Fosamax Femur Fracture Warning Label Change By Merck Seems Likely After Task Force Report

FDA Considering Issue Due To September 2010 American Society of Bone And Mineral Research Report About Bisphosphonate Side Effects

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 16, 2010; see http://bit.ly/9wqPN1)

A new task force report on bisphosphonates, like Fosamax (alendronate), and an association with atypical femur fractures in osteoporosis patients has caused the FDA to consider requiring drug companies like Merck to make a label change to increase the warning about this rare but serious side effect.

On September 14, 2010 the Journal of Bone and Mineral Research published online this article "Atypical subtrochanteric and diaphyseal femoral fractures: Report of a task force of the American Society for Bone and Mineral Research" (PDF format of full article). In summary, the task force reviewed 310 cases of "atypical femur fractures," and found that 94 percent (291) of patients had taken the drugs, most for more than five years.

From the Abstract for this September 2010 task force report:

> **Introduction**
> Reports linking long-term use of bisphosphonates (BPs) with atypical fractures of the femur led the leadership of the American Society for Bone and Mineral Research (ASBMR) to appoint a Task Force to address key questions related to this problem.
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> **Results and Conclusions**
> .... The Task Force defined major and minor features of complete and incomplete atypical femoral fractures and recommends that all major features, including their location in the subtrochanteric region and femoral shaft, transverse or short oblique orientation, minimal or no associated trauma and absence of comminution, be present to designate a femoral fracture as atypical.
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> **Recommendations**
> .... Physicians and patients should be made aware of the possibility of atypical femoral fractures and of the potential for bilaterality through a change in labeling of [bisphosphonates].

Also published online on September 14, 2010 was "FDA Statement on ASBMR report: Possible Increased Risk of Certain Types of Thigh Bone Fractures with Long-Term Bisphosphonates Use", which indicates that the FDA may want Merck and other drug companies marketing bisphosphonate drugs -- such as Actonel, Aredia, Boniva, Reclast, and Zometa -- to revise their respective package inserts, or labels, to better warn doctors and their parients about this apparent increased risk of femur fractures.

Two other medical journal articles that the FDA may be considering with regard to this femur fracture label change for Fosamax and other osteoporosis drugs in the bisphosphonate class:

(1) "Cumulative Alendronate Dose and the Long-Term Absolute Risk of Subtrochanteric and Diaphyseal Femur Fractures: A Register-Based National Cohort Analysis", which was published online on September 15, 2010 by the *Journal of Clinical Endocrinology & Metabolism*. From the Abstract:

> **Conclusions:** [Fosamax (alendronate)]-treated patients are at higher risk of hip and subtrochanteric/diaphysealfracture than matched control subjects. However, large cumulative doses of [Fosamax (alendronate)] were not associated with a greater absolute risk of subtrochanteric/diaphysealfractures than small cumulative doses, suggesting that these fractures could be due to osteoporosis rather than to [Fosamax (alendronate)].

(2) "Bisphosphonates and Fractures of the Subtrochanteric or Diaphyseal Femur", which was published in the May 13, 2010 edition of the *New England Journal of Medicine*. From the Abstract:

> **Conclusions**
> The occurrence of fracture of the subtrochanteric or diaphyseal femur was very rare, even among women who had been treated with bisphosphonates for as long as 10 years. There was no significant increase in risk associated with bisphosphonate use, but the study was underpowered for definitive conclusions.

For more about Fosamax and femur fractures, visit our Focus on Fosamax page, where we have a collection of articles and news reports relevant to the hundreds of Fosamax drug injury lawsuits that are currently pending against Merck.
