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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 are some facts not mentioned in the FDA Position

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/research.

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 or 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.

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.estrojel.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.