

Protecting and Advancing Women's Health

The FDA Office of Women's Health



FDA
Office of
Women's
Health

U.S. Food and Drug Administration

10 Years and Beyond...

OWH Mission

The FDA Office of Women’s Health Mission (OWH) is to:

- Protect and advance the health of women through policy, science and outreach
- Advocate for the inclusion of women in clinical trials as well as sex/gender and subpopulation analyses



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Looking Ahead to Decade Two

OWH will build on its prior success to accomplish myriad long-term goals, which include:

- Determining where advances in thinking, policy, and regulation are necessary, and taking appropriate actions
- Promoting a more individualized approach to the approval and labeling of regulated products through research projects and studies
- Developing processes, procedures, and instruments to identify or provide signals for reviewers regarding potential adverse events in women, men, and other subpopulations
- Establishing partnerships both internally and externally to identify and respond to the information needs of consumers that result in better health outcomes
- Continuously seeking internal and external feedback about the effectiveness and priorities of OWH activities through consultation and evaluation

An Invitation: Join Us to Protect and Advance Women's Health

Dear Friends,

Though we are immensely proud, OWH has little time to celebrate its decade of accomplishments. Each day, the Office proactively sharpens its focus on the growing number of health issues affecting women, including the increasing number and severity of side effects from the use of medications, the identification of safe and effective treatments for diseases such as depression and cardiovascular disease.

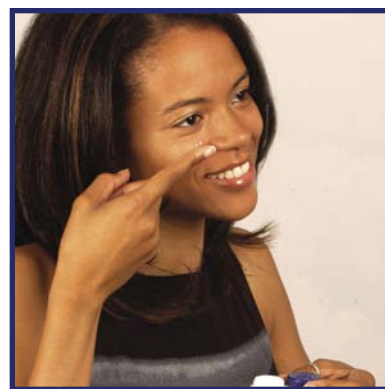
Whether in policy, science, or outreach, future OWH initiatives will certainly build on past successes. OWH will continually strengthen and expand its partnership model to include even more community and national organizations.

To this end, we'd like to take this opportunity to formally invite organizations from every sector to join us in our mission of protecting and advancing the health of women. We encourage you to engage with both our office and the Agency to tell us what we can do better. We can achieve far more together than we could alone. With combined resources, OWH and our partners can become even greater catalysts to and champions for women's health – ensuring equality and education where they are needed most.

Thank you again for your support of and interest in OWH. We look forward to working with you further in our second decade and beyond.

Sincerely,

FDA OWH Staff



Champion on Many Fronts

Throughout its first decade, the FDA OWH has:

- Supported key scientific research on behalf of women
- Provided unbiased science-based information to policy makers
- Crafted a rich legacy of innovative partnerships with the private sector, non-profits, and other government agencies

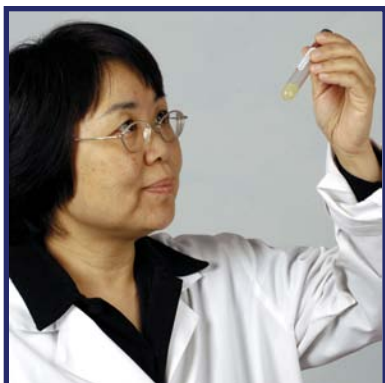
Today, OWH stands both as catalyst and champion for women's health, poised to transform past accomplishments into the foundation for a vibrant, productive future in the arenas of policy, science, outreach, and education.

This guide will highlight the remarkable past and future directions of OWH.



"Since the establishment of OWH, there has been considerable progress in addressing specific health needs of women, and an acceptance of the importance of understanding sex and gender differences in prevention and treatment. The Society for Women's Health Research looks forward to continuing our work with OWH in advancing research on conditions that disproportionately, differently or exclusively affect women."

*Phyllis Greenberger
MSW President and CEO
Society for Women's Health Research*



Opening Doors to Clinical Trials

OWH was a product of the times, born of necessity.

