

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE: FOSAMAX PRODUCTS LIABILITY :
LITIGATION :
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 : MDL No. 1789
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 : 1:06-md-1789 (JFK)
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This Document Relates to :

Gwendolyn Wolfe, et al., v. Merck : MEMORANDUM OPINION &
& Co., Inc., 1:06-cv-6295 (JFK) : ORDER
 :
Greta Murphy v. Merck & Co., Inc.,
1:07-cv-1946 (JFK) :

Aline Trahan v. Merck & Co., Inc., :
1:06-cv-9456 (JFK) :
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JOHN F. KEENAN, United States District Judge:

Introduction

In this multidistrict litigation ("MDL"), more than three hundred and sixty products liability actions have been filed by individuals who claim to have taken Fosamax, a prescription drug approved for the treatment of osteoporosis and other bone disorders, against Merck & Co., Inc., the drug's manufacturer. Common to all actions is the allegation that ingesting Fosamax caused plaintiffs to either develop a medical condition known as osteonecrosis of the jaw ("ONJ") or to suffer a significantly increased risk of developing the condition in

the future. These cases have been transferred to this Court for coordinated pretrial proceedings pursuant to 28 U.S.C. § 1407.

Currently before the Court are motions filed by putative class representatives to certify three state-wide classes. The proposed classes are defined to include all current and former users of Fosamax in the states of Pennsylvania, Florida and Louisiana who have not been diagnosed with ONJ. Each class would bring a claim for medical monitoring under the respective laws of those three states. They would seek to have Merck set up and fund a program that would administer to all class members a regimen of dental procedures intended to monitor for ONJ.

In connection with the present motions, the parties have established an extensive evidentiary record.¹ The Court heard oral argument on the motions on November 30, 2007.

¹ This record consists of the expert affidavits of plaintiffs' dental experts, Robert E. Marx, D.D.S. ("Marx Aff.") and Alistair N. Goss, D.D.Sc ("Goss Aff."); plaintiffs' claims administration expert Paul Mulholland, C.P.A., C.V.A. ("Mulholland Aff."), who described how the proposed dental monitoring program would be administered; defendant's medical expert, John Bilezikian, M.D. ("Bilezikian Aff."); defendant's expert Jeri W. Nieves, PH.D., an epidemiologist who specializes in osteoporosis ("Nieves Aff."); defendant's oral and maxillofacial expert Robert S. Glickman, D.M.D. ("Glickman Aff."); and defendant's chemistry expert, Paul A. Bartlett ("Bartlett Aff."). The parties have also submitted excerpts from the deposition transcripts of several of these experts (hereinafter referred to as the deponent's surname followed by "Dep. Tr."). The evidentiary record also consists of selected interrogatory responses, excerpts from the deposition transcripts and the plaintiff profile forms ("PPF's") of the three putative class representatives, Mr. Trent Nichols, Jr., M.D., Ms. Aline Trahan, and Ms. Greta V. Murphy; an August 2004 post-marketing safety review from the FDA's Office of Drug Safety ("2004 ODS Post-

This decision on class certification is not about whether Fosamax causes or significantly increases the risk of ONJ, or whether Merck was or was not negligent in labeling Fosamax, or whether the proposed dental monitoring program is an effective way to prevent the onset of ONJ. These questions will be resolved at future stages of these proceedings. The narrow question before the Court is whether, under Federal Rule of Civil Procedure 23, a class action is a proper vehicle for litigating the state-law medical monitoring claims brought by the named plaintiffs. For the reasons discussed below, the Court finds that class-treatment of these claims is inappropriate because they present too many individual questions of fact particular to each class member's claim. Accordingly, the motions for class certification are DENIED.

I. Background

A. Fosamax

Fosamax is an oral prescription drug approved by the U.S. Food and Drug Administration ("FDA") for the treatment of

Marketing Safety Review); and an FDA report showing the number of cases in which doctors reported adverse drug experiences associated with Fosamax in 1996 ("1996 FDA ADE Report"). The parties have also brought to the Court's attention over forty articles and chapters from the oral and maxillofacial, medical and dental literature discussing ONJ and, among other things, its causes, diagnosis, treatment and relationship to oral biphosphonates such as Fosamax.

osteoporosis and other bone disorders.² Osteoporosis afflicts more than 10 million Americans over the age of fifty, eighty percent of whom are women. (DX. 22.)³ The disorder is characterized by reduced bone density and quality that diminishes bone strength and increases susceptibility to fractures. Throughout a person's life, his or her bones continuously undergo a remodeling cycle whereby older bone is resorbed (broken down) and new bone is formed to replace it. Osteoporosis results from an imbalance in this bone turnover cycle that is associated with, among other things, aging and the drop in estrogen levels in post-menopausal women. The cells responsible for resorption (osteoclasts) are overactive and/or the cells responsible for bone formation (osteoblasts) are underactive, resulting in net bone loss. A person is diagnosed with osteoporosis when his or her bone density falls a certain level below normal.

