



November 16, 2005

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Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

To Whom It May Concern:

Re: *Docket Number 2005P-0411*

The North American Menopause Society (NAMS) has noted the Citizen Petition requesting the Commissioner of the U.S. Food and Drug Administration (FDA) to take action to address issues relating to manufacture and marketing by compounding pharmacies of so-called bioidentical hormone replacement therapies (BHRT). NAMS wishes to draw the attention of the FDA to the following comments and concerns of our organization.

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Founded in 1989, NAMS is North America's leading non-profit scientific organization dedicated to promoting the health and quality of life of women through an understanding of menopause. Its multidisciplinary membership of over 2000 leaders in the field – including clinical and basic science experts from medicine, nursing, sociology, psychology, nutrition, anthropology, epidemiology, pharmacy, and education – allows NAMS to be uniquely qualified to provide information that is both accurate and unbiased, not for or against any point of view. The Society, a 501(c)(3) nonprofit organization, is pleased to be recognized as the preeminent resource on all aspects of menopause to both healthcare providers and the public.

The NAMS structure and membership has allowed it to develop evidence-based Position Statements on many aspects of menopause and menopause-related care through multidisciplinary panels of experts with review and approval by the NAMS Board of Trustees. In particular, I refer to the NAMS Position Statement entitled "Recommendations for estrogen and progestogen use in peri- and postmenopausal women: October 2004 position statement of The North American Menopause Society", published in 2004 (*Menopause*, Volume 11, pages 589-600), a copy of which is attached. Specifically, I refer you to the marked item on page 594 which reads:

"The Panel recognized that specific compounds, dose, and route of administration may have different outcomes. Nonetheless, in the absence of clinical trial data for each specific product, the clinical trial results for one agent should be generalized to all agents within the same family. This proviso also applies to the so-called bioidentical products."

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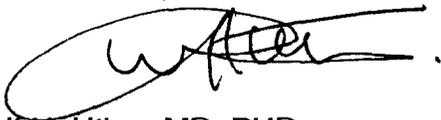
NAMS therefore wishes to draw the following points of concern to the attention of the FDA and hopes that they will be addressed as part of the response to the Citizens petition:

1. The mass volume of misleading information contained in marketing materials disseminated to the public suggesting that compounded mixtures of these products do not carry the same potential risks and that they offer greater efficacy than FDA-approved products.
2. The absence of package inserts for the consumer advising of safety and efficacy issues, and of appropriate black box warnings.
3. The advertising and use of salivary hormone levels to "tailor" dose of compounded BHRT's in the complete absence of evidence that such hormone levels are of any use or value, and absence of evidence in the scientific literature that very small changes in hormone dose, combination, or permutation have any significant effect on safety or efficacy.
4. Our major concern that compounding pharmacies are engaged in the unlicensed practice of medicine through the practice of marketing their products, requesting salivary hormone levels, and sending prescriptions to licensed medical practitioners for a "rubber stamp" signature, with care therefore being directed by the pharmacy and not by the licensed practitioner.

We look forward to the outcome of your deliberations and to determining whether you have adequately addressed our concerns as itemized herewith. There is urgency to this issue, as the health and safety of women are at risk.

Thank you for your kind attention.

Yours sincerely,

A handwritten signature in black ink, appearing to read "W. Utian", written over a large, light-colored oval shape.

Wulf H. Utian, MD, PHD
Executive Director