



# OWH eUpdate

[www.fda.gov/womens](http://www.fda.gov/womens)

Spring 2007

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## Message from the Director

OWH is continuing to find innovative methods to promote women's health through research and outreach. Last month, OWH announced the availability of our new medicine booklets that provide consumers with easy-to-read information on all FDA-approved products for HIV, elevated cholesterol, smoking cessation, hypertension, depression, and menopause. With the release of this update, OWH is pleased to announce another milestone - the availability of our newly revised Pregnancy Exposure Registry website. It is imperative that women have access to reliable information on the effects of medication use during pregnancy. Increasing numbers of reproductive age women are living with chronic diseases such as asthma, depression, HIV, epilepsy, and Multiple Sclerosis. At the same time, more drug manufacturers are being required to track the use of their products by pregnant women and subsequent pregnancy outcomes. Our registry website has been updated to provide comprehensive listings of exposure registries for a variety of drugs and vaccines. Please check out the article below on the new website as well as the other updates on OWH and FDA initiatives.

Kathleen Uhl, MD

Assistant Commissioner for Women's Health

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## OWH Research

### New Pregnancy Exposure Registry Website

The FDA Office of Women's Health has recently updated its web listing of pregnancy exposure registries. Pregnancy exposure registries are prospective observational studies that collect information on women who take medication during pregnancy. These studies provide important information on the effects of drug exposure on fetal development.

The OWH pregnancy exposure registry website provides links to 32 registries for specific medical products and medical conditions including HIV/AIDS, epilepsy, and cancer. The website also lists all the drugs or vaccines used in a specific disease registry.

To access the list and learn more information about pregnancy exposure registries, please visit:

<http://www.fda.gov/womens/registries/default.htm>

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### **OWH-Funded Research Wins Award**

Dr. Iacovos Kyprianou won the Best Poster Award at the 2007 International Society for Optical Engineering (SPIE) Medical Imaging Conference for his OWH-funded project to identify appropriate medical imaging methods to improve the diagnosis of coronary artery disease in women. Coronary vessels in females are typically shorter in length and smaller in diameter than those of males which makes the accurate detection of coronary artery disease in women a challenging task for physicians. Dr. Kyprianou's research presents one of the first methods to segment automatically the coronary arteries of a female patient CT scan. Projects like this one help develop accurate, high resolution models of the male and female heart that will be subsequently used as phantoms for medical imaging system optimization. This project is an excellent illustration of the need to better understand sex differences in disease diagnosis and treatment.

To learn more about this study, contact Iacovos Kyprianou, PhD – FDA Center of Devices and Radiological Health at:

[iacovos.kyprianou@fda.hhs.gov](mailto:iacovos.kyprianou@fda.hhs.gov)

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## **Outreach Initiatives**

### **OWH Sponsors Outreach Meetings**

The FDA Office of Women's Health sponsored two women's health information discussion groups on April 12–13, 2007. The meetings were hosted by the AARP at their national headquarters. The first meeting focused on Hispanic health issues while the second addressed issues impacting all women. The aim of the workshops was to provide participants with the opportunity to:

- Dialogue and network with their peers about shared women's health interests
- Discuss ways to collaborate in current and future outreach activities with FDA and other groups
- Learn about new FDA OWH consumer information that is available in English, Spanish and additional languages
- Link with the FDA field staff who can assist with consumer health projects

About 50 representatives from national organizations representing women's advocacy, health professionals, hospitals,

major corporations, employee assistance programs, military medicine, migrant health, minority groups, and disease groups attended the meetings.

During the round table discussions, several issues emerged as key health concerns including medication safety, HPV, smoking, mental health, CVD, clinical trials, diabetes, and HIV. The meetings produced tremendous interest in collaborating with FDA/OWH on consumer health information projects throughout the year.

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## **Celebrate National Women's Health Week**

National Women's Health Week is scheduled for May 13-19, 2007. This year's theme is "It's Your Time: Pamper Your Mind, Body and Spirit." The week is designed to highlight women's health issues and promote healthy lifestyles for women. The week also includes a celebration of Women's Check-up Day on May 14<sup>th</sup> to promote health screenings.

