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Filed November 12, 1998

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 97-1844

WILLIAM BARNES; CIARAN McNALLY; CATHERINE POTTS; NORMA RODWELLER; BARBARA SALZMAN; EDWARD SLIVAK; JOHN TEAGLE, ON BEHALF OF THEMSELVES AND ALL OTHERS SIMILARLY SITUATED

v.

THE AMERICAN TOBACCO COMPANY; AMERICAN BRANDS, INC.; R.J. REYNOLDS TOBACCO COMPANY; RJR NABISCO, INC.; BROWN & WILLIAMSON TOBACCO CORPORATION; BATUS, INC.; BATUS HOLDINGS, INC.; B.A.T. INDUSTRIES, P.L.C.; PHILIP MORRIS, INC.; PHILIP MORRIS COMPANIES, INC.; LORILLARD TOBACCO COMPANY, INC.; LORILLARD, INC.; LOEWS CORPORATION; UNITED STATES TOBACCO COMPANY; UST, INC.; THE TOBACCO INSTITUTE, INC.; THE COUNCIL FOR TOBACCO RESEARCH-U.S.A., INC.; LIGGETT GROUP, INC.; LIGGETT & MYERS, INC.; BROOKE GROUP, LTD.; PENNSYLVANIA DISTRIBUTORS ASSOCIATION, INC.; UNITED WHOLESALE TOBACCO AND CANDY, d/b/a UNITED VENDING SERVICE, INC.; BRITISH AMERICAN TOBACCO COMPANY

> William Barnes, Ciaran McNally, Catherine Potts, Norma Rodweller, Barbara Salzman and Edward Slivak, on behalf of themselves and all those similarly situated, Appellants

On Appeal from the United States District Court for the Eastern District of Pennsylvania (D.C. Civil Action No. 96-cv-05903) Argued June 4, 1998 Before: SCIRICA, NYGAARD and SEITZ, * Circuit Judges (Filed November 12, 1998) ROBERT J. LAROCCA, ESQUIRE (ARGUED) Ryan, Brown, McDonnell, Berger & Gibbons 1600 Market Street, Suite 3850 Philadelphia, Pennsylvania 19103 ARNOLD LEVIN, ESQUIRE (ARGUED) Levin, Fishbein, Sedran & Berman 510 Walnut Street, Suite 500 Philadelphia, Pennsylvania 19106 DIANNE M. NAST, ESQUIRE Roda & Nast 801 Estelle Drive Lancaster, Pennsylvania 17601 JULIA W. McINERNY, ESQUIRE Coale, Cooley, Leitz, McInerny & Broadus 818 Connecticut Avenue, N.W., Suite 857 Washington, D.C. 20006

*Judge Seitz heard argument in this matter but was unable to clear the opinion.

GARY R. FINE, ESQUIRE Rodham & Fine 633 Southeast Third Avenue, Suite 4R Fort Lauderdale, Florida 33301 THOMAS E. MELLON, JR., ESQUIRE Mellon, Webster & Mellon 87 North Broad Street Doylestown, Pennsylvania 18901 STEPHEN A. SHELLER, ESQUIRE Sheller, Ludwig & Badey 1528 Walnut Street, 3rd Floor Philadelphia, Pennsylvania 19102 Attorneys for Appellants HUGH R. WHITING, ESQUIRE Jones, Day, Reavis & Poque 901 Lakeside Avenue, North Point Cleveland, Ohio 44114 MORTON F. DALLER, ESQUIRE EDWARD A. GREENBERG, ESQUIRE GERHARD P. DIETRICH, ESQUIRE Daller, Greenberg & Dietrich Valley Green Corporate Center 7111 Valley Green Road Fort Washington, Pennsylvania 19034 Attorneys for Appellee, R.J. Reynolds Tobacco Company DANIEL F. KOLB, ESQUIRE ANNE B. HOWE, ESQUIRE Davis, Polk & Wardwell 450 Lexington Avenue

New York, New York 10017

MORTON F. DALLER, ESQUIRE EDWARD A. GREENBERG, ESQUIRE GERHARD P. DIETRICH, ESQUIRE Daller, Greenberg & Dietrich Valley Green Corporate Center 7111 Valley Green Road Fort Washington, Pennsylvania 19034

Attorneys for Appellee, RJR Nabisco, Inc.

JAMES L. GRIFFITH, ESQUIRE Klett, Lieber, Rooney & Schorling 18th and Arch Streets Two Logan Square, 12th Floor Philadelphia, PA 19103

VIRGINIA L. HOGBEN, ESQUIRE Wolf, Block, Schorr & Solis-Cohen Packard Building, 12th Floor 15th and Chestnut Streets Philadelphia, Pennsylvania 19102

PETER S. GREENBERG, ESQUIRE Schnader, Harrison, Segal & Lewis 1600 Market Street, Suite 3600 Philadelphia, Pennsylvania 19103

GARY R. LONG, ESQUIRE SHANNON L. SPANGLER, ESQUIRE Shook, Hardy & Bacon One Kansas City Place 1200 Main Street Kansas City, Missouri 64105

Attorneys for Appellee, Brown & Williamson Tobacco Corporation

ROBERT C. HEIM, ESQUIRE (ARGUED) JEFFREY G. WEIL, ESQUIRE Dechert, Price & Rhoads 4000 Bell Atlantic Tower 1717 Arch Street Philadelphia, Pennsylvania 19103

Attorneys for Appellees, Philip Morris, Inc. and Philip Morris Companies, Inc.

WILLIAM J. O'BRIEN, ESQUIRE HOWARD M. KLEIN, ESQUIRE Conrad, O'Brien, Gellman & Rohn 1515 Market Street, 16th Floor Philadelphia, Pennsylvania 19102

GARY R. LONG, ESQUIRE SHANNON L. SPANGLER, ESQUIRE Shook, Hardy & Bacon One Kansas City Place 1200 Main Street Kansas City, Missouri 64105

Attorneys for Appellees, Lorillard Tobacco Company, Inc. and Lorillard, Inc.

WILLIAM J. O'BRIEN, ESQUIRE HOWARD M. KLEIN, ESQUIRE Conrad, O'Brien, Gellman & Rohn 1515 Market Street, 16th Floor Philadelphia, Pennsylvania 19102

Attorneys for Appellee, The Tobacco Institute, Inc.

PATRICK W. KITTREDGE, ESQUIRE GARY M. MAREK, ESQUIRE Kittredge, Donley, Elson, Fullem & Embick 421 Chestnut Street, Fifth Floor Philadelphia, Pennsylvania 19106

Attorneys for Appellee, The Council for Tobacco Research-U.S.A., Inc.

J. KURT STRAUB, ESQUIRE
(ARGUED)
Obermayer, Rebmann, Maxwell &
Hippel
One Penn Center, 19th Floor
1617 John F. Kennedy Boulevard
Philadelphia, Pennsylvania 19103

Attorney for Appellees, Liggett Group, Inc., Liggett & Myers, Inc. and Brooke Group, Ltd.

OPINION OF THE COURT

SCIRICA, Circuit Judge.

In this suit against the major American tobacco companies, we must decide whether a medical monitoring class should be certified under Federal Rule of Civil Procedure 23(b)(2). The District Court decertified a proposed class of cigarette smokers on the grounds that significant individual issues precluded certification. After finding the statute of limitations had run with respect to the claims of five named plaintiffs and the sixth had failed to establish the need for medical monitoring, the District Court granted defendants summary judgment. We will affirm the District Court's decertification order and its grant of summary judgment.

FACTS AND PROCEDURAL HISTORY

Named plaintiffs William Barnes, Catherine Potts, Norma Rodweller, Barbara Salzman, Edward J. Slivak, and Ciaran McNally are Pennsylvania residents who began smoking cigarettes before the age of 15 and have smoked for many years. Plaintiffs filed suit against the defendant tobacco companies1 in the Court of Common Pleas of Philadelphia County. Defendants removed to the Eastern District of Pennsylvania, and plaintiffs filed an Amended Complaint asserting claims of intentional exposure to a hazardous substance, negligence, and strict products liability on behalf of a purported class of over one million Pennsylvania cigarette smokers. In their prayer for relief, plaintiffs asked (1) that defendants fund a court-supervised or courtapproved program providing medical monitoring to class members; (2) for punitive damages to create a fund for common class-wide purposes, including medical research, public education campaigns, and smoking cessation programs; and (3) for other monetary and injunctive relief the court deemed just and proper.

Α.

The District Court found the class did not meet the requirements of Rule 23(b)(2) or (b)(3). See Arch v. The American Tobacco Co., 175 F.R.D. 469 (E.D. Pa. 1997). The District Court rejected Rule 23(b)(2) certification because plaintiffs had not primarily sought injunctive or equitable

1. The defendants are The American Tobacco Company, Inc.; American Brands, Inc.; R.J. Reynolds Tobacco Company; RJR Nabisco, Inc.; Brown & Williamson Tobacco Corporation; Philip Morris, Inc.; Philip Morris Companies, Inc.; Lorillard Tobacco Company, Inc.; Lorillard, Inc.; United States Tobacco Company; UST, Inc.; The Tobacco Institute, Inc.; The Council for Tobacco Research-U.S.A., Inc.; Liggett Group, Inc.; Liggett & Myers, Inc.; Brooke Group, LTD. Pursuant to the parties' stipulations, American Brands, Inc.; Batus, Inc.; Batus Holdings, Inc., Loews Corporation, and UST, Inc. have been dismissed from this action without prejudice. In addition, B.A.T. Industries p.l.c. was dismissed for lack of personal jurisdiction by order of the District Court dated June 21, 1997.

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I.

relief, finding that "[p]laintiffs' medical monitoring claim is merely a thinly disguised claim for future damages" and that "the overwhelming majority of the relief sought by plaintiffs in their entire complaint is monetary in nature." Id. at 484. The court also found certification improper under Rule 23(b)(3) because issues common to the class did not predominate over plaintiffs' individual issues. In particular, the District Court found individual issues, such as addiction, causation, the need for medical monitoring, and affirmative defenses, made a class action unmanageable and not the superior method for fair and efficient adjudication of the case. Id. at 485-96.

The District Court suggested, however, that plaintiffs' request for a court-supervised program of medical monitoring to detect the latent diseases caused by smoking was the "paradigmatic" request for injunctive relief under a medical monitoring claim. Id. at 484. Specifically, the court stated:

> The Court finds that it may properly certify a medical monitoring claim under Rule 23(b)(2) when the plaintiffs seek such specific relief which can be properly characterized as invoking the court's equitable powers. See [Day v. NLO, Inc., 144 F.R.D. 330, 336 (S.D. Ohio 1992), rev'd on other grounds, 5 F.3d 154 (6th Cir. 1993)]; see also Fried v. Sunguard Recovery Serv., Inc., 925 F. Supp. 372 (E.D. Pa. 1996). In reaching this decision, the Court perforce rejects defendants' argument that a medical monitoring claim can never be characterized as injunctive.

The dispositive factor that must be assessed to determine whether a medical monitoring claim can be certified as a Rule 23(b)(2) class is-what type of relief do plaintiffs actually seek. If plaintiffs seek relief that is a disguised request for compensatory damages, then the medical monitoring claim can only be characterized as a claim for monetary damages. In contrast, if plaintiffs seek the establishment of a court-supervised medical monitoring program through which the class members will receive periodic medical examinations, then plaintiffs' medical monitoring claims can be

properly characterized as claim seeking injunctive relief.

In Day, Judge Spiegel cogently articulates the fine distinction between a medical monitoring claim that seeks monetary relief in the form of compensatory damages and a medical monitoring claim that seeks injunctive relief in the form of a court-supervised medical monitoring program. Judge Spiegel explains:

Relief in the form of medical monitoring may be by a number of means. First, a court may simply order a defendant to pay a plaintiff a certain sum of money. The plaintiff may or may not choose to use that money to have his medical condition monitored. Second, a court may order the defendants to pay the plaintiffs' medical expenses directly so that a plaintiff may be monitored by the physician of his choice. Neither of these forms of relief constitute injunctive relief as required by Rule 23(b)(2).

However, a court may also establish an elaborate medical monitoring program of its own, managed by court-appointed court-supervised trustees, pursuant to which a plaintiff is monitored by particular physicians and the medical data produced is utilized for group studies. In this situation, a defendant, of course, would finance the program as well as being required by the Court to address issues as they develop during the program administration. Under these circumstances, the relief constitutes injunctive relief as required by Rule 23(b)(2).

