



Our expert: **Jay S. Cohen, M.D.**, adjunct associate professor at the University of California at San Diego and the author of *Over Dose*, one of the first books to examine unsafe prescription drug practices.

years, unless there's a specific reason to use them rather than older formulas whose risk are better known.

"But even older drugs carry risks, because they're often prescribed at dangerously high doses. This has to do with the way they're tested: Pharmaceutical companies prefer to run trials on people with severe conditions, because those with milder forms often get better on their own. Unfortunately, the higher doses used in such trials are then established as the prescription strength for all patients, even though most have milder conditions that would respond to half or one quarter the medication. Most adverse side effects occur because the recommended dose of a drug is simply too high."

So my prescription isn't specifically calibrated to me? Why not?

"Doctors like drugs that come in a one-size-fits-all dose. Most are time-strapped and don't want to be bothered having to consider height, weight and gender every time they write a prescription. If a pharmaceutical company makes it the least bit complicated for them, they'll often choose another drug that's simpler to use." ▶

are you a drug GUINEA PIG?

You are if you're on a brand-new prescription med. Find out why the hottest drugs may be the most toxic to you—and what you can do about it

By Kathleen McAuliffe

Why should I be concerned about drug side effects?

"Every medication you're prescribed can put you at risk. Reactions to drugs are the fourth leading cause of death in the U.S. Even in hospitals—despite supervision and monitoring—side effects kill over a hundred thousand people each year and cause

severe adverse reactions in another two million."

Don't drugs get thoroughly tested before going on the market?

"Actually, the public is the main guinea pig for new medications. The FDA views the first years after some drugs hit the market as phase IV of a

clinical trial, because that's when it's really put to the test, treating a diverse cross-section of the population. A major study found that fifty-one percent of all new drugs have serious side effects that were not recognized prior to approval. I recommend that doctors and patients avoid medications that have only been on the market a few

Are women at greater risk of having severe side effects?

“Yes. Of the eleven drugs withdrawn by the FDA since 1997, eight had greater adverse effects in women; among them, Redux and Seldane. In my clinical experience, I have also found my female patients to be more susceptible to side effects. There is tremendous individual variation, but we do know that the genders metabolize certain drugs differently. One problem is that doses are based on what’s effective for men. Women are still grossly under-represented at the earliest stage of drug testing, when doses are established. As recently as 2001, the U.S. General Accounting Office reported that seventy-eight percent of subjects in such tri-

als were men—who, on average, are bigger than women.”

What medications taken by midlife women are prescribed at too strong a dose?

“Arthritis meds and other anti-inflammatories, antidepressants, sleep preparations, painkillers, anti-anxiety medicines and drugs for high blood pressure and cholesterol all qualify.

“Anti-inflammatories cause a large number hospitalizations and deaths. Their major adverse effects—including gastrointestinal bleeding and kidney damage—are dose-related. Celebrex, the top-selling anti-inflammatory, is commonly taken at 100 mg. twice daily (or 200 mg. once daily) for osteoarthritis. Yet in a large study involving mostly

women, the Mayo Clinic found that 50 mg. twice daily was effective. The company doesn’t produce 50-mg. pills or even mention that the drug is effective at half the standard dose. The newest is Bextra, a strong anti-inflammatory and another one-size-fits-all drug. We’re seeing this disturbing trend more and more.”

How can I tell if I’m having a bad reaction?

“Some common signs are headaches, lightheadedness, blurry vision, dry mouth, a feeling of sedation, diarrhea, constipation and others. Read the package insert to be familiar with the recognized side effects. It’s not always easy to sort out whether a symptom is a response to a medication, but be wary if it comes on

shortly after you take the drug, if you take a higher dose of the drug or the problem lessens or disappears once the dose is reduced or you stop taking it.

“If your symptoms are severe, seek immediate medical attention. Report any serious adverse reactions to the FDA. To fill out a form, go to www.accessdata.fda.gov/scripts/medwatch/.”

Aren’t doctors well informed about side effects?

“Many are not. They rely on the *Physician’s Desk Reference [PDR]*, which often omits information about lower, safer doses. The *PDR* sometimes underestimates the prevalence of side effects. Since doctors aren’t getting the right information, they’re inclined to

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Calcium

Information that could help **SAVE YOUR BONES**

DID YOU KNOW?

