



OWH eUpdate

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Fall 2007

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Message from the Director

Throughout 2007, OWH has worked diligently to promote women's health by facilitating high quality science and developing partnerships to deliver consumer health messages. In this final update for 2007, you will find articles on the outcomes of several OWH research and outreach programs including a nationwide outreach initiative and new publications. Explore the articles below as well as the links to upcoming FDA meetings and information on women's health issues, conferences, and presentations.

Finally, I encourage you to look to OWH in the coming year for new research and outreach activities focusing on patient safety and health disparities. The OWH research program will continue to support projects that aim to increase our understanding of the safety and efficacy of FDA regulated products used by women. The OWH outreach program will work to increase awareness of health conditions negatively impacting women in addition to educating women about medication safety.

Kathleen Uhl, MD

Assistant Commissioner for Women's Health

OWH Research

Journal Article Highlights OWH Research Program

A recent article in the **Journal of Women's Health** chronicles the impact of OWH-funded research on FDA policies and regulations affecting women. The article provides an overview of the OWH research program and discusses several key OWH-funded studies that have helped to advance the understanding of sex and gender differences. The full citation for the article is listed below. To view the PubMed abstract, check ID [17678451](#)

Article: The Food and Drug Administration Office of Women's Health: impact of science on regulatory policy.

Authors: Obias-Manno D, Scott PE, Kaczmarczyk J, Miller M, Pinnow E, Lee-Bishop L, Jones-London M, Chapman K, Kallgren D, Uhl K.

Journal: *Journal of Women's Health* 2007 Jul-Aug; 16(6):807-17

OWH supports NIH SCOR Initiative

In September, the NIH Office of Research on Women's Health announced the new Specialized Centers of Research (SCOR) on Sex and Gender Factors Affecting Women's Health. Eleven institutions will share a total of \$11 million per year for five years. The centers will conduct research on vital women's health concerns such as metabolic disorders, osteoporosis, mental health, and pain disorders. OWH was proud to collaborate with NIH to support this important research initiative.

To learn more about SCOR, visit:

<http://orwh.od.nih.gov/interdisciplinary/SCORs.html>

To read the press release, visit:

<http://www.nih.gov/news/pr/sep2007/od-24a.htm>

Outreach Initiatives

Nationwide Outreach Initiative with FDA Field Staff

In January 2007, OWH launched a new nationwide collaboration initiative. The aim of the initiative was to work with FDA field staff to develop collaborations with local organizations in urban and rural communities across the country. These organizations would help OWH get critical health information to women and their families through a variety of community and church events, adult education classes, health programs, and web outreach.

OWH provided funding to 18 FDA Public Affairs Specialists (PASs) who traveled around their regions to meet organizations, distribute OWH consumer health materials, and speak/ exhibit at conferences. Phase I of the initiative ended in September. To date, the PASs have collaborated with over 75 groups, including state and local health departments, community groups, universities, hospitals, and local businesses. Sample collaborations include:

Stewart Watson, Florida District Office

The Three Rivers Regional Library System has placed display racks of OWH publications in each of its branches.

Laurel Eu, Los Angeles District

The Union of Pan Asian Communities is using OWH publications in their health education classes.

Joan Lytle, New Jersey District

The New Jersey Department of Health and Senior Services distributed fact sheets and medicine booklets at the NJ Caregiver's Conference.

Ruth Marcano, US Virgin Islands

The Fredrick Lutheran Church held a Women's Convention that featured Take Time To Care materials.

OWH and AWHONN hold Nurses' Stakeholder Meeting

On September 18, OWH partnered with the Association of Women's Health, Obstetric, and Neonatal Nurses (AWHONN) to host an information gathering meeting with 20 national nursing organizations. The goal of the meeting was to discuss strategies for working with nurses and nurse practitioners to disseminate FDA health information to women. This meeting was the final in a series of three meetings designed to create women's health information networks. OWH met earlier this year with leaders from women's groups and organizations that serve Spanish-speaking communities.

Hot Topics

Online Course on Breast Cancer Detection

Medscape from WebMD is offering an online CME course called **"Follow Up of Abnormal Clinical and Imaging Findings of the Breast: Five Self-Study Modules for Primary Care Clinicians"**. The course is designed to educate healthcare providers on the early detection of breast cancer. It includes five modules on anatomy, health history and clinical breast exams, abnormal clinical findings, biopsy methods, and risk management.