Day, 144 F.R.D. at 335-36; see also Fried, 925 F. Supp. at 374 (implying that under medical monitoring case law, a creation of a medical monitoring program would be equitable in nature). Based on Judge Spiegel's insightful distinction, it is apparent that relief requested under a medical monitoring claim can be either injunctive or equitable in nature.

To determine whether the named plaintiffs in this case seek equitable relief under their medical monitoring claim, plaintiffs' specific request for relief under this claim must be closely scrutinized. Plaintiffs seek the establishment of a court-supervised program through which class members would undergo periodic medical examinations in order to promote the early detection of diseases caused by smoking. This portion of plaintiffs' request is the paradigmatic request for injunctive relief under a medical monitoring claim.

Arch at 483-84.

Accordingly, the District Court granted plaintiffs leave to file an amended complaint. In their Second Amended Complaint, plaintiffs brought only one claim against defendants--medical monitoring.2 Moreover, plaintiffs eliminated all requests for smoking cessation programs, medical treatment programs, punitive damages, and restitutional damages; the only relief they sought was a court-supervised fund that would pay for medical examinations designed to detect latent diseases caused by smoking. Plaintiffs sought certification under Rule 23(b)(2) for "[a]ll current residents of Pennsylvania who are cigarette smokers as of December 1, 1996 [the day the amended complaint was filed in federal court] and who began smoking before age 19, while they were residents of Pennsylvania."

The Second Amended Complaint alleged that plaintiffs and other class members had been exposed to proven hazardous substances through the intentional or negligent actions of the defendants and/or through defective products for which defendants are strictly liable. Plaintiffs alleged that as a proximate result of this exposure, they and other class members suffer significantly increased risks of contracting serious latent diseases and therefore need periodic diagnostic medical examinations. Specifically, plaintiffs contended that classwide expert evidence would prove that: (1) when cigarettes are used as defendants intended them to be used, the vast majority of those who use cigarettes become addicted and (2) cigarettes are the leading cause in the nation of cardiovascular disease, lung cancer, and chronic obstructive pulmonary disease, due to

2. As we will discuss more fully below, the Pennsylvania Supreme Court recognized a cause of action for medical monitoring in Redland Soccer Club, Inc. v. Department of the Army, 696 A.2d 137 (Pa. 1997).

the exposure of the throat, heart, and lungs to tobacco smoke. Barnes v. The American Tobacco Co., 176 F.R.D. 479, 491 (E.D. Pa. 1997).

In support of their claim, plaintiffs asserted the following:

- defendants have sold annually in Pennsylvania 22.6 billion cigarettes;

- there are numerous hazardous substances in cigarette smoke;

- defendants have known of the relationship between cigarettes and diseases but have concealed their research, publicly denied the relationship between cigarettes and disease, and continue to aggressively promote and sell cigarettes;

- defendants have known for many years of ways to make safer cigarettes but have intentionally chosen not to do so;

- defendants have known for many years that nicotine is addictive but have publicly denied both the fact that nicotine is addictive and their knowledge of this fact;

- defendants have intentionally controlled the level of nicotine and other toxic substances in the cigarettes in order to preserve the dependence of smokers on cigarettes;

- defendants have used additives such as ammonia, as well as designs for which defendants have sought patents, to make cigarettes a `package' for the delivery of nicotine;

- defendants have intentionally avoided researching or developing cigarettes that would not cause dependence or addiction in those who use them; and

- defendants have spent millions of dollars each year in advertising and promoting cigarettes and have geared their efforts particularly to teenagers and children through such efforts as the "Joe Camel" advertising campaign because defendants have allegedly known that unless a person begins smoking before the age of twenty, the person is unlikely ever to begin.

Plaintiffs' physician experts designed the monitoring program using objective medical tests and age-graded criteria. They stated that cigarette smoking was the principal cause of lung cancer, cardiovascular disease, and chronic obstructive pulmonary disease, the three diseases to be monitored.

On August 22, 1997, the District Court conditionally certified the class under Rule 23(b)(2). See Barnes v. The American Tobacco Co., 176 F.R.D. at 481-93. The court held:

Because defendants have been unable to demonstrate at this point in time that this case is beset with individual issues and manageability problems, the Court finds that plaintiffs' proposed case has the cohesiveness to survive as a Rule 23(b)(2) class. Plaintiffs allege that defendants, acting in concert or pursuant to a common design, have engaged in tortious conduct directed toward the entire class as a whole. Whether or not plaintiffs can prove that defendants have acted in concert or pursuant to a common design is not a proper question to be resolved in a certification motion, rather this merit-based question must be reserved for later proceedings. See [Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 178 (1974)]. However, for purposes of the instant issue sub judice, it is highly relevant that plaintiffs have alleged that defendants have acted in concert or pursuant to a common design. It is this allegation of concerted conduct that supports a finding that defendants have acted on grounds generally applicable to all members of plaintiffs' class. Although there may be individual variations with respect to each class members' relationship with the defendants, the common questions of defendants' liability, which are intimately connected with their concerted conduct, support a finding that defendants have acted on grounds generally applicable to all members of the proposed class.

Barnes, 176 F.R.D. at 492-93.

Subsequently, defendants asked the court to certify the class certification order for interlocutory appeal or, in the alternative, to reconsider the order. They alsofiled motions for summary judgment.3 The District Court denied defendants' request to certify or reconsider the class certification order but decertified the class under Rule 23(c)(1).4 See Barnes at 493-502. After reviewing the

3. On September 22, 1997, while these motions were pending, defendants moved to enforce the jury demand. On October 10, 1997, the District Court granted the motion for a jury trial. See Barnes v. The American Tobacco Co., 989 F. Supp. 661 (E.D. Pa. 1997). In reaching this decision, the District Court applied the two-part test of Chauffeurs, Teamsters & Helpers, Local No. 391 v. Terry, 494 U.S. 558 (1990). In Terry, the Court noted the Seventh Amendment right to a jury is applicable when legal rights are at stake. See id. at 564. "To determine whether a particular action will resolve legal rights [the court must] examine both the nature of the issues involved and the remedy sought. . . . First, [the court must compare] the[] action to 18th century actions brought in the courts of England prior to the merger of the courts of law

and equity." Id. at 565 (citation omitted). Second, the court must "`examine the remedy sought and determine whether it is legal or equitable in nature.' " Id. (citation omitted).

In applying part one of the Terry test, the District Court noted that no cause of action for medical monitoring existed in 1791 but determined that "the most analogous cause of action is a negligence action for future medical expenses" which was an action at law. Thus, the District Court concluded, the first line of inquiry "weighs in favor of finding that defendants have a right to a jury trial." Barnes v. The American Tobacco Co., 989 F. Supp. at 664-65.

Turning to the second line of inquiry under Terry, the District Court acknowledged the relief sought is equitable but noted plaintiffs could have "just as readily" requested lump sum damages. Plaintiffs' decision to pursue a medical monitoring fund instead of damages, the District Court concluded, should not deprive the defendants of their constitutional right to trial by jury. See id. at 667–68. See Dairy Queen, Inc. v. Wood, 369 U.S. 469, 477–78 (1962) ("[T]he constitutional right to trial by jury cannot be made to depend upon the choice of words used in the pleadings.").

Plaintiffs appeal this order. Because we will affirm the grant of summary judgment, we need not decide this issue.

4. An order to certify a class "may be conditional and may be altered or amended before the decision on the merits." Fed. R. Civ. P. 23(c)(1).

summary judgment record, the court held "the individual issue of addiction, which plaintiffs had previously represented as playing no part in this case, is still actually part of the present case"; defendants were not barred from asserting affirmative defenses; and these and other elements in the case presented numerous individual issues which "preclude[d] continuing this case as a class action." Id. at 500-02.

Specifically, the court found three individual issues precluded class certification: addiction, causation, and affirmative defenses. First, the court discussed the role of addiction:

> When compelled to discuss the substantive issues in the case on defendants' motion for summary judgment, plaintiffs primarily focused on "addiction" and purported nicotine "manipulation. . . ." As was explained in Arch, whether or not an individual is addicted is a highly individualistic inquiry:

Plaintiffs' own expert Dr. Burns recognizes that the assessment of addiction is an inherently individual inquiry. . . . Based on this statement, defendants argue that class certification under these circumstances would require a mini-hearing on the merits of each individual's case to determine injury. See Forman v. Data Transfer, Inc., 164 F.R.D. 400, 403 (E.D. Pa. 1995). Importantly, the Court finds that nowhere in plaintiffs' voluminous submissions do they actually refute that addiction is an inherently individual inquiry. Instead, plaintiffs offer a solution to this massive problem of proving addiction on an individual basis. Plaintiffs propose that once the general issue as to whether cigarettes can cause addiction is resolved, the issue as to whether each and every class member is addicted can be resolved by having them answer a questionnaire, consisting of six simple questions.

Under this rule, District Courts are required to reassess their rulings regularly as the case develops. Kuehner v. Heckler, 778 F.2d 152, 163 (3d Cir. 1985).

Defendants rejoin that this questionnaire cannot by itself determine whether a person is nicotine dependent.

The Court finds that even if the questionnaire were used to determine nicotine dependence, defendants would be permitted to cross-examine each and every class member as to their alleged dependence. Plaintiffs admittedly acknowledge that the plan they propose would be, at most, a prima facie indication of addiction. Plaintiffs' own experts concede that addiction is necessarily an individual inquiry. To refute plaintiffs' prima facie case, defendants would be permitted to cross-examine each individual about his specific choices, decisions and behavior, and defendants would be entitled to offer expert testimony about each person's specific circumstances and diagnosis.

Barnes, 176 F.R.D. at 500 (citing Arch, 175 F.R.D. at 487-88).

The District Court also found that causation was an individual issue precluding certification. Although plaintiffs had narrowed their theories of liability, the court found their claim for medical monitoring still implicated the same individual issue of causation their First Amended Complaint asserted in negligence, strict liability, and intentional exposure to a hazardous substance. "[I]nstead of completely dropping their claims for negligence, strict liability and intentional exposure to a hazardous substance, plaintiffs merely inserted these theories as the underlying theories of liability for their medical monitoring. Thus, these theories, with their attendant individual issues, are still in this case." Barnes, 176 F.R.D. at 500. The District Court then quoted its June 3, 1997 decision at length:

> To succeed on their products liability and negligence claims, plaintiffs will also have to prove "causation," which the Court finds is not capable of determination on a class-wide basis in this case. Resolution of the "general causation" question of whether cigarettes are capable of being addictive "is not common under Rule 23(a)(2)." Kurczi v. Eli Lilly & Co., 160 F.R.D. 667, 677

(N.D. Ohio 1995). Unless it is proven that cigarettes always cause or never cause addiction, "the resolution of the general causation question accomplishes nothing for any individual plaintiff." Id.; see also In re "Agent Orange" Product Liability Litigation, 818 F.2d 145, 165 (2d Cir. 1987) (the "relevant question is not whether Agent Orange has the capacity to cause harm," but rather the "highly individualistic" question of whether "it did cause harm and to whom").

* * *

Plaintiffs cannot satisfy the "causation" element of these claims by proving that all cigarettes can potentially cause the user to become addicted. This is a general causation issue. The resolution of this "general causation question" would accomplish nothing for any of the individual plaintiffs. See Kurczi, 160 F.R.D. at 677. Indeed, the jury would still be required to determine for each class member whether he or she is addicted to cigarettes, and, if so, whether defendants (and which defendant) caused that addiction. With respect to causation, the Court finds that this issue is highly individualized and does not lend itself to Rule 23(b)(2) certification.

To establish their strict products liability claim, plaintiffs will be required to prove a defect in defendants' products. This inquiry is also highly individualized. Defendants manufactured hundreds of different types of cigarettes over the years and have even made changes within each brand . . .

Plaintiffs claim that they can prove a common defect on a class-wide basis for all of defendants' products. Plaintiffs argue that all of defendants' products are inherently defective because they contain sufficient levels of nicotine to cause addiction and other hazardous substances. Thus, plaintiffs will attempt to establish a common defect by showing that this combination exists in all of the cigarettes sold by defendants. Nonetheless, the possibility that plaintiffs' common defect theory will fail and that the class will be splintered into various subclasses--creating

manageability concerns -- "weighs against a finding of predominance of common issues."

