

Briefing Summary
FDA Office of Women's Health
Twenty Years of Protecting and Advancing the Health of Women
September 18, 2014

On September 18, Women's Policy, Inc. (WPI) sponsored a briefing in cooperation with Reps. Jaime Herrera Beutler (R-WA) and Donna F. Edwards (D-MD), Co-Chairs of the Congressional Caucus for Women's Issues (the Women's Caucus); Reps. Kristi Noem (R-SD) and Doris Matsui (D-CA), Vice-Chairs of the Women's Caucus; and Reps. Jaime Herrera Beutler and Lois Capps (D-CA), Co-Chairs, Women's Health Task Force, the Women's Caucus. The fifth in a women's health series supported by the Robert Wood Johnson Foundation, the briefing celebrated the FDA Office of Women's Health on twenty years of protecting and advancing the health of women. Approximately 80 guests attended the briefing, including Members of Congress, senior congressional staff, representatives of federal agencies, corporate leaders, and health and women's advocacy organizations.

Cindy Hall, president of WPI, thanked the leadership of the Women's Caucus and Women's Health Task Force and the Robert Wood Johnson Foundation for supporting the briefing and for its work to improve the health and health care of all Americans. She recognized Dr. David Colby, Vice-President of Policy, and Kim Elliott, Director of Policy Outreach, at the Robert Wood Johnson Foundation, and thanked them for their support. Ms. Hall noted that WPI is a nonpartisan, nonprofit public policy organization whose mission is to help ensure that the most informed decisions on key women's domestic and global issues are made by policymakers. WPI works closely with the members and staff of the bipartisan Congressional Caucus for Women's Issues.

Cindy Hall said that WPI was privileged to host such an esteemed panel featuring Dr. Margaret Hamburg, the Commissioner of Food and Drugs, and Marsha Henderson, Assistant Commissioner for Women's Health at the FDA Office of Women's Health. She recognized and thanked all four of the former directors of the FDA Office of Women's Health: the founding director, Dr. Ruth Merkatz; Audrey Sheppard; Dr. Susan Wood; and Dr. Kathleen Uhl. She also acknowledged several other leaders in the field of women's health: Dr. Nancy Lee, Deputy Assistant Secretary of Health-Women's Health and Director of the Office on Women's Health at the Department of Health and Human Services; Dr. Janine Clayton, Director of the Office of Research on Women's Health (ORWH) and Associate Director for Research on Women's Health at the National Institutes of Health (NIH); Dr. Vivian Pinn, the first and longtime director of the Office of Research on Women's Health and Associate Director for Research on Women's Health at NIH; Ambassador and former Representative Connie Morella (R-MD), one of the founding board members of WPI and a former Co-Chair of the Women's Caucus; and Lorraine Cole, Director of the Office of Minority and Women Inclusion at the Department of Treasury, who also chairs WPI's board of directors.

Ms. Hall recognized Phyllis Greenberger, President and CEO for the Society for Women's Health Research, and Martha Nolan, Vice President for Public Policy at the Society, for their longtime work on behalf of the Office. She thanked all of the women's health advocates in attendance for working so hard over the years to ensure continued funding for the FDA Office of Women's Health.

Twenty Years of Protecting and Advancing the Health of Women

Cindy Hall noted that, over the years, the FDA Office of Women's Health has had many bipartisan congressional champions, particularly among the women Senators and Members. Twenty years ago, former Senator Olympia Snowe (R-ME, then serving in the House) introduced the Women's Health Office Act, legislation to permanently establish the FDA Office of Women's Health and four other federal agency offices, and continued to sponsor the bill with Senator Barbara Mikulski (D-MD) until it finally became law as a provision of the Affordable Care Act in 2010.

