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Fosamax, Merck's other drug problem

With thousands of Vioxx cases already in the courts, the drugmaker faces 15 suits over an osteoporosis drug blamed for rotting the jaw bone.

By Aaron Smith, CNNMoney.com staff writer

May 9, 2006: 10:08 AM EDT

NEW YORK (CNNMoney.com) - Merck, already in a long fight against thousands of Vioxx lawsuits, will soon face a two-front war, as plaintiffs begin to file suit over a different drug: Fosamax.

[Merck](#) (down \$0.01 to \$34.44, [Research](#)), the No. 2 U.S. drugmaker, will soon face a federal court suit from a Naples, Fla., woman who blames the osteoporosis treatment for the necrosis that rotted her mouth and exposed bone in her jaw. Linda Secrest, 60, who took Fosamax for six years, filed the suit April 10 in Fort Myers, Fla. She accuses Merck of withholding information about the drug's health risks.

A trial date has not been determined, said a court clerk.

Could this be another Vioxx? The plaintiffs in approximately 11,500 lawsuits blame the arthritis painkiller for causing their heart attacks, and accuse Merck of withholding information about the drug's health risks. Merck has said all along that Vioxx didn't kill anyone and denied all charges of corporate wrongdoing.

So far, Merck [has lost](#) two cases, won two, and there was a [split verdict](#) in another. The next trial begins June 5, in a case involving two plaintiffs in a New Jersey state court in Atlantic City.

Fosamax and Vioxx have been large contributors to Merck's earnings. Fosamax totaled \$3.2 billion in 2005 sales, while Vioxx sales totaled \$2.5 billion in 2003, its last full year on the market. Fosamax, which contains the active compound bisphosphonate, increases bone mass and reduces the risk of fractures in postmenopausal women, and also treats osteoporosis in men.

To be sold, or not to be sold

Merck dismisses comparisons between the two litigation battles, and there are some key differences. Fosamax is still being sold, while Merck pulled Vioxx from the market on Sept. 30, 2004 after a study revealed that the risk of heart attacks and strokes increases in Vioxx patients after 18 months of use. Vioxx plaintiffs interpret the market withdrawal as an admission of guilt, while Merck lawyers use it to discount charges the company deliberately misled patients.

There's another big difference: Merck says 15 Fosamax suits have been filed against the company, versus the thousands of Vioxx cases. But this is expected to change.

Attorney Tim O'Brien, who represents Secrest and Carmen Carr, 57, of Pensacola, who blames her nine years of taking the drug for "significant bone loss in her jaw" as well as some teeth, expects to file some 300 more Fosamax cases.

In the Secrest case, O'Brien said he is seeking "seven figures" for her personal injury claim, and in a class action suit he wants Merck to establish a fund to pay for a state education program about the drug's risks and for dental screening of Fosamax patients.

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Why Fosamax?

So why is Fosamax being blamed for causing the rare disease known as osteonecrosis of the jaw?

O'Brien, the plaintiff lawyer, said he used a process of deduction to pinpoint Fosamax as the cause of osteonecrosis in his plaintiffs. O'Brien said his plaintiffs never underwent radiation therapy or chemotherapy, which he identified as the only other proven causes of the disease.

"Merck is going to have significant problems defending this case in the way they defend the Vioxx cases, by saying something else in the woman's past caused jaw necrosis, because so few things cause it," said O'Brien.

But Merck spokesman Ray Kerins said the "underlying cause" of osteonecrosis of the jaw is "uncertain," though it might be triggered by a traumatic event like tooth extraction or oral surgery.

Also, a Merck press release said the "post-marketing" reports of osteonecrosis of the jaw "do not necessarily indicate causality" in Fosamax patients, and that this condition never surfaced in 10 years of controlled clinical trials with 17,000 patients.

Cause and effect

Thus, the plaintiffs in both the Vioxx and Fosamax litigations need to prove the drugs caused their problems. The Fosamax patients may have a tougher time.

"Anybody could sue, and they will, but it doesn't seem like the prevalence is high and you still have to demonstrate cause and effect," said Barbara Ryan, analyst for Deutsche Bank North America. "I don't think it's a good thing, but I don't think it poses a significant financial risk to Merck."

Ryan said that damages, if any, probably won't amount to much compared to the possible \$30 billion damage tally related to Vioxx, and she does not believe that the Fosamax litigation poses any serious threat to Merck's stock price.

But the Fosamax verdict would come from a jury that could be swayed by disfigured plaintiffs suffering from osteonecrosis, and Merck has lost some Vioxx cases after arguing the same type of causality defense that it plans for Fosamax.

So what's the best thing for Merck to do?

"The most risk-averse strategy of all is, of course, to pull it [from the market,] but then everybody who's on [Fosamax] will say there's a causal relationship and they'll pile on with more lawsuits," said Frances Miller, law professor at Boston University and expert in health care law and policy. "So you're damned if you do and damned if you don't. But they would be damned if they knew, or had reason to know, there was a serious risk here."

To read about Merck's first quarter earnings, [click here](#).

Ryan does not own shares of Merck stock but Deutsche Bank North America does. ■

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