



**DO YOU WANT  
TO BE THE ONE  
TO TELL THEM  
THAT THE  
SOLUTION  
THAT THEY'RE  
RELYING ON  
WILL BE  
TAKEN AWAY?**

**The FDA is at it again. They are giving Wyeth what they asked for - restricting access to bio-identical hormones. The FDA has announced a major assault on compounding medicine and bio-identical hormones by using a multi-prong approach that started last year with a Congressional Hearing before the Aging Committee, and continuing with banning estriol, denying the term "bio-identical" to characterize compounded hormones therapies, and encouraging consumers to use drugs instead.**

**Is this the type of healthcare we truly want in the U.S.?**

[www.healthfreedom.net](http://www.healthfreedom.net)

**Right of the Patient to Choose  
and the Practitioner to Practice**



AMERICAN ASSOCIATION FOR  
**HealthFreedom**



We acted swiftly last year and was able to stop the introducing of the so-called "Safe Drug Compounding Act of 2007" in Congress by powerful Senators. Now we have a new battle.

In a series of warning letters to compounding pharmacies across the country, the FDA is asserting a policy that would deny hundreds of thousands of women access to many compounded bio-identical hormones, substituting the FDA's judgment for that of doctors. (Remember when

Wyeth Pharmaceuticals, the number one manufacturer of synthetic hormone products, petitioned the FDA to do so in October 2005, more than 70,000 doctors, patients, and pharmacists filed comments with the FDA opposing Wyeth's petition.) By targeting estriol and indicating that they are planning on banning its importation, this will effectively end compounded hormones for women because 80% of all bio-identical hormone therapy uses estriol.

The FDA seems particularly upset with "marketing" claims that bio-identical hormones are a better choice than "FDA approved menopausal hormone therapy drug products."

In a Consumer Health Information flyer, the FDA points out that they have not approved any drug containing estriol so therefore the safety and effectiveness of estriol are unknown. Of course since estriol is a natural ingredient and is therefore unable to be patented, no company has submitted it to the billion dollar pipeline at the FDA. The FDA is ignoring the fact that before Premarin the work on hormone replacement therapy was with "bio-identical" hormones. There are also several European studies about estriol that are quite impressive.



The FDA also downplays the lack of adverse event reports in relation to bio-identical hormones. Their flyer says, "Unlike commercial drug manufactures, pharmacies aren't required to report adverse events associated with compounded drugs." What they are not saying is that **consumers can report any AER** and furthermore **doctors and hospitals are required to report all adverse events**.

### What You Can Do

This is an unexpected attack and we **need your financial support** in order to devote our resources to battle this important issue. Please join and donate today! For lobbying efforts join and donate to AAHF and for research and educational efforts, please make a tax-deductible donation to our Health Freedom Foundation.

**Spread the word.** Tell people to visit [www.healthfreedom.net](http://www.healthfreedom.net). Make copies of this flyer (or download from our website) and distribute this flyer (if you don't have a printer, let us know how many you need).

Be prepared to **contact Congress and the FDA** in a few weeks to let them know what you think about bio-identical hormones. Make sure that you have signed up for our free alerts at [www.healthfreedom.net](http://www.healthfreedom.net).

### What We'll Be Doing

- Engaging practitioners to get involved.
- Educating consumers about this serious threat.
- Working with scientists and academics in preparing a response
- A media campaign with the true facts on bio-identical hormones.
- Hosting a Congressional Briefing on bio-identical hormones.
- Organizing a united front to the FDA.
- Working with former Congressman and licensed pharmacist who wrote the current compounding pharmacy regulatory system.
- Introducing the Medical Information and Treatment to Access Act shortly which would allow for studies on bio-identical hormones in a cost-effective manner.

Please get involved in this struggle – we can't do it without you.

Don't forget to stay updated on this issue. Additional information and action items will be developed shortly. Please check [www.healthfreedom.net](http://www.healthfreedom.net) frequently for more information.

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