Approved by the FDA in September 1995, Fosamax seeks to restore this balance and decrease bone loss by inhibiting resorption and reducing the rate of bone turnover. The active ingredient in Fosamax is alendronate, a compound consisting of a bisphosphonate and a nitrogen-containing amino group. The

² Fosamax is also prescribed to treat Paget's disease of bone and osteopenia.

³ "DX" refers to defendant's exhibit.

parties dispute several issues with respect to the effects of nitrogen-containing bisphosphonates: whether they merely inhibit the function of osteoclasts or kill them; whether bone turnover is reduced to rates within a normal range or completely inhibited; whether or not bisphosphonate remains active over its 10-12 year half life when it is taken up into the bone, producing a cumulative effect on bone turnover; and whether or not it accumulates preferentially in the jaws, which have a relatively high turnover rate. These issues need not be addressed at this stage of the proceedings.

Fosamax is one of several oral bisphosphonates currently on the market to treat osteoporosis and other bone disorders. Since their market introduction, doctors have prescribed oral bisphosphonates over 191 million times; 77% of these prescriptions have been for alendronate (Nieves Aff. ¶ 20). The FDA has also approved intravenously-administered bisphosphonates, which are much more potent and are prescribed to treat metastatic bone disease resulting principally from myeloma and breast cancer.⁴

B. Osteonecrosis of the Jaws

Osteonecrosis of the jaws ("ONJ") is a condition

⁴ Actions filed by persons who have taken intravenous bisphosphonates and allege ONJ-related injuries have been consolidated in the Middle District of Tennessee as In re Aredia and Zometa Prods. Liab. Litig., MDL No. 1760.

characterized by an area of exposed bone in the oral cavity that does not heal or heals poorly within a normal healing time. The area often becomes infected, causing pain, swelling and purulent secretion. (PX R.)⁵ In a small percentage of cases where antibiotics and regular irrigations are not effective in preventing or treating infection, regions of necrotic bone must be surgically removed. (PX G, K.).

The cause or causes of this rare but painful, disfiguring and debilitating condition are not fully understood or agreed upon. Plaintiff's expert, Dr. Marx, states that ONJ may be caused by each of the following: osteoradionecrosis (radiation therapy to the head and neck), osteomyelitis (infection in the jaw), osteopetrosis (a genetic defect in the osteoclast cell) and trauma to the jaw. (Marx Aff. ¶ 17.) He also states that some practitioners believe that long-term steroid use and various forms of chemotherapy can cause ONJ, although he does not believe so. (Id.) Defendant's experts add to the list of risk factors for ONJ the following: cancer, HIV disease, immunosuppressed hosts, herpes infection, periodontal disease, poor oral hygiene, invasive dental procedure, anemia and coagulopathy (a defect in the blood-clotting process). (Bilezikian ¶ 31; Glickman ¶ 9; Nieves Aff. ¶ 17.)

⁵ "PX" refers to plaintiffs' exhibit.

There is no definitive treatment for ONJ. Studies have found that the treatment outcomes of surgery, antibiotics and hyperbaric oxygen therapy are poor and that, for most ONJ patients, the area of exposed bone will remain permanently. (PX R; Robert E. Marx, Oral & Intravenous Bisphosphonate-Induced Osteonecrosis of the Jaws 63 (2007)). Therefore, those at risk for the condition should seek to prevent its development by obtaining proper dental care and avoiding invasive dental procedures.

C. Bisphosphonate-associated ONJ

The first cases of ONJ associated with intravenous bisphosphonate use were reported by Dr. Marx in the medical and dental literature in the fall of 2003. ONJ associated with the use of oral bisphosphonates was first reported in the literature by another doctor in the spring of 2004. (Bilezikian ¶ 32; Glickman ¶ 10). Dr. Marx asserts that, since 2003, more than five thousand cases of ONJ have been reported in people using bisphosphonates. (Marx Aff. ¶ 24.) Invasive oral surgical procedures initiated ONJ in most of these cases, but the condition has also presented spontaneously in a small number of cases. The parties' experts agree that ONJ is much more rarely associated with oral bisphosphonates such as Fosamax than with the more potent intravenous bisphosphonates. (Bilezikian ¶ 33; Goss ¶¶ 38-39; Marx et al., Oral Bishposphonate-Induced

Osteonecrosis, J. Oral Maxillofacial Surgery 65: 2397-2410 (2007)).

