INTEGRATED
HEALTHCARE POLICY
CONSORTIUM

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May 30, 2008

Dear Member of Congress:

The Integrated Healthcare Policy Consortium (IHPC) is a broad, active coalition which advocates public policy to ensure all Americans access to the full range of safe and regulated healthcare systems and disciplines in a truly integrated system. Individuals and organizations involved in IHPC include consumers, business and education leaders, healthcare professionals, and educational institutions from conventional and complementary/alternative healthcare disciplines. The professional associations with which we work most closely jointly represent hundreds of thousands conventional and alternative health care providers.

In January of this year, the U.S. Food and Drug Administration (FDA) initiated steps to restrict the provision of prescriptions containing bio-identical estriol by compounding pharmacies to post-menopausal women. We find this action to be an unwarranted invasion of the physician-patient relationship, and an unjustifiable restriction of a woman's individual right to choose from among treatment options sharing similar risks and therapeutic benefits.

Estriol is the weakest of the estrogens, and research suggests it is effective treatment for vasomotor symptoms and sleep disturbances associated with menopause, providing relief comparable to that seen with conventional hormone therapy. A small number of studies suggest estriol may possess a better safety profile than other forms of estrogen therapy, and some have aggressively promoted compounded hormone therapy because of this. Long-term, head-to-head studies comparing the safety and efficacy of estriol with other forms of estrogen therapy are lacking, however, and most medical experts believe the risks associated with any form of estrogen therapy, conventional or bio-identical, to be similar. Reportedly the FDA itself is unaware of any adverse effects associated with estriol use over the previous 30 years. In addition, the United States Pharmacopeia (USP) has already produced a monograph on estriol.

Estriol represents a viable therapeutic option for women who cannot tolerate conventional prescription estrogens or who simply prefer a bio-identical option. Yet, the FDA is poised to remove this USP-reviewed agent from the market without having identified any specific or unique adverse event or health concern.

In 2006, then director of the North American Menopause Society Wulf Utian, MD noted that "the argument is not against the use of compounded hormones, the argument is that women aren't being informed." The issue before us is not one of legislation, but of education.

IHPC stands opposed to the proposed FDA action and in support of House Concurrent Resolution 342. Compounding pharmacists and healthcare practitioners should be allowed to perform to the limits of their licensed scope of practice, and patients should have access to the medications and remedies prescribed and deemed safe by their doctors. Estriol should not be taken off the market; rather factual information should be made available to the public in support of informed decision-making.

We appreciate your careful consideration of this matter, and specifically of House Concurrent Resolution 342.

Sincerely,

Janet R. Kahn, PhD
Executive Director

Sheila Quinn
Chair, IHPC Board of Directors