

# ALERT:

## BHRT AT RISK

In January 2008, FDA made a horrible decision—choosing Wyeth's wealth over patient health. FDA agreed to support Wyeth in their campaign to end compounded hormone replacement therapy—specifically by starting a crackdown on the use of estriol which FDA claims is illegal.

FDA also states that pharmacies must stop using the term bio-identical to describe the hormone therapies they offer in all marketing or advertising material. IACP is unequivocally opposed to FDA's efforts to restrict the use of estriol and believes the use of the term "bio-identical" is appropriate.

### THESE THINGS WE MUST DO:

- 1) Revisit your websites. It is critical that we avoid making claims as to the safety and efficacy of compounded hormone replacement. Read examples noted by FDA in warning letters included in this packet.
- 2) Inform your patients and prescribers about the implications of this new policy. To help, we have developed talking points. Use the talking points on the patient handout included in this packet to communicate the flaws of this new policy and encourage them to get involved in our fight to keep bio-identical hormones available.
- 3) Enroll all your patients and prescribers in P2C2, Patients and Prescribers for Customized Care. IACP has a new card available in light of FDA's support of Wyeth. Order cards and give each patient a card with each prescription (an order form is attached, or visit [www.iacprx.org/OrderP2C2](http://www.iacprx.org/OrderP2C2) to order). They can sign up for P2C2 for free at [www.savemymedicine.org](http://www.savemymedicine.org), where we will provide action alerts and further information.
- 4) Engage in IACP's grassroots mobilization where we call on all pharmacists, prescribers, patients and friends to write and call their members of Congress to stop FDA from choosing Wyeth over women's health. Send a letter today at [www.SaveMyBHRT.org](http://www.SaveMyBHRT.org).

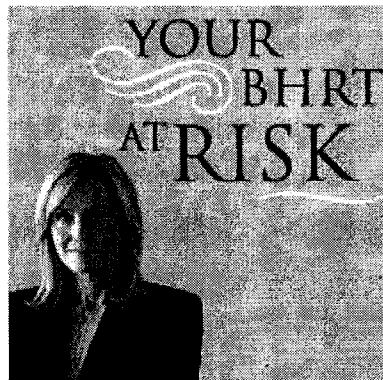
IACP members received an email on January 9 about this issue, but many have not read or acted. This is the most critical threat BHRT has ever faced. The time is now, the day is here. If you value your BHRT practice, and the hope you bring to the patients you serve, you must act now!

Visit  
**[www.SaveMyBHRT.org](http://www.SaveMyBHRT.org)**  
to learn more and take action now!

This action alert brought to you by the International Academy of Compounding Pharmacists (IACP) • P.O. Box 1365, Sugar Land, TX 77487 • (P) 281.933.8400 • (F) 281.495.0602 • [www.iacprx.org](http://www.iacprx.org) • [iacpinfo@iacprx.org](mailto:iacpinfo@iacprx.org)

## **BE ASSURED THAT YOU ARE ON THE RIGHT SIDE OF THIS ISSUE:**

- Hundreds of thousands of patients—perhaps millions—currently benefit from compounded hormone replacement therapy as prescribed by their physicians. For many patients, these medications are their only source of relief and health from symptoms of menopause and perimenopause. There is no evidence, clinical or otherwise, to suggest that these women should have their therapies stripped from them.
- In a press conference, FDA admitted there was not a single instance of an adverse event related to estriol that has been reported to FDA.
- Estriol has a USP monograph. It is recognized by USP. To compound estriol pursuant to a valid prescription is consistent with USP standards (chapters 795 and 1075), the Pharmacy Compounding Accreditation Board's standards, and state pharmacy law. Congress specifically recognized and approved the use of active ingredients that have a USP monograph as appropriate for use in compounding.
- There is currently an estriol product in phase III clinical trials for the treatment of Multiple Sclerosis. The safety data thus far has allowed the trials to continue to proceed.
- Estriol has been used in Asia and Europe for years. Its use is well-supported in medical literature.
- The use of the term bio-identical is an accurate descriptor of what these estrogens are. FDA-registered manufacturers use the term on their websites to describe FDA-approved estrogen and progesterone products.
- From both a clinical and legal point of view, the evidence supporting our cause is compelling. FDA is wrong. It is in the best interest of patients to continue to receive the medications they are prescribed.



