# BISPHOSPHONATES

# &

# OSTEONECROSIS OF THE JAW

A Review of Material – July 2006

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# 1 Summary

**Steven J. Spindler, D.D.S.**
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**Periodontal Specialists**

# Osteonecrosis of the Jaw (ONJ)

**Important notice to dentists regarding patients taking these bisphosphonate drugs for the treatment of osteoporosis, osteosarcoma, or post-menopausal bone loss:**

**Fosamax**
**Aredia**
**Actonel**
**Zometa**

Patients that have ever been treated with bisphosphonate drugs, should know there is a risk of osteonecrosis (bone death) of the jaw with extractions and any dental treatments that exposes the patients' bone. The risks are highest in patients receiving intravenous bisphosphonates, a common treatment for osteosarcoma and carcinomas that involve bone. However, 10 percent of osteonecrosis of the jaw (ONJ) patients took only oral Fosamax, Aredia, Actonel or Zometa.

Fosamax, Aredia, Actonel and Zometa affect the ability of bone tissue to break down or remodel itself thereby reducing its healing capacity. This risk of ONJ is increased after extractions, surgery or other invasive procedures that might cause mild trauma to the jawbone.

ONJ is a destructive process in the jawbone that is often difficult or impossible to eliminate Unlike the similar lesion of osteoradionecrosis, this type of osteonecrosis does not respond to hyperbaric O2 or aggressive debridement.

Periodontal maintenance and regular supportive care are important for prevention and early detection. ONJ patients should be treated just as you would treat a patient subject to osteoradionecrosis. Early detection and treatment of dental infections, caries and periodontal disease is most important. Patients taking oral bisphosphonates should be on more frequent recall to prevent the patients from reaching points where extractions or surgeries become necessary.

Because legal suits associated with ONJ are starting, We have created this notebook for you.

# Clinical Photos of ONJ

**From Journal of Oral and Maxillofacial Surg. 63:1567-1575, 2005.**



**FIGURE 1.** Exposed necrotic bone in the mandible related to pamidronate.

*Marx et al. Bisphosphonate-Induced Exposed Bone of Jaws. J Oral Maxillofac Surg 2005.*

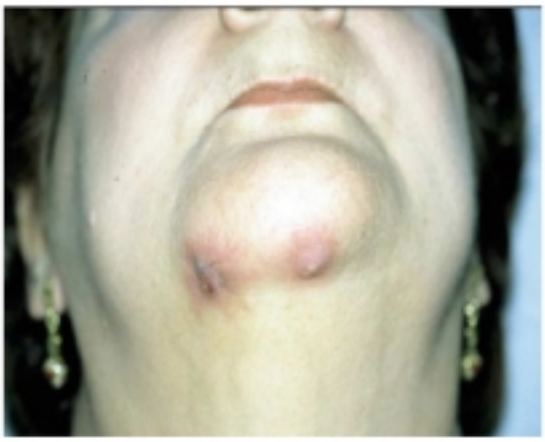

**FIGURE 2.** Draining oral cutaneous fistulas representing secondary infections from an exposed mandible in the oral cavity from zoledronate.

*Marx et al. Bisphosphonate-Induced Exposed Bone of Jaws. J Oral Maxillofac Surg 2005.*

**Steven J. Spindler, D.D.S.**
**Aymee C. Spindler, D.D.S.**
**Periodontal Specialists**

# Question & Answer Interview
# Regarding Osteonecrosis of the Jaw

**Are dentists liable if they treat patients who are taking oral bisphosphonates, such as Fosamax, and ONJ then develops?**

We don't yet know if dentists are liable. All we know is that law firms are advertising on television and the Internet for Fosamax patients who have developed osteonecrosis of the jaw.

We recently spoke with an attorney from one law firm who said they are developing a class action suit against pharmaceutical firms that are developing and selling oral bisphosphonates. They said they were not developing a class action suit against pharmaceutical firms that develop intravenous bisphosphonates.

The attorney said that the risk of developing something like osteonecrosis of the jaw for cancer patients is outweighed by the fact that the patient's life is saved by the intravenous bisphosphonate treatment.

The questions becomes, "will dentists and general dentists who inappropriately treat patients (who then develop ONJ) be caught in the cross fire of these larger suits?"

Again, this is unknown. This is one of the reasons we are talking to a large number of doctors about these problems. It seems that every doctor with whom we speak has a different story. All we know at this point is that we are in a transition period in which the legal actions are starting. Our advice is that you be careful in treating patients with a history of bisphosphonate use.

**Should dentists even be treating patients who are taking oral bisphosphonates?**

So far, we have spoken to 15 periodontists. 5 said they are postponing their treatment for patients who are taking oral bisphosphonates. They feel that more information is needed and are therefore hesitant to treat these patients in their usual manner. We suspect that they will start treating these patients when they get more information.

10 of the 15 periodontists said they already were modifying their treatment modalities for patients on bisphosphonates. We think this may be an excellent indication for dental endoscopy (Perioscope) and this is how we are proceding

**Should general dentists refer these type of patients elsewhere?**

Whether or not you should send these patients to periodontists or oral surgeons seems to be dependent of the type of whether or not you become familiar with treatment protocols for these patients and the potential complications. As an example, a local colleague experienced this complication on a 69 year old female. One week following surgery on the lower right region, lingual bone exposure was noted, and several attempts at achieving healing over the course of 15 months proved unsuccessful. The patient lost several teeth. This truly was a frustrating experience for the patient and the doctor.

