FDA Office of Women's Health

OWH eUpdate

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OWH Highlights

FDA Highlights

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Message from the Director

In line with our ongoing mission to provide the public with up-to-date health information, OWH has several new projects. First, we have restructured the OWH website to provide the public with easier access to health and safety information from the FDA and elsewhere in the U.S. Department of Health and Human Services. We have added several new features including links to drug information and women's health statistics on the OWH Home Page. In addition to the website, OWH has developed 10 new consumer fact sheets on topics ranging from sleep disorders to food safety. Visit the website to browse some of the new features or to order any of the free health materials.

OWH is also proud to announce several staff changes and accomplishments. OWH is combining the current Science Program and Demographic Data Initiative into the OWH Research and Development Program, and is announcing our new Program Director, Dr. Ameeta Parekh. You can read more about Dr. Parekh in the OWH research section below. Michelle Byrne also joins the science team in a short term position contributing to the oversight and management of OWH-funded intramural and extramural research. Lastly, OWH medical officer, Dr. Joseph Kaczmarczyk was appointed to the Association of Professors of Gynecology and Obstetrics (APGO) Undergraduate Medical Education Committee (UMEC), which focuses on faculty development and innovative methods for teaching medical students.

Kathleen Uhl, MD

Assistant Commissioner for Women's Health

OWH Research

New Director of OWH Science Program

The Office of Women's Health welcomes Ameeta Parekh, Ph.D. as the new Director of the OWH Research and Development Program. We are confident that Dr. Parekh's vast experience will be an asset to OWH and to the advancement of our science program. Dr. Parekh earned her Ph.D. in Pharmaceutics (with emphasis in Pharmacokinetics and Biopharmaceutics) in 1986 from University of Maryland at Baltimore. She joined the FDA in 1986 and served as a Clinical Pharmacologist in

the areas of gastrointestinal, cardio-renal, reproductive and urology drug products. Over the 20+ years of service in CDER, she has served as a Reviewer, Section Head, Branch Chief and a Team Leader. Dr. Parekh has an extensive list of presentations and publications in the multidisciplinary areas of exposure-response, optimal dosing, biomarkers, clinical pharmacology, biopharmaceutics and product quality.

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FDA and Duke Form Partnership

On September 27th, FDA announced a partnership, under the agency's Critical Path Initiative, with the Duke Clinical Research Institute (DCRI). The partnership will work to develop a new generation of tools to identify, as early as possible, the potential effects that drugs and devices may have on the heart.

The research will be conducted using a virtual electronic database of more than 200,000 electrocardiograms (ECGs) amassed by the agency from the clinical trial data submitted as part of new drug applications. Duke and FDA researchers, together with other industry and academic consortium partners, will use the database to identify early indicators for potentially life-threatening cardiac arrhythmias (abnormal heart beats).

Research shows that women are at higher risk of arrhythmias but it is not known whether this difference in susceptibility is related to different responses to drugs. The consortium will conduct a review of gender differences in the effects of drugs on the ECG.

The Office of Women's Health provided partial funding for this unique partnership. It is hoped that this research will further our understanding of the impact of drugs on the heart health of women.

For more information on the Critical Path Initiative, visit:
http://www.fda.gov/oc/initiatives/criticalpath/

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Clinical Trials Data Standards Project

The OWH Research and Development Program is involved in the evaluation of data standards that may make it easier to track the inclusion of women in clinical trials. The Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) is a standard method for describing clinical trial data. SDTM helps to ensure that data submitted by different pharmaceutical companies provides consistent demographic and other information on participants in clinical trials.

The OWH evaluated data submitted to the FDA between October 2004

and January 2006 in the SDTM standard format to determine the feasibility of using the SDTM demographic information to track the inclusion of women in trials. Preliminary findings indicate that the standard facilitates tracking but that there may still be some gaps in the model.

It is anticipated that data submitted in the SDTM format will enable OWH and FDA reviewers to better track the inclusion of women of diverse ages and racial backgrounds and enable timelier reporting of these data. Findings from the initial OWH study were presented at the CDISC Fall Interchange Meeting held September 26-27 in Bethesda. Check the OWH website for future updates on this project.

For more information on standards development, visit the FDA Data Standards Council website:
http://www.fda.gov/oc/datacouncil/

Outreach Initiatives

New HPV Fact Sheet

OWH has a new consumer fact sheet on the human papillomavirus (HPV) now available online. The fact sheet provides basic information about HPV and the newly approved HPV vaccine. To download copies of the fact sheet, visit:
http://www.fda.gov/womens/getthefacts/hpv.html

HPV is the most common sexually-transmitted infection in the United States. At least 50% of people who have had sex will have HPV at some time in their lives. There are many types of HPV and not all of them cause health problems. HPV types 6 and 11 cause about 90% of genital warts. HPV types 16 and 18 cause about 70% of cervical cancers.

