

IN EVERY ISSUE

Drug Company Questions Marketing of Bioidentical Hormones

BY NOBLE SPRAYBERRY

Ignoring her oncologist's warnings that estrogen treatment could increase her risk of breast cancer recurrence, Susie Beiman relies on an alternative form of hormone therapy to stop sleep-robbing hot flashes. Beiman was taken off traditional hormone replacement therapy after her breast cancer diagnosis in 2003. The hot flashes she had long suffered worsened.

"I would get hot flashes about every 10 minutes all night long, so I was always exhausted," the 52-year-old says. "Every crease of my body would get wet from sweat. Then I'd be freezing because I'd get chilled." She chose instead bioidentical hormone therapy, which allows her pharmacist in Indianapolis to individualize doses of hormones derived from soy or yams that are chemically altered to match hormones found naturally in a woman's body.

Proponents say these hormones represent a healthy alternative and lack the extraneous molecular structures found in synthetic hormones made by pharmaceutical companies. But others say bioidentical hormones have not been tested for their safety or effectiveness, whereas synthetic hormone therapies are regulated by the Food and Drug Administration. Since proper testing has not been done, the FDA says "natural" hormone therapies may carry the same risks as commercially available hormone products.

Working in conjunction with a physician, the pharmacist uses blood tests to determine a woman's hormone levels, and these tests guide dosage plans. (Saliva tests cannot accurately measure an individual's hormone levels, as the hormones in saliva fluctuate throughout the day.) The resulting personalized mix of estrogens and natural progesterone hormones can be administered through several methods, including capsules or transdermal or transmucosal forms, such as gels or suppositories.

Bioidentical hormones offer patients choice but no wide-ranging studies exist to prove they represent less of a risk or are more effective than traditional hormone therapy. A petition to the FDA last year by the pharmaceutical company Wyeth, manufacturer of the hormone therapy drugs Premarin® and Prempro™, included calls for additional oversight of the marketing and labeling of bioidentical hormones. Wyeth contends some compounding pharmacies created a niche commercial market for bioidentical drugs and veered away from traditional compounding duties.

No broad studies exist to determine the risks and benefits of bioidentical hormones, but while the research continues, caution remains.

Candace Steele, director of global public relations for Wyeth, says the petition does not seek FDA action against pharmacies that legitimately compound individual products but instead requests action to address alleged illegal compounding activities that do not follow rules set by the FDA's Compliance Policy Guide. Among the illegal activities described in the petition: mass production in anticipation of prescriptions; compounding copies of FDA-approved therapies; selling to women with claims of being safer and/or more effective than FDA-approved hormone therapy; and lack of appropriate labeling and other important information to educate women about the product's potential risks and side effects.

The International Academy of Compounding Pharmacists responded, in part, by saying that application of regulations meant for one-size-fits-all, off-the-shelf pharmaceuticals could rob patients of medications like bioidentical hormones. L.D. King, executive director of the 1,800-member IACP based in Texas, says Wyeth misses a vital point that pharmacists are not the ones prescribing the drugs. "Wyeth makes broad, sweeping allegations that I think are inappropriate," he says. "We want to give physicians options so they can treat their patients. I think they ignore the physician."

But according to Steele, it is Wyeth's awareness of physicians that led to the petition. "Information about violations came to our attention from physicians who asked us to look into it," says Steele, who adds that Wyeth began investigating possible violations back in 2001.

New perspective on hormone therapy arrived with the Women's Health Initiative, created in 1991 to address the most common causes of death, disability and poor quality of life in postmenopausal women. The study involved more than 160,000 women and found that women who took the synthetic hormones estrogen and progestin showed an increased risk of heart attack, stroke and breast cancer. Those who took only estrogen showed no difference in the risk of heart attack, an increased risk for stroke and an uncertain effect for breast cancer. Bioidentical hormones were not studied as part of the Women's Health Initiative.

Customized Pharmaceuticals

Compounding pharmacies, like the one used by Beiman, are a source for bioidentical hormones. All pharmacists are licensed to compound prescriptions, says King.

Uses for compounding include creation of higher or lower doses than those provided by pharmaceutical companies or creation of a different dosage form. Some cancer patients might have trouble swallowing a solid medication and a compounding pharmacist can create a liquid form. While most pharmacists do some form of compounding, between 5,000 and 10,000 pharmacies nationally

specialize in the process.

Baylor Rice is president of South River Compounding Pharmacy in Midlothian, Virginia. In 10 years of operation the pharmacy has served about 5,000 patients, about half of whom used bioidentical hormones. In addition to the hormones' inherent beneficial chemical structures, Rice says the therapy offers the ability to create low doses, customize treatment, and maintain frequent monitoring to ensure proper dosages.

Pharmacies are unable to prescribe medications themselves and must work through physicians, and Rice often holds educational seminars and visits with doctors to discuss bioidentical hormones. No broad studies exist to determine the risks and benefits of bioidentical hormones, but while the research continues, caution remains from groups like the National Women's Health Information Center (www.womenshealth.gov), which says: "Products that come from plants may sound like they are more natural or safer than other forms of hormones, but there is no proof they really are. There is also no proof that they are better at helping symptoms of menopause."

Wyeth filed the 36-page petition in October of last year. The FDA will accept comments from physicians and women who have experience with bioidentical hormones until April 4. At that point, the agency will decide how to act on the petition.