# 2

# Articles

**ADA News May 16, 2005**

# Osteonecrosis warning: Cancer drugs preclude some dental procedures.

*By Mark Berthold*

*East Hanover, N.J.* — Cancer patients treated with intravenous bisphosphonate drugs may be at increased risk for developing "osteonecrosis of the jaw" — and they should not undergo invasive dental procedures, advises a pharmaceutical manufacturer.

Novartis Pharmaceuticals Corp. is sending a letter to dentists across the country, informing them that ONJ has been observed in cancer patients who are receiving Aredia or Zometa — bisphosphonates used to treat complications of advanced cancer known as "hypercalcemia of malignancy."

Novartis recommends that cancer patients receive a dental examination prior to initiating therapy with Aredia or Zometa, and avoid invasive dental procedures while receiving these drugs because dental surgery may exacerbate the ONJ condition. It has added precautionary information on ONJ to the package insert for both products.

Novartis also encourages dentists to report any serious adverse events related to Aredia or Zometa to its toll-free number, 1-800-882-6577, or to the Food and Drug Administration's MedWatch Adverse Event Reporting program, by phone at 1-800-FDA-1088 or online at ww.fda.gov/MedWatch.

For more information, contact Novartis Oncology Medical Services at 1-888-669-6682.

## Bisphosphonate use growing

Bisphosphonate drugs are fairly common in the United States: greater than 23 million Americans took the oral form in 2003 to treat osteoporosis and other conditions, according to Dr. John W. Hellstein, clinical professor of oral and maxillofacial pathology at the University of Iowa.

"Less than 10 percent of reported cases of 'osteonecrosis of the jaw' are related to oral bisphosphonates," he says, "so the risks associated are real — but so far rare."

On the other hand, Dr. Hellstein believes, infusible bisphosphonates have a much higher risk of ONJ — about 90 percent of reported cases. Infusible bisphosphonates are used to treat cancers such as metastatic breast cancer, prostate cancer and multiple myeloma.

Signs of ONJ include exposed bone; pain, swelling or infection of gums; loosening of teeth; poor healing of gums; numbness or feeling of heaviness in the jaw; and draining with sequestration.

Problems have occurred after a tooth extraction in dental patients who had received the drug up to a year prior. The extraction site becomes necrotic and affects the surrounding bone, so that part of the jaw eventually may have to be removed. Spontaneous exposure of tori or the internal oblique ridge have also been reported.

However, "currently there are no indications to stop taking oral bisphosphonate medications for osteoporosis, such as ibandronate, alendronate or risidronate," says Dr. Hellstein. "And we don't want cancer patients to stop taking their infusible bisphosphonate, such as pamidronate or zoledronate, for hypercalcemia of malignancy." What Dr. Hellstein wants is for the dentist to be aware of the possible complications associated with periodontal disease, tooth extraction, exposed tori or dentoalveolar/perioral trauma, especially in patients having a history of being administered infusible bisphosphonates.

Thus, much more attention and reporting of complications associated with the oral bisphosphonates, he believes, will help delineate the risks associated with osteoporosis medications.

"Preventive dentistry and good oral health care are still the best tools to reduce risks due to these medications and reduce complications in these patients already medically at risk," he says.

Dr. Hellstein adds that conservative treatment modalities are being evaluated for patients who do experience ONJ and how to manage patients requiring tooth extractions or bone exposure.

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## Bisphosphonates and Osteonecrosis of the Jaw

Osteonecrosis of the jaw (ONJ) has multiple well-documented risk factors including a diagnosis of cancer, concomitant therapies (e.g. chemotherapy, radiotherapy, corticosteriods) and co-morbid conditions (e.g. anemia, coagulopathies, infection, pre-existing oral disease).

Over the last 2 years, cases of ONJ have been reported in patients treated with bisphosphonates, many of whom were cancer patients receiving chemotherapy and corticosteroids. In the majority of the cases, ONJ developed after tooth extraction although some developed the condition spontaneously. Many had signs of local infection including osteomyelitis.

One of the earliest reports[1] described osteonecrosis of the alveolar bone in 3 female patients undergoing chemotherapy for metastatic breast cancer. All 3 patients received pamidronate. Two of these patients developed bone necrosis after tooth extractions, but the third patient developed the condition spontaneously, resulting in an oroantral fistula. In all cases, histological examination of the lesions showed necrotic bone with no evidence of metastatic disease. There are other reports[2,3] of patients receiving pamidronate or zoledronic acid and developed necrosis of the bone after dental extractions.

Data from the UK[4] showed that cancer patients have an estimated 4 times higher risk at any site than the general population. Treatment with bisphosphonates is a standard of care in many types of bone complications of cancer. Therefore, it is not possible to determine if osteonecrosis of the jaw is related to bisphosphonates, concomitant drugs/other therapies, patient's underlying disease, or other comorbid risk factors.

