



**\*Alternatives to PMU Rejected\***

Some drugs to control the symptoms of menopause contain PMU or Pregnant Mare Urine. These estrogen hormones, derived from animals, have dangerous side-effects and have been the source of health alerts for years. Studies show that while the hormones derived from animals are close to what the female body produces, they are not close enough and when you try to fit a square peg into a round hole you are bound to find problems. These health issues include blood clots and cancer. There are alternatives and one which matches the naturally occurring hormones in a woman's body, Estriol.

Estriol, doesn't contain these harmful side-effects or any animal derived hormones. Estriol is associated with a vast number of health benefits, and NO negative side-effects. Estriol has been used safely for years in compounded medications prescribed by doctors. But the FDA has banned Estriol in favor of the animal derived hormones.

Here's why ...

Wyeth Pharmaceuticals, which makes hormone medications using Pregnant Mare Urine (PMU), petitioned the FDA to prohibit the use of Estriol on October 6, 2005. Wyeth didn't wish to see a product be allowed on the market that would directly compete with their drugs. The main reason? Estriol is chemically identical to human estrogen, while Wyeth's horse hormones are not and they wished to avoid competition.

On January 9, 2008 the FDA responded to Wyeth's petition by banning the use of Estriol. <http://www.fda.gov/ohrms/dockets/dockets/05p0411/BHRTletter.html>

The FDA claimed that their action was based on "a citizen's petition". The fact is that it was a petition from a corporation seeking government aid to prohibit a competing product from becoming available to women who need an alternative to a potentially dangerous product. In reality, 70,000 doctors, women, and other /real/ citizens petitioned the FDA to deny Wyeth's request, but the FDA sided with Wyeth anyway.

It's even more infuriating to note that the FDA admitted in a press conference announcing the ban that it knew of no evidence of any harm associated with the use of Estriol.

<http://www.fda.gov/bbs/transcripts/transcript010908.pdf>

The American Association for Health Freedom <http://www.healthfreedom.net> summarizes the case for Estriol as follows: "Compounded bio-identical hormones have been used for 50 years, are listed in the US Pharmacopoeia, are state-regulated, are available only with a doctor's prescription, and were protected by a previous Act of Congress (FDA Modernization Act 1997)."

The FDA admits that it granted Wyeth's request simply because Estriol has not endured the FDA's costly and time consuming approval process. Estriol, which is chemically identical to human estrogen, should be allowed as it is the same as naturally occurring hormones in the bodies of women; it is not a traditional drug. The FDA has allowed other "drugs" on the market before they complete their process, so it is not unheard of. But we say again, Estriol is NOT a drug, it is a naturally occurring hormone and has been in use for 50 years with no known adverse consequences.

In addition, Wyeth's petition should have been denied based on the fact that the US economy is based on a free market system that encourages competition. The US government is supposed to ensure that no monopoly is allowed, but apparently this doesn't apply to the pharmaceutical industry.

We would also like to note that the farms where PMU is produced largely send their "by-products", the foals of these pregnant mares, to slaughter. The mares are not bred to produce superior quality horses; they are not perpetuating any breed or exemplary line (although the majority are a Quarter Horse cross), and they are not bred for any specific purpose (such as racing, trail horses, cutting horses...) other than to gather urine for use in their drugs. These foals are the innocent victims of this industry, who pay with their lives. At a time when we talk about responsible breeding, this is completely irresponsible.

There are two resolutions pending in Congress to address this issue: H. Con. Res. 342 and S. Con. Res. 88. You can read the text of the identical bills below. If you support a free market system, are opposed to the slaughter of innocent foals, wish to see a safer alternative to the current PMU drugs, care about women who suffer from menopause having treatment options or disagree with the FDA's actions we ask that you read the wording of the bills. And if you agree with the wording of the bills, we ask you to contact your Representative and your two Senators and ask them to co-sponsor and support H. Con. Res. 342 and S. Con. Res. 88. H. Con. Res. 342 and S. Con. Res. 88 IS

**\*CONCURRENT RESOLUTION\***

Expressing the sense of Congress that the Food and Drug Administration's (FDA) new policy restricting women's access to medications containing estriol does not serve the public interest.

Whereas menopause is often a challenging transition for millions of women that requires specialized medications and medical treatments;

Whereas physicians prescribe a variety of pharmaceutical treatment options to treat women experiencing the symptoms of menopause;

Whereas individual women respond differently to different treatment options;

Whereas women's physicians determine on a case-by-case basis which treatment option is optimal for each woman;

Whereas many physicians prescribe compounded estrogen and other bioidentical hormone treatments for patients for a variety of reasons;

Whereas many physicians prescribe compounded estrogen treatments that contain estriol to treat menopausal and perimenopausal women;

Whereas estriol is one of three estrogens produced by the human body;

Whereas estriol has been prescribed and used for decades in the United States;

Whereas Congress has long recognized active pharmaceutical ingredients meeting standards set by the United States Pharmacopeia as permissible options for physician prescribing and pharmacy compounding;

Whereas the Food and Drug Administration (FDA) has announced that it will no longer permit compounding pharmacists to prepare medications containing estriol pursuant to a doctor's prescription;

Whereas insurers are now denying women reimbursement for compounded medications containing estriol as a result of the FDA's announcement; and Whereas the FDA has acknowledged that it is unaware of any adverse events associated with use of compounded medications containing estriol: Now, therefore, be it Resolved by the House of Representatives (the Senate concurring),/ That it is the sense of the Congress that--

(1) physicians are in the best position to determine which medications are most appropriate for their patients;

(2) the Food and Drug Administration (FDA) should respect the physician-patient relationship; and

(3) the FDA should reverse its policy that aims to eliminate patients' access to compounded medications containing estriol that their physicians prescribe for them.

