

**Inside**

**2002 Provider  
Education Events**

*Plan ahead for these  
popular seminars*

*Page 8*

**Ask the Doctor**

*The facts on soy  
and menopause*

*Page 5*

**Treatment Chart**

*How do osteoporosis  
drugs compare?*

*Page 3*

**Exercise Study**

*Join our class and  
start 2002 off right*

*Page 4*

**New FORE Staff**

*Six people join our team—  
that's 1,236 more bones!*

*Page 7*

**Research**

*Consider being part  
of this vital effort*

*Page 6*

**Donor Appreciation**

*And your opportunity  
to honor a loved one*

*Page 4*

# New Drug Revolutionizes Osteoporosis Treatment

## An Interview with Claude Arnaud, MD, UCSF Professor Emeritus

For the 30 million women and men in the US who suffer bone loss due to osteoporosis, a second chance at youthful bones is around the corner. The FDA is in the process of approving a synthetic form of the naturally occurring hormone PTH (parathyroid hormone). It will be the first drug on the market to actually build bone and to reduce the risk of fractures 60-90 percent.

PTH is a protein hormone made in the body by the parathyroid glands, located in the neck. PTH functions to regulate calcium and phosphate levels in the body. If calcium levels are low, the body releases PTH which directs the bone to release calcium into the body. In premenopausal women this system works well; calcium freed from the bones is quickly replaced. But with the loss of estrogen, the system falls out of balance and postmenopausal women experience higher bone breakdown and less bone building activity.

In clinical trials using PTH, sponsored by Eli Lilly and Company and the National Institutes of Health under the direction of Dr. Claude Arnaud, professor emeritus of medicine

and physiology at the University of California at San Francisco, two-thirds of women experienced restoration of bone mass to its original level of a young normal adult. Low bone mass, osteoporosis and fractures have a domino relationship with each other. Reversing this chain of events is a significant advancement in the treatment of osteoporosis. Upon FDA approval, Eli Lilly and Company is planning to market PTH (teriparatide) under the name Fortéo.

Researchers believe that PTH actually increases osteoblast activity to achieve the net gains of new bone, a phenomenon otherwise only seen naturally in children and young adults. Patients took the drug for about 18 months, and in the trials the risk of new severe vertebral fractures was reduced by 90 percent. With results this compelling, Arnaud believes that the development of PTH brings us closer than ever to curing osteoporosis.

Because PTH is a protein it cannot be taken by mouth and will be available via an injection. Patients will

*(Continued on page 2)*

# New Drug Treatment

(Continued from page 1)

administer it to themselves under the skin, similarly to insulin. These injections will lead to bone gain.

## How is it different?

In a recent interview with FORE, Arnaud discussed the mechanism that distinguishes Fortéo from existing osteoporosis drugs.

The most commonly used drugs that treat osteoporosis are antiresorptive, which means that they put the brakes on bone breakdown. Depending on the condition of the patient and the drugs used, one might expect a 30-50 percent reduction of vertebral fracture risk over three to four years. Arnaud hypothesizes that antiresorptive drugs are limited in effect because they do not build new bone, but instead fill in the nooks and crannies of recently excavated bone and slow osteoclastic activity. In postmenopause, retarding the bad guys (osteoclasts) also means reducing the good guys (osteoblasts) that build bone, and so the strength of antiresorptive

drugs lies in *maintaining* bone mass and preventing further bone loss. In sum, Arnaud suggests that antiresorptives are excellent fillers, and their efforts may be given a big boost with the help of PTH.

It stands to reason that people with the lowest bone mass will also experience the most gains with PTH, and so postmenopausal women with bone density T-scores of -3 and lower are obvious candidates. Further study is being performed on

the effects with men and premenopausal women with genetically low bone density and history of osteoporosis, and Arnaud has high hopes for both groups.

