

The Bone Health Revolution

by Vivian Goldschmidt

Free Sample Chapter

Notice: This book is not intended to replace recommendations or advice from physicians or other healthcare providers. Rather, it is intended to help you make informed decisions about your health and to cooperate with your healthcare provider in a joint quest for optimal wellness. If you suspect you have a medical problem, we urge you to seek medical attention from a competent healthcare provider.

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Chapter 5

THE DANGERS OF DRUGS USED TO TREAT OSTEOPOROSIS: WITCH'S BREW OR PANACEA?

WHY YOU SHOULDN'T EAT LAUNDRY DETERGENT AND OTHER CLEANING PRODUCTS.

Let's take a closer look at the osteoporosis drugs currently used by millions of people worldwide. These medicines are classified as bisphosphonates which are synthetic analogs of pyrophosphates. It is a fancy name for a common ingredient used for many years in laundry soaps, fertilizers, and industrial lubricants to prevent corrosion. They are still widely used mainly in the textile industry (laundry products) and oil industries (additives in engine hydraulic fluids, as another example). In fact, when you do an internet search of the word pyrophosphates, you will get among the results the websites for osteoporosis medicines and several U.S. patents for detergents, hydraulic fluids and toothpaste.

There are three medicines available that can be taken orally.

- Fosamax is the world's top-selling bisphosphonate, approved by the FDA in 1995. It is Merck's second best-selling drug, with sales in 2005 of \$3.2 billion, according to the Associated Press., and the drug research firm IMS Health reports that in the US alone, more than 22 million prescriptions for Fosamax were written last year.
- Actonel became the fastest product in Procter & Gamble's history to reach \$1 billion in sales. Coincidentally, Procter & Gamble is the manufacturer of Tide laundry detergent and Crest toothpaste, among many other products. In my research I discovered that both Tide and Crest contain bisphosphonates. In Crest, the bisphosphonates act as an anti-tartar agent.
- Boniva was developed by Hoffman-LaRoche, and is co-marketed with GlaxoSmithKline, with sales reaching \$417 million for 2006. It can be taken once a month while Fosamax and Actonel must be taken weekly.

Novartis markets Aredia and Zometa, the two intravenous versions used in chemotherapy. Nearly 3 million cancer patients have been treated with these intravenous drugs.

For business and for pressure (pun intended)

The osteoporosis drug arena is a dream come true to its manufacturers: total market sales of osteoporosis drugs are forecasted to reach 10.4 billion by 2011. And doctors are somewhat held captive by the current mainstream belief that Osteoporosis is a disease that requires treatment. In a conversation I had with a physician (who asked me to remain anonymous), he told me that if the Bone Density Test results show that the patient has osteoporosis (following current diagnostic guidelines), he is forced to prescribe a drug, because should the pa-

tient break a bone he could get sued for malpractice. "But I tell them that they don't have to take it", he remarked. Now that's what I call an effective marketing campaign: doctors under the pressure to prescribe, fearing multi-million dollar lawsuits if they don't!

Osteoporosis meds: bone builders or bone hardeners?

As explained in Chapter 3, the bisphosphonates attach themselves to the bone matrix, altering its normal function by affecting the normal replacement of old bone with new bone. Indeed, bone loss will be drastically reduced; but at what price? A very high price, because what the makers of these prescription drugs don't mention is that, as explained in Chapter 3, inhibiting bone loss also inhibits new bone formation. Bones remain thick, but old bone is more prone to fractures than less dense yet more flexible newer bone.

Not surprisingly, researchers have found that these medicines can make the bones more brittle, actually increasing the risk of fractures. "Many people believe that these drugs are 'bone builders,' but the evidence shows they are actually bone hardeners," wrote Dr. Susan M. Ott in the *Annals of Internal Medicine* in 2004, pointing out that they depress "the bone resorption rate as well as the bone formation rate" and "bones could become brittle with long-term accumulation."

Adding insult to injury, the bisphosphonates remain in the bone forever and worse, no one knows the long term side effects this could cause, independently of the direct effect it may have on bone chemistry.

By now you are probably wondering if bisphosphonates are safe or not, and if they aren't safe, how come there are millions of prescrip-

tions written every year. Continue reading to find out what's really going on "behind the scenes" and to draw your own conclusions.

The long saga of side-effects

The longest study to test Fosamax for safety and efficacy took place for ten years during which time half of the test population dropped out because of intolerable side-effects. According to Business Week, researchers have found that 70% of patients taking top-selling osteoporosis drugs drop out in the first year of treatment because of heartburn, ulcers, and other side effects.

