NATIONAL WOMEN'S LAW CENTER
EXPANDING THE POSSIBILITIES

February 16, 2006

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
HFA-305
Room 1061
Rockville, MD 20852

Docket #2005P-0411

To Whom It May Concern:

The National Women's Law Center is a non-profit organization that has been working since 1972 to advance and protect women's legal rights. The Center focuses on major policy areas of importance to women and their families, which, in addition to women's health, includes economic security, education, and employment, with special attention given to the concerns of low-income women.

Since its inception over 30 years ago, the Center has looked to the FDA to protect women's health, both by assuring that drugs and devices of importance to women are subject to appropriate regulatory action that is science-based, and that women are provided with the information needed for them to make informed decisions.

Last November, the American College of Obstetricians and Gynecologists (ACOG) released a Committee Opinion from its Committee on Gynecologic Practice raising concerns about compounded bioidentical hormones, described by ACOG as plant-derived hormones that are biochemically similar or identical to those produced by the ovary or body. [1]

According to the ACOG Committee Opinion, "Given the lack of well-designed and well-conducted clinical trials of these alternative therapies, compounded hormone products should be considered to have the same safety issues as those associated with hormone therapy agents that are approved by the FDA. They also may have additional risks intrinsic to compounding." Moreover, the ACOG Committee Opinion found "there is no scientific evidence to support claims of increased efficacy or safety for individualized estrogen or progesterone regimens."

[1] "Compounded Bioidentical Hormones," ACOG Committee Opinion No. 322, Obstetrics & Gynecology, 106:1139-40 (November 2005).

Amplifying on these important conclusions, the Committee Opinion stated "most compounded products have not undergone any rigorous clinical testing for either safety or efficacy, and issues of quality assurance regarding the purity, potency, and quality of compounded products are a concern." The Committee Opinion pointed to the studies conducted by FDA itself as long ago as 2001, finding that "34% of the compounded products tested failed one or more standard quality tests performed." Also troubling, the Committee Opinion stated that "hormone therapy does not belong to a class of drugs with an indication for individualized dosing." Finally, the Committee Opinion pointed to the FDA requirements of a black box warning and package insert information that manufacturers of estrogen and progestogen products must meet, which reflect the findings of the Women's Health Initiative. But such warnings and information are not currently required for these compounded products.

On October 6, 2005, Wyeth filed a citizen petition with the FDA[2] requesting the FDA to take a series of actions to address the growing problems of the type identified by ACOG related to the manufacture and marketing of "bio-identical hormone replacement therapies" (BHRT). The petition also described troubling claims, in conflict with ACOG's findings, made to the public about the safety and efficacy of these products.

The FDA has a wide range of regulatory tools available to protect women's health and safety, and to ensure that they are given needed information on BHRT. The National Women's Law Center urges the FDA to address this serious health concern promptly, and to exercise its full authority to ensure that women are protected under all relevant provisions of the Federal Food, Drug and Cosmetic Act and FDA regulations. The women of this country, whose health is on the line, deserve no less.

Sincerely,

Marcia D. Greenberger
Co-President

cc: Jane A. Axelrod, Director, Office of Regulatory Policy
Sheldon T. Bradshaw, Chief Counsel, Office of the Chief Counsel
David J. Horowitz, Director, Office of Compliance
Kathleen Uhl, Director, Office on Women's Health

Food and Drug Administration
Department of Health and Human Services

[2] Wyeth Pharmaceuticals, Inc.'s Citizen Petition Seeking FDA Actions Docket Number 2005-P-0411