



OWH eUpdate

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Spring 2008

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Message from the Director

In this Spring update, OWH will share some exciting announcements about several new research and outreach projects. Our increased funding has allowed us to support more projects than ever before. Thus far in FY2008, we have funded over 20 research projects by investigators/scientists in the FDA Centers who will be conducting regulatory research pertinent to women's health. We are also able to fund a comprehensive outreach collaboration with HRSA. These new scientific and educational projects along with our ongoing efforts will advance our knowledge of sex differences and promote healthy lifestyle behaviors among women. We look forward to sharing the results of these projects with you.

Kathleen Uhl, MD

Assistant Commissioner for Women's Health

OWH Research

Intramural Research Grants Announced

The OWH Intramural Research Program awarded approximately \$1.5 million in grants to fund projects on breast cancer, lupus, cardiovascular disease, and hormone therapy. These studies will utilize innovative and translational science tools such as genetics, imaging, and pharmacometrics to advance our understanding of these vital women's health issues. In addition, OWH helped support the participation of FDA investigators in a large Interagency collaboration studying the complications of Lasik eye surgery.

Each year, OWH supports intra-Agency research that addresses sex differences in disease prevalence and response to therapy; health issues unique to women, and women's participation in clinical trials. These research collaborations with FDA scientists are key to fostering the Agency's ability to examine sex differences.

Outreach Initiatives

OWH Partners with Laura Bush Institute

OWH is collaborating with the Laura W. Bush Institute for Women's Health at the Texas Tech University Health Sciences Center (TTUHSC) to provide health education information to women and their families. OWH publications will be used as teaching tools at each of TTUHSC's five schools – Medicine, Nursing, Allied Health Sciences, Pharmacy and Graduate School of Biomedical Sciences. In addition, OWH materials will be disseminated at hospitals and clinics throughout West Texas.

OWH and HRSA Create Pharmacy Education Initiative

OWH and the HRSA Office of Pharmacy Affairs have joined forces to develop and implement a Medication Safety and Effectiveness Health Education Outreach Project. This new initiative will target underserved communities and individuals with special health care needs including those diagnosed with HIV/AIDS. OWH will provide free consumer information that will be disseminated along with an educational tool kit to HRSA grantees. OWH and HRSA will also collaborate on a web-based course and information portal for pharmacists and other health professionals working at more than 6,000 urban and rural clinics across the country.

Hot Topics

Manufacturer Limits Availability of Zelnorm

Novartis has voluntarily decided to supply Zelnorm (tegaserod maleate) for emergency use only. Zelnorm will no longer be available under a treatment IND (investigational new drug) protocol.

Use of Zelnorm was previously restricted at the request of FDA in 2007 following a safety analysis that found a higher chance of heart attack, stroke, and unstable angina (heart/chest pain) in patients treated with Zelnorm compared with those treated with an inactive substance (placebo).

For more information on who may qualify for treatment with

Zelnorm for emergency use, visit the FDA Zelnorm information page at: <http://www.fda.gov/cder/drug/infopage/zelnorm/default.htm>

Physicians may contact FDA's Division for Drug Information about the emergency IND process at druginfo@fda.hhs.gov.

New FDA Homepage

In March, FDA unveiled its new home page. The newly designed page features an improved layout and user-friendly sections like "FDA For You" that provide links to information for consumers, health professionals, and industry. The new home page represents the first step in the complete re-design of the FDA web site. The Agency is working to update the entire site by the end of the year.

View the new homepage at: www.fda.gov

Comment on the new homepage at: [FDA Home Page Comments](#)

Reports from the Field

OWH provides support for FDA field staff to conduct educational and outreach efforts. FDA Public Affairs Specialists exhibit at conferences, hold community health events, and foster partnerships with local organizations that serve women and their families. Highlights of these regional activities are listed below.

Atlanta District Office

PAS JoAnn Pittman partnered with the South Atlantic Medical Association to print and distribute OWH publications at their expense. SAMA will print over 40 fact sheets and medicine booklets for their 60,000 physician members across the South.

Los Angeles District Office

PAS Laurel Eu is teaming with the Little Tokyo Service Center to distribute OWH health materials in Asian and Pacific Islander communities throughout Los Angeles.

New Orleans District Office

PAS Natalie Guidry showcased Take Time To Care consumer health information at the Alabama Food Service & Nutrition Expo in Birmingham, AL in March. For the second consecutive year, the OWH exhibit was awarded first place in the General Products Category.

Update Extras

Upcoming Meetings

[Ophthalmic Devices Panel Of The Medical Devices Advisory Comm.](#)

Topic: Post Marketing Experience with Lasik

Date: April 24-25, 2008

Time: 8:30 a.m. to 5:00 p.m.

Location: Gaithersburg Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD

Website: <http://edocket.access.gpo.gov/2008/E8-5810.htm>

Awards

Kathleen Uhl, MD, Assistant Commissioner of Women's Health received the Henry W. Elliott Distinguished Service Award at the 2008 American Society for Clinical Pharmacology and Therapeutics (ASCPT) meeting in Orlando, Florida. Dr. Uhl was recognized for her ongoing service to ASCPT including her current efforts as Associate Editor for the Society's journal, Clinical Pharmacology and Therapeutics.

Marsha Henderson, OWH Deputy Director, was honored with the Jacob W. Miller Award from the American Pharmacists Association (APhA) Foundation. The award was presented in recognition of her leadership in improving the quality of consumer health efforts.

Join us in congratulating Kathleen and Marsha on their distinguished honors.

Conferences

Visit the OWH exhibit booth at these upcoming conferences:

National Black Women's Health Conference, [May 1-3](#) – Atlanta, GA

American Psychiatric Association, [May 4-7](#) – Washington, DC

CDC Diabetes Translation Conference, [May 5-8](#) – Orlando, FL

National Farmworker Health Conference, [May 6-8](#) – San Juan, PR

American College Health Association, [June 4-6](#) – Orlando, FL

Organization for the Study of Sex Differences, [June 4-6](#) – New Orleans
Mental Health America, [June 4-8](#) – Washington, DC
American Diabetes Association, [June 6-10](#) – San Francisco, CA
HIV Prevention Leadership Summit, [June 11-14](#) – Detroit, MI

Presentations

Conference: **Organization for the Study of Sex Differences**
Poster: Information on QT Prolongation potential in Labels:
New Molecular Entity Drugs Approved by FDA,
2003-2006
Authors: [Ameeta Parekh](#), Natalie Gevorkian, Pellavi Sharma,
Ellen Pinnow
Date: June 4-6, 2008
Location: New Orleans, LA

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