In June, FDA approved Gardasil, the first vaccine developed to prevent cervical cancer, precancerous genital lesions and genital warts due to HPV types 6, 11, 16 and 18. The vaccine is approved for use in females 9-26 years of age.

For more information, see:
http://www.fda.gov/cber/products/hpvmer060806.htm

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OWH Honors FDA Public Affairs Specialists

The Office of Women's Health honored four FDA Public Affairs Specialists whose programs have helped to advance the outreach mission of OWH. Using OWH health materials and funding, the four honorees developed innovative, model programs that were adopted by

other public affairs specialists, federal agencies, and national organizations. They also leveraged additional resources by establishing partnerships outside of FDA. To recognize these efforts, the OWH Diamond Award plaque was presented to the following individuals:

Sheryl D. McConnell – Houston, TX
For creating the "Pink Ribbon Sunday" national mammography awareness model.

Sandra S. Baxter – Nashville, TN
For implementing the Take Time To Care (TTTC) Scholars geriatric medicine safety model with the VA and AHECs.

JoAnn M. Pittman – Atlanta, GA
For establishing the Women's Health Town Hall partnership model.

Laurel Eu – West Hills, CA
For establishing a national women's health Asian language information repository.

The above recipients were presented with their plaques at the FDA Office of Regulatory Affairs Focus Training held in Rockville in July.

Hot Topics

E. coli outbreak in Fresh Spinach

FDA is continuing to work with the CDC and the state of California to investigate the ongoing E. coli outbreak. In a September 29th press release, FDA reported that there have been 187 cases of illness due to E. coli O157:H7, including 29 cases of Hemolytic Uremic Syndrome (HUS), 97 hospitalizations and one death. To date 26 states have been affected. FDA has determined that the spinach implicated in the outbreak was grown in three California counties: Monterey, San Benito, and Santa Clara.

FDA advises that spinach grown in the rest of the US can be consumed. Consumers are also advised not to purchase or consume fresh spinach if they cannot verify that it was grown in areas other than the three California counties implicated in the outbreak. Other produce grown in these counties is not implicated in this outbreak. Processed spinach (e.g., frozen and canned spinach) is also not implicated in this outbreak.

E. coli O157:H7 causes diarrhea, often with bloody stools. Although most healthy adults can recover completely within a week, some people can develop a form of kidney failure called HUS. HUS is most likely to occur in young children and the elderly. The condition can lead to serious kidney damage and even death.

To view the latest press release, go to:

http://www.fda.gov/bbs/topics/NEWS/2006/NEW01474.html

To view Outbreak Questions and Answers, go to:

http://www.cfsan.fda.gov/~dms/spinacqa.html

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Ortho Evra Label Updated

On September 20, 2006, FDA announced that the Ortho Evra label was updated with the results of two separate epidemiology studies that evaluated the risk of developing a serious blood clot in women using Ortho Evra compared to women using a different oral contraceptive.

The first study found that the risk of non-fatal venous thromboembolism (VTE) associated with the use of Ortho Evra contraceptive patch is similar to the risk associated with the use of oral contraceptive pills containing 35 micrograms of ethinyl estradiol and norgestimate. The second study found an approximate two-fold increase in the risk of medically verified VTE events in users of Ortho Evra compared to users of norgestimate-containing oral contraceptives containing 35 micrograms of estrogen. Although the results of the two studies differ, the results of the second study support FDA's concerns regarding the potential for Ortho Evra use to increase the risk of blood clots in some women.

Prescribing information for Ortho Evra continues to recommend that women with concerns or risk factors for thromboembolic disease talk with their healthcare professionals about using Ortho Evra versus other contraceptive options.

For more information, check the following:

Updated Prescribing Information - Ortho-McNeil
Q&A's - FDA
Drug Information Page - FDA

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Plan B

On August 24, 2006, FDA announced the approval of the emergency contraceptive drug Plan B as an over-the-counter (OTC) option for women aged 18 and older. Plan B will remain available by prescription-only for young women aged 17 and younger. Plan B will be available behind the counter at the pharmacy and will only be sold in pharmacies/stores staffed by a licensed pharmacist. Individuals will be required to provide ID showing proof of age in order to purchase Plan B over-the-counter.

If you want more information about Plan B from FDA:

- Visit the **FDA Plan B Information page** at: **http://www.fda.gov/cder/drug/infopage/planB**
- Call Drug Information at: 888-INFO-FDA (888-463-6332)

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:

American College of Nurse Practitioners, October 12-15 – Orlando, FL

National Hispanic Women's Conference, October 12 -13 – Phoenix, AZ

Association of Nurses in AIDS Care, October 26 -29 – Las Vegas, NV

AARP, October 26 - 28 – Anaheim, CA

American Public Health Association, November 5 - 8 – Boston, MA

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