



Controversy concerning natural hormone therapy is making the news again with the Food and Drug Administration (FDA) announcing a policy that would deny thousands of women – and men – access to many commonly compounded medications.

*Find out what this policy might mean to you in this special message from Marla Ahlgrimm, R.Ph., CEO and Founder, Women's Health America, Inc.*

**Dear Friends:**

*It seems inconceivable that the FDA would renew their efforts to take regulatory action against compounded menopause hormone therapy just when women are beginning to enjoy a wider range of therapeutic options with growing numbers of providers embracing the concept of “personalized” healthcare.*

Personalized healthcare stresses a more individualized approach to treatment, with a greater emphasis on long-term health and wellness and an improved quality of life. When prescription therapy is personalized, your provider may recommend lower medication dosages than are commonly prescribed. After decades of enduring a “one-size-fits-all” approach to hormone therapy, this is a major step forward.

This change in how you are treated as a patient is critical if you are trying to decide whether hormone therapy is right for you. You're an individual: What is best for your health will not be the same for your sister, mother, daughter, neighbor or friend. Shouldn't you have individualized options for your hormonal health?

Apparently the FDA doesn't think so.

### **Just What Is The Newest FDA Policy?**

- **First of all, let's be clear on a critical point:**  
**The FDA is not outlawing the use or prescribing of bioidentical hormones.**  
**They are objecting to the use of a marketing term.**

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**What's in a name?** In the January 9, 2008, FDA press release, “FDA Takes Action Against Compounded Menopause Hormone Therapy Drugs,” the FDA indicated that it wants compounding pharmacies to stop using the term “bioidentical” to ‘promote’ or ‘characterize’ compounded hormone therapies. The FDA appears to believe that the term implies a benefit and is misleading to the public, even though the chemicals used in such compounds are molecularly identical to hormones produced by the human body. *Ironically the term “bioidentical” is already used by several major drug manufacturers to characterize FDA approved conventional hormone therapies.*

**The FDA does have the authority to watch-guard the public in regard to ‘unsubstantiated marketing claims’.** That was the regulatory basis of the warnings issued to seven compounding pharmacy operations in January -- the FDA citing that the pharmacies made misleading claims about the safety and efficacy of their products.

**Second, the FDA press release also targeted the compounding of estriol, the weakest of the three estrogen hormones.**

**Why is estriol suddenly under attack?** It’s a good question. Estriol is a natural hormone and has been prescribed for over 20 years in the United States—even longer in Europe-- for women suffering from symptoms of PMS, perimenopause, menopause, and post-menopause. Estriol is a component in many low-dose compounded hormone therapy prescriptions such as Biest and Triest. Estriol has also been prescribed for use vaginally to manage vaginal dryness and urinary incontinence. UCLA researchers are currently conducting a **phase III multi-center clinical trial** to determine the safety and efficacy of estriol treatment for Relapsing Remitting Multiple Sclerosis, indicating the potential for other therapeutic uses of this hormone.

Like many commonly prescribed drugs (e.g., phenobarbital, quinine, tinidazole), estriol has a monograph from the U.S. Pharmacopeia (USP), but is not currently a component of an FDA approved drug product.

***When it passed the FDA Modernization Act in 1997, Congress clearly indicated that drugs with a USP monograph could be compounded.***

The National Association of the Boards of Pharmacy and the United States Pharmacopeia (the national standard setting organization for pharmacy and pharmaceutical manufacturers) have established standards for compounding that are strictly enforced by each state. The medicinal chemicals that are used in the preparation of compounded prescriptions are all sourced from licensed FDA-registered manufacturers. In many cases they are the same sources used by large pharmaceutical manufacturers.

**The Food and Drug Administration, the Supreme Court, Congress and virtually every major health professional organization recognizes the value of compounding.**

Pharmacy compounding is a long-standing, state-regulated and medically vital practice. Millions of Americans have unique health needs that off-the-shelf prescription medicines cannot meet. For them, customized, compounded medications prescribed by licensed healthcare providers and prepared by trained, licensed compounding pharmacists are the only way to better health.

Despite the attempt of large pharmaceutical manufacturers to deny patients the right to have access to compounded prescriptions, the legal precedence that allows pharmacists to compound pharmaceutical agents and dispense compounded prescriptions was upheld by a Federal District

Court Judge in Midland, Texas on May 25, 2006. [NCPA] The court's ruling confirmed that compounded preparations are not illegal, are not unapproved, and are not new drugs subject to FDA's new drug approval process for new manufactured products.

## **What Is The FDA Really Trying To Accomplish With This Latest "Action" Against Compounded Hormone Therapy?**

The issue is supposedly safety, but doctors and pharmacists across the country, including Women's Health America/Madison Pharmacy Associates believe the real issue is profits.

**Please remember, this is not a new issue, just the latest salvo in the war.**

In October of 2005, Wyeth Pharmaceuticals filed a petition with the FDA for this kind of policy to restrict compounding pharmacies' ability to provide individualized hormone therapy. More than 70,000 doctors, patients and pharmacists filed comments with the FDA – the vast majority opposing such action – causing the FDA to delay their ruling.

