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# Obstacles to Certification of Medical Monitoring Class Actions

## The parameters and impediments of class certification

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On June 4, the New Jersey Supreme Court, in *Sinclair v. Merck & Co., Inc.*, expounded upon its trilogy of medical monitoring decisions (*Ayers v. 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)) and again clarified the parameters of the limited medical monitoring remedy under New Jersey law. The Court held that in a products liability case, a plaintiff may not recover the costs of medical monitoring in the absence of a manifest personal injury. The personal physical injury requirement heightens the already substantial obstacles to obtaining class certification of medical monitoring claims.

In *Sinclair*, plaintiffs claimed no personal injury, yet sought medical monitoring for the alleged enhanced risk of future injury as a result of their use or exposure to the recalled drug Vioxx. Plaintiffs asserted that the costs of diagnostic testing to determine whether they had suffered an unrecognized or latent injury as a result of direct exposure to Vioxx represented an ascertainable economic loss. The trial court granted defendant's motion to dismiss, finding, among other things, that the existence of a manifest injury was a necessary prerequisite to the relief sought under various legal theories. The Appellate Division reversed.

The Supreme Court in *Sinclair* framed the "essential question" as "whether plaintiffs' effort to recover medical monitoring damages is limited by the definition of 'harm' in the [Product Liability Act]" ("PLA"). The Court concluded that the "injury" portion of the definition of harm (i.e., "personal physical illness, injury or death") requires "personal physical injury," and not merely an economic injury. Therefore, as plaintiffs were unable to satisfy the definition of harm under the PLA, plaintiffs claims for medical monitoring failed.

Perhaps more significantly, *Sinclair,* like the Appellate Division's decision a few days earlier in *McDarby v. Merck & Co.*, 2008 WL 2199871, rejected the notion that separate causes of action under the PLA and the Consumer Fraud Act ("CFA") could be pursued for harm caused by a product. Specifically, *Sinclair* held that a plaintiff cannot circumvent the requirements of the PLA by pleading their medical monitoring claims under the CFA. Quoting from its recent decision in *In re Lead Paint*, 191 N.J. 405, 436-37 (2007), the Court again explained that "[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." Thus, *Sinclair* concluded, "[t]he language of the PLA represents a clear legislative intent that, despite the broad reach we give the CFA, the PLA is paramount when the underlying claim is one for harm caused by a product." Since the "heart of plaintiffs' case" was the "potential for harm caused by [defendant's product]," it was "obviously a product liability claim" and subject to the PLA's harm requirement.

The Supreme Court's highly anticipated decision in *Sinclair* has effectively closed the potential floodgates of so-called "economic loss only" no-injury medical monitoring claims feared by the pharmaceutical industry in New Jersey. Far from breaking new ground, though, *Sinclair* is largely consistent with the growing trend among courts requiring a present, manifest injury to state a viable medical monitoring claim. *See e.g., Paz v. Brush Engineered Materials, Inc.*, 949 So.2d 1 (Miss. 2007); *Lowe v. Philip*

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*Morris USA Inc.* (Ore. May 1, 2008).

While *Sinclair* may limit the types of medical monitoring claims in this state, medical monitoring in this and other jurisdictions will remain a remedy that is largely inappropriate in a class action setting. Indeed, recent decisions from federal courts demonstrate a clear trend denying class certification of medical monitoring claims in product-related actions.

As a preliminary matter, in multistate class actions, choice of law considerations create a significant obstacle for class certification because states' laws vary greatly on the availability of and requirements for a medical monitoring claim. *See, e.g., Foster v. St. Jude Medical, Inc.*, 229 F.R.D. 599 (D.Minn. 2005). More importantly, though, regardless of the theory of liability, courts are now routinely denying certification of medical monitoring class actions because such claims present predominantly individualized issues. These issues include inquiries assessing the proofs and defenses of the underlying causes of action, particularly with respect to causation, and whether medical monitoring is a reasonable or necessary remedy, both of which require consideration of member-specific characteristics and circumstances.

In a recent case with implications far beyond medical monitoring claims, the Eighth Circuit Court of Appeals in *In re St. Jude Medical, Inc.*, reversed the certification of a consumer fraud class which sought both damages and medical monitoring. 2008 U.S. App. (8th Cir. Apr. 9, 2008) (No. 06-3860). After the Eighth Circuit had initially reversed certification of a medical monitoring class of asymptomatic recipients of a silicone prosthetic heart valve because of a "myriad of individual issues," the district court on remand certified a consumer protection class.

