

**Wyeth Bio-Identical Hormone Controversy by Dr Erika Swartz, MD
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As a woman, I can say that we are our own worst enemy when it comes to women's healthcare. Our so-called advocacy groups are bought off, sometimes for a few thousand dollars, by multi-billion-dollar pharmaceutical conglomerates.

Please Take Action Below! But first please read the letter I sent to the FDA in support of freedom of choice in Women's Health.

As a woman, I can say that we are our own worst enemy when it comes to women's healthcare. Our so-called advocacy groups are bought off, sometimes for a few thousand dollars, by multi-billion-dollar pharmaceutical conglomerates. We then expect healthcare to get better - only to find ourselves sitting on the sidelines, watching as the Wyeths of the universe attempt to undermine a piece of the healthcare system that actually works for women.

I am referring to Wyeth's Citizen Petition of October 6, 2005 filed with the FDA against the production of bioidentical hormones. Allow me to offer a snapshot of my credentials, which will illustrate that I am thoroughly qualified to refute Wyeth's allegations and claims against bio-identical hormones.

My 30-plus years in the medical profession began at New York University on an academic scholarship, continued with receiving my medical degree and graduating Cum Laude from SUNY-Downstate College of Medicine, then becoming Medical Director of the department of emergency medicine at Westchester County Medical Center, the first and youngest female ER director in the country. I moved into private practice, pioneering in bioidentical hormone therapy before the medical establishment recognized it, and went on to become a nationally renowned expert in this area of medicine. I am a best-selling author of four books on the subject, and I currently pen a health/advice column in two national publications, one of which has a weekly readership of nearly 10 million. During the past 10 years, I have prescribed bioidentical hormones to tens of thousands of patients with great success.

I condemn Wyeth's Citizen Petition to the FDA as baseless and without merit. I do this not as an agent of the compounding industry, not as a special interest group with an agenda, nor as a multi-billion-dollar industry Goliath trying to increase shareholder value. I do this purely as a lifelong, career-long advocate for women's health.

Wyeth condemns bioidentical hormones by casting doubt on their safety and effectiveness and demands that the FDA penalize compounding pharmacies through enforcement of actions such as seizures, injunctions and warning letters.

I don't remember Wyeth calling for such sanctions against itself when the 2002 NIH study - Women's Health Initiative linked Premarin and Prempro®, synthetic hormone drugs manufactured by Wyeth to increased risk of stroke, breast cancer, heart attacks and circulatory disease. Wyeth was roughed up financially as a result of the study. Sales of the drugs plummeted from \$1.3 billion in 2002, to \$880 million in 2004.

Therein lies the timing, and motive, for Wyeth's latest attempt at burying bioidentical hormones. It has nothing to do with concerns for women's health and issues of safety and effectiveness of bioidentical hormones. It has everything to do with revenue and profit.

Wyeth's allegations against compounding pharmacies and its call for investigations of the safety and effectiveness of bioidentical hormones are baseless, irresponsible and transparent. Wyeth offers no evidence, proof or studies to support its allegations. It offers no valid reasons for an investigation. As protector of the public interest, the FDA should demand more information and data from Wyeth. The FDA should not close down the bioidentical option of healthcare unless there is another safe, proven, viable option to replace it.

I welcome studies of bioidentical hormones even though they are already FDA-approved and have been working effectively for decades. We already have the proof - hundreds of thousands of women, who over the past two decades have chosen bioidentical hormones based on their physician's assessment. They are living proof that bioidentical hormones are safer and more effective and reliable than synthetic hormone drugs.

>>With bioidentical hormones long-approved by the FDA, why is Wyeth raising the noise level now? The company never fully recovered from the 2002 WHI study, and now more and more American women are finding their way to bioidentical hormones - and that scares the hell out of Wyeth and Big Pharma. Wyeth's Citizen Petition is driven by declining sales and profits rather than concern over women's healthcare and their safety.

Wyeth's Citizen Petition is replete with misinformation, which I am sure others will address, and which I am certain that the FDA is well aware. **But to set the record straight on one allegation, compounding pharmacies don't manufacture bioidentical hormones or dictate what patients should take. Physicians such as myself write prescriptions that are then filled by compounding pharmacies, which are supervised by licensed pharmacists.**

If the FDA acts on Wyeth's Citizen Petition where would that leave the hundreds of thousands of American women who rely on this safe, proven and effective healthcare option? We all know the answer, which is why the FDA would better utilize its time, money and resources by standardizing bioidentical hormones. Don't put an end to bioidentical hormones; rather, make them more available and accessible.

This issue is not about synthetic hormone drugs vs. bioidentical hormones or who stands to make more money. It's about women having an option in a healthcare landscape that's already a mess. That is my primary concern and it should be the FDA's primary concern. The FDA must not entertain Wyeth's request for action against bio-identical hormones.

I am ready to do my part, drastically reducing the hours of my clinical practice to embark on a nationwide campaign to educate women so that they can take a stand against Wyeth's position. My patients are prepared to do their part, fully supportive of this campaign. Is the FDA ready to do its part? If the FDA needs a reason, I can think of millions - the millions of women across America who are counting on this agency to protect them.

On behalf of these millions of women, as a pioneer in bioidentical hormones and advocate of women's health, I urge the FDA to take no action on Wyeth's Citizen Petition.
Take Action Now!

As a woman currently benefiting from prescription strength bioidentical hormones I take exception to the fact Wyeth is accusing the Compounding Pharmacy industry of unsafe practices. As a citizen of the United States I expect the FDA to stand up for my rights and the rights of all women who have found consistent, safe and effective treatment with bio-identical hormones. Eliminating options by bowing to a large pharmaceutical company like Wyeth is not in the public interest and would deprive hundreds of thousands of American women from access to bioidentical hormones. Synthetic hormone replacement has been proven unequivocally unsafe in a government sponsored study and should not be forced as the sole treatment option for women. I hereby request the FDA rule against Wyeth's request and ask for more information on the safety of the Wyeth synthetic hormone