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Fosamax: The Hiding of a Public Hazard

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In September 1995, the U.S. Food and Drug Administration approved Merck's compound alendronate for various uses, including the treatment of osteoporosis and Paget's Disease. Alendronate is marketed by Merck as Fosamax. It is one of Merck's biggest sellers, with approximately \$3.5 billion per year in sales.

Since Fosamax was released, there have been a significant number of reports of osteonecrosis of the jaw ("ONJ") among users of Fosamax. On Aug. 25, 2004, the FDA posted its Office of Drug Safety Post-Marketing Safety Review on bisphosphonates, including those used in chemotherapy and those contained in Fosamax. This was an epidemiologic review of the FDA adverse events database conducted by the FDA's Division of Drug Risk Evaluation. As a result of the review, the FDA observed that there was a risk of ONJ that was not confined to bisphosphonates used for chemotherapy. The FDA's review indicated that the ONJ was a class effect, which specifically extended to the oral bisphosphonate, Fosamax.

Despite the FDA's review, Merck has yet to warn patients or issue a "Dear Doctor" letter to prescribing physicians. Instead, it continues to defend Fosamax by minimizing unfavorable findings through statements such as those made in *The Wall Street Journal*: "The cause of osteonecrosis is not well understood and is likely to include a number of conditions." *Wall Street Journal*, April 12, 2006, p. B1. Additionally, while the author knows of no Merck clinical study directed to the relationship of osteonecrosis of the jaw and Fosamax use, Merck implies that the fears of ONJ are unfounded by arguing "in all our controlled clinical trials, including the 10-year data with Fosamax, which have included more than 17,000 patients, we have not had reports of osteonecrosis of the jaw occurring in patients taking Fosamax." *Id.*

So the issue presents itself: Once the Fosamax litigation gets rolling, in light of these public statements, is it right to agree automatically to a confidentiality order, or should information gleaned from the files of Merck regarding the extent of the potential Fosamax public hazard be made available to the public -- patients and physicians alike?

When examining this issue, within the context of the law discussed below, courts and litigants should consider the following factors:

- 1) The peer-reviewed literature appearing in dental and oral surgery journals clearly establishes the relationship between Fosamax and ONJ. See Matthew W. Farrugia et al., "Osteo-necrosis of the Mandible or Maxilla Associated with the Use of New Generation Bisphosphonates," *Laryngo-scope* 116: 115-120, pp. 115, 117 (Jan. 2006); Cesar A. Migliorati et al., "Bisphosphonate-Associated Osteone-crosis of Mandibular and Maxillary Bone," *Cancer* 104: 83-93 (2005); Salvatore Ruggiero et al., "Osteone-crosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," *J. Oral Maxillofac. Surg.* 62: 527-534 (2004); Robert E. Marx et al., "Bisphosphonate-Induced Exposed Bone (Osteonecrosis/Osteopetrosis) of the Jaws: Risk Factors, Recognition, Prevention, and Treatment," *J. Oral Maxillofac. Surg.* 63: 1567-1575 (2005).
- 2) Most physicians who prescribe Fosamax do not read dental and oral surgery journals.
- 3) In its prescriber's information, Merck has not issued any warnings about Fosamax and the risk of ONJ.
- 4) Merck has done no "Dear Doctor" letter to prescribing physicians advising them of the risk of ONJ linked to Fosamax use.
- 5) Merck has made public statements assuring prescribing physicians that there is no risk of ONJ with Fosamax.
- 6) Merck previously has been rebuked by the FDA for misleading the public about the risks of another Merck "blockbuster" drug, Vioxx.

With respect to item 6, consider the following:

Merck completed a study called VIGOR (Vioxx Gastrointestinal Outcomes Research) relating to its prescription cox-2 inhibitor, Vioxx. The VIGOR study showed that Vioxx patients had more than double the rate of serious cardiovascular problems than those on Naproxen, an older non-steroidal anti-inflammatory drug.

In September 2001, the FDA warned Merck to stop misleading doctors about Vioxx's effect on the cardiovascular system. Merck was admonished to stop minimizing the risks of the drug in its marketing.

