HEALTH AND STRESS

The Newsletter of
The American Institute of Stress

Number 6 June 2010

ARE DRUG COMPANIES NOW SELLING SICKNESS?

KEYWORDS: Pharmacracy, osteomalacia, osteopenia, Bone Measurement Institute, The Bone Measurement Act, Actonel, Boniva, Reclast, ONJ, phossy jaw, Aredia, Zometa, biphossy jaw, Evista, SERM, Prolia, Forteo, alendronate, CBD/PTH, PEMF bone growth stimulators, vibrating platforms and astronauts, Pulsed Signal Therapy

Up until the last century, the primary purpose of developing new drugs was to treat or prevent disease. Over the past six decades, there has been a progressive proliferation of pharmaceutical companies promoting multiple medications, many of which fiercely compete for the same patients. As a result, their goal is now to produce patented products to increase income for executives and shareholders, rather than the health of consumers. There is little doubt that this has been phenomenally successful, as evidenced by the fact that drug companies have consistently been the most profitable U.S. industry, and that pharmacracy now dominates the practice of medicine.

Also Included In This Issue

Pharmacracy is a term that was coined in 1974 by Thomas Szasz because "while we have words to describe medicine as a healing art, we have none to describe it as a method of social control or political rule." It is derived from the Greek *pharmakon* (medicine or drug) and *kratein* (to rule or to control), just as theocracy is rule by religious sects and democracy is rule by the majority of people.

Pharmacracy refers to 1) **The transfer of authority for defining diseases and how to treat them** from physicians to politicians (and others who are reimbursed by pharmaceutical manufacturers). 2) **A deliberate blurring of boundaries between disease and non-disease** and between medical treatment of disease and the use of medical personnel or technology to alter

non-disease. 3) **The severing of contractual economic relationships between doctors who deliver medical care and patients who receive it**. While originally designed to illustrate how this applied to the specialty of psychiatry, pharmacracy has now metastasized to permeate and essentially control virtually every facet of medical research and practice.

This emphasis on disease mongering and the selling of sickness has been facilitated by regulatory agencies, legislators, prestigious medical institutions and organizations, prominent physicians, insurance companies and other influential groups or individuals, all of which receive huge payments and other perks for their promotional efforts. **Approximately $5 billion are spent annually on direct to consumer ads** on TV and print media presumably designed for educational purposes, but are primarily messages that hype benefits and minimize dangers, which is why they are banned in all other countries save New Zealand. The price tag for up to 100,000 drug company representatives **to promote products to U.S. practicing physicians is well over $7 billion/year**. The pharmaceutical industry, health organizations and insurance companies **spend over $1.5 million/day lobbying members of Congress** to preserve and possibly increase their current exorbitant profits. It is estimated that **annual pharmaceutical marketing expenses may be close to $57 billion, which is over twice as much as is invested for drug research and development.**

Why We Spend Much More On Health Care But Are Sicker And Die Earlier

As a result, the U.S. pays much more for health care per capita than any other country. We spend over 44 percent more than Switzerland, which is the next highest, over twice as much as Great Britain, and four times as much as South Korea, whose citizens live at least a year longer than we do. Several months ago, a *New York Times* article touted a Centers For Disease Control report indicating that in 2007, Americans were living almost two-and-a-half months longer, nearly 78 years, up from 77.7 the previous year. Not mentioned was the fact that some 22 countries had life expectancies of 80 or higher. Among the United Nation Member States, we rank a mere thirty-sixth, behind Bosnia and Jordan and on a par with Albania. Most all of the countries outranking us have some type of public health option for everyone, and each of the top three provides a government-run health care system. **Canada**, which has been disparaged by pharmaceutical manufacturers, the insurance industry and other groups with vested interests, **ranked eighth.** Canadian men and women live three years longer than Americans even though they spend half as much per person on health care. Many Medicare recipients and others who have to choose between food and essential medications purchase drugs from Canada because costs for identical items can be 40% to 50% of the lowest prices available in the U.S.

This should be a wakeup call for some sort of reform, since our present system is deficient in many other areas. According to a Commonwealth Fund Study that included all developed countries, we ranked 45th in life expectancy, close to first in infant mortality, and **in last place with respect to health-care quality, access and efficiency**. Surprisingly, Americans had fewer physician visits, and hospital stays were shorter compared to most other industrialized nations. Another clue as to why our medical costs are so high comes from a measurement called DALY (Disability-Adjusted Life Expectancy). It was developed by the World Health Organization to estimate how many years one can expect to live before becoming disabled, mainly by old-age illnesses. **More money is spent by Medicare to treat senior citizens in their last two months of life than the total of all other expenses**. It has been suggested that we spend more because our prices for health goods and services are so much higher than all other countries. Support comes from by studies showing that **U.S. regions that spend the most on health care have higher mortality rates than regions spending the least**. This seeming paradox has been attributed to increased hospitalization, which is associated with high rates of fatalities due to serious hospital acquired infections, medication errors and other mistakes. A recent government report expressed concern that these nosocomial infections are increasing, with an 8% jump in postoperative sepsis and a 3.6% rise in catheter associated infection of the urinary tract. Approximately 250,000 patients die each year from **physician related (iatrogenic) activities, which now represent the third leading cause of death**. Most of these occur in hospitals but the total is probably much higher, since **the vast majority of iatrogenic errors are never reported or not diagnosed.**