Barnes, 176 F.R.D. at 500-01 (citing Arch, 175 F.R.D. at 488-89 (footnotes omitted)). The court concluded, "[b]ecause plaintiffs intend to prove their medical monitoring claim by using the theories of negligence and strict liability, the individual issues, which are implicated by these theories still exist, and thus preclude class certification." Barnes, 176 F.R.D. at 501.

Finally, the court found that affirmative defenses available to the defendants raised individual issues.5 The court explained: "For example, the defense of assumption of risk requires this Court to examine whether each and every plaintiff was subjectively aware of the risk and/or danger. . . . In determining whether the statute of limitations precludes a plaintiff from suing on his claim, the Court necessarily would have to examine when plaintiff's injury accrued, and whether plaintiff knew or should have known of the injury and its cause. This is clearly an individual issue. . . These issues clearly preclude certification." Barnes, 176 FRAUD at 502.

Β.

The District Court also granted defendants' motions for summary judgment, finding the statute of limitations had expired for five of the six named plaintiffs and that the sixth plaintiff had failed to demonstrate a need for medical monitoring. Barnes v. The American Tobacco Co., 984 F. Supp. 842 (E.D. Pa. 1997).6

5. As we discuss below, in its memorandum opinion disposing of defendants' summary judgment motions, the court concluded, over plaintiffs' objections, that certain affirmative defenses (e.g. assumption of

risk) are available to the defendants.

6. Defendants also moved for summary judgment on the issue of product identification. In granting summary judgment for all defendants the District Court did not reach this issue. Defendants Liggett Group Inc., Liggett & Myers Inc., and Brooke Group Ltd. joined defendants' joint brief but also ask us to affirm on the additional ground that plaintiffs failed to produce any evidence that exposure to any Liggett cigarette was a substantial factor in causing injury to any of the named plaintiffs. Because we will affirm the District Court's grant of summary judgment to all defendants, we need not reach this issue.

Plaintiffs contended their cause of action was governed by the equitable doctrine of laches, not the statute of limitations. But finding the action "both inherently equitable and legal," the District Court held the statute of limitations "should apply to this action because plaintiffs could have brought this action at law or in equity." Barnes, 984 F. Supp. at 855.

Examining the theories of liability underlying a medical monitoring claim, the District Court applied a two-year statute of limitations. In Redland, the Pennsylvania Supreme Court held a plaintiff must prove defendant's negligence caused his exposure to a proven hazardous substance. For this reason, the District Court predicted the Pennsylvania Supreme Court would apply the two-year statute of limitations for negligence actions to medical monitoring claims. See Barnes, 984 F. Supp. at 856-57 (citing 42 Pa. Cons. Stat. Ann. S 5524). Furthermore, to the extent that plaintiffs base their claims on strict products liability or an intentional tort, a two-year statute of limitations would still apply. See id. at 857.

In deciding when the claim accrued, the court noted that generally, a plaintiff "is under a duty to use all reasonable diligence to be properly informed of the facts and circumstances upon which a potential right of recovery is based and to institute suit within the prescribed statutory period." Pocono Int'l Raceway, Inc. v. Pocono Produce, 468 A.2d 468, 471 (Pa. 1983). A claim under Pennsylvania law accrues at "the occurrence of the final significant event necessary to make the claim suable." Mack Trucks, Inc. v. Bendix-Westinghouse Automotive Air Brake Co., 372 F.2d 18, 20 (3d Cir. 1966). The "discovery rule" is, however, a "narrow exception to this general rule," Tohan v. Owens-Corning Fiberglass Corp., 696 A.2d 1195, 1200 n. 4 (Pa. Super. Ct. 1997), and tolls the statute of limitations during the "plaintiff's complete inability, due to facts and circumstances not within his control, to discover an injury despite the exercise of due diligence." Kingston Coal Co. v. Felton Mining Co., Inc., 690 A.2d 284, 288 (Pa. Super. Ct. 1997). Under the discovery rule, the statute of limitations begins to run when the "plaintiff knows, or in the exercise of reasonable diligence should have known, (1) that he has

been injured, and (2) that his injury has been caused by another's conduct." Bradley v. Ragheb, 633 A.2d 192, 194 (Pa. Super. Ct. 1993) (quoting MacCain v. Montgomery Hosp., 578 A.2d 970, 972-73 (Pa. Super. Ct. 1990)).

Because a claim under Pennsylvania law accrues at "the occurrence of the final significant event necessary to make the claim suable," Mack Trucks, 372 F.2d at 20, the court found the plaintiffs' medical monitoring cause of action accrued when the plaintiffs were placed at a "significantly increased risk of contracting a serious latent disease." Redland, 696 A.2d at 145. To determine when that event occurred, the court examined plaintiffs' expert testimony. According to the expert testimony, plaintiffs suffered this significantly increased risk when they reached the "twenty pack-year" level.7 The court found that five of the six plaintiffs were at that level. Thus, the court concluded, without applying the discovery rule, the medical monitoring claims of these five plaintiffs were barred by the two-year statute of limitations. Barnes, 984 F. Supp. at 859-61.

The court found that even applying the discovery rule would not save these five plaintiffs' claims because each "should have known that smoking cigarettes put him or her at a significantly increased risk of contracting a serious latent disease years before they filed the instant lawsuit. . . . When a Court is asked to apply the discovery rule, the relevant question is whether an ordinary person, exercising reasonable diligence, would have known or should have known of his injury and its cause. In this case, each plaintiff should have known or did know that smoking caused them to be placed at an increased risk of contracting a serious disease." Id. at 862-63.

Reviewing the evidence, the court concluded that Barnes, Potts, Rodweller, Salzman, and Slivak had all had notice of the dangers of cigarette smoking for more than two years. Id. With respect to the sixth plaintiff, McNally, the court

7. "Pack-year" refers to the number of years during which an individual has smoked a pack of cigarettes per day. For example, a person who smokes one pack a day for 10 years has a 10 pack-year history. A person smoking half a pack per day for 10 years has a five pack-year history. Barnes, 984 F. Supp. at 852 n.6.

determined that, since she had only been smoking for 11 years, her claim could not have accrued until sometime last year. See Barnes, 984 F. Supp. at 861 n.14.8

С.

But the District Court granted summary judgment against McNally on a different ground, finding she failed to demonstrate a need for medical monitoring. With regard to McNally, the District Court found:

> Under the Burns Program, Ms. McNally is only entitled to participate in the first level of the proposed medical monitoring program. Under the first level, Ms. McNally would be entitled to receive, annually or biannually, a physical examination, cardiovascular risk assessment and an EKG. However, Ms. McNally herself does not seek monitoring in the form of an EKG. (Defs.' Mot. Summ. J. Medical Monitoring Ex. 1 Pls.' Resp. Interrog. 10). Thus, the only monitoring that Ms. McNally seeks, and would be qualified for under the Burns Program, is a physical examination and cardiovascular risk assessment.

* * *

Because annual physical examinations and cardiovascular risk assessment are routinely recommended to all persons in the absence of exposure, the Court finds Ms. McNally can not establish that "the prescribed monitoring regime is different from that normally recommended in the absence of the exposure." [Redland, 696 A.2d at 146]. . . The substance of this requirement is to ensure that "a plaintiff may recover only if the defendant's wrongful acts increased the plaintiff's incremental risk of

8. Although the District Court applied the Petty-Hyers program's twenty pack-year threshold to determine the date upon which a medical monitoring claim accrued for the other named plaintiffs, it applied the Burns program's ten pack-year threshold to McNally. See Barnes, 984 F. Supp. at 860, 861 n.14. Because we conclude that McNally has not demonstrated a need for medical monitoring, we do not decide which (if either) pack-year threshold is appropriate. incurring the harm produced by the toxic substance enough to warrant a change in the medical monitoring that otherwise would be prescribed for that plaintiff." [Id. at 144 (citation omitted)].

Here, Ms. McNally only seeks monitoring for two tests which would be recommended for her even if she did not smoke. Any increase in Ms. McNally's incremental risk of incurring the harm produced by the allegedly hazardous substances in cigarettes would not warrant a change in the medical monitoring that would be prescribed for her. Indeed, in the absence of exposure, it would be recommended that she receive the tests she seeks under her medical monitoring claim. Thus, she cannot satisfy the sixth element of Redland.

Barnes, 984 F. Supp. at 871-72.

Plaintiffs appealed from the final judgment.

II.

JURISDICTION AND STANDARD OF REVIEW

The District Court had jurisdiction under 28 U.S.C. S 1332. We exercise jurisdiction under 28 U.S.C. S 1291.

We review the District Court's decision to decertify the class for an abuse of discretion. See Baby Neal v. Casey, 43 F.3d 48, 56 n.15 (3d Cir. 1994). We exercise plenary review of a grant of summary judgment. Wicker v. Consol. Rail Corp., 142 F.3d 690, 696 (3d Cir. 1998) (citation omitted), and apply the same test as the District Court; namely, we must determine if there is a "genuine issue as to any material fact" and if "the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). In so doing, we must view all evidence and draw all inferences therefrom in the light most favorable to the nonmoving party. Wicker, 142 F.3d at 696 (citation omitted).

III.

DISCUSSION

A. Medical Monitoring

The crucial issue is whether plaintiffs' medical monitoring claim requires inquiry into individual issues. We begin by briefly describing the evolution of this cause of action and its elements.9

In In re Paoli Railroad Yard PCB Litigation, 916 F.2d 829 (3d Cir. 1990) (Paoli I), we predicted the Pennsylvania Supreme Court would recognize a cause of action for medical monitoring. We reaffirmed that prediction in In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717 (3d Cir. 1994) (Paoli II).10 The issue of medical monitoring first reached the Pennsylvania Supreme Court in Simmons v. Pacor, Inc., 674 A.2d 232 (Pa. 1996), where the unanimous court recognized medical monitoring as a viable cause of action under Pennsylvania law. In Simmons, the court permitted plaintiffs with asbestos-related asymptomatic pleural thickening to recover for medical monitoring. It was not until Redland Soccer Club v. Department of the Army, 696 A.2d 137 (Pa. 1997), however, that the Pennsylvania Supreme Court had the opportunity to articulate the specific elements of a claim for medical monitoring.

9. For another discussion of the evolution of the medical monitoring cause of action, see Metro-North R.R. Co. v. Buckley, 521 U.S. 424 (1997).

10. In Paoli I, we predicted the Pennsylvania Supreme Court would require a party to meet a four-part test to establish a claim for medical monitoring: (1) plaintiff was significantly exposed to a proven hazardous substance through the negligent actions of the defendant; (2) as a proximate result of exposure, plaintiff suffers a significantly increased risk of contracting a serious latent disease; (3) that increased risk makes periodic diagnostic medical examinations reasonably necessary; and (4) monitoring and testing procedures exist which make the early detection

monitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial. Paoli I, 916 F.2d at 852. In Paoli II, we added another element to the claim, holding that a plaintiff had to show that "a reasonable physician would prescribe for her or him a monitoring regime different than the one that would have been prescribed in the absence of that particular exposure." Paoli II, 35 F.3d at 788 (citation omitted). Building on this court's decisions in Paoli I and Paoli II, the Supreme Court found that plaintiffs must prove the following elements:

(1) exposure greater than normal background levels; (2) to a proven hazardous substance; (3) caused by the defendant's negligence; (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease; (5) a monitoring procedure exists that makes the early detection of the disease possible; (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and (7) the prescribed monitoring to contemporary scientific principles.

