

## Health and Behavior

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### Menopausal women turn to 'natural' hormones

By Rita Rubin, USA TODAY

As a 54-year-old psychotherapist, Laurie Forbes has had professional as well as personal experience in dealing with the effects of fluctuating hormones around menopause.

For a couple of years, Forbes tried commercial estrogen and progestin products to relieve hot flashes and other menopause symptoms. But, she says, the treatment was even worse.

Then she heard about Women's International Pharmacy in Madison, Wis., and Youngtown, Ariz. Women's International is one of what appears to be a growing number of pharmacies making and selling "bioidentical hormones," so called because their chemical structure is identical to that of some hormones made by the ovaries.

According to the Women's International website, bioidentical hormones "are 'natural' to the human body," leading many women to assume they are safer than drug companies' hormones.

For about four years, Forbes has been using hormone creams compounded, or formulated, in the Women's International laboratory and mailed to her home in Miami. "I don't have any side effects. None," she says.

The problem, critics say, is that no one has ever put compounded bioidentical hormones to the test. In this case, they argue, no news about harm isn't necessarily good news.

"In the U.S., there aren't that many examples of dangerous alternative therapies, but this is one of them, because it's being promoted to people as being harmless," says physician Adriane Fugh-Berman, an associate professor in

complementary and alternative medicine at Georgetown University.

Just because compounded hormones are identical to hormones made by the ovaries doesn't mean they're safe, Fugh-Berman says. She notes that a number of studies have found a link between naturally higher levels of estrogens and higher breast cancer risk.

### **'Black box' warnings**

Drug companies also make products that are identical to ovarian hormones, such as patches, tablets and creams containing estradiol, an estrogen. Like all commercial estrogen products, they carry a "black box" warning — the strongest type of warning on drug labels — about risks revealed in 2002 by the Women's Health Initiative.

The study found that Prempro, the leading brand of estrogen plus progestin, raised postmenopausal women's risk of heart attacks, strokes and breast cancer. After the findings were released, sales of all commercial hormone therapy products plummeted.

Many women who quit taking hormones never looked back, but some, like Forbes, found the return of menopausal symptoms intolerable. They tried soy and herbal remedies, but nothing worked as well as estrogen. So "natural" and "bioidentical" hormones held great appeal, especially given that the estrogen in Prempro comes from the urine of pregnant mares.

"There are quite a few women like me who have not had success with traditional approaches and have looked for something else," says Barb Gomach, 54. "If they work, you stick with them."

Gomach, of Madison, Wis., says she tried vitamin E, black cohosh and finally Prempro to relieve her severe hot flashes. The first two were no help, and she experienced such side effects as vaginal bleeding on Prempro. For several years, she has been buying progesterone capsules from Women's International, although she still uses a commercial estradiol patch because, unlike the compounded hormones, her insurance covers it.

## 'Breakdown in regulation'

Although some compounded hormones are identical to FDA-regulated drugs, they don't have to carry a black-box warning. Compounding pharmacies "fly a little under the radar," says Michelle Curtis, chair of an American College of Obstetricians and Gynecologists' panel that published a critique of bioidenticals this month. Curtis is an OB/GYN at the University of Texas-Houston Health Science Center.

Wulf Utian, executive director of the North American Menopause Society, says compounded hormones "speak to a breakdown in the regulation by the FDA. ... Active hormones have suddenly begun to be marketed as if they were foodstuffs or herbal products," which do not have to demonstrate safety or efficacy.

Prempro maker Wyeth cried foul last month. Wyeth petitioned the FDA to crack down on what it sees as illegal and potentially dangerous sales of compounded hormones. "Some of the compounds are copies of FDA-approved therapies," says Ginger Constantine, Wyeth's vice president for women's health. "They're not regulated. People are paying a lot of money for stuff, and they really don't know what they're getting."

Pharmacist Carol Peterson of Women's International says she wouldn't object to putting black-box warnings on her hormones. And, Peterson says, she recognizes that bioidentical hormones have never been studied as rigorously as Wyeth's hormones.

But, she says, "I know of practitioners doing studies in their offices with their patients, and they're unable to get them published." Besides, Peterson says, what's important is what works for the individual: "There are always going to be people who fall outside the generalities you've made."

And, Utian says, when women come in the office brandishing computer printouts and asking for prescriptions for bioidentical hormones, "the truth is there are a lot of physicians who just don't have time to argue."

[http://www.usatoday.com/news/health/2005-11-06-bioidentical-hormones\\_x.htm](http://www.usatoday.com/news/health/2005-11-06-bioidentical-hormones_x.htm)