Senator Snowe and former Congresswoman Patricia Schroeder (D-CO) co-chaired the Women's Caucus in the House for over a decade, and led the congressional effort with Senator Mikulski, then-Health Subcommittee Chair Henry Waxman (D-CA), Congresswoman Connie Morella (R-MD) and many others, beginning in the mid-1980's, to ensure that federally-funded research included women. When Sen. Snowe was elected to the Senate, Rep. Morella became the House sponsor of the Women's Health Office Act. Congresswoman Carolyn Maloney (D-NY) later became the House sponsor after Rep. Morella left Congress, joined by then Congresswoman Deborah Pryce (R-OH).

Over the past twenty years, other women Senators and Members have worked hard to ensure adequate funding for the Office, including Senator Mikulski, chair of the Senate Appropriations Committee, and Congresswomen Rosa DeLauro (D-CT), who both chaired and served as Ranking Member of the Appropriations Subcommittee with jurisdiction over FDA, up until the last Congress, and Nita Lowey (D-NY), Ranking Member of the House Appropriations Committee.

Speakers

Cindy Hall introduced Dr. Margaret Hamburg, Commissioner of Food and Drugs. As the top official at the Food and Drug Administration, Dr. Hamburg is committed to strengthening programs and policies that enable the Agency to carry out its fundamental mission—to protect and promote the public health. Only the second woman ever to serve as Commissioner, Dr. Hamburg has provided leadership for the implementation of three groundbreaking measures: the Family Smoking Prevention and Tobacco Control Act, a 2009 law that gives FDA the authority to regulate the manufacture, distribution, and marketing of tobacco products; the Food Safety Modernization Act of 2011, which changed the focus of food safety measures from responding to food-borne outbreaks of illness to preventing them; and a thorough review of the system for the evaluation and approval of medical devices.

Dr. Hamburg thanked Cindy Hall and members of the Women's Caucus with special appreciation to Senator Olympia Snowe and Congresswoman Connie Morella for their hard work in the early years to establish the FDA Office of Women's Health. She also recognized the Robert Wood Johnson Foundation for sponsoring this event and all the important work undertaken by the Foundation to prevent disease and advance health, including women's health. Dr. Hamburg noted that so much has changed in the twenty years since Congress established the Office of Women's Health (OWH) with two goals: 1) to protect and advance the health of women through policy, science, and outreach, and 2) to advocate for the participation of women in clinical trials.

The results of that early vision for OWH have been quite impressive. Since its inception, the Office has supported research to identify and understand sex differences in the safety and efficacy of FDA-regulated products, providing more than \$30 million to support over 300 research projects on cardiovascular disease, cancer, sexually transmitted diseases, and other important health topics. Although this represents a significant commitment from FDA, much more research could be done with additional resources. Dr. Hamburg emphasized the importance of including critical subgroups and subgroup population analyses in health research.

OWH has done an important job in expanding communications and outreach to millions of women on FDA safety and other health issues, building partnerships with other government agencies, retailers, industry and national organizations, patient and consumer groups, and other important stakeholders. Over the years, women's groups and other organizations have expressed appropriate concerns about the underrepresentation of women in clinical trials to support marketing applications for medical products. FDA continues to make progress in providing guidance to industry about including women and evaluating sex differences in clinical research.

Last year, Congress asked FDA to look at the inclusion trends in clinical trials for demographic subgroups, including women, and to examine whether safety and effectiveness data were adequately available for these subgroups. The good news is that women make up, on average, about half of the participants in clinical studies that support drug applications. Because the numbers are not as robust for the inclusion of women in research on medical devices, targeted and aggressive efforts are needed to increase women's representation in that arena. The Center for Devices and Radiological Health recently released a guidance document to help industry enhance the inclusion of women and the evaluation of sex-specific differences in studies focused on medical devices. More work also is needed with industry and the academic biomedical research community to ensure adequate inclusion of women in studies supporting drug development.

The FDA just issued an important and dynamic action plan on Section 907 of the FDA Safety and Innovation Act. This action plan, which will be updated as more is learned and additional areas for action are identified, outlines a number of key recommendations to promote appropriate representation of demographic subgroups, including women, in clinical research. OWH is taking responsibility for a number of items in this plan, starting with a campaign to promote the inclusion of women in clinical trials.