The most common complaints users have are gastrointestinal abnormalities which can include:

- Nausea
- Abdominal cramping
- Flatulence
- Diarrhea
- Obstipation (severe constipation)
- Inflammation and ulceration of the esophagus
- Chest Pain, heartburn or difficulty swallowing

These side effects are not surprising at all if you realize that patients are unknowingly attempting to digest a chemical found in laundry detergents, cleaning liquids for toilet bowls and for all kinds of floors among other things.

There are other general side effects that can result from the use of bisphosphonate drugs:

- Skin rash

- Eye problems, vision loss, blurred vision
- Generalized pain of the muscles, joints and/or bones
- Decreased mobility of the joints
- Blood clotting disorders
- Anemia
- Dental problems
- Numbness, tight muscles in the face as well as seizures
- Irritability and unusual thoughts or behaviors.
- Altered taste

The worst irreversible side-effect

By far, one of the most serious side effects of these drugs is osteonecrosis of the jaw, also known as dead jaw. Osteonecrosis is characterized by the inability of the jaw to heal following dental trauma or surgery, which can cause the jawbone tissue to become infected, rot and eventually die.

The first case of osteonecrosis was reported in 2003. Why osteonecrosis occurs is unclear - although it generally appears after dental surgery or tooth extraction, and in some cases it develops spontaneously.

Osteonecrosis of the jaw can be an incredibly painful problem. It often causes ulcers of the mouth and skin sores, infections, exposed bone, and disfigurement.

These are some of the symptoms of osteonecrosis:

- Pain, swelling, or infection of the gums
- Loosening of teeth
- Poor healing of the gums

- Numbness or the feeling of heaviness in the jaw
- Partial or complete loss of the jaw bone

Given the severity of these symptoms and the difficulty and sometimes impossibility of treating this serious condition, the American Association of Oral and Maxillofacial Surgeons is investigating the link between bisphosphonates and osteonecrosis. Some dental experts predict that up to 10% of people who received bisphosphonates may be affected by osteonecrosis of the jaw at one point in their lives, especially patients who have taken the medicine for many years.

When everything else fails...try an IV

Unlike oral bisphosphonate therapies that have to be taken daily, weekly or monthly, Reclast is given as a once-yearly 15-minute intravenous (IV) infusion.

It was originally developed by the Swiss company Novartis and approved by the FDA in the year 2007 for the treatment of Paget's disease. This condition is a metabolic and often painful bone disorder that causes abnormal bone growth due to a malfunction in the body's regular bone-building process. It is also used to treat bone cancer under the name Zometa, but in a different dose. Reclast is now also prescribed to simply "treat" osteoporosis.

The most common side effects associated with Reclast are fever, pain in the muscles, bones or joints, flu-like symptoms, and headache. This drug also has warnings of possible osteonecrosis of the jaw, kidney problems, and increased risk of a serious cardiac condition called atrial fibrillation.

Interestingly, the earliest cases of Osteonecrosis of the jaw were reported by patients taking intravenous doses of bisphosphonates. It is relevant to mention here a study conducted in Japan on dogs injected with bisphosphonates. Based on the study results, T. Mashiba and colleagues seem to suggest (and therefore confirm Susan Ott's observations quoted earlier in this book) that microfractures increase and may accumulate as a result of the hardening of the bone caused by bisphosphonates.

Playing with hormones can be no fun at all

Besides the bisphosphonates, a relatively new way to treat Osteoporosis is with a daily injection of Forteo . This drug, approved by the FDA at the end of 2002, is a synthetically manufactured form of the Parathyroid Hormone (PTH).

Forteo is an incomplete man-made copy of human PTH because natural parathyroid hormone has 84 amino acid residues and the synthetic version has only 34. According to Eli Lilly, its manufacturer, research demonstrates that only 33 to 35 are necessary for biological activity. So they settled for 34.

Here's a summary of the very important role the parathyroid glands play in relation to bone health:

- The four parathyroid glands monitor the calcium in the blood 24 hours a day.
- The parathyroid glands make more or less parathyroid hormone (PTH) in response to the level of calcium in the blood.
- When calcium levels in our blood are too low, the parathyroid glands make more PTH.

- Increased PTH causes the bones to release their calcium into the blood.
- When calcium levels in our blood are too high, the parathyroid glands stop producing PTH.

The most common side effects of Forteo are body aches and headaches.

