



OWH eUpdate

<http://www.fda.gov/womens>

Summer 2006

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Message from the Director

Over the years, the FDA Office of Women's Health (OWH) has sent periodic e-blasts to update our partners and stakeholders on FDA actions and activities. This summer we are making some changes to our electronic outreach as we work to find innovative ways to provide you with timely information from OWH, FDA, and HHS. The new look of this quarterly, online update reflects these efforts. The new format provides snapshots of OWH research and outreach initiatives below. To the left you will also find links to OWH and FDA websites of interest to health professionals, researchers, advocates, and community leaders. We aim to connect you to the latest news on topics from drug recalls and approvals to media outreach and public meetings.

This e-update is only one example of new OWH initiatives. This year we will begin new research initiatives from the OWH Science Program and creative health education campaigns on health fraud and drug safety from the Take Time To Care program. So, read this update and look out for e-blasts of breaking news regarding FDA safety efforts and initiatives of particular interest to women.

Kathleen Uhl, MD

Assistant Commissioner for Women's Health

OWH Research

The OWH Science Program continues its commitment to fund FDA research that examines gender differences. In May, OWH announced its FY 2006 funding awards. We congratulate the FDA scientists listed below for their outstanding submissions and look forward to learning more from them about their research. Check the OWH website for future updates about research findings and publications from OWH funded studies.

Six projects will be funded through the OWH Intramural Science Program:

Hanna Golding - CBER

HIV SELECTEST: A novel assay for diagnosis of HIV infections in the presence of antibodies induced by candidate HIV vaccines – Evaluation of gender bias in sensitivity and specificity

Ohidul Siddiqui – CDER

Statistical analyses of gender-specific data from New Drug Application (NDA) submissions.

Leslie Kenna – CDER

Quantitative Tumor Size – Survival relationship in oncology clinical trials.

Azadeh Shoaibi & Dale Tavris – CDRH

Assessment of the accuracy of the Troponin Assay in the diagnosis of myocardial infarction by gender/ How gender influences treatment.

Varsha Desai – NCTR

Molecular mechanisms underlying gender-associated differences in the adverse reactions to the anti-retroviral agent, zidovudine (AZT): Role of mitochondrial toxicity.

Ying Huang – NCTR

Sex differences in chemotherapeutic toxicity: Profiling of transporter genes in humans.

In addition to the above awards, OWH will provide funds for several Special Funding Initiatives Grants.

Christopher Elkins, Ph.D. and Mark Hart, Ph.D. - NCTR

Protective effect of vaginal Lactobacillus species against Staphylococcus aureus-mediated toxic shock syndrome

Kara Morgan, Ph.D. - OC

Evaluation of How Best to Communicate to Health Care Providers about the Risks and Benefits of Prescription Drug Use for Pregnant and Nursing Women

OWH and CDER Collaboration/ Mary Willy, Ph.D. - CDER

Drug Use in Pregnancy

Demographic Data Initiative

OWH instituted the "**Inclusion of Women in Clinical Trials Initiative**" to support research by FDA investigators to track the inclusion of women in clinical trials and to monitor sex analyses submitted in market applications. In May, five projects were selected for funding under this new initiative:

Angela Men – CDER

Impact of Gender and Pharmacogenomics on Clinical Efficacy, Safety and Pharmacokinetics of Drugs Used for the Treatment of Alzheimer's Disease

Greg Soon – CDER

Women in HIV Trials: A comprehensive review and meta-analysis

Shasi Amur – CDER

Gender differences and impact of Pharmacogenomics in Rheumatoid Arthritis

Yongsheng Yang – CDER

Participation of women in clinical trials and gender analysis of data in original NDAs approved 2000-2004

Kathryn O'Callaghan – CDRH

Evaluation of availability and quality of information available on females included in mechanical heart device implant trials

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Outreach Initiatives

The Office of Women's Health is expanding its efforts to reach women in both rural and urban communities nationwide who may not have access to easy-to-read health education materials.

During Women's Health Week in May, OWH collaborated with **Parade Magazine** and the "**Hints from Heloise**" syndicated column to announce the availability of free "Women's Health Kits". The kits contain OWH fact sheets and brochures on topics ranging from heart disease and depression to asthma and sleep disorders. Women were directed to call 1-888-8PUEBLO or visit the website of the Federal Citizen Information Center (FCIC) to have the kits mailed to them. The announcement in Parade Magazine ran on Mother's Day while the "Hints for Heloise" column was published in papers nationwide during the week of May 14-20. To date, over **1 million** publications have been distributed through the Heloise campaign and **500,000** through Parade.

In addition to these media efforts, OWH reached out to public libraries, particularly those in communities impacted by the recent hurricanes. Recognizing that public libraries are a trusted source of information for many women, OWH lifted restrictions on the number of free OWH publications librarians could order to distribute to women in their communities. From March through June, librarians could place bulk orders for materials through FCIC by visiting:

http://www.pueblo.gsa.gov/rc/library_p15.htm

OWH and NACHC collaborate to reach nearly 500,000 women

As a part of the Menopause Hormone Therapy (MHT) Initiative, OWH joined forces with the National Association of Community Health Centers (NACHC) to distribute OWH MHT materials to the low income and minority women who use community health centers (CHC) nationwide. According to NACHC, approximately 91% of CHC patients are low income; 40% are uninsured; 36% depend on Medicaid; and approximately 63.5% are members of racial and ethnic minority groups. Approximately 50% of all CHC patients reside in rural areas and the other half live in economically depressed inner city communities.

