



*...Protecting & Advancing the Health of Women*

## UPDATE

May/June 2005

### **Dear Abby Features FDA OWH Take Time To Care Information Series**

*Dear Abby:*

*Your readers have a history of responding enthusiastically to the good advice you share with them. Because of that, I'm writing on behalf of the Food and Drug Administration's Office of Women's Health and the Federal Citizen Information Center to offer our new, free Women's Health Information Kit. It contains some of Uncle Sam's best advice on more than a dozen health topics that concern today's women.*

*All of these materials are part of the **Take Time to Care** information series. Between caring for their families and staying busy at work, women are always on the go. That is why it's more important than ever for women to "take time to care" about their own health. Whether they're managing their medications, looking for ways to minimize their risk of heart attack or learning about menopause -- they'll find some great advice in our Women's Health Information Kit.*

*Thanks, Abby, for always providing timely, practical and good advice to your readers. And please ask them to place their orders now, because supplies are limited.*

**Marsha Henderson**  
**Assistant Commissioner for Women's Health (Acting)**  
**Food and Drug Administration**

I'm delighted to spread the word. Readers, as many of you know, the information in these special kits for women has been compiled by the government at taxpayer expense. That's why they're offered at no cost to you -- not even postage. I have reviewed the kit, and it contains a gold mine of handy-dandy information on topics that include heart disease (the leading killer of women in the United States), mammography, Pap smears, menopause, depression, strokes -- and more.

There are three ways to order this TTTC Women's Health Information Kit. Order online at <http://www.pueblo.gsa.gov>. Send your name and address to Women's Health Information kit, Pueblo, Colo. 81009. Or call toll-free 888-878-3256 weekdays 8 a.m. to 8 p.m. and ask for the Women's Health Information Kit. If you're interested, don't wait. Do it today.

*Dear Abby is written by Abigail Van Buren, also known as Jeanne Phillips, and was founded by her mother, Pauline Phillips. Write Dear Abby at [www.DearAbby.com](http://www.DearAbby.com) or P.O. Box 69440, Los Angeles, Calif. 90069.*

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During the first two weeks of the offer, FCIC's Pueblo received an overwhelming **164,789** consumer requests for the Women's Health Information Kit. Thousands of requests for the materials continue to pour in daily.

### **Pregnant Women and Bioterrorism**

In 2002, OWH and the Center for Drug Evaluation and Research jointly funded a study to collect safety information on pregnant women exposed to medicines that would be used to treat infections caused by agents of bioterrorism. The study, conducted at Vanderbilt University by William Cooper, was recently completed. Using claims data in the Tennessee Medicaid database, Dr. Cooper was able to show that exposure to ciprofloxacin, amoxicillin, azithromycin or doxycycline did not increase the risk of birth defects in the infants. Women who might need these anti-infective medicines during pregnancy should be reassured that these medicines will not harm the fetus.

### **Demographic Information and Data Repository DIDR**

The DIDR are a set of data repositories containing labeling, reviews, study data and protocols that will allow reviewers and researchers to query and build reports so they may conduct more informed assessments and better manage the risks of products for all sub-populations. The DIDR will also allow OWH to track participation in clinical trials, monitor gender analysis in reviews and conduct research on women's health issues. This data will be analyzed and used to develop policy and standards for data collection and analysis, clinical trial design, and the dissemination of information regarding the risks associated with use of medical products.

OWH is developing Review Templates to enable storage and reporting on components of reviews. In May the proof of concept for a Review Template was tested and programming modifications are being made in June/July.

### **American Diabetes Association Diabetes Expo**

JoAnn Pittman, the Atlanta District Public Affairs Specialist collaborated with Kroger School of Cooking and Kroger Pharmacy at the Expo, held in Atlanta, GA. The event was a trade show and interactive health fair. FDA presented four exhibits including OWH, CFSAN, CDER, and MedWatch. Pittman and Kroger chef and pharmacists interacted with participants and discussed FDA outreach programs including Take Time To Care...Use Medicines Wisely, Calories Count, Fight BAC!, and Be An Active Member of Your Health Care Team. A serving of OWH Pineapple Salsa Recipe was a hit. More than 1800 visited the combined booths.

### **FDA First Centennial Planning Meeting**

The FDA Southeast Centennial Team and FDA History Office held the First Centennial Planning Meeting with its stakeholders at the FDA Atlanta Complex. The purpose of the meeting was to offer a unique opportunity for FDA and other stakeholders to broaden public awareness of FDA's responsibilities and to increase the Agency's ability to carry out its mission. More than 40 participated in an interactive dialogue. Attendees represented

government, industry, associations, health professionals, academia, and corporate businesses. The Centennial Celebration will kick-off in January 2006.