Other reported side effects are:

- Chest pain
- Constipation
- Difficulty swallowing
- Feeling lethargic
- Heartburn or pain upon swallowing
- Irritation or pain of the esophagus
- Muscle pain and weakness
- Increased sweating
- Skin rash
- Nausea and vomiting

This is a warning posted in the official Forteo website:

“Blood and urine calcium levels: Your doctor may test your blood and urine for calcium levels to make sure that they are within the normal range. If you experience nausea, vomiting, constipation, lethargy, and muscle weakness, contact your doctor as soon as possible.”

And below I’m quoting an unbelievable BLACK BOX warning about Forteo that in my opinion makes it unacceptable:

“In male and female rats, teriparatide caused an increase in the incidence of osteosarcoma (a malignant bone tumor) that was dependent on dose and treatment duration. The effect was observed at systemic exposures to teriparatide ranging from 3 to 60 times the exposure in humans given a 20–mcg dose. Because of the uncertain relevance of the rat osteosarcoma finding to humans, teriparatide should be prescribed only to patients for whom the potential benefits are considered to outweigh the potential risk.”(www.drugs.com)

Eli Lilly has explained that teriparatide has been used in clinical trials involving more than 2,000 participants, and not one case of osteosarcoma has been reported. A spokesperson for Eli Lilly of Indianapolis said that the FDA approved Forteo under several conditions, and the company is conducting a post approval osteosarcoma surveillance study. Because of this still unresolved issue, Forteo is used only for a two year treatment period.

We should be afraid of tampering with the very delicate and complex balance of our natural parathyroid hormone activity. Forteo’s potentially deadly side-effects and short history make it a very unattractive therapy option for the treatment of osteoporosis.

Double duty and double trouble

Evista (raloxifene hydrochloride) was approved by the FDA in 1997 for the treatment of osteoporosis in postmenopausal women, and like Forteo, it is manufactured by Eli Lilly. Additionally, Evista got its FDA approval ten years later to reduce the risk of invasive postmenopausal breast cancer.

This double-duty medicine is the first in a class of new drugs called selective estrogen receptor modulators (SERMs) approved to treat osteoporosis. It is supposed to have the selective ability to act like estrogen in some tissues but not in others.

Raloxifene is reportedly easier on patients' digestive systems than bisphosphonates but it may cause an increased risk of both venous thromboembolism (VTE; deep vein thrombosis, pulmonary embolism, and retinal vein thrombosis) commonly described as blood clots and stroke, especially in women who are at high risk of having a heart attack. Besides the very serious combo of side-effects, hot flashes are commonly reported when taking Evista.

Long-term side effects of this drug are still unknown and common sense would lead us to think that interfering with our normal hormonal balance with the purpose of treating future fracture risk is not a good idea, especially in view of the serious potential side effects already in record.

Treating Osteoporosis a la French

There is a new medicine used to treat Osteoporosis in Europe called Protelos. It is a synthetic form of strontium ranelate manufactured by France's largest independent drug company Servier. Because strontium is a natural product it isn't patentable. Therefore, by creating the novel combination of strontium and ranelic acid (because the latter is a purely synthetic molecule), Servier was able to obtain a patent and convert this mineral into a prescription drug.

Protelos (also marketed as Bivalos, Osseor, Ossum, Protaxos, and Protosis) has not been approved by the FDA and is not available in America as of yet. It may show up eventually as a prescription drug in

the United States and Canada. However, strontium citrate and other forms of strontium can be found in America as over-the-counter supplements.

Protelos has its own list of side effects. During clinical trials, the most common side effects were nausea, diarrhea, headaches and skin irritation. Other quite dangerous but fortunately less commonly reported side-effects were blood clots, fainting, memory troubles and, in rare cases, seizures.

We must remember that long-term safety and efficacy of any form of strontium (except for Servier's studies) have never been evaluated on humans using large-scale medical trials. And furthermore, some scientists point out that it would be difficult to assess actual bone improvement because traditional bone mineral tests like DEXA will give artificially high results as strontium is much denser than calcium.

Recent short-term studies on Strontium show that it contributes to bone thickening. Several forms of strontium salt have been used in clinical studies and each strontium salt has had thickening results for bone, so it is hypothesized that strontium is the active component, and not the carbonate, ranelate, lactate, or citrate part the strontium is attached to. Obviously, this is a very touchy subject with Servier laboratories.

George Boivin and colleagues at Universite Claude Bernard in Lyon, France, suggest that strontium does not affect the quality of the bone mineral, but that it does affect the quantity. In other words, the outer cortical bone becomes thicker. This was confirmed by Jiang and colleagues at the University of California and the University of Michigan Osteoporosis and Arthritis Lab.