The breadth of FDA's impact on women's health is evident in the work that is done across the agency, often coordinated by OWH. For example, in 1996, FDA approved a product for use in Pap smears that revolutionized the detection of cervical cancer and ten years later, FDA approved the first vaccine for the actual prevention of cervical cancer. FDA also approved advances in breast imaging, including 3-D Breast Tomosynthesis and automated screening ultrasounds, as well as the development of the latest generation of cardiac synchronization therapy devices, which have special benefits for women with heart failure. FDA has pressed to ensure that important reproductive health products are available to women. Agency scientists are working to ensure the safety and accuracy of claims on cosmetics, including wrinkle creams, and have developed a method for assessing the levels of lead in lipstick and other cosmetic products.

Shortly before OWH was established, the Mammography Quality Standards Act was enacted. As FDA began to exercise oversight in this area, the agency realized the importance of the act in ensuring women's access to quality mammography imaging. Although the quality in mammography screening was quite variable at the time, radiation doses have since decreased while the quality of mammograms has improved.

Together, these FDA achievements have expanded our understanding of women's health to include a broad set of health issues that affect women across the lifespan. Some of the greatest burdens of disease and disability lie in domains that are not traditionally thought of as women's health issues, such as heart disease, diabetes, and osteoporosis, as well as other chronic conditions and infectious diseases that cause a significant burden for women. As a science-based health agency, FDA has expanded scientific knowledge about critical health conditions and developed new tools to assess the safety, efficacy, and performance of products that have made a difference and helped to better deliver health care to women and all Americans.

Dr. Hamburg applauded the leadership provided by the Office of Women's Health. The Office has been at the center of efforts to ensure that the right science is undertaken and that FDA has a strong voice in communicating important health information to women and all Americans. She said that it was very meaningful to be a part of this celebration, to recognize those who have made a difference over time, and to reaffirm the commitment of OWH going forward. Dr. Hamburg closed with a quote from Malala Yousafzai, the brave young Pakistani woman who stood up to the Taliban, "I raise up my voice not so I can shout but so that those without a voice can be heard. We cannot succeed when half of us are held back."

Dr. Hamburg then recognized and turned the podium over to Marsha Henderson, Assistant Commissioner for Women's Health at the FDA Office of Women's Health. In this capacity, Ms. Henderson directs and coordinates FDA policy and research. She has been a leading advocate of greater inclusion of women in clinical trials, and is the first recipient of the Dr. Estelle Ramey Award for Women's Health Leadership in recognition of her exemplary leadership in women's health and a commitment to the study of the impact of sex differences on health.

Ms. Henderson thanked Women's Policy, Inc. and the Robert Wood Johnson Foundation for sponsoring this celebration of OWH, and Dr. Hamburg for her leadership and unwavering support for women's health issues. She also recognized her predecessors—the founding director, Dr. Ruth Merkatz; Audrey Sheppard; Dr. Susan Wood; and Dr. Kathleen Uhl—who collectively charted a course for OWH with great intelligence, compassion, and sometimes courage—leading the way to new regulation and guidance for industry and creating a national network of partnerships to reach women with critical health information. Ms. Henderson noted that her predecessors led OWH through many controversies including those surrounding HIV, toxic shock, hormone replacement, folic acid, breast implants, HPV, and contraception. She also recognized Dr. Stephen Ostroff, her supervisor and chief scientist for the FDA, as well as her incredible staff.

Ms. Henderson stated that OWH has become a force for analysis and regulatory science, professional training, and consumer education in women's health—and noted that in twenty years, OWH has demonstrated the importance of including women in clinical trials and evolved to meet new challenges. She said that OWH has made an important difference in a number of ways at FDA and in the lives of women. The Office has elevated the importance of research and the analysis of sex differences in women's health conditions throughout the lifespan. OWH-funded research has directly led to important advances in women's health and specific FDA regulatory guidance regarding product withdrawals, labeling changes, and improved standards in such areas as research around breast implant ruptures.