OWH would like to encourage groups and individuals to order any of the free OWH fact sheets and brochures for use during women's health week activities.

To order OWH publications, go to:

<http://www.pueblo.gsa.gov/rc/f06owhcard.htm>

To download OWH publications, go to:

<http://www.fda.gov/womens/getthefacts/default.htm>

To visit the National Women's Health Week website, go to:

<http://www.4woman.gov/whw/>

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## Hot Topics

### **Zelnorm Discontinued in the U.S.**

On March 30, 2007, FDA announced that the marketing of Zelnorm (tegaserod) has been voluntarily suspended in the United States due to an increased risk of serious cardiovascular adverse events (heart problems) associated with use of the drug.

Zelnorm is a prescription medicine approved in July 2002 for short-term treatment of women with irritable bowel syndrome whose primary symptom is constipation. It was subsequently approved in August 2004 for treatment of chronic constipation for men and women under age 65.

FDA is currently advising patients who are using Zelnorm to contact their health care providers to discuss treatment alternatives. Patients who are taking Zelnorm should seek emergency medical care if they experience severe chest pain, shortness of breath, dizziness, sudden onset of weakness or difficulty walking or talking, or other symptoms of a heart attack or stroke.

To view the **FDA Public Health Advisory on Zelnorm**, visit:  
<http://www.fda.gov/cder/drug/advisory/tegaserod.htm>

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## **Tykerb Approved for Advanced Breast Cancer**

On March 13, 2007, the FDA approved Tykerb (lapatinib) as a new targeted anti-cancer treatment. Tykerb is to be used in combination with capecitabine (Xeloda), another cancer drug, for patients with advanced, metastatic breast cancer that is HER2 positive (tumors that exhibit HER2 protein). The combination treatment is indicated for women who have received prior therapy with other cancer drugs. Tykerb is a kinase inhibitor that works through multiple pathways (targets) to deprive tumor cells of signals needed to grow.

To view the **FDA Press Release**, visit:  
<http://www.fda.gov/bbs/topics/NEWS/2007/NEW01586.html>

**For more information on Breast Cancer**, visit:

The National Cancer Institute  
<http://www.cancer.gov/cancertopics/types/breast>

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## **Medwatch**

FDA's MedWatch program is a reporting system that allows **healthcare professionals** and **consumers** to let the agency know about serious problems that they believe are caused by FDA regulated products (prescription and over-the-counter drugs, biologics/vaccines, and medical devices).

MedWatch reports can be submitted by phone at (800) FDA-1088, by fax at (800) FDA-0178, or on the **MedWatch** website. If the report involves a serious adverse event with a vaccine, call 1-800-822-7967.

Consumers can either work with their health care provider to report a problem or they can complete the online reporting form on the MedWatch website.

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## Update Extras

### Conferences

The OWH Outreach Team is busy exhibiting at conferences across the country to increase awareness and dissemination of the over 50 OWH health education fact sheets and brochures available for consumers.

**Visit the OWH exhibit booth at these upcoming conferences:**

**National Osteoporosis Foundation**, [April 18 -22](#) – Washington, DC

**CDC Diabetes and Obesity Conference**, [April 30 –May 3](#) – Atlanta, GA

**Organization for the Study of Sex Differences**, [May 9 -12](#) – Washington, DC

**Tavis Smiley Road to Health Expo**, [May 11 -12](#) – Oakland, CA

**National Rural Health Association**, [May 14 -18](#) – Anchorage, AK

**American Academy of Physician Assistants**, [May 29 - 30](#) – Philadelphia, PA

**American College Health Association**, [May 30 – June 2](#) – San Antonio, TX

**National Mental Health Association**, [June 7 -9](#) – Washington, DC

**American Diabetes Association**, [June 22 -26](#) – Chicago, IL

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### Other Events and Presentations

#### **DIA Issues in Gender Hormone Therapy Meeting**

Chairperson: Kathleen Uhl

Date: May 9, 2007

Location: Washington Marriott Hotel, Washington, DC

Website: [Drug Information Association](#)

#### **FDA Public Hearing**

Topic: **Use of Medication Guides to Distribute Drug Risk Information to Patients**

Dates: June 12-13, 2007

Time: 8:30 a.m. – 4:30 p.m.

