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

The Society for Women's Health Research (SWHR®) urges the Committee to prioritize and provide an increase to the **FY 2017 budget authority (BA) appropriations (non-user fees) for the Food and Drug Administration (FDA) of $2.85 billion, an increase of $120 million over FY2016. Our request is based on FDA's current workload, planned programs, and emerging public health priorities. Additionally, SWHR supports an allocation of $10 million for the FDA Office of Women's Health (OWH) for FY 2017**.

For over 25 years, SWHR has been widely considered a thought-leader in promoting research on biological differences in disease and we are dedicated to transforming women's health through science, advocacy, and education.

Our organization has long advocated that drug and device scientific advancements should demonstrate adequate subpopulation testing prior to approval by FDA. The Agency has made great improvements in improving the completeness and quality of demographic subgroup data collection, reporting and analysis of subgroup data collection, identifying barriers to subgroup enrollment in clinical trials, employing strategies to encourage greater participation, and making demographic subgroup data more available to the public. However, in order for greater improvement, Congress must invest in FDA's core functions. SWHR is committed to the belief that **the FDA, as regulator of products representing approximately 20% of American consumer spending, should receive priority funding as its responsibilities are critical to the health and well-being of all Americans.**

The FDA has broad jurisdiction and is responsible for:

- Protecting public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.
- Advancing public health by helping to speed innovations that make medicines more effective, safer, and more affordable and providing accurate, science-based information needed by patients and consumers to safely use medicines and foods to maintain and improve their health.
- Regulating the manufacturing, marketing and distribution of tobacco products to protect public health and to reduce tobacco use by minors.
- Ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

Each year, Congress adds ever increasing responsibilities to the Agency (most recently food safety, sunscreen labeling, drug safety, and compounding) but fails to provide appropriate funds to meet those demands reasonably, thereby straining the FDA's abilities and forcing it to choose among competing public health priorities. This is a dangerous precedent which poorly serves the

health and safety of the America people. Many of the mandated programs that Congress has tasked the Agency with are not covered by user fees, leaving FDA in need of a larger budget authority appropriation in order to fulfill its duty. SWHR believes that sustained investment in 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 scientific transformation and medical product advancement.

SWHR is a strong supporter of stakeholder engagement with the Agency, and are active in the user fee agreement process for prescription and generic drugs, as well as medical devices and biologics. Such opportunities allow for FDA to discuss process improvements that will speed the approval of safe and effective medical products for patients and consumers. The increased emphasis on patient-focused drug development, risk/benefit analysis, and innovative clinical trial design will only further efforts to bring lifesaving treatments to market.

However, Congressionally-allocated funds are desperately needed to support FDA post-market surveillance activities, improve technical assistance to industry to reduce review times, and enhance its communications with patients and consumers. Post-market surveillance is critical to ensure that drugs and devices, when available to a wider patient population, are truly safe and effective for all populations. The American public cannot, and should not, rely on industry to conduct the bulk of these activities. **The 21st Century Cures Act, recently passed by the House, and its companion Senate Innovation's effort, focus on the need to bring medical products to the market more quickly. A large part of that process is improving clinical trials to be faster and less expensive. The biopharmaceutical and biopharmaceutical services industries, along with the FDA and other key stakeholders, have made great strides in improving the clinical trial process; however, clinical trials will never be able to give us the information that is obtained once the drug or device is approved and used in the population. This makes it more critical that FDA has a strong and robust post marketing surveillance program. While the MedWatch and similar programs do exist, they will need additional resources to ensure FDA staff and others as appropriate can quickly respond to reduce morbidity and mortality related to potential safety issues.**

Additional FDA funding will also support improved technical assistance for its industry partners by supporting staff resources to develop, review, and approve guidance. Timely release of guidance documents is critical to ensure industry partners can develop processes and submit applications with the most pertinent information for review. Such releases would also allow for increased opportunities for innovation by promptly responding to a changing drug/device development environment.

Finally, additional funding would allow FDA to enhance its communications with the public. Such funding could support building a consumer-friendly FDA interface; making it much easier for patients and consumers to navigate. Funding could also be used to continue the patient-focused drug development meetings and other workshops and listening sessions, allowing FDA to connect directly with the American public it serves.

Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data

FDA, working with industry, must ensure that clinical trials examine differences in subpopulations ensuring appropriate representation to achieve statistical significance and analysis. In 2014, FDA released its "Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data" (Action Plan), as directed by section 907 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). The Action Plan, largely developed and implemented by the OWH and the Office of Minority Health, provided an outline of long and short term actions and implementation strategies the FDA is undertaking to examine sex, race, ethnicity and age-based differences through medical research, to allow subgroup-specific data to be more widely available for use in medical practice, and to improve the participation of women, minorities and the elderly in research trials.

SWHR hopes that FDA will continue to work towards the goals outlined in that plan which will be beneficial for patients, consumers, and the healthcare community at large. The Agency has worked with stakeholders to ensure that the subgroup data is appropriately analyzed, reported and presented by FDA and sponsors in a meaningful way to patients and the medical community. However, many components of the Action Plan remain, for example, it is critical that the Agency update its *2005 Guidance for Industry on the Collection of Race/Ethnicity Data in Clinical Trials*.

As part of the Action Plan, FDA also has a critical regulatory role in human subject research. Women and minority populations have historically been underrepresented in medical research, and although women and minorities are now being enrolled in clinical trials at greater rates, much work remains to ensure that these groups are included and retained in trials at appropriate levels to provide statistically significant results. Through the Action Plan, FDA recognized the need to increase representation of these population groups in clinical trials and the need for more analyses on how medical drugs and devices in development affect women and men differently as well as racially, ethnically and by age. Women should have confidence that drugs, devices and biologics approved for patient use have been appropriately analyzed for sex differences and the finding publicly reported in a meaningful way for usage by both health care providers and patients.

SWHR has long sought the transparency of demographic subgroup data that FDA uses as the basis of its approval decision. This issue was a priority area of the Action Plan and in 2014, the Agency launched the "Drug Trial Snapshot" website to provide information about who participated in clinical studies for new molecular entities and original biologics. The Snapshot website also includes information on study design, results of efficacy and safety studies, and information on any differences in efficacy or safety that were apparent in subgroup populations.

The Snapshot website is a step in the right direction; however, we believe that the website could be improved to revolutionize the way Snapshots benefits patients. SWHR believes that Snapshots could be improved by contextualizing the data presented with all relevant information relating to the intersection of age, race, and sex to provide those using the website a thorough understanding of their benefits and risk as individual users of a certain drug or biologic. Additionally, the website is not easily found on FDA's webpage. FDA has signaled that they view the website as an iterative process, and are open to hearing stakeholder feedback on how to improve the site. **However, these efforts require the Agency to receive sustained funding and**

resources and SWHR believes that Congress must commit to continued and robust investment in FDA to provide for the advancement and increased transparency of drug development.

FDA Office of Women's Health

OWH has proven itself to be vital player in advancing women's health issues at the Agency; including the expansion of existing research projects and helping to foster new collaborations related to advancing the science of women's health. 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.

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. These pamphlets discuss topics such as breast cancer screening, diabetes, menopause hormone therapy, and medication use during pregnancy. In addition, OWH's 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. Among the most popular, OWH provides medication charts on select chronic diseases, listing all the treatment options available for each disease. **We must maintain these vital functions that health care professionals and the public understand and utilize daily to make health care decision**.

In partnership with the National Institutes of Health Office of Research on Women's Health, OWH created a website for on-line sex and gender courses to provide additional educational tools for medical practice and scientific innovation. All three courses offer free continuing education credits for physicians, pharmacists and nurses.

Last year, OWH unveiled the Women's Health Research Roadmap (Roadmap) to build on knowledge gained from previously funded research and assist OWH in coordinating future research activities with other FDA research programs and external partners. The Roadmap outlined priority areas where new or enhanced research is needed, creates strategic direction for OWH to help maximize the impact of OWH initiatives, and ultimately promote optimal health for women. It was also designated a key FDA commitment in FDA's August 2014 Action Plan.

To fully implement the Research Roadmap and continues it's important work, **SWHR requests an allocation of $10 million for the FDA Office of Women's Health (OWH) for FY 2017.** We believe these recommended budget allocations would enable the FDA to address resource shortages across its centers, but also implement critical improvements in infrastructure and support a substantial investment in the OWH, the office responsible for advancing the health of women through policy, science, and outreach and one of the leading voices in increasing the participation and analysis of women and other subpopulations in clinical trials.

In conclusion, we thank the Committee for its past support of the FDA and its centers. It is our hope that the Committee continue to invest in the Agency to help ensure a healthier future for all Americans. We look forward to continuing to work with you.