Since 1994, OWH has funded over 300 intramural research projects with some extramural research collaborations. Cardiovascular disease, the number one cause of mortality for women and men, has been the top research priority for OWH. The Office funded early investigations of drug-induced heart arrhythmia that could be fatal, especially in women, which led to changes in FDA policy and the withdrawal of specific drugs from the market. Now OWH is funding research to learn more about QT prolongation that hopefully will lead to new guidance. In addition to research on women and heart disease, OWH has funded research projects and workshops in more than twenty therapeutic areas covering women's health across the lifespan and resulting in 290 scientific journal publications.

In 2015, OWH will release a research roadmap setting the future direction for all OWH research funding. This document will include a review of the science supported by OWH to date, an analysis of the gaps in this science, and a multi-year strategy for future investments, using internal and external partners to reach important goals. OWH plans to reach out to many organizations to solicit their input on this research roadmap, and will work with international partners to build a better understanding of sex differences in health research.

OWH also will continue to educate women and health professionals about the health conditions that affect women. *Take Time to Care* is an important OWH consumer education initiative designed to reach women where they live and work with crucial health information. Starting with a safe medication campaign, *Take Time to Care* has touched more than 50 million people with information in twenty languages about more than 40 important health topics. The Office has pursued a multi-pronged approach that has included working with Las Vegas casinos, creating a Spanish language soap opera, appearing in a yearly feature in the Dr. Abby column, helping to launch FDA's movement into social media, and communicating with women at community health centers, libraries, and women's clubs. Additional people have been reached through organizations that have reprinted and

distributed OWH materials. To illustrate the breadth of partnerships developed by OWH, a video was shown highlighting collaborations with the Society for Women's Health Research, the National Association of Chain Drug Stores Foundation, the American Association of Colleges of Pharmacy, and the National Healthy Mothers, Healthy Babies Coalition.

Ms. Henderson reminded participants that the primary reason for the establishment of the FDA Office of Women's Health was to elevate the number of women included in clinical trials, and the analysis of sex differences in the data. Great progress has been made in the last several decades so that women now make up 53.4 percent of clinical trial participants in studies designed to secure new drug approvals at FDA. Although this was not always the case, FDA now expects the reviewers and pharmaceutical companies to routinely analyze sex differences in their new drug applications, and when findings suggest that there are sex-based safety issues, FDA works with companies to include this information in labels.

Ms. Henderson emphasized that a limitation in these studies is that the participants included in clinical trials are typically white. Because women from varied backgrounds can experience unique health conditions and respond differently to drugs and medical devices, clinical trials must be expanded to include diverse populations of women from different race, ethnic, age, disability, and comorbidity backgrounds. Partnering with the National Institutes of Health, OWH plans to launch an initiative to promote greater diversity of women in clinical trials. These agencies will create a network to elevate the importance of including diverse groups of women in clinical trials, and to educate patients and health professionals about the importance of clinical trials. Before launching this new initiative, OWH will engage a broad cross-section of groups with special expertise and insights, as well as women from across the country. Mr. Henderson closed by stating, "We know that we can do better, we already have."

Former and current members of Congress

Cindy Hall introduced Connie Morella who is currently Ambassador-in-Residence at American University. She formerly served as US Ambassador to the Organization for Economic Cooperation and Development in Paris from 2003-2007 and represented Maryland's 8th Congressional district in Congress from 1987 to 2003. During her tenure in Congress, Rep. Morella was a strong supporter of women's health and a champion for the FDA Office of Women's Health. The Congresswoman also served as Co-Chair of the Women's Caucus in the 104th Congress.