Redland, 696 A.2d at 145-46.11

The injury in a cause of action for medical monitoring is the "costs of periodic medical examinations necessary to detect the onset of physical harm." Id. at 144; see also Friends for All Children, Inc. v. Lockheed Aircraft Corp., 746 F.2d 816, 826 (D.C. Cir. 1984) ("It is difficult to dispute that an individual has an interest in avoiding expensive diagnostic examinations just as he or she has an interest in avoiding physical injury."); Hansen v. Mountain Fuel Supply Co., 858 P.2d 970, 977 (Utah 1993) (citations omitted) ("Although the physical manifestations of an injury may not appear for years, the reality is that many of those exposed have suffered some legal detriment; the exposure itself and the concomitant need for medical testing constitute the

11. Other jurisdictions have authorized recovery for medical monitoring in the absence of physical injury. See, e.g., Bourgeois v. A.P. Green Indus., 716 So.2d 355 (La. 1998); Potter v. Firestone Tire & Rubber Co., 863 P.2d 795 (Cal. 1993); Hansen v. Mountain Fuel Supply Co., 858 P.2d 970 (Utah 1993); Ayers v. Township of Jackson , 525 A.2d 287 (N.J. 1987). In addition, some federal courts predicting state law have reached the same conclusion. See Cook v. Rockwell Int'l Corp., 755 F. Supp. 1468 (D. Colo. 1991); Johnson v. Armstrong Cork Co., 645 F. Supp. 764 (W.D. La. 1986). But see Ball v. Joy Techs., Inc., 958 F.2d 36 (4th Cir. 1991) (holding that, under the laws of Virginia and West Virginia, recovery of medical monitoring expenses is only available where a plaintiff has sustained a physical injury); Werlein v. United States, 746 F. Supp. 887 (D. Minn. 1990). injury."). It is evident that this injury is somewhat different from an injury in a traditional tort, which rests on physical harm. See, e.g., Restatement Second of Torts S 402A (requiring plaintiff to prove in a products liability case "physical harm" which S 7 defines as "physical impairment of the human body"); Simmons, 674 A.2d at 237 (denying plaintiffs recovery other than medical monitoring for asymptomatic pleural thickening because inter alia plaintiffs demonstrated no physical injury). In recognizing medical monitoring as a compensable injury, the Pennsylvania Supreme Court quoted at length from our distinction in Paoli I between a cause of action for increased risk of future harm and a cause of action for medical monitoring. We concluded that a claim for medical monitoring is different from a claim for increased risk of harm because the medical monitoring plaintiff has an identifiable rather than a speculative injury. Id. at 850-51. We explained:

> The injury in an enhanced risk claim is the anticipated harm itself. The injury in a (medical monitoring claim is the cost of the medical care that will, one hopes, detect that injury. The former is inherently speculative because courts are forced "to anticipate the probability of future injury. The latter is much less speculative because the issue for the jury is the less conjectural question of whether the plaintiff needs medical surveillance.

Paoli I, 916 F.2d at 851.12

In Redland, the court cited four important policy reasons for recognizing a cause of action for medical monitoring. First, medical monitoring promotes "early diagnosis and treatment of disease resulting from exposure to toxic substances caused by a tortfeasor's negligence." Second, "[a]llowing recovery for such expenses avoids the potential injustice of forcing an economically disadvantaged person

12. There is no doubt the costs of medical monitoring are a compensable portion of a plaintiffs' damages when asserted with other injury claims. It appears, however, that allowing plaintiffs to recover in the absence of some injury pushes the limit of the Constitution's case-or-controversy requirement.

to pay for expensive diagnostic examinations necessitated by another's negligence," and "affords toxic-tort victims, for whom other sorts of recovery may prove difficult, immediate compensation for medical monitoring needed as a result of exposure." Third, medical monitoring "furthers the deterrent function of the tort system by compelling those who expose others to toxic substances to minimize risks and costs of exposure." Finally, such recovery is"in harmony with `the important public health interest in fostering access to medical testing for individuals whose exposure to toxic chemicals creates an enhanced risk of disease.' " Id. at 145 (citations omitted).

B. Certification

To be certified, a class must satisfy the prerequisites of Rule 23(a) and the "parties seeking certification must also show that the action is maintainable under Rule 23(b)(1), (2), or (3)." Amchem Prods., Inc. v. Windsor, ____ U.S. ___; 117 S. Ct. 2231, 2245 (1997). Plaintiffs seek certification under 23(b)(2).

As noted, the District Court conditionally certified the class, stipulating its order could be altered or amended. See Barnes v. The American Tobacco Co., 176 FRAUD 479 (E.D. Pa. 1997); Fed. R. Civ. P. 23(c)(1). Under Rule 23(c)(1), District Courts are required to reassess their class rulings as the case develops. Kuehner v. Heckler, 778 F.2d 152, 163 (3d Cir. 1985); see also Richardson v. Byrd, 709 F.2d 1016, 1019 (5th Cir. 1983) ("Under Rule 23 the district court is charged with the duty of monitoring its class decisions in light of the evidentiary development of the case. The district judge must define, redefine, subclass, and decertify as appropriate in response to the progression of the case from assertion to facts."). In accordance with 23(c)(1), the District Court examined the evidence adduced for summary judgment purposes and decided to decertify the class. Barnes, 176 FRAUD at 502.

In considering whether certification is proper, we refrain from conducting a preliminary inquiry into the merits. See Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 177-78 (1973) (citation omitted) ("`In determining the propriety of a class action, the question is not whether the plaintiff or plaintiffs have stated a cause of action or will prevail on the merits, but rather whether the requirements of Rule 23 are met.' ") At the same time, we must carefully examine the factual and legal allegations. See General Tel. Co. v. Falcon, 457 U.S. 147, 160 (1981) ("[S]ometimes it may be necessary for the court to probe behind the pleadings before coming to rest on the certification question."); Coopers & Lybrand v. Livesay, 437 U.S. 463, 469 (1977) (citation omitted) ("[T]he class determination generally involves considerations that are `enmeshed in the factual and legal issues comprising the plaintiff's cause of action.' ").

1. Fed. R. Civ. P. 23(a)

Rule 23(a) presents four requirements: (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy of representation.13 "The requirements of Rule 23(a) are meant to assure both that class action treatment is necessary and efficient and that it is fair to the absentees under the particular circumstances." Baby Neal v. Casey, 43 F.3d 48, 55 (3d Cir. 1994). The District Court determined the class satisfied Rule 23(a).

Finding the putative class consisted of more than one million Pennsylvania residents,14 the court held the class was "so numerous that joinder of all members[is] impracticable." Fed. R. Civ. P. 23(a)(1). Defendants do not dispute that numerosity is satisfied.

The District Court also found plaintiffs satisfied the commonality requirement of Rule 23(a)(2) because they demonstrated there is at least one common question of law or fact. See Baby Neal, 43 F.3d at 56 ("The commonality requirement will be satisfied if the named plaintiffs share at

13. Specifically, Rule 23(a) provides: "One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class."

14. In defendants' post-hearing memorandum, defendants place the number of potential class members at 2.8 million.

least one question of fact or law with the grievances of the prospective class.").15 "For example, whether defendants have acted in concert or pursuant to a common design is one common question." Arch, 175 FRAUD at 477.16

"The concepts of commonality and typicality are broadly defined and tend to merge." Baby Neal v. Casey, 43 F.3d at 56 (citation omitted). The typicality requirement is designed to align the interests of the class and the class representatives so that the latter will work to benefit the entire class through the pursuit of their own goals. Id. at 57. This requirement does not mandate that all putative class members share identical claims. Id. at 56 (citations omitted). Moreover, "[f]actual differences will not render a claim atypical if the claim arises from the same event or practice or course of conduct that gives rise to the claims of the class members, and if it is based on the same legal theory." 1 Newberg on Class Actions S 3.15, at 3-78; see also Baby Neal, 43 F.3d at 58 ("[E]ven relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories.").

15. In Georgine, the court recognized that Baby Neal and other Third Circuit cases "stated a very low threshold for commonality." Georgine v. Amchem Prods. Inc., 83 F.3d 610, 627 (3d Cir. 1996). The court noted that the "commonality barrier is higher in a personal injury damages class action, like [Georgine], that seeks to resolve all issues, including noncommon issues, of liability and damages." Id. Ultimately, the court did not decide whether that class met the commonality requirement and concluded instead that "the commonality requirement is subsumed by the predominance requirement, which this class cannot conceivably meet." Id. As the District Court noted, in contrast to Georgine, this case is not a personal injury damages class action, nor does it involve a settlement class that was national in scope, where class members are asked to compromise future claims without knowing what those claims might be. Thus, the District Court did not impose a higher commonality requirement. See Arch, 175 FRAUD at 476-77.

16. In addition, the District Court found that"whether defendants' actions and omissions in the manufacture, promotion and sale of cigarettes to class members have been sufficiently egregious to warrant the imposition of punitive damages" is also a common question. Arch, 175 FRAUD at 477. Of course, the plaintiffs have since dropped their demand for punitive damages so this is no longer a common issue.

The District Court found plaintiffs met the typicality requirement. Although defendants had demonstrated there "exist many individualized questions which arise from the factual differences between the putative class members' individual claims, defendants fail[ed] to demonstrate that the `legal theories of the named plaintiffs potentially conflict with those of the absentees . . . ' " Arch, 175 FRAUD at 479 (quoting Baby Neal, 43 F.3d at 57). Specifically, the District Court found:

> "Plaintiffs allege that their claims arise from the same course of conduct undertaken by defendants. Specifically, plaintiffs have alleged that defendants have engaged in a concerted course of conduct whereby defendants have concealed their knowledge of nicotine's addictive properties and have purposefully and deliberately emphasized efforts to addict children and adolescents--resulting in an epidemic pediatric disease. In this process, plaintiffs allege that these consumers were involuntar[il]y subject to the cumulative, repetitive assault of the many different carcinogens contained in tobacco smoke. Although plaintiffs' claims may be factually different, plaintiffs have alleged a course of conduct that has given rise to plaintiffs' claims which are based upon the same legal theories, thus satisfying the typicality requirement of Rule 23(a)(3)."

Arch, 175 FRAUD at 478-79.

Finally, the District Court found that plaintiffs "fairly and adequately protect the interests of the class." Id. at 480 (quoting Fed. R. Civ. P. 23(a)(4)). The adequacy of representation requirement encompasses two distinct inquiries designed to protect the interests of absentee class members. First, it "tests the qualifications of the counsel to represent the class." G.M. Trucks, 55 F.3d at 800. Second, it "serves to uncover conflicts of interest between named parties and the class they seek to represent." Amchem, 117 S. Ct. at 2250.17

17. In the District Court, defendants claimed the named plaintiffs were not adequate class representatives because (1) they have split their

2. Fed. R. Civ. P. 23(b)(2)

A class action is maintainable under Rule 23(b)(2) when "the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole." Fed. R. Civ. P. 23(b)(2). Subsection (b)(2) class actions are "limited to those class actions seeking primarily injunctive or corresponding declaratory relief." 1 Newberg on Class Actions S 4.11, at 4-39. The (b)(2) class "serves most frequently as the vehicle for civil rights actions and other institutional reform cases that receive class action treatment." Baby Neal v. Casey, 43 F.3d 48, 58-59 (3d Cir. 1994). Indeed, (b)(2) was "designed specifically for civil rights cases seeking broad declaratory or injunctive relief for a numerous and often unascertainable or amorphous class of persons." 1 Newberg on Class Actions S 4.11, at 4-39.

As noted, in its June 3, 1997 Order, the District Court found that under certain circumstances medical monitoring

causes of action and (2) they may have failed to make a knowing and voluntary amendment to their complaint. The District Court found these claims were not "split" or "waived" by the absent class members. In its August 22, 1997 order, the court found: "the Court has already determined that the absent class members cannot bring in this putative class action those claims which have been omitted from the Second Amended Complaint because those claims are not suitable for class action treatment. Consequently, there cannot be any splitting' or `waiver' by these absent class members: there is no other cause of action they can bring, or could have brought, in this action, except possibly the medical monitoring claim set forth in the Second Amended Complaint." 176 FRAUD at 485. In addition, after reviewing plaintiffs' deposition testimony, the District Court found that the named plaintiffs made a knowing and voluntary amendment. The court noted that it is "unrealistic . . . to require the named plaintiffs to have an in-depth understanding as to the legal theories behind their claim." Instead, "courts have required the class representatives to actively seek vindication of his or her rights and engage competent counsel to prosecute the claims. In this case, named plaintiffs have actively sought vindication of their rights on a class-wide basis and have engaged competent counsel to litigate their claims." Id. at 486.

could constitute the injunctive relief required by Rule 23(b)(2). Arch, 175 FRAUD at 483. The District Court initially held that plaintiffs could not be certified under 23(b)(2) because most of the relief they sought was monetary in nature. Arch, 175 FRAUD at 484. In response to the court's analysis, plaintiffs amended their complaint so it contained only a claim for medical monitoring and asked only for the establishment of a court-supervised medical monitoring program.

