



OWH eUpdate

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Winter 2006

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Message from the Director

As another year comes to a close, the FDA Office of Women's Health has begun to take stock of the many initiatives we've undertaken in 2006. The OWH research and development team has strengthened its commitment to fund research that will advance the understanding and treatment of conditions in women, as well as, advance knowledge of sex and gender differences in diagnosis and treatment. The outreach program has continued to make great strides in providing national organizations, health professionals, community sites, and individual women with reliable, easy-to-read health information. Whether it be through scientific research or health education, we have reaffirmed the true mission of our office, agency, and department which is to, in some measure, improve the health of women and their families.

In the new year, look for new OWH projects and opportunities for collaboration. We welcome your input and efforts as we prepare for the future.

Kathleen Uhl, MD

Assistant Commissioner for Women's Health

OWH Research and Development

OWH & Society for Women's Health Research hold Workshop

On November 13, 2006, the FDA Office of Women's Health and the Society for Women's Health Research sponsored a one-day, public workshop to address the potential impact of sex and gender differences on research related to FDA's Critical Path Initiative. The workshop focused on the areas of biomarker development, pharmacogenomics, and bioinformatics. The aim of the workshop was to advance the understanding of the impact of sex differences on the development of FDA regulated products – drugs, medical devices, and vaccines. The ultimate goal is to improve the diagnosis, treatment, and prevention of diseases in women.

Industry representatives, researchers, HHS staff, and policy leaders were invited to hear presentations on the three research areas as well as an overview of the FDA Critical Path Initiative. Breakout sessions were also held to provide workshop attendees an opportunity to share

ideas on the direction of future OWH-sponsored research.

A recurrent theme in the workshop presentations and discussions was the need to move beyond the mere inclusion of women in clinical trials towards more "meaningful" data analysis by sex and gender that prospectively looks for safety and efficacy outcomes. The need for increased public/private partnerships to maximize data sharing was also emphasized. Collaborative efforts were encouraged between government, academia, industry and patient groups to bring about biomarker qualification and validation. Workshop attendees also called for the development and universal adoption of data standards and for modernization in the areas of in-vitro diagnostics, medical imaging, and pre-clinical safety markers.

The Society for Women's Health Research will compile and publish a report detailing all workshop findings. The report will be made available in Spring 2007.

Update on FDA/ DCRI Cardiac Safety Partnership

In September, FDA announced its partnership with the Duke Clinical Research Institute (DCRI) to form the Cardiac Safety Research Consortium. FDA, under the Critical Path Initiative, will partner with the consortium to research new methods for identifying the potential effects that drugs and devices have on the heart.

The FDA Office of Women's Health is continuing to work with the consortium on projects that will identify gaps in knowledge of cardiac biomarkers. OWH provided seed money for two research projects. The first project will review gender differences in the effects of drugs on electrocardiograms (ECGs). A second project will evaluate the four current methods of measuring ECGs and develop criteria to determine the best method to be used in a separate research study.

More information about DCRI and cardiac safety can be found at:

<http://cardiac-safety.org/>

For more information on the Critical Path Initiative, visit:

<http://www.fda.gov/oc/initiatives/criticalpath/>

The FDA press release on the FDA/ DCRI partnership can be found at:

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01467.html>

OWH Outreach

Over 3 Million OWH Publications Distributed

Throughout the year, OWH has utilized multiple partnerships and venues to distribute more than 3 million OWH publications to women across the country. Materials on a range of women's health issues including menopause, heart disease, and medication safety were disseminated. OWH women's health information kits were promoted through Parade Magazine and the "Hints from Heloise" syndicated column. Special efforts were also made to provide health information to rural women, seniors, and other underserved populations. 50,000 Spanish language kits were distributed and over 18,000 fact sheets and brochures were included in the "Savvy Senior Health Kits". The outreach team also partnered with the Federal Citizen Information Center (FCIC) to make OWH publications available to National Extension Service staff in rural areas and to librarians in areas impacted by Hurricane Katrina. In addition, the OWH outreach team developed and distributed new fact sheets on HIV, food safety, cosmetics, sleep disorders, hypertension and more.

In 2007, look for new outreach initiatives and publications including: a health fraud campaign, outreach events for college-aged women, more Spanish language materials, and redesigned fact sheets and medication charts. Also, 22 FDA Public Affairs Specialists who have been certified as "Take Time To Care" Coordinators will take part in a special partnership initiative to encourage lasting ties between the FDA and local organizations in communities around the country.