On Aug. 25, 2004, a representative from the FDA presented results of a database analysis of 1.4 million patients. The analysis demonstrated that Vioxx users were more likely to suffer a heart attack or sudden cardiac death than those taking Celebrex or older non-steroidal drugs. The FDA representative concluded that Vioxx was linked to more than 27,000 heart attacks or sudden cardiac deaths nationwide from the time it came on the market in 1999 through 2003.

On Aug. 26, 2004, Merck released a press statement that refuted the FDA analysis and restated Merck's support for the cardiovascular safety of Vioxx. One month later, Merck recalled Vioxx from the market, after having to halt the APPROVe study (Adenomatous Polyp Prevention on Vioxx). The researchers found an alarming number of cardiovascular events among the drug's users in the APPROVe study.

At that same time, Merck was aware that, as of Aug. 24, 2004, the FDA was advising it to distribute a warning about the risk of ONJ for its Fosamax patients. Complaints filed in *Secrest v. Merck and Co., Inc.* in the U.S. District Court for the Middle District of Florida, Ft. Myers Division and *Toelke v. Merck and Co., Inc.* in the U.S. District Court for the

Southern District of Illinois, East St. Louis Division, allege that because Merck knew that Vioxx (\$2 billion in annual sales) was about to be pulled from the market, placing more importance on the \$3 billion-plus annual sales of Fosamax, it deliberately chose to not amend its packaging of Fosamax to warn of the risk of ONJ, fearing that such a warning would result in reduced revenues for its second-largest income producer, Fosamax.

The reason it would be important to air Merck's conduct with regard to Vioxx in connection with its conduct concerning Fosamax is that a court will need to query whether Merck would be likely to comply voluntarily with the labeling provisions of Title 21, Code of Federal Regulations, and provide the necessary information about the alleged Fosamax hazards to prescribers or patients. Specifically, 21 C.F.R. §314.70(c)(6)(iii)(A) allows a manufacturer to strengthen its label warning of adverse reactions without FDA approval. Furthermore, 21 C.F.R. §201.57(e) requires a manufacturer to issue a warning whenever there is "reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." Because far more than reasonable evidence of an association between the serious hazard of ONJ and ingestion of Fosamax exists -- and given what I argue is Merck's prior reluctance to warn patients and physicians of both Vioxx and Fosamax -- the public hazards doctrine should be applied in the Fosamax case.

A PUBLIC HAZARD IS A DANGEROUS SECRET

In one Fosamax case filed in the U.S. District Court for the Middle District of Tennessee, the plaintiffs and Merck have stipulated to a protective order for all documents produced by Merck. The stipulation automatically presumes that every document produced is subject to a protective order. Such a stipulation turns on its head the notion of who bears the burden of keeping "secret" the information contained in Merck's internal files and does not serve the public interest.

In these circumstances, litigants must remind themselves that we are not a society that tolerates secrecy lightly, and that intolerance does not evaporate at the courthouse door. "Pretrial discovery must take place in public unless compelling reasons exist for denying the public access to the proceedings." *Wilk v. American Medical Ass'n*, 635 F.2d 1295, 1299 (7th Cir. 1980).

Even if a party seeking entry of a protective order satisfies its initial burden of demonstrating that there is good cause for entry of an order, such a showing does not end a court's inquiry into whether the order should issue. *Farnsworth v. Procter & Gamble Co.*, 758 F.2d 1545, 1547 (11th Cir. 1985) (district court had duty to balance interest of party seeking information against interest of party seeking to avoid disclosure of information); see also *McCarthy v. Barnett Bank of Polk County*, 876 F.2d 89, 91 (11th Cir. 1989).

This balancing of interests must take into account the interest of the public where a public hazard is involved. Consequently, even where the parties in the litigation agree to the terms of a proposed protective order, the court has a responsibility to evaluate and balance the public interest. Consider Professor Miller's statement: "When all the parties support the protective order or seal, as often is the case when the defendant seeks confidentiality and the plaintiff wants to facilitate its own access to discovery materials, the court is faced with an essentially non-adversarial situation and must assume the duty of making an independent inquiry. A useful analogue is the fiduciary burden assumed by federal judges in evaluating a proposed class action settlement under Federal Rule 23(e)." *Jepson, Inc. v. Makita Elec. Works, Ltd.*, 30 F.3d 854, 858 (7th Cir. 1994) (quoting Arthur R. Miller, "Confidentiality, Protective Orders and Public Access to the Courts," 105 Harv.L.Rev. 427, 492 n. 322 (1991)).