Recently, the Supreme Court reexamined the requirements for Rule 23 certification in the context of mass tort class actions. In Amchem Products, Inc. v. Windsor, ____ U.S. ___; 117 S. Ct. 2231 (1997), the Supreme Court affirmed our decision in Georgine v. Amchem Products, Inc., 83 F.3d 610 (3d Cir. 1996), decertifying a settlement class of claimants exposed to asbestos. As in this case, the issue in Amchem was "whether [the] proposed classes [were] sufficiently cohesive to warrant adjudication by representation." Amchem, 117 S. Ct. at 2249. We found that cohesiveness lacking and the Supreme Court agreed. Quoting Judge Becker's opinion, the Court noted: " `Class members were exposed to different asbestos-containing products, for different amounts of time, in different ways, and over different periods . . . The [exposure-only] plaintiffs especially share little in common, either with each other or with the presently injured class members . . . They will also incur different medical expenses because their monitoring and treatment will depend on singular circumstances and individual medical histories.' " Id. at 2250 (quoting Georgine, 83 F.3d at 626). As we explained, such factual differences "translate into significant legal differences. Differences in amount of exposure and nexus between exposure and injury lead to disparate applications of legal rules, including matters of causation, comparative fault, and the types of damages available to each plaintiff." Georgine, 83 F.3d at 627. We also noted that "individualized issues can become overwhelming in actions involving long-term mass torts (i.e. those which do not arise out of a single accident)." Id. at 628.

While Amchem involved a Rule 23(b)(3) class action, the cohesiveness requirement enunciated by both this court

and the Supreme Court extends beyond Rule 23(b)(3) class actions. Indeed, a (b)(2) class may require more cohesiveness than a (b)(3) class. This is so because in a (b)(2) action, unnamed members are bound by the action without the opportunity to opt out.

While 23(b)(2) class actions have no predominance or superiority requirements, it is well established that the class claims must be cohesive. Discussing the requirements for 23(b)(2) classes in Wetzel v. Liberty Mutual Insurance Company, 508 F.2d 239 (3d Cir. 1974), we noted, "[b]y its very nature, a (b)(2) class must be cohesive as to those claims tried in the class action. . . Because of the cohesive nature of the class, Rule 23(c)(3) contemplates that all members of the class will be bound. Any resultant unfairness to the members of the class was thought to be outweighed by the purposes behind class actions: eliminating the possibility of repetitious litigation and providing small claimants with a means of obtaining redress for claims too small to justify individual litigation." Id. at 248-49 (citations omitted). In Geraghty v. United States Parole Commission, 719 F.2d 1199, 1205-06 (3d Cir. 1983) (citation omitted), we again emphasized that a 23(b)(2) class must be cohesive, noting the District Court has the "discretion to deny certification in Rule 23(b)(2) cases in the presence of `disparate factual circumstances.' " See also Santiago v. City of Philadelphia, 72 FRAUD 619, 628 (E.D. Pa. 1976) (holding that a "court should be more hesitant in accepting a (b)(2) suit which contains significant individual issues than it should under subsection 23(b)(3)"); Rice v. City of Philadelphia, 66 FRAUD 17, 20 (E.D. Pa. 1974) (holding that a case should not proceed as a (b)(2) action where "virtually all of the issues would have to be litigated individually in order to determine whether a particular alleged class member was entitled to any damages at all").18

18. "At base, the (b)(2) class is distinguished from the (b)(3) class by class cohesiveness. . . Injuries remedied through (b)(2) actions are really group, as opposed to individual injuries. The members of a (b)(2) class are generally bound together through `preexisting or continuing legal relationships' or by some significant common trait such as race or gender." Holmes v. Continental Can Company, 706 F.2d 1144, 1155 (11th Cir. 1983) (quoting Note, Notice in Rule 23(b)(2) Class Actions for Monetary Relief: Johnson v. General Motors Corp., 128 U.Pa.L.Rev. 1236, 1252-53 (1980) (footnotes omitted).

In Santiago, the court recognized two reasons why courts must determine whether a proposed (b)(2) class implicates individual issues. First, unnamed members with valid individual claims are bound by the action without the opportunity to withdraw and may be prejudiced by a negative judgment in the class action. "Thus, the court must ensure that significant individual issues do not pervade the entire action because it would be unjust to bind absent class members to a negative decision where the class representatives's claims present different individual issues than the claims of the absent members present." Second, "the suit could become unmanageable and little value would be gained in proceeding as a class action . . . if significant individual issues were to arise consistently." Santiago, 72 FRAUD at 628.

In decertifying the class, the District Court decided that "too many individual issues exist which prevent this case from proceeding as a class action." Barnes, 176 FRAUD at 500. As noted, the District Court found that addiction, causation, and affirmative defenses all presented individual issues not properly decided in a class action. We believe that addiction, causation, the defenses of comparative and contributory negligence, the need for medical monitoring and the statute of limitations present too many individual issues to permit certification. As in Amchem, plaintiffs were "exposed to different . . . products, for different amounts of time, in different ways, and over different periods." See Amchem, 117 S. Ct. at 2250 (citation omitted). These disparate issues make class treatment inappropriate.19

preclude class certification. See, e.g., Castano v. The American Tobacco Co., 84 F.3d 734 (5th Cir. 1996) (decertifying 23(b)(3) class because individual issues predominated); Smith v. Brown & Williamson Tobacco Corp., 174 FRAUD 90 (W.D. Mo. 1997) (denying certification under 23(b)(1), (2) & (3) because of the presence of individual issues); Ruiz v. The American Tobacco Co., No. 96-2300 (JAF) (D.P.R. March 17, 1998) (denying certification under 23(b)(2) and 23(b)(3) because "cigarette addiction" claims raised too many individual issues). Significantly, no federal appeals court has upheld the certification a class of cigarette smokers or reversed a District Court's refusal to certify such a class. In some state cases, however, plaintiff smokers have succeeded in

a. Nicotine addiction and causation

The District Court found nicotine addiction plays a central role in the case and that addiction is a "highly individualistic inquiry." Barnes, 176 F.R.D. at 500. The District Court noted that when plaintiffs were "compelled to discuss the substantive issues in the case on defendants' motion for summary judgment, [they] primarily focused on `addiction' and purported nicotine `manipulation. . . ' " Id. While plaintiffs do not seem to dispute that addiction requires an individual inquiry, they maintain nonetheless that addiction plays no part in the case.

Plaintiffs contend that throughout the litigation, they have

asserted that defendants' knowledge and intentional misuse of the addictive properties of nicotine--their intentional design of cigarettes to contain a level of nicotine they knew would be addictive--went to their intentional misconduct and liability for designing a defective product. Plaintiffs do not contend that all smokers are addicted, that addiction is a pre-requisite to class membership, or that addiction is determinant of a need for medical monitoring. Addiction is a term and concept that is difficult to avoid in any smoking case. The documents show that defendants intended and designed cigarettes to be addictive. That they have largely succeeded may be all too apparent. But the addiction of any particular smoker--much less the class as a whole--is simply not an element of plaintiffs' claims.

Brief of Appellant at 41.

We disagree. Addiction remains an essential part of plaintiffs' claim. In order to prevail on their medical

certification. See Richardson v. Phillip Morris, No. 96145050/CE212596 (Baltimore Cir. Ct. Jan. 28, 1998) (certifying class of Maryland smokers seeking compensatory and punitive damages); R.J. Reynolds Tobacco Co. v. Engle, 672 So.2d 39 (Fla. App. 3 Dist. 1996), rev. denied, 682 So.2d 1100 (1996) (certification of state-wide class of tobacco smokers suing for damages caused by smoking). monitoring claim--under any of their three theories of liability (negligence, strict products liability, and intentional exposure to a hazardous substance)--plaintiffs must demonstrate that defendants caused their exposure to tobacco. See Redland, 696 A.2d at 145-46. Indeed, plaintiffs' Second Amended Complaint alleges "[p]laintiffs and class members have been significantly exposed to proven hazardous substances through the intentional or negligent actions of the Defendants, and/or through defective products for which Defendants are strictly liable" and that "[a]s a proximate result of this exposure, Plaintiffs and class members suffer significantly increased risks of contracting serious latent diseases." Second Amended Complaint PP 20-21.

It is apparent from plaintiffs' Second Amended Complaint as well as their omnibus response to the defendants' joint motions for summary judgment that addiction is the linchpin of causation in this case. According to plaintiffs' complaint, defendants' actions that give rise to liability include the following:

> - Defendants have . . . known for many years that nicotine is addictive, but have publicly denied both the fact that nicotine is addictive and their knowledge of this fact, in order to conceal the addictive nature of cigarettes from the public, including Plaintiffs and the class. . .

- During the same time that Defendants have publicly denied the addictive nature of nicotine, Defendants have intentionally controlled the level of nicotine and other toxic substances they have sold, in order to preserve the dependence of smokers on cigarettes that Defendants sell. To this end, Defendants have utilized additives such as ammonia, as well as designs for which Defendants have sought patents, to make cigarettes, in effect, a "package" for the delivery of nicotine. Defendants have intentionally sought to "increase the delivery of nicotine and almost double the nicotine transfer efficiency of cigarettes," maintain "the proper amount of nicotine in tobacco smoke," and "deliver

a pharmacologically active dose of nicotine to the smoker."

- During the same period of time, despite this voluntary and public undertaking to protect the public's "health as a basic responsibility paramount to every other consideration," Defendants have also intentionally avoided researching or developing cigarettes that would not cause dependence or addiction in those who use them.

- In their efforts to conceal the health hazards of smoking and the addictive nature of nicotine, Defendants have testified falsely under oath before the United States Congress, provided false explanations to customers and governmental entities about the health hazards of tobacco and the harmful qualities of nicotine; concealed their secret research and testing on the dangers of cigarette smoking; [and] concealed their deliberate manipulation of the nicotine levels of cigarettes. . .

Plaintiffs' Second Amended Complaint PP 12-14, 16.

Moreover, as the District Court pointed out, in their omnibus response to the defendants' joint motions for summary judgment, plaintiffs focused on addiction and purported nicotine manipulation. Plaintiffs asserted the evidence will establish inter alia that (1) defendants intentionally designed cigarettes to addict smokers; (2) defendants allowed the number of addicted smokers to grow, knowing full well that the smoke caused cancer and lung disease; and (3) defendants intentionally manipulated and controlled nicotine levels. As we understand plaintiffs' theory, defendants' actions caused plaintiffs to become addicted to cigarettes and thereby rendered their choice to smoke nonvoluntary.

Plaintiffs suggest that causation can be proved on a class-wide basis, contending they need to show only that smoking cigarettes was a "substantial factor" in "causing" the three diseases to be monitored in the program. See Parks v. AlliedSignal, Inc., 113 F.3d 1327, 1332 (3d Cir. 1997) (under Pennsylvania law, a "substantial factor" is legal cause, and requires only proof that a factor is "not

merely negligible" in producing a result). Plaintiffs point to the Surgeon General's Reports conclusively determining that cigarette smoking is the major cause of the diseases for which the medical monitoring program was constructed. This evidence, they claim, more than satisfies their burden on the issue of causation.

But plaintiffs cannot prove causation by merely showing that smoking cigarettes causes cancer and other diseases. They must demonstrate that defendants' intentional or negligent nicotine manipulation caused each individual plaintiff to have a significantly increased risk of contracting serious latent diseases thereby demonstrating the need for medical monitoring. Alternatively, under a strict products liability theory, as the District Court found, "each class member will have to establish that the type of cigarettes he or she smoked contained a defect at the time he or she smoked them." Barnes, 176 F.R.D. at 501 (citation omitted). According to plaintiffs, the alleged defect is that defendants intentionally designed these cigarettes to be addictive. But whether defendants caused the injury depends on whether each individual actually is addicted. These are all issues that must be determined on an individual basis.

We note that plaintiffs do not contest the District Court's conclusion that "whether or not an individual is addicted is a highly individualistic inquiry." Barnes, 176 F.R.D. at 500. Instead, plaintiffs suggested to the District Court that once the general issue whether cigarettes can cause addiction is resolved, they could resolve the issue of individual addiction by having each class member answer a questionnaire consisting of six questions.20 The District Court noted that

even if the questionnaire were used to determine nicotine dependence, defendants would be permitted to cross-examine each and every class member as to their

20. On appeal, plaintiffs refer only sparingly to their proposed trial plan. At one point in their brief, however, plaintiffs suggest the District Court erred when it "did not refer or consider plaintiffs' proposed trial plan at all in decertifying the class" because of the many individual issues. But the District Court clearly considered the plan and found it inadequate. alleged dependence. Plaintiffs admittedly acknowledge that the plan they propose would be, at most, a prima facie indication of addiction. Plaintiffs' own (experts concede that addiction is necessarily an individual inquiry. To refute plaintiffs' prima facie case, defendants would be permitted to cross-examine each individual about his specific choices, decisions and behavior, and defendants would be entitled to offer expert testimony about each person's specific circumstances and diagnosis.

