

Women in Balance Health Alert

FDA threatens your rights to have health care choices you need to balance your life.

At ***Women in Balance (WIB)*** we want you to be informed about issues that affect your health choices. Please read and share the following information with your friends and colleagues.

WIB is dedicated to providing factual and unbiased information, so you can make decisions about your own health. Action by the FDA on January 9, 2008 seriously threatens your future ability to obtain individualized hormone therapy. WIB wants you to know the points – and facts – of this action, so you can get involved and have your voice heard!

The Issue

FDA issued warnings to seven compounding pharmacies, declaring that use of the term bio-identical (natural) hormone therapy (BHRT) is a term not recognized by the agency and should not be used to market compounded hormones, nor can claims be made that these compounds are better and safer than “FDA approved” hormone containing drugs. And of most concern is that the hormone estriol, (being used in 80% of compounded hormones for menopause) is not recognized as safe by FDA, as this compound is not currently found in any “FDA approved” hormone containing drugs.

Here’s our take on FDA’s key points

FDA Action:

Compounding pharmacies cannot include estriol, a main ingredient in many compounded hormone prescriptions, since the FDA has not approved any commercial drugs containing estriol.

FACT

- Estriol is a very mild estrogen. It is one of the three estrogens natural to a woman’s body, and the main estrogen during a pregnancy – the fetus is bathed in it.
- Estriol is primarily used in cream form for vaginal dryness and urinary problems for women in perimenopause and menopause.
- The FDA recognizes that individually compounded medications should be available to patients (by prescription) for “those drugs for which no FDA approved option exists”. There is no FDA approved drugs containing estriol, so it is a perfect example of

- where a compounded prescription would be needed in select cases.
- The FDA claims that there is no safety and patient response data for estriol. In fact there is a body of literature about this which can be accessed in the Research section on the Women in Balance website; www.womeninbalance.org
 - Estriol has been used in Europe and Japan for years with no reported ill effects.
 - Like many commonly prescribed drugs, estriol has a monograph from the U.S. Pharmacopeia (USP), the ingredient compendium that sets the national standards for compounding medicines.

FDA Action:

The terms “bio-identical hormone replacement therapy” and “BHRT” are considered marketing tools with no medical or scientific basis.

FACT:

- “Bio-identical hormone” is a term in wide use today, and has a very clear definition and meaning. It simply refers to the chemical structure of a hormone molecule being identical to the hormone molecule found in humans.
- A simple web search reveals hundreds of entries using the term “bio-identical”.
- The North American Menopause Society held an all day conference titled “Understanding the Controversy: Hormone Testing and Bio-identical Hormones” in October 2005.
- The manufacturer of FDA approved hormone products accurately promote their drugs as being “bio-identical” in their literature and on their websites (www.prometrium.com and www.estrogel.com). Will the FDA begin sanctioning these companies as well?

FDA Action:

Compounding pharmacies cannot claim in their promotional materials that compounded bio-identical hormones are safer or more effective than hormones approved by the FDA.

FACT:

- The FDA must protect the public from fraudulent and misleading claims with potentially dangerous drugs and foods.
- Pharmacies and pharmaceutical companies making unwarranted claims of safety and efficacy should indeed be sanctioned.

Women have a right to choose their treatment when multiple options exist, and practitioners have a right to prescribe drugs to benefit each

individual patient. In the absence of observed and documented danger of a compounded prescription, the FDA should not interfere in the doctor-patient-pharmacist relationship.

We will be monitoring this situation over the weeks to come and will provide actions steps you can take to make your voice heard on this important issue.

At **WIB**, we believe women have a right to accurate, unbiased information and resources to help them through the often tumultuous transition at menopause. As part of our educational mission, we will soon release a thoroughly documented scientific paper; *The State of the Science of Bio-identical Hormones*. This publication is made possible by your generous support. Please join **WIB** today and receive a copy of this important publication in the near future. Go to www.womeninbalance.com and click "Support the Cause" .