In an August 2004 Post-Marketing Safety Review, the FDA found that, as of May of that year, physicians had reported 139 cases of ONJ associated with intravenous bisphosphonates and 12 associated with oral bisphosphonates to the FDA's Adverse Event Reporting System. The review concluded that the incidence of ONJ may be an event associated with all bisphosphonates, rather than limited to intravenous bisphosphonates, and recommended that the product labels of oral bisphosphonates include language reflecting this association. In January 2005, the FDA asked Merck to update Fosamax's label to include class-labeling for ONJ. After obtaining FDA approval of the language of a revised label, Merck made the new label publicly available in July 2005. On Page 13 of the revised label, under the heading "Precautions," it states in pertinent part:

Osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported in patients taking bisphosphonates. Most reported cases of bisphosphonate-associated osteonecrosis have been in cancer patients treated with intravenous bisphosphonates, but some have occurred in patients with postmenopausal osteoporosis. Known risk factors for osteonecrosis include a diagnosis of cancer, concomitant therapies (e.g., chemotherapy, radiotherapy, corticosteroids), poor oral hygiene, and comorbid disorders (e.g., pre-existing dental disease, anemia, coagulopathy, infection).

Patients who develop osteonecrosis of the jaw (ONJ) while on bisphosphonate therapy should receive care by an oral surgeon. Dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of

bisphosphonate treatment reduces the risk for ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on individual risk/assessment.

(DX 23). Six pages later, under the heading of "Adverse Reactions," the label states that "Localized osteonecrosis of the jaw, generally associated with tooth extraction and/or local infection, often with delayed healing, has been reported rarely." (Id.)

ONJ's association with oral bisphosphonates has been documented by many experts and leading oral and maxillofacial, dental, and medical associations. (PX BB, CC, EE). Estimates of the incidence of oral bisphosphonate-associated ONJ vary widely. On the high end, plaintiff's expert Dr. Goss estimates that the frequency of ONJ for patients taking oral bisphosphonates for osteoporosis is 1 in 2,260 to 8,470 (0.01 to 0.04%) (Goss Aff. ¶¶ 20, 23). He found the frequency to be substantially higher for the relatively small percentage of patients taking oral bisphosphonates to treat Paget's disease and for those patients who had dental extractions (Goss ¶¶ 20, 22, 24). On the low end, Merck's experts estimate the frequency at about 0.7-1.0 in 100,000 patient years of exposure (0.0007 to

0.001%), noting that this is only slightly higher than the risk of death by lightning strike.⁶ (Bilezikian ¶ 36.)

Not surprisingly, the parties dispute whether a causal relationship exists between oral bisphosphonates such as Fosamax and ONJ. This merits question need not be addressed in order to decide the class certification motions.

There seems to be some consensus that oral bisphosphonate-associated ONJ may depend on several factors. For example, Dr. Goss states that the frequency of the disease depends on the dosage taken, the duration of use and whether the drug was prescribed to treat osteoporosis or Paget's disease. (Goss Aff. ¶¶ 9, 36, 39). Dr. Marx also states that the degree of bone turnover suppression, which he asserts is the mechanism by which Fosamax causes ONJ, depends upon the length of time that a patient uses the drug and whether and for how long the patient discontinues its use. (Marx Aff. ¶ 39). He reports that, according to his research, the risk of ONJ is "small" and "insignificant" until a patient uses Fosamax continuously for three years. (Marx Dep. Tr. at 80.) It also appears from the expert affidavits submitted that a Fosamax user's medical history, i.e. the absence or presence of the risk factors for

⁶An American Dental Association panel concluded that "there is a very low risk (estimated at 0.7 cases per 100,000 patient-years exposure) of developing [bisphosphonate-associated ONJ]." (PX BB at 1147.)

ONJ listed above, affects his or her risk of developing the condition.

D. The Proposed Classes

1. The Class Representatives

The present motions seek certification of three state-wide classes under Federal Rule of Civil Procedure 23(b)(3).

The three putative class representatives are Dr. Trent Nichols, Jr., a resident of Pennsylvania, Ms. Greta V. Murphy, a resident of Florida, and Ms. Aline Trahan, a resident of Louisiana.