Arch, 175 F.R.D. at 488.

Because nicotine addiction must be determined on an individual basis and remains an essential part of plaintiffs' medical monitoring claim, we agree with the District Court that class treatment is inappropriate.

b. The need for medical monitoring

We also believe the requirement that each class member demonstrate the need for medical monitoring precludes certification. In order to state a claim for medical monitoring, each class member must prove that the monitoring program he requires is "different from that normally recommended in the absence of exposure." Redland, 696 A.2d at 146.21 To satisfy this requirement, each plaintiff must prove the monitoring program that is prescribed for the general public and the monitoring program that would be prescribed for him. Although the general public's monitoring program can be proved on a classwide basis, an individual's monitoring program he

21. See also Paoli II, 35 F.3d at 788; Arch, 175 F.R.D. at 490 ("The fact that [Barnes] smokes would not require any additional monitoring for heart disease not already warranted by the multiple, significant risk factors for heart disease he already has."); Hansen v. Mountain Fuel Supply Co., 858 P.2d 970, 979-80 (Utah 1993); Supplemental Declaration of David Burns, M.D. ("Exercise stress testing and an EKG would not normally be recommended for nonsmokers at the ages recommended in the proposed monitoring program, unless they had some other risk factor that placed them at dramatically increased risk of disease.").

requires, a plaintiff must present evidence about his individual smoking history and subject himself to cross-examination by the defendant about that history. This element of the medical monitoring claim therefore raises many individual issues.

c. Defenses

The District Court also held that defenses raise individual issues precluding certification. Over plaintiffs' objection, the District Court found defendants may assert the defenses of contributory negligence, assumption of risk, and consent to exposure to a hazardous substance. Barnes, 984 F. Supp. at 867-69.22 After reviewing Pennsylvania caselaw, the District Court concluded

> First, legal defenses do not become equitable defenses simply because they are asserted in an action in equity. Second, equitable principles such as the doctrine of unclean hands may not be used to deprive a defendant of legal rights--remedies or defenses. Applying these lessons, the Court finds that defendants have a legitimate right to raise the legal defenses of contributory negligence, assumption of risk and consent.

Barnes, 984 F. Supp. at 866. The court noted this suit was not purely equitable but instead "implicates both legal and equitable rights" making it "even less appropriate for [the court] to exercise its equitable powers to bar defendants from asserting its affirmative, legal defenses." Id.

As noted, plaintiffs asserted three theories of liability. They claimed that they were significantly exposed to proven hazardous substances through defendants' intentional actions, negligent actions, and defective products (strict

22. Defendants moved for summary judgment against Ciaran McNally, William Barnes, and Catherine Potts on the grounds that their claims were barred by contributory negligence, assumption of risk, and consent to exposure to a hazardous substance. Barnes, 984 F. Supp. at 864. The District Court only considered the defendants' arguments against McNally because it entered summary judgment against Barnes and Potts on statute of limitations grounds. liability). Defendants assert the defenses of consent, comparative negligence, and assumption of risk. Plaintiffs contend that these defenses are not available and that individual issues relating to these defenses should not preclude class certification. Plaintiffs maintain that "comparative negligence" is only available in actions for damages resulting in death or injury, that assumption of risk is not available because the defendants will not be able to show that any plaintiff assumed the risk of the specific defect, and that consent requires a full awareness of defendants' specific conduct and there is no record evidence of such awareness in this case.

The District Court found defendants could raise the defense of comparative negligence, predicting the Pennsylvania Supreme Court would apply Pennsylvania's Comparative Negligence Act23 rather than contributory negligence to a medical monitoring claim. See Barnes, 984 F. Supp. at 867-68. Although acknowledging that the Comparative Negligence Act expressly applies to"actions brought to recover damages for negligence resulting in death or injury to person or property," and that plaintiffs seek a court-supervised monitoring program, the District Court found "[t]he application of the Comparative

23. 42 Pa. Cons. Stat. S 7102 provides:

(a) General rule.--In all actions brought to recover damages for negligence resulting in death or injury to person or property, the fact that the plaintiff may have been guilty of contributory negligence shall not bar a recovery by the plaintiff or his legal representative where such negligence was not greater than the causal negligence of the defendant or defendants against whom recovery is sought, but any damages sustained by the plaintiff shall be diminished in proportion to the amount of negligence attributed to the plaintiff.

(b) Recovery against joint defendant; contribution.--Where recovery is allowed against more than one defendant, each defendant shall be liable for that proportion of the total dollar amount awarded as damages in the ratio of the amount of his causal negligence to the amount of causal negligence attributed to all defendants against whom recovery is allowed. The plaintiff may recover the full amount of the allowed recovery from any defendant against whom the plaintiff is not barred from recovery. Any defendant who is so compelled to pay more than his percentage share may seek contribution. Negligence Act to these claims would more properly advance the goals of the Redland Soccer court, and would also adequately protect the rights of defendants." Barnes, 984 F. Supp. at 867-68. The District Court reasoned that plaintiffs could have requested lump sum damages which would have clearly invoked the Comparative Negligence Act; that plaintiffs asked for equitable relief instead of damages is not dispositive. Furthermore, because Redland expressly encouraged the use of medical monitoring funds, 696 A.2d at 142 n.6, the District Court predicted the Pennsylvania Supreme Court would not apply the "harsh" and "anachronistic doctrine of contributory negligence" to medical monitoring claims seeking equitable relief. Barnes, 984 F. Supp. at 868.

We need not decide whether the Pennsylvania Supreme Court would apply the Comparative Negligence Act to plaintiffs' negligence claim. If the Comparative Negligence Act does not apply, defendants still have the defense of contributory negligence available to them. See Commonwealth Fed. Sav. and Loan Assoc. v. Pettit, 586 A.2d 1021, 1026 (Pa. Comm. Ct. 1991) ("The doctrine of contributory negligence continues to be applicable to situations where both parties are negligent but the resulting injury is not covered under the Pennsylvania Comparative Negligence Act.").24 Either defense will raise many individual issues.25

Under Pennsylvania law, the tort of intentional exposure to hazardous substances is predicated on a theory of battery. See Field v. Philadelphia Elec. Co., 565 A.2d 1170, 1178 (Pa. Super. Ct. 1989). Plaintiffs must prove as a constituent element they did not consent to the tortious

24. For purposes of our certification inquiry, we need not decide whether these defenses bar plaintiffs' recovery. Instead, we merely conclude that one of these defenses is available to the defendants.

25. We acknowledge that the existence of affirmative defenses as to some class members may not by itself enough warrant the denial of certification. See Merk v. Jewel Food Stores Div., Jewel Companies, Inc., 702 F. Supp. 1391, 1395 (E.D. Ill. 1988); Lorber v. Beebe, 407 F. Supp. 279, 294 (S.D.N.Y. 1975). But we note that the defenses are only one of many matters raising individual issues in this case. conduct. See Levenson v. Souser, 557 A.2d 1081, 1088 (Pa. Super. Ct. 1989); Prosser & Keeton S 18, at 113 ("Consent avoids recovery simply because it destroys the wrongfulness of the conduct as between the consenting parties, however harmful it might be to the interests of others."); Restatement (Second) Torts S 892A ("One who effectively consents to the conduct of another intended to invade his interests cannot recover in an action of tort for the conduct or for the harm resulting from it.") Express consent may be given by words or affirmative conduct and implied consent may be manifested when a person takes no action, indicating an apparent willingness for the conduct to occur. Restatement (Second) Torts S 892 cmt. b & c. The consent must be to the "defendant's conduct, rather than to its consequences." Prosser & Keeton S 18, at 118. A plaintiff's consent is not effective if "the consenting person was mistaken about the nature and quality of the invasion intended by the conduct." Prosser & Keeton S 18, at 114.

Plaintiffs argued in the District Court that the court should use its equitable powers to bar defendants from asserting their affirmative defenses because of defendants' intentional and fraudulent conduct. See Barnes, 984 F. Supp. at 864-65. But the District Court rejected this argument and plaintiffs do not press it on appeal. Instead, plaintiffs argue there is no record evidence they consented to defendants' specific conduct. Defendants maintain plaintiffs knew they were exposing themselves to a hazardous substance yet continued to smoke. There is some evidence on the record, including plaintiffs' own deposition testimony, to support defendants' position that despite warnings, plaintiffs continued to smoke. See id. ("By her own admission, Potts learned `for sure' that cigarette smoking created an increased risk of disease in 1966, when the Surgeon General's warnings were put on cigarette packages. In addition, and more importantly, Ms. Potts was informed by her cardiologist in the late 1980s that she was at a significantly increased risk of contracting heart disease, in the form of clogged arteries, from smoking.").

Under Pennsylvania law, plaintiffs may recover on a theory of strict liability where a product in a defective condition unreasonably dangerous to the consumer or user

causes harm to the plaintiff. See Spino v. John S. Tilley Ladder Co., 696 A.2d 1169, 1172 (Pa. 1997). Plaintiff must prove the product was defective and the defect was a substantial factor in causing the injury. See id. While a defendant may not assert comparative negligence in a strict products liability action, see Kimco Development Corp. v. Michael D's Carpet Outlets, 637 A.2d 603, 606-07 (Pa. 1993), Pennsylvania courts allow defendants to introduce "evidence of a plaintiff's voluntary assumption of the risk, misuse of a product, or highly reckless conduct . . . insofar as it relates to the element of causation." Charlton v. Toyota Indus. Equip., 714 A.2d 1043, 1047 (Pa. Super. Ct. 1998). To demonstrate that a plaintiff's actions are highly reckless, defendants must show plaintiff "knew or had reason to know of facts which created a high degree of risk of physical harm to himself or that he deliberately proceeded to act, or failed to act, in conscious disregard of that risk." Id. (citation omitted).

Assumption of risk is also available in negligence claims. See Kaplan v. Exxon Corp., 126 F.3d 221, 224-25 (3d Cir. 1997).26 In a negligence action, a defendant is relieved of his duty to protect the plaintiff when the plaintiff was aware of the risk and faced it voluntarily. See Barrett v. Fredavid Builders, Inc., 685 A.2d 129 (Pa. Super. Ct. 1996). The defendant must show that the "nature and extent" of the risk were "fully appreciated" and that the plaintiff voluntarily proceeded to face that risk. Childers v. Power Line Equip. Rentals, Inc., 681 A.2d 201, 208 (Pa. Super. Ct. 1996).

Plaintiffs make essentially the same arguments regarding consent and assumption of risk, contending that because defendants concealed the nature and extent of their

26. In light of Pennsylvania's adoption of comparative negligence, see 42 Pa. Cons. Stat. Ann. S 7102(a), the existence of the assumption of the risk defense under Pennsylvania law is a matter of some debate. See Kaplan v. Exxon Corp., 126 F.3d 221, 223-25 (3d Cir. 1997). In Kaplan, we predicted the Pennsylvania Supreme Court would incorporate assumption of the risk into the duty analysis. Therefore, it is a plaintiff's burden to establish that a defendant has a duty. This issue goes to the jury "unless reasonable minds could not differ." Id. at 225 (citation omitted). conduct, no plaintiff can have consented to or assumed the risks of cigarette smoking. Therefore, consent and assumption of risk present no individual issues and can be resolved on a classwide basis. We are inclined to believe that individual considerations predominate here as well, but recognize that the question is a close one. Therefore we do not rely on the presence of individual issues with the defenses of consent and assumption of risk in reaching our decision to affirm class decertification. But we note other courts have permitted cigarette companies to assert affirmative defenses such as contributory negligence and assumption of risk. See Cipollone v. Liggett Group, Inc., 893 F.2d 541, 559 (3d Cir. 1990), aff'd in part, rev'd in part, 505 U.S. 504 (1992) (remanded for jury to consider comparative fault issues); Horton v. The American Tobacco Co., 667 So.2d 1289, 1292 (Miss. 1995) (jury considered comparative fault and held that plaintiff was solely responsible for his injury); Gilboy v. The American Tobacco Co., 582 So.2d 1263, 1265 (La. 1991) (recognizing assumption of risk defense).27

d. Statute of Limitations

Finally, we believe that determining whether each class member's claim is barred by the statute of limitations raises individual issues that prevent class certification.28 It is fundamental that a plaintiff must bring a claim before the applicable statute of limitations expires. Determining whether the statute of limitations has expired necessarily involves determining when it began to run. Under Pennsylvania law, the statute of limitations starts running when the plaintiff's cause of action accrues; a medical

27. But see Wilks v. The American Tobacco Co., 680 So. 2d 839, 843 (Miss. 1996) ("[We] find that the trial court properly struck the defense of assumption of the risk. . . Even if it was a viable defense, it may not be employed unless the defendant admits the existence of a risk. [American Tobacco] firmly denied that smoking was hazardous to one's health.")

