SYLLABUS

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Phyllis Sinclair v. Merck & Co., Inc. (A-117-06)

Argued October 22, 2007 – Decided June 4, 2008

WALLACE, J., writing for a majority of the Court.

In this products liability case the Court considers whether plaintiffs may recover the costs of medical monitoring despite their failure to allege a physical injury.

This litigation arises from the use of Vioxx, a prescription drug manufactured and sold by Merck. On May 20, 1999, Vioxx was approved for sale by the United States Food and Drug Administration (FDA) for the relief of the signs and symptoms of acute pain, dysmenorrhea, and osteoarthritis. Five years later, on September 30, 2004, the FDA acknowledged the voluntary withdrawal from the market of Vioxx. The FDA explained that the withdrawal came after a board overseeing a long-term study of the drug recommended the study be halted because of an increased risk of serious cardiovascular events, including heart attacks and strokes, among patients taking Vioxx.

Since the withdrawal of Vioxx from the market, numerous plaintiffs have instituted lawsuits against Merck alleging cardiovascular injuries due to Vioxx. In November 2004, plaintiffs filed a class action complaint against Merck and various other parties. Plaintiffs alleged negligence, violation of the Products Liability Act (PLA), violation of the Consumer Fraud Act (CFA), breach of warranties, and unjust enrichment. Plaintiffs brought the action on behalf of a proposed national class of individuals who ingested Vioxx and who may suffer from serious silent or latent injury for which they may require medical monitoring.

In March 2005, an amended complaint redefined the class as consisting of individuals who ingested Vioxx for at least six consecutive weeks and who had not sought to recover damages for personal injuries caused by Vioxx. Plaintiffs also refined the factual allegations advanced in the complaint and alleged that as a result of the direct consumption of Vioxx, they are at enhanced risk of serious undiagnosed and unrecognized myocardial infarction, commonly referred to as "silent heart attack," and other latent and unrecognized injuries. In addition to seeking punitive damages, plaintiffs asserted that the cost of diagnostic testing designed to determine whether they have suffered unrecognized or serious latent injury represents an ascertainable economic loss for which they are entitled to medical monitoring relief paid for by defendants. They sought to have defendants fund a court-administered screening program to provide medical diagnostic tests for each member of the proposed class and follow-up with an epidemiologist. Plaintiffs did not allege that they have had an Electrocardiogram (EKG) since they began taking Vioxx or that they have suffered any known adverse effect as a result of taking Vioxx.

In April 2005, Merck moved to dismiss the amended complaint for failure to state a cognizable claim under New Jersey law. The trial court reviewed the standards governing pleadings and motions to dismiss, as well as the facts and holdings of several significant cases that addressed medical monitoring: Ayers v. Township of Jackson, 106 N.J. 557 (1987), Mauro v. Raymark Industries, Inc., 116 N.J. 126 (1989), and Theer v. Philip Carey Co., 133 N.J. 610 (1993). The trial court granted Merck's motion and dismissed plaintiffs' complaint. It found that the PLA limits compensation to harm as defined by N.J.S.A. 2A:58C-1b(2), and reasoned that medical monitoring has not been applied to a products liability action to which the PLA applies. Additionally, the trial court noted that the CFA only allows for recovery of economic damages, and medical monitoring is therefore an unavailable remedy under that act.

On appeal, the Appellate Division reversed and remanded for further proceedings. Sinclair v. Merck & Co, 389 N.J. Super. 493 (2007). The panel cautioned that it did not read the relevant cases to require dismissal without analysis of the scientific and other evidence relevant to plaintiffs' claims. It noted the lack of facts and expert testimony at this stage of the proceedings, and remanded for discovery and an evidentiary hearing. Although the panel explained that even though the PLA's requirement of harm, which is defined in relevant part as "personal physical illness, injury or death," may ultimately lead to the dismissal of plaintiffs' claims, they must be accorded an opportunity to demonstrate such harm before the portions of the suit premised on the PLA can be dismissed as

legally insufficient. This Court granted Merck's petition for certification and also granted amicus curiae status to five entities.

HELD: The Products Liability Act, which is the sole source of remedy for plaintiffs' defective product claim, does not include the remedy of medical monitoring when no manifest injury is alleged.

1. This Court held in Ayers that a plaintiff can recover the cost of medical monitoring under the Tort Claims Act. In that case, a landfill operated by the defendant contaminated the plaintiffs' well water. The Court identified several factors to be considered in determining whether medical monitoring is an appropriate remedy, including the extent of exposure to chemicals, the toxicity of the chemicals, the seriousness of the diseases, relative increase in chance of onset of disease, and the value of early diagnosis. Two years later, in Mauro, the Court allowed damages that included future medical surveillance in a suit by a repairman employed at a state hospital against manufacturers of products containing asbestos. The complaint alleged plaintiff's injuries were sustained as a result of inhalation of asbestos fibers. The next case was Theer, where the widow of an asbestos worker brought a products liability action against manufacturers of asbestos products to recover for her husband's death and her risk of future injury due to her indirect exposure to asbestos through the handling of her husband's clothes. This Court determined that the remedy of medical surveillance was not available to the plaintiff in Theer, because that remedy applied only to persons who have been directly exposed to a hazardous substance. (pp. 9-13)

2. In 1987, the Legislature enacted the PLA to limit the liability of manufacturers so as to balance the interests of the public and the individual with a view towards economic reality. A product liability action is defined as "any claim or action brought by a claimant for harm caused by a product." N.J.S.A. 2A:58C-1b(3). "Harm" is defined as "personal physical illness, injury or death." N.J.S.A. 2A:58C-1b(2). Merck argues that the word "physical" modifies both "illness" and "injury," and because plaintiffs have no "physical" injury, their claims must fail. This Court reads the PLA to require a physical injury. In the definition, the word "injury" is surrounded by "physical illness," which explicitly requires something physical, and "death," which inherently is physical. The sense and reason of the definition is that the adjectives "personal physical" are intended to modify the words "illness," "injury," and "death." It is not disputed that plaintiffs do not allege a personal physical injury. Thus, the Court concludes that they cannot satisfy the definition of harm to state a product liability claim under the PLA, and their claim for medical monitoring must fail. (pp. 13-18)