As recently as the 1990s, women of child-bearing potential were not eligible to participate in early stages of clinical trials. There was great fear in industry and government that women of childbearing age who participated in clinical trials would expose their fetuses to drugs that could potentially cause harmful birth defects. As a result, little was known about the effects of many drugs and medical devices on women.

“OWH brings much-needed constancy to women’s health issues. Within the agency, women’s health is always top of mind. And women are now asking more questions about their care, as they should.”

*Gloria E. Sarto, MD, Ph.D.
Co-Director
Center for Women’s Health Research
a National Center of Excellence*

In 1992, Congress sent the first clear signal to FDA that women’s health merited rigorous regulation, research, and attention. That year, Congress passed the **Mammography Quality Standards Act** to establish standardized policies and procedures at U.S. mammography facilities. In 1993, Congress passed legislation that required inclusion of women in clinical trials funded by NIH. FDA followed suit by removing a ban that kept women of reproductive potential out of early-stage clinical trials regulated by the agency. In 1993, FDA also issued its **“Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs”** to inform the pharmaceutical industry on how to evaluate data on women included in drug-development trials.

In 1994, Congress again responded to appeals to address women’s health by mandating the establishment of an Office of Women’s Health within the FDA. The office was to advise the commissioner and other FDA officials on scientific, ethical, and policy issues relating to women’s health. The Office of Women’s Health began its work by establishing a science program to address the gaps in scientific knowledge about women’s health.

FDA furthered its commitment to women’s health in 1997 by strengthening regulations on any trial for drugs used to treat life-threatening illness. Any trial that excluded women or men solely because of their reproductive potential now could be stopped. In 1998, spurred by OWH efforts, FDA also required that anyone enrolled in clinical studies be identified by gender, age, and race and that safety and effectiveness data be evaluated to identify differences based on these same categories.

These historic events set the stage for the ground-breaking scientific and outreach efforts that have marked the first decade of the FDA Office of Women’s Health.

OWH Science Program: Building a Solid Foundation

Scientific research is essential to filling knowledge gaps between laboratory bench studies and regulatory actions, such as product approval and labeling. The OWH Science Program was created to address deficits in current scientific knowledge about the effects of drugs and devices on women. The OWH Science Program achieves this goal by funding scientific research conducted both within the FDA and outside the Agency. Over the past decade, the OWH Science Program has provided approximately **\$12 million** in funding to more than 100 research projects.

Much of the remarkable headway this program achieved was through a 1999 partnership with the Department of Health and Human Services National Centers of Excellence in Women's Health. The six Centers for Excellence located at academic institutions across the country, integrate:

- Health-care services
- Research programs
- Public education
- Health-care professional training

The partnership enabled FDA to conduct timely clinical studies that otherwise might have remained outside the grasp of the agency, including recent research in the areas of:

- Counterterrorism
- Product safety
- Cardiovascular disease



"The first place we turn for a women's health issue is OWH, whether we're seeking information, sharing information, or searching for a partner. Regardless of the topic, someone in that office knows about it, cares about it, is working on it or wants to work on it. Plus, OWH is a true team player. They work as equal partners. They're not interested in getting credit. They just want to help get things done."

*Diana Zuckerman, PhD
President
National Research Center for Women & Families*

OWH Science Program: Encouraging New Directions in Research

Since its inception in 1994, OWH has funded over 100 studies, resulting in more than 75 peer-reviewed publications. The following list represents only a small sample of recent studies and publications:

Heart Disease: OWH has funded numerous projects to better understand heart disease in women and to produce the most accurate information regarding gender considerations in research and treatment.

- Tavis DR, Gallauresi BA, Lin B, et al. (2004). Risk of local adverse events following cardiac catheterization by hemostasis device use and gender. *Journal of Invasive Cardiology*, 16, 459-464.
- Benton, RE, Sale, M, Flockhart MA, et al. (2000). Greater quinidine-induced QTc interval prolongation in women. *Clinical Pharmacology & Therapeutics*, 67, 413-441.
- Rodriguez I, Kilborn MJ, Liu XK, et al. (2001). Drug-Induced QT Prolongation in Women During the Menstrual Cycle. *Journal of the American Medical Association*, 285, 1322-1326.