Medications that fight osteoporosis need calcium to work.

If you’re taking a prescription medication to treat osteoporosis, you should be aware they do not contain calcium. You need adequate dietary calcium and vitamin D to help your medicine function properly in your body. But studies show most women don’t get enough calcium in their diets. If you’re taking medications like these below, talk to your doctor about starting calcium supplementation.

- Actonel® (risedronate)
- Evista® (raloxifene)
- Fosamax® (alendronate)
- Miacalcin® (calcitonin-salmon)

DID YOU KNOW?

Some common types of prescription medicines can speed up bone loss.

Some common types of medication can interfere with bone metabolism, which can lead to bone loss. If you’re taking medications like the ones listed below, talk to your doctor about the potential benefits of calcium supplementation.

- Corticosteroids
- Phenytoin

DID YOU KNOW?

There’s a calcium clinically proven to help prevent bone loss.

If you’re wondering about which calcium to take, you should know Os-Cal® calcium has been proven effective in multiple clinical studies. And it has been recommended by more doctors than any other calcium brand. Most prescription medications used to treat osteoporosis were proven effective in clinical studies where they were used in combination with Os-Cal 500+D. Os-Cal contains highly absorbable calcium—the most concentrated form available. Plus, Os-Cal Ultra® has more added nutrients for bone health than any other leading brand, and it’s the only calcium supplement with the antioxidant vitamins C&E.

DID YOU KNOW?

A bone density test actually shows if you have “younger” bones.

Bone density tests compare bone mass versus a national average for women in their late 20’s. If you’re over 40 and your bone mass is equal to that average, your bones are “younger” than you are. The calcium in Os-Cal helps slow down the aging process of bones at the cellular level. Take a bone density test, and you’ll see if you have “younger” bones.

switch patients from drug to drug. It doesn't occur to them that they simply need to reduce the dose.

"When Prozac first came out, it was sold in a 20-mg. capsule. About half my patients did great at that dose, but the other half had real problems, such as severe panic attacks. I found a study showing that fifty-four percent of patients on Prozac got relief from 5 mg., or one quarter the standard dose. Yet the manufacturer didn't tell doctors about that, and they didn't make it at a dose low enough—even though it would work for half the population. In the past few years, the company came out with a 10-mg. dose, as well as a liquid that can be taken at almost any strength. But the PDR still lists 20 mg. as the

standard dose, and the liquid is rarely prescribed."

What about hormone therapy?

"The Women's Health Initiative study found that those on hormone therapy have a small but significant increased risk of breast cancer, blood clots and heart disease. The estrogen dose used was 0.625 mg.—half the dose that was commonly prescribed from 1964 through 1999. Meanwhile, studies done over a decade ago showed that many women can get relief from hot flashes and vaginal dryness and get the same bone benefits with just 0.3 mg. In fact, that's the mindset now—that a lower dose is better." ■

*Kathleen McAuliffe is a contributing editor for **more**.*

STOPPING SIDE EFFECTS BEFORE THEY START



MOST DRUG REACTIONS ARE PREVENTABLE. TAKE THESE STEPS TO PROTECT YOURSELF:

- **Start low.** Whenever possible, begin treatment at the lowest effective dose; increase if necessary until symptoms clear or the desired effect is achieved.
- **Use your history.** If you've had adverse reactions to drugs (prescription or OTC) or if you're sensitive to alcohol or caffeine, tell your doctor. These are all red flags that you could have an adverse reaction to certain medications.
- **Research, research, research.** When filling a prescription, always ask for, and read, the drug-package insert. Pharmacy computer printouts are often far less complete. Use the Internet to research medication. A good place to start is Cohen's Web site at www.medicationsense.com. Discuss any concerns you may have with your doctor.
- **Take dose-lowering measures.** If the lowest available dose is still too high, see if your doctor thinks it wise to split the pill or open a capsule and mix part of the contents in juice. Or ask for a prescription to a compounding pharmacy, which can fashion drugs at any desired dose. For more on compounding pharmacies, visit www.pccarx.com or www.iacprx.org.—K.M.



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Peggy Fleming
Olympic Gold Medalist
with grandson Miles