This excess utilization of hospitalization and diagnostic procedures is driven by multiple factors, such as practicing defensive medicine by doctors trying to avoid lawsuits; unrealistic expectation and demands by patients that result from direct to consumer advertising; the pervasive belief that newer and/or more expensive drugs and technology are always better; and the current reimbursement system that encourages doctors to order tests and perform procedures that may not be necessary, but are reimbursed by insurance companies, Medicare, Medicaid and other fiscal intermediaries since they are easy to justify. The use of sophisticated imaging procedures has steadily increased, and some, such as MRIs and CTT scans, deliver doses of ionizing radiation up to 50 times higher than a routine chest x-ray or mammogram. **One study estimated that 29,000 unnecessary deaths from cancer could result from just the CTT scans performed in 2007.** The U.S. also has the most MRI machines, **26.5 per million population, compared with 5.6 in the U.K.** However, these and other equipment expenses pale in comparison to the costs of maintaining pharmacracy.

How Merck's Fosamax Converted The Worried Well Into Paying Patients

In a 1976 *Fortune* magazine interview, Merck CEO Henry Gadsen complained that his only customers were people who were sick, and he wanted his company to make drugs for healthy individuals so he could "sell to everyone." Three decades later, pharmacracy has turned that dream into an expensive and dangerous nightmare. Drug companies have successfully expanded the definition of illness and lowered the criteria for prescribing their products by creating millions of new patients who fear they are sick or will become sick from some trivial or poorly understood ailment. This has been accomplished by a combination of manipulative marketing and massive corruption of the medical care system that has permitted ordinary complaints to become magnified and "medicalized". This triumph of spurious and often specious salesmanship over science has also been responsible for turning healthy people into paying patients by creating new diseases, exaggerating the dangers of relatively insignificant complaints and/or the benefits of drugs to prevent age related but asymptomatic disorders like osteopenia. As emphasized in prior *Newsletters*, such medications often produce more damage than the conditions for which they are prescribed.

Osteoporosis refers to a reduction of bone mineral density that may increase the risk for hip, vertebral body, rib and other fractures. Bone density tends to decrease with age, especially in postmenopausal women, due to a decline in the protective effects of estrogen. Other risk factors include rheumatoid arthritis, taking corticosteroids, vitamin D deficiency, a family history of fractures, insufficient exercise, smoking, excess alcohol, and malnutrition. The diagnosis of osteoporosis originally depended on evidence of a spontaneous fracture. In many instances, there were few symptoms, such as vertebral fractures that are common in osteoporotic elderly women and are responsible for loss of height and the "Dowager's Hump." Over 50 years ago, in an attempt to improve the diagnosis of osteoporosis, our Department of Metabolism at Walter Reed published the first definitive article dealing with this entitled "Decreased Density of Bone: An Etiologic Approach to Diagnosis" (*Metabolism* 8:293-318, 1959). At the time, it was difficult to differentiate between osteoporosis and osteomalacia without a bone biopsy, since both disorders could result in a similar degree of decreased bone density on x-rays. Osteoporosis is due to the degeneration of existing bone whereas osteomalacia is a defect in the ability to make bone because of a deficiency in calcium and phosphates. Since osteomalacia most often resulted from inadequate levels of vitamin D or exposure to sunlight, the treatment of these two disorders was different. The only tool we had to differentiate the two was a metal wedge of varied thickness that we included on each x-ray to assess the degree of loss of density in different bone areas.

Over the next several decades, the development of more sophisticated imaging procedures progressively led to improved methods for measuring bone density. Since these advances had the potential for objectively defining osteoporosis, the World Health Organization convened a group of international experts in Rome in 1992 for that specific purpose. It was not an easy assignment, since all bones start to lose density after the age of 30. It was unclear how much loss might fall into a normal range at ages 50, 60, or 70. And how much osteoporosis was necessary to put women at such a significantly increased risk that it should be viewed as a disease? One of the participants, Dr. Anna Tosteson, Professor of Medicine at Dartmouth Medical School, said they spent several days going over research reports in an attempt to decide where on a graph of diminishing bone density with age they should draw a line. "And as I recall, it was very hot in the meeting room, and people were in shirt sleeves and, you know, it was time to kind of move on, if you will. And, I can't quite frankly remember who it was who stood up and drew the picture and said, 'Well, let's just do this.' "

