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From the Los Angeles Times

Another Merck Drug Is Under Legal Attack

Trial lawyers may file hundreds of suits over an osteoporosis remedy linked to jaw decay.

By Molly Selvin
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July 5, 2006

As Merck & Co. defends itself against a deluge of litigation involving its pain reliever Vioxx, the pharmaceutical giant also is fielding the first of what could be another wave of lawsuits involving Fosamax, its second-biggest seller.

The emerging litigation targeting the osteoporosis drug, still in its early stages, illustrates how quickly lawyers can organize themselves and assemble prospective plaintiffs after reports of adverse drug effects — even when those problems appear to be relatively rare.

Reports in the last few years have linked Fosamax and similar drugs, known as bisphosphonates, to a serious side effect in which the jawbone partially crumbles and dies. Researchers agree that the incidence of this problem, called osteonecrosis, is quite small.

But trial lawyers are advertising on the Internet and in newspapers for patients who have taken Fosamax or the other drugs, and they are finding potential clients.

"We're getting people calling every day," said Gary Wilson, a lawyer in the Minneapolis office of Robins, Kaplan, Miller & Ciresi.

Wilson said his firm had enlisted medical and dental experts to thoroughly review the records of potential plaintiffs who have taken one of the drugs, adding that he would probably file about 20 cases in the coming months.

"It's too early to tell whether these cases will be successful," said Edward Weltman, a San Francisco defense lawyer who represents drug makers. "But as soon as there is publicity about any kind of possible problems with a medication, the plaintiffs get geared up."

Merck spokesman Skip Irvine says that Fosamax is safe and effective in treating osteoporosis and that the company "will vigorously defend ourselves against these suits."

"Osteonecrosis is very rare and not well understood," Irvine said, noting that in controlled clinical trials involving more than 17,000 patients, there had been no reports of the malady.

Ethel Siris, a professor of medicine at Columbia University College of Physicians and Surgeons who has also consulted for Merck, said new research studies were underway to understand what

triggers the onset of this jaw problem.

In the meantime, she said, she tells her osteoporosis patients that the benefits of the bisphosphonate drugs greatly outweigh their risks.

Fosamax is probably the best-known brand-name drug for preventing hip fractures and deteriorating bones that often destroy the quality of life for older women.

Millions of women have taken the drug since it was first marketed in 1995. Fosamax generated \$3.2 billion in sales last year, outstripping the other major oral osteoporosis remedies, Actonel, produced by Procter & Gamble Co. and Sanofi-Aventis, and Boniva, made by Roche Laboratories.

Scientific reports of jaw problems have generated a wave of newspaper articles that in turn have sown panic among users of the drugs.

Many have turned to their doctors or dentists for advice on how to prevent jaw decay and the best treatment options. Last month, the American Dental Assn. released a set of treatment guidelines.

Some users have turned to lawyers as well.

A Florida attorney, Timothy O'Brien, has filed 30 damage suits involving Fosamax and expects to file at least 300 more over the next few months involving that drug as well as Actonel.

One of his clients is Rochelle Kenig, who took Fosamax for nine years until she woke up one morning in 2004 with "excruciating, excruciating" pain in her jaw.

"This has been a living nightmare, and nobody knew anything about it," the Boynton Beach, Fla., resident recalled.

Kenig, 67, said she underwent multiple courses of potent antibiotics, repeated surgeries, treatment in a hyperbaric chamber and acupuncture. Yet the pain and bone deterioration continued, she said.

She finally got some relief in April after a new group of surgeons replaced part of her jaw with a titanium plate secured with metal hinges. But, Kenig said, the decay and infections had caused a permanent loss of sensation on the right side of her lip and face, as well as the loss of several teeth.

Merck's Irvine declined to comment on Kenig's claim, adding, "We don't want to argue cases in the newspapers."

O'Brien has asked a Florida federal court to certify a class action for the Fosamax suits. He estimated that he and other lawyers had filed a total of 50 lawsuits with possibly hundreds more to come.

Two bisphosphonates produced by Novartis Pharmaceuticals Corp., Aredia and Zometa, are given intravenously in treating some forms of bone cancer. The drugs have also been targeted in lawsuits from about 100 claimants to date.

Some experts see the relatively slow pace of lawsuit filings against Fosamax and its related drugs — compared with the flood of Vioxx suits that followed Merck's decision to pull the drug in 2004 — as evidence that plaintiffs' lawyers have become more cautious in recent years.

Litigation involving silicone gel breast implants and Bayer's cholesterol-lowering drug Baycol proved less successful than lawyers initially expected, said Francis McGovern, a Duke University law professor.

"Now, you might take a particularly good case and see how good it is before you take lots of others and invest a lot of money," McGovern said.

Drug makers are also taking more precautions. Merck added language about the potential problem to Fosamax's label in July after a request from the Food and Drug Administration, which had reviewed reports of osteonecrosis, Irvine said.

The revised label "communicates the issue clearly to physicians," Irvine said.

But attorney Wilson said that precaution statement "is buried deep in the label and just doesn't have the same impact" as a formal warning, which he thought the company should have issued. A warning is "a whole different thing, especially for the physicians who prescribe the drugs," Wilson said.

Attorney O'Brien characterized Merck's posture as "significantly more quiet about the relationship between Fosamax and osteonecrosis of the jaw than they were in disputing the relationship between Vioxx and heart attacks."

"They were very defensive on Vioxx," he said, "and I think they've learned from that and are playing things closer to the chest on Fosamax."

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