

## Benefit and Risk

Hippocrates is credited with the statement, "Extreme remedies are very appropriate for extreme diseases." This is an early example of a benefit-risk analysis applied to medical care. All of us assess benefit and risk every day. If the alarm goes off in the morning, we must make a decision to get out of bed or sleep a little longer. There are benefits and risks either way. Sleeping longer may feel good and give us more rest, but lead to being rushed when we finally get up and perhaps being late for work. When approaching a stoplight turning yellow, we must decide whether to stop, risking a delay in our progress and irritating the driver behind us, or proceed, risking a ticket for a traffic violation. With investments, it is generally accepted that a chance of greater rewards usually involves taking greater risk. Conservative investments are less risky but the return is usually small.

So it is with medical care. If you have an extreme disease, such as some types of cancer, you may be willing to accept a very risky treatment with a small chance of success, because the consequences of no treatment could be very severe. If you have a minor problem, such as a cold, you may be happy with chicken soup and plenty of fluids, knowing that the symptoms will soon pass.

Unfortunately, many medical concerns fall into a "gray zone" of uncertainty, where the balance of benefit and risk is less clear. Take prostate cancer in men, for instance.

This can be a fatal disease, but many men have a very slow growing type of tumor that may never cause a serious problem. It is not always known in advance who has which kind of tumor. Choices for treatment include surgery, radiation implants, external radiation, and no treatment at all. It is a tough decision that is often made on the basis of patient preference and physician experience rather than "hard science."

With osteoporosis, we evaluate the risk of breaking bones (having a fracture) and the consequences, which include disability, loss of independence, and death. When the risk of fracture is high, treatment with drugs to improve bone strength and reduce fracture risk is often recommended. In this situation, the benefits of treatment usually far outweigh the risks, although the risk is never zero. Each drug has its pros and cons, and the choice of treatment needs to be individualized. To fully understand the potential risks, we need reliable sources of information. Reports on the Internet, newspapers, and TV may or may not be accurate, and the information provided may be "one-sided." That is, it may present only one side of the story- the risks, without the other side- the benefits. This may be because something scary that happens to someone taking a drug may be considered more newsworthy than something that does not happen, such as a fracture. To learn more about the balance between benefits and risks, talk to a knowledgeable healthcare provider and find the real scoop.

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## Clinical Research

Our clinical research program is recruiting patients to participate in studies to test new medications and evaluate new uses for currently available drugs. By participating in a study you will have the opportunity to use one of these medications, have free examinations and tests, and receive reimbursement for your time and travel. If this interests you, please take a few minutes to read the major criteria for participation.

If you think you may qualify for a study or are interested in participating in a research study, call a study specialist at (505) 923-3232.

Feel free to pass this newsletter to a friend or relative who may be interested. The drug study information will be updated quarterly, since we are continually starting new studies and closing out old ones. We do studies for high blood pressure, high cholesterol, osteoarthritis, osteoporosis, heartburn, GERD, irritable bowel syndrome and others. Please feel free to call and give your information to a study specialist for consideration for future studies. If there is nothing for you now, there may be next time.

### Gout with Heart Problems

A research study comparing two approved medications for those diagnosed with gout who also have cardiac risk such as diabetes, previous heart attack or stroke:

- Are between 45 and 85 years old
- Suffering from gout whether or not you are currently taking daily medication

Takeda TMX-67-301

### Constipation caused by Pain Medications

A research study of an investigational medication for treating constipation caused by daily use of pain medications. You may be eligible to participate if you are:

- Are over the age of 18
- Take narcotic pain medications daily for chronic pain not due to cancer
- Have fewer than 3 bowel movements a week

AZ-OIC3008

### COPD

A research study of an investigational medication for Chronic Obstructive Pulmonary Disease (COPD). You may be eligible to participate if you are:

- Are over age 40
- Are a current or ex Smoker

Forest COPD

### Gout

This is a study of an approved medication for gout. You may be eligible to participate if you are:

- Are between the age of 45-85 years old
- Have gout and have had more than 2 flares in the past 12 months

Ardea LASSO

### Healthy Women Osteoporosis Study

This is a research study to study the effect of a medication on bones. You may be eligible to participate if you are:

- Are a postmenopausal woman 45 to 75 years old
- Have not been diagnosed with osteoporosis
- Are at least 5 years post menopausal

Takeda 390104

### Frequent Night Time Urination

This is a clinical trial to assess the safety and efficacy of an investigational medication for Nocturia or frequent night time waking for urination. You may be eligible to participate if you:

- Are age 50 or over
- Wake more than twice a night

Serenity



**Woman  
To  
Woman**  
By  
Julia Chavez, CNP

**DO YOU TAKE YOUR MEDICINES CORRECTLY?**

Nearly three out of every four Americans admit that they don't always take their medicines correctly as ordered by their physicians. There can be consequences attributed to incorrect taking of medicines and some can be very serious. There are a few things you can do to help yourself and to help your provider help you.

1. Take a list or a bag with all your medications when you go see your provider or pharmacist, or when you go to the hospital. Be sure to include all prescription and over-the-counter medicines including herbs and vitamins.
2. Find out the name of any new medication that is prescribed and ask if a generic version is available. Ask what it is for and how and when it should be taken. Ask if you will be taking the new medicine only temporarily or for a long time.
3. Ask if you need to stop one of the other medicines when you start the new one.
4. Ask if it will interfere or interact with any medicines or over-the-counter medications you are already taking.
5. Ask if there are any tests that need to be taken while you are on the new medication.