### **The Role of the Pharmacist in Diabetes Health Care**

Florida District Public Affairs Specialist Faye Bronner presented "The Role of the Pharmacist in Diabetes Health Care" at a Pharmacy Council Workshop. The event was sponsored by the Pharmacists Planning Service, Inc. (PPSI) and was held at the American Pharmacy Association (APhA) annual meeting. Bronner was one of six speakers on the diabetes program and she encouraged pharmacist, physicians and student pharmacists to visit FDA's website on diabetes and to utilize FDA's Medwatch Reporting Program.

### **Promotores Trained in Texas**

OWH funded a Train-the-Trainer Course on Chronic Disease Prevention for health promoters. About 60 health promoters and observers representing diverse community based organizations, federal, city, and county municipalities attended the two-day event. The keynote speaker was Dr. Mary Luna-Hollen, Director of the Promotores Program at the University of Texas Health Science Center School of Public Health. Promotores learned about diabetes, cardiovascular disease, cancer, and menopause hormone therapy.

### **Conferences**

American Academy of Nurse Practitioners Conference, June 19-21, 2005. Fort Lauderdale, [www.aanp.org](http://www.aanp.org)  
Drug Information Association, June 26-30, 2005. Washington, DC [www.diahome.org](http://www.diahome.org)  
LULAC National Convention, June 27-July 2, 2005. Little Rock, AR. [www.lulac.org/events](http://www.lulac.org/events)  
National Association of Area Agencies on Aging, July 9-13, 2005. Bellevue, WA. [www.n4a.org](http://www.n4a.org)  
NAACP 96th Annual Convention, July 9-12, 2005. Milwaukee, WI. [www.naacp.org/convention](http://www.naacp.org/convention)  
National Council of La Raza Conference, July 16-19, 2005. Philadelphia, PA.  
[www.nclr.org/selecion/events/conference](http://www.nclr.org/selecion/events/conference)  
National Association of Hispanic Nurses, July 20-22, 2005. Orlando, FL.  
Federally Employed Women, July 19-21, 2005. Reno, NV. [www.few.org](http://www.few.org)

### **Recalls / Safety Alerts**

**Able Laboratories** of Cranbury, NJ, is conducting a nationwide recall of all of its manufactured drugs (mostly generic prescription drugs, including drugs containing acetaminophen) because of serious concerns that they were not produced according to quality assurance standards. Able Laboratories has ceased all current production. Consumers with questions may contact Able Laboratories at 1-800-982-2253.

**McNeil Consumer & Specialty Pharmaceuticals** is voluntarily recalling all lots and all flavors of Children's **TYLENOL®** Meltaways 80 mg packaged in bottles and blisters, Children's **TYLENOL®** SoftChews 80mg packaged in blisters, and Junior **TYLENOL®** Meltaways 160mg packaged in blisters. The blister package design, as well as the information on the blister package and on the blister and bottle cartons may be confusing and could lead to improper dosing, including over-dosing.

For a list of all recalls and alerts in the past 60 days, please visit  
<http://www.fda.gov/opacom/7alerts.html>.

### **Approvals**

FDA approved a manufacturing supplement for the **Today Sponge** (nonoxynol 9), an already approved OTC contraceptive product. This approved manufacturing supplement allowed the Today Sponge to re-enter the U.S. market for the first time since 1994.

**Rithron-XR Coronary Stent System** consists of a stent and a stent delivery catheter. The stent, an expandable, slotted, stainless steel tube, is mounted over a deflated balloon attached to the end of a long, thin, flexible tube (*stent delivery catheter*). The stent has gold markers that help the surgeon place it in an artery. The stent and markers are completely coated with silicon carbide. The stent is permanently implanted within the coronary artery, acting as a support (scaffold) for the newly opened section of vessel.

### **FDA Advisory Committee Meetings**

#### **Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee - CDRH**

Topic: The FDA Critical Path Initiative and a fetal heart-monitoring device.

Date: June 23, 2005

Location: Holiday Inn, Gaithersburg, MD

Advisory Committee Meeting Information:

<http://www.fda.gov/oc/advisory/accalendar/2005/cdrh12524d062305.html>

Advisory Committee Telephone Information Line: 1-800-741-8138, code 3014512524.

FDA Advisory Committees

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

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