

*[Note: This was well known to Dr. Royal Lee and basis behind the supplement CAL-MA PLUS]*

## **Osteoporosis breakthrough rebuilds brittle, decayed bone**

[San Francisco Chronicle](#)

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[Carl T. Hall, Chronicle Science Writer](#)

Daily injections of a hormone known as PTH [parathyroid hormone] can reverse bone loss and protect against fractures in people with advanced osteoporosis, doctors report today.

Results of the first large-scale international study of PTH suggest the hormone has the potential to rescue millions of older Americans, primarily women, from the ravages of chronic bone disease.

The study, which appears in this week's *New England Journal of Medicine*, already has been submitted to the U.S. Food and Drug Administration by drug giant Eli Lilly & Co., sponsor of the new research.

Based partly on the strength of the latest findings, the company said it hopes to win marketing approval of PTH, or parathyroid hormone, as an osteoporosis treatment within about six months.

Other companies are known to be in hot pursuit of their own versions, presaging a new front in the pharmaceutical marketing wars targeting the most common diseases of aging.

If approved, Lilly plans to market PTH under the brand name Forteo. It's a synthetic copy of the key, biologically active portion of the natural PTH molecule.

It's being touted as the first "bone formation" agent, meaning it has the power to stimulate new bone growth rather than merely stopping or slowing further erosion.

'THIS IS A NEW APPROACH'

All the osteoporosis drugs now on the market -- such as the Merck blockbuster Fosamax, the most commonly prescribed -- fall into this latter category, known as anti-resorptive agents.

"This is a new approach," said Dr. Claude Arnaud, an emeritus professor at the University of California at San Francisco and co-author of the new study, led by

researchers at Harvard University. "You build new bone. This is exactly what people with osteoporosis so desperately need."

An estimated 28 million Americans, 80 percent of them women, either have the classic symptoms of osteoporosis or have abnormally low bone density that puts them at the threshold of the disease. One in 2 women and one in 8 men older than 50 are expected to sustain at least one osteoporosis-related fracture in their lifetimes.

The new study tracked 1,637 postmenopausal women for up to two years of daily injections with PTH at two different dosages, or a placebo. Ninety-nine scientists in 17 countries participated.

The study participants had previous fractures of bones in the spinal column and had an average age of 69 when the study began.

Results showed significantly fewer new fractures in those receiving the drug compared with those on placebo. Bone mineral density clearly improved at such critical places as the spine and hip.

## **DRUG APPEARS TO BE SAFE**

No major adverse side effects were uncovered, although there is a risk that surprises may turn up after the drug is more widely used. Evidence of cancerous growths appeared in earlier studies in rats, but researchers concluded that was a result of very high dosages administered for the lifetime of the animals.

In humans, the drug appears to be safe, but "you never can be really sure until you get out in the market," said Dr. Conrad Johnston, president of the National Osteoporosis Foundation and a professor of medicine at the University of Indiana School of Medicine.

Chronic high levels of PTH are associated with breakdowns in calcium metabolism and such problems as kidney stones. But Johnston said those issues are not expected to arise if the hormone is given as a drug, mainly because the drug would not remain in circulation for long at elevated levels.

Normally, PTH is generated from specialized areas alongside the thyroid gland that respond to low levels of circulating calcium. In this system, PTH stimulates cells called osteoclasts that break down bone, which has the effect of releasing more calcium into the bloodstream.

When given as a drug, PTH has the opposite effect, seemingly tricking the finely tuned sentinels of the body that monitor blood chemistry. And so rather than liberating calcium from the skeleton, regular doses of PTH wind up stimulating bone-building cells, which are known as osteoblasts.

As Lilly has designed it, PTH would be administered by daily self-injection -- a potential drawback that might well dissuade many people and frail elderly. Fosamax is taken orally and now comes in a once-weekly form.

On the other hand, the gains in bone strength from PTH sometimes appeared within just three months of treatment, the new study found, in contrast to current treatments, which typically take a year or more to achieve substantial improvement.

Also, patients may need to take PTH for only a year or two of bone regrowth, after which the treatments can be halted. Patients might then be able to stop taking any osteoporosis drug, or might revert to a standard oral anti-resorptive medication to protect their newly strengthened bones.

The relatively short time needed to be taking the hormone shots could make PTH more attractive to very sick people or those with advanced bone loss who may not have time to wait for slower acting medications, some bone health specialists said.

## **MORE LAB WORK NEEDED**

"This is the first time we've seen anything this dramatic," said Beverley Tracewell, a registered nurse who serves as director of research at the Osteoporosis Research and Education Foundation, a nonprofit based in Oakland. "Now it's reasonable and logical for older folks to anticipate good bone health, from a fairly short period (of) taking this drug."

Tracewell said enthusiasm has been building in anticipation of the latest study and FDA action, which would follow a long period of lab work, much of it by Arnaud and researchers at UCSF, where some of the preliminary human studies also were done.

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### New drug for bone health

A new drug is being developed to treat osteoporosis by stimulating bone regrowth. It would be the first drug of its kind if the FDA approves.

Bone is constantly being broken down and rebuilt by specialized cells called osteoclasts and osteoblasts, respectively.

Parathyroid hormone (PTH) responds to low levels of calcium in the blood, stimulating bone breakdown.

But when given as a drug in daily injections, PTH has the opposite effect - it stimulates bone regrowth.

Osteoclasts secrete acids to break down bone.

Osteoblasts secrete collagen to create new bone.

### Osteoporosis precursors

- A history of fracture as an adult, regardless of cause
- Cigarette smoking
- Having a small, thin frame
- Advanced age
- Postmenopause
- Inactive lifestyle Sources: UCSF; Lilly pharmaceuticals