If you enjoyed this newsletter and would like to be placed on an electronic mailing list, email [ybrusuelas@nmbonecare.com](mailto:ybrusuelas@nmbonecare.com). The newsletter is produced on a quarterly basis.

**Osteoporosis Foundation  
of New Mexico  
Educational  
Presentations**

Manzano Mesa  
Multigenerational Center  
501 Elizabeth SE  
Albuquerque, NM 87123  
(505) 275-8731

1:30-3:00 PM

**2011 Meetings:**

February 10, 2011

Molly Grady

*Topic: "The Benefits of Tai Chi Chih that relate to Osteoporosis and Balance"*

May 12, 2011

Isabel Torres, RT

*Topic: "Bone Density Testing-What to Expect"*

August 11, 2011

George Fraser, Fifty n' Fit

*Topic: "Smart Exercises for Osteoporosis"*

November 10, 2011

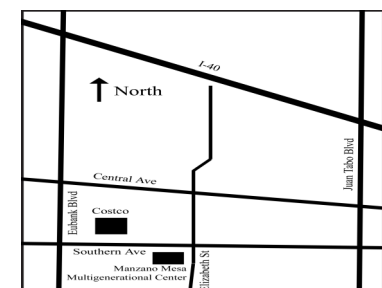
E. Michael Lewiecki, MD

*Topic: "New Treatments in Osteoporosis"*

These meetings are open to the public. It is a great opportunity to talk to osteoporosis experts for as long as you want. There is limited space, so please sign up by calling 275-8731 in order to attend. A \$1 fee is collected in order to cover the cost of educational material.

Consider attending if:

- ❖ You have osteoporosis,
- ❖ You have a loved one with osteoporosis, or
- ❖ You are interested in learning more about osteoporosis.



**Ask Dr. Mike Lewiecki about . . . . OSTEOPOROSIS**

**Drugs and Safety**

**Dear Dr. Lewiecki– I just read a news story about an FDA meeting on osteoporosis drugs. There was concern about side effects of treatment, but I did not understand what it meant. Can you explain?**

**Samantha B., Los Alamos, NM.**

Dear Samantha – On September 9, 2011, an FDA advisory panel met to discuss recent reports of possible side effects with long-term bisphosphonate treatment for osteoporosis. This is a family of drugs that includes Fosamax, its generic version alendronate, Actonel, Boniva, and Reclast. There was particular interest in two potential problems: osteonecrosis of the jaw (ONJ) and atypical femur fractures (AFFs). Testimony was heard from many osteoporosis experts and a report from the FDA was presented. At the end of the day, the advisory panel voted 17 to 6 in favor of a recommendation for the FDA to update the product label for these drugs. The FDA is now

considering this recommendation but is not bound to it. At the time of this writing, a final ruling from the FDA has not been issued. Those are the facts, but what does it all mean?

These are my thoughts..... Osteoporosis is a serious disease with serious consequences due to fractures. Bisphosphonates have been proven to prevent fractures, save lives, and reduce healthcare expenses. For most patients with osteoporosis, the benefits of treatment far outweigh the risks. Serious side effects are rare in comparison to the number of fractures prevented. It is not known whether ONJ and AFFs are caused by the drugs or due to something else, such as the osteoporosis itself. Treatment decisions for every patient should consider the expected benefits and potential risks that are unique for that patient. There is no one rule that works for all of us.

*Mike Lewiecki*

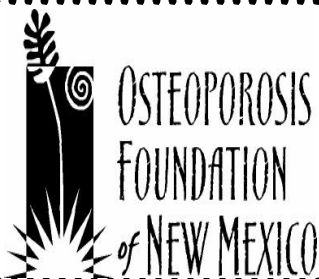
*From the editor: If you have a question for Dr. Lewiecki, please send it by mail to the address on the front page of this newsletter or by email to [mlewiecki@nmbonecare.com](mailto:mlewiecki@nmbonecare.com). It is not possible to respond to all questions submitted, but those that are of general interest will be considered for publication with an answer in future issues of this newsletter.*

**DON'T FALL DOWN**

In this age of high technology, it is easy to forget the simple things in life that can make a big difference. One of those is the #1 rule in the treatment of osteoporosis: don't fall down.

If you are over the age of 50, you may have noticed that almost nothing works as well as it used to. Loss of muscle strength and balance are sadly a part of the aging process. Eventually we may become so frail that staying upright and avoiding falls is a constant challenge. Falls can result in fractures as well as other injuries. Falls are a common reason for 911 calls and hospital emergency visits in the elderly. Most hip fractures are a result of falling. That is the bad news. The good news is- you can do something about it.

While it is not possible to stop the aging process, we can delay onset of frailty and reduce the risk of falling. How do you do it? Give old age the one-two punch. First, stay fit. You may have physical limitations in what you can do because of arthritis or other problems, but anything you do is better than nothing. Keep moving. Don't be a couch potato. Walking is a terrific form of physical activity. Make it part of your daily routine. And don't forget your core strength with abdominal and back muscles. Second, work on your balance. Practice balancing on one foot, walking on a straight line, and take a yoga, pilates, or Tai Chi class. What you have heard is true- use it or lose it.



**Support osteoporosis education in New Mexico. Help to reduce the burden of osteoporotic fractures. Osteoporosis Foundation of New Mexico is a local non-profit 501(c)(3) foundation. Consider a tax-deductible donation or bequest. Donations may be mailed to Osteoporosis Foundation of New Mexico at 300 Oak St. NE, Albuquerque, NM 87106. For more information, call Yvonne Brusuelas at 505-855-5627.**