28. We discuss our rationale for applying the statute of limitations rather than laches in affirming the grant of summary judgment against the named plaintiffs. For now, we describe only how the statute of limitations applies to the class. monitoring claim accrues when the plaintiff suffers a "significantly increased risk of contracting a serious latent disease." Redland, 696 A.2d at 145. Under plaintiffs' analysis, a cigarette smoker suffers this risk when he reaches the ten or twenty "pack-year" level. A "pack-year" is equivalent to a year in which a person smokes a pack of cigarettes per day. To calculate a particular plaintiff's packyear history, the court multiplies the number of packs of cigarettes the plaintiff smokes daily by the number of years he has smoked. For example, a person who has smoked a pack of cigarettes each day for twenty years has a twentypack year history; a person who has smoked a half a pack per day for twenty years has a ten pack-year history. Under the pack-year approach to claim accrual, determining when a plaintiff's claim accrued necessitates two individual inquiries for each plaintiff: when he began smoking and how much he has smoked since then. The need to conduct such a determination for each plaintiff augurs that a class action will devolve into a lengthy series of individual trials and therefore makes a class action an improper method for resolving these claims.

Because of the individual issues involved in this case-nicotine addiction, causation, the need for medical monitoring, contributory/comparative negligence and the statute of limitations--we believe class treatment is inappropriate.29

C. Summary Judgment

Having concluded the District Court did not abuse its

29. In support of certification, plaintiffs point to other medical monitoring claims that have been certified under Rule 23(b)(2) or 23(b)(3). See, e.g., Gibbs v. E.I. Dupont de Nemours & Co., 876 F. Supp. 475 (W.D.N.Y. 1995) (exposure to chemicals); Yslava v. Hughes Aircraft Co., 845 F. Supp. 705, 713 (D. Ariz. 1993) (class alleging long-term exposure to contaminated ground water certified); Boggs v. Divested Atomic Corp., 141 F.R.D. 58, 67 (S.D. Ohio 1991) (long term exposure to radioactive materials and hazardous waste). Plaintiffs' case, however, presents numerous individual issues not involved in those cases. In addition, the cases plaintiffs cite all involve involuntary exposure to hazardous materials rather than the voluntary exposure involved in this case.

discretion in decertifying the class, we now turn to its order granting summary judgment against the six named plaintiffs. The court held the claims of five of the six plaintiffs--Barnes, Potts, Rodweller, Salzman and Slivak-were barred by the statute of limitations. Because each has smoked for over thirty years, the court found they knew long before this suit was filed that smoking cigarettes put them at an increased risk of contracting a serious disease. See Barnes, 984 F. Supp. at 861-63. The court held the sixth plaintiff, Ciaran McNally, was not barred by the statute of limitations because, given her age and smoking history, her claims for monitoring did not accrue more than two years before this action was brought. Id. at 861 n. 14, 864. But the court held that McNally had no cause of action for medical monitoring because the only monitoring she sought--routine physical examinations and cardiovascular risk assessment--was not different from that normally recommended in the absence of her particular exposure. See id. at 872.

We will briefly set forth the medical and smoking history of the named plaintiffs, as summarized by the District Court:

> Norma Rodweller has high cholesterol and a family history of heart disease. She has been diagnosed with vocal chord polyps and COPD, and has shown abnormalities in pulmonary function tests. She has also been tested for potential coronary insufficiency. She nevertheless continues to smoke despite having been told by doctors that smoking aggravates her medical illnesses. She has also refused her doctor's directions to obtain necessary medical screening such as pap smears and mammograms.

> Ciaran McNally is 26 years old. She has been a regular smoker since she was 15 years old and smokes 10-15 cigarettes per day. She received chest x-rays when appropriate in response to symptoms. She has not followed her doctors' advice to quit smoking while taking oral contraceptives.

William Barnes is mildly obese with hypertension and elevated cholesterol. He has a history of coronary

artery disease, and he has been diagnosed with hypertensive atherosclerotic heart diseases. He is also a heavy drinker. He has received EKGs, chest x-rays, and pulmonary function testing as appropriate in response to symptoms. He has been told to quit smoking every time he visited his doctor, and continues to smoke despite evidence of fibrosis of his lung.

Catherine Potts has been diagnosed with COPD, coronary heart disease, angina, hyperlipidemia, and hypertension. She continues to smoke despite being advised by her doctors to cease due to cardiac problems and a potential vocal chord malignancy. She has not followed her doctor's directions for testing, including a recommended colonoscopy following rectal bleeding. On one occasion, she insisted on being discharged from the hospital against medical advice after being diagnosed with possible myocardial infarction. She continues to drink caffeinated beverages despite being advised by doctors to cease doing so.

Edward Slivak has continued smoking despite abnormal pulmonary function tests and abnormal chest x-rays leading to a diagnosis of COPD. He has high blood pressure and elevated cholesterol, has received EKGs, and has been diagnosed with myocardial infarction. Although he has been advised repeatedly not to smoke due to his various medical conditions, he is still smoking.

Barbara Salzman continues to smoke despite having been diagnosed with emphysema and mild to moderate COPD based on pulmonary function tests and chest xrays. She has received chest x-rays, MRI scans, and EKGs in response to her symptoms. She has not, however, mentioned her emphysema to her family physician, explaining that she does not desire to followup because "I don't like to look for trouble." She drinks an excessive amount of caffeine and has a family history of heart disease.

Barnes, 984 F. Supp. at 854.

1. Statute of Limitations

Looking to the underlying theories of liability--intentional tort, negligence, and strict products liability--the District Court applied a two-year statute of limitations, finding the claims accrued on the date when the plaintiffs were placed at a "significantly increased risk of contracting a serious latent disease." See Redland, 696 A.2d at 145. Plaintiffs faced this risk when, according to their experts' testimony, they had smoked for twenty pack-years. Rodweller reached this level in 1970, Salzman in 1976, Slivak in 1978, Barnes in 1990, and Potts in 1973. Therefore the court held the claim of each named plaintiff was barred by the statute of limitations. The court also found the discovery rule could not save plaintiffs' claims because each knew or should have known that smoking put him or her at a significantly increased risk of contracting a serious latent disease years before this lawsuit was filed. See Barnes, 984 F. Supp. at 863-64.

Plaintiffs contend the equitable doctrine of laches should apply, arguing their medical monitoring claim is analogous to a suit for nuisance abatement based in equity. Citing Simmons v. Pacor, 674 A.2d 232 (Pa. 1996) and Redland, plaintiffs maintain the Pennsylvania Supreme Court implied it would not apply the statute of limitations to a medical monitoring claim based on long-term exposure.30 But we discern no detectable direction from the Pennsylvania Supreme Court that it would apply laches rather than the statute of limitations.

As the District Court found, plaintiffs could have brought their claim at law or in equity depending on the type of relief sought.

30. Plaintiffs point to the following language. In Simmons, the court found that "recovery for medical monitoring is appropriate and just" and that though plaintiffs' experts had recommended medical monitoring, plaintiff had "unfortunately" not sought the relief in the lawsuit. Id. at 240. In Redland, the Court opined that "a medical monitoring trust fund is a more appropriate remedy than lump sum damages in mass exposure toxic tort cases. However, because the Redland Plaintiffs are seeking only a medical monitoring trust fund, we offer no opinion whether lump sum damages are recoverable under HSCA." Redland, 696 A.2d at 142-43 n.6. If plaintiffs seek relief that is a disguised request for compensatory (damages, then the medical monitoring claim can only be characterized as a claim for monetary damages. In contrast, if plaintiffs seek the establishment of a court-supervised medical monitoring program through which the class members will receive periodic medical examinations, then plaintiffs' medical monitoring claims can properly be characterized as a claim seeking injunctive relief.

Arch, 175 F.R.D. at 483. Plaintiffs themselves apparently believed their claim for medical monitoring seeks a legal remedy since both their original and first amended complaints requested money damages.

Because plaintiffs could have brought their medical monitoring claim at law or in equity, the statute of limitations, not the doctrine of laches, applies. "[I]t is well established that equity will frequently follow the statute of limitations which controls analogous proceedings at law. This is especially, if not invariably, true if the cause of action is not exclusively cognizable in equity, which is the situation here " Ebbert v. Plymouth Oil Co., 34 A.2d 493, 495-96 (Pa. 1943). Similarly, in Algrant v. Evergreen Valley Nurseries, Ltd., 126 F.3d 178, 181 (3d Cir. 1997) (citations omitted), we stated: "It is settled . . . that where legal and equitable claims coexist, equitable remedies will be withheld if an applicable statute of limitations bars the concurrent legal remedy." Because plaintiffs could have sought an award of damages, their decision to pursue a claim for a medical monitoring fund instead cannot deprive defendants of the statute of limitations defense. Statutes of limitations are primarily designed to assure fairness and "promote justice by preventing surprises through the revival of claims that have been allowed to slumber until evidence has been lost, memories have faded, and witnesses have disappeared. The theory is that even if one has a just claim it is unjust not to put the adversary on notice to defend within the period of limitation and that the right to be free of stale claims in time comes to prevail over the right to prosecute them." Order of R.R. Telegraphers v. Railway Express Agency, Inc., 321 U.S. 342, 348-49 (1944); see also Carey v. Kerr-McGee Chem. Corp., 999 F. Supp. 1109 (N.D.

Ill. 1998) (holding medical monitoring claims barred by twoyear tort statute of limitations).

In predicting what statute of limitations the Pennsylvania Supreme Court would apply, we look to the theories of liability that underlie a medical monitoring claim. Under Redland, a plaintiff must prove that he was exposed to a proven hazardous substance as a result of the defendant's negligence. See Redland, 696 A.2d at 145-46. In Pennsylvania, a two-year statute of limitations applies to negligence actions. See 42 Pa. Cons. Stat. Ann. S 5524. As noted, plaintiffs also allege intentional exposure to a hazardous substance and strict liability for manufacturing a defective product. To the extent that strict products liability or an intentional tort can act as the underlying theory of liability for a medical monitoring claim, the applicable statute of limitations would still be two years. See 42 Pa. Cons. Stat. Ann. S 5524.31

Next we must decide when plaintiffs' claims accrued. Generally, a plaintiff "is under a duty to use all reasonable diligence to be properly informed of the facts and circumstances upon which a potential right of recovery is based and to institute suit within the prescribed statutory period." Pocono Int'l Raceway, Inc. v. Pocono Produce, 468 A.2d 468, 471 (Pa. 1983). A claim under Pennsylvania law accrues at "the occurrence of the final significant event necessary to make the claim suable." Mack Trucks, Inc. v. Bendix-Westinghouse Automotive Air Brake Co., 372 F.2d 18, 20 (3d Cir. 1966).

A plaintiff's medical monitoring cause of action accrues when he has been placed at a "significantly increased risk of contracting a serious latent disease." Redland, 696 A.2d at 145. To determine when that event occurred, we refer to the testimony of plaintiffs' experts. As the District Court noted, their experts proposed specific dates when plaintiffs

31. In Redland, the Pennsylvania Supreme Court held that "medical monitoring" plaintiffs must prove that defendant's negligence caused the exposure. See Redland, 696 A.2d at 146. We assume without deciding that the Pennsylvania Supreme Court would allow an intentional tort or strict products liability to be the underlying theory of liability in a claim for medical monitoring.

would be entitled to participate in the proposed medical monitoring program. Under the Petty-Hyers Program, a plaintiff would be entitled to medical monitoring when he or she reaches the "twenty pack-year" level. 32

We agree with the District Court that five of the six named plaintiffs reached that level more than two years ago. Rodweller had been smoking one to one-and-a-half packs since 1953 and became a twenty pack-year smoker in 1970. Salzman had been smoking at least one-and-a-half packs per day for forty-one years and her claim accrued, at the latest, in 1976. Slivak had been smoking at least one to two packs per day for thirty-nine years and his claim accrued, at the latest, in 1978. Barnes had been smoking a pack a day since 1970 and his claim accrued in 1990. Potts had been smoking a pack a day since the early 1950s and her claim accrued no later than 1975.

