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A legal update from Dechert's Mass Torts and Product Liability Group

"Signature Disease" Status Doesn't Change the Analysis for Certifying Medical Monitoring Claims in a Prescription Drug Case

The federal court charged with overseeing the Fosamax multi-district products liability litigation recently declined plaintiffs' request to certify three state-specific classes seeking recovery for medical monitoring. The putative representative claimants had failed to satisfy the requirements for class certification under Rule 23, according to Judge John F. Keenan of the United States District Court for the Southern District of New York, because the proposed class definitions were irreparably overbroad and because too many individual questions of fact particular to each class member's claim rendered class treatment an inappropriate method of adjudication. *In re Fosamax Prods. Liab. Litig.*, No. 06-1789, 2008 WL 58890 (S.D.N.Y. Jan. 3, 2008). Each class sought a dental monitoring program of indefinite duration for anyone in the state "who took even a single tablet of Fosamax at any time." *Id.* at *7.

Judge Keenan's decision to deny certification may have come as little surprise to many: federal and state courts have repeatedly rebuffed similar efforts by the plaintiffs' bar in recent years to seek class treatment of medical monitoring claims in the context of pharmaceutical and over-the-counter drug litigation.[1]

However, this latest attempt to pursue monitoring claims on a class-wide basis has garnered heightened attention from legal and industry professionals alike because the injury at issue—osteonecrosis of the jaw ("ONJ")—was what is known as a "signature" injury. Since early 2006, when the first Fosamax lawsuits were filed, plaintiffs attorneys touted the osteoporosis drug's association with ONJ as providing the ideal setting for an award of medical monitoring relief. The Fosamax litigation, it was suggested, would offer renewed hope for the viability of medical monitoring class actions in prescription drug cases where a signature injury was involved.

Background

ONJ is a painful and debilitating condition in which the bones of the jaw progressively decay, eventually leading to an exposed area of the oral cavity that does not heal properly. It is also an exceptionally rare disease whose possible causes are varied and not clearly understood. Within the last decade, scientists have determined that the more potent form of bisphosphonate drug that is administered intravenously

[1] *See, e.g.*, *In re Aredia & Zometa Prods. Liab. Litig.*, No. 06-MD-1760, 2007 WL 3012972 (M.D. Tenn. Oct. 10, 2007); *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450 (E.D. La. 2006); *Wyeth, Inc., v. Gottlieb*, 930 So.2d 635 (Fla. App. 3d Dist. 2006); *In re Prempro Prods. Liab. Litig.*, 230 F.R.D. 555 (E.D. Ark. 2005); *Foster v. St. Jude Medical, Inc.*, 229 F.R.D. 599, 604-05 (D. Minn. 2005); *Albertson v. Wyeth*, 2005 WL 3782970 (Pa. Com. Pl. May 3, 2005); *Zehel-Miller v. Astrazeneca Pharms.*, LP, 223 F.R.D. 659, 663 (M.D. Fla. 2004); *In re Baycol Prods. Litig.*, 218 F.R.D. 197 (D. Minn. 2003); *Perez v. Metabolite Int'l, Inc.*, 218 F.R.D. 262 (S.D. Fla. 2003); *In re Paxil*, 212 F.R.D. 539 (C.D. Cal. 2003); *Harris v. Purdue Pharma, L.P.*, 218 F.R.D. 590, 597 (S.D. Ohio 2003); *In re Rezulin Prods. Liab. Litig.*, 210 F.R.D. 61 (S.D.N.Y. 2002); *In re Propulsid Prods. Liab. Litig.*, 208 F.R.D. 133, 147 (E.D. La. 2002).

to cancer patients may be causally linked to ONJ. However, there is no scientific consensus on whether a similar link exists between ONJ and oral bisphosphonate drugs, such as Fosamax, and none of the clinical trials investigating oral versions of these drugs has shown a causal association with the development of ONJ.

Moreover, oral bisphosphonates are widely prescribed for the prevention and treatment of osteoporosis—a condition that afflicts nearly 8 million post-menopausal women in the U.S. and is estimated to be the primary contributing factor for half of all hip, wrist, and spine fractures in women over age 50 each year. Millions of women have taken Fosamax alone for osteoporosis since the drug was approved by the FDA in 1995, and yet, as both sides' experts acknowledged, the incidence of ONJ reported in Fosamax users remains exceedingly small by comparison.

To support their medical monitoring claims then, plaintiffs who have not been diagnosed with ONJ, including current and former users, rely largely on anecdotal evidence suggesting an increased risk of ONJ among Fosamax patients, as well as the relative dearth of known causative agents for the disease. In contrast to earlier unsuccessful attempts at class-wide monitoring relief, where the ubiquity of the alleged injury in the population at large necessitated a searching, individualized review of each claimant's medical circumstance (for instance, breast cancer in the hormone therapy litigation and cardiovascular events in the Vioxx litigation), the Fosamax plaintiffs reasoned that the limited universe of potential alternative causes of ONJ militated strongly in favor of class relief. By this logic, the rarity of ONJ, coupled with the fact that published reports of the disease emerged with increasing frequency at roughly the same time that Fosamax came into widespread use, meant that individual causation inquiries would not present so onerous an obstacle to satisfying the "predominance" requirement of Rule 23(b)(3).

