

“BIOIDENTICAL HORMONES: WHAT YOU (AND YOUR PATIENT) NEED TO KNOW,” BY JOANN V. PINKERTON, MD (JANUARY 2009)

Safety of bioidenticals has already been proved

As a physician who prescribes bio-identical hormones from both man-ufactured and compounded sources, I found your article insulting to my intelligence and that of other physi-cians I know who use this therapy across the United States.

I agree that bioidentical hor-mone replacement therapy (HRT) from manufactured and compound-ed sources carry the same risks. However, to say that bioidentical hormones carry the same risks as “conventional” HRT—i.e., nonbio-identical hormones—is absurd. The Women’s Health Initiative and the Million Women’s Study have already disproved that. And the E3N study demonstrated that estrogen and pro-gesterone supplementation do not raise cancer risk; that study is backed up by use in thousands of women.¹ To ignore these studies because they in-volve bioidentical HRT is to ignore the practice of evidence-based medicine.

To say that compounding is un-safe is also illogical, as every IV solu-tion in hospitals and multiple pain and pediatric medicines are com-pounded from FDA-approved agents. I imagine that, like hand-washing to prevent disease, the use of bioidentical hormones to improve care will be reviled, accepted, and then embraced. Until then, tell me why the FDA hasn’t approved bioidentical testosterone for women who have vaginal dryness after complete hysterectomy.

Alison McAllister, ND
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Reference

1. Fournier A, Berrino F, Clavel-Chapelon F. Un-equal risks for breast cancer associated with differ-ent hormone replacement therapies: results from the E3N cohort study. *Breast Cancer Res Treat.* 2008;107:103-111.



JANUARY 2009

How do we counteract broad-based misinformation?

Here is a link to video from a recent segment of the Oprah show that fo-cused on bioidentical hormones: www.oprah.com/media/20090114_tows_prudence.

What can I do as a generalist to help my patients understand their choices regarding bioidentical HRT and the current evidence when this is what they see on TV?

Michael Baker, MD
Kinston, NC

>> Dr. Pinkerton responds: Hormones are not benign

My patients often walk in thinking that they cannot get cancer or other harm-ful effects from compounded bioiden-tical products. However, I believe that hormones, whether compounded or FDA-approved, have potential risks. I have seen both breast cancer and en-dometrial cancer in patients who were taking bioidentical HRT—but there is no way to know whether there is an as-sociation or whether the malignancies arose by chance.

Compounded products are not backed by the same degree of scientific

safety and efficacy data that is required by the FDA for approved products. That does not make them less safe or safer; it just means that they carry unknown or less known potential for risks.

When I see patients who are re-questing compounded bioidenticals after watching the Oprah show, I first address whether they need hormone therapy of any kind. Then I discuss the differences between FDA-approved and compounded bioidentical hormones, and mention the media hype and lack of scientific efficacy, safety, and moni-toring of compounded therapies. In the end I try to individualize the deci-sion with each woman, and determine whether she needs hormones and what products and dosages might be most ef-fective with the fewest risks.

I have also been handing out cop-ies of a recent Newsweek.com article that rebutted the Oprah segment on bio-identicals. It can be accessed at www.newsweek.com/id/183842/page/1. An accurate information sheet on bio-identicals is also available at www.healthywomen.org. In addition, the North American Menopause Society offers expert information on hormone therapy, including the bioidentical op-tion, at www.menopause.org.

Like Dr. McAllister, I am frustrated that we don’t have more data on the safety and efficacy of compounded products, particularly those that include testosterone. I am also unhappy that we lack an FDA-approved physiologic tes-tosterone product for those women in whom it might make a significant dif-ference. However, I appreciate the FDA’s caution because of the lack of long-term safety data on the risk of cardiovascular disease and cancer and mixed reports of the risk of breast cancer with use of bioidentical testosterone.

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