Ambassador Morella thanked Cindy Hall and the Robert Wood Johnson Foundation for supporting this important briefing, and expressed delight to be a part of this important celebration of the 20th year of the OWH at FDA. Rep. Morella said that she is proud of what OWH has achieved to date and impressed with its roadmap for the future. Looking back, Rep. Morella noted that early on, when FDA and NIH were in her district, a commission was established to look at women's involvement in the health professions and research supported by NIH. The Government Accountability Office (GAO) issued a report giving NIH a flunking grade with respect to including women in clinical trials and supporting women scientists. This led to meetings with the Director of NIH where a bicameral and bipartisan group of women—Senator Barbara Mikulski (D-MD), Congresswoman Patricia Schroder (D-CO), and Congresswoman Connie Morella (R-MD)—pressed the issue of expanding the number of women scientists and the participation of women in clinical trials at NIH. (Senator Olympia Snowe (R-ME) was unable to attend this meeting.) In 1993, legislation was passed calling for the establishment of the Office of Research on Women's Health at NIH, and Dr. Vivian Pinn was appointed as its first director.

GAO then undertook another study showing that FDA was falling short in recruiting women for clinical trials, and that something more needed to be done. This led to the genesis of OWH at FDA in 1994. Since that time, important research has shown that cardiovascular disease, lung cancer, and

depression affect women in unique ways. Amb. Morella emphasized the importance of bipartisan support for women's health research, making the point that "every cell has a sex, and it's not Republican or Democrat." She noted that attention has recently focused on how women are disproportionately affected by Alzheimer's disease, even when women's longer life expectancy is taken into account. Amb. Morella emphasized that more research is needed on a range of health topics affecting women, including research on a vaccine for HIV/AIDS and research on sex differences in dosage for different drugs. She urged OWH to keep up its great work, and applauded the leadership provided by Dr. Hamburg and Ms. Henderson. Ambassador Morella closed with a comment about the importance of collaboration from the book, *All I Really Need to Know, I Learned in Kindergarten*: "When you go out into the world, watch out for traffic, hold hands, and stick together."

Congresswoman Donna Edwards (D-MD), who serves as Co-Chair of the Women's Caucus, was the final speaker. Rep. Edwards is currently serving her 4th term in Congress, representing the 4th district of Maryland, and is Ranking Member of the Science, Space, and Technology Subcommittee on Space and serves on the Transportation and Infrastructure Committee. She is co-founder and former Executive Director of the National Network to End Domestic Violence, and has always been a strong women's health advocate.

Congresswoman Edwards recognized Amb. Connie Morella for her important leadership to improve women's health, and WPI for its leadership and guidance. She expressed her appreciation for this special opportunity to celebrate twenty years of the tremendous work undertaken by OWH. Rep. Edwards emphasized that those who have spent many years in the advocacy community appreciate the unique attention paid by OWH to women's health concerns. The question for Members of Congress is this: *Can we keep up this journey so that support for women's health research really becomes a part of the way we think of our overall health?*

Over the past twenty years, OWH has made sure that advancing the health and well-being of women is a top priority for the federal government. Rep. Edwards recognized the strong leadership provided by Dr. Hamburg and the important work undertaken by Marsha Henderson. FDA has put the focus on understanding the health conditions that are unique to women and to ensuring that research initiatives and regulatory decision-making accurately reflect the needs of constituents. As an African-American woman, Rep. Edwards knows that it is critically important to understand the health dynamics that are particular to women from a race or an ethnicity. She stressed that it is imperative that women's health concerns be addressed in an integrated way that factors in the concerns of diverse communities and increases public awareness and engagement.

Rep. Edwards underscored that the Women's Caucus is committed in a bipartisan way to maintaining an equal footing for women to ensure that their health needs are met. She emphasized that a stronger commitment must be made to ensure adequate funding for medical research; to understand health differences between men and women, and among underrepresented populations; and to minimize the health risks encountered by young women and girls. Rep. Edwards said that many women are underserved in our health care system; not having access to mammograms, for example, can result in loss of life. OWH understands the value of investing in women's health in all our communities, cutting across generations. Thanking everyone for participating in this important briefing, Rep. Edwards closed with this reminder, "We can't just be the caregivers and nurturers; every once in a while, we require the caregiving and nurturing ourselves."

The webcast of the briefing can be viewed by clicking this [link](#).