3. Plaintiffs also seek to avoid the requirements of the PLA by asserting their claims as CFA claims. However, the Legislature expressly provided in the PLA that claims for harm caused by a product are governed by the PLA irrespective of the theory underlying the claim. The heart of plaintiffs' case is the potential for harm caused by Merck's drug. It is obviously a product liability claim. Consequently, plaintiffs may not maintain a CFA claim. (pp. 18-19)

The judgment of the Appellate division is **REVERSED**, and the matter is **REMANDED** to the Law Division to **REINSTATE** the judgment dismissing plaintiffs' complaint.

JUSTICE LONG filed a separate, **DISSENTING** opinion, expressing her disagreement with the majority's conclusion that plaintiffs did not suffer "harm" under the PLA, and her view that even if the majority is correct on that issue, plaintiffs are entitled to pursue their remedies at common law.

CHIEF JUSTICE RABNER and JUSTICES LaVECCHIA, RIVERA-SOTO and HOENS join in JUSTICE WALLACE's opinion. JUSTICE LONG filed a separate, dissenting opinion. JUSTICE ALBIN did not participate.

SUPREME COURT OF NEW JERSEY
A-117 September Term 2006

PHYLLIS SINCLAIR, JOSEPH MURRAY and ROBBIE L. TRAYLOR, Individually and for all others similarly situated,

Plaintiffs-Respondents,

v.

MERCK & CO., INC.,

Defendant-Appellant,

and

JANE DOES DISTRIBUTORS (1-50), JILL DOES MANUFACTURERS (1-50), JACK DOES PHARMACEUTICAL ADVERTISERS (1-50), JAKE DOES SELLERS (1-50), JOHN DOES MARKETING PARTNERS (1-50) and JOAN DOES PROMOTERS (1-50),

Defendants.

Argued October 22, 2007 – Decided June 4, 2008

On certification to the Superior Court, Appellate Division, whose opinion is reported at 389 N.J. Super. 493 (2007).

John Beisner, a member of the District of Columbia bar, argued the cause for appellant (Dechert, attorneys; Mr. Beisner, Diane P. Sullivan, Christopher J. Michie, Richard Jasaitis III and Johnathan Hacker, a member of the District of Columbia bar, on the briefs).

Elizabeth J. Cabraser, a member of the California bar, argued the cause for respondents (Williams Cuker Berezofsky, attorneys; Ms. Cabraser and Esther E. Berezofsky, on the briefs).

Thomas D. Begley, Jr., submitted a brief on behalf of amicus curiae AARP (Begley & Bookbinder, attorneys).

E. Drew Britcher submitted a brief on behalf of amicus curiae Association of Trial Lawyers-New Jersey (Britcher, Leone & Roth, attorneys; Mr. Britcher and Jessica E. Choper, on the brief).

David G. Evans submitted a brief on behalf of amicus curiae Pacific Legal Foundation.

Michael Dore submitted a brief on behalf of amicus curiae Pharmaceutical Research and Manufacturers of America (Lowenstein Sandler, attorneys; Mr. Dore and Rosemary E. Ramsay, on the brief).

Anita R. Hotchkiss submitted a brief on behalf of amicus curiae Product Liability Advisory Council, Inc. (Hotchkiss Law and Porzio, Bromberg & Newman, attorneys; Ms. Hotchkiss and John T. Chester, on the brief).

JUSTICE WALLACE, JR., delivered the opinion of the Court.

In this products liability case we consider whether plaintiffs may recover the costs of medical monitoring despite their failure to allege a physical injury. The trial court granted defendant Merck & Co., Inc.'s (Merck) motion to dismiss, reasoning that medical monitoring is an uncommon remedy that should not be applied to plaintiffs who did not allege any manifest injury. The Appellate Division disagreed, concluding that our limited medical monitoring jurisprudence does not necessarily preclude plaintiffs' cause of action and remanded for discovery. We granted Merck's petition for certification, and now reverse.

We hold that the definition of harm under our Products Liability Act (PLA), N.J.S.A. 2A:58C-1 to -11, does not include the remedy of medical monitoring when no manifest injury is alleged. We also hold that the PLA is the sole source of remedy for plaintiffs' defective product claim; therefore, the Consumer Fraud Act (CFA), N.J.S.A. 56:8-1 to -106, does not provide an alternative remedy.

I.

This litigation arises from the use of Vioxx, a prescription drug manufactured and sold by Merck. On May 20, 1999, Vioxx was approved for sale by the United States Food and Drug Administration (FDA) for the relief of the signs and symptoms of acute pain, dysmenorrhea, and osteoarthritis. Sequence of Events with VIOXX, since opening of IND, http://www.fda.gov/OHRMS/DOCKETS/AC/05/briefing/2005-4090B1_04_E-FDA-TAB-C.htm (last visited Mar. 20, 2008). Five years later, on September 30, 2004, the FDA "acknowledged the voluntary withdrawal from the market of Vioxx." FDA Issues Public Health Advisory on Vioxx as its Manufacturer Voluntarily Withdraws the Product (Sept. 30, 2004), http://www.fda.gov/bbs/topics/news/2004/NEW01122.html [hereinafter FDA Release]. The FDA Release explained that the withdrawal came "after the data safety monitoring board overseeing a long-term study of the drug recommended that the study be halted because of an increased risk of serious cardiovascular events, including heart attacks and strokes,

among study patients taking Vioxx compared to patients receiving placebo."

