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Drug linked to death of jawbone

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By Rita Rubin, USA TODAY

Salvatore Ruggiero was puzzled.

Over a three-year period, the jaws of dozens of patients who had undergone oral surgery at his hospital had failed to heal properly. Part of the jawbone had died and become exposed.

"We never saw this before in the jaw" except in patients who had received radiation therapy to that part of the face, says Ruggiero, chief of oral and maxillofacial surgery at Long Island Jewish Medical Center. "It just never existed."

Further investigation revealed one common thread: All of the patients had been treated with at least one of a class of drugs called bisphosphonates.

Most were cancer patients who had received the intravenous bisphosphonates Zometa or Aredia or both for excessive calcium in their blood or bone tumors.

But about 10% were osteoporosis patients who had taken an oral bisphosphonate, mainly Fosamax.

In May, Ruggiero co-wrote a report on 63 patients with osteonecrosis — or bone death — of the jaw in the *Journal of Oral and Maxillofacial Surgery*. Six had taken Fosamax, and a seventh had taken Actonel, another oral bisphosphonate for osteoporosis.

The problem doesn't appear to be as severe with oral bisphosphonates as it is with the IV drugs, Ruggiero notes. Patients who have been receiving IV bisphosphonates should avoid having teeth pulled "at all costs," he says.

Based on his cases, a Food and Drug Administration review posted last week on the agency's Web site suggests that osteonecrosis of the jaw (ONJ) is a risk of all bisphosphonates, not just the IV drugs.

Bisphosphonates remain in bone indefinitely. Ruggiero speculates that their long-term use could upset the delicate balance between cells that put calcium in bone and cells that take calcium away.

The FDA review concluded that all bisphosphonate labels should mention osteonecrosis.

Novartis, maker of Zometa and Aredia, added a precaution about ONJ to their package inserts in August, although the inserts note that cancer patients have other osteonecrosis risk factors, such as their malignancies.

Merck spokesman Tony Plohoros says his company is in the process of adding information about the ONJ cases to the Fosamax label. And Terri Pedone, spokeswoman for Sanofi-Aventis, which markets Actonel with Procter & Gamble, says, "We are currently addressing the FDA's request to update the label" with information about ONJ.

Rugierro says he has now seen a total of 12 or 13 cases of ONJ in patients treated with an oral bisphosphonate. Robert Marx, chairman of the division of oral and maxillofacial surgery at Florida's University of Miami, says he's aware of at least 40 or 50 cases of ONJ nationwide in patients who had taken Fosamax.

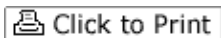
That's a infinitely small fraction of the approximately 3 million women in the USA who are taking the drug, although most experts agree that only 1% to 10% of adverse events linked to drugs are reported.

Interestingly, some doctors have prescribed IV bisphosphonates "off label" for osteoporosis. And Roche and GlaxoSmithKline announced in December that they are seeking FDA permission to market an IV form of their oral bisphosphonate, Boniva, for osteoporosis.

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