Gender Differences in Product Safety and Efficacy: Women experience more – and often more serious – adverse reactions to medicines than men. OWH-sponsored research seeks to play a role in improving product labeling to minimize harmful, gender-specific side effects.

- Paine MF, Shana SL, Chen M-L, et al. (2005). Do men and women differ in proximal small intestinal CYP3A or P-Glycoprotein expression? *Drug Metabolism Dispositions*, 33, 426-433.



Dioxin: An OWH-funded study investigated whether tampons contained dioxin, a possible carcinogen and teratogen. The evidence revealed that most tampons contain undetectable levels of dioxin: less than 0.2% of the allowable monthly intake.


- Archer JC, Mabry-Smith R, Shojaee S, Threet J, et al. (2005). Dioxin and furan levels found in tampons. *Journal of Women's Health*, 14, 311-315.

Dietary Supplements: Women use dietary supplements to prevent osteoporosis, lose weight, improve athletic performance and maintain mental health. A number of OWH funded studies have looked at how these supplements can be used to treat conditions such as menopause and how they interact with prescription drugs. Oral contraceptives and similar medicines now come with a warning label based on an OWH-funded study that revealed St. John's Wort could decrease their efficacy.

- Hall SD, Wang C, and Huang SM. (2003). The interaction between St John's Wort and an oral contraceptive. *Clinical Pharmacology Therapeutics*, 74, 525-535.
- Mahady GB, Parrot J, Lee C, et al. (2003). Botanical dietary supplement use in peri- and postmenopausal women. *Menopause*, 10, 65-72.

Breast Implants: An OWH-funded study of silicone gel implants reported about 55% of women with implants experienced ruptures, with about one-third of them requiring corrective surgery. Based in part on these concerns, new guidance was published strengthening requirements for approval.

- Brown SL, Middleton MS, Berg WA, et al. (2000). Prevalence of rupture of silicone gel breast implants revealed on MR imaging in a population of women in Birmingham, Alabama. *American Journal of Roentgenology*, 175, 1057-1064.



Medicines in Pregnancy: Empowering the medical community to give pregnant women safe, effective drug treatments is an important role of FDA. In 2002, OWH's medications and Pregnancy Research Design Group supported this mission by designing and funding groundbreaking studies on the use of medication during pregnancy. OWH continues to work with FDA's Centers to monitor and evaluate ongoing research projects that collect medicine dosing, efficacy, and safety information for numerous subpopulations of the general public, including pregnant women.

- Cooper, W. Assessment of Maternal Effects & Infant Outcomes Using Large Automated Healthcare Data Systems in Women Exposed to Prescription Medications During Pregnancy. Final report submitted to the Office of Women's Health May, 2005

Visualization tools for studying gender differences/Data mining techniques: Women have more drug-related adverse events than men. FDA/OWH has funded a range of projects to better understand the influence of sex and gender on drug-associated adverse events. One project developed an automated screening and alert system based on data-mining methodology.

- Szarfman, A, Machado SG, O'Neill RT. (2002). Use of screening algorithms and computer systems to efficiently signal higher-than-expected combinations of drugs and events in the US FDA's spontaneous reports database. *Drug Safety*, 25, 381-392.



At the Forefront of Studies for Pregnant Women

Which medicines are safe to take during pregnancy? OWH helps the medical community and expectant mothers answer this question through its online directory of pregnancy registries.

A pregnancy registry is a surveillance study that gathers information from women who take various medicines during pregnancy for conditions ranging from asthma to cancer. OWH developed its master directory of pregnancy registries to encourage pregnant women who are taking medications to participate in these important studies. The Pregnancy Registries section of OWH's website also contains a database of resources for women who want to learn more about taking medicines while they are pregnant.