Since the withdrawal of Vioxx from the market, numerous plaintiffs have instituted lawsuits against Merck alleging cardiovascular injuries due to the use of Vioxx. In November 2004, plaintiffs Phyllis Sinclair and Joseph Murray filed a class action complaint against Merck and various fictitiously-named distributors, manufacturers, advertisers, sellers, marketing partners, and promoters. Plaintiffs alleged negligence, violation of the PLA, violation of the CFA, breach of express and implied warranties, and unjust enrichment. Plaintiffs brought the action on behalf of a proposed national class of individuals who ingested Vioxx during the period from when Vioxx was introduced in May 1999 through the period when it was withdrawn from the worldwide market in September 2004, and who may suffer from serious silent or latent injury for which they may require medical monitoring.

In March 2005, an amended complaint substituted plaintiff Robbie L. Traylor for plaintiff Sinclair and redefined the class sought to be certified as consisting of national or statewide individuals who ingested Vioxx for at least six consecutive weeks during the previously mentioned period who had not sought to recover damages for personal injuries caused by Vioxx. Plaintiffs also refined the factual allegations advanced in the complaint and alleged that as a result of their direct and prolonged consumption of Vioxx, they are at enhanced risk of

serious undiagnosed and unrecognized myocardial infarction, commonly referred to as "silent heart attack," and other latent and unrecognized injuries. In addition to seeking punitive damages, plaintiffs asserted that the cost of diagnostic testing designed to determine whether they have suffered unrecognized or serious latent injury as a result of their direct exposure to Vioxx represents an ascertainable economic loss for which they are entitled to medical monitoring relief paid for by defendants. They sought to have defendants fund a court-administered screening program to provide medical diagnostic tests for each member of the proposed class and follow-up with an epidemiologist. Plaintiffs did not allege that they have had an Electrocardiogram (EKG) since they began taking Vioxx or that they have suffered any known adverse effect as a result of taking Vioxx.

Thereafter, in April 2005, Merck moved to dismiss the amended complaint for failure to state a cognizable claim under New Jersey law. In framing the issue, the trial court reviewed the standards governing pleadings and motions to dismiss, as well as the facts and holdings of several significant cases that addressed medical monitoring: Ayers v. Township of Jackson, 106 N.J. 557 (1987), Mauro v. Raymark Industries, Inc., 116 N.J. 126 (1989), and Theer v. Philip Carey Co., 133 N.J. 610 (1993). The court determined that Theer, as it related to Ayers and Mauro, limited the extent to which the Supreme Court would extend medical monitoring relief. The trial court also found that the

present matter was significantly different from Ayers and its progeny.

Central to the case, the trial court concluded that "the PLA applies to Vioxx and . . . limits compensation to harm as defined by" the statute. The trial court reasoned that this Court "has indicated that medical monitoring may be necessary in asbestos products-liability actions, [but] it has yet to apply a medical monitoring remedy to a pure products liability action where the PLA applies." Additionally, the trial court noted that "the CFA only allows for recovery of economic damages" and medical monitoring is therefore an unavailable remedy under that act. Consequently, the trial court dismissed plaintiffs' complaint with prejudice as to all claims.

On appeal, the Appellate Division reversed and remanded for further proceedings. Sinclair v. Merck & Co., 389 N.J. Super. 493, 496 (2007). The panel noted that the sole issue on appeal was "[t]he viability of plaintiffs' medical monitoring claim." Ibid. The panel then reviewed Ayers, Mauro, and Theer. See id. at 496-503. It cautioned that, although the trial court's conclusion "'that Ayers, as clarified by Theer, was not meant to extend to all products liability actions and should be limited rather than expanded,'" may ultimately prove to be correct, it did "not read Theer as dictating that result without analysis of the scientific and other evidence relevant to plaintiffs' claims." Id. at 503. Noting the lack of facts and expert testimony at that stage of the proceedings, the panel remanded

the matter for discovery and an evidentiary hearing. Id. at 508-09. The panel explained that even though the PLA's "requirement of 'harm[,]' which is defined in relevant part as 'personal physical illness, injury or death,'" may ultimately lead to the dismissal of plaintiffs' claims, plaintiffs "must be accorded an opportunity to demonstrate 'harm' cognizable under the [PLA] before the portions of their suit premised on th[e PLA] can be dismissed as legally insufficient." Id. at 509-10.

We granted Merck's petition for certification. 190 N.J. 392 (2007). We also granted amicus curiae status to Pharmaceutical Research and Manufacturers of America, Pacific Legal Foundation, Product Liability Advisory Council, Inc., ATLA-NJ, and AARP.

II.

Merck urges that further development of a record is not necessary because plaintiffs have not alleged any manifest injury from the use of Vioxx. Merck argues that this Court's decision in In re Lead Paint Litigation, 191 N.J. 405 (2007), controls the outcome here because the Court held that the PLA exclusively governs all product liability claims, and plaintiffs do not allege the physical harm required to succeed on a product liability claim under the PLA. Further, Merck argues that the case cannot proceed on a fraud theory under the CFA because the Lead Paint decision made clear that the PLA is a comprehensive statute intended to address "all legal issues arising out of the potential risks associated with the use of consumer products in

New Jersey." Merck adds that the analysis in Lead Paint of the environmental tort exception to the PLA clarifies the distinction between this case involving a products liability claim and Ayers and Mauro, involving environmental contaminate and workplace asbestos exposure in which medical monitoring remedies were approved. Amici, Pharmaceutical Research and Manufacturers of America, Pacific Legal Foundation, and Product Liability Council, largely support Merck's position.