On appeal, the Eighth Circuit again reversed, concluding that the proofs necessary to establish the consumer fraud claim — whether each class member or their physician received a representation from defendant and whether the representation caused the alleged damages — would be dominated by individual issues of causation and reliance. The *St. Jude* Court rejected plaintiffs' argument that individual issues would not predominate because the Minnesota consumer protection statutes (like the N.J. CFA) did not require proof of individual reliance. Instead, the court held that a consumer fraud claim requires proof of a causal nexus between the alleged unlawful conduct and plaintiffs' damages, and this causation requirement included a reliance component. That is, where plaintiffs allege that their damages were caused by deceptive, misleading, or fraudulent statements or conduct in violation of consumer protection laws, it is not possible that the damages could be caused *by* a violation without some reliance on the statements or conduct at issue. Equally important, defendants have the right to present evidence negating plaintiffs' direct and circumstantial showing of causation and reliance, which again would involve individualized inquiries. Thus, even before reaching the highly individualized medical monitoring issues, the court reversed class certification because individual inquiries would be necessary to establish liability on the consumer protection claims.

Individual inquiries relating to specific causation also defeated class certification in *In re Fosamax Prods. Liab. Litig.*, where plaintiffs sought three statewide medical monitoring class actions for individuals who had used the drug Fosamax, which allegedly caused a condition known as osteonecrosis. 2008 U.S. Dist. (S.D.N.Y. Jan. 3, 2008) (No. 06-1789). The court rejected class certification because, among other reasons, questions relating to proximate causation — including the dosage taken, how long members took the drug, how much time had elapsed since members ceased use of the drug, and the reason the members took the drug — presented insurmountable obstacles to certification. Indeed, the *Fosamax* court noted that "the inherently individualized nature of the proximate cause inquiry is a major reason why class certification has been denied in nearly every pharmaceutical products liability medical monitoring case to date."

Similarly, in *In re Aredia & Zometa Prods. Liab. Litig.*, the court denied class certification of a medical monitoring claim brought by individuals who were treated with the drugs Aredia and Zometa because (1) plaintiffs' strict liability and negligence claims required proof of intentional conduct with respect to each class member and causation depended upon member-specific factors, including the dosage, the duration of the treatment, the members' age and other characteristics, and the member's medical history, and (2) plaintiffs' failure to warn claims involved individual inquiries relating to what, if any, warnings were provided to members and whether a member's treatment would have been different had warnings been provided. 2007 U.S. Dist. (M.D. Tenn. Oct. 10, 2007) (No. 3:06-MD-1760). The court also noted that certain affirmative defenses, such as comparative negligence, statute of limitations and the "learned intermediary doctrine," would have to be evaluated in terms of availability and applicability on a case-by-case basis.

In addition to individual questions regarding causation, the medical monitoring remedy itself presents member-specific inquiries that strongly militate against class certification. In *St. Jude Medical*, for example, the Eighth Circuit, quoting from its earlier opinion in the case, stated that whether each member needed additional medical monitoring, and, if so, the type of medical monitoring needed, was "an individualized inquiry depending on that patient's medical history, the condition of the patient's heart valves at the time of implantation, the patient's risk factors for heart valve complications, the patient's general health, the patient's personal choice, and other factors."

Similarly, in *Fosamax*, the court found that individual questions surrounding the propriety of the medical monitoring sought precluded class certification, stating that it was "not satisfied that the need for the proposed monitoring program could be proven on a class-wide basis" because the susceptibility to osteonecrosis depended on the member's individual medical history and the circumstances surrounding his or her use of Fosamax. *See also Perez v. Metabolife Int'l, Inc.*, 218 F.R.D. 262 (S.D. Fla. 2003) (denying certification of medical monitoring

class action for users of Metabolife where "individual differences in risk factors, medical histories, and history of usage of Metabolife . . . will likely affect the level of medical monitoring, if any, that is appropriate for each specific individual," and "[t]herefore, medical monitoring and preventative care would have to be custom-tailored to each individual in order to account for these vast differences in usage and risk of injury.").

The New Jersey Supreme Court's decision in *Sinclair* will undoubtedly be closely analyzed for its impact on the ability to plead a claim for medical monitoring under the PLA. However, while precluding the ability of plaintiffs to seek medical monitoring in no-injury product liability actions, *Sinclair* will likely do nothing to reverse the trend in the federal courts against class certification of medical monitoring claims. Indeed, the array of individual issues presented in product-related class actions requesting this remedy, particularly with respect to causation and the need for, type of, and reasonableness of the subject medical monitoring, are simply too numerous and require far too many class-member specific inquiries to permit class certification. That a plaintiff will have to plead a personal physical injury to state a claim will only multiply the individual issues in most cases. ■