



Women's International Pharmacy
Custom Compounded Prescriptions for Men and Women

FREEDOM TO CHOOSE BHRT IS AT RISK!

The Food and Drug Administration (FDA) and Wyeth Pharmaceuticals are on a mission to eliminate access to bioidentical hormone replacement therapies (BHRT). ***The FDA admits that this is not a safety issue, so why would they even consider getting involved?***

Let the facts speak for themselves. Here's the timeline of how this issue has escalated:

- 1997:** A Federal clinical trial, known as the Women's Health Initiative (WHI), begins to evaluate the effectiveness of Premarin® and Prempro® (FDA-approved drugs manufactured by Wyeth). These were – and still are – the most commonly prescribed treatment for menopausal symptoms such as hot flashes and vaginal dryness, having been on the market since the early 1940s.
- JUL 2002:** Federal officials abruptly halt a phase of the WHI study after finding increased rates of breast cancer, heart attack, and stroke in the women taking Prempro.
- FEB 2004:** Federal officials halt another phase of the WHI study after finding increased rates of stroke and dementia in the women taking Premarin.
- 2002-present:** Wyeth's sales of Premarin plummet (from more than \$2 billion in 2001 to \$880 million in 2004) as women and their practitioners evaluate alternative treatments for menopausal symptoms, with many switching to custom compounded BHRT prescriptions.
- OCT 2005:** Wyeth files a "citizen petition" requesting that the FDA essentially ban all bioidentical hormones that compete with their products.
- AUG 2006:** A Texas District Court rules that pharmaceutical compounding upon the order of a licensed prescriber is not considered a "new drug" and therefore not subject to FDA scrutiny. The FDA appeals the case, and Wyeth continues to advocate banning all BHRT compounding on behalf of the FDA.
- JAN 2008:** The FDA issues a warning letter to seven compounding pharmacies (2 more letters were issued thereafter), threatening to ban BHRT, specifically any compound containing estriol, which is an ingredient in about 80% of BHRT. The letter also bans any false claims of safety or efficacy, including banning the use of the term "bioidentical," even though it is commonly used in marketing some FDA-approved drugs. ***The letter indicates that the FDA may broaden the threat to all compounding pharmacies that provide BHRT.***
- MAR 2008:** The FDA issues a warning letter to suppliers of compounding pharmacies regarding their distribution of bulk estriol.
- APR 2008:** The FDA issues an "Import Alert" cutting off the supply of estriol and other ingredients of custom compounded BHRT.
- APR 2008:** A huge public response to the FDA's actions regarding BHRT prompts Senator Tom Coburn, MD, to request "documentation of specific adverse events and demonstrated safety issues related to the use of estriol" and other details on the research or studies that support the FDA's decision. ***To date, the FDA has not responded to this request.***
- MAY 2008:** More than a dozen professional medical associations, ***all substantially funded or supported by Wyeth***, submit a joint letter to members of congress in support of the FDA's actions, ***without disclosing their ties to Wyeth.***

- MAY 2008:** US House Representatives Mike Ross (D-Ark.) and Jo Ann Emerson (R-Mo.) introduce resolution *H.Con.Res.342* to counter the efforts of the FDA and Wyeth against compounded BHRT. The resolution states that the “FDA has acknowledged that it is unaware of any adverse events” associated with the use of estriol, and raises serious concern over the FDA’s move to ban the use of it. ***The resolution asks for a reversal of the FDA’s action, deeming it “not in the public interest.”***
- JUN 2008:** The International Academy of Compounding Pharmacists (IACP) visit Capitol Hill, and Senator John Cornyn (R-Tex.) introduces a concurrent resolution, *S.Con.Res.88*, ***also asking for a reversal of the FDA’s action because it does not serve the public interest.***
- JUN 2008:** US supplies of estriol and other bioidentical hormones are rapidly diminishing, which is threatening the availability of compounded BHRT and other treatment options, especially the treatment of menopausal symptoms.

We believe that the FDA’s actions are being driven and manipulated by Wyeth’s continuing loss of market share. Additional pertinent facts include:

- Compounding pharmacies are regulated by individual State Boards of Pharmacy.
- The majority of FDA funding comes from large pharmaceutical companies, such as Wyeth. The FDA is caught in the middle between those who fund their very existence and the public they are chartered to protect.
- Wyeth and other drug manufacturers cannot patent estriol’s chemical structure because it is a naturally occurring substance in the human body; without a patent, they cannot profit from it, as they have with Premarin and Prempro, both of which include estrogens derived from the urine of pregnant mares.
- Estriol is commonly included in compounded BHRT as it is one of the three primary estrogens produced in the human body, and necessary for hormone balance. It is also considered the weakest of the three primary estrogens.
- Reports indicate that Wyeth manufactures products in Europe that contain estriol.
- The WHI study proved that Wyeth’s synthetic hormones have serious side effects for some women. There is no proof or reports of adverse effects for estriol (the bioidentical alternative), and decades of evidence of their efficacy.

We agree with both Wyeth and the FDA on two points:

1. ***Additional studies of bioidentical hormones are needed.***
2. ***Validated false claims of safety or effectiveness – for any drug, whether bioidentical or not – should not be tolerated.***

Furthermore, we believe that:

- ***Healthcare practitioners and their patients – including both men and women – should have a choice of treatments, especially with regard to hormone therapies, where a “one size fits all approach” typically does not work for everyone.***
- ***The patient and healthcare practitioner are the best equipped to make the appropriate choice regarding hormone therapy.***

If you feel the same way, please see our CALL TO ACTION on our website www.womensinternational.com and do your part to protect our healthcare freedom. For more information, call 800-279-5708.