



OWH eUpdate

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Contact Us

5600 Fishers Lane
Room 16-65
Rockville, MD 20857
301-827-0350 (phone)
301-827-0926 (fax)
owh@fda.gov

Message from the Director

In this exciting time, OWH is looking forward to new opportunities to work with our partners to address the health issues impacting the nation's women. With your help, we will continue our innovative strategies for promoting policies and programs that support and hopefully improve women's health. In this update, we highlight our ongoing efforts to further dialogue and research on the treatment and diagnosis of cardiovascular disease in women. We also acknowledge OWH and Agency-wide projects to expand consumer access to FDA information. Finally, we provide links to FDA product safety information, upcoming meetings, and more.

I will end by thanking you for your previous support of women's health and reminding you to look to us for continued access to timely scientific and consumer health information.

Kathleen Uhl, MD

Assistant Commissioner for Women's Health

OWH Research

OWH Co-Sponsors 2nd Workshop on Cardiac Devices

On December 9, 2008, OWH collaborated with FDA's Center for Devices and Radiologic Health (CDRH) to hold a second public workshop on the current state of cardiovascular device interventions in women. This workshop, like the previous one in June, invited experts from academia, industry, FDA, and NIH to discuss sex differences in disease presentation, prevalence, diagnosis, and testing, as well as the efficacy and/or safety outcomes of cardiovascular disease device trials. The workshop also continued dialogue on ways to facilitate inclusion of an adequate number of men and women in device trials to allow for sex-specific performance evaluation in pre-market applications. Both workshops represent OWH's ongoing efforts to promote a greater understanding of the differences in cardiovascular disease treatment and intervention options between men and women.

OWH Funded Research Honored with Two Awards

OWH-funded researcher Dale Tavris was awarded a 2008 Honorable Mention at the 24th International Conference on Pharmacoepidemiology and Therapeutic Risk Management in Copenhagen, Denmark for being 'one of three best papers published in Pharmacoepidemiology and Drug Safety in 2007'. The paper entitled "Risk of Local Adverse Events by Gender Following Cardiac Catheterization" [Pharmacoepidemiology and Drug Safety 16 (2): 125-31, 2007] discussed an OWH-funded study which found that following cardiac catheterization, the hemorrhagic events associated with hemostasis devices were significantly higher in women. The risk varied with the device type.

An educational exhibit co-developed by OWH-funded researchers, I. Kyprianou and S. Park, along with their colleagues in CDRH/OSEL/DIAM was honored with a Merit Award at the Radiological Society of North America 2008 Conference. The poster entitled "Quantitative in Silico Imaging and Biomarker Assessment Using Physical and Computational Phantoms : A Review of New Tools & Methods Available from the NIBIB/CDRH Lab for the Assessment of Medical Imaging Systems" outlined the open source cardiac and mammography imaging system simulation, phantoms, and statistical analysis tools that they developed for their OWH-funded projects. The use of these tools by academia and industry may lead to improved diagnosis and better treatment outcomes for patients.

OWH congratulates the researches for their efforts to increase awareness and understanding of sex differences in cardiovascular disease diagnosis and treatment.

Outreach Initiatives

New Collaboration on Diabetes

Diabetes Health Network

OWH will collaborate with the Diabetes Health Network (DHN), an independent network that provides free educational television to diabetes-focused clinics throughout the U.S. DHN will co-brand and reprint over a dozen OWH publications on Diabetes, Cholesterol, Heart Disease and other topics to distribute to patients in their 600+ member clinics across the country.

Hot Topics

FDA Teams with WebMD

FDA and WebMD are collaborating to expand consumers' access to FDA Health information. The partnership includes:

A New FDA Portal on WebMD.com

This website (www.webmd.com/fda) will feature FDA Consumer Updates, information on the safety of FDA-regulated products, and links to report problems with these products directly to the FDA. In addition, WebMD will provide access to FDA public health alerts to all WebMD registered users and site visitors that request them.

FDA Contributions to WebMD the Magazine

FDA Consumer Updates will also be featured at least three times a year in WebMD's bimonthly magazine which reaches nearly nine million consumers in physician office waiting rooms across the country.

Update Extras

Upcoming FDA Meetings

Cardiovascular and Renal Drugs Advisory Committee

Date: February 3, 8:00 a.m.

Location: Hilton, Washington DC/Silver Spring, Ballroom
8727 Colesville Road, Silver Spring, Maryland

Website:

http://www.fda.gov/cder/audiences/acspage/meetings/crdac_meeting_20090203.htm

The committee will discuss new drug application (NDA) 22-307, prasugrel hydrochloride film coated oral tablets, 5 milligrams (mg) and 10 mg, Eli Lilly and Company, for the proposed indication for use in acute coronary syndrome

Risk Communication Advisory Committee

Date: February 26-27, 8:00 a.m.

Location: National Transportation Safety Board Conference Center
429 L'Enfant Plaza SW, Washington, DC 20594

Website:

<http://www.fda.gov/oc/advisory/acalendar/2009/OCRCACMtg02262709.html>

On both days there will be a discussion of different types of prescription drug information currently available to patients in the form of Medicating Guides, Patient Package Inserts (PPIs), and Consumer

Medication Information (CMI).

Presentations

Conference: North American Society For Psychosocial Obstetrics and Gynecology (NASPOG)

Presentation: FDA's Pregnancy Labeling: Changes to Improve Information for Prescribing During Pregnancy

Speaker: **Kathleen Uhl**

Date: February 4, 2009

Location: New Haven, CT

Conference: Dartmouth Hospital Medical Center Grand Rounds

Presentation: The Intersection of Science, Policy, and Politics of Women's Health: Effect on FDA-Regulated Products

Speaker: **Kathleen Uhl**

Date: February 27, 2009

Location: Hanover, NH

Conference: American Society of Clinical Pharmacology and Therapeutics

Presentation: Drug Use in Pregnant Women: Clinical Studies and Labeling

Speaker: **Kathleen Uhl**

Date: March 19, 2009

Location: Washington, DC

Conference: Women's Health 2009: The 17th Annual Congress
Poster: Recently approved medical devices: Are females adequately represented in device clinical trials?

Presenter: **Beverly Gallauresi**, Lauren DiPaola, Ameeta Parekh, Zimmerman, Kathleen Uhl

Date: March 27-29, 2009

Location: Williamsburg, VA

Conference: Women's Health 2009: The 17th Annual Congress
Poster: The FDA OWH National College Campaign: Increasing college students' access to FDA health information

Presenter: **Kimberly Thomas**

Date: March 27-29, 2009

Location: Williamsburg, VA

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:

Sister-To-Sister Women's Heart Health Fair, [February 6](#) – Washington, DC

Sister-To-Sister Women's Heart Health Fair, [February 7](#) – Atlanta, GA

National Conference on Chronic Disease Prevention, [February 23-25](#) – National Harbor, MD

National Conference on African Americans & AIDS, [February 23-24](#) – Philadelphia, PA

ASA/ NCOA Aging in America Conference, [March 16-18](#) – Las Vegas, NV

American Counseling Association, [March 20-22](#) – Charlotte, NC

Planned Parenthood National Conference, [March 26-27](#) – Houston, TX

Women's Health Congress, [March 27-29](#) – Williamsburg, VA

We endeavor to provide timely information for your use.

Please share this with your network, members, constituents, and community.