**Now the issue has resurfaced again, with a slightly different twist. The new policy asserted by the FDA is once again prompted by Wyeth.**

## **Why Is Wyeth Doing This?**

Wyeth manufactures the synthetic hormone replacement therapy (HRT) drugs Premarin® and Prempro®. Sales of these drugs dropped significantly after 2002 when the Women's Health Initiative, a study funded by the National Institutes of Health, specifically linked these two drugs to increased risk of stroke, breast cancer, and heart attack. Wyeth has suffered financially as a result of the study with a significant decline in sales of Premarin hormone products.

Many women are now choosing low-dose natural hormones as an alternative to synthetic hormones. The reasons are simple. Natural hormones have the same molecular structure as those made in the human body. Synthetic hormones do not have the same chemical structure and so the body's response to them may be different. This difference is thought to be the cause of the increased health risks seen in the WHI study.

In the wake of studies like the WHI and ongoing research that continues to highlight concerns regarding the continuing use of synthetic hormone therapy, why haven't the major pharmaceutical companies like Wyeth developed more "natural" alternatives? ***Synthetic hormones can be patented and sold for high profits while bioidentical hormones, considered by the FDA to be "natural," cannot be patented.***

These facts beg the question: Is this a safety issue, or is Wyeth simply attempting to regain the market share it lost by eliminating the competition?

**However you answer, one thing is clear:** "Under this policy, patients will suffer while Wyeth profits," said L.D. King, executive director of the International Academy of Compounding Pharmacists (IACP). "Thousands of doctors are making patient-by-patient decisions that compounded hormones are medically appropriate, sometimes because Wyeth's products are found to be ineffective or produce side effects. This is a decision that should be left to doctors."

***And patients.***

*(continued)*

## What Does The Current Controversy Mean To You?

This type of contentious debate that creates fear and confusion for both patients and healthcare providers is a continuing source of frustration for me. Patients are justifiably alarmed when they read that their choices for hormone therapy to promote balance and healthy aging are being threatened. Healthcare providers who are trying their best to address their patients' individual therapy needs are restricted from prescribing what they believe to be in their patients' best interests – because of FDA policies influenced by major pharmaceutical companies intent on protecting their profits.

- **If you're currently on low-dose prescription therapy, be assured we will continue to work closely with your healthcare provider to help determine the best choices for your therapy. We will continue to fill prescriptions as written by your healthcare provider.**

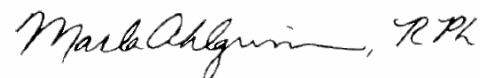
**If you are filling your low-dose hormone therapy prescriptions through Madison Pharmacy Associates, you've chosen wisely.** Madison Pharmacy Associates was the first pharmacy in the U.S. to specialize in women's health, beginning with PMS, then expanding to perimenopause, menopause, and other women's health concerns. Since 1982 we have consistently provided custom-compounded prescriptions individualized to meet a woman's unique hormonal needs.

We continue to lead the field of customized prescriptive care through ongoing research, improving drug delivery and diagnostic testing methods, *and by maintaining the highest standards of prescription purity, accuracy, and strict quality control.*

- Madison Pharmacy Associates tests the quality of prescriptions using sensitive HPLC (liquid chromatography) to assure the prescription you receive is exactly what your doctor prescribed.
  - Medications are compounded for a specific healthcare provider prescribing for a specific patient.
  - We compound each prescription using sophisticated pharmaceutical technology, one ingredient at a time, to help assure accurate dosage.
  - Our customized prescriptions use advanced ingredients combined with USP pharmaceutical-grade chemicals.
- **If you are a patient testing hormone levels and rate of bone loss through our innovative Restore<sup>®</sup> Program you can also be assured that you and your healthcare provider are receiving the ongoing health information needed to address and manage your specific situation.**

The controversy over bioidentical hormones will continue to rage, but remember, we've been through this before. We're here to help, so if you have any questions or concerns, please contact us at 800.558.7046.

To your good health,



Marla Ahlgrimm, R.Ph.  
Founder and CEO, Women's Health America

January 22, 2008

## LINKS

- If you're interested in additional information, visit the [International Academy of Compounding Pharmacists \(IACP\)](#) main website, or go to [savemymedicine.org](http://savemymedicine.org), the online home of Patients and Professionals for Customized Care (P2C2).

Sign up for a **free membership** to P2C2 and you can receive an electronic newsletter to stay up-to-date on the latest news and information affecting your ability to prescribe or be prescribed compounded medications.

You can also sign up for **P2C2 Action Alerts** to let others know--from your representative in Congress to your local newspaper editor--that you rely on compounded medicines and that you are committed to making sure they remain available.

- In addition, you can voice your concerns by visiting the FDA's [Office of Special Health Issues](#) webpage and filling out their web-form. Tell your story about how individualized, compounded hormone therapy has benefited you:
  - Let the FDA know that you want individualized options for your hormonal healthcare.
  - Voice your support of a personalized approach to medicine where you and your healthcare provider work together with a wide range of therapeutic options to create a health and wellness plan that is specific to your needs.
  - Speak out for your right to choose medically appropriate, natural compounded medications as recommended and prescribed by your healthcare provider.



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