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February 14, 2006

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

Re: Docket Number 2005P-0411

To Whom It May Concern:

The Women in Balance Association is writing to discuss the Citizen Petition and to voice our support for the millions of women and their health care providers who have found health benefits from utilizing bioidentical hormone therapy.

As an association of women, healthcare professionals, and other national organizations promoting research and advancing education on the range of optimal health solutions for women, we seriously question the validity of many of the claims outlined in the Petition and respectfully call upon the FDA to reject this petition and retain access for women to bioidentical hormone options. The health care provider-patient relationship is very important and practitioners should have the option to prescribe and patients should retain the choice to take individualized, bioidentical hormone therapies. This choice should be respected and protected.

We want to make clear that physicians must prescribe compounded bioidentical hormone therapies for each patient before a pharmacist can provide her with this medication. The Petition completely ignores the critical role doctors play in prescribing. Pharmacists prepare customized medicines for women based upon physician's orders.

Most importantly, we believe it is time to address this vital treatment option already in use by an estimated 2 million women nationwide as prescribed by their physicians. We would like to recommend that an independent agency (such as the Agency for Healthcare Research and Quality) meet with researchers and clinicians well versed and knowledgeable about bioidentical hormone therapy in order to gain a better understanding of current research and practices in this neglected area of treatment.

At Women in Balance we work with physicians who have conducted and published evidence-based clinical research on the efficacy and benefits of bioidentical hormone therapies and could provide much needed information on the range of best practices available for treatment of menopausal symptoms, including the use of bioidentical hormones as well as non-drug approaches.

Our collective goal must be to advance our knowledge base of information on beneficial, efficacious, and safe options for women in alleviating menopausal symptoms and helping them to achieve their best health status. Individualized treatment including the use of bioidentical hormone therapy is proving to be a beneficial treatment approach for many women. It is vital that we conduct further research on this neglected and crucial field of women's health.

Every day millions of women confront uncomfortable and sometimes painful health problems related to menopause and hormone imbalances. These problems are real and, particularly during menopause and the years leading up to it, can seriously affect the emotional, physical and social aspects of their lives.

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Certainly, not all women require hormone therapy, and many successfully manage their menopausal symptoms through other approaches such as nutrition and exercise.

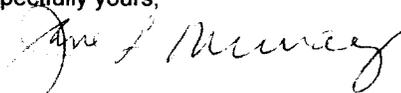
However, the interest in and use of bioidentical hormones – by women and health care providers – has been increasing. We know this is largely due to women experiencing benefits from this individualized treatment approach including a reduction in menopausal symptoms, and improvements in sleep, mood, energy and overall functioning – often with fewer side effects than with non-bioidentical hormone options.

Bioidentical hormones are extracted from soy or wild yams in a laboratory and modified in such a way that the *molecular* structure is identical to the body's own hormones. For this reason, they are referred to as "bioidentical hormones." Some of these are manufactured drugs marketed by pharmaceutical companies and some of the same compounds are mixed into formulations prescribed by a physician and compounded by a pharmacist for an individual patient's needs. Compounded medications are available in a dose or delivery system different from a commercially available product. Many menopausal women are very sensitive to even slight fluctuations in hormone levels, and compounded bioidentical hormones allow for more individualized management and improved outcomes for some women.

Since the Women's Health Initiative (WHI) was halted in 2002, there has been widespread confusion about the course of treatment and safety of any and all hormones. However, the WHI was confined to the drugs Premarin® and Prempro®, and linked these specific drugs to increased risk of breast cancer and/or increased heart and circulatory diseases in older women. While the Petition suggests that the WHI studied bioidentical hormones, in fact it did not. Therefore, the claims in the Petition that suggest bioidentical hormones are the same as those studied in the WHI are not accurate.

Women in Balance's mission is to advance education and promote research on the spectrum of healthy options and approaches for alleviating menopausal symptoms, achieving balance and creating optimal health for women. It is time that we address the interests of women and their providers. Women in Balance respectfully calls upon the Food and Drug Administration (FDA) to preserve the choices women have for hormone therapy and to promote more research in this important area. We look forward to hearing your response to the requests outlined in this letter.

Respectfully yours,



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Chair, Women in Balance

Cc:

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