



# OWH eUpdate

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

Fall 2008

## In This Issue

- OWH Research
- Outreach Initiatives
- Hot Topics
- Update Extras

## OWH Highlights

Join Us

Research & Development

Medication Booklets

Free Publications

e-Update Archive

## FDA Highlights

Misbranded Ovasure Test  
*FDA issues warning letter*

Mammography Website  
*Find a certified  
mammography facility*

Melamine Contamination  
*FDA assessment of  
melamine in formula & other  
foods*

FDA Newsroom  
*Public notices, safety alerts,  
media contacts and more*

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## Message from the Director

As we begin a new fiscal year in the federal government, the OWH staff has already begun to take stock of the initiatives we have conducted throughout the previous year and to make plans for the future. Throughout the year, OWH has supported research and outreach efforts with a focus on safety. In this update we highlight an educational project on safe medication use and a new publication on the assessment of the sex differences impacting the safety and efficacy of FDA-regulated products. I encourage you to read these articles as well as the highlights of other Agency initiatives. As always, we will continue to provide future updates about our ongoing programs and new collaborative projects with our diverse partners.

Kathleen Uhl, MD

Assistant Commissioner for Women's Health

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## OWH Research

### OWH Director Pens Article on Assessing Sex Differences

OWH Director Kathleen Uhl co-authored a recent article entitled "Assessing sex differences: methodological considerations" that was published in the September 2008 edition of *Expert Reviews in Clinical Pharmacology* [Vol. 1(5): 585-587]. Uhl and co-author Sherry Marts called for the consideration of sex differences in the design and implementation of clinical studies. The article highlighted the need to address issues related to clinical study recruitment, data analysis, measurement methodology, and other study design factors.

The Journal can be found at: [www.expert-reviews.com](http://www.expert-reviews.com)

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## Outreach Initiatives

### OWH Celebrates “Talk About Prescriptions Month”

OWH will team up with InnovationRx, a prescription management and medication adherence service, and PPSI, Pharmacists Planning Service, Inc, to target pharmacists throughout California during “Talk About Prescriptions Month”. In October, 5,000 pharmacists will receive a medication safety tool-kit that features the OWH My Medicines brochure. In addition to the tool kit, InnovationRx will reprint an additional 10,000 My Medicines brochures at their expense for distribution to participating pharmacists.

Visit the My Medicines Website at:

<http://www.fda.gov/womens/taketimetocare/mymeds.html>

My Medicines is now available in **Arabic** at:

[http://www.fda.gov/womens/TakeTimeToCare/Meds\\_Ara.html](http://www.fda.gov/womens/TakeTimeToCare/Meds_Ara.html)

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## Hot Topics

### FDA Approves Expanded Uses for Gardasil

On September 12, 2008, FDA announced the approval of the vaccine Gardasil for the prevention of vaginal and vulvar cancer caused by Human Papillomavirus (HPV) types 16 and 18 in girls and women ages 9 to 26. These two HPV types cause 70 percent of cervical cancers, and are known to also cause some vulvar and vaginal cancers, but the percentages are not well defined.

Gardasil's label has been revised to note that presently available information is insufficient to support use beyond age 26, the current FDA-approved age. Also, new information has been added showing that Gardasil does not protect against diseases caused by HPV types not contained in the vaccine.

FDA originally approved Gardasil in 2006 for girls and women ages 9 to 26 for the prevention of cervical cancer caused by HPV types 16 and 18, precancerous genital lesions caused by HPV types 6, 11, 16, and 18 and genital warts caused by HPV types 6 and 11.

Updated safety information on Gardasil was published on July 22 and can be found at:

[www.fda.gov/cber/safety/gardasil071408.htm](http://www.fda.gov/cber/safety/gardasil071408.htm)

The full FDA press release can be viewed at:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01885.html>

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## **FDA to Post Quarterly Report of Potential Safety Issues**

On September 5, 2008, FDA posted on its Web site its first quarterly report of drugs that are being evaluated for potential safety issues. The drugs have been identified based on reviews of reports in FDA's Adverse Event Reporting System (AERS).