Phase I of the collaboration targeted 900 community health centers and 3500 of their respective sites. The targeted CHCs received a NACHC-developed marketing tool that included samples of OWH materials and an order form. During Phase I, **282,500** English fact sheets and **180,000** Spanish fact sheets were distributed in 47 states and territories. In addition, **180,000** Spanish and **241,000** English purse-sized, MHT question guides were distributed. OWH looks forward to another successful collaboration with NACHC as we begin the second phase.



Hot Topics

FDA Advisory Committee Endorses Cervical Cancer Vaccine

On May 18, 2006, the FDA Center for Biologics Evaluation and Research (CBER) Vaccines and Related Products Advisory Committee unanimously endorsed the approval of Gardasil[®], a vaccine for human papilloma virus (HPV) types 6, 11, 16, and 18. The vaccine has not yet been approved by the FDA.

This vaccine is intended for the prevention of cervical cancer and genital warts, as well as vulvar and vaginal precancers related to HPV types 6, 11, 16, and 18. It is a recombinant type of vaccine made from a protein from the outer coat of each of the four types of HPV. The vaccine cannot cause an infection. The vaccine will need to be given as a sequence of three shots. It appears to be most effective in women who have not had a prior HPV infection. Even after receiving this vaccine, women will also need cervical cancer screening with pap smears and other technologies and procedures.

About 70% of cervical cancer is associated with HPV types 16 and 18. Condyloma accuminata, commonly referred as genital warts, are associated with HPV types 6 and 11. To learn more about cervical cancer visit the National Cancer Institute website at:

<http://www.cancer.gov/cancertopics/types/cervical/>

For more information on FDA Advisory Committee Meetings visit:

<http://www.fda.gov/oc/advisory/default.htm>

OWH and ORWH develop New Online Course

OWH collaborated with the NIH Office of Research on Women's Health (ORWH) to develop an online course entitled "**The Science of Sex and Gender in Human Health.**" The course provides information on: the major physiological differences between the sexes, their influence on illness and health outcomes, and their policy, research and treatment implications. This free course is self-paced and consists of six lessons. Following successful completion of the course, participants will receive Continuing Medical Education (CME) credit and/or a certificate from NIH.

The course is accessible at <http://orwh.od.nih.gov>.

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 Mental Health Association, [June 8 -10](#) – Washington, DC

American Diabetes Association, [June 9 -12](#) – Washington, DC

NAO Annual Conference, [June 10 -13](#) – Omaha, NE

LULAC, [June 26 – July 1](#) – Milwaukee, WI

La Raza, [July 8 -11](#) – Los Angeles, CA

World Cancer Conference, [July 8 -15](#) – Washington, DC

NAACP, [July 15 - 20](#) – Washington, DC

National Association of Area Agencies on Aging, [August 6 - 10](#) – Chicago

American Association of Diabetes Educators, [August 9 -12](#) – Los Angeles

American Psychological Association, [August 9 - 13](#) – New Orleans, LA

NACHC, [August 25 - 29](#) – Chicago, IL

Upcoming OWH Presentations

To learn more about OWH programs and research, join us at the following presentations:

Requirements for Contraception Use in Clinical Drug Trials submitted to FDA

Authors: Kathleen Uhl, Ellen Pinnow, Pamela Scott, Janelle Derbis, Theresa Toigo

[14th Annual Congress on Women's Health](#)

[June 3-6 @ Hilton Head Marriott Beach & Golf Resort](#)

[Hilton Head, SC](#)

Including Human Data in Drug Product Labels: A Conceptual Framework

Presenter: Kathleen Uhl

Session: Use of SSRI's and Mood Stabilizers during Pregnancy: Weighing the Risks

[46th Annual New Clinical Drug Evaluation Unit \(NCDEU\) Meeting](#)

[June 12-14 @ Boca Raton Hotel](#)

[Boca Raton, FL](#)

Session Title - Ensuring Diversity: Monitoring Sub-population Participation in Clinical Trials

FDA Policies and Sub-Populations: Katherine A. Hollinger, D.V.M., M.P.H.

Enrollment of Women in Clinical Trials: A View from the Published Literature: Pamela Scott, Ph.D.

Tracking Enrollment of Women in New Drug Applications: Ellen Pinnow, MPH

Barriers to Recruiting Women and Minority Populations: Angela Silverman BSN

[Drug Information Association – 42nd Annual Meeting](#)

[June 18-22 @ the Philadelphia Convention Center](#)



Philadelphia, PA

Reports from the Field

FDA Public Affairs Specialists help to spread the word about OWH publications and activities. The following are a sample of recent activities.

Natalie Guidr participated in the 50th Anniversary Celebration of the Alabama Public Health Association on May 3rd in Birmingham, AL.

Sandra Baxter provided OWH publications and information at the Spirituality and Women's Health Issues Conference at Antioch Baptist Church in Boutte, LA on May 3rd.

Sheryl McConnell attended the 2nd Annual Health Fair in observation of National Women's Health week and National Women's Check-Up day.

JoAnn Pittman was invited to participate in the International Conference on Women and Infectious Diseases in Atlanta.

We endeavor to provide timely information for your use. Feel free to share this with your network, members, constituents, and community.