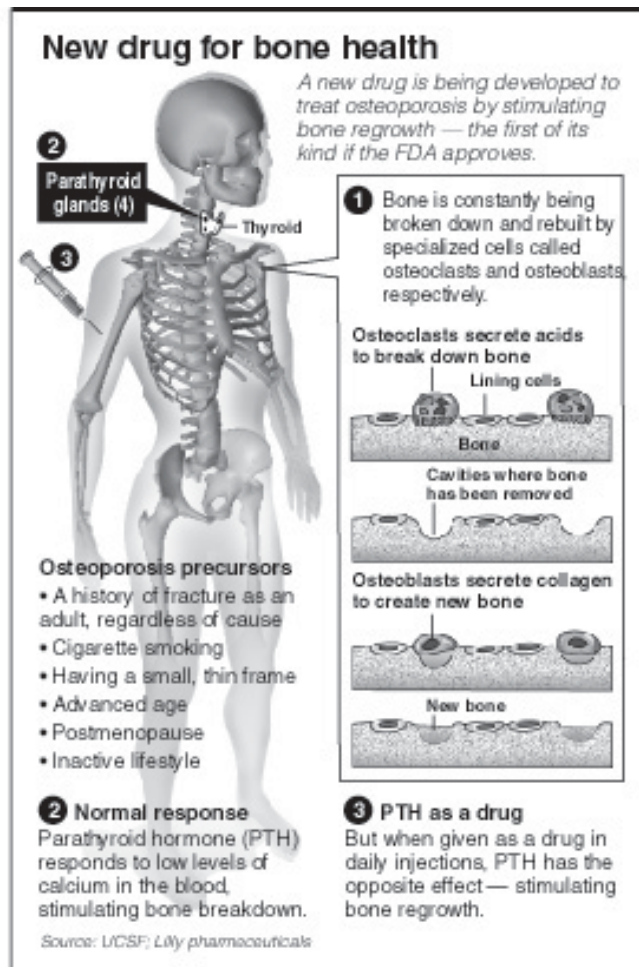
## Is PTH for me?

With all this knowledge, should a patient stop taking his or her antiresorptive drug and switch to PTH? Arnaud advises individuals talk with their

health provider about their family's history and perform a bone density screening if appropriate. It is possible, Arnaud suggests, that the most effective way to use PTH will be immediately before menopause to build up bone to an optimum, normal level, cease its use after 18 months, and take an antiresorptive to maintain the bone mass level. However, anyone with extremely low bone density driven by genetics, regardless of their menopausal status, should experience great gains from PTH as well.

## The future

We talked with Arnaud about his vision for osteoporosis care in the future. Because 80 percent of people with osteoporosis in the US are undiagnosed, he is interested in reaching people in new ways and curbing the growing costs of care for baby boomers. Most importantly, he emphasizes that severe osteoporosis is preventable. Bone density screening works, Arnaud says, and with the advent of PTH we have a more complete toolbox than ever before to wipe out fractures.



## Where Does PTH Fit in?

### *Postmenopausal Osteoporosis Treatment Options*

<b>Treatment Option</b>	<b>Parathyroid Hormone (PTH)</b>	<b>Estrogen Replacement Therapy (ERT)</b>	<b>Selective Estrogen Receptor Modulator (SERMS)</b>	<b>Bisphosphonates</b>	<b>Salmon Calcitonin</b>
<b>Types</b>	synthetic PTH (teriparatide)	estrogen	rалoxifene	alendronate and risedronate	calcitonin
<b>Brand Name</b>	Fortéo®	Various regimens available	Evista®	Fosamax® and Actonel®, respectively	Miacalcin®
<b>Approval</b>	Specific indications uncertain until FDA approval	Prevention and management for postmenopausal women	Prevention and treatment for postmenopausal women	Prevention and treatment for postmenopausal women, men*, steroid-treated	Treatment for postmenopausal women
<b>Form of Administration</b>	Daily injection (subcutaneous)	Pill or skin patch, daily or weekly	Pill daily	Pill daily, Alendronate available in weekly dose	Nasal spray, one spray daily
<b>Other Considerations</b>	To be administered 12- 18 months.	Estrogen taken alone can increase the risk of developing uterine cancer. To eliminate this risk, doctors prescribe the hormone progestin in combination with estrogen. This combination is called Hormone Replacement Therapy (HRT).	Raloxifene may have a protective effect against breast cancer.	Medication should be taken on an empty stomach with a full glass of water first thing in the morning. After taking the medication, remain in an upright position and do not eat or drink for at least one-half hour.	Calcitonin is for women at least 5 years beyond menopause.
<b>Possible Side Effects</b>	May include headaches, leg cramps, nausea.	Slightly elevated risk of breast cancer, deep vein thrombosis.	May include hot flashes & deep vein thrombosis.	May include abdominal or musculoskeletal pain, nausea, heartburn, or irritation of the esophagus.	Runny, irritated nose.
<p>All of these treatments require the intake of adequate calcium (1000-1500 mg/day) and vitamin D (400 IU-800 IU).            *Alendronate has an indication for men.</p>					