In other words, in order to end the stalemate, someone drew an arbitrary line through the graph, and it was decreed that every women on one side of this line had osteoporosis. But there were other problems and questions, such as "How should you categorize those women who are just on the other side of that line?" They decided "more or less off the cuff" to use the term osteopenia from the Greek *osteon* (bone) and *penia* (poverty). This "bone poverty" osteopenia classification was created solely to assist public health researchers who require clear categories for their studies. In 1994, the World Health Organization experts agreed to define osteoporosis as a bone density 2.5 standard deviations below that of an average 30-year-old white woman. They then defined osteopenia as a bone density one standard deviation below that of an average 30-year-old white woman. **Both of these definitions were entirely arbitrary**. They were designed to track the emergence of a problem in different populations, not as a measurement that had any precise diagnostic, much less therapeutic, significance for an individual. As Tosteson noted, "**It was never imagined that people would come to think of osteopenia as a disease to be treated.**" John Kanis from the WHO Collaborating Centre for Metabolic Bone Diseases, who chaired the conference, has emphatically confirmed all of the above.

However, Merck saw this as a opportunity to realize its dream of treating healthy and asymptomatic people come true. Few women were being screened for osteoporosis because the only diagnostic procedure was an expensive table-sized machine that provided images of the hip and spine, which cost patients up to $300 per test. Since there were only a few hundred of these in the country, Fosamax, Merck's newly approved osteoporosis drug, was not selling well. Jeremy Allen was hired to solve the

problem, and in 1995, he convinced Merck to establish a nonprofit organization called the Bone Measurement Institute. Its Board of Directors included six of the most respected U.S. osteoporosis researchers, but Allen was the only employee. As he later admitted, **"There was no payroll, there was no building, there was no office with the name 'Bone Measurement Institute'". The "Institute" consisted solely of Allen's desk at Merck**. He learned that there were small portable units that measured bone density in the forearm, heel, wrist or finger that were much less costly. Allen approached several companies and offered them funding to manufacture more of these peripheral bone density devices but was rejected because "I was a threat to their business model. They wanted to sell just a few machines at a very, very high price and I wanted them to sell lots of machines at a much lower price."

According to the founder of the Lunar Corporation, one of the largest manufacturers of bone density machines, his opposition to Allen's offer had nothing to do with money or business models, but rather the merits of peripheral devices. As he explained, "taking a measurement of someone's heel or forearm isn't going to tell you what you need to know about the bones in the parts of the body that, if fractured, increase a woman's risk of death — the hip and spine. It was diametrically opposed to what the academics thought was best for diagnosis and would just lead to bad medicine. We were not about to go ahead and tell physicians to use inadequate diagnostic equipment simply because Merck wanted that." Lunar was threatened because it refused to cooperate, and he was told, "You're not going to get support from Merck. And we will support your competitors, and we will tell people working with Merck not to use Lunar machines." Lunar was not the only company put on notice, and to drive down the cost of bone density exams, Merck purchased a peripheral bone measurement device company to show just how low the price could be. Merck then helped get FDA approval for peripheral bone density devices by funding trials that showed a correlation between their results and hip or spine fractures. Pamphlets explaining the value of these new inexpensive instruments were distributed by the Fosamax sales force to all physicians. Merck also provided an attractive financing program so that doctors could purchase or lease any bone density machine, regardless of size.

1997 was a banner year for Merck. Its bogus Bone Measurement Institute and other interested groups it funded successfully lobbied Congress to pass The Bone Measurement Act, which changed Medicare reimbursement rules to cover all bone density scans. As Steve Cummings, an authority on bone density research noted, "It is impossible to overemphasize just how important this legislation was. Up to that point patients needed to pay for bone densitometry out of their own pocket, but once it's reimbursed,

clinicians get paid for making measurements of bone density." Most of the machines that were leased or purchased by doctors as result of this ruling could scan peripheral bone and provide a report with three distinct colors: green (normal), red (osteoporosis) and yellow for osteopenia. Cummings also emphasized "The very existence of the word 'osteopenia' on a medical report, along with the clear green-yellow-red graph, had a profound effect. When millions of women are getting the word 'osteopenia' from the bone density test that they are getting in their 50s and 60s, they get worried. When a clinician sees the word 'osteopenia' on a report, they think that it's a disease. They want to know: What should I do?" Merck had the answer. 1997 was also the year they obtained FDA approval for Fosamax to treat osteopenia, although there were no long-term studies to show any benefits. What happened subsequently can be synopsized as follows.