These findings seem to indicate that strontium affects the normal bone remodeling process by thickening the bones. Let's not forget that thick bones may be more prone to fracture than thinner, more flexible bones.

Our bodies naturally contain between 320 to 400 mg of strontium, a trace element chemically very similar to calcium. So similar, in fact, that strontium competes with the calcium protein carrier in our blood (that is why it's supposed to be taken at least 4 hours after or before taking calcium). Calcium is the naturally occurring bone mineral that handles our bone strength, not strontium.

Regardless of the results, altering the very delicate mineral balance in our bones could one day prove to have harmful effects that we don't know as of yet.

Merck's legal woes are just beginning

I was not surprised when during my research I found an article published by Consumer Affairs (June 2007) reporting that Merck has put aside \$48 million to set up a defense fund for lawsuits related to Fosamax. It is one tenth of what the company spent on legal costs for Vioxx in 2006. Yet the fact that they are already creating a reserve for legal costs can make anyone suspicious that Merck knows something that the general public doesn't know, at least for the time being.

Quoting the same Consumer Affairs article, "Merck's CEO Richard Clark said the company now faces about 104 cases over Fosamax, the bulk of which have been filed in federal court. He added that the first of these cases will likely not go to trial until 2008."

Although this may seem like a negligible number of personal injury lawsuits for a company as large as Merck & Co., especially compared to the roughly 27,400 lawsuits still pending against Merck because of Vioxx, many legal experts believe that it is only the beginning. They expect the filing of thousands more cases in the future.

Since almost half of the women over 50 are alleged by conventional medicine to be at risk of osteoporosis, it looks as though we are in the midst of another public experiment of much greater scope than the HRT and Vioxx fiasco combined. Is it possible that in this day and age humans are used as guinea pigs? Once again, I invite you to continue to read and to formulate your own opinion.

Killing an ant with an elephant

With this information on hand, it is quite obvious that the "cure" seems a lot worse than the disease, something not uncommon in modern medicine. Also, we must be aware that more often than not, side-effects of medicines are treated with yet more medicines that have their own side effects.

For example, when patients taking osteoporosis medicines complain of gastrointestinal discomfort, doctors are typically not ready to stop the drug treatment and will therefore prescribe an acid reducer such as Nexium or Prevacid, the most popular proton pump inhibitors. Little does the patient know that these medicines hinder the proper absorption of calcium, causing even more bone loss by depriving the body of this crucial mineral. It is clear that bone health is highly dependent on your stomach's ability to digest important nutrients such as calcium and other minerals and vitamins.

As far as the unquestionable inflammatory effect of osteoporosis drugs, a common side effect is painful muscles and joints; sometimes with decreased mobility. Adding insult to injury, stiff and dried-up bones most likely contribute to that painful condition as well. Again, most of the time doctors will persist with the osteoporosis treatment and tackle this side effect by recommending an over-the-counter pain-killer, typically a non-steroidal anti-inflammatory drug (NSAIDS) such as Aleve (naproxen). It is not a secret that NSAIDS can cause gastrointestinal bleeding. A limited study of Fosamax combined with Aleve showed that around 40% of users developed stomach ulcers and almost 70% of users experienced serious side effects.

Again, by hurting the lining of the stomach, among other things, these drugs actually hinder the correct digestion of minerals and vitamins needed to maintain bone health.

You will soon find out that there is an easy and natural way to maintain healthy bones at any age without taking toxic medicines. The last chapter in this book will show you exactly how to do that. It's about time we try to prove Albert Einstein wrong. He said that "Only two things are infinite, the universe and human stupidity, and I'm not sure about the former."

LET'S SUMMARIZE:

Osteoporosis medicines are derived from industrial chemicals used mainly in laundry detergents and other cleaning products. The three main brands are prescribed in the billions of dollars with little research to prove their safety and long-term effects. We cover in detail the gruesome side-effects and how they affect the result of bone density tests.

WHAT THIS MEANS TO YOU:

Understanding what osteoporosis medicines are made of, their side-effects, and long-term safety begs for an in-depth analysis of the validity of current prescription drug treatment protocols. Bearing in mind that a true osteoporosis diagnosis is rarely accurate, its treatment with dangerous drugs is unnecessary and often times causes more medical problems that require more drugs to treat. It's a loose-loose situation for the patient, particularly when there are safe and healthy methods to prevent bone loss.

This chapter was taken from my book 'The Bone Health Revolution.'

The information herein is just some of the many findings revealed in the book.

For more information on 'The Bone Health Revolution' and on how you can prevent and even reverse osteoporosis and osteopenia without drugs....

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To your health,

Vivian Goldschmidt