Thousands of women currently rely on replacement hormones that are prescribed by their doctors and compounded in local pharmacies. These compounded hormones are biologically identical to the ones produced in the human body. The formulas include bio-identical, naturally occurring estrogen hormones such as estradiol.

Nevertheless, on January 9, the U.S. Food and Drug Administration ordered pharmacies to stop providing bio-identical estradiol. Even though 80% of natural hormone replacement therapy prescriptions use it, and estradiol is manufactured by the human body, the FDA makes the outrageous and nonsensical claim that estradiol is “a new and unapproved drug” and that “the safety and effectiveness of estradiol is unknown.”

Bio-Identical Estradiol is Safe

In a press conference, the FDA admitted that no adverse event involving compounded bio-identical estradiol has ever been reported. Research involving 15,000 women funded by the Department of Defense and conducted at Kaiser-Permanente Oakland found that women who produced the most estradiol during their first pregnancy had 85% less breast cancer over the next forty years. Every woman who has ever had a menstrual cycle or been pregnant knows that natural estradiol is both safe and effective. Estradiol is a major estrogen throughout a woman’s reproductive years, and it attains enormous levels (up to a thousand times) during pregnancy.

How can bio-identical estradiol, identical to every woman’s natural estradiol, be unsafe or ineffective? And how can the FDA claim that a substance present in our bodies from the dawn of humanity is a “new and unapproved drug”?

Speaking the Truth is Not a “False Claim”

The FDA is also ordering pharmacies to stop using the terms “bio-identical hormone replacement therapy” and “BHRT” on the grounds that these terms represent “false claims.” False claims do exist in any field and should not be allowed. But describing these hormones accurately is not a false claim.

What’s Going on Here?

For decades the FDA has called any claim about biologically identical hormones an ad, and a false one. But there’s a big Catch-22: It costs up to a billion dollars to achieve FDA approval. As a general rule, companies cannot afford to spend up to a billion dollars to achieve FDA approval. As a result, the FDA has ordered to do so by a judge.

Why is the FDA so hostile?

A possible explanation: the FDA is worried that natural substances will eat into the sales and profits of its clients, the big drug companies. Fees from the big drug companies pay for a sizeable share of the FDA’s budget and staff. There are many other financial ties as well.

In October 2005, Wyeth, a large patent medicine (drug) company, filed a “citizens’ petition” demanding that the FDA ban bio-identical hormones that compete with Wyeth’s synthetic hormones. Sales of Wyeth’s hormones had plummeted as more and more women and their doctors turned to bio-identical hormones. (Recently Wyeth has faced layoffs and facility closings for this and other reasons.)

Over 70,000 women, pharmacists, and doctors wrote to the FDA, the overwhelming majority asking the Agency to reject Wyeth’s attempt to shut down the competition and preserve access to bio-identical hormones. The FDA sided against the women and with Wyeth.

Are the FDA “Approved” Drugs Safe?

And what do we know about the “approved” patent medicines (drugs)? From Wyeth and others that the FDA wants you and your doctor to use for hormone replacement? These once-bestselling drugs come from horses or are imprecise versions of natural human hormones. Why would any woman prefer horse hormones or imprecise-yet-patentable copies of human hormone molecules to ones precisely identical to those found naturally in her body?

Studies have also raised questions about possible heart and cancer risks from these hormones. (See the Journal of the American Medical Association 288[3], p. 133-137 (2002) and 291[3], pp. 872-884.) This is why these drugs currently have Black Box Warnings on them.

Why Shouldn’t Women and Their Doctors Have a Choice?

It’s time to take action again! We are the HOME (HANDS OFF MY ESTROGENS!) Coalition, a coalition of licensed doctors and concerned citizens. Please contact your congressional representative, senators, and the White House immediately for sample letters and e-mails, and a simple interactive form for sending your messages, visit the HOME Coalition website: www.homecoalition.org

For the HOME Coalition:

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