

FDA Office of Women's Health

Protecting and Advancing Women's Health

OWH Mission

In response to public concerns about the lack of participation of women in clinical trials, the Food and Drug Administration Office of Women's Health (OWH) was established by Congressional mandate in 1994. The mission of the office is to:

- Protect and advance the health of women through policy, science, and outreach and
- Advocate for the participation of women in clinical trials and for sex, gender, and subpopulation analyses.

OWH achieves its mission by supporting scientific research and collaborating with other government agencies and national organizations to sponsor scientific and consumer outreach efforts. OWH initiatives are coordinated through two program areas: Research and Development and Outreach.

Research and Development

From 1994-2007 OWH has awarded over **\$18 million** for research projects and public workshops that:

- Look for potential sex-based differences in the safety and efficacy of FDA regulated medical products
- Promote a better understanding of health conditions that solely or disproportionately affect women.

OWH funds scientific research conducted both within the FDA and

outside the Agency. OWH-funded research has examined health topics including: diabetes, auto-immune diseases, breast cancer, reproductive health, and heart disease.

Information Technology

OWH supports initiatives to develop IT tools to help track women's participation in clinical trials and promote data standardization that will facilitate analyses of data by sex. In addition, OWH has developed web-based tools to educate consumers and researchers*.

- **Pregnancy Exposure Registry** website connects women to resources about the use of medicines during pregnancy.
- **Sex and Gender Online Course**, co-developed by the NIH Office of Research on Women's Health, educates health professionals and researchers about sex based biology and the impact of sex differences on treatment, policy, and research. (*see back page for web links)

Outreach

Recognizing the need for reliable, easy-to-read health information on FDA-regulated products, OWH created the Take Time To Care (TTTC) program. This national outreach campaign focuses on key women's health issues such as:

- Safe Medication Use
- Mammography
- Diabetes

OWH has developed fact sheets in English and Spanish and select brochures in 14 languages. OWH has also created a series of medication booklets to educate women about FDA-regulated products for the treatment of HIV, hypertension, birth control, high cholesterol, depression, menopause, and smoking.

OWH materials are distributed free-of-charge to women and their families throughout the U.S., Puerto Rico, and the U.S. Virgin Islands.

To date, more than **30 million publications** have been distributed in collaboration with other Federal agencies, national organizations, health professionals, and businesses. Utilizing creative partnerships, TTTC has provided a cost effective way to reach millions of women where they live and work.

In the coming years, OWH will continue to promote innovative research and public education projects through public/ private partnerships with academia, industry, and other institutions that serve women.

To learn more about the research and outreach activities of the FDA Office of Women's Health, visit:

www.fda.gov/womens

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Additional FDA OWH Resources

Order English Publications: www.pueblo.gsa.gov/rc/fo6owhcard.htm

Order Spanish Publications: www.pueblo.gsa.gov/rc/owhspanish.htm

Pregnancy Registry Website: www.fda.gov/womens/registries/registries.html

Sex and Gender Online Course: <http://sexandgendercourse.od.nih.gov/>