Location: National Transportation and Safety Board Conference Center – 429 L'Enfant Plaza SW, Washington, DC

Website:

[http://www.fda.gov/cder/meeting/medication\\_guides\\_200706.htm](http://www.fda.gov/cder/meeting/medication_guides_200706.htm)

#### **2007 Minority Women's Health Summit**

Date: August 23-26, 2007

Location: Hyatt Regency on Capitol Hill, Washington, DC

Website: [HHS Office of Women's Health](#)

## Presentations

Conference: **Organization for the Study of Sex Differences**

Poster Title: [Standardization of Clinical Trial Data Submitted to the FDA: Is it Valuable to Track the Inclusion of Women in Clinical Trials?](#)

Authors: Ellen Pinnow<sup>1</sup>, Armando Oliva<sup>2</sup>, Jonathan Levine<sup>2</sup>, Ameeta Parekh<sup>1</sup>, Kathleen Uhl<sup>1</sup>, <sup>1</sup>OWH and <sup>2</sup>Office of Critical Path Programs, FDA

Dates: May 11, 2007

Location: Washington Plaza Hotel, Washington, DC

Conference: **Organization for the Study of Sex Differences**

Poster Title: [Sex Differences of Inclusion Criteria in Clinical Trials: A Regulatory Review of Contraception Requirements](#)

Authors: Ellen Pinnow<sup>1</sup>, Pamela Scott<sup>1</sup>, Janelle Derbis<sup>2</sup>, Theresa Toigo<sup>2</sup>, Kathleen Uhl<sup>1</sup>, <sup>1</sup>OWH and <sup>2</sup>Office of Special Health Issues (OSHI), FDA

Dates: May 11, 2007

Location: Washington Plaza Hotel, Washington, DC

Conference: **Home Healthcare Technology: Promoting the Safe Migration of Medical Devices into the Home**

Panel: [Talk with the Government](#)

Authors: Ellen Pinnow

Dates: May 22, 2007

Location: Houston, TX

Conference: **AcademyHealth Annual Research Meeting**

Poster Title: [Drug or Biologic Exposure During Pregnancy: An Update on Pregnancy Exposure Registries](#)

Authors: Pellavi Sharma<sup>1</sup>, Ameeta Parekh<sup>1</sup>, Elizabeth Duvall-Miller<sup>2</sup>, Connie O'Leary<sup>2</sup>, Kathleen Uhl<sup>1</sup> (<sup>1</sup>OWH)

Dates: June 03, 2007

Location: Orlando Florida

Conference: **15<sup>th</sup> Annual Congress on Women's Health**

Poster Title: [Updates to the FDA Office of Women's Health Pregnancy Exposure Registries Listing](#)

Authors: Pellavi Sharma, Ellen Pinnow, Ameeta Parekh, Elizabeth Duvall- Miller, Connie O'Leary, Kathleen Uhl

Dates: June 3-5, 2007

Location: Hilton Head, SC

Conference: **Organization of Teratology Information Specialists (OTIS)**

Poster Title: [A Revamped Tool for Pregnant Women: Updates to the FDA Office of Women's Health Pregnancy Exposure Registries Listing](#)

Authors: Pellavi Sharma<sup>1</sup>, Ameeta Parekh<sup>1</sup>, Elizabeth Duvall-Miller<sup>2</sup>, Connie O'Leary<sup>2</sup>, Kathleen Uhl<sup>1</sup> (<sup>1</sup>OWH)

Dates: June 25, 2007

Location: Pittsburgh, PA