## Local Case Report

The bisphosphonates registered locally include alendronate, clodronate, etidronate, ibandronic acid, pamidronate, risedronate and zoledronic acid. Bisphosphonates are commonly used for the treatment of postmenopausal and corticosteriod included osteoporosis, Paget's disease, hypercalcemia associated with malignancy and osteolysis and bone pain associated with metastatic bone disease.

To-date, the Pharmacovigilance Unit has received one local report of a patient with jaw osteolysis and suspected osteomyelitis while he was on zoledronic acid (Zometa®) 4 mg injection. There is another report of exostosis and aseptic bone necrosis after a dental extraction during alendronate (Fosamax®) therapy.

## Recommendation

The following recommendations have been made in the updated prescribing information of the pamidronate and zoledronic acid in the US:

- A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors (e.g. cancer, chemotherapy, corticosteriods, poor oral hygiene).
- While on treatment, these patients should avoid invasive dental procedures, if possible. For patients who develop ONJ while on bisphosphonate therapy, dental surgery may exacerbate the condition. For patients requiring dental procedures, there are no data available to suggest whether discontinuation of bisphosphonate treatment reduces the risk of ONJ. Clinical judgment of the treating physician should guide the management plan of each patient based on the individual benefit/risk assessment.

It has been highlighted that cases of avascular bone necrosis were reported with high doses potent nitrogen-containing bisphosphonates e.g. pamidronate and zoledronic acid. There is limited data to suggest that the other bisphosphonates may have similar, albeit less, effects on jawbones as well. Healthcare professionals are encouraged to report all serious adverse reactions suspected to be associated with the use of bisphosphonates to the Pharmacovigilance Unit of the HSA.

## References


1. Wang J et al. Osteonecrosis of the jasw associated with chemotherapy. J Oral Maxillofac Surg 2003; 61:1104-7.
2. Marx RE. Pamidronate (Aredia®) and zoledronate (Zometa®) induced avascular necrosis of the jaws: a growing epidemic. J Oral Maxillofac Surg 2003: 61:1115-7.
3. Migliorati CA. Bisphosphonates and oral cavity avascular bone necrosis. J Clin Oncol 2003; 21:4253-4.
4. The General Practice Research Database, compiled by a dedicated multi-disciplinary team based at the Medicines and Healthcare products Regulatory Agency (MHRA) in London, UK.
5. Robinson NA, Yeo JF. Bisphosphonates-A word of caution. Ann Acad Med Singapore 2004; 33(suppl):48S-49S

**Abstract**
Journal of Periodontology
2006, Vol. 77, No. 4, Pages 738-743
(doi:10.1902/jop.2006.050187)

# Oral Post-Surgical Complications Following the Administration of Bisphosphonates Given for Osteopenia Related to Malignancy

Background: This case report seeks to illustrate the clinical consequences of the administration of bisphosphonate therapy to prevent osteopenia secondary to malignancy in one patient.

Methods: A 69-year-old white female with a history of breast cancer with metastasis presented with pain in the upper left quadrant and periodontal pocketing of at least 6 mm in each of the four quadrants of the oral cavity. One week following surgery on the lower right region, lingual bone exposure was noted, and several attempts at achieving healing over the course of 15 months proved unsuccessful.

Results: Upon referral to a surgeon at the Louisiana State University Medical Center, New Orleans, Louisiana, a potential causative factor was finally identified. The drug zoledronic acid, a bisphosphonate given for prevention of osteoclastic activity of bone metastasis, secondary to breast cancer, was identified as the possible cause of inhibition of healing, most likely from regional vascular insufficiency. The drug was immediately discontinued. The patient is healing very slowly with the aid of hyperbaric therapy; she has been unable to achieve smoking cessation, which is deterring thorough healing of the exposed bony area on the lower right lingual side.

Conclusions: Physicians and dentists alike must become increasingly aware of impaired oral healing following the use of bisphosphonates given for malignancy-related osteopenia. A dental exam should be performed before bisphosphonate therapy, as recommended for radiation therapy related to malignancy.

# 3 AAP Statement

# AAP Statement on Bisphosphonates

The Food and Drug Administration and Novartis Pharmaceuticals Corporation have each issued a drug precaution for health professionals regarding a condition known as Osteonecrosis of the Jaw (ONJ). According to these precautions, this condition has been observed in cancer patients who undergo invasive dental procedures such as dental implants or tooth extractions while receiving treatment with intravenous bisphosphonates. ONJ can cause severe, irreversible and often debilitating damage to the jaw. The two intravenous bisphosphonates that were mentioned in the precautions are marketed by Novartis under the trade names Aredia and Zometa. The precautions are available on the FDA Web site as a general background docket and a Medwatch letter to dental health professionals.

Bisphosphonates, also known as bone-sparing drugs, are commonly used in the treatment of osteoporosis and cancer that has spread to the bone. Doctors prescribe intravenous bisphosphonate therapy, which was the subject of the precautions, for patients with cancer that has spread to the bone to help decrease associated pain and fractures. In addition, emerging research is exploring the ability of intravenous bisphosphonate therapy to inhibit the spread of some cancers to the bone.

