



OWH eUpdate

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Summer 2008

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Message from the Director

Throughout the summer, OWH is continuing to promote scientific dialogue, research, and educational initiatives on vital women's health issues. I encourage you to read about a recent public workshop on trials for medical devices used in the treatment of cardiovascular disease, as well as, the results of our successful consumer outreach through the Dear Abby column and the OWH national college campaign. Also, don't forget to check out the Hot Topics articles and other links to up-to-date information on FDA actions related to the new genetic test for patients with breast cancer, new warnings for antimicrobial drugs, and the ongoing Salmonella Saintpaul outbreak.

Kathleen Uhl, MD

Assistant Commissioner for Women's Health

OWH Research

OWH Co-Sponsors Workshop on Cardiac Devices

On June 2, 2008, OWH collaborated with FDA's Center for Devices and Radiologic Health (CDRH) to hold a public workshop to gather input from industry, academia, and regulatory experts regarding the challenges related to the enrollment of women in pre and post market cardiac device trials. Meeting participants discussed strategies for improving recruitment and ensuring that adequate numbers of women are enrolled in these trials to support subgroup analyses. They also offered suggestions for ways to facilitate the inclusion of data from sex/gender-specific subgroup analyses in product labeling. The information gathered in the workshop will potentially inform FDA efforts to develop a draft guidance for industry.

This workshop is a part of OWH's continuing efforts to influence future FDA policy development related to the analysis of sex/gender differences and to promote greater understanding of the treatment of cardiovascular disease in women. Check future eUpdates for

additional information about a follow-up meeting.

Outreach Initiatives

OWH College Campaign Goes National

OWH launched its college campaign to increase college students' access to information on vital women's health issues such as HIV prevention, depression, pap tests, sunscreens, contraception, and safe medication use. Throughout the year, OWH has expanded its outreach to Women's Colleges, Historically Black Colleges and Universities, Hispanic Serving Institutions, and other universities across the country. Participating schools receive a free display stand and free publications for their health center or health education programs.

OWH materials are being distributed at 70 colleges and universities nationwide including the University of Mississippi, Spelman College, Mount Holyoke College, Tuskegee University, and the University of Alaska - Anchorage.

Colleges or universities interested in joining the campaign should complete the online [OWH collaboration form](#) and fax it to the OWH office at 301-827-0926.

Dear Abby Recognizes OWH Health and Beauty Kit

Once again, the nationally syndicated Dear Abby column has recognized OWH during National Women's Health Week. Dear Abby announced the availability of the new OWH Health and Beauty Information Kit. The kit was designed to help women make informed choices about the health and beauty products they use everyday. It included OWH consumer fact sheets on Botox, Contact Lens Care, Cosmetics, and other topics.

Dear Abby readers ordered over **122,000** English and Spanish kits through the Federal Citizen Information Center.

Hot Topics

FDA Approves New Genetic Test for Patients with Breast Cancer

On July 8, 2008, FDA announced the approval of a novel genetic test

for determining whether patients with breast cancer are good candidates for treatment with the drug Herceptin (trastuzumab). The SPOT-Light HER2 CISH kit is a test that measures the number of copies of the HER2 gene in tumor tissue. This gene regulates the growth of cancer cells. The SPOT-Light test counts the number of HER2 genes in a small sample of removed tumor.

To view the full press release, visit:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01857.html>

FDA Requests Boxed Warnings on Fluoroquinolone Antimicrobial Drugs

FDA is requiring manufacturers of fluoroquinolone antimicrobial drugs to add a Boxed Warning to the product labeling concerning the increased risk of tendinitis and tendon rupture in patients taking these drugs. Manufacturers of the drugs will also have to provide a Medication Guide to patients about possible side effects. The new Boxed Warning and Medication Guide would strengthen warning information already included in product labeling.

Fluoroquinolones are drugs approved for the treatment or prevention of certain bacterial infections. The medications involved in this action are: Cipro and generic ciprofloxacin, Cipro XR and Proquin XR (ciprofloxacin extended release), Factive (gemifloxacin), Levaquin (levofloxacin), Avelox (moxifloxacin), Noroxin (norfloxacin), and Floxin and generic ofloxacin.

The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is further increased in people older than 60, in those taking corticosteroid drugs, and in kidney, heart, and lung transplant recipients.

FDA Information for Healthcare Professionals:

<http://www.fda.gov/cder/drug/InfoSheets/HCP/fluoroquinolonesHCP.htm>

Full FDA Press Release:

<http://www.fda.gov/bbs/topics/NEWS/2008/NEW01858.html>

Proposed Changes to Pregnancy and Lactation Labeling

In May 2008, FDA announced proposed revisions to prescription drug labeling on the effects of medicines used during pregnancy and breast-feeding. Current pregnancy labeling uses five categories—A, B, C, D, and X. The proposed rule would remove the categories from the labeling of all drug products. Under FDA's proposed rule, the

labeling would contain two subsections: one on pregnancy and one on lactation. Both the pregnancy and lactation subsections would have three principal components: a risk summary, a clinical considerations section, and a data section.

The proposed rule and other information on pregnancy and lactation labeling can be viewed at:

http://www.fda.gov/cder/regulatory/pregnancy_labeling/default.htm

Comments on the proposed rule should be submitted by August 27, 2008 at:

<http://www.regulations.gov/fdmspublic/component/main?main=DocKetDetail&d=FDA-2006-N-0515>

Update Extras

Upcoming FDA Meetings

Arthritis Advisory Committee

Topic: Actemra (tocilizumab) for Rheumatoid Arthritis

Date: July 29, 2008

Time: 8:30 a.m. to 3:30 p.m.

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

Website: <http://edocket.access.gpo.gov/2008/E8-12646.htm>

Other Meetings

NIH Office of Research on Women's Health Seminar Series

Topic: Sex and Gender Research On Pain

Date: July 17, 2008

Time: 1:00 p.m. to 3:00 p.m.

Location: Lipsett Amphitheater, Building 10, NIH Campus
Bethesda, MD

Contact: Marsha Love at lovem@od.nih.gov

What a Difference an X Makes: The State of Women's Health Research

Date: October 3, 2008

Time: 9:00 a.m. - 4:30 p.m.

Location: Washington, D.C.

Website: [Agenda and Registration](#)

FDA Speakers:

Kathleen Uhl - Sex Differences and the FDA Critical Path Initiative

Katie O'Callahan - Sex Differences and Devices and Diagnostics

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 Council of La Raza, [July 12-15](#) – San Diego, CA

NAACP, [July 12-17](#) – Cincinnati, OH

National Association of Hispanic Nurses, [July 16-18](#) – Boston, MA

Delta Sigma Theta Public Service Conf., [July 24-30](#) – Orlando, FL

National Medical Association, [July 27-29](#) – Atlanta, GA

National Urban League, [July 30-Aug 2](#) – Orlando, FL

National Black Nurses Association, [August 4-8](#) – Las Vegas, NV

American Assoc. of Diabetes Educators, [August 6-9](#) – Washington, DC

American Psychological Association, [August 14-17](#) – Boston, MA

NACDS Pharmacy & Technology Conf., [August 23-27](#) – San Diego, CA

AARP, [September 4-6](#) – Washington, DC

National Association of Community Health Centers, [September 14-16](#) – New Orleans, LA

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