

Bio-Identicals: Sorting Myths from Facts

“A natural, safer alternative to dangerous prescription drugs”

“Can slim you down by reducing hormonal imbalances”

“Prevents Alzheimer’s disease and senility”

FDA is concerned that unfounded claims like these are misleading women and health care professionals about products known as “bio-identical hormone replacement therapy” (BHRT) for relief of the symptoms of menopause.



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“BHRT” is a marketing term not recognized by FDA. Sellers of bio-identicals often claim that these “all-natural” pills, creams, lotions, and gels are without the risks of synthetic FDA-approved drugs for menopausal hormone therapy (MHT).

FDA-approved MHT drug products provide effective relief of the symptoms of menopause such as hot flashes and vaginal dryness. They also can prevent thinning of bones.

During menopause, a woman’s body produces less of the hormone estrogen, which may lead to these symptoms. MHT drug products,

which are approved by FDA for prescription only, contain estrogen or a combination of estrogen and another hormone, progesterin.

FDA has approved drugs for use in hormone therapy for menopause symptoms, and advises women who choose to use hormones to take them at the lowest dose that helps, for the shortest time needed.

Although some “BHRT” drug products are sold over the counter, many are compounded in pharmacies. Traditional compounding involves combining, mixing, or altering ingredients by a pharmacist, in response to

a licensed doctor’s prescription, to produce a drug to meet an individual’s special medical needs. FDA considers traditional compounding to be a valuable service when used appropriately, such as customizing a drug for someone who is allergic to a dye or preservative in an FDA-approved medicine. But some pharmacies that compound “BHRT” drug products are making unsupported claims that these made-to-order drugs are more effective and safer than FDA-approved MHT drug products.

FDA is taking action against pharmacies that make false and mislead-

ing claims about “BHRT” drug products and is advising consumers to be informed about these products. Here is some information to help sort the myths from the facts:

Myth: Bio-identical hormones are safer and more effective than FDA-approved hormone therapy drugs.

Fact: FDA is not aware of credible scientific evidence to support claims made regarding the safety and effectiveness of “BHRT” products. No “BHRT” product has met federal standards for approval. “They are not safer just because they are ‘natural,’” says Kathleen Uhl, M.D., Director of FDA’s Office of Women’s Health.

Myth: Bio-identical hormone products can prevent or cure heart disease, Alzheimer’s disease, and breast cancer.

Fact: “BHRT” drug products have not been shown to prevent or cure any of these diseases. In fact, like FDA-approved hormone therapy drugs, they may increase the risk of heart disease, breast cancer, and dementia in some women.

Myth: Bio-identical hormone products that contain estriol, a weak form of estrogen, are safer than FDA-approved estrogen products.

Fact: FDA has not approved any drug containing estriol. The safety and effectiveness of estriol are unknown. “No data have been submitted to the FDA that demonstrate that estriol is safe and effective,” according to Daniel Shames, M.D., a senior official in the FDA office that oversees reproductive products.

Myth: If bio-identical products were unsafe, there would be a lot of reports of bad side effects.

Fact: “Unlike commercial drug manufacturers, pharmacies aren’t required to report adverse events associated with

compounded drugs,” says Steve Silverman, Assistant Director of the Office of Compliance in FDA’s Center for Drug Evaluation and Research. “Also, while some health risks associated with “BHRT” drug products may arise after a relatively short period of use, others may not occur for many years. One of the big problems is that we just don’t know what risks are associated with these so-called bio-identicals.”

Myth: A pharmacy can make “BHRT” drug products just for you based on hormone levels in a saliva sample.

Fact: “Advertisements that a drug can be created ‘just for you’ are appealing,” says Uhl, “but unrealistic.” There is no scientific basis for using saliva testing to adjust hormone levels. Hormone levels in saliva do not accurately reflect the amount of hormones present in a woman’s body for the purpose of adjusting those levels. A woman’s hormone levels change throughout the day, and from day to day. FDA-approved tests can tell a woman’s hormone level in a specific body fluid, such as saliva, blood, or urine, at that particular point in time. “These tests are useful to tell if a woman is menopausal or not,” says Uhl, “but they have not been shown to be useful for adjusting hormone therapy dosages.”

Myth: FDA wants all compounded hormone therapies off the market.

Fact: “We are not trying to pull all compounded hormone therapies off the market,” says Silverman. “We believe that, like all traditionally compounded drugs, a woman should have access to a compounded hormone therapy drug when her physician decides that it will best serve her specific medical needs. That said, we want women to know that they should be careful about choosing products that have not been proven safe and effective. And pharmacies cannot promote compounded drugs with false or misleading claims.” In addition, as noted above, FDA has not

approved any drug containing estriol, and consistent with FDA policy, pharmacies should not compound drugs containing estriol.

Myth: All women who take FDA-approved menopausal hormone therapy are going to get blood clots, heart attacks, strokes, breast cancer, or gall bladder disease.

Fact: Like all medicines, hormone therapy has risks and benefits. For some women, hormone therapy may increase their chance of getting these conditions. However, there are no convincing data that there is less risk of developing a blood clot, heart attack, stroke, breast cancer, or gall bladder disease with a “BHRT” product. Women should talk to their health care professional about taking hormones. If you decide to use hormone therapy for menopause

- use at the lowest dose that helps
- use for the shortest time needed

If you are taking a “bio-identical” hormone now, talk to your doctor and pharmacist to determine if compounded drugs are the best option for your particular medical needs. [FDA](#)

For More Information

FDA’s Office of Women’s Health
www.fda.gov/womens/

Menopause and Hormones
www.fda.gov/womens/menopause/

Free publications for women and their families
www.fda.gov/womens/pubs.html

FDA Press Release: FDA Takes Action Against Compounded Menopause Hormone Therapy Drugs
www.fda.gov/bbs/topics/NEWS/2008/NEW01772.html

Consumer Update: The Special Risks of Pharmacy Compounding
www.fda.gov/consumer/updates/compounding053107.html