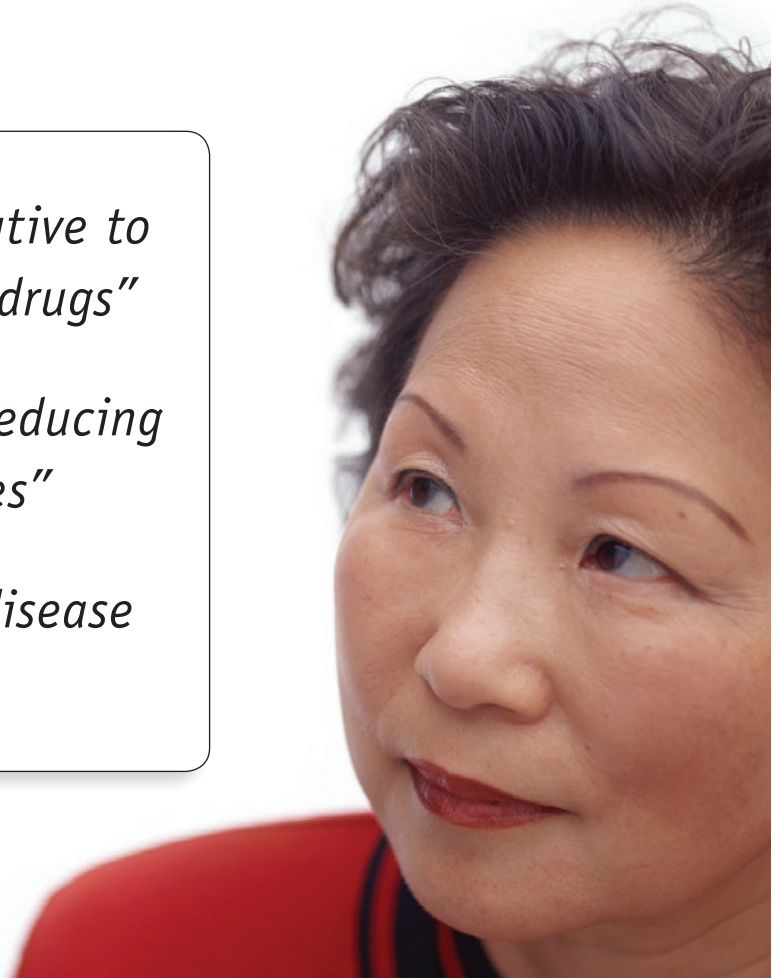


Bio-Identicals: Sorting Myths from Facts

"A natural, safer alternative to dangerous prescription drugs"

"Can slim you down by reducing hormonal imbalances"

"Prevents Alzheimer's disease and senility"



Getty Images

All of these claims have been made by marketers of compounded "bio-identical" hormones, also known as "bio-identical hormone replacement therapy" (BHRT). But these claims are unproven. FDA is concerned that claims like these mislead women and health care professionals, giving them a false sense of assurance about using potentially dangerous hormone products.

FDA is providing the facts about "BHRT" drugs and the uncertainties surrounding their safety and effectiveness so that women and their doctors can make informed decisions about their use.

"BHRT" is a marketing term not recognized by FDA. Sellers of compounded "bio-identical" hormones often claim that their products are identical to hormones made by the body and that these "all-natural" pills, creams, lotions, and gels are without the risks of drugs approved by FDA for menopausal hormone therapy (MHT). FDA-approved MHT drugs provide effective relief of the symptoms of menopause such as

FDA is not aware of any credible scientific evidence to support claims made regarding the safety and effectiveness of compounded “BHRT” drugs.

hot flashes and vaginal dryness. They also can prevent thinning of bones. FDA has not approved compounded “BHRT” drugs and cannot assure their safety or effectiveness.

During menopause, a woman’s body produces less of the hormone estrogen, which may lead to hot flashes, vaginal dryness, and thin bones. MHT drugs contain estrogen or a combination of estrogen and another hormone, a progestin. FDA-approved MHT drugs are sold by prescription only, and FDA advises women who choose to use hormones to use them at the lowest dose that helps, for the shortest time needed.

Some “BHRT” drugs are compounded in pharmacies. Traditional compounding involves combining, mixing, or altering ingredients by a pharmacist, according to a prescription from a licensed health care professional, to produce a drug that meets 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” drugs make unsupported claims that these drugs are more effective and safer than FDA-approved MHT drugs.

FDA is taking action against pharmacies that make false and misleading claims about “BHRT” drugs and is encouraging consumers to become informed about these products and their risks. Here is some information to help sort the myths from the facts:

Myth: “Bio-identical” hormones are safer and more effective than FDA-approved MHT drugs.

Fact: FDA is not aware of any credible scientific evidence to support claims made regarding the safety and effectiveness of compounded “BHRT” drugs. “They are not safer just because they are ‘natural,’” says Kathleen Uhl, M.D., Director of FDA’s Office of Women’s Health.

Drugs that are approved by FDA must undergo the agency’s rigorous evaluation process, which scrutinizes everything about the drug to ensure its safety and effectiveness—from early testing, to the design and results of large clinical trials, to the severity of side effects, to the conditions under which the drug is manufactured. FDA-approved MHT drugs have undergone this process and met all federal standards for approval. No compounded “BHRT” drug has met these standards.

Pharmacies that compound these “BHRT” drugs may not follow good drug manufacturing requirements that apply to commercial drug manufacturers. Compounding pharmacies custom-mix these products according to a health care professional’s order. The mix contains not only the active hormone, but other inactive ingredients that help hold a pill together or give a cream, lotion, or gel its form and thickness so that it can be applied to the body. It is unknown whether these mixtures, which are not FDA-approved, are properly absorbed or provide the appropriate levels of hormones needed in the body. It is also

unknown whether the amount of drug delivered is consistent from pill to pill or each time a cream or gel is applied.

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

Fact: Compounded “BHRT” drugs have not been shown to prevent or cure any of these diseases. In fact, like FDA-approved MHT drugs, they may increase the risk of heart disease, breast cancer, and dementia in some women. (See www.nhlbi.nih.gov/whi/index.html for information on the Women’s Health Initiative, a large, long-term study that tested the effects of FDA-approved MHT drugs.) No large, long-term study has been done to determine the adverse effects of “bio-identical” hormones.

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 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.

... a woman should be able to get a compounded hormone therapy drug when her physician decides that it will best serve her specific medical needs.

Fact: “Bio-identical” products are typically compounded in pharmacies. “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’ drugs 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 a “BHRT” drug just for you based on hormone levels in a saliva sample.

Fact: “Advertisements that a drug can be created ‘just for you’ based on saliva testing are appealing,” says Uhl, “but unrealistic.” Hormone levels in saliva do not accurately reflect the amount of hormones a woman has in her body for the purpose of adjusting hormone therapy dose 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 be able to get a compounded hormone therapy drug when her physician decides that it will best serve her specific medical needs. But we also want women to be informed and 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, FDA has not approved any drug containing the hormone estriol. Pharmacies should not compound drugs containing estriol unless the prescriber has a valid investigational new drug (IND) application. INDs provide benefits that include allowing physicians to treat individual patients with drugs that are not FDA-approved, while also providing additional safeguards for patients.

Myth: All women who take FDA-approved MHT drugs 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 chances 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 MHT drugs for menopause

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

If you are taking a compounded “BHRT” drug now, talk to your health care professional about treatment options 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

Article first published January 9, 2008
Updated: April 8, 2008