

Addressing the double standard

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A new editorial by JoAnn Manson, MD, DrPH in *JAMA Internal Medicine* highlights the need for physicians and pharmacists to educate women about the important distinctions between these hormone therapies

With an estimated 26 to 33 million prescriptions filled annually, Manson and her coauthor address the increasing use of compounded bioidentical [hormone](#) therapies by [menopausal women](#), and why this is of concern, in a Viewpoint published in *JAMA Internal Medicine*. Compounded hormones are promoted as safer and more "natural" hormones obtained from special compounding pharmacies, but they actually contain the same hormones (e.g., estradiol and progesterone) obtained at regular pharmacies. The article highlights that many women are unaware that the compounded drugs are not FDA-approved, lack the quality control of FDA-approved products, and have the same risks as FDA-approved hormone therapy products. Although many FDA-approved "bioidentical" hormone products are available in a wide range of doses, women often are not aware of these options and are led to believe that compounded hormones are a safer and more effective approach to managing their hot flashes and other symptoms.

Manson explains women are commonly misled about the difference between the two. "With the increased use of compounded medications, women are not being properly informed that these are not FDA-approved drugs, nor do women receive a patient package insert about the risks, leading them to believe they're a safer choice. The reality is these products have the same risks as FDA-approved medications, except they

aren't required to include boxed warning inserts that explain that," says Manson. "Professional societies responsible for safe guarding women's health recommend that women use FDA-approved medications rather than the compounded formulations due to concerns about the latter's inconsistent dosing, potential for contamination, and missing patient package inserts that explain the risks of the drug."

Manson and her coauthor are issuing a "call to action" to require that this information be routinely provided to [women](#) and to tell them the truth about their options.

More information: "Compounded Bioidentical Hormone Therapy. Does the Regulatory Double Standard Harm Women?" *JAMA Internal Medicine* (2017)

Provided by Brigham and Women's Hospital

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