Demographic Information & Data Repository Managing Information with Amazing Efficiency

The FDA Office of Women's Health is creating a powerful new resource that will ensure sub-population health issues – including women's health – receive the attention they need in the medical review process.

The Demographic Information and Data Repository (DIDR) is a direct response to a 2002 Congressional mandate calling for an "agency-wide database focused on women's health activities." DIDR will house information, data and software to support a fully electronic review environment that enables highly efficient processing, archiving and analysis of data – with an end focus on product safety and efficacy. FDA will use DIDR to review clinical studies, enhance product labeling, identify gaps, and coordinate data collection.

Because OWH has evaluated data gathering and reporting practices in all Centers of the FDA, we are able to formulate information-gathering practices that are consistent and flexible enough to work across the entire agency, so gender and other minority differences can be captured and reported more efficiently.

Informed by Research

Dr. Tara Rusoff of Palm Beach Gardens, Florida, was in the final trimester of her first pregnancy when she read something that alarmed her. Her pregnancy guide warned about the use of beauty products that contained retinyl palmitate, or Vitamin A. Too much of this ingredient, the book advised, could lead to birth defects.

"This really worried me," recalls Rusoff, "because the beauty salon sold me a face cream that had Vitamin A. I had been using that product for months." The beautician had told her the cream was safe. An experienced researcher, Dr. Rusoff immediately looked online to learn more. The little information she found only added to her confusion. Then she discovered the website for OWH.

FDA was in the midst of sponsoring a study on the effect of retinyl palmitate on fetuses. "I knew I would get reliable information from FDA," she said. An e-mail from Dr. Rusoff expressing her concerns was forwarded to Dr. Margaret Miller, the OWH Science Program Director.

"I was impressed by how quickly I got a return phone call, and that a doctor was calling me personally," said Dr. Rusoff. Dr. Miller explained that research showed no evidence that the product retinyl palmitate was absorbed when applied to the skin. Therefore, the product was not a threat to her baby. "That information really made me feel much better," said Dr. Rusoff, who is now the mother of a healthy baby girl.

Mis Medicinas

Esta es una publicación de la Oficina para la Salud de la Mujer (OWH) de la Administración de Alimentos y Medicamentos de los Estados Unidos (FDA), la Asociación Nacional de Cadenas Farmacéuticas (NACDS) y la Asociación Americana de la Diabetes (ADA). Agradecemos a todas las organizaciones que hicieron posible la reproducción y distribución de este folleto.

Tómese el tiempo para cuidarse de... LA DIABETES

Para obtener más información llame o visite:
 1-800-3-2-2373
www.fda.gov/womens
www.diabetes.org
www.nacds.org



Dulce de manzana
 Para la torta
 1 taza de harina común
 1/2 cucharadita de nuez moscada molida
 1/2 cucharadita de canela molida

Nutrition Facts/Datos De Nutrición		
Servicio por porción: 1/8 taza (16 cucharaditas)		
Cantidad por porción		
Calorías 428		
Colesterol 156mg		
Sodio 21g		
Grasas 21g		
Carbohidratos 21g		
Fibra 21g		
Proteínas 21g		
Vitamina A 2%		
Vitamina C 2%		
Calcio 2%		
Hierro 2%		
*Porcentaje Daily Value basado en una dieta de referencia de 2,000 calorías por día. Los valores diarios pueden variar ligeramente de los valores de las etiquetas de los productos.		
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Grasas Totales	21g	42%
Grasas Saturadas	10g	20%
Grasas Trans	0g	0%
Grasas Monoinsaturadas	11g	22%
Grasas Poliinsaturadas	11g	22%
Carbohidratos Totales	21g	42%
Fibra Alimentaria	21g	42%
Proteínas	21g	42%
Cholesterol	156mg	31%
Sodio	21g	42%
Vitamina A	2%	4%
Vitamina C	2%	4%
Calcio	2%	4%
Hierro	2%	4%

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Sodio	21g	42%
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Vitamina C	10%	20%
Calcio	10%	20%
Hierro	10%	20%

OWH Outreach: Providing Essential Information

Data indicate that between family, work, and community responsibilities, women are often so busy taking care of others that they overlook their own health needs. Recognizing the need to provide busy women with trustworthy, easy-to-read health information, OWH launched the **“Take Time to Care”** (TTTC) outreach initiative in 1998. Over the years, TTTC has become a multi-faceted campaign that focuses on the dissemination of health education materials through outreach activities and collaborative partnerships.

