

FDA warns Boniva, Fosamax and other osteoporosis drugs may cause bone fractures

Gergana KolevaGergana Koleva

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Osteoporosis drugs taken to prevent bone fracture may cause rare, but critical, fractures of their own, the Food and Drug Administration announced today in a warning to consumers. The agency also noted it would require a change to the medications' labels, which currently don't indicate that risk.

The findings, based on ongoing but inconclusive research by the American Society for Bone and Mineral Research, concern a widely-prescribed class of medicines known as bisphosphonates. They are typically used over long periods of time to prevent bone loss and breakage.

The brands affected by this warning include Boniva, Fosamax, Fosamax Plus D, Actonel, Actonel with Calcium, Atelvia, and Reclast, and their generic equivalents. In 2009, more than 5 million patients, mostly women over 50 years old, took the drugs, the FDA said in a conference call with reporters.

Although no clear connection has been made between these drugs and the rare type of thigh bone fractures they're believed to cause, the research society associates the unusual fractures -- which are different than the common injuries osteoporosis drugs are meant to prevent -- with long-term bisphosphonate use.

Most patients who report these atypical fractures, known as subtrochanteric femur fractures and occurring just below the hip joint, have been on bisphosphonates for 10 to 15 years and tend to be younger, the FDA said. According to the agency, many of them describe a dull aching side pain that may begin weeks or months before a complete fracture occurs.

"We suspect there is a lack of awareness that this type of fractures may be associated with the actual drugs consumers are taking to prevent fractures," Dr. Theresa Kehoe, an FDA osteoporosis expert, said. She recommended that doctors reevaluate the health of patients who have taken the drugs for more than five years.

Kehoe noted the problem is an area of intense research in the bone and mineral medical community.



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