Rule 26 enables the court to exercise its discretion to enter a protective order upon a finding of "good cause." No longer should parties stipulate to the entry of a protective

order simply because the defendant is holding up production until such a "stipulation" is agreed to. "'Good cause' is not established merely by the prospect of negative publicity. A party seeking to file documents under seal must show both that the documents are confidential and that disclosure will result in a 'clearly defined and very serious injury.'" *Department of Econ. Dev. v. Arthur Andersen & Co.*, 924 F. Supp. 449, 487 (S.D.N.Y. 1996) (citations omitted).

The showing of good cause must be particularized, *Baker v. Liggett Group, Inc.*, 132 F.R.D. 123, 126 (D. Mass. 1990), and, accordingly, the showing of serious injury must be based on a "particular factual demonstration of potential harm, not on conclusory statements." *Anderson v. Cryovac, Inc.*, 805 F.2d 1, 7 (1st Cir. 1986). Any information as to whether the defendant's products were dangerous and whether the defendant knew of that danger and failed to take appropriate action does not warrant protection. *Culinary Foods, Inc. v. Raychem Corp.*, 151 F.R.D. 297, 300-01 (N.D. Ill. 1993).

Furthermore, embarrassment from the public disclosure of untoward conduct is not sufficient reason to prevent public disclosure of the internal documents. "Although the information regarding the hazards of products and the corporation's knowledge of the information may be embarrassing and incriminating, this alone is insufficient to be public disclosure." *Id.* at 301.

When deciding whether to stipulate voluntarily to a blanket order of protection, lawyers should keep in mind Judge Jack Weinstein's brave order requiring the public disclosure of highly embarrassing government documents showing the link to the carcinogenic exfoliant and the various forms of cancer that Vietnam veterans sustained as a result of their exposure. *In re Agent Orange Product Liab. Litig.*, 104 F.R.D. 559 (E.D.N.Y. 1985). In that order, Judge Weinstein flatly ruled out the "blanket stamp" of confidentiality desired by the defendant and properly put the burden on the defendant to show precisely why any particular document was confidential. *Id.* at 574-75. Judge Weinstein thought the need for a better understanding of the public hazard presented by Agent Orange was so important that he eventually ordered that a library of the documents be created so that members of the public could freely examine the documents on their own accord. *In re Agent Orange Product Liab. Litig.*, 689 F. Supp. 1250, 1280-81 (E.D.N.Y. 1988).

But the prevention of corporate embarrassment through the exposure of misdeeds by stipulation seems to be the rule of the day rather than the exception. Perhaps the 3rd U.S. Circuit Court of Appeals best expressed the irony about "corporate embarrassment" and public disclosure with the following quote from an order requiring disclosure of the public hazards of tobacco use: "[A]n applicant for a protective order when the chief concern is embarrassment must demonstrate that the embarrassment must be particularly serious. As embarrassment is usually thought of as a nonmonetizable harm to individuals, it may be especially difficult for a business enterprise, whose primary measure of well-being is presumably monetizable, to argue for a protective order on this ground." *Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1121 (3rd Cir. 1986).

The time has come for a review of the use of confidentiality in stipulations and the need for public disclosure of documents pertaining to public hazards. Attorneys practicing in the areas of pharmaceutical product liability, particularly when a product is still on the shelves, should challenge blanket protective orders and refuse to agree to an order endorsing such protection. Ours should not be a society of secrets for, in the case of Fosamax, secrets can cause not only theoretical and philosophical harms, but also potentially physical harm to the patients whose prescribers have not yet been informed about the true risks associated with the drug and who rely upon the absence of a warning from Merck, and assurances of the drug's safety, when prescribing the medication to their patients.

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