FOSAMAX TIMELINE

1995	FDA approves Fosamax to treat postmenopausal osteoporosis
	Application approved only 6 months after submission
	Merck establishes Bone Density Institute to increase bone scan availability
1996	**Fosamax sales $281 million**, 213 bone scanners sold
1997	FDA approves Fosamax to treat osteopenia and prevent osteoporosis
	Fosamax sales $532 million, 439 bone scanners sold
	U.S. has 4,000 bone density scanners, quadruple the 1995 number
1998	Bone Measurement Act becomes effective requiring Medicare to cover bone mineral density screening tests for post-menopausal women
	Fosamax sales $775 million, 768 bone scanners sold.
1999	1.25 million Medicare claims for bone density scans
	Fosamax sales $1.04 billion, 1,381 bone scanners sold
2004	2.6 million Medicare bone scan claims, over 70 percent more than 1999
2005	**Fosamax sales $3.2 billion**.
2007	2.8 million Medicare claims for bone screening exams
2008	Fosamax goes off patent and generic alendronate becomes available.

The phenomenal success of Fosamax was also due to the fact that it was the first non-hormonal drug approved for postmenopausal osteoporosis. Most women relied on estrogens that they also took to prevent hot flashes, sweats and other menopausal symptoms. Fosamax sales shot up by a third in 2002 after warnings that hormonal replacement therapy could increase risk for cancer and possibly heart attacks and strokes. However, it was not long before similar drugs started to threaten its stranglehold on osteoporosis treatment. Fosamax was generally given as a morning daily dose shortly after arising, but there were certain restrictions. Women were warned that it had to be taken with an 8 oz. glass of water that was immediately and completely swallowed, that they had to stand, walk or sit and remain fasting for 30-45 minutes before eating breakfast, since reclining could cause esophageal reflux and irritation. It was also necessary to avoid daily calcium supplements or hormone replacement therapy that many required and there

might be interactions with several foods and drugs, including aspirin. It was not a very pleasant way to start the day, especially for those who looked forward to a cup of coffee or tea shortly after getting out of bed.

To avoid this daily nuisance, Actonel, previously used to treat Paget's disease, was approved for osteoporosis in 2000 and only had to be taken once a week. A monthly dose of Boniva was approved in 2005, and a yearly intravenous infusion of Reclast became available in 2007, that completely obviated this annoying daily ritual. All the above biphosphanate drugs were heavily advertised and became popular because people tend to believe that newer drugs are likely to be more effective, safer or somehow superior. This is hardly new. Over 200 years ago William Heberden wrote "New medicines, and **new methods of cure, always work miracles for a while**." And the 19th century French physician Armand Trousseau advised his colleagues "Be sure to use the new medicines as soon as they come out, before they lose their effectiveness." Bone densitometry had become widely available and more women wanted these tests after learning that, based on the results, their friends were now being treated to prevent future fractures. Fosamax faded as most women wanted to take advantage of the newer medications.

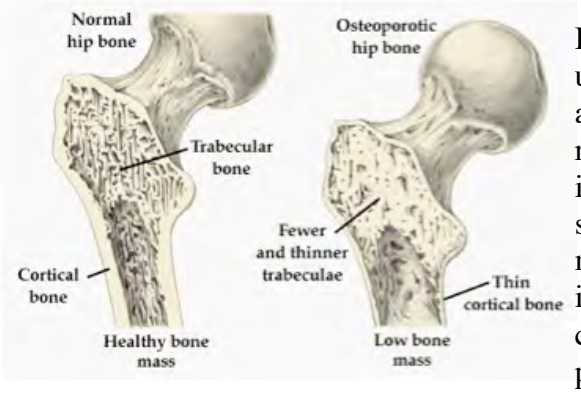
Confusing Osteopenia, Osteoporosis And Bone Density With Risk For Fracture

Merck and its competitors cranked out TV commercials and print ads about how their products **could not only stop, but reverse osteoporosis**. None of these featured any frail or humped elderly grandmothers, but rather attractive, youthful and athletic looking middle-aged women. Some ads even implied in a subtle fashion that they took these drugs to preserve this appearance as well as reverse osteoporosis. The Boniva blitz touted 60-year-old celebrity Sally Field, because her girlish fresh face looks gave the impression she was closer to 40. She also had a low bone density score that made her claims more legitimate.

As the Nobel Laureate Richard Feynman emphasized "I learned a long time ago the **difference between knowing something and the name of something.**" This certainly applies to osteopenia, which is an artificial and completely invented condition that has no symptoms or signs. It is not a disease that requires treatment, there is no proof that it will progress to osteoporosis in the near future or that current drugs will help prevent this. The vast majority of people with osteoporosis also have no complaints other

than age related loss of stature that usually does not impair quality of life. The goal of treatment is to prevent or decrease the likelihood of fractures, especially of the hip, and it is assumed that this can only be accomplished by increasing bone density. It is also assumed that if you have a bone density osteoporosis rating in the wrist or some other peripheral part of the body that there is likely a similar degree of osteoporosis in the hip and spine.

