of collateral source payments is offered in federal court not for the purpose of reducing a damages award improperly, but rather because it “is relevant to some other contested issue,” that evidence—including proof of insurance coverage—“may be admitted if it is not unfairly prejudicial”); Law, 457 Mass. at 360-61 (same rule applies in state court). The Court notes that Philip Morris’s concerns relating to Plaintiffs’ claims for injunctive relief have been resolved by the Court’s decision regarding the lack of an adequate remedy at law, D. 247, above. However, whether insurance coverage may

be admissible regarding, for example, the reasonable cost of the remedy is an issue for trial. Therefore, the Court GRANTS IN PART Plaintiffs' motion, D. 243, as to the substantive application of the collateral source rule but will reserve ruling on any evidentiary issues at trial.

E. Timeliness (D. 254)

Plaintiffs have moved to strike Philip Morris's second affirmative defense, D. 254, which seeks dismissal based on the statute of limitations, and Philip Morris's seventeenth affirmative defense regarding the doctrines of laches, waiver, and equitable estoppel. D. 30 at 22, 25. As a threshold matter, the Court notes that although Plaintiffs have moved to strike Philip Morris's seventeenth defense regarding laches, waiver and equitable estoppel, Philip Morris did not devote any time to briefing or arguing those issues. To the extent that Philip Morris did not respond, the Court GRANTS Plaintiffs' motion as to laches, waiver and equitable estoppel, D. 254. Regarding the statute of limitations defense, Plaintiffs argue that there is no view of the record that would allow a factfinder to conclude that this action is time-barred. D. 255 at 2. The Court disagrees. Accordingly, the Court DENIES Plaintiffs' motion to strike Philip Morris's second affirmative defense regarding statute of limitations, D. 254.

1. Statute of Limitations

Plaintiffs' breach of implied warranty and 93A claims are subject to three and four year statutes of limitations, respectively. Mass. Gen. L. c. 260 § 2A; Mass. Gen. L. c. 260 § 5A; Donovan I, 455 Mass. at 219 n.7. In Donovan I, the Supreme Judicial Court considered the application of the statute of limitations to Plaintiffs' medical monitoring claims. Donovan I, 455 Mass. at 227-229. The Donovan I Court held that "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. at 229. The Supreme Judicial Court proceeded to conclude that if Plaintiffs can establish that they had “no remedy until LDCT technology appeared” then “their claims are timely.” Id. In other words, “[t]he plaintiffs must show that the standard of care . . . did not call for monitoring of any precancerous condition prior to the statute of limitations period, not just that the technology at that time was less effective.” Id.

Plaintiffs do not dispute that the first prong of the Supreme Judicial Court’s test was satisfied prior to December 2002. See D. 255; D. 297 at 6. According to Plaintiffs’ own experts, a physiological change that causes a substantial increase in the risk of cancer occurs almost the instant that someone begins to smoke. Miller Deposition (excerpts provided by Plaintiffs), D. 116-2 at 8 (observing that “[y]ou could start seeing [the effects] within hours or days of starting to smoke . . .”). The Court will therefore focus its analysis on the second prong of the Supreme Judicial Court’s statute of limitations test.

2. *Efficacious Method of Lung Cancer Screening Consistent with Standard of Care*

In Donovan II, this Court analyzed the statute of limitations inquiry in the context of class certification. Donovan II, 268 F.R.D. at 19-20. Finding that the statute of limitations determination did not require an individual inquiry, the Court described at some length the possible statute of limitations determinations:

First, plaintiffs could demonstrate that LDCT screening became a standard of care within the limitations period and that prior to then, no other effective monitoring technology existed. Plaintiffs’ claims are then timely. Second, the factfinder could find that LDCT screening has become a standard of care, but either it did so before 2002 or some other earlier screening technology existed, such that the statute of limitations has run. Third, the factfinder could find that LDCT screening has not become a standard of care and no other screening exists. In that case, the cause of action will not have accrued. Finally, a factfinder could find that LDCT

screening is not a standard of care, but some other screening technology was, and the limitations period will have run.

Donovan II, 268 F.R.D. at 19.