On the contrary, plaintiffs argue that the Appellate Division correctly applied this Court's medical monitoring precedents. Plaintiffs contend that they asserted each of the elements required by Ayers, and that Mauro did not change the Ayers' requirements. Further, they contend that "[t]he PLA does not impose a physical injury requirement" and that economic harm is consistent with the concerns underlying this Court's recognition of the monitoring cause of action in Ayers. Plaintiffs urge that Lead Paint supports their claims for medical monitoring because it recognized that the costs of testing for contamination and of medical treatment are actionable harms under the PLA. They assert that although the PLA covers their tort claims, they can also proceed under the CFA because Lead Paint is silent on consumer fraud and the requirements for preempting such claims. Amici, ATLA-NJ and AARP, support plaintiffs' position, and urge this Court to affirm the judgment of the Appellate Division.

III.

A.

Before addressing whether plaintiffs may seek to recover the costs of medical monitoring without an allegation of physical injury in a products liability case, we review the limited authority for medical monitoring.

Prior to the adoption of the PLA, we held in Ayers, supra, that under limited circumstances, a plaintiff can recover the cost of medical monitoring under the Tort Claims Act (TCA), N.J.S.A. 59:1-1 to 12-3. 106 N.J. at 606. In Ayers, a landfill operated by the defendant contaminated the plaintiffs' well water when toxic pollutants leaked into the Cohansey Aquifer. Id. at 565. The plaintiffs sued the defendant. Ibid. The jury found that the defendant created a "nuisance" and a "dangerous condition" in the operation of its landfill and awarded damages for emotional distress, deterioration of plaintiffs' quality of life, and future costs of annual medical surveillance. Id. at 565-66. The Appellate Division set aside the jury's $8,204,500 award for medical surveillance. Id. at 566. In reinstating the award, this Court listed several factors to be considered in deciding claims involving the compensability of medical surveillance expenses. Id. at 605-06.

> [T]he cost of medical surveillance is a compensable item of damages where the proofs demonstrate, through reliable expert testimony predicated upon the significance and extent of exposure to chemicals, the

> toxicity of the chemicals, the seriousness of the diseases for which individuals are at risk, the relative increase in the chance of onset of disease in those exposed, and the value of early diagnosis, that such surveillance to monitor the effect of exposure to toxic chemicals is reasonable and necessary.
>
> [Id. at 606.]

This Court held that the plaintiffs were entitled to their lump-sum jury verdict awarding medical-surveillance damages, but that in the future, a fund would be used to disburse medical surveillance benefits, because a fund offered numerous advantages over a lump-sum verdict. Id. at 607-11.

Two years later, this Court decided Mauro. There, a repairman employed at a state psychiatric hospital sued private manufacturers of products containing asbestos for "injuries allegedly sustained as a result of inhalation of asbestos fibers." Mauro, supra, 116 N.J. at 128-29. After participating in tests conducted by the New Jersey Department of Health (Department) in 1981, the plaintiff was informed "that although the results of his physical examination and lung function test were 'normal,' he had bilateral thickening of both chest walls and calcification of the diaphragm." Id. at 129. The Chief of Occupational Medicine for the Department informed the plaintiff of his condition and opined that the plaintiff's "'exposure to asbestos has been significant and there is some evidence that this exposure may increase the risk of development of lung cancer.'" Ibid. The plaintiff subsequently consulted a

pulmonary specialist and was examined every six months beginning in 1982. Ibid. At trial, the court permitted the jury to consider the plaintiff's claim for damages caused by emotional distress, his present medical condition, and the cost of future medical surveillance, but rejected the plaintiff's claim for damages based on his enhanced risk of cancer. Id. at 131. The jury awarded the plaintiff $7,500 and the Appellate Division affirmed. Ibid. This Court distinguished between the plaintiff's enhanced-risk claims and claims for medical surveillance, id. at 136, and found that recovery for enhanced risk of contracting a disease due to exposure to toxic chemicals is only possible upon proof that it is more probable than not (the rule of reasonable medical probability) that the plaintiff will develop the disease, id. at 132-33. The Court found that the plaintiff failed to submit evidence establishing that the future occurrence of cancer was a reasonable medical probability and therefore that claim was properly withheld from the jury. Id. at 139. As for the plaintiff's claims for medical surveillance and emotional distress, the Court held that "[r]ecognition of present claims for medical surveillance and emotional distress realistically address[] significant aspects of the present injuries sustained by toxic-tort plaintiffs, and serve[] as an added deterrent to polluters and others responsible for the wrongful use of toxic chemicals." Id. at 145.

The next case in which this Court addressed medical monitoring was Theer. In Theer, supra, the widow of an asbestos worker brought a products liability action against manufacturers of asbestos products to recover for her husband's death and for the risk of her own future injury due to her indirect exposure to asbestos through the handling of her husband's clothes. 133 N.J. at 613-14. At trial, the jury found that Mrs. Theer did not have an asbestos-related injury; for that reason, "the court did not allow the jury to reach her claim for damages for emotional suffering and costs of medical surveillance based on the increased risk of cancer." Id. at 616. The Appellate Division reversed and remanded in part for the jury to consider the plaintiff's medical surveillance claims. Id. at 617. This Court granted certification in part to address "whether costs of medical surveillance are available as compensatory damages for one exposed to asbestos." Ibid. In reviewing both the Ayers and Mauro cases, the Court explained that

> Ayers indicates that medical surveillance damages constitute a special compensatory remedy designed to address the unique harm entailed in an increased risk of future injury arising from the exposure to toxic chemicals. It is not easily invoked. The remedy in Ayers was fashioned to help a class of person who had been victimized by a public entity. The feasibility of developing a fund to provide limited compensation was a relevant consideration. Because persons may often be exposed to toxic chemicals in a product-liability context, we recognize the soundness of Mauro, which, in a limited context, extends the Ayers cause of action to plaintiffs who have suffered increased risk of cancer when

> directly exposed to a defective or hazardous product like asbestos, when they have already suffered a manifest injury or condition caused by that exposure, and whose risk of cancer is attributable to the exposure.
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> [Id. at 627.]

