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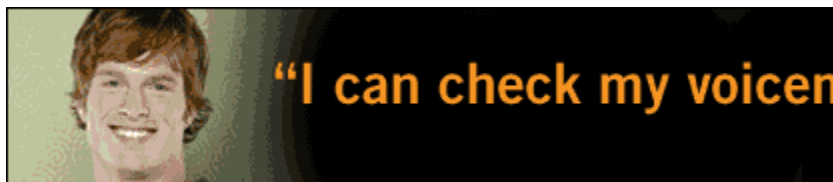


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Jaw Bone Decay, Or Osteonecrosis, Is Serious Albeit Rare Side Effect Of Fosamax Use

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POSTED: Monday, April 21, 2008

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

The following blog post is from an independent writer and is not connected with Reuters News. The opinions and views expressed herein are those of the author and are not endorsed by Reuters.com.

This Condition Is Referred To Generally As Bisphosphonate-Related Osteonecrosis Of The Jaw (BRONJ)

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

The April 8, 2008 edition of *Journal Watch General Medicine* included a brief article titled "[Should We Be Concerned About Jaw Osteonecrosis with Oral Bisphosphonates?](#)", by Allan S. Brett, MD, and Peter B. Lockhart, DDS.

The first part of this article provides some background information:

[Bisphosphonate-related osteonecrosis of the jaw (BRONJ)] is defined as exposed, necrotic bone in the maxillofacial region that persists for more than 8 weeks in current or past recipients of bisphosphonate therapy. The condition can occur spontaneously or after invasive dental procedures. These lesions often expand — sometimes involving large areas of the alveolar bone — and no treatment has been proven to be effective. Reports of BRONJ first surfaced about 5 years ago, primarily in cancer patients who had received IV bisphosphonates for hypercalcemia and bone metastases. Experts generally accept the association between jaw osteonecrosis and IV bisphosphonates, which are often given repetitively in high doses. [footnotes omitted].

Next, Dr. Brett and Dr. Lockhart turn their attention to the incident rate of oral bisphosphonates such as Fosamax causing BRONJ, also referred to simply as ONJ. They point out that such a determination is made difficult due to this fact:

No ICD-9 code exists for jaw osteonecrosis, so the researchers had to use other codes (e.g., diagnostic codes for inflammatory conditions of the jaw and procedure codes for jaw surgery) as surrogate markers for jaw osteonecrosis.

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In view of this "important limitation", for their article Brett and Lockhart spoke to dentists with patients treated with Fosamax and other oral bisphosphonates who developed symptoms of ONJ after either invasive dental procedures or, in some instances, even without any apparent jaw-area trauma. From those discussions, the authors conclude:

Although these anecdotal unpublished observations hardly prove cause and effect, they should not be dismissed out of hand for at least two reasons. First, if we accept that IV bisphosphonates can cause jaw osteonecrosis, we can reasonably assume that oral therapy occasionally might cause the same complication in highly susceptible people. And second, biopsy-proven severe suppression of bone turnover — resulting in spontaneous fractures of the femur, pelvis, and ribs — has been described in several patients after long-term oral bisphosphonate therapy. [footnote omitted]


This April 2008 *Journal Watch* article is followed by a list of eight source items; each has a link to its free Medline abstract for those who want to delve deeper into this issue.

One recent medical article that is not listed therein is "[Osteonecrosis of the jaw.](#)", by NB Watts and RD Marciani, which appeared in the *Southern Medical Journal* dated February 1, 2008. Its Medline abstract includes the following statement, however, which suggests this article does not add much to the discussion -- perhaps why it was not referenced by Brett and Lockhart:

Although ONJ occurs exclusively or almost exclusively in patients receiving bisphosphonate therapy, a causal association has not been shown, and the mechanism is not clear.

In the legal arena, at present Merck & Co. faces numerous product liability lawsuits brought by patients who have developed ONJ after using Fosamax. These lawsuits are based on [the allegation that Merck failed to warn doctors and patients in a timely manner](#) about reports of jaw bone decay, or rot, being associated with its osteoporosis drug Fosamax.

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