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# FDA Warns of Femur Fractures from Fosamax, Other Bone Drugs

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Several years after concerns first surfaced, federal drug regulators are now warning about the risk of rare femur fractures from side effects of Fosamax and other bisphosphonate drugs that are designed to make bones stronger.

The FDA issued a thigh bone fracture warning for Fosamax and other osteoporosis drugs on Wednesday. Research published in 2008 first raised concerns about the risk of these low-energy femur fractures, but the FDA warning notes that the agency is still not clear that bisphosphonates are actually the cause of the rare fractures. However, the fractures have been predominantly reported in patients who were taking bisphosphonate medications.

The list of drugs affected by the warning includes the oral bisphosphonates Fosamax, Fosamax Plus D, Actonel, Actonel with Calcium, Boniva, Atelvia and all generic equivalents. The warning also affects the injectable bisphosphonates Reclast and the injectable version of Boniva. The agency will require the drug manufacturers to add the warning to labels and medication guides.

Not included in the warning are bisphosphonates used only to treat Paget's disease or high blood calcium levels due to cancer, including Didronel, Zometa, Skelid and their generic equivalents.

The warning comes less than a month after the recommendations of an expert task force of doctors and scientists were published in the Journal of Bone and Mineral Research. The task force, convened by the American Society of Bone and Mineral Research, determined that there appeared to be enough of a connection between bisphosphonates and atypical femur fractures to merit a warning, even though no direct link has been found.

The FDA has been reviewing possible connections since March 2010, and noted in its press release that it had included the findings of the task force in its review. Late last month the European Medicines Agency, the drug regulatory agency for the European Union, also began its own review of atypical femur fracture and bisphosphonates.

Fosamax, which is the most widely used oral bisphosphonate, was approved by the FDA in October 1995, and has been used by more than 20 million people. The drug generated over $3 billion in annual sales for Merck before it became available as a generic last year.

The FDA review was sparked by concerns about an increasing number of reports of low-trauma bone breaks among Fosamax users, usually involving the thigh bone or femur, which is one of the strongest bones in the human body.

In June 2008, a report published in the Journal of Orthopedic Trauma first raised concerns that Fosamax may increase the risk of these low-energy femur fractures. Researchers performed a retrospective review of 70 femur fractures that resulted in emergency room treatment between January 2002 and March 2007, most involving impacts with falls from standing height or less. A fracture pattern that was 98% specific to Fosamax was identified by the researchers.

A number of Fosamax thigh bone fracture lawsuits have been filed against Merck alleging that the drug maker failed to adequately research their medication or warn users about the risk of the bone breaks. The drug maker also already faces hundreds of Fosamax lawsuits over rare jaw side effects, involving a rare condition known as osteonecrosis of the jaw (ONJ), which cause portions of the jaw to decay or die.

According to the FDA, the fractures are atypical subtrochanteric femur fractures that occur just below the hip joint, and diaphyseal femur fractures, which happen in the long part of the thigh bone. Generally, these types of femur fractures are very uncommon and account for less than 1% of all hip and femur fractures. The FDA found that they occur predominantly in people taking bisphosphonates.

The FDA review's findings also seem to suggest that the fractures might be related to long-term use of the drugs. As a result, the new warning labels will include the fact that the FDA does not know how long it is safe to take bisphosphonates.

"The FDA is continuing to evaluate data about the safety and effectiveness of bisphosphonates when used long-term for osteoporosis treatment," said Dr. Sandra Kweder, deputy director of the FDA's Office of New Drugs. "In the interim, it's important for patients and health care professionals to have all the safety information available when determining the best course of treatment for osteoporosis."