The Court emphasized that such a special remedy "applies only to persons who have been directly exposed to hazardous substances." Ibid. Because the plaintiff was not exposed to the product in a direct manner and had not suffered from any injury or condition relating to the exposure, this Court held that the plaintiff could not recover damages for medical surveillance. Id. at 627-28.

B.

We now consider whether a claim for medical monitoring requires a different result when the claim is neither brought under traditional tort principles for exposure to an environmental contaminate, nor for personal injuries as the result of exposure to asbestos, but rather is brought specifically under the PLA for the ingestion of a pharmaceutical product.

In 1987 the Legislature enacted the PLA based on an "urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products." N.J.S.A. 2A:58C-1a. This Court declared that "[t]he Legislature intended . . . to limit the liability of manufacturers so as to 'balance[] the interests of

the public and the individual with a view towards economic reality.'" Zaza v. Marquess & Nell, Inc., 144 N.J. 34, 47-48 (1996) (second alteration in original) (quoting Shackil v. Lederle Labs., 116 N.J. 155, 188 (1989)).

A product liability action is defined as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. 2A:58C-1b(3). In addition to the exception for breach of an express warranty, the PLA excludes from its reach environmental tort actions, N.J.S.A. 2A:58C-6, defined as "a civil action seeking damages for harm where the cause of the harm is exposure to toxic chemicals or substances, but does not mean actions involving drugs or products intended for personal consumption or use," N.J.S.A. 2A:58C-1b(4). See Lead Paint, supra, 191 N.J. at 437 (noting PLA "excludes claims seeking coverage for harm where the cause of the harm is exposure to toxic chemicals or substances" (citation and quotation marks omitted)). It is evident that Vioxx is a drug product and plaintiffs' cause of action is encompassed by the PLA.

The essential question is whether plaintiffs' effort to recover monitoring damages is limited by the definition of "harm" in the PLA. "Harm" is defined in the PLA as

> (a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services

> or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.
>
> [N.J.S.A. 2A:58C-1b(2) (emphasis added).]

Merck argues that the word "physical" in the definition of harm modifies both "illness" and "injury," and because plaintiffs have no physical injury, their claim must fail. Plaintiffs disagree and urge that the PLA does not limit the type of injury that may occur.

We have not found, nor have the parties called our attention to, any reported decision in this State determining whether the word "physical" modifies the words "illness" and "injury" or merely modifies the word "illness." Our canvas from other jurisdictions has not been informative. At the present time, only a handful of product liability statutes exist in which the word "physical," "personal," or "bodily," does not modify the word injury or harm.[1] In those jurisdictions, we did

[1] See, e.g., Ga. Code Ann. § 51-1-11(b)(1) (2007) (declaring liability when consumer suffers "injury to his person or property"); Idaho Code Ann. § 6-1402(4) (2008) ("'Claimant' includes any person or entity that suffers harm."); Miss. Code Ann. § 11-1-63(g)(i) (2008) (referring to "product that caused harm for which recovery of damages is sought"); Mo. Rev. Stat. §§ 537.760(3)(a) (2008) ("[T]he term 'products liability claim' means . . . the plaintiff was damaged as a direct result of [a] defective condition . . . ."); Wash. Rev. Code. § 7.72.010 (2008) ("'Harm' includes any damages recognized by the courts of this state . . . ."). But see Ala. Code § 6-5-501(2) (2008) (including actions "brought by a natural person for personal injury, death, or property damage"); Ariz. Rev. Stat. Ann. § 12-681(5) (2008) ("'Product liability action' means any action . . . for damages for bodily injury, death or property damage . . . ."); Ark. Code Ann. § 16-116-102(5) (2008) (including actions "on account of personal injury, death, or property damage"); Colo. Rev. Stat. § 13-21-401(2) (2008) (same); Conn. Gen. Stat.

not find any cases interpreting the type of harm necessary to assert a cognizable claim under those statutes. However, some courts interpreting those product liability statutes generally have suggested that a physical injury would be required.[2]

We read our PLA to require a physical injury. Prior to the enactment of the PLA, we adopted generally the view of Restatement (Second) of Torts § 402A (1965), in which strict

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§ 52-572m(d) (2008) ("'Harm' includes . . . personal injuries including wrongful death . . . ."); Ind. Code § 34-20-1-1 (2008) (applying product liability article to actions "for physical harm caused by a product"); Kan. Stat. Ann. § 60-3302 (2006) ("'Harm' includes: . . . personal physical injuries, illness or death."); Ky. Rev. Stat. Ann. § 411.300(1) (LexisNexis 2008) (including actions "brought for or on account of personal injury, death or property damage"); Me. Rev. Stat. Ann. tit. 14, § 221 (2007) ("One who sells . . . products in a defective condition . . . is subject to liability for physical harm thereby caused to a person . . . ."); Mich. Comp. Laws § 600.2945(h) (2008) (including claims "brought for the death of a person or for injury to a person or damage to property"); Mont. Code Ann. § 27-1-719 (2007) (naming statute: "Liability of seller of product for physical harm to user or consumer"); N.C. Gen. Stat. § 99B-1(3) (2007) (including actions "on account of personal injury, death or property damage"); Ohio Rev. Code Ann. 2307.71(A)(7) (LexisNexis 2008) ("'Harm' means death, physical injury to person, serious emotional distress, or physical damage to property . . . ."); Or. Rev. Stat. § 30.900 (2007) (defining "product liability action" as action for "damages for personal injury, death or property damage"); S.C. Code Ann. § 15-73-10(1) (2007) (declaring sellers of defective products liable for "physical harm"); Tenn. Code Ann. § 29-28-102(6) (2008) ("'Product liability action' . . . includes all actions . . . on account of personal injury, death or property damage"); Texas Civ. Prac. & Rem Code Ann. § 82.001 (Vernon 2007) (permitting recovery for "damages arising out of personal injury, death, or property damage"); Utah Code Ann. § 78-15-6 (2007) (governing actions for "damages for personal injury, death, or property damage").

