

THE DELUSION OF BONE DRUGS

By Byron J. Richards, CCN, January 15, 2008

Women across the country are being duped to consume billions of dollars worth of bone poisons under the false pretense that if they take them long enough they will not develop osteoporosis. Even the FDA is becoming alarmed by the side effects of these bone drugs – a rather stunning event considering the FDA hardly ever acts to cast suspicion on the propaganda put out by a Big Pharma blockbuster class of drugs being slickly marketed for prevention.

The drugs in question are known as bisphosphonates. The biggest selling drug in this class is called Fosamax, made by Merck – the very same company that killed thousands of Americans with Vioxx while hiding cardiovascular risks from the FDA and patients. Does anyone trust them? Other commonly recognized names are Actonel (Proctor and Gamble) and Boniva (Roche and GlaxoSmithKline). Collectively these drugs had \$4.3 billion in U.S. sales during 2006 (27 million prescriptions).

A recent flood of negative information about these drugs is finally coming to light, including an alarming FDA pain warning, the risk for atrial fibrillation, the numerous cases of rotting jaw bones, and a new major study that concludes after 15 years of widespread use there is not enough science to show if the medications are safe or effective. Sure bone health is extremely important; however, taking bisphosphonate bone drugs does not produce stronger or healthier bones – quite to the contrary.

The FDA Warning – Severe Pain from Bone Drugs

On Monday, January 7, 2008, the FDA [issued a warning](#) on bisphosphonate drugs saying that there is a possibility of “severe and sometimes incapacitating bone, joint, and/or muscle (musculoskeletal) pain in patients taking bisphosphonates.” The FDA explained that the pain “may occur within days, months, or years after starting bisphosphonates. Some patients have reported complete relief of symptoms after discontinuing the bisphosphonate, whereas others have reported slow or incomplete resolution.”

Translated to English this means that any woman experiencing any bone, joint, or muscle pain of any kind since starting a bisphosphonate bone drug, even if the pain started several years after first taking the drug, should work with her prescribing physician to immediately discontinue use of the drug to see if the pain stops or gets better. Of course, taking [statins to lower cholesterol](#) can also cause severe muscle pain and many women are on both drugs – a double whammy.

Think about it for a minute – how could a drug that is supposed to be good for bones cause incapacitating bone pain in anyone?

Since the FDA has trouble understanding how the drugs it has approved behave in the human body, they had no explanation as to why bone drugs were causing such horrendous pain. Thus, I will be happy to explain the nature of the problem.

Bisphosphonates are Highly Inflammatory Drugs

Bisphosphonates are a caustic chemical. They damage any human tissue they come in contact with. They have been proven to induce inflammation by direct contact with body surfaces and they have been proven to set in motion a chain reaction of inflammatory events. Indeed, one way they work is by poisoning to death a type of bone cell known as an osteoclast. The medical profession thinks it is a good idea to poison osteoclasts because there are too many of them in people with accelerated bone loss. Never do they bother asking why there are too many and treat the source of the problem. Even though osteoclasts are a normal bone cell required for healthy bone metabolism, the pushers of these poisons have come up with an excuse to perform a type of chemotherapy on bone cells, often in the name of preventive health!

It has been proven beyond any doubt that these drugs cause swollen bone due to their highly inflammatory nature. In fact, the unreliable and inaccurate X-Ray-generated pictures doctors claim are better bone density after a person has been taking these drugs for a while are actually pictures of swollen and inflamed bone that is being chaotically disorganized and weakened by these drugs. A sprained ankle looks bigger than a normal ankle, so does a sprained bone.

It is worth noting that in addition to the fact the pictures are of swollen bones, the pictures themselves are never an accurate measure of true bone density in any person. These bone pictures are referred to as Dual energy X-ray Absorptiometry (DXA). The flaws include a huge variance in human operator skill and the inability of the machine to judge bone depth, thus all pictures are guesses anyway. The best-guess reference charts are easily skewed by tall people, short people, thick-boned people – and the lack of skill of the machine operator. The pictures cannot show bone strength or bone integrity (a convenient shortcoming for bisphosphonate drugs). Because bisphosphonates also glue calcium in an abnormal manner onto bone, the mirage is that there appears to be more density – true smoke and mirrors. Numerous studies with bone biopsy show that bisphosphonate-treated bone is actually swollen, chaotically disorganized, and weaker than healthy bone.

If you would like to understand the details of this issue, as well as basic bone metabolism, you may read for free [Chapter 18: The Illusion of Bone Drugs](#), from my book *Fight for Your Health – Exposing the FDA's Betrayal of America*. Also, included in the appendix are numerous references documenting all of the many side effects of these drugs up through 2006.

The FDA is now warning that at some point while taking these drugs there can be intense and even debilitating pain. This is obviously due to the caustic and highly inflammatory nature of these drugs.

Here is a question for the medical profession. Since it is now clearly understood that excessive inflammation is part of the primary cause of every single disease of aging – what makes you think you are helping the overall health of anyone by giving them a highly inflammatory bisphosphonate drug for a number of years?