Doctors also prescribe an oral dose of bisphosphonates for patients at risk for osteoporosis to help delay the onset of disease by slowing the natural progression of bone tissue destruction, or to reduce its complications. Orally administered bisphosphonates were not the subject of the drug precautions. **However, the FDA noted that there have been anecdotal reports of ONJ in association with oral bisphosphonates administered for osteoporosis.**

Osteonecrosis literally means death, or necrosis of bone. According to the National Osteonecrosis Foundation, the many risk factors for osteonecrosis can be divided into two categories: definite and probable. Definite risk factors include major trauma, fractures, dislocations, Caisson Disease, Sickle Cell Disease, post-irradiation, chemotherapy, Arterial Disease and Gaucher's Disease. Probable risk factors include corticosteroids, blood clotting, alcohol, lipid disturbances, connective tissue disease, pancreatitis, kidney disease, liver disease, lupus, and smoking.[1]

The FDA recognizes additional risk factors associated with the development of osteonecrosis (not limited to the jaw) in cancer patients, such as female sex, advanced age, edentulous regions, combination cancer therapy, blood dyscrasias/metastatic disease, anemia coagulopathy, surgical dental procedures, and prior infection.[2]

Of course, the decision about what treatment to provide to a patient must be made by a periodontist in the exercise of his or her best judgment. However, in light of the precautions, periodontists are advised to determine whether a patient is receiving intravenous bisphosphonate therapy. If so, invasive dental procedures should be avoided unless absolutely necessary. Conversely, if a periodontist becomes aware that a patient is going to be treated with intravenous bisphosphonates, any needed invasive dentistry should, if possible, be performed before the initiation of such treatment. Finally, periodontists should endeavor to identify ONJ and other oral complications of cancer and cancer therapy.

Any questions about ONJ associated with intravenous bisphosphonate therapy can be addressed to Novartis at 1.888.669.6682.

**Footnotes**

1 The National Osteonecrosis Foundation Web Site. Accessed August 5, 2005. An introduction to osteonecrosis by the National Osteonecrosis Foundation and the Center for Osteonecrosis Research and Education.

2 The Food and Drug Administration Web site. 03-02-2005. Accessed August 5, 2005. Expert Panel Recommendation for the Prevention, Diagnosis and Treatment of Osteonecrosis of the Jaw.

# 4 Bisphosphonate Drugs

# Bisphosphonate Drugs

**DEFINITION OF BISPHOSPHONATES: (also called diphosphonates)**

A class of drugs that inhibits the resorption of bone. Its uses are the prevention and treatment of osteoporosis, osteitis deformans ("Paget's disease of bone"), bone metastasis (with or without hypercalcemia), multiple myeloma and other conditions that feature bone fragility.

**From Wikipedia**

**CLASSES OF BISPHOSPHONATES:**

Pamidronate (Aredia)
Alendronate (Fosamax)
Zolendrate/Zolendronic Acid (Zometa)
Risedronate (Actonel)
Clondronate (Bonefos, Clostobon, Loron, Ostac)
Etidronate (Didronel)
Ibandronate/Ibandronic Acid (Boniva)
Tiludronate (Skelid)
Neridronate
Olpadronate

5

# Signs of Osteonecrosis Of the Jaw

# Signs of Osteonecrosis of the Jaw (ONJ)

**Signs of ONJ include:**

- ✓ Exposed bone
- ✓ Pain, swelling or infection of gums
- ✓ Poor healing of gums
- ✓ Numbness or feeling of heaviness in jaw
- ✓ Drainage with sequestration
- ✓ Loosening of teeth

"Problems have occurred after a tooth extraction in dental patients who have received the drug up to a year prior. Extraction site becomes necrotic [dead] and affects the surrounding bone, so that part of the jaw eventually may have to be removed. Spontaneous exposure of tori or the internal oblique ridge have been reported."

From *Osteonecrosis warning: Cancer drugs preclude some dental procedures* by Mark Berthold.

