

# Compounded Bioidentical Hormone Replacement Scrutinized by Panel

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May 08, 2019

An ad hoc committee of the National Academies of Sciences, Engineering, and Medicine (NASEM) held its second information gathering session on compounded bioidentical [hormone replacement therapy](#) (BHRT) on May 6.

The meeting follows a September 26, 2018, US Food and Drug Administration (FDA) [announcement](#) that the NASEM would conduct two studies related to compounded drugs in collaboration with the University of Maryland and Johns Hopkins University Centers for Regulatory Science and Innovation. The studies are intended "to help inform the public and the agency's policies regarding compounded drugs," the agency said in a news release.

The Committee on Clinical Utility of Treating Patients With Compounded "Bioidentical Hormone Replacement Therapy" is examining issues such as the active and inactive ingredients in these products, dosage forms, administration routes, and strengths. For their report, they will evaluate the scientific evidence related to these issues and make recommendations on the clinical utility of compounded BHRT products in comparison to that of FDA-approved drug products.

Before the report is finalized, the committee will issue a draft version that will be thoroughly reviewed by experts who are unknown to the committee.

## Why BHRT?

Settings in which a compounded product may be needed include those in which patients are unable to swallow a pill, as well as for the treatment of children and of pain patients who require a medication dose different from what is commercially available.

Compounded BHRT products, including progesterone and [testosterone](#), are sometimes used instead of products approved by the FDA.

Jim Hrcir, RPH, Las Colinas Pharmacy (503A compounding pharmacy), said during the session that it is possible to get much higher concentrations of the active pharmaceutical ingredient in a smaller pill or a smaller amount of liquid. "The manufactured testosterone gel requires 5 to 10 mL to be applied to the skin...and we can put that dose in ½ to 1 mL. If you're thinking about transference and safety, does ½ to 1 mL sound safer than 5 to 10 mL when you're applying it all over, and now you're picking up your dog and your kid? We have a big advantage there," he explained.

In 2002, the [estrogen](#) plus progestin arm of the Women's Health Initiative [found](#) that the risk for [breast cancer](#), cardiovascular disease, [stroke](#), and thromboembolic events was higher in women who took conjugated equine estrogen and [medroxyprogesterone](#) acetate compared to women who took placebo. As a result of these findings, many women stopped receiving

hormone therapy or sought a safer alternative to FDA-approved hormone treatment to relieve [menopause](#) symptoms. Many women asked their healthcare providers for non-FDA approved compounded BHRT, which they believed was safer.

In compounded products, bioavailability data are available on the active ingredients, but compounded products are not tested in humans. Several speakers at the meeting emphasized that the FDA has not assessed the quality, safety, efficacy, and bioavailability of compounded BHRT products.

Compounded bioidentical [hormone therapy] presents safety concerns such as minimal government regulation and monitoring, overdosing or underdosing, presence of impurities or lack of sterility, lack of scientific efficacy and safety data, and lack of a label outlining risks. Salivary hormone testing to determine dosing is unreliable," the North American Menopause Society said in a 2017 position statement.

Compounded products must be made in an FDA-registered facility; however, there was some question by attendees about what that means. Compounding pharmacies must register with the FDA, but that is a separate process from the FDA approval process.

The Endocrine Society writes in a position statement that although compounded BHRT products such as estrogen and progesterone have been marketed as being safer and more effective than FDA-approved products, there is little scientific evidence to support these claims.

Although it is usually possible to determine where a compounding pharmacy obtained a particular active pharmaceutical ingredient, it can be difficult to trace an ingredient further back in the chain.

### Medical Organizations Against Compounded BHRT

The North American Menopause Society [recommends](#) against the use of compounded BHRT and says that if it is prescribed, clinicians should document the indication for prescribing it rather than a government-approved BHRT, such as allergy, a medical need for a lower dose than is available, or the need for a different preparation.

The American College of Obstetricians and Gynecologists Committee on Gynecologic Practice and the Practice Committee of the American Society for Reproductive Medicine wrote, "Despite claims to the contrary, evidence is inadequate to support increased efficacy or safety for individualized hormone therapy regimens based on salivary, serum, or urinary testing" in a committee opinion [published](#) in August 2012 and reaffirmed in 2018.

The committee opinion authors also warned, "These preparations have variable purity and potency and lack efficacy and safety data."

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Cite this: Compounded Bioidentical Hormone Replacement Scrutinized by Panel - Medscape - May 08, 2019.