

Wyeth's Campaign to Protect Market Share At the Expense of Women's Health

Wyeth Pharmaceuticals has a long history of campaigning to restrict competition to its patented hormone products – Premarin and Prempro – in order to protect its market share. Unfortunately, this harms women in need of hormone treatment to alleviate the painful symptoms of menopause.

Why is Wyeth Concerned about Alternatives?

The National Institutes of Health Women's Health Initiative (WHI) was cut short in 2002 after the results showed that Wyeth's products increased the risk of strokes, breast cancer, heart attacks and blood clots. According to Wyeth's annual reports, sales of Premarin-related products fell off significantly, down almost 50 percent in 2007 from Premarin's peak in 2001.

Restricting competition could help Wyeth bring its sales back to pre-WHI levels.

Restricting Generic Hormones

According to a 1997 report from Citizens Against Government Waste, a Washington, D.C.-based think tank, Wyeth waged a political campaign to influence FDA's decision to keep a generic version of Premarin off the market. In this campaign Wyeth asserted that its products could not be copied by generic manufacturers. Wyeth claimed that the active ingredients in the conjugated estrogen products could not be adequately identified and, therefore, that there can be no generic copy of Premarin because the precise characteristics of the drug cannot be characterized.

Wrote CAGW: "Although the FDA and Premarin's manufacturer, Wyeth-Ayerst, would like the American public to believe that this decision was in their best interests, the reality is that it was driven by hoards of lobbyists, fraught with conflicts of interest, and characterized by questionable behind-the-scenes political maneuvering."

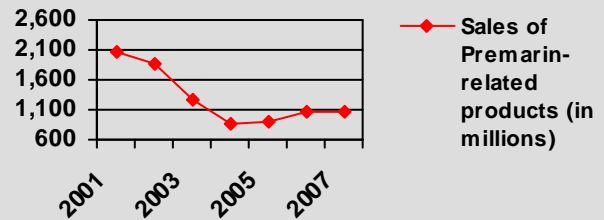
Citizen Petition against Bio-identical Hormones

On October 6, 2005, Wyeth filed a citizen petition with the FDA requesting actions that would severely restrict the availability of compounded bio-identical hormone replacement therapy (BHRT) drugs, which are prescribed by physicians and prepared by pharmacists to meet the patients' individual needs.

In its citizen petition, Wyeth stated that BHRT drugs compounded with the human estrogen estriol "pose a serious threat to public health" and asked FDA to take enforcement action against such products. However, according to the news website Pharmalot.com, "At the same time the petition was filed, Wyeth was selling Cyclo-Menorette, a menopausal drug in four European countries - Estonia, Germany, Latvia and Poland - that contained, yes, estriol." In fact, Wyeth called this product "the ideal therapy to enter into the years of change."

FDA received over 70,000 public comments in response to the petition, the majority from women and doctors who wanted to preserve patients' access to compounded BHRT. Ignoring those comments, FDA announced in January 2008 that it will restrict compounded BHRT containing one key form of estrogen – estriol. This is something Wyeth and its surrogates asked for in the petition. Unfortunately, the FDA's policy hurts women and helps Wyeth.

Sales of Premarin-related Products Fall after WHI Study Results



Wyeth Double Speak on Estriol

"The ideal therapy"

- German ad for estriol-based
Wyeth drug

"A serious threat to public health"

- Citizen Petition to FDA

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Financing Groups and Experts to Weigh in Against Bio-identical Hormones

Wyeth has funded a number of supposedly independent health organizations, many of which are publicly supporting the company's campaign to restrict women's access to alternatives to its hormone products. Soon after Wyeth filed its Citizen Petition with the FDA, several organizations that purport to be independent followed suit. In fact, though, each of these organizations has financial and other ties to Wyeth. Unfortunately, these organizations consistently fail to disclose their financial ties to the drug maker when voicing their support

These links include the following. Sources and more information are available at www.compoundingfacts.org.

- Wyeth has been a corporate partner of the American Association of Clinical Endocrinologists (AACE) since 1993. On its website, AACE notes that its corporate members' "generous support and valuable input helps make possible the many educational programs and activities that AACE provides for its members." Wyeth is also a regular exhibitor at AACE's Annual Meeting. Wyeth is among four other pharmaceutical companies that provide significant financial support for AACE's publications. In addition, one of AACE's Board Members has received grant/research support from Wyeth.
- On November 15, 2006, Dr. Wulf Utian, executive director of the North American Menopause Society (NAMS), appeared on CNN's Larry King Live to defend Wyeth's position. Concerning his relationship with Wyeth, Dr. Utian stated: "I am not funded by Wyeth Pharmaceuticals. I'm not." His declaration is patently false. Wyeth endows a \$200,000 lectureship fund named for Dr. Utian and was named a "Partner in Menopause Education" (requiring a contribution of at least \$8,000) for the NAMS' 2007 Annual Meeting. Additionally, half of NAMS's Board of Trustees for 2007-2008 receives consulting fees or research support from Wyeth, including Dr. Utian.
- The Endocrine Society counts Wyeth as a Corporate Liaison Board member and a frequent exhibitor at the Society's Annual Meetings. The Society recognized Wyeth as a Leadership Donor in 2002, honoring those donors who have contributed at least \$100,000 to the Society in the previous year.
- Wyeth funds several annual awards for the American College of Obstetricians and Gynecologists (ACOG), totaling approximately \$29,000 per year. Wyeth is also a Friends of ACOG Participant, where Friends donate \$3,000 per annum, and is a frequent exhibitor at ACOG's Annual Clinical Meetings and sponsors ACOG's annual "Resident Reporter" Program.
- The Society for Women's Health Research, which also commented in favor of Wyeth's Citizen Petition, counts Wyeth as a member of its Corporate Advisory Council and one of the corporate dinner chairs of the Society's 2007 Annual Gala Dinner. SWHR also received a \$250,000 donation in 2002 at Wyeth's 60th anniversary celebration of Premarin, one of the company's HRT drugs.
- On its web site, American Medical Women's Association lists Wyeth as one of 12 members of its Corporate Partners Program, which it "thank[s] for their generous support." Wyeth is also listed as a member of AMWA's Elizabeth Blackwell Diamond Circle of Honor, which recognizes donations of \$10,000 and above.
- Wyeth is a member of The American Society of Reproductive Medicine's 2007 Corporate Council. The American Society of Reproductive Medicine received at least \$75,000 from Wyeth last year, which was in the top echelon of sponsors of its annual meeting.
- Wyeth is a Gold Corporate Sponsor for the National Association of Nurse Practitioners in Women's Health. The Association's President and CEO, Susan Wysocki, serves on both the advisory board and the speaker's bureau for Wyeth.
- Wyeth was the largest single corporate contributor to the National Consumers League for the period 2001 and 2002, with total contributions of \$337,500. In 2003, Wyeth began funding an NCL campaign called MenoPAUSE: Take Time to Talk about Your Symptoms." Wyeth has also sponsored various NCL surveys and reports going at least as far back as 1999.

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