The report lists any potential signals of serious risks and new safety information that were identified using the AERS database during the indicated quarter. The appearance of a drug on this list does not mean that FDA has concluded that the drug has the listed risk or that FDA has identified a causal relationship between the drug and the listed risk. It is on the list only because FDA has identified a potential safety issue. FDA will complete its evaluation of each potential safety issue and may issue additional public communications as appropriate.

FDA emphasized that the listing of a drug on this Web site does not mean that FDA is suggesting that healthcare providers should not prescribe the drug or that patients taking the drug should stop taking the medication. Patients who have questions about their use of the identified drug should contact their health care provider.

The quarterly report can be found at:

[http://www.fda.gov/cder/aers/potential\\_signals/default.htm](http://www.fda.gov/cder/aers/potential_signals/default.htm)

The full FDA press release can be viewed at:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01881.html>

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## **New FDA Websites on Drug/ Device Advertisements**

On September 3, FDA launched two new websites to provide information for consumers and industry about how FDA regulates the promotion of medical products.

The "**Advertising Prescription Drugs and Medical Devices**" website provides industry and policy users with access to relevant laws, regulations, and guidances on medical product promotion. This site can be found at: <http://www.fda.gov/oc/promotion/>

The "**Be Smart about Prescription Drug Advertising: A Guide for Consumers**" website is designed to educate the general public about direct-to-consumer (DTC) advertising. The site includes

interactive examples of advertisements, as well as, other useful tools on DTC ads. This site can be found at:  
<http://www.fda.gov/cder/ethicad/index.htm>

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## Update Extras

### HHS NEWS

HHS has issued **Physical Activity Guidelines for Americans**. The 2008 guidelines outline the types and amounts of physical activity that will provide health benefits. Materials are available for consumers, health professionals, researchers, and policy makers.

The guidelines can be accessed at:

[www.health.gov/PAGuidelines/](http://www.health.gov/PAGuidelines/)

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### Upcoming Meetings

#### **Peripheral and Central Nervous System Drugs Advisory Committee**

Topic: Radionuclide imaging products for the detection of amyloid to assist in the diagnosis of Alzheimer's Disease

Date: October 23, 2008

Time: 8:00 a.m. to 5:00 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD

Website:

<http://www.fda.gov/oc/advisory/accalendar/2008/PandCNSMtg102308.html>

#### **NIH Office of Research on Women's Health Seminar Series**

Topic: Sex and Gender Research in the Urinary Tract

Date: October 16, 2008

Time: 1:00 –3:00 p.m.

Location: Lipsett Amphitheater, Building 10, NIH Campus

Contact: Marsha Love at [lovem@od.nih.gov](mailto:lovem@od.nih.gov) or 301-402-1770

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### Presentations

**Conference:** American Public Health Association

**Presentation:** Educating African American and Hispanic women about early detection of breast cancer through mammography

**Speaker:** [Kimberly Thomas](#)

**Date:** October 28, 2008

**Location:** San Diego, CA

**Conference:** National Caregiver Conference  
**Presentation:** FDA Office of Women's Health: Providing Caregivers with Free, High-Quality Health Care Information  
**Speaker:** [Susana Perry](#)  
**Date:** October 29, 2008  
**Location:** Woodbridge Hotel - Iselin, NJ

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## 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:

**NRHA Critical Access Hospital Conf.,** [October 15-17](#) – Savannah, GA

**Nurse Practitioners in Women's Health,** [October 15-17](#) – Seattle, WA

**Employee Assistance Professionals,** [October 15-18](#) – Atlanta, GA

**National Conf. on Correctional Healthcare,** [October 18-22](#) – Chicago, IL

**New York College Health Association,** [October 22-24](#) – Atlanta, GA

**American Public Health Association,** [October 26-29](#) – San Diego, CA

**National Caregiver Conference,** [October 29](#) – Iselin, NJ

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**We endeavor to provide timely information for your use.**

Feel free to share this with your network, members, constituents, and community.