Plaintiffs assert that it is undisputed that, prior to this action's filing on December 14, 2006, LDCT technology had not yet become consistent with the standard of care. D. 255 at 2; see also Goodman, M.D. Declaration, D. 255-1 at ¶12 ("LDCT screening for lung cancer is not the standard of care"); McCunney, M.D. Declaration and Report, D. 255-2 at ¶¶ 15-21. The Court agrees. Philip Morris does not dispute that "its experts have stated that LDCT screening for lung cancer is not yet the standard of care . . ." D. 300 at 2. For example, at late as May 13, 2011, Philip Morris's expert, Dr. Samuel Spagnolo, stated in his declaration that "LDCT lung cancer screening is not the standard of care." Spagnolo, M.D. Declaration and Report, D. 255-3 at ¶ 14 (declaring that "LDCT lung cancer screening is not standard of care. Every major public health organization and medical society which has examined the issue of lung cancer screening, through the use of LDCT or any other technology, has considered the data insufficient to recommend screening for any group of people, including groups considered to be at high risk"). Philip Morris does raise the fact that Plaintiffs' experts have testified that they used LDCT scans prior to December 2002. D. 297 at 3. However, the mere use of LDCT scans by physicians prior to 2002 does not address whether the scans were considered the standard of care and nothing in the record suggests that LDCT scans were consistent with the standard of care prior to 2002. Therefore, the only remaining question as to whether this action is time-barred is whether another efficacious method of lung cancer screening was available prior to 2002.

Plaintiffs contend that although the parties disagree about whether LDCT screening is effective and whether it is the current standard of care, that "throughout this litigation, the parties and their respective experts have agreed that no efficacious or accepted technique existed to

monitor for lung cancer prior to LDCT scans.” D. 255 at 2. Plaintiffs point to a number of experts who have testified that prior to LDCT technology that no other screening technology, including traditional x-ray technology, was effective. Spagnolo, M.D. Declaration and Report, D. 255-3 at ¶ 12 (noting that “[p]rior to the development of LDCT technology, research had demonstrated that neither lung cancer screening with chest x-rays nor with sputum cytology resulted in a reduction in lung cancer mortality”); Miller Deposition (excerpts provided by Plaintiffs), D. 255-10 at 5-6 (explaining that chest x-rays were offered despite “various stages of doubt” in the medical community as to their effectiveness). However, as noted above, “[t]he plaintiffs must show that the standard of care” did not call for any monitoring, “not just that the technology at that time was less effective.” Donovan I, 455 Mass. at 229. Philip Morris points out that the exact record evidence cited to by Plaintiffs indicates that many practitioners prescribed chest x-rays for lung cancer screening before LDCT screening was available. For example, in his deposition, Dr. Miller stated that prior to LDCT scanning’s availability that he recommended chest x-rays to his patients as part of “a standard of care” that existed before 2002. Miller Deposition (excerpts provided by Plaintiffs), D. 255-10 at 5, 6. Admittedly, Dr. Miller is clear in his deposition that there was doubt in the medical community regarding the efficacy of x-rays to reduce cancer mortality. Id. at 5. Nevertheless, Dr. Miller acknowledges that given the “simplicity, the lack of danger, the minimum even radiation exposure and the other benefits of a chest x-ray” that he felt it “appropriate” to recommend the x-ray to his smoking patients and that many of his colleagues did as well. Id. at 5-6. This may raise concerns about whether under Donovan I a technology can be “an efficacious method of lung cancer screening or surveillance” that is triggered “under the standard of care,” without being considered truly “effective.” Therefore, the Court finds that there is still a genuine issue of material fact as to whether x-ray

technology was “an efficacious method of lung cancer screening” consistent with the standard of care prior to 2002. Accordingly, the Court DENIES IN PART Plaintiffs’ motion, D. 254, as to Philip Morris’s second affirmative defense.

VI. Conclusion

For the foregoing reasons, the Court:

1. GRANTS Plaintiffs’ motion to strike Philip Morris’s thirty-sixth affirmative defense respecting the adequacy of a legal remedy, D. 247;
2. DENIES IN PART and GRANTS IN PART Plaintiffs’ motion for partial summary judgment, D. 259;
3. DENIES Plaintiffs’ motion to strike Philip Morris’s thirty-third affirmative defense regarding an alternative safer design, D. 251;
4. GRANTS IN PART and DENIES IN PART Plaintiffs’ motion to strike to strike all defenses based upon class members’ conduct, D. 257;
5. DENIES Plaintiffs’ motion to strike Philip Morris’s twenty-fourth affirmative defense regarding superseding and intervening cause, D. 249;
6. GRANTS IN PART Plaintiffs’ motions to strike Philip Morris’s fourteenth, sixteenth and thirty-eighth affirmative defenses respecting damages, D. 245 and D. 243; and
7. GRANTS IN PART and DENIES IN PART Plaintiffs’ motion to strike Philip Morris’s second and seventeenth affirmative defenses respecting timeliness, D. 254.

So Ordered.

/s/ Denise J. Casper
United States District Judge