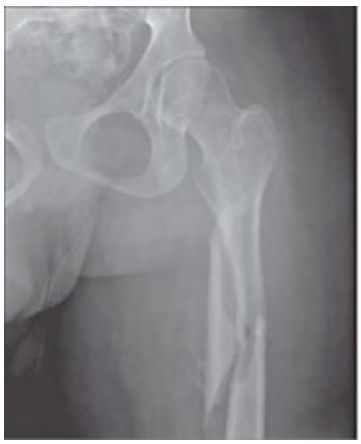
These and other speculations have been transformed into facts in deceptive ads despite the fact that they are not supported (and in many instances have been contradicted) by scientific studies. Boniva has been a bonanza because it targets the more than 40 million healthy middle-aged American women estimated to have osteopenia. Since Boniva is not indicated for this admittedly normal state, osteopenia is never mentioned in commercials. What Sally Field says is that "After 1 year on Boniva 9 out of 10 women have improved bone density." This is what osteopenic women want to hear, since most have been led to believe that they will soon develop osteoporosis, despite studies showing that they can remain in this category for ten or more years without medication. Boniva ads claiming to "reverse bone loss" in 90% of women after one year are based on the assumption that higher density means that their bones are stronger, which is also erroneous.

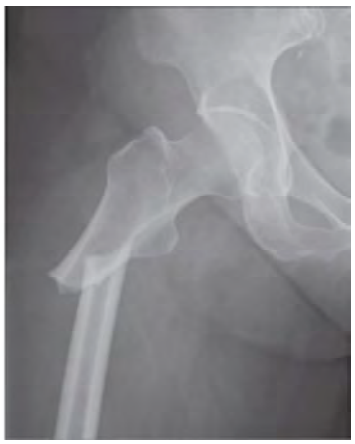


Bone is constantly broken down by osteoclasts and built up by osteoblasts. Some 3% of outer, hard cortical bone and 25% of inner, honeycomb trabecular bone are replaced annually in adults. This remodeling activity is influenced by hormones, calcium, vitamin D, exercise, smoking, certain drugs, and other factors. As we age, more bone is resorbed than new bone is built to replace it, largely due to diminished hormone production. Both cortical and trabecular bone become much thinner in postmenopausal osteoporosis, as illustrated to the left.

Boniva and other biphosphonates destroy the osteoclasts that absorb old bone, which is what normally stimulates osteoblasts to replace it with new bone. Bone density increases during the first year of taking these drugs because new bone is being laid down over old bone that is no longer being resorbed. But what the Boniva ads don't reveal is that after another year or two this process slows down and stops. Few old bone cells are cleared away and virtually no new bone cells are formed. Since the remaining bones contain less water and more minerals, they may appear much denser on test results, but these do not reflect the quality of bone or its strength. After a few years, **the steady accumulation of this type of dense bone can boomerang because it is very brittle, and risk of fracture from trivial trauma actually increases.** The longer biphosphonates are taken, the greater the risk. In addition, stopping them doesn't solve the problem because they can remain in bones throughout the body for years.

The femur is the largest and strongest bone in the body, but these drugs reduce its strength and increase susceptibility to fractures, as shown below.





Far left x-ray – A typical osteoporotic fracture of the femur that usually occurs following a fall. Note the presence of multiple fragments as well as the thinness of cortical bone.

Adjacent x-ray - An atypical femoral fracture in a patient on Fosamax for 7 years that occurred while walking. It is a much cleaner break despite thick cortical bone, which is thought to provide the most protection.

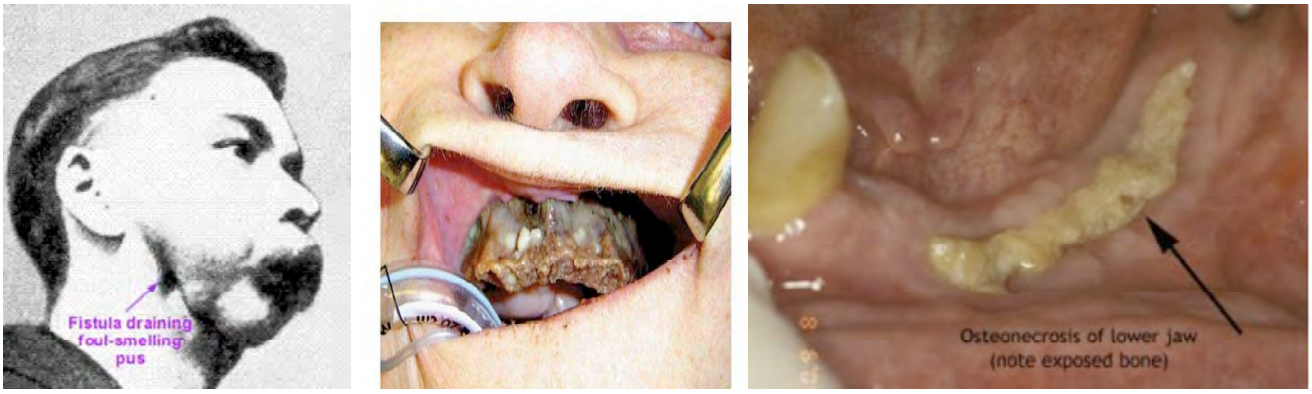
More of these fractures have been seen with Fosamax because it has been around the longest, but similar breaks have been increasingly reported with Actonel, Boniva and Reclast. In some instances, simply walking up or down stairs can cause a break, and one 60-year-old woman fractured both her femurs. Many feel that all biphosphonates should carry a black box warning because physicians as well as patients are unaware of this growing problem or the dangers of taking these drugs for more than five years. The FDA warned Merck about reports of femur fractures in 2008, but it took 16 months for the company to respond, by simply adding six words to the list of possible side effects reported by patients, "low energy femoral shaft and subtrochanteric fractures." Neither the FDA nor Merck has made any other effort to inform physicians or the public about this growing menace.

