

FOR IMMEDIATE RELEASE
June 16, 2008

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Senators Join Thousands of Patients, Doctors, Pharmacists in Supporting Women's Access to Critical Hormone Treatments

*Sense of the Congress Resolution Introduced in Senate;
House Companion Gains Momentum*

MISSOURI CITY, Texas – The International Academy of Compounding Pharmacists (IACP) today joined hundreds of thousands of women and doctors in applauding the introduction of [S. Con. Res. 88](#), a resolution stating that “the Food and Drug Administration’s (FDA) new policy restricting women’s access to medications containing estriol does not serve the public interest” and calling on the FDA to “reverse its policy.”

The resolution, introduced in the U.S. Senate by Senators John Cornyn (R-Texas) and Jim Bunning (R-Ky.) follows the introduction of a similar measure in the U.S. House of Representatives in early May, which has gained 24 new cosponsors in the past two weeks. Thirty-two members of the House total now co-sponsor H. Con. Res. 342.

“We applaud Sen. John Cornyn and Sen. Jim Bunning for their commitment to protecting hundreds of thousands of women,” said IACP’s Executive Director L.D. King. “Women with menopause suffer enough. Fortunately, this resolution aims to provide them with some relief.”

For decades, doctors have prescribed hormones containing estriol to women suffering from the painful symptoms of menopause. IACP estimates that hundreds of thousands of women are prescribed these drugs today. Unfortunately, in Oct. 2005, Wyeth Pharmaceuticals — maker of proprietary hormones — petitioned the FDA to eliminate women’s access to hormones containing an ingredient called estriol, one of three estrogens produced by the woman’s body and a common component of individualized, bio-identical hormone treatments. In Jan. 2008, FDA announced a policy that would do exactly that.

The response from patients, doctors and pharmacists has been overwhelming. Since Oct. 2005, more than 70,000 patients, doctors and pharmacists have written to FDA opposing Wyeth’s petition. Since Jan. 2008, more than 10,000 have written to FDA opposing the agency’s new estriol policy. And since the first resolution was introduced in the House last month, more than 4,000 have written to Congress in strong support of the measure.

“My doctor and I decided to treat my menopause symptoms with a medication containing estriol and it works for me,” said Judy Sabin of Tomball, Texas. “I am grateful that Sen. Cornyn understands that my healthcare decisions should not be dictated by FDA and pharmaceutical manufacturers.”

For years, Wyeth has waged a self-serving, and at times duplicitous, campaign to restrict patients' access to alternatives to its own products. In its Oct. 2005 petition, Wyeth claimed that estriol posed a "serious threat to public health." At the same time, though, Wyeth was marketing drugs containing estriol as "an ideal therapy" across Europe. The company has also funded many seemingly independent organizations to support its campaign.

"Congress has heard from some groups claiming to speak for women who support the restriction of estriol. In fact, many of these groups are funded by Wyeth," said Dawn Heinen of Albany, Ky. "I am not being paid by Wyeth and I am proud that Sen. Bunning chose to listen to my concerns over special interests."

Compounded hormones containing estriol are lawfully prescribed, prepared and dispensed in all 50 states and their use is accepted by the United States Pharmacopeia and the Pharmacy Compounding Accreditation Board. The FDA has acknowledged that it is unaware of any adverse events associated with the use of these drugs. Estriol is a component of a multiple sclerosis treatment undergoing Phase II/III clinical trials.

Since FDA announced its estriol policy in January, the agency has attempted to allay the concerns of thousands of women by stating that doctors may prescribe hormones containing estriol if they complete an Investigational New Drug Application (IND). Unfortunately, this process is unworkable.

"FDA is trying to fit a square peg in a round hole," concluded Mr. King. "FDA is setting doctors up to fail, leaving them in the same position as they are in now — unable to treat women with the medication of their choice."

Pharmacy compounding is a long-standing, state-regulated and medically vital practice. Millions of Americans have unique health needs that off-the-shelf prescription medications 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 pharmacy compounding 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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