[2] See Chrysler Corp. v. Taylor, 234 S.E.2d 123, 124 (Ga. Ct. App. 1977); Shields v. Morton Chem. Co., 518 P.2d 857, 860 (Idaho 1974); Williams v. Bennett, 921 So. 2d 1269, 1274-75 (Miss. 2006); Rodriguez v. Suzuki Motor Corp., 996 S.W.2d 47, 65 (Mo. 1999); Lenhardt v. Ford Motor Co., 683 P.2d 1097, 1099 (Wash. 1984).

liability in tort for defective products spoke only in terms of physical harm. See Cepeda v. Cumberland Eng'g Co., 76 N.J. 152, 163, 169 (1978), overruled on other grounds by Suter v. San Angelo Foundry & Mach. Co., 81 N.J. 150, 177 (1979); see also Brown v. United States Stove Co., 98 N.J. 155, 178 (1984). Nothing in the legislative history of the PLA suggests that the Legislature intended to eliminate that physical component.

To be sure, in the definition of harm, the word "injury" is surrounded by "physical illness," which explicitly requires something physical, and "death," which inherently is physical. We give words their common acceptance and usage, but "particular words may be enlarged or restricted in meaning by their associates and the evident spirit of the whole expression." Salz v. State House Comm'n, 18 N.J. 106, 111 (1955). In our view, the sense and reason of that definition is that the adjectives "personal physical" are intended to modify the words "illness," "injury," and "death." Consistent with that interpretation, we determined in Lead Paint, supra, that harm under the PLA "includes 'physical damage to property[,] . . . personal physical illness [or] injury,' and the like." 191 N.J. at 437. Consequently, we read the injury portion of the definition to require "personal physical" injury, just like there must be a "personal physical" illness and "personal physical" death.

Here, it is not disputed that plaintiffs do not allege a personal physical injury. Thus, we conclude that because

plaintiffs cannot satisfy the definition of harm to state a product liability claim under the PLA, plaintiffs' claim for medical monitoring damages must fail. See Myrlak v. Port Auth. of N.Y. and N.J., 157 N.J. 84, 97 (1999) (noting that elements of prima facie product liability case are proof product was defective, defect existed when product left manufacturer's control, defect proximately caused injuries to plaintiff, and plaintiff was reasonably foreseeable or intended user). Plaintiffs' effort to expand the definition of harm to include medical monitoring is best directed to the Legislature.

IV.

Plaintiffs also seek to avoid the requirements of the PLA by asserting their claims as CFA claims. However, the Legislature expressly provided in the PLA that claims for "harm caused by a product" are governed by the PLA "irrespective of the theory underlying the claim." N.J.S.A. 2A:58C-1b(3). We explained in Lead Paint, supra, that "[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action in relating to harms caused by consumer and other products." 191 N.J. at 436-37. As a result, we declared that "[i]n light of the clear intention of our Legislature to include all [product liability] claims within the scope of the PLA, we find no ground on which to conclude that the claims being raised by plaintiffs, regarding an ordinary household product used by

consumers, were excluded from the scope of" the PLA. Id. at 437. We reach that same conclusion here.

The language of the PLA represents a clear legislative intent that, despite the broad reach we give to the CFA, the PLA is paramount when the underlying claim is one for harm caused by a product. The heart of plaintiffs' case is the potential for harm caused by Merck's drug. It is obviously a product liability claim. Plaintiffs' CFA claim does not fall within an exception to the PLA, but rather clearly falls within its scope. Consequently, plaintiffs may not maintain a CFA claim.

V.

We reverse the judgment of the Appellate Division and remand to reinstate the judgment of the Law Division dismissing plaintiffs' complaint.

CHIEF JUSTICE RABNER and JUSTICES LaVECCHIA, RIVERA-SOTO, and HOENS join in JUSTICE WALLACE's opinion. JUSTICE LONG filed a separate dissenting opinion. JUSTICE ALBIN did not participate.

SUPREME COURT OF NEW JERSEY
A-117 September Term 2006

PHYLLIS SINCLAIR, JOSEPH MURRAY and ROBBIE L. TRAYLOR, Individually and for all others similarly situated,

Plaintiffs-Respondents,

v.

MERCK & CO., INC.,

Defendant-Appellant,

and

JANE DOES DISTRIBUTORS (1-50), JILL DOES MANUFACTURERS (1-50), JACK DOES PHARMACEUTICAL ADVERTISERS (1-50), JAKE DOES SELLERS (1-50), JOHN DOES MARKETING PARTNERS (1-50) and JOAN DOES PROMOTERS (1-50),

Defendants.

JUSTICE LONG, dissenting

The plaintiffs in this class action contend that they ingested a substantial amount of Vioxx, a toxic product; that as a result, their risk of undetected myocardial infarction (UMI) is statistically significant; that according to their experts, some members of the class have already suffered a UMI; and that there are medical procedures to detect the existence of the condition. Accordingly, they seek medical surveillance damages from the drug manufacturers, distributors, and advertisers who placed Vioxx in the stream of commerce and urged them to consume it.