These individuals would represent all persons in their respective home states "who are taking or have taken Fosamax, and who do not have a prior diagnosis of osteonecrosis of the jaw." (Plaintiffs' Mem. at 15.)

Dr. Nichols is a licensed physician specializing in gastroenterology who used Fosamax between September 1996 and May 1999 to treat osteoporosis. He took samples provided to him by Merck pharmaceutical representatives and also received extensive information about Fosamax from these representatives. On his plaintiff profile form ("PPF"), he reports that his dentist warned him that he has "a very dense jaw due to taking Fosamax." (Nichols PPF § I.D.5.b). An orthopedic surgeon has told him that "there was a possibility of having future harm because if I get a tooth extracted it could go from [o]steopetrosis, dense jaw, to [o]steonecrosis." (Id. § I.D.7.) He does not recall the

date of either of these discussions. Nichols seeks dental monitoring for the alleged increased risk of ONJ that he has suffered as a result of taking Fosamax. He also claims that Fosamax caused him avascular necrosis of the hip, a disease resulting from insufficient blood supply to the bone, and osteonecrosis of the hip and is seeking monetary damages. Dr. Nichols has observed good dental hygiene both before and after using Fosamax, brushing twice a day, flossing once a day, and seeing a dentist for a cleaning four times a year.

Ms. Murphy was prescribed Fosamax for treatment of osteoporosis between January 2001 and August 2005. Her prescription records indicate several long gaps in her use of the drug. On her PPF, she specifies no other injury caused by Fosamax other than an increased risk of ONJ. During her deposition, she stated that she had never been told by a doctor or anyone else that she has a heightened risk of developing ONJ. She also indicated a belief that Fosamax caused the enamel to break off one of her teeth. In addition to dental monitoring, she is seeking unspecified monetary damages for medical expenses related to conditions caused by Fosamax. Like Dr. Nichols, Ms. Murphy claims that she maintains proper dental hygiene.

Ms. Trahan used Fosamax between 2001 and 2006 to treat osteopenia and osteoporosis. Like the other proposed representatives, she claims to have suffered an increased risk

of ONJ as a result of using the drug. She also alleges that the increased risk has caused her mental distress for which she seeks monetary damages. She has had no diagnosis of other bone disorders and maintains good dental hygiene.

2. The Classes' Claims

Each state-wide class would bring a claim for medical monitoring under the laws of Florida, Pennsylvania and Louisiana, respectively. Courts in each of these states have recognized a substantive cause of action for medical monitoring. Under Pennsylvania and Florida law, a plaintiff may recover for medical monitoring after proving seven elements:

- (1) exposure greater than normal background levels;
- (2) to a proven hazardous substance;
- (3) caused by the defendant's negligence;
- (4) as a proximate result of the exposure, plaintiff has a significantly increased risk of contracting a serious latent disease;
- (5) a monitoring procedure exists that makes the early detection of the disease possible;
- (6) the prescribed monitoring regime is different from that normally recommended in the absence of the exposure; and
- (7) the prescribed monitoring regime is reasonably necessary according to contemporary scientific principles.

Redland Soccer Club, Inc. v. Dept. of the Army and Dept. of Defense of the U.S., 696 A.2d 137, 145-46 (Pa. 1997); Wyeth, Inc. v. Gottlieb, 930 So. 2d 635 (Fla. App. 3 Dist. 2006).

Louisiana's highest court ruled in 1998 that a plaintiff may recover on a medical monitoring claim upon proof of essentially

the same seven elements, but the Louisiana Legislature amended the law the next year to require proof of the additional element that the medical monitoring is "directly related to a manifest physical or mental injury or disease." La Civ. Code Ann. art. 2315; Bourgeois v. A.P. Green Indus., Inc., 783 So. 2d 1251 (La. 2001).

The relief sought by all three putative classes is the creation and funding by Merck of a monitoring program that would provide a regimen of dental and medical tests and services to each class member. Specifically, each class member would receive a twice yearly dental examination that includes the taking of a comprehensive dental and medical history, a panoramic radiograph, a CTX test, which measures bone resorption, dental cleaning, a detailed examination, and a consultation report that would be shared with the class member's medical physician.

II. Applicable Law

Class certification is proper where an action satisfies the requirements of Federal Rule of Civil Procedure 23. A court must conduct a "rigorous analysis" to determine if those requirements are met, In re Initial Public Offering Securities Litig., 471 F.3d 24, 29 (2d Cir. 2006) (quoting Gen. Telephone Co. of the Southwest v. Falcon, 457 U.S. 147, 160-61