OWH has also developed dozens of fact sheets and publications on topics including:

- Heart Disease
- Stroke
- Lasik Eye Surgery
- Mammography
- Food Safety
- Contraception
- Depression
- HIV
- Osteoporosis
- Tattoos
- Botox
- Menopause and Hormones

Since 1999, OWH has reached over **26 million** consumers with its literature. OWH publications also are distributed through Internal Revenue Service and Congressional mailings. In 2005, OWH materials received the highest response of any mailing to Congress. An article in the nationally syndicated advice column **Dear Abby** promoting the Women’s Health Education Kit sparked an overwhelming number of consumer requests for more than **two million** publications.

Women are often so busy taking care of others that they overlook their own health needs.

Take Time to Care: Use Medicines Wisely

Up to half of all the people who use medicines don't do so as directed. In 1999, OWH initiated the **"Use Medicines Wisely"** campaign to educate women on proper medicine usage. The centerpiece of the initiative was the "My Medicines" brochure developed by OWH to help consumers track their medication usage. During the initial three-year campaign, **six million** "My Medicines" brochures were distributed at over **20,000** community pharmacies through the support of the National Association of Chain Drug Stores (NACDS) – a partner in the campaign. An independent assessment demonstrated that consumers gave the "My Medicines" brochure a 98.6% approval rating. Public officials in cities across the U.S. promoted the "Use Medicines Wisely" message. OWH also partnered with community groups to translate "My Medicines" into 14 languages, including Spanish, Cantonese, Russian, and Hmong.

Take Time to Care About Diabetes

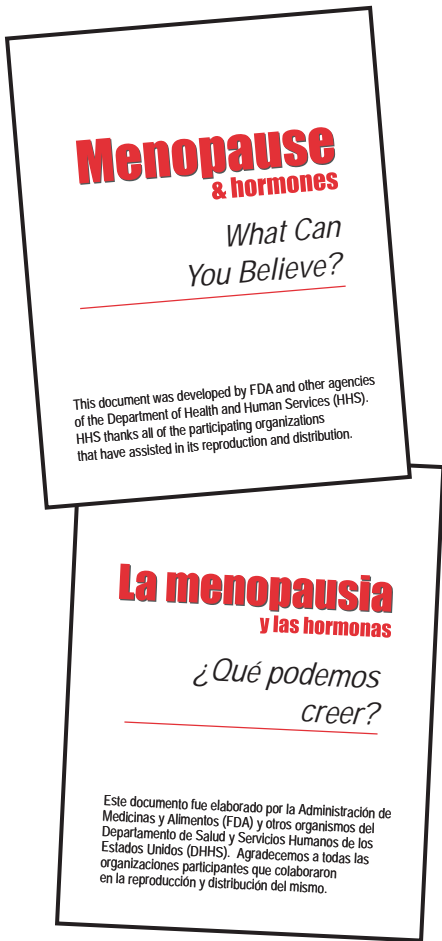
Diabetes currently affects more than 21 million Americans, more than half of them women. Taking aim at this epidemic, OWH partnered again with NACDS and the American Diabetes Association on the "Take Time to Care about Diabetes" initiative. OWH created a disease-specific educational website – the first of its kind at the FDA – to support the dissemination of diabetes-related health information to consumers. In addition, diabetes educational materials were printed in English, Spanish, and 10 Asian languages, and received national media attention.

