

Office of Women's Health, Food and Drug Administration: Future Directions for Women's Health

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The Office of Women's Health serves as an advocate for women's health throughout the Food and Drug Administration (FDA). Through programs and policies, the Office supports research in gender-related issues in the regulation and use of drugs, devices, biologics, and foods; initiates outreach and disseminates health information to women; provides leadership in increasing the number of women and appropriate data analysis in all phases of clinical trials; and promotes women's health in FDA actions. This article summarizes current activities and future directions in women's health at the FDA. (*JAMWA*. 2001;56:197-198)

The Food and Drug Administration's (FDA) Office of Women's Health (OWH) has been dedicated to fulfilling the FDA's mission to protect and preserve the public health and to help women lead healthier and longer lives since its creation in 1994. On April 18, 2001, the FDA/OWH hosted a "Women's Health Dialogue," the purpose of which was to solicit input from leaders of the scientific, health, and women's communities; to encourage dialogue and obtain insights into 3 of the most important issues facing the FDA (women in clinical trials, product safety, and consumer education/outreach); and to learn how the FDA/OWH can collaborate with outside groups. Statistical analysis of clinical trials, direct consumer advertising, improving the process for identifying adverse reactions, labeling products used during pregnancy and lactation, improving mechanisms for outreach and

education, and creating new ideas for collaboration between the FDA and other organizations and institutions were discussed at the meeting. As a result of the Women's Health Dialogue, the FDA/OWH will continue many of its current programs and will focus on the following issues in the future.

Research and Regulation. The FDA/OWH Science Program continues to provide leadership in research directed at regulatory issues in women's health; it addresses gaps in current knowledge, encouraging new directions in scientific research and setting new standards of excellence in women's health. The Science Program has funded more than 100 projects and awarded more than \$10 million in support of scientific research on women's health. This research has provided access to the latest developments in science and has helped the FDA set practical standards in drug and device testing, develop regulatory tools for product testing, and provide information that has improved policies and decisions concerning women's health. These research projects have involved a range of scientific disciplines and identified gender-related issues in the regulation and use of drugs, devices, dietary supplements, and biologics.

Research projects completed by the FDA/OWH in 2001 have expanded our knowledge of breast implants, women's exposure to estrogens through cosmetic products, maternal risk and progression of Down Syndrome and the possibility of nutritional intervention, interactions between some dietary supplements and oral contraceptives, and statistical techniques for identifying potential serious drug interactions in women.

Medication Use During Pregnancy. This year, the FDA/OWH will support research that assesses changes in the pharmacokinetics and pharmacodynamics of medicines when prescribed to pregnant

women in their second and third trimesters, given that certain medical conditions, such as hypertension, depression, and diabetes, may require such treatment. Product labeling of medications is the FDA's primary means of communicating drug information to health care providers. Pregnant and lactating women are rarely addressed in drug research, and studies involving pregnant women must have minimal risk to mother and fetus. These studies will demonstrate that this type of research can provide important dosing information for this particular group, and the data collected may be useful for incorporation into product labels.

Demographic Database. The FDA/OWH is working to correct gender disparities in drug, device, and biologics testing and to implement clinical trial guidelines. In order to improve the knowledge base, facilitate reporting, and track gender, age, and race, the FDA/OWH plans to develop a demographics database. Current FDA regulation requires product sponsors to report and analyze the safety and effectiveness of their product(s) for gender, age, and race. The FDA and the GAO have studied the degree to which women have been included in clinical trials in recent years. We know that women have been included in large numbers in the late-phase clinical trials, but it is difficult to determine whether sex or gender differences have been evaluated. More precise and ongoing monitoring of the levels of participation of various groups in clinical studies as well as analyzing data by sex and gender have the potential to improve dosing for women and prevent a variety of adverse events.

Outreach—Take Time to Care. The FDA/OWH continues to promote important public health messages under its "Take Time to Care" campaign, the only one of its kind in the United States. In recent years it has targeted women

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with a critical message: "Use medicines wisely," which encourages women to educate themselves and their families about using medicines correctly. The "Use Medicines Wisely" brochure provides women a place to accurately record their various medications, including over-the-counter drugs and dietary supplements. This effort has reached out, in partnership with private industry and many nonprofit organizations, to 26 million individuals, and the brochure has been translated into 14 languages, including Spanish, Polish, Russian, and Japanese. The Health Care Quality Alliance (consisting of 97 major health associations) presented its prestigious "Year 2000 Pinnacle Award" to the FDA/OWH's Take Time to Care campaign.

Faith-Based Mammography Initiative.

Because of the FDA's role in ensuring mammography quality, all mammography facilities must be certified by the Agency. The FDA/OWH has worked with communities to promote mammography through "Pink Ribbon Sunday." Hundreds of churches participated in Breast Cancer Awareness Month activities in collaboration with the FDA Office of Public Affairs in three cities (Houston, Dallas, and Atlanta). "Pink Ribbon Sunday" activities in 2000 encouraged more than 100 000 women to get screened for breast cancer. For these efforts, the OWH received the American Cancer Society's Partner of Courage Award. The FDA/OWH has also developed a breast cancer "Early Detection Saves Lives" videotape that encourages community-based screening and educational activities; it will be distributed in partnership with the National Cancer Institute.

Diabetes Initiative. Our next public health promotion will be "Take Time to Care about Diabetes," to be carried out with the American Diabetes Association, the National Association of Chain Drug Stores, and many other partners. Diabetes significantly affects 1 in 12 women in the United States—about a third aren't even aware that they have it. Diabetes is the sixth leading cause of death by disease in the United States, and complications stemming from inadequate control of blood glucose levels—blindness, kidney disease, amputation, heart attack, and stroke—produce nearly \$100 billion in

medical costs annually. For women in particular, diabetes significantly increases the risk of cardiovascular disease. The FDA regulates a wide range of products that affect the health of diabetics, ranging from foods and food labeling to drugs and devices to help manage this disease. We hope that by reaching women around the nation, we will ensure that these products are used safely and will both prevent and manage this serious disease.

For more information about the FDA/OWH, visit our website at www.fda.gov/womens. 

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