



NEW JERSEY SUPREME COURT SOUNDS THE DEATH KNEEL FOR CONSUMER FRAUD CLAIMS IN PERSONAL INJURY PRODUCT CASES AND SEVERELY LIMITS MEDICAL MONITORING DAMAGES; APPELLATE DIVISION FOLLOWS SUIT, LIMITING AVAILABILITY OF PUNITIVE DAMAGES

In a huge win for manufacturers of pharmaceuticals, medical devices, and other consumer products, the New Jersey Supreme Court held on June 4, 2008, in Phyllis Sinclair v. Merck & Co., Inc.,¹ that: 1) personal injury Consumer Fraud Act (“CFA”) claims are entirely subsumed by the New Jersey Products Liability Act (“PLA”); and 2) plaintiffs who do not allege a present physical injury may not sue for medical monitoring.

These significant rulings come hard on the heels of another pro-manufacturer decision from the New Jersey Appellate Division. The Appellate Division’s consolidated opinion was handed down on May 29, 2008, in two Vioxx cases: John McDarby v. Merck & Co. Inc.; and Thomas Cona v Merck & Co. Inc.² The court found that the PLA does not permit punitive damage awards in cases involving drugs approved by the Food and Drug Administration (“FDA”). It, too, determined that CFA claims are subsumed within the PLA.³

These far-reaching rulings were major courtroom wins for Merck⁴ and a significant blow to plaintiffs’ attorneys because the Appellate Division threw out a \$9 million punitive damages award based on the United States Supreme Court’s decision in Buckman Co. v. Plaintiffs’ Legal Comm.⁵ and several million dollars in attorneys’ fees and costs⁶ awarded pursuant to the CFA.

¹ A-117-06, slip op. (N.J. Sup. Ct. June 4, 2008).

² A-0076-07T1, A-0077-07T1, slip op. (N.J. App. Div. May 29, 2008).

³ In another holding, the court also discussed and rejected the conclusion that the 2006 Preamble to a final rule governing “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products” 71 Fed. Reg. 3922, 3933-36 (Jan. 24, 2006) promulgated under the FFDCA preempts state-law tort remedies under theories of express conflict or implied preemption in a duty-to-warn context. A-0076-07T1, A-0077-07T1, slip op. at 53-60.

⁴ Merck pulled Vioxx from the market in 2004 after a study showed the drug was associated with an increased risk of heart attacks and strokes. In a nationwide settlement, Merck agreed to pay \$4.85 billion to settle thousands of claims by consumers of Vioxx who blamed their heart attacks and strokes on their use of Vioxx. The cases above were specifically exempted from the settlement.

⁵ 531 U.S. 341 (2001). In Buckman, the plaintiffs claimed injuries resulting from the use of an orthopedic bone screw designed for spinal surgery that was approved under an abbreviated form of review commonly known as the “510(k) process.” The 510(k) application filed by the manufacturer sought pre-market approval for use in arm and leg bones, not the spine. The plaintiffs sought damages under a “fraud-on-the-FDA” theory claiming that the FDA would not have approved the screws had the manufacturer not made fraudulent representations to the FDA regarding their intended use. The Supreme Court held that plaintiffs’ claims were impliedly preempted by federal statute because “[p]olicing fraud against federal agencies is hardly ‘a field which the States have traditionally occupied.’” Buckman, 531 U.S. at 347 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)).

⁶ In McDarby and Cona the trial court awarded \$2.3 million in attorneys’ fees, and \$178,000.00 in costs.

Consumer Fraud Act Personal Injury Claims are Subsumed Within the Products Liability Act

In Sinclair,⁷ the Supreme Court held that plaintiffs' CFA personal injury claims were entirely subsumed by the PLA and rejected plaintiffs' effort to avoid the requirements of the PLA by casting their claims as violations of the CFA. The Court noted that the New Jersey 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. "[T]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products."⁸ This is a major defeat for the plaintiff's bar because it eliminates the possibility of treble damages and the recovery of attorneys' fees and costs.