The trial judge dismissed plaintiffs' complaint for failure to state a claim upon which relief can be granted. R. 4:6-2(e). The majority has concluded that the dismissal was proper because plaintiffs do not allege a "manifest injury" and therefore fall outside the definition of harm in the Products Liability Act (PLA), N.J.S.A. 2A:58C-1 to -11.

I cannot accept that conclusion for two distinct reasons. If the majority is correct that plaintiffs did not suffer "harm" under the PLA, then they are excluded from the Act and are entitled to pursue their remedies at common law. If the majority is incorrect in its analysis of what constitutes harm under the PLA, as I believe it is, the action can proceed. Either way the dismissal cannot stand.

I

The PLA was enacted in 1987 to create a unified statutorily defined theory of recovery for harm caused by a product. See Senate Judiciary Committee, Statement to Senate Committee Substitute for Senate Bill No. 2805 (Mar. 23, 1987). In general, the PLA adopted the strict liability standards established in Suter v. San Angelo Foundry and Machine Co., 81 N.J. 150 (1979), but left unchanged the theories under which a manufacturer or seller may be held strictly liable. William A. Dreier et al., New Jersey Products Liability & Toxic Torts Law, § 1:2-2 (2008). The Act accomplished only a few very specific reforms related to the availability of punitive damages and to the defenses accessible to a manufacturer or seller in a

products liability action. See, e.g., N.J.S.A. 2A:58C-5c (limiting recovery of punitive damages in cases involving defective drugs, devices, or foods); N.J.S.A. 2A:58C-3a(1) (adopting "state of the art" as complete defense in design defect claims). See also William A. Dreier, Analysis: 1987 Products Liability Act, 41 Rutgers L. Rev. 1279, 1293, 1296 (1989) (noting, among other things, major consequences of PLA involve punitive damages and manufacturers' defenses).

By its very terms, the PLA was "not intended to codify all issues relating to product liability, but only to deal with matters that require clarification." N.J.S.A. 2A:58C-1a. "Both [N.J.S.A. 2A:58C-1a] and the legislative committee statements accompanying the statute make clear that it is not intended to supersede any prior statutory or common law not inconsistent with the Act's provisions, nor is it intended to codify all issues relating to product liability." Dreier, supra, § 1:2-2. Only "conflicting common law principles" are superseded by the Act. Hinojo v. N.J. Mfrs. Ins. Co., 353 N.J. Super. 261, 270 n.2 (App. Div.), certif. denied, 175 N.J. 76 (2002).

> The aspects of the [PLA] that are inconsistent with the common law, and therefore supersede that law, concern defenses as well as standards and procedures for the award of punitive damages. . . . [T]he substance of product liability law as developed prior to the enactment of the statute is largely unchanged. See Dewey v. R.J. Reynolds Tobacco Co., 121 N.J. 69, 94 (1990); Jurado v. Western Gear Works, 131 N.J. 375, 384 (1993); Fabian v. Minster Mach. Co., Inc. 258 N.J. Super. 261, 271 (App. Div. 1992), certif. den[ied,] 130 N.J.

598 (1992). Therefore prior law may be consulted for guidance on most issues.

[Dreier, supra, § 1:2-2 (emphasis added).]

Importantly, the scope of the Act is limited by exclusions from coverage. See In re Lead Paint Litig., 191 N.J. 405, 437 (2007) (noting PLA "excludes claims seeking coverage for harm where the cause of the harm is exposure to toxic chemicals or substances" (citation and quotation marks omitted)).[1] As a general matter, where a case falls within an exclusion, the result is not that a plaintiff is without a remedy "but rather that the action is governed by the common law rather than the statute." Dreier, supra, at § 1:2-2. See also Macrie v. SDS Biotech Corp., 267 N.J. Super. 34, 39 n.1 (App. Div. 1993) (environmental tort claim excluded from Act but plaintiffs not foreclosed from common law failure-to-warn claim).

Some exclusions are "accomplished by the combined definitions of 'product liability action' and 'harm.'" Dreier, supra, at § 1:2-2. The point is that if the majority is correct in declaring that plaintiffs are excluded from recovery because they have not suffered "harm" under the PLA, they fall outside the PLA, which defines a "product liability action" as "any claim or action brought by a claimant for harm caused by a product." N.J.S.A. 2A:58C-1b(3). Thus, plaintiffs are entitled to continue with this action under the common law theories that

[1] This case is entirely distinct from Lead Paint, supra, 191 N.J. at 437, because there the Court denied the plaintiffs the right to sue under a public nuisance theory because the harm they alleged was cognizable under the PLA.

were also pleaded in the complaint. Accordingly, dismissal was unwarranted.

II

The dismissal was wrong on other grounds as well, in particular because the Court erred in concluding that plaintiffs failed to vault the harm threshold in the PLA.

A.

The term "harm" is defined in the PLA as follows:

> (a) physical damage to property, other than to the product itself; (b) personal physical illness, injury or death; (c) pain and suffering, mental anguish or emotional harm; and (d) any loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.
>
> [N.J.S.A. 2A:58C-1b(2).]

As its language underscores, the statutory definition is an expansive one, including every conceivable variation on the theme of harm. It encompasses property damage, illness, injury, death, pain, suffering, mental anguish, and emotional harm. N.J.S.A. 2A:58C-1b(2)(a) to –1b(2)(c). In addition, it includes loss of consortium or any other loss derived from the prior categories. N.J.S.A. 2A:58C-1b(2)(d).

