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Before the Senate 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 2015 budget authority (BA) appropriations (non-user fees) for the Food and Drug Administration (FDA) of $2.784 billion, a $223 million increase over FY 2014 and $200 million above the President's budget proposal for FDA. In addition, SWHR supports an allocation of $7 million for the FDA Office of Women's Health (OWH) for FY 2015**. These recommended allocations will allow the FDA to address resource shortages across all centers, implement critical improvements in infrastructure, and continue investment in OWH, the critical voice on women's health and women's health research within the Agency.

The FDA, as regulator of products covering more than a quarter of the US economy, should receive priority funding as its responsibilities are critical to the health and well-being of all Americans. Each year, Congress adds to FDA's ever increasing responsibilities but does not provide appropriate funds to meet those demands reasonably, straining the FDA's abilities. The FY 2015 appropriations must reflect an amount that meets the needs of the Agency demanded by Congress.

More than 47% of Americans have a chronic disease and 22% have multiple conditions. Eighty –two percent of Americans take over the counter or prescription medications and 30% take more than 5 medications. American consumers and patients expect proactive scientific and research leadership from the FDA while demanding assurance of the safety and effectiveness of their food, drugs and cosmetics. To meet this expectation, the FDA spends over 80% of its budget on salary costs in maintaining and recruiting talented and smart researchers and scientists who can keep pace with scientific innovation. Globalization and the complexity of our scientific research world have put demands on the FDA that need additional appropriated resources. Unfortunately, due to congressional funding levels and COLA requirements, FDA annually is challenged and must frequently postpone needed investments in infrastructure, technology, and human collateral due to budget constraints.

While SWHR recognizes that Congress is focused on reducing our federal deficit, appropriate budgetary allocation must be provided to allow FDA to react in a proactive manner for new scientific innovation and against emerging or known threats to food and drug security. As the thought leader in research on biological sex 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, and maintain its gold standard.

In the past two decades, scientists have uncovered significant biological and physiological differences between men and women. Traditionally, the term women's health represented a women's reproductive capability because science and medicine believed that women and men were biologically the same. We now know this is not the case.

Biological and physiological differences and hormonal fluctuations 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. Information about the ways drugs may differ in various populations, however, is often unexplored. As was noted by the FDA in a recent The 60 Minutes segment (Feb. 9, 2014), women may require a lower dosage of some drugs because of different rates of absorption or metabolism (Ambien). The 60 Minutes highlighted the importance of sex and gender differences research and the need to examine sex from the earliest phases of research, starting in basic science.

The FDA has a critical role in human subject research in assuring female recruitment and retention is set at appropriate levels and not too low to provide statistically significant results in research. American women should have the confidence that drugs, devices and biologics that have been approved for use in both men and women have been appropriately analyzed for sex differences and the finding publicly reported to a meaningful way for usage by both health care providers and patients. America's biomedical development process, while continuing to deliver new and better targeted medications to combat disease, does not routinely analyze and reported sex differences. **FDA's must enforce its own requirement that the data acquired during research of a new drug or device's safety and efficacy be reported and analyzed by sex.**

Pursuant to Section 907 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), the FDA released a report on August 20, 2013 on the inclusion of demographic subgroups in clinical trials and data analysis in drugs, biologic and device applications submitted to the agency. The report, both the summary and the data, coordinated and written by OWH and the Office of Minority Health (OMH) demonstrated that while demographic data was submitted significant gaps still existed with respect to representation, reporting and analysis of the data for women, minorities and the elderly. The FDA is currently designing an action plan, with short and long term recommendations and implementation strategies to help FDA transform its approach toward important demographic data. SWHR believes this will result in greater knowledge of reactions to drugs and medical treatments by sex, age, race and ethnicity, and further, greater understanding of devices and their usage or limitations in women.

SWHR has long advocated that sex differences data discovered from clinical trials be presented in a meaningful way to the medical community and to patients through education, drug labels and packaging inserts, and other forms of alerts directed to key audiences. Through more accurate, sex-specific drug and device information and labeling the FDA will better serve male and female patients, and will ensure that appropriate sex specific data analysis of post-market surveillance is placed in the hands of physicians and ultimately the patient in a timely manner.

SWHR believes that Congress must commit to continued investment in FDA's informational technology to assure continued advancement of data standardization, collection and analysis. In our ever evolving digital world, the FDA needs to keep pace with scientific discoveries and must

have the tools to do so. **Congress must dedicate resources from appropriated dollars and user fees to FDA's IT systems and infrastructure to meet this demand.**

FDA Office of Women's Health (OWH)

OWH must have a steady and sustained investment to remain the key resource in advancing regulatory science in women's health and reporting of sex differences. OWH's programs 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 and monitors women's health priorities, through leadership and active engagement with the FDA Centers.

American women rely on the tools OWH provides to them to help with their health care decisions. Each year, OWH **consumer pamphlets are the most requested** of any documents at the government printing facility in Colorado, with more than 8 million 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.

In partnership with the National Institutes of Health Office of Research on Women's Health, OWH created a website for an on-line sex and gender course to provide additional educational tools for medical practice and scientific innovation. Most recently, a third course in the series will be going on-line. All courses offer free continuing education credits for physicians, pharmacists and nurses. In addition, OWH developed a toolkit and curriculum in a joint effort with the American Association of Colleges of Pharmacy. It is a Women's Health curriculum elective given for credit by the schools and also contains a tool kit so teachers can incorporate elements into other courses. Further, OWH is a strategic partner in the planning of the research roadmap for FDA, helping to align the research and structural needs for the agency for the next three years.

Women across our great nation rely on OWH's high quality, timely information to make medical decisions on behalf of themselves and their families. OWH's highly regarded website is 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. 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.