

# FDA Bans Hormone Produced by Human Body as “Unapproved” Drug

***The FDA has told women and their doctors: stop using bio-identical hormones. Your choice and your doctor’s prescription don’t matter. Heart and cancer questions raised in 2002 about FDA “approved” synthetic women’s hormones don’t matter. Act now to defend your right to bio-identical hormones!***

Countless 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 estriol.

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

## Bio-Identical Estriol is Safe

In a press conference, the FDA admitted that no adverse event involving compounded bio-identical estriol 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 estriol during their first pregnancy had 58% less breast cancer over the next forty years.

Every woman who has ever had a menstrual cycle or been pregnant knows that natural estriol is both safe and effective. Estriol is a major estrogen throughout a woman’s reproductive years, and soars to enormous levels (up to a thousand times) during pregnancy.

How can bio-identical estriol, identical to every woman’s natural estriol, 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 a natural substance, no matter how accurate, a “false claim” if it is not specifically FDA “approved.” 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 these huge sums unless their drug is patent-protected. And again, as a general rule, natural substances such as bio-identical hormones cannot be patent-protected. As a result, the FDA has “approved” only a very small handful of natural substances, sometimes only after being sued and ordered to do so by a judge.

Bottom line: The FDA says that natural substances must be “approved” to make any claims about them, but knows full well that, under the current FDA system, there is no way to get most natural substances “approved.”

## Why is the FDA So Hostile to “Natural” Medicine?

“Alternative,” “natural,” and “integrative” medicine is booming today. A growing number of doctors and patients believe that natural substances are often safer and more effective than

synthetic, hyper-expensive but “approved” patent medicines (drugs). So 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-best-selling 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], pp. 321-333; [7], 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](http://www.homecoalition.org)**

Or contact your elected officials directly. You can use these numbers to obtain an address or to leave your comments:

**The U.S. Senate and the House of Representatives:**  
(202) 224-3121 (switchboard)

**The White House:**  
(202) 456-1414 (switchboard);  
(202) 456-1111 (comments)

Please do it NOW, or your access to bio-identical hormones will disappear!

—Jonathan V. Wright, MD

Tahoma Clinic, Renton, Washington  
A.B., Harvard University (1965); M.D., University of Michigan (1969)  
First North American prescriber of bio-identical hormones for clinical use, 1983

**For the HOME Coalition:**

American Academy for Advancement in Medicine (ACAM)  
American Academy of Environmental Medicine (AAEM)  
International College of Integrative Medicine (ICIM)  
The Bio-identical Hormone Initiative (BHI)

*Paid for by the Tahoma Clinic Foundation*