



The Vision and Voice of Women in Medicine

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November 7, 2005

Robert J. Temple, MD  
Director, Office of Medical Policy  
Food and Drug Administration  
Rockwall Two  
5515 Security Lane, Suite 7201  
Rockville, MD 20852

Dear Dr. Temple:

Representing women of all specialties, the American Medical Women's Association (AMWA) has been supporting women in medicine for 90 years. AMWA is a national association, with local branches and medical student chapters across the country, dedicated to advancing women in medicine and improving the health of women and their families. We recently had an opportunity to learn about and then review the Citizen Petition requesting that FDA take action against the manufacture and marketing of the "bio-identical hormone replacement therapies" (BHRT) that are not regulated by FDA and would like to express our support for this petition.

The American Medical Women's Association is concerned about the safety and purity of these unregulated compounds and about misleading claims related to of the marketing of some of these BHRT products, both to women and to health care providers. Women seeking to relieve their menopausal symptoms and who, for a variety of reasons, may not want to use FDA-approved, commercially available pharmaceutical hormone therapy (HT) or BHRT, may be drawn to non-FDA-approved BHRT products mixed through compounding pharmacies. These women may also be particularly vulnerable to misleading claims about the compounded BHRT products. As these compounded products are unregulated, so are the claims for them. Such claims have included:

- Fewer side effects versus synthetic derivatives;
- Protection against heart disease;
- Reduced risk of breast cancer; and
- Improved cholesterol and lipid profile.

This is particularly concerning in the HT environment, where FDA-approved products must carry health warnings that are regulated; and yet, for the unregulated compounded BHRT products, there is currently no control on the veracity of benefit or side effect claims. In addition, for these compounded products, there is no regulation of production, purity of product and safety of dose, nor safety and efficacy studies.

In addition to misleading women, some BHRT compounding pharmacies may also be contributing to the confusing discourse about hormone therapy. As an AMWA-sponsored survey conducted last year found, more than half of OB/GYNs and two-thirds of nurse practitioners and primary care physicians are unclear about the guidance they

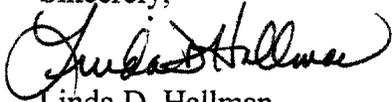
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can/should take from the Women's Health Initiative study findings in caring for their patients. Unsubstantiated claims, directed at both women and health care professionals by some marketers of compounded BHRT products, raise serious public health concerns and add to the confusion among those who are making decisions about management of menopausal symptoms. AMWA calls on the FDA to address the challenge of the Citizen Petition and to take appropriate enforcement action.

The American Medical Women's Association will continue to work to provide health care professionals and consumers with reliable and accurate information about hormone therapy. We look forward to FDA's immediate intervention in this matter.

Sincerely,



Linda D. Hallman  
Executive Director

cc: Scott Gottlies  
Deputy Commissioner for Medical and Scientific Affairs

Theresa Toigo  
Acting Director, Office of Women's Health

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Attention: Docket Number 2005P-0411