# Clinical Photos of ONJ

**From Journal of Oral and Maxillofacial Surg. 63:1567-1575, 2005.**



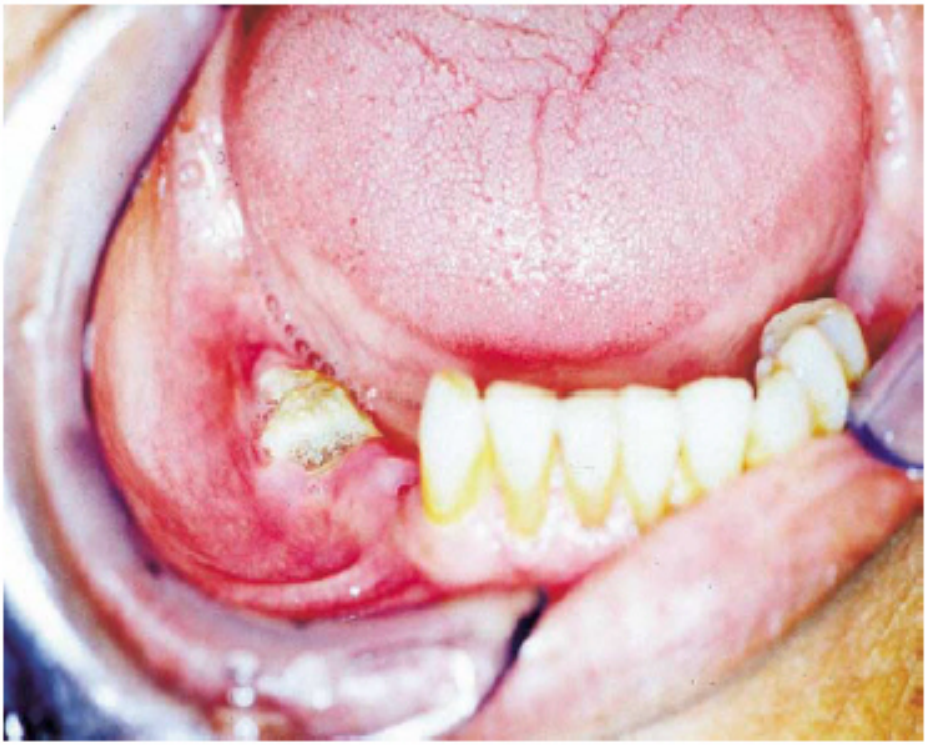

**FIGURE 7.** A nonhealing extraction socket such as this is a common complication when teeth are removed in patients receiving pamidronate or zoledronate therapy.

*Marx et al. Bisphosphonate-Induced Exposed Bone of Jaws. J Oral Maxillofac Surg 2005.*

# Clinical Photos of ONJ

**From Journal of Oral and Maxillofacial Surg. 63:1567-1575, 2005.**

BISPHOSPHONATE-INDUCED EXPOSED BONE OF JAWS

**FIGURE 6.** Mandibular tori represent an anatomic comorbidity. Seen here is exposed bone related to zoledronate therapy over a multilobulated mandibular torus.

*Marx et al. Bisphosphonate-Induced Exposed Bone of Jaws. J Oral Maxillofac Surg 2005.*

# 6

# Lawsuits are Beginning

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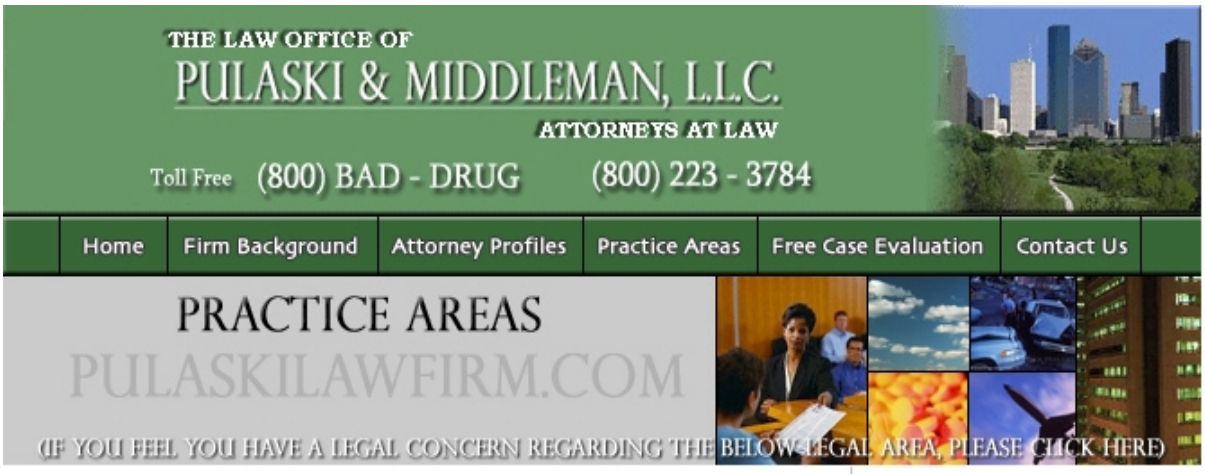
## Sample Website seeking patients:




**Fosamax**

FOSAMAX PLUS D (alendronate sodium/cholecalciferol) tablets

Fosamax (Generic: Alendronate), manufactured by Merck, gained FDA approval in 1995. Fosamax is prescribed to treat osteoporosis and Paget's disease. Fosamax is a type of drug known as bisphosphonates. Individuals using Fosamax or other bisphosphonates should attempt to steer clear of tooth extractions and other major dental work while on the drugs.

A connection between Fosamax and other bisphosphonates and a serious bone disease called Osteonecrosis of the Jaw (ONJ) was found. Osteonecrosis of the Jaw (ONJ) is also known as Dead Jaw. This finding was published in the Journal of Oral and Maxillofacial Surgeons, and it prompted the US Food and Drug Administration (FDA) and the manufacturer of Fosamax to issue a warning to health care professionals on September 24, 2004.

Bisphosphonates are commonly used in tablet form such as Fosamax (generic: Alendronate Sodium) to prevent and treat osteoporosis in post-menopausal women. Stronger forms of bisphosphonates are commonly used in the management of advanced cancers that have metastasized to the bone, where the disease often causes bone pain and possibly even fractures. Several cancers can involve or

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**Another example of a website seeking patients:**

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# Fosamax

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## Fosamax - What You Need To Know


Fosamax (Alendronate Sodium) is a type of drug known as bisphosphonates. Recently a link has been found between bisphosphonates and a serious bone disease called osteonecrosis of the jaw (ONJ aka. Dead Jaw). This important discovery clearly shows that Fosamax side effects may include osteonecrosis of the jaw, aka, dead jaw or jaw death as well as osteomyelitis.