At the same time, plaintiffs' experts conceded that there is no known background rate against which to quantify any elevated risk of ONJ associated with oral bisphosphonates. They further acknowledged that the risk of developing the disease likely depends on dosage, duration, and discontinuation of Fosamax use, in addition to whether a class member's medical history also included one of the other suspected risk factors for ONJ, albeit very few, that the available science has been able to identify. Despite these variables, plaintiffs maintained that the requisite typicality and commonality existed because each class member was asymptomatic, each sought the same dental monitoring program, and each was proceeding under his or her own state's substantive law. In essence, that Fosamax allegedly placed patients at some generalized but undefined, increased risk for ONJ was sufficient, in plaintiffs' view, to warrant a class-wide monitoring program for all current and former users of the drug.

The Court's Decision

Judge Keenan was not persuaded that the "signature disease" nature of the injury alleged sets Fosamax apart from any other pharmaceutical mass tort case for purposes of Rule 23 analysis, noting, "at the outset . . . that the class action device typically is not very useful in mass tort cases, which tend to present significant questions, not only of damages but of liability and defenses of liability, affecting the individuals in different ways." *Id.* at *7 (internal citations omitted). Central to his decision to deny class certification was the recognition that "almost every element of a medical monitoring claim will require highly individualized proof of each class member's medical condition and the circumstances of their use of Fosamax," *id.* at *9, regardless of the merits of the general causation issue. Put simply, a court could not decide whether Fosamax use *significantly* increased the risk of ONJ in an individual class member without considering other factors unique to his or her own medical history. *Id.* at *10.

Further, the "typicality" requirement for class certification is not satisfied where the success of the claim, or defenses thereto, depends on "an assessment of the reasonableness of [the defendant's] actions or omissions in light of what it knew or should have known about the risk of ONJ at the particular time that each class member used Fosamax." *Id.* at *9. Here, there could be no "single collective theory of negligence" applicable to all class members because the state of the science and, in turn, the warnings provided in the product labeling, changed over time. *Id.* To illustrate the point, the court noted that one of the named representatives, who stopped taking Fosamax in 1999, would have to prove that the defendant should have known of a risk before any association between ONJ and the drug was published in the medical literature, whereas for those class members who started taking Fosamax in 2005, the negligence element centered on whether the Fosamax label adequately warned of the ONJ risk. *Id.* at *9 – *10.

Judge Keenan also found flaws with the proposed class definition to be fatal to certification. Specifically, the proposed class, which was broadly defined to include all

current and former Fosamax users, did not set limitations on duration of use or dosage. *Id.* at *7. Second, no attempt was made to screen out putative class members whose medical histories included risk factors for ONJ other than Fosamax. *Id.* Additionally, the dental monitoring recommended by plaintiffs was impractical insofar as it failed to limit the program to a specific duration. *Id.*

Notably, Judge Keenan rejected plaintiffs' invitation to adopt a "wait-and-see" approach, whereby the class definition could later be refined and restricted based on evidence presented at the merits stage of the action. *Id.* Looking to other courts' decisions denying class certification in pharmaceutical products liability cases as support, he explained that "class membership is not feasibly ascertainable where it hinges on myriad medical factors individual to each class member." *Id.* at *8.

Finally, and equally significant, Judge Keenan expressed reservation with the idea that a pharmaceutical drug which currently enjoys FDA approval could ever be proven inherently hazardous for purposes of a medical monitoring action, particularly where, as in this instance, neither the FDA nor any other medical authority has recommended monitoring procedures to mitigate the risk of developing ONJ from the ingestion of Fosamax. *Id.* at *11, *14. Certifying the proposed class here would work an "extraordinary intrusion into the FDA's regulatory mandate." *Id.* at *14.

Implications

The court's decision to deny certification ultimately turned on the "inherently individualized" proof required to state a medical monitoring claim and, in that sense, is no different than the overwhelming majority of courts to have considered and rejected class-wide status in the products liability context. It remains to be seen whether the *Fosamax* decision, as the latest in a long line of decisions denying class-wide medical monitoring, heralds the end to plaintiffs' assiduous pursuit of this theory of liability in pharmaceutical mass tort litigation. At the very least, the Fosamax defeat will force plaintiffs to rethink their strategy, for the decision makes clear that the existence of a "signature" relationship between the pharmaceutical drug and the harm alleged does not *ipso facto* permit class certification under Rule 23.

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