Of course, doctors may warn their patients to walk around after taking these drugs and not lay down. This is because bisphosphonates are so caustic and inflammatory to the digestive system that they may cause significant damage to the lining of the intestinal tract. In fact, the drug is only 1% absorbed which leaves 99% of the poison to batter the digestive lining. The drug even comes

with warnings not to give it to people with digestive problems – a warning that is routinely ignored by many prescribing physicians.

The FDA issued its pain warning because doctors are also ignoring that bisphosphonates are a likely cause of a terrible inflammatory pain which may even start long after first taking the drug. Doctors have been treating this pain with pain killers, the typical style of the drug-dispensing paradigm governing “modern” medicine – give one drug to offset the side effects of another (IQ=70).

If we had to stretch the imagination of these brilliant men of medicine then possibly they might conceive of the notion that once this caustic drug is absorbed and before it arrives at the bones to work its inflammatory damage in the name of “health,” it must go through the circulation and past the heart. Would you like to guess what the drug is doing while it is in the cardiovascular system? Are doctors somehow not aware that filling the arteries with plaque, which leads to heart attacks and strokes, is clearly an [inflammatory disease](#)?

Bisphosphonates Increase the Risk for Atrial Fibrillation

Since October 1, 2007 the FDA has also announced that it is reviewing the link between bisphosphonate drugs and atrial fibrillation (a potentially life-threatening heart problem). The [FDA updated its posting](#) about this issue on January 7, 2008 when it released its pain warning. In essence, the FDA says it is confused about the issue and trying to study the matter.

This is simply another instance of FDA incompetence and failure to do its job. Back in 1997 it was clear to the FDA that a Merck study showed a 50% increased risk in serious atrial fibrillation from Fosamax. The FDA did not demand that Merck conduct a specific post-marketing safety analysis relating to atrial fibrillation. This was a major failure on the part of the FDA to protect the public. Thus, the only data the FDA can review are studies regarding bisphosphonates that may report atrial fibrillation but are not designed to test for it. The FDA also has its MedWatch program, but most physicians and patients don't link the two issues so don't know to report it.

The FDA is only now becoming interested in the issue as a new type of powerful bisphosphonate that involves a once a year intravenous infusion are showing a 150% increased risk for atrial fibrillation. This is obviously a higher potency of the drug in the circulation, giving its highly inflammatory and caustic characteristics more of a chance to weaken the heart in one major “blast attack.” If this therapy catches on with women atrial fibrillation problems will triple.

The FDA says it plans to drag its feet on the issue for another 10 months, at which point it is likely to say it does not have enough data to know for sure one way or the other – great job FDA. It appears that any woman taking bisphosphonates who has a concern about heart health should think twice – considering the FDA has no clue what the real risks are. While the risk of a problem may be only 0.5% to 1% of those taking the drug, that can easily translate to 15,000 – 30,000 cases of serious atrial fibrillation per year based on the large numbers of women on these medications.

Of course, if a patient should develop atrial fibrillation due to a bisphosphonate drug then their doctors will put them on the rat poison called Coumadin (Warfarrin). This drug has been shown to

increase the [risk of fractures by 25%](#) after one year of use.

Atrial fibrillation is not the only potential cardiovascular risk. Science shows that bisphosphonates [activate adhesion molecules](#) which are known to initiate plaque formation in arteries. A mouse study shows that bisphosphonates trigger the [rupturing of atherosclerotic plaque](#) – which causes strokes and heart attacks in humans. The FDA is not demanding the makers of these drugs prove they are safe for cardiovascular health and that they do not contribute to plaque formation in the arteries. Once again, the FDA has left the public groping in the dark. We already know that Merck does not disclose heart risks of its drugs to the FDA or the public, as clearly proven by the Vioxx case.

Rotting Jaw Bone

Here is another simple question. How can a drug that rots out someone's jaw bone possibly be good for the bones of any person?

Rotting jaw bone, otherwise known as osteonecrosis of the jaw, became a hot topic back in the summer of 2005 when it was first widely reported that patients on intravenous bisphosphonates ran the risk of developing this debilitating jaw condition, especially if they needed some dental work done.

As the drama unfolded patients taking oral Fosamax began reporting their deteriorating jaw bone problems, now known as Fossie jaw. Merck currently faces a number of [lawsuits](#) on the issue.

Individuals who need any kind of significant dental work should think twice before taking a bisphosphonate drug, as their jaw may have trouble healing and teeth may have trouble staying firmly in place. While having one's jaw rot completely out is a horrendous problem, it is far more likely that many people are experiencing jaw-related stress and wear from these drugs. Any person developing TMJ, jaw pain, or any kind of dental problem after being on a bisphosphonate should be very concerned.

[Japanese researchers warned](#) of this problem back in 2000 and the need to be cautious for jaw health in patients taking Fosamax, but the FDA was not paying any attention. In fact, the FDA let millions of American women take this drug to prevent osteoporosis when the drug never even went through a normal approval process for its common uses in today's world (it was only approved for serious bone disease). This is rather shocking to say the least – but true.