The discovery, published in the Journal of Oral and Maxillofacial Surgeons, prompted both the US, Food and Drug Administration ( FDA ) and Novartis, the manufacturer of bisphosphonates used in cancer chemotherapy, to issue a warning to health care professionals on September 24, 2004. The warning letter contained information about bisphosphonates and the risks of osteonecrosis in the jaw.

Bisphosphonates such as Fosamax (Alendronate Sodium), Zometa (Zoledronate), Didronel (Etidronate), Aredia (Pamidronate), Actonel (Risedronate), and Boniva (Ibandronate) are commonly used to treat, prevent, and even reverse bone loss associated with osteoporosis, chemotherapy, and other bone loss disorders. The Strongest forms of bisphosphonates are commonly used in the management of advanced cancers that have metastasized to the bone, where the disease often causes bone pain and possibly even fractures. Several cancers can involve or metastasize to the bone, including lung cancer, breast cancer, prostate cancer, multiple myeloma, and others. When bisphosphonates are given in cancer chemotherapy, the drugs are given intravenously, and usually for longer periods of time.

If you or a loved one have taken Fosamax and have been injured as a result of Fosamax side effects such as osteonecrosis of the jaw contact the Fosamax lawyer of Ennis & Ennis, P.A. today. The Fosamax lawyers of Ennis & Ennis specialize in Fosamax lawsuits resulting from Fosamax side effects injuries. Ennis & Ennis, P.A. is a national mass tort litigation / drug litigation law firm with offices in Washington DC and throughout Florida. Contact us today for your free, confidential case evaluation.

**Osteonecrosis of the Jaw**
Osteonecrosis of the jaw ( ONJ ) aka. dead jaw, is a condition in which the bone tissue in the jaw fails to heal after minor trauma such as a tooth extraction, causing the bone to be exposed. The exposure can eventually lead to infection and fracture and may require long-term antibiotic therapy or surgery to remove the dying bone tissue. Experts say that prevention and early treatment of individuals using bisphosphonates such as Fosamax is extremely important in preserving the jaw bone. Individuals using Fosamax or other bisphosphonates should attempt to avoid tooth extractions and other major dental work while on the drugs.



## Current Fosamax News

**June 17 , 2006**

Millions of midlife and older Americans rely on the medication Fosamax to stave off osteoporosis, a crippling disease that turns bones so brittle that someone can break a hip just by walking around inside the house.
More >>>

**May 20 , 2006**

Millions of midlife and older Americans rely on the medication Fosamax to stave off osteoporosis, a crippling disease that turns bones so brittle that someone can break a hip just by walking around inside the house.
More >>>

**April 14 , 2006**

In an interview with WUSA news in Washington D.C. Attorney David P. Ennis of Ennis & Ennis, P.A. spoke candidly about the need for drug makers to warn patients of serious and sometimes life threatening side effects. Attorney David Ennis spoke of the potential for Fosamax to do damage to the jaw bone (osteonecrosis of the jaw) and the lack of a clearly stated warning in the patient

# 7 Consent Forms

# CONSENT FOR DENTAL/SURGICAL TREATMENT FOR PATIENTS WHO HAVE RECEIVED BISPHOSPHONATE DRUGS

Patient's Name Date

Please initial each paragraph after reading. If you have any questions, please ask your doctor BEFORE initialing.

Because you have been treated previously with Bisphosphonate drugs, you should know there is a risk of future complications with dental treatment. Bisphosphonate drugs appear to adversely affect the ability of bone to break down or remodel itself, thereby reducing or eliminating its ordinarily excellent healing capacity. This risk is increased after surgery, especially from extraction, implant placement and other "invasive" procedures that might cause mild trauma to bone. Osteonecrosis of the jaw may result. This is a smoldering, long-term, destructive process in the jawbone that is often very difficult or impossible to eliminate.

Your medical/dental history is very important. We must know the medications and drugs that you have received/taken or are currently receiving/taking. An accurate medical history, including names of physicians, is important.

1. Antibiotic therapy may be used to help control possible post-operative infection. For some patients, such therapy may cause allergic responses or have undesirable side effects such as gastric discomfort, diarrhea, colitis, etc.

2. Despite precautions, there may be delayed healing, osteonecrosis, loss of bone and soft tissue, pathological fracture of the jaw, oral-cutaneous fistula or other significant complications.

3. If osteonecrosis should occur, treatment may be prolonged and difficult, involving ongoing intensive therapy including hospitalization, long-term antibiotics and debridement to remove non-vital bone. Reconstructive surgery may be required, including bone grafting, metal plates and screws, and/or skin flaps and grafts.

4. Even if there are no immediate complications from the proposed dental treatment, the area is always subject to spontaneous breakdown and infection. Even minimal trauma from a toothbrush, chewing hard food, or dental sores may trigger a complication.

5. Long-term post-operative monitoring may be required and cooperation in scheduled appointments is important. Regular and frequent dental check-ups with your dentist are important to monitor and attempt to prevent breakdown in your oral health.