The Ultimate Impact: Life-Saving Information

When 66-year-old Coral Thomas suffered a heart attack in the summer of 2002, she did not even realize what was happening to her. "There was no history of heart problems in my family. I was more prepared for something like a stroke," she remembers. An active volunteer, the Clarksville, Tennessee, resident was working at her local public library when she began to feel uncomfortable, as though gas was building up in her throat. When her symptoms worsened, colleagues rushed her to the hospital.

Coral took daily medicine for high blood pressure and for a few other conditions. Fortunately, she had recently picked up from her doctor's office the OWH **"My Medicines"** brochure, developed by Outreach Program Director Marsha Henderson. Coral knew how important it was to keep a careful record of her medications with her at all times, and that list was in her purse when she suffered her heart attack. That careful planning may have saved her life. "The heart doctor at the hospital told me this was the smartest thing I could have done," she recalls. After reading her list, **the doctor changed his treatment plan.** He told her he wished that each and every patient would carry such a list – it helps caregivers know the best way to proceed with treatment.

After her recovery, Coral remembered her doctor's words. She ordered dozens more "My Medicines" brochures from OWH and distributed them to her friends. "It's just the best thing to have," says Coral. "Women should carry one in their purses and keep a spare in their cars. Believe me, it can save your life."



“OWH calls attention to women’s health issues far beyond childbirth. They have information that’s easy to access and easy to understand. They also know how to get things done. They helped us pull together an unprecedented statewide alliance of cancer groups to launch a mammography initiative.”

Zora Brown
 Founder and President
 Breast Cancer Resource Committee, Inc.

Menopause and Hormones

OWH has been at the forefront of efforts to educate the nation’s women about the risks and benefits associated with the use of hormone therapy for symptoms of menopause. OWH collaborated with other federal agencies and women’s health organizations to develop science-based information materials for English- and Spanish-language audiences. The menopause campaign has included print, radio, and Internet advertisements as well as community outreach activities. To date, menopause materials have reached over 15.1 million women across the United States.

Having Faith in Pink Ribbon Sunday

FDA regulates all mammography facilities in the United States. OWH seized the opportunity to help save lives by launching its faith-based “Pink Ribbon Sunday: Quality Mammography Saves Lives” initiative. Historically, African-American and Hispanic women are less likely to get routine mammography screenings. OWH created the “Pink Ribbon Sunday” guide for use by leaders in minority churches. This guide has been distributed to over 1,600 churches and continues to be used by congregations to develop their own initiatives to promote mammography screening and other breast-health awareness activities.



*“Pink Ribbon Sunday:
 Quality Mammography
 Saves Lives”*

FREE - Information Available From FDA Office of Women's Health

- To download copies of OWH materials, please visit: <http://www.fda.gov/womens/pubs.html>
- Call 1-888-878-3256 to order FREE copies of printed materials, while supplies last.
- To learn more about research funded by OWH, visit <http://www.fda.gov/womens/science.html>
- For more information on pregnancy registries, go to <http://www.fda.gov/womens/registries/default.htm>
- To learn more about DIDR, the Demographic Information and Data Repository, visit: <http://www.fda.gov/womens/didr/default.htm>
- For more information about the Food and Drug Administration, go to <http://www.fda.gov>

“OWH is the model example of how to assemble the components of a consumer public education effort. They do the research to find out what people want to know, and they pay attention to every important detail, from reading level to cultural sensitivity.”

*William M. Ellis, RPh, MS,
Executive Director/CEO
American Pharmacists Association (APhA) Foundation*

Powered by Partnership

Over the years, OWH has developed a network of powerful partnerships to maximize both the resources and reach of its “Take Time to Care” initiatives. OWH first collaborated with women’s organizations and other stakeholder groups and later with business and industry leaders.

TTTC partners have advised OWH on campaign development, printed and distributed materials, and contributed translation services. Partners also lent their expertise to local radio and television call-in shows, question-and-answer sessions, community health assessments, and program evaluation efforts.

OWH educates through its partner relationships as well. Approximately 400 partner organizations receive e-mail updates of FDA activities through quarterly communications and periodic alerts.

The OWH partnership model of leveraging assets is now used across the FDA and the U.S. Department of Health and Human Services.