*Adapted from Data Source: National Institutes of Health Osteoporosis and Related Bone Disease  
 ~National Resource Center © 2001 National Asian Women's Health Organization*

# Have You Had a Fracture?

## Beginning January 2002

OsteoLife and FORE are conducting a study on the effects of an exercise program on:

- ◆ *Fracture risk*
- ◆ *Balance*
- ◆ *Ability to walk*
- ◆ *Quality of life*

### **Don't be a statistic!** *Fracture Facts*

- ◆ 300,000 Hip fractures annually
- ◆ 24% Mortality first year post fracture
- ◆ 50% Never fully recover
- ◆ 25% Require long term nursing home care

## Qualifications:

- ◆ *Previous fracture below the waist*
- ◆ *Walking ability*

## Qualified participants may receive:

- ◆ *Study related physical exam*
- ◆ *Supervised exercise program*
- ◆ *Bone density testing*

## **Recruitment is beginning now!**

*If you are interested or would like more information, please call Kristen Card at (510) 832-2662 EXT. 14.*

In America, there are over a million osteoporotic fractures annually. Hip fractures represent 300,000 of these fractures and their consequences can be quite staggering. In the initial phase of rehabilitation, orthopedic precautions, weight bearing status, and pain dictate the amount and scope of therapy given. Due to financial and time constraints built into the present health care system, patients are discharged from traditional therapy prior to reaching their maximum physical potential. Fifty percent who survive will never live or walk independently again.

FORE, in conjunction with *OsteoLife*, will be starting a new exercise class for those with osteoporosis and a history of fractures. The program has been designed by physical therapists to develop balance, coordination, strength, endurance and walking ability. If you have had a fracture and are interested in joining a low cost exercise class, please call FORE and a physical therapist will get back to you.

## Tribute Giving Honors Others

*We are entering the season of caring and sharing. This is an excellent time to think of a favorite doctor, nurse, friend or relative with a gift that benefits others. Your tribute gift will help promote good bone health and help our work in finding a cure for osteoporosis. Tell us whom you are honoring and we will send an acknowledgment.*

*For your convenience, an envelope is enclosed.*

*For more information, contact Cecilia Tonsing, Chief of Development, at (510) 832-2663, EXT. 33.*

By Risa Kagan, MD



### Can I avoid the usual menopausal bone loss by using soy products or isoflavones <sup>1</sup>?

This question, although very frequently asked, does not have a single clear-cut answer. Soy has been a staple of the Asian diet for centuries, and in the last couple of years American women in particular have begun to see this product in a whole new light for everything from breast cancer to bone health. In attempting to address the advantages or disadvantages of soy (or isoflavones) as it relates to bone health, we have the results of a small but growing collection of human studies.

I will comment on two such studies which were both of short duration (6 months), so we must be cautious in drawing conclusions. One of the studies was with perimenopausal women; the other was with postmenopausal women. In both studies, the women who were taking isoflavone-rich soy were able to maintain their bone density over the six-month period. In the case of the postmenopausal women, bone density increased slightly.

Cautiously, we can assume from these results that isoflavone-rich soy can help maintain bone, but does not have the ability to restore lost bone. To rely exclusively on soy and isoflavones for

your bone health would at the least assume that your bone density was at a desirable level as you entered menopause.

In regard to menopausal symptoms, patients report that soy-rich foods do seem to give some relief. This was first noted in Japan where menopausal women reported many fewer hot flashes than their American counterparts.

Last year the American Heart Association endorsed the incorporation of 25 – 50 grams of soy protein daily in a “heart healthy” diet. There is credible evidence that soy protein containing isoflavones (food sources, not supplements) may lower cholesterol levels.

Finally, we must remember that there are possible side effects. There are unanswered questions about changes to other body systems with high contact with soy isoflavones. Researchers are looking at the long-term effects on brain tissue, the reproductive tract, the endocrine system, the thyroid gland, and the high incidence of allergies to these products.



1 Soy contains two isoflavones, genistein and daidzein, that mimic or counter the effects of estrogen.

## How Many People Have Undiagnosed Osteoporosis?

In May 2001, FORE began a study to find people with osteoporosis in various residential living settings. This ODS program (Osteoporosis Detection Study) provided revealing statistics and was funded with a generous grant from Merck and Co.

Kristi Baird, the coordinator of this ambitious project, selected twenty-five appropriate facilities to implement a comprehensive program of osteoporosis education and bone density testing.