How Bisphosphonate Bone Drugs Work

The bisphosphonate bone drugs work in two main ways:

A) By killing osteoclasts – the carpenter cells in charge of the demolition part of the remodeling process. New healthy bone cannot be built by osteoblasts until old worn bone has been removed by osteoclasts.

B) By gluing calcium onto bone in abnormal ways, providing the appearance of greater bone density. However, this is like nailing a piece of plywood over a hole in the wall. Yes, there is

something there, but it is not a normal wall and it does not have the proper strength of a normal wall.

Once bisphosphonates arrive at bone they are stuck there forever, as a completely abnormal substance residing within and on the bone. The human body has no enzyme system that can break them down. Thankfully, after one year the biological activity of the poison is reduced; however, it is still stuck in the bone indefinitely. It is not a trivial issue to give a patient a toxic drug that accumulates in bones and is highly active even after it is stopped, which explains why some of the patients did not get rid of their pain even after discontinuing the drug.

Such a therapy may have some advantages in a situation of very poor health wherein a person is rapidly losing bone. The idea is that it is better to have some bone, regardless of its true condition, compared to no bone. Indeed, these drugs were first approved for diseases of rapid bone loss, such as Paget's disease. In such high risk cases it can be demonstrated that the risk of fracture can be reduced. In other words, bones glued together with Fosamax may be better than really weak bones in horrid health.

However, healthy bone has a fairly high activity of osteoclasts (the demo crew) and osteoblasts (bone building carpenter cells), operating in balance. By killing osteoclasts all that happens is old bone is left in place and new bone can't properly form due to all the clutter in the way – resulting in highly disorganized and abnormal bone matrix. This is a far cry from healthy bones. If a healthy woman does this for 5-10 years in an effort to ward off osteoporosis it is pretty clear that she has been conned – and actually worsened her bone health.

A Comprehensive Review of Bone Drug Effectiveness

A major study was recently conducted in an effort to compare these bone drugs to other drug options to see which drugs or therapies actually produced the best patient outcomes in the real world. The goal of such research is to help prescribing physicians know what options are best based on scientific review. The researchers found that bisphosphonates were no better than anything else – a disturbing finding in and of itself.

The research was reported in a January 2008 issue of the *Annals of Internal Medicine* ([full article here](#)). The conclusion of the study states “Although good evidence suggests that many agents are effective in preventing osteoporotic fractures, data are insufficient to determine the relative efficacy or safety of these agents.” This conclusion, worded to be as politically correct as could be contrived in a drug-related journal, is a shocking indictment of the ineptitude of the FDA. How could a drug be in use for 15 years, with billions of dollars of sales per year, and the FDA has never demanded proof that the drug was safe or effective???

The bisphosphonates, as I explain above, work best in people with serious bone health issues wherein bones glued together with bisphosphonates are better than extremely fragile bones. Here we can see a slight reduction in fracture in a difficult patient population, which is a valid use of medicine. Keep in mind that there are not enough people in this high risk group for Big Pharma to make a profit. Big Pharma has to convince low risk people (millions of baby boomers) to take these

drugs for 10 years as a prevention tool – a marketing campaign that has been in full swing for a number of years (a low risk population).

When you look deep within this study about the use of Fosamax in this low risk population the study authors state Fosamax in this group “may in fact have had no effect on or even have increased the risk for fracture.” Not exactly a glowing report for a drug that is being crammed down the throats of generally healthy women in the billions of dollars per year. And far different than the fudged conclusion the media is likely to read.

An unbiased conclusion of this study would be “Various drug therapies, including bisphosphonates, may be able to reduce the risk of osteoporotic fractures in some patients in the high risk category – though safety and efficacy is not clear. In the low risk category there is no evidence of long-term benefit, and safety and efficacy is also not clear – there may even be a risk for fracture increase.”

Bone Health is Important

Bone health is very important. There are many dramatic discoveries relating to bones and how to help them, all centered on safe and natural options to improve health. The new science shows that the reason there are too many osteoclasts causing bone loss is because of an underlying inflammatory problem in the bones – part of an overall inflammatory wear and tear trend. When this trend occurs at a normal pace it is considered routine aging. When this inflammatory trend is accelerated then the weakest link in the chain manifests as a disease (heart disease, cancer, Alzheimer’s, osteoporosis, etc).

It is sheer idiocy to treat an inflammatory bone problem with an inflammatory bone drug, especially for prevention. Numerous nutrients are now proven to directly lower inflammation in bone, thus naturally promoting the healthy balance and function of osteoclasts and osteoblasts. There are no shortcuts or quick fixes for bone health. Stress is highly inflammatory and a major problem. The foundation of a proper plan is a good diet, maintaining proper body weight, consistent exercise that produces fitness, having some fun in life, and dietary supplements that work directly with the gene signals within bones to foster health and build strong bone - naturally. It is time that we as a culture put to rest the barbaric use of toxins that do nothing but bolster the profits of Big Pharma at the expense of human health.