All we see are deceptive ads claiming that Boniva can provide protection from hip fractures in women by up to 65%, and up to 50% for Fosamax. But these impressive statistics are from studies in elderly women with evidence of at least one vertebral fracture who are very likely to sustain a subsequent break. In the 3 year Fracture Intervention Trial, twice as many in the placebo group (2.2%) suffered a fracture, compared to 1.1% taking Fosamax, and since 1.1 is half of 2.2, Merck can claim a **relative risk reduction of 50%**. They don't tell you that **the absolute risk reduction is 1.1** (2.2% minus 1.1%). Put another way, if 100 women took Fosamax for 3 years, it would prevent one from getting a fracture, but 99 would receive no benefit. As the old saying goes, "Figures don't lie – but liars can figure." The belief that increased bone density prevents hip fractures in the elderly is equally fallacious and misleading since over 90% are from falls due to loss of balance, coordination and rapid reflexes. Such falls could have had the same effect in younger people, but since osteoporosis is so common in senior citizens, there is a statistical association that has been exploited. In

studies of elderly women at increased risk for hip fracture for reasons other than low bone density, biphosphonates provided absolutely no protection.

The reason most people, including doctors, believe that Boniva will prevent two thirds of hip fractures is a testimony to the power of pharmacracy advertising. As Lewis Carroll wrote, "What I tell you three times is true." He was referring to the snark, a mythical animal, but studies show that if you repeat anything several times and others spread this about, it is eventually accepted as being true. William James, the father of psychology noted, "**There's nothing so absurd that if you repeat it often enough, people will believe it**." Both Lenin and Hitler knew that "A lie told often enough becomes truth" and did this repeatedly to incite the public in their rise to power. Another problem is that once a drug is released, the reporting of adverse events is entirely voluntary, and it is well established that well over 90% are never reported. Many more are not recognized since they did not surface in clinical trials. However, these only involve a small fraction of the huge population that will subsequently be exposed to them, and for much longer periods of time. **In many instances, problems do not occur until many years later, and even when repeatedly reported, little is done.**

Dr. Salvatore Ruggiero noted that a surprising number of his patients developed a rare disorder called osteonecrosis of the jaw (ONJ) after routine tooth extractions. The disease was reminiscent of phosphorous necrosis of the jaw (phossy jaw) seen during the 18th and early 19th century in workers who manufactured matches and were exposed to the vapors of white phosphorous, their main ingredient. Affected individuals suffered painful toothaches and gum infections with a foul smelling discharge due to rotting tissue. Some jaws had a greenish glow in the dark from the deposition of phosphorus, and the disease was painful and disfiguring, as shown below.



Left – phossy jaw from white phosphorus. This was replaced with more expensive red phosphorus in safety matches after the 1888 London matchgirls strike.
Middle – ONJ of the maxilla from biphosphonates. Note absent teeth and receded mucosa.
Right – ONJ of the mandible from biphosphonates. The lower jaw is most often affected.

