March 20, 2013 Submitted for the Record

Before the House Appropriations Committee, Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies

SWHR is pleased to submit written testimony to urge the Committee to prioritize and provide an increase to the **FY 2014 budget authority (BA) appropriations (non-user fees) for the Food and Drug Administration (FDA) of $2.76 billion, a $250 million increase over FY 2013 and allocate $7 million for the Office of Women's Health for FY 2014**. These recommended allocations will allow the agency to implement critical improvements in infrastructure, address resource shortages, and support needed investment into the Office of Women's Health (OWH), the focal point on women's health within the Agency.

While SWHR recognizes the need for responsible discretionary spending, proper and sustained funding of the FDA must remain a public priority. Fiscal Year 2014 appropriations must reflect the FDA's increased responsibilities and workload mandated by Congress. Americans rely on the FDA every day, from promoting wellness and meeting health care needs to ensuring the safety of our food and keeping drugs safe and effective. In total, 25% of every consumer dollar spent in America is on products regulated by the FDA.

The FDA must meet the demands of American consumers and patients that expects proactive scientific and research leadership while assuring the safety and effectiveness of food, drugs and cosmetics. These demands result in the majority of FDA's budget, over 80%, already being allocated toward the salary of its scientists and staff; thus making needed investments in

infrastructure, technology, and human collateral all but impossible. Each year brings new congressional mandates in addition to the increased globalization and complexity of our scientific research world. Thess challenges cannot be met without additional resources. Appropriate budgetary allocation must be provided to allow FDA to react acting in a proactive manner against emerging or known threats to food and drug security.

SWHR recognizes that Congress is focused on reducing our federal deficit; however, proper and sustained investment in the FDA is important to the health, economic and national security of the nation. As the thought leader in research on biological differences in disease SWHR is dedicated to transforming women's health through science, advocacy, and education and believes that sustained funding for the FDA and its regulatory responsibilities is absolutely essential if the U.S. is to meet the needs of its citizens, especially women.

In the past two decades, scientists have uncovered significant biological and physiological differences between men and women. Physiological differences and hormonal fluctuations may play a role in the rate of drug absorption, distribution, metabolism, elimination as well as ultimate effectiveness of response in females as opposed to males. However, information about the ways drugs may differ in various populations (e.g., women may require a lower dosage because of different rates of absorption or metabolism) are often unexplored, or female enrollment in studies is too low to adequately power statistically significant results. America's biomedical development process, while continuing to advance in delivering new and better targeted medications to combat disease, does not routinely analyze and reported sex differences. Though, recently the FDA did take the appropriate steps to inform the public about important sex

differences finding in the dosing for sleep medications, however, **FDA's requirement that the data acquired during research of a new drug or device's safety and efficacy be reported and analyzed as a function of sex is not universally enforced.**

Under Section 907 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) the FDA now must prepare a congressional report and publish on the FDA website on the inclusion of demographic subgroups in clinical trials and data analysis in drugs, biologic and device applications submitted to the agency. The official response to this mandate is being coordinated by the Office of Women's Health (OWH) and the Office of Minority Health (OMH) and the FDA has established a Clinical Trials Data Workgroup to compile and share inclusion data from across the FDA. SWHR believes this important report, the publication on the website and internal FDA actions will help to rapidly transform our medical knowledge.

Sex differences data discovered from clinical trials can be presented to the medical community and to patients through education, drug labeling and packaging inserts, and other forms of alerts directed to key audiences. The FDA must assure accurate, sex-specific drug and device labeling to better serve male and female patients, as well as to ensure that appropriate data analysis of post-market surveillance reporting for these differences is placed in the hands of physicians and ultimately the patient.

The FDA must have the information technology to meet the daily demands of increased scientific complexity, globalization, the American public and Congress in order to guard the safety, efficacy, and security of human drugs, biological products, and medical devices. It was

only 6 years ago in a Science Board Report review of the FDA, requested by then Commissioner von Eschenbach, that it was found that FDA's information technology (IT) systems were inefficient and incapable of handling the current demands placed on the Agency (2007). We do not want the FDA to fall behind again. Through advocacy efforts and appropriations increases, tremendous advances have been made throughout the Agency to modernize in the 6 years since that Science Board's report; however, it still remains a challenge for the Agency to access and maintain the information technology needed to meet the growing expectations from the American public and to fulfill its mission**. FDA IT systems and infrastructure must be given the dedicated resources needed from appropriated dollars and user fees to meet the complex global and scientific world in which it operates.**

FDA Office of Women's Health

OWH like the Agency that houses it, requires steady and sustained investment to remain a key resource in advancing regulatory science and reporting of sex differences. OWH's programs endeavor to ensure that sex and gender differences in the efficacy of drugs (such as metabolism rates), devices (sizes and functionality) and diagnostics are taken into consideration in reviews and approvals. OWH seeks to correct sex and gender disparities within FDA jurisdiction and monitors women's health priorities, providing both leadership and an integrated approach to problem solving across the FDA.

OWH provides women with invaluable tools for their health. Each year, OWH exhausts its budget as **its consumer pamphlets are the most requested** of any documents at the government printing facility in Colorado. More than 8 million OWH pamphlets were distributed to women

across America, including target populations such as Hispanic communities, seniors and low-income citizens on topics such as breast cancer screening, diabetes, menopause hormone therapy, and medication use during pregnancy. OWH also partnered with the Federal Citizen Information Center and Usa.gov to conduct outreach promotions to disseminate OWH consumer publications to targeted minority groups and other special populations such as college students. During National Women's Health Week May, 2012, FDA OWH collaborated with the nationally syndicated Dear Abby advice column and the Federal Citizen Information Center to distribute 1.7 million OWH publications and 35,000 publications downloads as a part of OWH's "Healthy Women Action Kit". Such important outreach will be repeated this year. Further, OWH's intramural research program funded over 21 new and 17 continuing research studies conducted by FDA scientists in 2012 and 14 out of 22 concept papers have been selected in 2013.

Women across our great nation rely on the high quality, timely information they need by OWH to make medical decisions on behalf of themselves and their families. OWH's website is regarded as a vital tool for consumers and physicians, providing free, downloadable fact sheets on over one hundred different illnesses, diseases, and health related issues for women, as well as web trainings and on line courses for medical professionals. OWH has created medication charts on several chronic diseases, listing all the medications that are prescribed and available for each disease. These are vital functions that our health care professionals and the public understand and utilize daily to make health care decision and must be maintained.