FDA OWH Recognition

"FDA's Office of Women's Health serves as a clear voice, empowering millions of consumers by providing reliable health information."

- from GSA's Consumer Choice Award, given to OWH in 2004

2005

- **Leveraging/Collaboration Award: OWH Cardiovascular Disease Initiative**, for funding extramural research investigating sex differences in cardiovascular disease and the FDA products used to treat it
- **Commissioner's Special Citation, presented to the "Fitness Challenge to FDA" Working group**, for designing a 100-day program to encourage employees to stay fit through walking

2004

- **GSA Consumer's Choice Award**, for a decade of extraordinary service as a clear voice, empowering millions of consumers by providing reliable health information
- **Clear Science Communication Award, 10th Annual FDA Science Forum**, for the poster "Studies in Pregnant Women: Yes You Can!"
- **Commissioner's Award of Excellence, DIDR Congressional Report Working Group**, for demonstrating outstanding collaboration to prepare reports to Congress
- **Commissioner's Special Citation, Menopause and Hormones Campaign Working Group**

- **Commissioner's Special Recognition Award, Take Time to Care Fact Sheet Team**, for the creation of a new consumer information series of fact sheets about FDA-regulated products for women and their families

2003

- **National/Regional Coalition Award, Take Time to Care Public Awareness Campaign**, by CDC/ASTDHPPHE for successful collaboration and an innovative approach to increase awareness of diabetes in our nation
- **DHHS Secretary's Award for Distinguished Service, Take Time to Care Diabetes Team**, for outstanding leadership in creating a model DHHS-wide public/private sector partnership reaching millions of Americans with prevention tools to "Take Time to Care About Diabetes"
- **Clear Science Communication Award, 9th Annual FDA Science Forum**, for the poster "Studies in Pregnant Women: Pharmacokinetics/Pharmacodynamics and Fetal Safety"
- **Commissioner's Award of Excellence, Agency-wide Race and Ethnicity Guidance Working Group**, for the development of guidance recommending standards for the collection of race and ethnicity in clinical trials

2002

- **Group Recognition Award, Medications and Pregnancy Research Design Group**, for designing and funding groundbreaking studies investigating the pharmacokinetics and pharmacodynamics of antihypertensive medication use in pregnancy
- **Group Recognition Award, OWH Dialogue Workgroup**, for exceptional performance in creating and holding the Women's Health Dialogue

2001

- **Group Recognition Award, OWH Scientific Review Panel on Dietary Supplements**, for establishing a collaborative grants program with the DHHS Public Health Service Office of Women's Health Centers of Excellence

- **Award for Excellence in Community Partnership Development**, in honor of outstanding contributions in the field of women's health by the National Association for Women's Health

2000

- **Pinnacle Award, Take Time to Care Campaign**, for contributions to medication-use quality by the American Pharmaceutical Association and Health Care Quality Alliance (representing 97 national health organizations)
- **OBGYN.net "Hot Find Award"**, for redesign of the OWH website

1999

- **DHHS Secretary's Award for Distinguished Service, Women's Health: Take Time to Care Team**, for creating a national network to reach millions of women with the message "Use Medicines Wisely"

1998

- **Community Service Award, Breast Cancer Awareness**, for creating a unique partnership with local churches and Howard University, reaching over 600,000 people (particularly African Americans) with the message "Early detection saves lives"
- **Group Recognition Award, OWH Take Time to Care National Design Team**, for establishing a national network to reach millions of women with the message "Use Medicines Wisely"

“During the Take Time to Care campaigns, I was impressed by OWH’s ability to stimulate grassroots involvement among hard-to-reach segments of the population, which can be more challenging to work with. The Take Time to Care About Diabetes program saved lives for people who went through screenings. A considerable number of people screened were unaware of their elevated blood pressure and glucose levels. They needed immediate medical attention. You can’t say much more about effectiveness than that.”

*Phil Schneider, President
National Association of Chain Drug Stores (NACDS) Foundation*

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