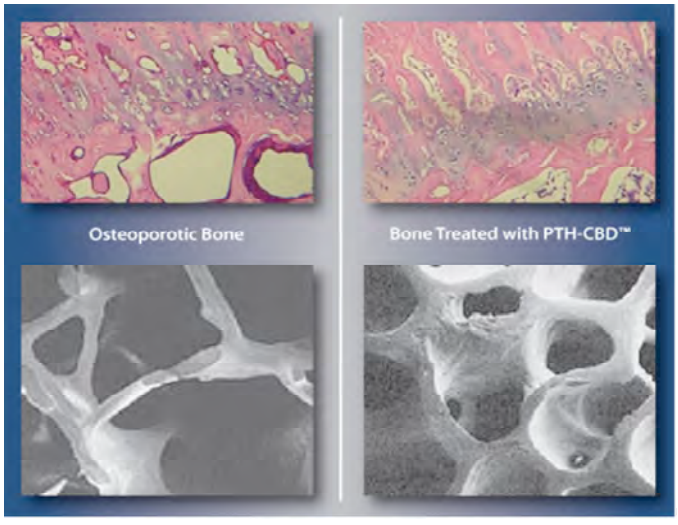
Phossy jaw was a horrible disease that often caused brain infections and death and the only treatment was amputation. In Ruggiero's patients, jaw tissue and bone failed to heal, progressively deteriorated, and antibiotic resistant infections were common. After a thorough review of their records, he discovered they had received Aredia, a biphosphonate given intravenously to treat metastatic bone disease. In 2001, he notified the FDA and the manufacturer and asked if there were any other such cases. He received no response and in 2002, because of mounting cases due to Aredia and Zometa, a similar drug, he called the FDA to confirm receipt of his report and asked, "How many of these do I have to submit before something gets done?" The FDA had actually received over 140 such complaints before ever being contacted by Ruggerio **but did nothing!** In 2003 an article calling attention to the problem attracted nationwide attention, and the FDA was flooded with reports that now included oral biphosphonates being taken for osteopenia and postmenopausal osteoporosis. Most of these were for Fosamax since it was the first, but others soon joined the list as causing what was now being called "biphossy jaw" or "dead jaw". In 2004, the FDA finally "recommended" that all biphosphonate drug manufacturers should warn patients of this potential problem, but this was not implemented until 2006. In addition, hundreds of patients on oral biphosphonates "had been stricken with such incapacitating bone, joint, or muscle pain that some became bedridden and others required walkers, crutches or wheelchairs." In 2008, the FDA reported that there were 23 cases of esophageal cancer and eight deaths linked to Fosamax. Since then, Actonel and Boniva have also been incriminated. All are esophageal irritants, which is why patients must take them with 8 oz. of water and remain upright for 30-60 minutes.

Many people assume that newer drugs must be superior or safer since those are the main reasons to seek FDA approval to market them. Patients welcomed Reclast in 2007 because it only required a yearly intravenous injection. It also appealed to physicians and facilities that were reimbursed for its 15-minute administration. In addition it was significantly more effective in preventing recurrent hip fractures and associated deaths than Actonel. But Reclast was the same as i.v. Zometa, which had been approved in 2001 for metastatic bone disease. The only difference was that 4 mg. of Zometa was given i.v. every three or four weeks, whereas the annual dose of Reclast was 5 mg. However, it also produced jaw osteonecrosis, and since Reclast was given to considerably more patients, other problems started to surface, including, atrial fibrillation, inflammation of the eye, interference with diuretics or drugs excreted by the kidney, as well as acute and anaphylactic responses such as fever, severe muscle and joint pain. These usually disappeared in a few days, but one patient died after her second dose and many others have succumbed to kidney failure. Some have suggested a limit of 3 Reclast doses until more long-term data is available.

Is There More Hope Or More Hype For Osteoporosis On The Horizon?