In McDarby,⁹ the Appellate Division also considered this issue and, in a unanimous decision, overturned the trial court's finding that Merck violated the CFA, holding that plaintiffs' CFA claims are subsumed by the PLA. The Appellate Division found that plaintiffs' claim that Merck intentionally suppressed safety information while marketing Vioxx was in essence a failure to warn claim, which is cognizable under the PLA. It went on to affirm that by enacting the PLA "the New Jersey Legislature manifested its intent to replace all existing claims by 'one unified, statutorily defined theory of recovery for harm caused by a product.'"¹⁰ To recognize a cause of action for the fraudulent withholding of safety information under the CFA "would be to permit an award of attorneys' fees in the majority of product liability actions without Legislative authorization for such relief."¹¹ The Appellate Division concluded "we find no basis, in legislative history, statutory language or Court decisions, to conclude that plaintiffs can maintain separate causes of action under the PLA and the CFA in this case."¹²

Plaintiffs Who Do Not Allege a "Manifest Injury" May Not Sue For Medical Monitoring

The Supreme Court in Sinclair held that with regard to medical monitoring the PLA provides a remedy for only "physical" harm due to a product. Claims brought by those who had not sought to recover damages for physical injuries, but alleged that, as a result of the direct consumption of Vioxx, they were at an enhanced risk of serious undiagnosed and unrecognized myocardial infarction ("silent heart attack") did not satisfy the definition of harm under the PLA and, therefore, the remedy of medical monitoring was not available to them.¹³ In her dissent, Justice Virginia Long argued that, if plaintiffs' medical monitoring claims were not cognizable under the PLA, then they must be cognizable under the common law and, therefore, plaintiffs' case should not have been dismissed.¹⁴ The majority did not agree.

⁷ A-117-06, slip op. (N.J. Sup. Ct. June 4, 2008).

⁸ Id. at 18. (citation omitted).

⁹ A-0076-07T1, A-0077-07T1, slip op. (N.J. App. Div. May 29, 2008).

¹⁰ Id. at 121 (quoting In re Lead Paint Litig., 191 N.J. 405 (2007)).

¹¹ Id. at 125.

¹² Id.

¹³ A-117-06, slip op. at 4-5, 12-17.

¹⁴ Id. at 5-9.

Punitive Damages Claims Pursuant to the “Fraud-on-the-FDA” Exception to the PLA are Now Preempted Under Buckman

In its unanimous decision, the Appellate Division overturned the trial court’s finding that the jury could consider whether Merck’s actions constituted “fraud-on-the-FDA.” It held that the provision of the PLA barring punitive damages except where “the product manufacturer knowingly withheld or misrepresented information required to be submitted to the [FDA], which information was relevant and material to the harm in question”¹⁵ was preempted by the Federal Food, Drug and Cosmetic Act¹⁶ because plaintiff would have to prove that the manufacturer fraudulently misled the FDA. Plaintiff’s claims of regulatory fraud “closely resembled” the regulatory fraud claim in Buckman – that is, if the manufacturer had disclosed certain safety information to the FDA during the pre-market approval process, the FDA would not have approved the product or required a warning – McDarby’s claim conflicted with, and is therefore impliedly preempted by federal statute.

Conclusion

The New Jersey Appellate Division’s holding that the provision of the PLA barring punitive damages except where there is a claim of “fraud-on-the-FDA” is a critical win for pharmaceutical manufacturers because it eliminates punitive damage awards for FDA-approved products and the single greatest financial incentive for plaintiffs’ attorney to bring suits based on an alleged withholding of risk information from the FDA. The decision of the New Jersey Supreme Court that the CFA is subsumed within the PLA in all product liability related actions is a landmark holding for all consumer product manufacturers – including manufacturers of medical devices – because it eliminates once-and-for-all the tactic of plaintiffs’ attorneys claiming fraud-on-the-consumer in an effort to recover treble damages for economic losses and, more importantly, attorneys’ fees and costs. Personal injury plaintiffs’ attorneys will now be limited to the remedies provided in the PLA.

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¹⁵ N.J.S.A. 2A:58C-5c.

¹⁶ See 21 U.S.C. § 360c, *et seq.*

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