



Executive Summary

Bioidentical Hormones: Facts, Women's Rights, and Choices

by Elizabeth Lee Vliet, M.D. © 2006

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Soon to be reality if Wyeth has its way with the FDA:

- *Imagine you had surgical removal of your ovaries, causing abrupt and severe onset of menopause. It's analogous to a man having his testicles removed. Drenching night sweats rob you of sleep, zap your memory, and sap your energy. You tried all the commercial product options; nothing worked. Your physician prescribed an individually-compounded, bioidentical-hormone tablet that restored exactly what your ovaries made. Finally, relief and sanity again. **Then the FDA says you can't have it.***
- *Suppose you have asthma and can't take tablets with dyes? Your physician prescribed dye-free compounded asthma medicines. You can breathe again. **Then, the FDA says you can no longer have a compounded prescription.***
- *You are a cancer patient, and need individually-compounded pain medicine to relieve intense suffering from metastases. **Now the FDA restricts compounding.***

This reality must not be allowed to happen. But it could, if pharmaceutical giant Wyeth has its way.

Wyeth, maker of Premarin, the estrogen mixture derived from **pregnant mares' urine**, and Prempro (horse estrogens plus a potent synthetic progestin), filed a "Citizens Petition" with the FDA to restrict compounding and dispensing of bioidentical hormones (i.e., estradiol, progesterone, and testosterone) for women needing hormone therapy.

Wyeth's petition focuses on its market competitor, *bioidentical hormones*. But it doesn't end there. The restrictions they seek are so draconian, it would effectively be impossible for pharmacists to prepare and dispense any individually-compounded medicines. Physicians and patients would lose a crucial therapeutic option.

Why on earth would a giant pharmaceutical company worry about such "small potatoes"? The answer, sadly for consumers, is that it's all about lost market share and lost profits.

Wyeth had over 80% of the U.S. hormone therapy market prior to the WHI. When women abruptly stopped hormones, Wyeth's sales plummeted. Within a few years, their revenue had dropped by two thirds. Economic losses triggered aggressive measures to regain market share.

Now they're trying to strike back by blocking sales of bioidentical hormones prescribed by physicians and compounded by pharmacies.

The story begins with the July 2002 media coverage of the Women's Health Initiative (WHI), a national study of elderly post-menopausal women who were taking Wyeth's products, Prempro or Premarin. Women on Prempro had more blood clots, heart attacks, strokes and breast cancer than women taking a placebo. It was a shock wave heard around the world.

Media coverage did not specify that it was *only Prempro and Premarin* used in the WHI, *not* natural progesterone or the human form of estradiol. After intensive lobbying, the FDA gave a "black box" warning to *all* estrogens and *all* progestins, even though the WHI only used one product with pharmacologic properties and risks quite different from medications made with bioidentical hormones.

Menopausal women were made to think that **ALL** hormones caused the same problems seen with Wyeth's products. *That is simply false.* Worldwide clinical studies have shown otherwise for over 30 years.

Not once during my career in medicine have I seen all products in a class tarred with the same brush when problems arose with one brand. The FDA did not generalize to all antihistamines, statins, or

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diabetes medicines when serious side effects came to light with Seldane, Baychol, and Rezulin.

What's even more frightening is that a number of national women's health organizations—***all of which have significant research and other financial ties to Wyeth***—have filed statements with the FDA in support of Wyeth's petition. Consumers are in the dark about the financial relationships.

Consumers need to know the facts here before it is too late. I speak as an independent physician in private practice, who has *no* financial ties to any pharmaceutical company, compounding pharmacy, or other commercial entity involved with this issue.

Bioidentical products are not new. They are an exact copy of hormones produced by the human body, much like a duplicate of a key. Ovarian hormones were identified and synthesized by major pharmaceutical researchers as early as the 1930s. By 1975, we had available the first FDA-approved commercial bioidentical estradiol tablet (Estrace). Other examples are FDA-approved commercial bioidentical hormones for thyroid, cortisol, insulin, and growth hormone.

Bioidentical estradiol and progesterone are markedly different in chemical makeup from Wyeth's Premarin and Prempro. Consumers and many physicians do not recognize the difference between the Wyeth products used in the WHI and bioidentical hormones, either compounded or the commercial ones already approved by the FDA. In fact, this distinction appears to be deliberately blurred as a strategy to prevent greater product liability fallout from the WHI.

Wyeth's Petition to the FDA asserts that compounded bioidentical hormone products have the same risk profile as Premarin and Prempro. *Research, as presented again at the International Menopause Society World Congress in October 2005, shows this is false.*

Wyeth's Citizens Petition implies that the WHI clinical studies evaluated bioidentical hormones. *This is also false.*

Media reports, many women's health organizations, and nationally-known physicians have said we have no studies on bioidentical hormones. *This is also false.*

There are many studies showing safety and effectiveness of these FDA-approved bioidentical products. *How else could they have gained FDA approval?*

This makes no sense at all! Why restrict compounded hormone options *that use the same USP estradiol and progesterone supplies already used in FDA-approved bioidentical commercial products?*

Restricting compounded options would also seriously reduce the flexibility for physicians to individually tailor hormone therapy prescriptions at a time *when this is the very standard of care being promoted by the FDA and national women's health organizations.*

Flexibility in care for patients must keep open BOTH

FDA-approved commercial products, AND the alternative for physicians to prescribe individually-compounded medicines to meet special patient needs.

Make no mistake. Women are not taking compounded prescriptions because they are cheaper or easier. Most have to pay out of pocket for these compounded prescriptions since few insurance plans cover them. It is often difficult for patients to find physicians who know how to use them. If compounded Rx were less effective, or caused more side effects, obviously patients would not continue to seek them!

Wyeth claims there are abuses by compounding pharmacies. If so, then existing regulations need to be enforced. *We do not need to impose new regulations that restrict physicians from tailoring therapies for individual patients.*

In 25 years of medical practice, I have treated thousands of patients who needed lower doses or dye-free special preparations compounded. As we learn more about genetic differences in our ability to metabolize medications, *we all need more options, not fewer.*

It would be tragic if men, women, and children who need individually-compounded medicines for special health needs are denied their right to choose this option.

We can't let one drug company's focus on profits prevent our having options for individualized health care for millions of Americans. We must act now to prevent a blow to individualized health care by government giving in to Big Pharma.

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Elizabeth Lee Vliet, M.D., physician and founder of HER Place: Health Enhancement and Renewal for Women, Inc, is also the author of six acclaimed women's health books: The Savvy Woman's Guide to Testosterone, The Savvy Woman's Guide to PCOS, Screaming to Be Heard: Hormone Connections Women Suspect and Doctors Ignore, It's My Ovaries, Stupid!, Women Weight and Hormones, and The Savvy Woman's Guide to Estrogen (in press). She has been widely recognized for her pioneering work in addressing hormone connections in women's health, has taught several hundred continuing medical education seminars around the country and overseas for physicians, conducted hundreds of seminars for consumers, and was a featured speaker at a May 2004 Congressional Briefing on women's healthcare issues. For additional information go to www.herplace.com

Disclosure Statement:

Dr. Vliet is an independent physician in private practice who has *no financial ties* to any pharmaceutical company, compounding pharmacy, or other commercial entity involved with products either directly or indirectly referenced in this article.