



FOR IMMEDIATE RELEASE

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FOR MORE INFORMATION

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**FDA Asserts New Policy to Restrict Women's Access to
Bioidentical Hormones**

Agency Warns Pharmacies Not to Compound Commonly Prescribed Hormone
Treatments, Use the Term "Bio-identical"

MISSOURI CITY, Texas – In a series of warning letters to compounding pharmacies across the country, the Food and Drug Administration (FDA) has asserted a policy that would deny hundreds of thousands of women access to many commonly compounded bioidentical hormones, substituting its judgment for that of doctors. 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, the vast majority of whom opposed the petition.

"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."

In the letters, the FDA states that it will "halt" compounding of medications containing estriol, an estrogen produced by the human body. Estriol is one of the most widely prescribed hormones and is regularly compounded with other bio-identical hormones pursuant to doctors' prescriptions for women suffering from symptoms of menopause. Like many commonly prescribed drugs, estriol has a monograph from the U.S. Pharmacopeia (USP), but is not a component of an FDA-approved drug. When it passed the FDA Modernization Act in 1997, Congress clearly indicated that drugs with a USP monograph could be compounded.

The FDA also stated in its letters that pharmacies may not use the term "bio-identical" to characterize compounded hormone therapies, even though the chemicals used in such compounds are chemically identical to what is produced by the human body.

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Furthermore, manufacturers of drugs containing the same bio-identical hormones commonly use the term to characterize their products. The chemical structure of these drugs is indisputable.

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 or ordered by licensed physicians or veterinarians and mixed safely by trained, licensed compounding pharmacists are the only way to better health.

About IACP

The International Academy of Compounding Pharmacists (IACP) is a non-profit association founded in 1991 to protect and promote the art and skill of the compounding pharmacy profession. We represent more than 2,000 pharmacists, physicians, technicians and patients who are committed to the safe practice of pharmacy compounding. We are committed to ensuring the rights of physicians to prescribe, of pharmacists to prepare and of patients to take customized medications that meet their unique, individual needs.

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