

## US Congress Seeks to Reverse FDA's Blockade on Estriol

The US Congress is taking a key step in attempting to overturn the FDA's action to halt the sale of estriol. The FDA recently sent out a series of warning letters to compounding pharmacies across the country demanding they stop using estriol and the term bioidentical in their hormone-replacement formulas. The attack by the FDA followed a citizen's petition filed by the pharmaceuticals giant, Wyeth, which has effectively denied hundreds of thousands of women access to many natural bio-identical hormones that doctors have prescribed for them, forcing them to use standard pharmaceuticals instead. In announcing its decision, the FDA admitted that this action was not over any adverse event or health issue associated with estriol. Instead, it appears to be directly related to Wyeth's request to eliminate competition for its own hormone-replacement therapies.

Resolution 342 is being backed by notable members of the Congress and is calling on the FDA to lift the restriction on prescriptions containing estriol and protect Americans' access to compounded bioidentical hormone therapies. Up to 80% or more of these custom-made treatments for women contain estriol, which is chemically identical to the naturally occurring hormone produced by women, especially during the third trimester of pregnancy, and which has been used successfully and without problems for decades.

There are significant differences between Wyeth's hormone drug Premarin® (conjugated estrogen) and bioidentical hormones. Premarin® is derived from pregnant horse urine, while estriol is chemically identical to what the human body produces. Premarin® has been shown to increase the risks of cancer and vascular disease,<sup>1,2</sup> which have resulted in Wyeth being ordered to pay multimillion dollar court settlements following guilty verdicts that the company concealed a material fact about the safety of the product. Wyeth is also fighting over 5,000 similar lawsuits of fraud across the country.

Estriol, on the other hand, is a natural ingredient that cannot be patented and is therefore unavailable for exploitation by a drug company. In essence, Wyeth is seeking to use the FDA to eliminate healthy market competition as more women choose estriol in its bioidentical form.

A number of studies have shown that estriol is effective in relieving menopausal symptoms such as hot flashes, diminished libido, vaginal dryness, irritability, depressed mood, and bone loss.<sup>3-6</sup> Estriol provides many of the benefits of pharmaceutical hormone drugs but without the harsh side effects.<sup>7</sup>

The FDA's action is essentially implying that the side effects of Premarin® apply to bioidentical hormone therapies, but the studies that showed increased risks only examined Wyeth's products and not these natural therapies. The support of the US Congress on this issue is welcome news indeed, given the FDA's own recent admissions that it is incapable of keeping up with advances in science<sup>8</sup> that could save millions of lives.

You can support women's right to choose their own treatment and the rights of practitioners to practice medicine by emailing your Congressional Representative to support Resolution 342 on estriol by logging onto <http://www.lef.org/lac/>.

—Bina Singh



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