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WOMEN'S HEALTH RESEARCH

Changing the Face of Medicine

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November 21, 2005

Andrew C. von Eschenbach, MD
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Parklawn Building, Room 14-71
Rockville, MD 20857

Dear Acting Commissioner von Eschenbach:

The Society for Women's Health Research is writing to you to add its voice to others who are bringing to your attention an issue that we believe may pose a threat to women's health - namely, the unlawful marketing and manufacturing of so-called bio-identical hormone replacement therapy (BHRT) products. A Citizen Petition on this issue has recently been filed, and we wanted to express our support for this Petition.

The Society for Women's Health Research has worked since its inception in 1990 to promote women's health research, including research on conditions affecting women disproportionately, predominately, or differently than men. The Society was an early proponent of the Women's Health Initiative (WHI). This landmark study has given us the most comprehensive data yet on the risks and benefits of hormone therapy (HT). Unfortunately, the abrupt ending of the combined HT and estrogen-alone arms of the trial led to great confusion and many unanswered questions.

While we now have a more defined picture of hormone therapy's risks and benefits based on the WHI studies, though a great deal more research needs to be done, the FDA has determined that in the absence of evidence to the contrary, the risks and benefits of other forms of hormone therapy must be assumed to be similar. The Society is alarmed by the potential harm to women caused by misleading claims made about the alleged benefits of bio-identical hormone replacement therapy products over other FDA-approved forms of HT.

Bolstered by testimonials from celebrities such as Suzanne Somers, these misleading safety and efficacy claims will be very effective in convincing many women to choose bio-identical HRT over other hormone therapy products, without hearing appropriate information about risks and benefits associated with products containing estrogen as required by the FDA.

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While it is a woman's choice, an informed decision cannot be made without first receiving truthful information about therapy options. These pharmacies should not be promulgating false and misleading information not only about the benefits of compounded BHRT products, but also about the nature of the risks associated with FDA-approved forms of HT.

The Society feels that it is incumbent upon the FDA to investigate BHRT compounding pharmacies' practices, and to take strong action against any unlawful activities. Women need clear guidance and information from the FDA about BHRT products.

We respectfully request that you include this letter in Docket Number 2005P-0411.

We look forward to hearing the steps FDA plans to take to address this serious women's health issue.

Kind regards,



Phyllis Greenberger, MSW
President and CEO

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