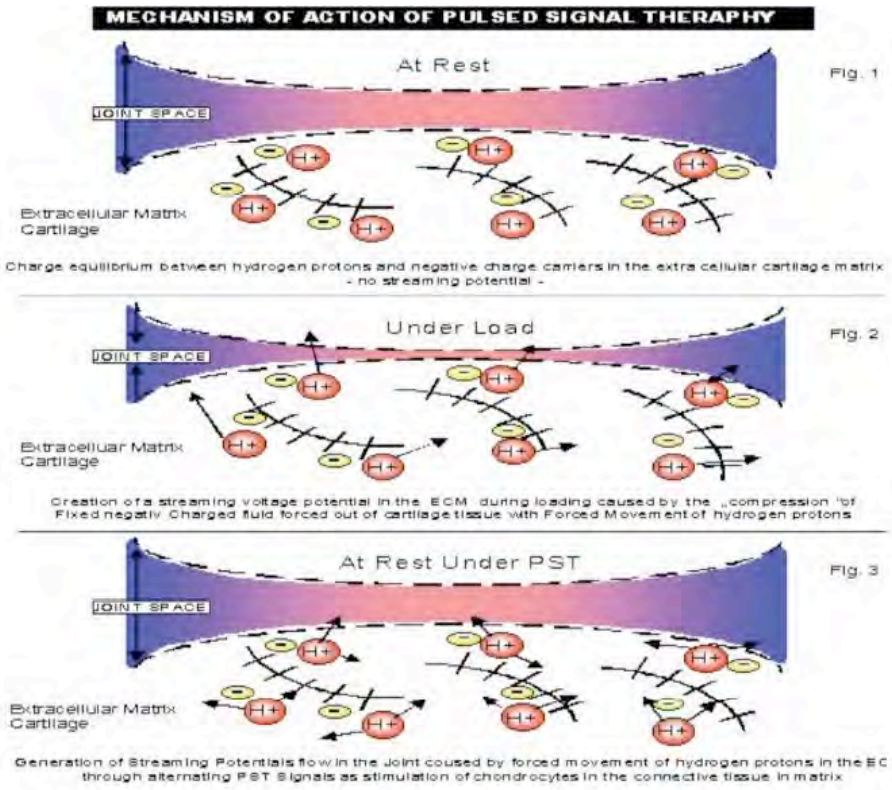
The risk of a woman over the age of fifty dying from an osteoporosis-related fracture is greater than her risk of dying from breast, uterine, and ovarian cancer combined. That is why drug companies are racing to develop drugs to prevent osteoporosis and get a share of what will soon be a $14 billion/year market. Biphosphonates, estrogens and calcitonin decrease bone resorption by blocking osteoclast activity but can have significant adverse side effects and/or have not been shown to reduce hip fractures. **Evista** is a selective estrogen receptor modulator (SERM), a class of drugs that works like estrogen in some tissues but can have the opposite effect in others. Evista mimics the effects of estrogen on bone, but blocks its stimulating effects on uterine and breast tissue, so it is approved for postmenopausal osteoporosis as well as reducing invasive breast cancer in such patients. Side effects include hot flashes and sweats and it also increases risk for deep vein blood clots and pulmonary emboli. It reduces osteoporotic fractures of the spine but this has not been demonstrated for the hip. **Prolia** a human monoclonal antibody that inhibits osteoclast formation and function was just approved in Europe for treating and preventing postmenopausal osteoporosis and is expected to be available here shortly. It is administered as a subcutaneous injection every six months at an estimated yearly cost of $8,000 to $12,000. Whether insurance companies will cover this without a significant co-pay or proof that other drugs have failed is not clear. Many are already urging physicians to prescribe alendronate (generic Fosamax), which costs around $100/year.

As a result, the focus is now on developing drugs that build new bone. **Forteo**, a recombinant form of parathyroid hormone was approved in 2002 for osteoporotic patients at high risk of hip fracture. It is administered by daily subcutaneous injection at a cost up to $10,000/year and should not be given for more than two or three years because of increased risk of osteosarcoma. It also interferes with the action of over 30 common drugs.



CBD/PTH (Collagen binding domain parathyroid hormone) binds to bone and is three times more effective than other drugs in increasing bone density in laboratory animals. According to the manufacturer, since it remains in the body, **a single dose of CBD/PTH is all that is needed to treat, cure and prevent osteoporosis, and will only cost $250!** Although the gross and microscopic illustrations to the left look impressive, no studies or clinical trials have been conducted in humans and only time will tell if this is a real breakthrough.

pulsed electromagnetic field (PEMF) have been used for decades to promote healing of ununited fractures, but have not been demonstrated to be effective in preventing osteoporosis. The main stimulus for bone growth is a piezoelectric signal generated when it is subjected to any pressure, which is why bones atrophy after immobilization in a cast or space travel weightlessness. Even standing on vibrating platforms for 10 minutes 5/days a week has been shown to progressively increase femoral neck bone density after 3 and 6 months in postmenopausal women. NASA scientists believe astronauts might prevent bone loss by standing on a lightly vibrating plate for 10 to 20 minutes each day. Held down with the aid of elastic cords, the astronauts could keep working on other things, rather then spending hours strapped into exercise equipment.



Pulsed Signal Therapy (PST®) is very effective for increasing bone and cartilage growth because it generates the identical piezoelectrical signal produced by pressure on bone. PST's proprietary alternating signals stimulate chondrocytes in connective tissue to recreate the same streaming potential seen when bone is subjected to a load, as can be seen to the lower left. PST is widely used in Europe for the treatment of osteoarthritis of the knee and other joints. Costs are covered by the equivalent of Medicare because it has been shown to be so cost effective and safe. Studies show that PST can also prevent osteoporosis, but it is currently approved in the U.S. only for veterinary use.

Exercise, calcium and vitamin D build up bone and should be considered first. However, some novel future approaches may prove superior – so stay tuned!

Paul J. Rosch, MD, FACP
Editor-in-Chief

Health and Stress
The Newsletter of
The American Institute of Stress
124 Park Avenue Yonkers, NY 10703

ANNUAL SUBSCRIPTION RATE:

E-Mail.....$25.00

ISSN#108-148X

PAUL J. ROSCH, M.D., F.A.C.P.
EDITOR-IN-CHIEF
www.stress.org
e-mail: stress124@optonline.net