

May 2013

www.fda.gov/womens

Message from the Director

As we celebrate National Women's Health Week, I encourage you to look to FDA for women's health resources. FDA is an active partner in helping you to understand, diagnose and treat the health problems that affect women. Whether we are approving new products, inspecting manufacturers, drafting safety alerts, conducting research, or educating consumers, the dedicated professionals at FDA strive each day to protect and promote the health of women and their families. To learn more about these efforts, check out the resources and activities highlighted in this update. Also, visit the [FDA for Women website](#) for links to other helpful tips, and safety information.

Marsha Henderson, M.C.R.P.
Director FDA Office of Women's Health

WOMEN'S HEALTH HIGHLIGHTS

Resources for Pregnant Women and New Moms

FDA has new resources to help pregnant women and new mothers make good choices about the medicines, foods and other products that are safe for them and their babies. These resources include:



- A new video, "Resources for You and Your Baby," developed in collaboration with text4baby
- An improved FDA Pregnancy page at (www.fda.gov/pregnancy)
- A new consumer update "Pregnancy: A Time for Special Caution"
- [OWH Pregnancy Exposure Registries Website Buttons](#), which you can embed on your website to connect your patients to over 50 registries
- Free medication safety fact sheets, post cards and brochures, available for [bulk order](#)

Help start a dialogue by sharing these resources with your networks.

Join a Pregnancy Twitter Chat on Thursday, May 16

OWH and text4baby will hold a Twitter chat with MotherToBaby, a service of the non-profit Organization of Teratology Information Specialists. The chat will discuss resources for moms during pregnancy and up to baby's first birthday.

To join the chat, follow [@FDAWomen](#) [@mytext4baby](#) and [@MotherToBaby](#) and search for the hash tag [#pregchat](#).

New Graphic on Mammography Myths



Knowing the truth about mammography could help save a woman's life. OWH released a new infographic to help women separate fact from fiction and better understand the procedure. The graphic highlights mammography myths, facts, and information to know prior to a mammogram.

View the [graphic](#) and share with your networks.

[Get more information on mammograms.](#)

FDA Advises Against Use of Valproate Anti-seizure Medications by Pregnant Women For Migraine Prevention



FDA is advising health care professionals and women that the anti-seizure medication valproate sodium should not be taken by pregnant women for the prevention of migraine headaches. There is evidence that these medications can cause decreased IQ scores in children whose mothers took them while pregnant. Women who are planning to become pregnant or are pregnant and taking a valproate product should talk to their health care professional right away. Women should not stop taking valproate products without talking to their health care professional.

Valproate products include: valproate sodium (Depacon), divalproex sodium (Depakote, Depakote CP, and Depakote ER), valproic acid (Depakene and Stavzor), and their generics.

[Read the Drug Safety Communication.](#)

Plan B One-Step Approved for Use by Women 15 Years and Older



On April 30, FDA approved Plan B One-Step (active ingredient levonorgestrel) for use without a prescription by women 15 years of age and older. Plan B One-Step is an emergency contraceptive intended to reduce the possibility of pregnancy following unprotected sexual intercourse. Plan B One-Step will be packaged with a product code prompting a cashier to request and verify the customer's age. A customer who cannot provide age verification will not be able to purchase the product.

[Read more about Plan B and Plan B One-Step.](#)

New FDA Patient Website

FDA recently launched the Patient Network website, which helps people find reliable information about medical products and their approvals, clinical trials and other treatment options. The website also includes links to FDA public meetings and information on how to become a FDA Patient Representative.

[Visit the new FDA Patient Network.](#)

RESEARCH

OWH Awards 2013 Research Grants

OWH recently awarded grants for 11 new women's health research projects by FDA scientists. The projects will address mechanical causes of hip implant failures in women, MRI safety testing of breast tissue expanders, among other issues. OWH funds scientific research that can be used to facilitate regulatory decision-making and advance the understanding of sex differences.

[View the full list of OWH research projects.](#)

[Read publications from previous OWH-funded projects.](#)

New Report Examines Safety of PCI

A recent article in the American Heart Journal summarizes the key safety issues related to percutaneous coronary intervention (PCI) which is used to treat narrowed arteries in the heart. Women have higher rates of bleeding than men after PCI, and female sex independently predicts bleeding and death after PCI. Leaders from OWH, other government agencies, academia, professional societies, and industry met to examine approaches for improving the overall safety of PCI. The meetings called

TransRadial Education and Therapeutics (TREAT) resulted in the SAFE-PCI for Women trial which will compare the efficacy and feasibility of two approaches to PCI in women.

[Read more about the SAFE-PCI for Women Trial.](#)

Article Citation: Hess CN et al., TransRadial Education And Therapeutics (TREAT): Shifting the balance of safety and efficacy of antithrombotic agents in percutaneous coronary intervention: A report from the Cardiac Safety Research Consortium. Am Heart J. 2013 Mar; 165(3):344-353

FDA Advisory Committee Meeting

Joint Meeting of the Endocrinologic and Metabolic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee

June 5-6, 2013 – FDA White Oak Campus

On both days, the committees will discuss the results of an independent readjudication of the Rosiglitazone Evaluated for Cardiovascular Outcomes and Regulation of Glycemia in Diabetes (RECORD) trial. Rosiglitazone (AVANDIA) is used as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

[View the full meeting announcement and materials.](#)

FDA Public Meeting

Generic Drug User Fee Amendments of 2012/ Regulatory Science Initiatives

June 21, 2013 – FDA White Oak Campus

FDA will be holding a public meeting to provide an overview of the current regulatory science initiatives for generic drugs and to solicit public input on research priorities in this area. FDA will take the information it obtains from the public meeting into account in developing the 2014 Regulatory Science Plan.

[View the meeting announcement.](#)

Exhibits and Presentations

Check out an OWH exhibit booth or presentation at one of these conferences to learn more about OWH programs, research, and free educational resources.

American Academy of Physician Assistants, May 28-29 – Washington, DC

American College Health Association, May 28-Jun 1 – Boston, MA

YWCA, Jun 5-8 – Washington, DC

American Academy of Nurse Practitioners, Jun 20-22 – Las Vegas, NV

American Library Association, Jun 28-Jul 1 – Chicago, IL

American Association of Colleges of Pharmacy, Jul 13-17 – Chicago, IL

National Council of La Raza, Jul 20-23 – New Orleans, LA

National Black Nurses Association, Aug 1-3 – New Orleans, LA

Please share this update with your network, members, constituents, and community

FDA Office of Women's Health
10903 New Hampshire Avenue
WO32 - Room 2333
Silver Spring, MD 20993*0002
301-796-9440