



Protecting the Health of Women: How the FDA Serves Women's Health Care Needs

Some of the brightest highlights of the FDA's long history are actions to protect the **health of women**. The FDA created the Office of Women's Health (OWH) in 1994 to advocate for women and serve as a champion for women's health. Over the years, the agency has addressed the health issues of the nation's largest population group by providing scientific and policy input on issues that face women, funding research and education/outreach programs, and encouraging industry to include women in clinical trials. The FDA achieves this through consumer information, product approvals, research requirements, and support for studies.

Women's health activities have included the FDA's first package insert with **information** for consumers, issued in 1971 to explain the benefits and risks of oral contraceptives; **marketing approvals** for such landmark products as the first over-the-counter pregnancy test kit; and an effective **public health campaign** that helped reduce the incidence of toxic shock in women who use tampons to five cases and no deaths in 1997.

One of the FDA's most significant recent actions was a rule issued in 2000 enabling the agency to halt studies of new drugs to treat life-threatening diseases if those clinical trials exclude

women participants solely because they could become pregnant. After passage of the **Mammography Quality Standards Act of 1992**, the FDA announced high standards designed to ensure that all mammograms are of the highest quality and initiated regular inspections of the over 9,100 mammography facilities in the United States.

In addition, the agency has launched several innovative programs for women:

- OWH has been highly recognized for "**Take Time To Care**," an award-winning FDA grassroots campaign on **safe medication use, diabetes, and menopausal hormone therapy**. The office communicates these important health messages through brochures, fact sheets, the OWH Web site, and quarterly updates, primarily to women over 45 in underserved communities.
- The **Take Time To Care About Diabetes** campaign of 2002 addressed the looming epidemic of diabetes, a condition that affects 17 million Americans, more than half women. The diabetes campaign will be launched in 10 new cities in February 2004.
- A **menopausal hormone therapy information campaign** was launched nationwide in September 2003 in collaboration with other agencies and women's health organizations to distribute materials that women can use as

tools to gain a better understanding of the health risks and benefits of hormone therapy.

- **Preventing the spread of HIV:** The FDA requires that HIV drug labels include information on how to prevent the transmission of the disease from mother to infant.
- **The Pink Ribbon Sunday mammography initiative**, an outreach program that targets African American and Hispanic women across the country.
- **Fact sheets:** OWH developed fact sheets on a variety of topics such as menopausal hormone therapy, mammography, food safety, Botox, tattoos, and sunscreen.
- **Pregnancy labeling initiative:** The FDA developed a Pregnancy Registry Web site to encourage pregnant women to participate in these important studies.

New Products for Women

In 2002-2003, the FDA approved several important products for women, including drugs to treat metastatic breast cancer, two barrier contraceptive devices, and low dose hormonal products to treat symptoms of menopause.

For more information, contact the FDA's Office of Women's Health at (301) 827-0350 (www.fda.gov/womens) or visit the National Women's Health Information Center at www.4woman.gov.