6. I have read the above paragraphs and understand the possible risks of undergoing my planned treatment. I understand and agree to the following treatment plan:

   _____

   _____

   _____

7. I understand the importance of my health history and affirm that I have given any and all information that may impact my care. I understand that failure to give true health information may adversely affect my care and lead to unwanted complications.

8. I realize that, despite all precautions that may be taken to avoid complications, there can be no guarantee as to the result of the proposed treatment.

## CONSENT

I certify that I speak, read and write English and have read and fully understand this consent for surgery, have had my questions answered and all blanks were filled in prior to my initials or signature.

_____

Patient's (or Legal Guardian's) Signature Date

_____

Doctor's Signature Date

_____

Witness' Signature Date

# CONSENT FOR DENTAL/SURGICAL TREATMENT FOR PATIENTS WHO HAVE RECEIVED BISPHOSPHONATE DRUGS

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Please initial each paragraph after reading. If you have any questions, please ask your doctor BEFORE initialing.

Because you have been treated previously with Bisphosphonate drugs, you should know there is a risk of future complications with dental treatment. Bisphosphonate drugs appear to adversely affect the ability of bone to break down or remodel itself, thereby reducing or eliminating its ordinarily excellent healing capacity. This risk is increased after surgery, especially from extraction, implant placement and other "invasive" procedures that might cause mild trauma to bone. Osteonecrosis of the jaw may result. This is a smoldering, long-term, destructive process in the jawbone that is often very difficult or impossible to eliminate.

Your medical/dental history is very important. We must know the medications and drugs that you have received/taken or are currently receiving/taking. An accurate medical history, including names of physicians, is important.

_____ 9. Antibiotic therapy may be used to help control possible post-operative infection. For some patients, such therapy may cause allergic responses or have undesirable side effects such as gastric discomfort, diarrhea, colitis, etc.

_____ 10. Despite precautions, there may be delayed healing, osteonecrosis, loss of bone and soft tissue, pathological fracture of the jaw, oral-cutaneous fistula or other significant complications.

_____ 11. If osteonecrosis should occur, treatment may be prolonged and difficult, involving ongoing intensive therapy including hospitalization, long-term antibiotics and debridement to remove non-vital bone. Reconstructive surgery may be required, including bone grafting, metal plates and screws, and/or skin flaps and grafts.

_____ 12. Even if there are no immediate complications from the proposed dental treatment, the area is always subject to spontaneous breakdown and infection. Even minimal trauma from a toothbrush, chewing hard food, or dental sores may trigger a complication.

_____ 13. Long-term post-operative monitoring may be required and cooperation in scheduled appointments is important. Regular and frequent dental check-ups with your dentist are important to monitor and attempt to prevent breakdown in your oral health.

_____ 14. I have read the above paragraphs and understand the possible risks of undergoing my planned treatment. I understand and agree to the following treatment plan:

_____

_____

_____

_____ 15. I understand the importance of my health history and affirm that I have given any and all information that may impact my care. I understand that failure to give true health information may adversely affect my care and lead to unwanted complications.

_____ 16. I realize that, despite all precautions that may be taken to avoid complications, there can be no guarantee as to the result of the proposed treatment.

## CONSENT

I certify that I speak, read and write English and have read and fully understand this consent for surgery, have had my questions answered and all blanks were filled in prior to my initials or signature.

_____

Patient's (or Legal Guardian's) Signature Date

_____

Doctor's Signature Date

_____

Witness' Signature Date

# Aymee and Steven Spindler, D.D.S.

## Periodontal Specialists

## Important notice to patients taking medications for the treatment of:

**Osteoporosis**
**Osteopenia**
**Bone cancer**
**Post-menopausal bone loss**

If you are currently taking or have been previously treated with Fosamax, Aredia, Actonel, or Zometa you should know there may be a risk of future complications with surgical dental treatment. This is especially true if you have received the drugs directly intravenously.

**Fosamax**
**Aredia**
**Actonel**
**Zometa**

These four drugs, which are taken in pill form, can be associated with the problem of poor bone healing. This reduction in bone healing can occur after dental treatments that affect the bone surrounding your teeth, such as: tooth extraction, periodontal infection, or dental implant placement. If the bone surrounding your teeth does not heal properly, it could result in osteonecrosis of the jaw. This is a destructive process in the jawbone that is often difficult or impossible to eliminate.

If you have ever taken one of these drugs, maintaining your oral health is even more important. Speak to your general dentist and boost your hygiene visits to three of four times per year. Make sure you get at least one dental check-up per year from your general dentist. These additional actions will help prevent complications and preserve your jawbone.

## SIGNATURE

I certify that I speak, read and write English and have read and fully understand the above notice and have had my questions answered.

_____

Patient's (Or Legal Guardian's) Signature Date

_____

Witness Signature Date

# 8 Where to Refer

# Where to Refer

After reviewing the information on osteonecrosis of the jaw, the question becomes where should we send these patients if they appear to have a bone lesion or a bone that is not healing.

The following research paper in this section was written by an oral surgeon. The author suggests that once an osteonecrosis of the jaw lesion becomes evident in a patient who has had surgery, the patient should be sent to an oral surgeon trained in this complication. Ideally the surgeon should have access to a facility where hyperbaric oxygen therapy can be rendered. If we encounter this type of patient, this is how Aymee and I will proceed.