Absent an exception to the statute of limitations, the medical monitoring claims of these five plaintiffs are timebarred. The "discovery rule" is a "narrow exception to this general rule," Tohan v. Owens-Corning Fiberglass Corp., 696 A.2d 1195, 1200 n.4 (Pa. 1997), and tolls the statute of limitations during the "plaintiff's complete inability, due to facts and circumstances not within his control, to discover an injury despite the exercise of due diligence." Kingston Coal Co. v. Felton Mining Co., 690 A.2d 284, 288 (Pa. Super. Ct. 1997). Under the discovery rule, the statute of limitations begins to run when the "plaintiff knows, or in the exercise of reasonable diligence should have known, (1) that he has been injured, and (2) that his injury has been caused by another's conduct." Bradley v. Ragheb, 633 A.2d 192, 194 (Pa. Super. Ct. 1993). The plaintiff has the burden of proving that he exercised reasonable diligence in bringing his claim. See Cochran v. GAF Corp., 666 A.2d 245, 249-50 (Pa. 1995).

32. We note that plaintiffs' other expert Dr. Burns proposes that monitoring begin before a person reaches the 20-pack year level. Dr. Burns suggests, for example, that a person who has smoked 15-20 cigarettes for 10 years would be entitled to three of the seven proposed tests. Barnes, 984 F. Supp. at 860. In choosing the 20-pack year level as the accrual date, we, like the District Court, are erring in plaintiffs' favor by choosing a later date. We agree with the District Court that the discovery rule does not save the claims of these five plaintiffs. Each plaintiff should have known that cigarettes put him or her at a significantly increased risk of contracting a serious latent disease years before this lawsuit was filed. As the District Court found:

> - "Since the 1980s, every doctor seen by Mr. Barnes for hypertension has told him to stop smoking. . . . Dr. Brownstein, his doctor in the mid-1980s, took Barnes' cigarettes and threw them away every time Barnes came in for a visit. . . . Indeed, Mr. Barnes stated that at the time of these visits in the 1980s, he `kn[e]w that cigarettes are no good for you if you have any type of lung disease. . . . Further, Mr. Barnes stated that he believed that his father's death from lung cancer was partially caused by smoking Finally, Mr. Barnes testified at deposition that none of the warnings on cigarettes, which inform smokers of the risks of smoking, provided him with any information that he already did not possess. Based on these facts, it is obvious Barnes knew that smoking caused him to be placed at an increased risk of contracting a serious latent disease by at least the mid-1980s.' "

- "By her own admission, Potts learned `for sure' that cigarette smoking created an increased risk of disease in 1966, when the Surgeon General's first warnings were put on cigarette packages. In addition, and more importantly, Ms. Potts was informed by her cardiologist in the late 1980s that she was at a significantly increased risk of contracting heart disease, in the form of clogged arteries, from smoking."

- "As early as 1959 . . . Rodweller was told by a doctor that smoking would put scar tissue on her vocal cords and it was in that year that she realized that `cigarettes affected [her] body. . . .' Since this time, Ms. Rodweller admits that all of her doctors have advised her to quit smoking because `[i]t can make [her] ill' and because `[she] was a good candidate for emphysema.' "

- "In the 1980s, one of Salzman's doctors told her to stop smoking. The doctor explained, `it's really bad for you, you can get emphysema, cancer . . .' In addition to being told by her doctors that she could contract these diseases, Ms. Salzman urged her son, throughout the 1980s, to quit smoking because of the dangers of smoking."

- "After 1985, Mr. Slivak had read the warnings on the packages of cigarettes. . . In addition, in the early 1980s, Slivak discussed with his family that smoking may have been the cause of his wife's cancer. Most importantly, Slivak's doctors connected smoking to his heart disease."

- With respect to plaintiff McNally, the court determined that, since she has only been smoking for approximately 11 years, her claim could not have accrued until sometime last year. FN 14.

Barnes, 984 F. Supp. 862-63 & n.14.

Plaintiffs argue the claims did not accrue when they were placed "at a significantly increased risk" of developing smoking-related illnesses. They claim instead that the "touchstone of accrual is the suffering of actual, demonstrable injury, not increased risk" and note that Pennsylvania courts have "expressly held that a plaintiff cannot sue for `increased risk.' " Similarly, they argue the court erred in invoking the discovery rule because there was no injury to discover since none had occurred. These arguments lack merit. If, as plaintiffs maintain, they have suffered no demonstrable injury-or even no injury at all-then we would have to dismiss the case because it lacks an Article III case or controversy. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992). The Pennsylvania Supreme Court has held that the costs of periodic medical examinations necessary to detect the onset of physical harm, Redland, 696 A. 2d at 144, are a compensable injury even in the absence of physical harm. Plaintiffs' argument begs the question of when that injury accrued. Examining plaintiffs' claims, the District Court found the injury accrued when plaintiffs began needing medical monitoring. The District Court determined this date by looking at the

testimony of plaintiffs' own experts. We agree with the District Court's analysis.33

Citing Page v. United States, 729 F.2d 818 (D.C. Cir. 1984) and Fowkes v. Pennsylvania Railroad Co., 264 F.2d 397 (3d Cir. 1959), plaintiffs contend the "continuing harm" doctrine should operate to toll the statute of limitations. In Page, the D.C. Circuit found

> It is well-settled that `when a tort involves continuing injury, the cause of action accrues, and the limitation period begins to run, at the time the tortious conduct ceases.' Since usually no single incident in a continuous chain of tortious activity can `fairly or realistically be identified as the cause of significant harm,' it seems proper to regard the cumulative effect of the conduct as actionable. Moreover, `since one should not be allowed to acquire a right to continue the tortious conduct,' it follows logically that statutes of limitations should not run prior to its cessation.

Page at 821-22 (citations omitted). There, the court applied the continuing tort doctrine to a claim by an army veteran that the army subjected him to harmful drugs.

In Fowkes, we found the plaintiff's claim under the Federal Employers' Liability Act was not barred by the three-year statute of limitations under a continuous harm theory. We noted

> `If the relation is continuous, as in that of master and servant, and the default is likewise continuous until the cumulative effect produces disability in the form of occupational disease, total or partial, the master's failure to perform his duty . . . is regarded as a single wrong continuing so long as the employment

33. We acknowledge this statute of limitations analysis leads to some "odd conclusions." For instance, with respect to Mr. Barnes' claim, we have held that it accrued in 1990 under the 20 pack-year rule but that he "discovered his injury five years before it accrued, in the mid-1980s when his doctor threw away his cigarettes." But the source of this seeming incongruity is our decision to err in favor of the plaintiffs in calculating the accrual date. In calculating Barnes' accrual date, we used the 20-pack-year level. This is the latest date suggested by plaintiffs. continues. Such wrong must therefore be redressed by action brought within . . . (the statutory period) from the time when the employment terminates.'

Fowkes, 264 F.2d at 399 (citation omitted).

In Kichline v. Consolidated Rail Corp., 800 F.2d 356 (3d Cir. 1986), however, in declining to apply the continuing harm doctrine to a FELA claim, we limited the applicability of Fowkes. In doing so, we specifically rejected the position now advanced by plaintiffs. We noted that in Fowkes, the "jury found specifically that the plaintiff was unaware that the physical condition for which he sought damages had existed for more than three years before the suit had been filed." Kichline, 800 F.2d at 359. We then stated: "We understand Fowkes to mean that continuing conduct of defendant will not stop the ticking of the limitations clock begun when plaintiff obtained requisite information. On discovering an injury and its cause, a claimant must choose to sue or forego that remedy." Id. at 360.34 Unlike this case, the discovery rule was not applicable in Fowkes because plaintiff did not know about his injury. But here, as we have discussed, there is unrefuted evidence that plaintiffs knew or should have known about their injury more than two years before filing suit. Under Kichline, the clock began to run when plaintiffs obtained the requisite information.

2. Ciaran McNally

The District Court also granted summary judgment against the sixth named plaintiff, McNally, finding she failed to demonstrate a need for medical monitoring. 35 The

34. While plaintiffs are correct that in Kichline we distinguished Page as an "intentional conduct case," Kichline, 800 F.2d at 360, we did not adopt Page as the rule in intentional tort cases. We believe our unequivocal adoption of the discovery rule in Kichline disposes of plaintiffs' argument. We further note that Page, unlike this case, involved

involuntary exposure to a hazardous substance.

35. Before reaching this issue, the District Court concluded defendants were not entitled to summary judgment on the issues of McNally's comparative negligence, assumption of risk, and consent. The District Court found genuine issues of material fact exist with respect to each defense. See Barnes, 984 F. Supp. at 868-70.

District Court found (1) under the Burns Program, McNally is only entitled to participate in the first level of the proposed monitoring program which includes regular physical examinations, cardiovascular risk assessment, and an EKG; (2) McNally only requested cardiovascular risk assessment and annual physical examinations and not EKGs; and (3) annual physical examinations and cardiovascular risk assessment are routinely recommended to all persons even in the absence of exposure. The court concluded that because McNally only seeks monitoring for two tests that would be recommended for her even if she did not smoke, "[a]ny increase in Ms. McNally's incremental risk of incurring the harm produced by the allegedly hazardous substances in cigarettes would not warrant a change in the medical monitoring that would be prescribed for her. Indeed, in the absence of exposure, it would be recommended that she receive the tests she seeks under her medical monitoring claim." Barnes, 984 F. Supp. at 870-72. Therefore, the court reasoned, she cannot satisfy the sixth element of Redland because she cannot establish that "the prescribed regime is different from that normally recommended in the absence of the exposure." See id.36 We

36. The parties' briefs and the record demonstrate a great deal of confusion and disagreement on this issue. The dispute centers around what kind of monitoring program McNally requested and what kind of program plaintiffs' expert recommended for her.

Dr. Burns made contradictory statements with respect to the appropriate program for McNally. In describing the different levels of monitoring, Dr. Burns recommended three tests for smokers at McNally's level (at least 25 years old and at least 10 years of smoking): (1) an EKG,

(2) a cardiovascular risk factor assessment, and (3) a physical examination. But later in his affidavit Dr. Burns specifically stated McNally "should initially receive [cardiovascular risk assessment] and [physical examination]." He did not mention the EKG. Moreover, in plaintiffs' response to defendants' first set of interrogatories, McNally indicated she would only need cardiovascular risk factor assessment and physical examination and did not mention an EKG.

McNally claims for the first time on appeal that Dr. Burns' report contains a typographical error. She claims paragraph 7 of the report inadvertently stated that only a cardiovascular risk factor assessment and a physical examination would be prescribed for her, and forgot to mention the EKG. She argues this error was "carried through" to the agree with this reasoning and the District Court's decision to grant summary judgment against McNally.

IV.

For the foregoing reasons, we will affirm the judgment of the District Court.

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interrogatory and contend the District Court erred by failing to recognize and resolve a resulting "tension" between the interrogatory answer, which neglected to mention the EKG, and the more general statement in Dr. Burns' second report that EKGs should be administered to persons 25 or older who have smoked 10-15 cigarettes per day for 10 years. Defendants claim McNally waived this argument because she did not raise it below. We agree with defendants that this argument is waived.

Alternatively, plaintiffs contend that Dr. Burns, in his expert report, stated that both tests--cardiovascular risk factor coupled with physical examination--were different from that normally prescribed and therefore satisfied the sixth element of Redland. We do not agree with plaintiffs' analysis of Dr. Burns' testimony. Dr. Burns said: "Cardiovascular risk factor assessment and a physical examination are measures that are recommended for all individuals to identify modifiable causes of heart disease including smoking. They are useful in preventing disease only for those who have an identifiable and modifiable risk factor. All smokers have an identifiable and modifiable risk factor, and the risk of disease increases synergistically when smokers have additional risk factors. Therefore, smokers have a particularly urgent need for this screening in comparison to the general population and will have a potential benefit that is substantially greater than the general population of smokers." Plaintiffs argue this statement supports the position that these tests were different from that normally prescribed for the general population. But as defendants contend, Dr. Burns' report indicates these are "measures recommended for all individuals." We also note Dr. Burns' deposition statement that "most organizations recommended screening for cardiovascular risk factors at almost any interaction with the health care system regardless of age."