It seems clear that, in codifying the term "harm" in the PLA, the Legislature incorporated all of the various conceptions of harm already recognized in the common law. Certainly, prior to the enactment of the PLA, our tort jurisprudence had established recovery for harms spanning from property damage to

severe emotional distress. See, e.g., Ayers v. Twp. of Jackson, 106 N.J. 557, 606-07 (1987) (accepting enhanced risk of disease due to toxic exposure requiring medical monitoring as cognizable harm); Portee v. Jaffee, 84 N.J. 88, 97-98 (1980) (permitting derivative action for severe emotional distress for individual who observed injury to family member); Heavner v. Uniroyal, Inc., 63 N.J. 130, 133 (1973) (finding personal injury resulting from defective truck tire compensable damages); Rosenau v. City of New Brunswick, 51 N.J. 130, 134 (1968) (recognizing property damage as compensable harm); Falzone v. Busch, 45 N.J. 559, 569 (1965) (holding psychological or mental injuries significant enough to cause sickness compensable harm).

Despite the statute's wingspan, the majority interprets it in a way that carves out these plaintiffs from recovering otherwise viable medical monitoring damages because they have not suffered a "manifest injury." That is what divides me from my colleagues.

Under the common law, there was no such manifestation requirement for medical monitoring. Indeed, in Ayers, supra, 106 N.J. at 557, Mauro v. Raymark Industries, Inc., 116 N.J. 126 (1989), and Theer v. Phillip Carey, Co., 133 N.J. 610 (1993), we declared that where a plaintiff's risk of injury is increased due to exposure to a toxic substance, medical surveillance damages could be awarded in the absence of a claim for present physical harm. In particular, in Ayers, we recognized that the need for pre-symptom medical surveillance, as a result of the

increased risk of injury due to toxic exposure, is a compensable element of damages where a plaintiff establishes

> through reliable expert testimony predicated upon the significance and extent of exposure to chemicals, the toxicity of the chemicals, the seriousness of the diseases for which individuals are at risk, the relative increase in the chance of onset of disease in those exposed, and the value of early diagnosis, that such surveillance to monitor the effect of exposure to toxic chemicals is reasonable and necessary.
>
> [106 N.J. at 606.]

Although the harm suffered by a plaintiff exposed to a toxic product and seeking monitoring is not capable of a straight-forward categorization as either purely physical or purely economic, that did not prevent this Court from declaring it generally cognizable in Ayers.[2] Dreier, supra, § 7:1-2 ("While damages awarded to cover these costs are not exactly compensation for a physical injury they are closer conceptually to that than to compensation for economic loss.").

Ayers, Mauro, and Theer were toxic tort cases, but that factor, in itself is not a distinguishing metric. As Judge Payne underscored below,

> [t]he legal differences between the environmental tort actions asserted in that case are insufficiently distinguishable from the products liability claims asserted in Mauro to provide a foundation for the argument that the existence of an illness or condition, alone, should dictate the viability of a medical monitoring cause of

[2] In Ayers, plaintiffs also had to satisfy the stringent standard of the Tort Claims Act, N.J.S.A. 59:1-1 to 12-3, because a public entity defendant was involved.

> action when presented in a products liability context.
>
> [Sinclair v. Merck & Co., Inc., 389 N.J. Super. 493, 507 (App. Div. 2007).]

In my view, the PLA contains no language that directly or inferentially signals a retreat from the common law notion that increased risk of injury that creates a need for medical surveillance is a cognizable harm.[3] Indeed, directly in the face of Ayers, of which it was presumptively aware, Yanow v. Seven Oaks Park, Inc., 11 N.J. 341, 350 (1953), the Legislature enacted an all-encompassing definition of harm that mirrored common law principles. That definition is devoid of any suggestion that it was intended to clip Ayers's wings.

Had the Legislature actually determined to limit what had been declared in Ayers, it could easily have done so. For instance, the insertion of the word "present" or "manifest" or some similar term in describing physical harm would have unequivocally signaled the Legislature's desire to reject Ayers, in favor of a requirement of present or manifest physical symptoms. Without such limiting words, and without any evidence of the Legislature's contrary intent, its silence regarding the holding in Ayers speaks volumes.

[3] The present definition of harm in the PLA is exactly the same as the definition in the original bill introduced in 1986. In 1987, while the bill was pending, Ayers was decided with a splash of publicity. See Kathleen Bird, Limit Lump Sum Payments In Toxic Tort Awards, Court Says, 119 N.J.L.J. 837, 837 (May 14, 1987) (noting in front-page article nature and importance of Court's holding in Ayers that made medical monitoring damages available to "families who made no claims seeking recovery for specific 'illnesses'").

In short, I continue to read the word "harm" in subsection (b) of the Act as wholly consistent with the common law, in which we recognized that a plaintiff who is exposed to a toxic substance and needs medical surveillance qualifies for that remedy even in the absence of present symptoms. Ayers, supra, 106 N.J. at 606-07.

III

Because it is clear to me that dismissal under Rule 4:6-2 was unwarranted, I would affirm the judgment of the Appellate Division and reinstate plaintiffs' complaint for medical surveillance damages.

SUPREME COURT OF NEW JERSEY

NO. A-117 SEPTEMBER TERM 2006

ON CERTIFICATION TO Appellate Division, Superior Court

PHYLLIS SINCLAIR, JOSEPH MURRAY and ROBBIE L. TRAYLOR, Individually and for all others Similarly situated,

Plaintiffs-Respondents,

v.

MERCK & Co., Inc.,

Defendant-Appelant.

DECIDED June 4, 2008

Chief Justice Rabner PRESIDING

OPINION BY Justice Wallace

CONCURRING/DISSENTING OPINIONS BY

DISSENTING OPINION BY Justice Long

CHECKLIST	REVERSE/ REMAND/ REINSTATE	AFFIRM
CHIEF JUSTICE RABNER	X	
JUSTICE LONG		X
JUSTICE LaVECCHIA	X	
JUSTICE ALBIN	----------	----------
JUSTICE WALLACE	X	
JUSTICE RIVERA-SOTO	X	
JUSTICE HOENS	X	
TOTALS	5	1