

The Truth About 'Bio-identical' Hormone Therapy

Much remains unknown about these treatments for menopausal symptoms, FDA says

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FRIDAY, Jan. 30 (HealthDay News) -- They're marketed as "bio-identical" hormones or "bio-identical hormone replacement therapy," and they claim to do everything from helping menopausal women lose weight to preventing senility.

They're touted as safer and sometimes even more effective than conventional hormone-replacement therapy.

But the U.S. Food and Drug Administration warns that these claims are "unproven" and that the products are "potentially dangerous." What's more, bio-identical hormone replacement therapy -- or "BHRT" -- is a "marketing term not recognized by FDA," the agency said.

Experts also are expressing some concerns about the products.

"We don't know anything [about these products]," said Dr. Suzanne Steinbaum, director of Women and Heart Disease at Lenox Hill Hospital in New York City. "This isn't FDA-approved. It's the same thing as a hormone. What concerns me is that people believe if it's not from a drug company, it's safe."

Added Dr. James Liu, chairman of the department of obstetrics and gynecology at MacDonald Women's Hospital at Case Medical Center, University Hospitals in Cleveland: "Over-the-counter products that are not listed as drugs can make some claims, and they have to be careful about it. Usually these are considered supplements. Suffice it to say, there is science behind some of what they say and a little bit of lack-of-science in other things."

And the Endocrine Society issued this position statement back in October 2006, expressing concerns about these products: " 'Bioidentical hormones,' particularly estrogen and progesterone, have been promoted as safer and more effective alternatives to more traditional hormone therapies, often by people outside of the medical community. In fact, little or no scientific and medical evidence exists to support such claims... Additionally, many 'bioidentical hormone' formulations are not subject to FDA oversight and can be inconsistent in dose and purity."

Since the release in 2002 of a Women's Health Initiative report, hormone replacement therapy (HRT) -- used to relieve symptoms of menopause -- has generated worrisome, and sometimes conflicting, headlines. While linked to a reduced risk of colon cancer and fractures, the therapy has also been associated with an increased risk of breast cancer, stroke, blood clots and heart attack. And -- so far, at least -- there are no indications that HRT has any effect on the development of dementia.

The not-inconsiderable list of potential risks of hormone-replacement therapy has left an opening for manufacturers of "natural products" to step up with supposedly better and safer versions of hormone therapy, according to the FDA.

Marketers of bio-identical hormones often say the products are identical to hormones produced by the body, and these "all-natural" pills, creams, lotions, and gels don't carry the risks of menopausal hormone therapies approved by the FDA. Agency-approved HRT drugs are typically prescribed to treat symptoms of menopause, such as hot flashes and vaginal dryness.

But the FDA said it hasn't approved compounded "BHRT" drugs and can't assure their safety or effectiveness.

Liu said that " 'bio-identical' really means that the structure of the compound you're claiming to be identical is biologically identical. It [the term] is applied primarily to female hormones that are used in hormone therapy."

But, Liu added, "the main problem is how a woman would obtain [bio-identicals]. If it's pharmaceutical grade, FDA-grade, it's prescribed. It's just how it's made."

Some of the bio-identical hormones are "compounded," meaning they are mixed specially to meet an individual's needs. For example, some dyes or preservatives may be eliminated if a person is allergic to them, according to the FDA.

"The pharmacist assumes that responsibility and the physician should specify that on the prescription," Liu said. So the bio-identical product may not have exactly the same ingredients as a standard product, he said.

But be leery if a pharmacy claims that such compounded mixtures are safer or more effective than other hormone formulations, the FDA warned. They may not be mixed according to a licensed health-care professional's instructions, the agency said.

"Women should be cognizant that both products have similar potencies, similar biological action and similar side effects," Liu said. "There's no reason to think bio-identicals are superior. There are either anecdotal or testimonial claims that one is better than the other. We're swayed by that as human beings."

Here are some points the FDA says to keep in mind:

- Approved hormone therapies are available by prescription only.
- Bio-identicals will have the same risks as the products they're identical to -- namely a heightened risk of breast cancer and serious heart problems. There may be other, as-yet-unknown risks, as well.
- Beware of claims that bio-identical products can be made based on hormone levels measured from a woman's saliva sample. Hormone levels fluctuate constantly. Saliva tests, which are FDA-approved, aren't specific enough to determine drug dosages.
- No drug containing the hormone estriol (the weakest of the three estrogens produced by the body) has been approved by the FDA. Only prescribers who have an investigational new drug (IND) application can compound drugs with estriol.
- In general, when using approved hormone-replacement therapies, the FDA and health-care professionals recommend using the lowest dose possible for the shortest period needed.

More information

Visit the FDA for more on [menopause and hormones](#).

SOURCES: James Liu, M.D., chairman, department of obstetrics and gynecology, MacDonald Women's Hospital, Case Medical Center, University Hospitals, Cleveland; Suzanne Steinbaum, D.O., director of Women and Heart Disease, Lenox Hill Hospital, New York City; *Bio-Identicals: Sorting Myths from Facts*, U.S. Food and Drug Administration

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