Now, what about patients who are taking or have taken an oral bisphosphonate, like Fosamax, and who need an extraction? Should you ever do the extraction? From what I understand, most dentists are still performing extractions. However, it might be a good idea to check more deeply into the patient's medical history and verify:

1. How long has the patient been taking the medication?
2. Has the patient ever taken bisphosphonates intravenously?
3. Does the patient have a history of cancer?
4. Does the patient have any history of any kind of trouble with the healing of bone tissue other than the jaw? Osteonecrosis of the jaw is a special case of osteonecrosis.
5. Make sure the patient is well educated regarding the risks.
6. Have the patient sign a consent form.

As we learn more about this problem, we will let you know what we find.

Please continue your study by reviewing “Bisphosphonate Induced Exposed Bone of the Jaws: Risk Factors, Recognition, Prevention and Treatment,” by Marx, et al.

**Journal of Oral and Maxillofacial Surg. 63:1567-1575, 2005.**

**This file is attached as joms.pdf**

**If you click on this file in your email it should automatically open the article if you have Adobe Acrobat Reader installed.**

**<u>The Continuing Education Exam</u> is on the next two pages. Please print out the next two pages and make as many copies as you like to share the CE Opportunity with your hygiene staff.**

# Continuing Education

If you would like to obtain 1.5 hours of Continuing Education credit for your study of "Bisphosphonates and Osteonecrosis of the Jaw," please complete the following exam and return it to our office. Please print out this page and the next page. Upon receipt of exams with passing test scores ( 70 % or higher) , we will return a valid CE certificate for any participants via email or fax. **Please feel free to share this educational opportunity with the dental hygienists in your office** by simply copying as many exams as needed and sending them along with yours. You may also fax your completed exam to 504- 613- 4687

1. What percent of osteonecrosis of the jaw cases reported thus far are due to oral bisphosphonate use?
   A. Between 50 to 60 %.
   B. Between 35 to 45 %.
   C. Between 12 to 22%.
   D. Less than 10 %.

2. What are the possible symptoms of osteonecrosis of the jaw ?
   A. Numbness or feeling of heaviness in the jaw.
   B. Pain, swelling or infection in the tissues near the necrosis site.
   C. Looseness of teeth near the necrosis site.
   D. Exposed bone.
   E. B,C,and D above.
   F. All of the above.

3. Identifiy the possible risk factors for osteonecrosis of the jaw ?
   A. A diagnosis of cancer.
   B. Concomitant cancer therapies of chemotherapy, radiotherapy or corticosteroid therapy.
   C. Co-morbid conditions like anemia, coagulopathies, anemia or pre existing oral conditions.
   D. All of the above.
   E. None of the above.

4. What possible conditions listed below are bisphosphonates commonly used for ?
   A. Bone pain associated with metastatic bone disease.
   B. Paget's disease.
   C. Osteoporosis.
   D. Addison's disease.
   E. Adrenal insufficiency.
   F. All of the above.
   G. A, B, and C above.

5. What should be done for a dental patient about to receive bisphosphonate therapy ?
   A. Advise them to wait until the drug regimen is complete to resume their preventive dental care.
   B. Advise them to have all of their amalgam restorations replaced with composites.
   C. Perform a comprehensive dental examination.
   D. Complete all necessary dental treatment whenever possible before bisphosphonate treatment begins.
   E. Develop and implement an appropriate preventive care schedule for the patient.
   F. Only A and C above.
   G. C, D, and E above.
   H All of the above.

6. Osteonecrosis literally means death of bone. True False
7. Osteonecrosis of the jaw only occurs with intravenous bisphophonates. True False
8. Bisphosphonates are a class of drugs that inhibit the resorption of bone. True False
9. Obtaining an Informed Consent would be prudent before treating these patients. True False
10. In study by Marx, et. al., osteonecrosis of the jaw affects the mandibular bone with a greater incidence than the maxillary bone. True False

Please continue on reverse side

**First Name:** _____

**Last Name:** _____

**E-mail Address:** _____

**Fax Number:** _____

I am a: Dentist Dental Hygienist

License Number:

If you are an AGD Member please provide your Membership Number-
_____

**To help us evaluate our Continuing Education (CE) courses, we would appreciate it if you would take a few moments to answer the following questions:**

**1) Thinking of the CE course you just took, how would you rate it overall?**
Excellent Very good Good Fair Poor

**2) How well did this CE course meet your expectations?**
A. Much better than expected.
B. Somewhat better than expected.
C. About the same as expected.
D Somewhat worse than expected.
E. Much worse than expected.

**3) Did you find this type of education is beneficial to you? Yes**
**No**

**4) Did you find the material presented was applicable to your practice? Yes**
**No**

**5) List any suggestions for improvement.**
_____
_____
_____
_____
_____

***Steven J. Spindler, D.D.S. has been designated an approved sponsor by the Louisiana constituent of the Academy of General Dentistry. This sponsors formal CDE programs are accepted by the AGD for membership maintenance, Fellowship and Mastership credits. Sponsorship approval extends to 11-14-2008.***