Designed to scan 2,000 male and female residents at assisted living, retirement, and skilled nursing facilities, our primary goal was to identify the seniors in these settings who have undiagnosed low bone density. Each resident received printed results of the completed radiographic absorptiometry scan, and

these were discussed with the technician. The results were also sent to their physician to allow for follow-up treatment if necessary. Family members and facility staff were included in the educational component.

The data from the study to date suggest that about 50% of seniors over 70 years old have undiagnosed osteoporosis. It also established that very few preventative measures were in place for most of this population.

The study and data collection will be complete in October 2001. "The findings from the study are astonishing," reports FORE's Co-Medical Director Elliott N. Schwartz, MD.

FORE plans to seek additional funding in order to broaden the geographic scope of this research to include those who are suffering with bone fractures due to osteoporosis.

## Osteoporosis Research is Accelerating!

Using the word "accelerating" in today's world can be an uncomfortable thing. However, in this context it is definitely a very positive thing.

Gratefully, more and more research is being done on existing therapies and a variety of new therapies in the field of osteoporosis. FORE is proud to be a part of all of this, which keeps us on the cutting edge of prevention and treatment.

Baby boomers are rushing toward a time when osteoporosis will be a critical part of their overall

evaluation of future health needs. It will be a major consideration as they assess what their quality of life will be in the 20 to 30 years of life after 70. We all are going to be the beneficiaries of this evaluation.

The research department at FORE has been profoundly impacted by this phenomenon. Many of you could also be the beneficiaries of this expanded role that we are filling in the Bay Area. Consider being a part of this vital effort.

**Postmenopausal women interested in participating in osteoporosis or women's health research studies should call (510) 832-2663 ext. 55 or visit our website at [www.fore.org](http://www.fore.org)**

## Osteoporosis on the Web



**Powerful Girls Have Powerful Bones**

[www.cdc.gov/powerfulbones](http://www.cdc.gov/powerfulbones)



**National Asian Women's Health Organization**

[www.nawho.org](http://www.nawho.org)



**The Office on Women's Health**

[www.4woman.gov/owh](http://www.4woman.gov/owh)

## Welcome Our New Staff Members



*New staff members:* L, R (back) Kristen Card, Education Program Coordinator; Emily Bower, Education Program Manager; Calisha Harmon, Receptionist; (front) Kathleen Cody, Executive Director; Katharine Vieira, Clinical Research Coordinator; Janet Sabatino, Clinical Research Coordinator

### FORE in Your Neighborhood

Our twenty-member scanning team has visited dozens of cities in Northern California this year, from Bakersfield to Arcata. You'll find us in Longs Drug Stores, which has partnered up with FORE to provide you with affordable pDXA scanning. This x-ray technology examines your forearm bone density, which likely reflects the bone density in other areas of your body. The 5-minute test will help you and your physician in making better-informed decisions about your bone's health and provide a baseline for future monitoring.

We test both men and women, and anyone over 30 years of age could find it helpful. In addition to scanning at Longs Drug Stores, FORE can bring bone density testing to your workplace, gym or health fair. We will also provide you with information to help assess your fracture risk, and diet and exercise literature to improve your bone health. Two out of every five women and one out of every eight men over the age of fifty will suffer an osteoporotic-related fracture in their lifetime. Through education and screening, we hope to stop osteoporosis in our lifetime. Remember, knowledge is your most important tool in preventing osteoporosis and fractures.

### Did You Know?

- ◆ Men finally have FDA-approved drug treatment for the first time this year?
- ◆ One of the best exercises for maintaining bone density is skipping rope?
- ◆ The Food and Drug Administration's preliminary approval for PTH (Fortéo) occurred just as FORE Front went to press.

### FORE's Advances in 2001

FORE doubled its number of osteoporosis research studies over the last year, bringing the current number to 18.

FORE will publish a revised 100-page manual late this year entitled "Physicians Guidelines of Care on Osteoporosis".

FORE has performed 7,600 peripheral bone density scans around northern California so far in 2001 .

We project 30,000 people will have visited [www.fore.org](http://www.fore.org) this year.

## 2002 Provider Education Calendar

### January

Northern California Bone And Mineral Club Meeting  
*Parathyroid Hormone*

Claude Arnaud, MD

### February

Case Studies ~ Dinner Seminar and Discussion *TBA*

### March

Northern California Bone And Mineral Club Meeting

### April

Center of Excellence

*Seminar on osteoporosis diagnosis, monitoring and treatment*

Elliott Schwartz, MD & Risa Kagan, MD

### May

Northern California Bone And Mineral Club Meeting

## 2001 Board of Directors

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