To download any of the free OWH publications, go to:
<http://www.fda.gov/womens/pubs.html>

To order free OWH materials in bulk, go to:
<http://www.pueblo.gsa.gov/>

Hot Topics

Silicone Breast Implants

The FDA recently approved the marketing of silicone gel-filled breast implants made by two companies for breast reconstruction in women of all ages and breast augmentation in women ages 22 and older. The products are manufactured by Allergan Corp. (formerly Inamed Corp.), Irvine, Calif., and Mentor Corp., Santa Barbara, Calif.

FDA approved the silicone gel-filled breast implants with a number of conditions, including requiring each company to track each implant and to conduct a large postapproval study following about 40,000

women for 10 years after receiving breast implants.

Women should consider many factors when deciding whether to get silicone gel-filled breast implants including:

- Breast implants are not lifetime devices and a woman will likely need additional surgeries on her breast at least once over her lifetime;
- Many of the changes to a woman's breast following implantation are irreversible;
- Rupture of a silicone gel-filled breast implant is most often silent, which means that usually neither the woman nor her surgeon will know that her implants have ruptured; and
- A woman will need regular screening MRI examinations over her lifetime to determine if silent rupture has occurred. The device labeling states that a woman should have her first MRI three years after her initial implant surgery and then every two years thereafter. The labeling also states that if implant rupture is noted on an MRI, the implant should be removed and replaced, if needed.

For more information, visit www.fda.gov/cdrh/breastimplants

To view the full press release, visit:

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01512.html>

FDA Approves Herceptin for Early Stage Breast Cancer

FDA expanded the approved use of Herceptin, a biological cancer drug. The new indication is for Herceptin, in combination with other cancer drugs, for the treatment of HER2 positive breast cancer after surgery (lumpectomy or mastectomy).

In 1998, FDA approved Herceptin for the treatment of metastatic breast cancer (cancer that has spread to other sites in the body). On November 17, 2006, FDA granted approval to expand the use of Herceptin to women with cancer only in the breast or lymph nodes which have been removed with surgery. Herceptin should only be prescribed for women diagnosed with HER2 positive breast cancer.

For more information, visit:

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01511.html>

New FDA Nutrition Tools For Consumers

On November 14, 2006, the Department of Health and Human Services (HHS) and the FDA Center for Food Safety and Applied Nutrition (CFSAN) announced the availability of two new learning tools to help consumers use the Nutrition Facts label to choose nutritious foods and achieve healthy weight management. The tools are **Make**

Your Calories Count, a Web-based learning program, and a **new Nutrition Facts Label brochure**.

Make Your Calories Count is designed to help consumers understand and use the Nutrition Facts label to plan a healthy diet while managing calorie intake. The program guide features an animated character called "Labelman" who expertly leads the viewer through a series of exercises on the food label. The program includes exercises to help consumers explore the relationship between serving sizes and calories, while they learn how to limit certain nutrients and get enough of others.

To access Make Your Calories Count, go to:

www.cfsan.fda.gov/labelman

The new Nutrition Facts Label brochure describes how consumers can use the Nutrition Facts label as they shop and plan meals. It includes information that will help consumers understand the relationship between calories and serving size. The brochure can also be used by health professionals to teach people how to make healthier food choices.

This brochure is available at:

<http://www.cfsan.fda.gov/~dms/lab-gen.html>

To view the full press release on this initiative, go to:

<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01508.html>

Update Extras

Upcoming OWH Presentations

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

Presenter: Kathleen Uhl

Topic: "FDA's Office of Women's Health - Mission, Role, & Programs"
December 6 @ Slone Epidemiology Center - Boston, MA

Presenter: Kathleen Uhl

Topic: "Cardiovascular Disease in Women: What FDA is Doing to Address the Gaps in Knowledge"
December 7 @ University of Massachusetts (Medicine Grand Rounds) - Worcester, MA

Presenters: Marsha Henderson and Pamela Scott

Topic: MQSA & Use of Mammography Services
January 5-7 @ Miami Chapter of Links, Inc

Guest Speaker: Kathleen Uhl

January 9 @ Thomas Jefferson University
Division of Clinical Pharmacology, Department of Medicine



Guest Speaker: Kathleen Uhl

Focus: Translating complicated women's health issues into understandable health information

January 18 @ National Consumers League - Women's Health Forum

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