## **IACP Resources in Effort to Preserve BHRT**

**[www.iacprx.org/BHRT\\_Resources](http://www.iacprx.org/BHRT_Resources)**

IACP Legal Response to FDA  
Joint Pharmacy Response to FDA Actions  
Advocacy Materials – Write Congress, Write FDA  
Leave Behind Materials for Congressional Offices  
SaveMyBHRT.org  
SaveMyBHRT.org Web Graphic  
Talking Points to Explain the Situation to Your Patients and Prescribers  
P2C2 Postcards to Distribute in Your Pharmacy  
FDA Misleading Email to Patients  
Analysis of FDA Standardized E-mail Response to Patients  
Why FDA IND process is unworkable  
Support for Estriol – Why You Are on the Right Side of the Issue  
Estriol Literature Review  
Trimesta—Phase II/III trials of estriol for MS patients  
IACP Marketing Guidance  
Website Claims Deemed Inappropriate by FDA  
Combating Wyeth Front Groups  
Wyeth Selling Estriol in Europe  
IACP's Freedom of Information Act (FOIA) Requests to FDA regarding Estriol  
Insurance Handout for Patients  
Common Q&A on FDA's recent actions  
Special Edition BHRT eLinks  
FDAOverload.com

### **Allies**

APhA House of Delegates Resolutions  
Dr. Erika blog  
HOME Coalition  
Ad by Dr. Jonathan Wright and HOME Coalition  
Joint Pharmacy Letter

### **Media/News**

BHRT News Page  
IACP Press Release  
IACP Press Release – Wyeth Sales of Estriol in Europe  
IACP Press Release regarding Freedom of Information Act Request

### **FDA**

FDA Press Release  
FDA Warning Letters to Compounding Pharmacies  
FDA Consumer Education Article  
*Bio-identicals: Sorting Myths from Facts*  
FDA Q&A on Compounded Menopausal Hormone Therapy  
FDA Response to Wyeth Citizen Petition  
Wyeth Citizen Petition Docket 2005P-0411



Patients and Professionals for Customized Care (P2C2) is an affiliate organization that enlists and engages your patients and prescribers who depend on you for compounding services.

The power of P2C2 was undeniable in July 2007 at IACP's Compounders on Capitol Hill. Of the 285 Congressional offices visited, the overwhelming majority indicated that they had heard from patient and prescriber members of P2C2 about the importance of compounding. Some offices reported receiving thousands of letters from P2C2 members!

**Strategy** Keep up the great work! It is because of you—dedicated and diligent pharmacists—that these patients and prescribers are engaged in our fight to protect compounding. Continue to put P2C2 postcards with every compounded prescription that you dispense. Postcards instruct patients and prescribers to visit a special website and join P2C2 (membership is free). Those who join have formed a powerful online database of patients, physicians, pet owners and veterinarians who will advocate for pharmacy compounding for years to come.

**Order your supply of postcards today!** Visit [www.iacprx.org/OrderP2C2](http://www.iacprx.org/OrderP2C2) to place your order or use the order form below and fax back to IACP @ (281) 495-0602.



## Quantity

Cards are available in packs of 1,000 @ \$50 per pack.  
Posters are available for \$30 each.



\_\_\_ Pack(s) of 1,000 cards—*BHRT at Risk*



\_\_\_ Pack(s) of 1,000 cards—*Mature adult patients*

\_\_\_ Poster(s)—*Mature adult patients*



\_\_\_ Pack(s) of 1,000 cards—*Prescribers*



\_\_\_ Pack(s) of 1,000 cards—*Animal patients / veterinarians*



\_\_\_ Pack(s) of 1,000 cards—*General purpose*

\_\_\_ Poster(s)—*General purpose*

Other quantity options available online.  
\*\*\*\*Add \$15 for shipping and handling.\*\*\*\*

Name: \_\_\_\_\_ Phone: \_\_\_\_\_

Pharmacy Name: \_\_\_\_\_ E-mail: \_\_\_\_\_

Address: \_\_\_\_\_

Please charge my:  VISA  MasterCard  American Express (credit card only please)

Card Number: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

Name on Card: \_\_\_\_\_ CVV#: \_\_\_\_\_

Billing Address: \_\_\_\_\_

Signature: \_\_\_\_\_