



Congress Should Reverse FDA's Action that Restricts Access to Doctor-Prescribed Compounded Hormones

Over a million women may be forced to discontinue hormone treatments prescribed by their doctors

On January 9, 2008, the Food and Drug Administration responded to a citizen's petition filed by Wyeth Pharmaceuticals and announced that it will "halt" the compounding of hormone treatments that contain estriol. This action was specifically requested by Wyeth. Estriol – one of three estrogens produced by the human body – has been prescribed by doctors and used by women for decades as a component of compounded bioidentical hormones. As many as 80 percent, if not more, of all compounded hormone treatments contain estriol, which is a relatively weak, naturally-occurring hormone produced by women, especially during the third trimester of pregnancy.

If FDA's action is allowed to stand, it would force hundreds of thousands of women off of medications that their doctors have prescribed for them – *and for no scientific or medical reason*. In its press conference announcing this action, the FDA admitted that it was not prompted by any adverse event or health issue associated with estriol, nor was it even aware of any such events or issues.

While estriol is not a component of an FDA-approved drug, it:

- Has a long-standing United States Pharmacopeia (USP) monograph;
- Has been used successfully and without problems for decades;
- Is allowed to be compounded by every state board of pharmacy;
- Is approved and widely available in Europe and other countries in drugs manufactured by major pharmaceutical companies, including Wyeth; and
- Is a drug being tested in advanced clinical trials with great promise to treat women with Multiple Sclerosis (MS).

Congress has recognized that compounded medications may contain active ingredients with a USP monograph, even if they are not components of an FDA-approved drug.

There does not appear to be a precedent for removing a drug ingredient from the market that has a USP monograph absent specific adverse events and health concerns. As such, FDA's action appears to be directly related to Wyeth's request to eliminate competition for its products.

In taking action, the FDA ignored an overwhelming response by patients, doctors and pharmacists to Wyeth's citizen petition request. A near-record 70,000 comments were filed in response to the petition, almost all in opposition to Wyeth's requests. Of the few comments filed in support of the petition, almost all were from organizations with significant financial ties to Wyeth.

Congress should immediately take action to reverse FDA's action before countless women suffer the hardship and inconvenience of being denied access to the medications that have been prescribed to them by their doctors.

**For more information and resources, visit www.iacprx.org/Congress
Congressional Offices may also contact Sarah Dodge at (703) 283-3601
or Jim Rock at (202) 547-4000**