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HEALTH JOURNAL By MELINDA BECK



Sorting Through the Choices For Menopause Hormones

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Amid all the confusion over hormone-replacement therapy for women, one key aspect is often overlooked: Not all HRT products are the same.

The big Women's Health Initiative that has been generating headlines since 2002 studied women using Premarin and Prempro, both made by Wyeth, which were the state-of-the-art hormone drugs many years ago. Today, estrogen and progesterone are available in forms that are much closer to what women lose in menopause. While the Food and Drug Administration has said it thinks all HRT products pose the same risks, a growing number of doctors and patients prefer the newer varieties.

Bear with me for a brief biology lesson.

Women make three kinds of estrogen. The predominant one from puberty to menopause is 17-beta estradiol, which is involved in over 400 functions in the female body, from skin to hair, bones, heart and brain. The estrogen left after menopause is estrone, made primarily by body fat. Some researchers suspect that estrone may be responsible for the higher risk of breast and endometrial cancer in women who are obese.

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The weakest estrogen is estriol, produced by the placenta during pregnancy and not normally present in measurable amounts at other times.

Premarin, approved in 1942, is nearly 50% estrone. It's made from pregnant mare's urine and contains several horse estrogens not found in humans. Though sales have fallen sharply since 2002, when part of the WHI was halted out of concern for heart-attack risks, Premarin remains the best-selling estrogen in the U.S.

But a number of FDA-approved patches and gels that deliver solely 17-beta estradiol are gaining market share. Since "transdermal" forms don't have to pass through the liver, as Premarin does, they pose less risks for blood clots that can cause stroke and heart attack.

"If we'd had effective estradiol products back when Premarin was introduced, no one would have prescribed it," says Geoffrey Redmond, an endocrinologist who works with women's hormone issues in New York City.

"People are not driving 1942 cars anymore," says Elizabeth Lee Vliet, a women's health physician in Tucson and author of six books on menopause. "Why gynecologists have been so resistant to moving off horse-derived estrogen is beyond me. These estradiol products have been around for years."

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Women who take estrogen and still have a uterus need to take progesterone to guard against endometrial cancer. But the synthetic version used in the WHI --medroxyprogesterone acetate, or MPA -- has been linked to unpleasant side effects such as moodiness, breast tenderness and bloating. "It's PMS in a pill," says Dr. Redmond. He also notes that in the WHI, the increased risk of breast cancer was found only in the women taking Prempro, which combines MPA and Premarin. Women taking Premarin alone had a 33% decrease in breast-cancer risk.

Hormone Options

FDA-approved products with 17-beta estradiol:

- Alora
- Climara
- Vivelle
- Estraderm
- Estrace

FDA-approved natural progesterone:

- Prometrium
- Crinone

Source: WSJ reporting

A number of doctors have switched to Prometrium, a natural form of progesterone approved by the FDA in 1998, which has different pharmacological properties and fewer side effects.

Joe Camardo, Wyeth's senior vice president for global medical affairs, says Premarin and Prempro have demonstrated their safety and effectiveness over many years of experience. There may be "a bias toward believing that natural somehow is better," he says. But "it's not based on clinical trial data."

Indeed, since 2002, many women have flocked to "bio-identical" hormones made by compounding pharmacies, believing that they pose fewer risks than traditional hormones. These BHRT blends often contain high concentrations of all three estrogens and progesterone -- generally made from plant sources, as are the estradiol products. In January, the FDA warned seven such pharmacies

to stop making unsubstantiated marketing claims that their products are safer and more natural than traditional hormones. The FDA also told compounding pharmacies to stop using estriol, since it isn't FDA approved.

BHRT proponents say that women should be able to choose whatever hormones they want to use. Actress Suzanne Somers has been an energetic booster. "My libido is rockin', my weight is perfect, my hair has shine and luster, my skin is less wrinkled than my contemporaries. I have energy, passion, my brain is sharp; no senior moments for me," she wrote in an email. "Before I started on bioidenticals, I could not make any of these claims. In fact, it was just the opposite."

"You look at this beautiful woman and everyone wants to look like her," says Michelle Warren, director of the Center for Menopause, Hormonal Disorders and Women's Health at Columbia University's College of Physicians and Surgeons. "But there's no quality control with these pharmacies, and no packaging information, so women assume there's no risk."

"It's like buying food from a street vendor compared to a restaurant that's been inspected," says Dr. Vliet. "I have moved away from using as much of the compounded products because they are less stable, less reliable, than the pharmaceutical grade."

To minimize such risks, the FDA is recommending that doctors who want to prescribe estriol file an investigational new drug application, which requires informing patients of drug risks and benefits and reporting any adverse events.

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