Co-authored by OWH medical officer, Joseph Kaczmarczyk, the course was developed by Medscape, CDC, and ACOG in consultation with the FDA. The course is open to registered members of Medscape. (Registration is FREE.)

To view the course, visit:

<http://www.medscape.com/editorial/public/breastcancer-cdc>

New Drug Safety Newsletter

In September, FDA launched a new quarterly newsletter for health professionals. The **Drug Safety Newsletter** aims "to enhance communication of new drug safety information, raise awareness of reported adverse events, and stimulate additional adverse event

reporting". The newsletter is designed to alert providers to postmarketing safety signals detected through reviews conducted by the FDA Center for Drug Evaluation and Research (CDER).

To learn more about the Drug Safety Newsletter, go to:
<http://www.fda.gov/cder/dsn/default.htm>

To subscribe to the Drug Safety Newsletter, go to:
<https://list.nih.gov/cgi-bin/wa?SUBED1=fda-dsn&A=1>

Lead Levels in Lipstick

The FDA is aware of reports regarding lead levels in lipstick. FDA analyses to date have not supported the concerns about lead. However, the agency is looking into the specific details of recent reports and will need to independently confirm this information to determine what action, if any, needs to be taken.

Under the Food Drug and Cosmetic Act, FDA can take regulatory action against cosmetics deemed to be "adulterated". The Act does not give the FDA legal authority to require that cosmetics be approved before they go on the market. The Act does require pre-market approval for color additives – including those used in lipstick.

To learn more about FDA's authority over cosmetics, go to:
<http://www.cfsan.fda.gov/~dms/cos-206.html>

Update Extras

Upcoming Meetings

Mammography Quality Assurance Advisory Committee

Topic: Interventional Mammography
Date: November 5, 2007
Time: 9:00 am – 5:00 pm
Location: Crown Plaza Rockville – Remington II and III in Ballroom
3 Research Ct., Rockville, MD
Website: <http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-17795.htm>

Public Meeting on Behind-the-Counter Availability of Drugs

Date: November 14, 2007
Time: 8:00 a.m. – 5:00 p.m.
Location: National Transportation Safety Board conference Center
429 L'Enfant Plaza SW, Washington, DC
Website: <http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-19329.pdf>

Pediatric Advisory Committee

Topic: Draft Guidance on Clinical Lactation Studies
Date: November 29, 2007
Time: 8:00 am – 4:00 pm
Location: Hilton – Grand Ballroom
620 Perry Parkway, Gaithersburg, MD
Website: <http://www.fda.gov/OHRMS/DOCKETS/98fr/E7-20304.htm>

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:

American Public Health Association, [November 3-7](#) – Washington, DC

US Conference on AIDS, [November 7-9](#) – Palm Springs, CA

Association of Nurses in AIDS Care, [November 8-11](#) – Orlando, FL

CDC HIV Prevention Conference, [December 2-5](#) – Atlanta, GA

Presentations

Conference: **American Heart Association**
Presentation: What is new at FDA's Office of Women's Health
Session: Heart Disease in Women: Where are We Now, Where are We Going?
Authors: Kathleen Uhl
Date/ Time: November 3, 2007 – 1:30 p.m.
Location: Orlando, FL

Conference: **American Public Health Association**
Presentation: Enrollment of women and racial minorities in clinical trials for diabetes medications
Authors: **Ellen Pinnow**, Pellavi Sharma, Ameeta Parekh, Kimberly Thomas, Lina Aljuburi, Kathleen Uhl
Date/ Time: November 5, 2007 – 10:30 a.m.
Location: Convention Center, Washington, DC

Conference: **American Public Health Association**
Presentation: Lack of Planned Subgroup Analysis: Review of Drug Protocols Submitted to the FDA
Authors: **Pellavi Sharma**, Ellen Pinnow, Pamela Scott, Janelle Derbis, Theresa Toigo, Kathleen Uhl
Date/ Time: November 5, 2007 1:30 PM

Location: Convention Center, Washington, DC

Conference: **American Public Health Association**

Presentation: Bringing science to consumers: Designing appropriate health education materials

Authors: Alison Lemon

Date/ Time: November 6, 2007 – 2:30 p.m.

Location: Convention Center, Washington, DC

Conference: **American Public Health Association**

Poster: An update on the OWH pregnancy exposure registry listing

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

Date/ Time: November 7, 2007 8:30-9:30 AM

Location: Convention Center, Washington, DC

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