Society for Women's Health Research

May 22, 2017

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Charles Schumer
Minority Leader
United States Senate
Washington, DC 20510

The Honorable Paul Ryan
Speaker
United States House of Representatives
Washington, DC 20510

The Honorable Nancy Pelosi
Minority Leader
United States House of Representatives
Washington, DC 20510

Dear Majority Leader McConnell, Speaker Ryan, and Minority Leaders Schumer and Pelosi,

On behalf of the Society for Women's Health Research (SWHR®), I am writing to express our organization's support of the continuation of the Food and Drug Administration (FDA) user fee programs through the negotiated Prescription Drug User Fee Act (PDUFA) VI, Medical Device User Fee Act (MDUFA) IV, Biosimilar User Fee Act (BsUFA) II, and Generic Drug User Fee Act (GDUFA) II agreements. These agreements are the culmination of months of negotiations between FDA, industry, and the patient advocate community. They include many important improvements for ensuring greater consistency, certainty, and predictability of the FDA regulatory review and approval process; facilitating timely access to safe and effective medical innovations to millions of patients who need them.

We applaud the Senate Health, Education, Labor and Pensions Committee and House Energy and Commerce Committee for their leadership in advancing reauthorization legislation for pharmaceuticals, generic drugs, biosimilar medicines, and medical devices from fiscal year 2018 to fiscal year 2022 that aligns closely with the negotiated agreements. Reauthorizing the user fee agreements will guarantee sufficient scientific capacity and expertise at the FDA through essential hiring and retention of its workforce, thereby allowing the agency to carry out its public mission.

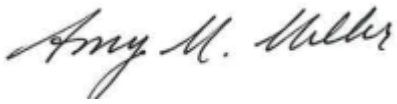
SWHR supports user fee reauthorization legislation that strengthens FDA processes and initiatives, which ultimately benefits patients. We recommend the legislation's continuation of the Patient-Focused Drug Development (PFDD) Program, which integrates a patient's perspective into the development process, and the use of data collection tools such as patient reported outcomes. SWHR also endorses the inclusion of provisions consistent with the 21st Century Cures Act that advance the development and application of 21st century regulatory science to explore the use of real world evidence and innovative clinical trial approaches. Application of innovative evidence sources and approaches have the potential to greatly improve the quality and knowledge of the risk-benefit framework during the development review and approval process.

Society for Women's Health Research

For nearly three decades, SWHR has been widely recognized as the thought leader in women's health research and the study of biological differences between women and men. Our organization has long advocated for programs and policies that will accelerate the development and availability of safe and effective treatments for women allowing them to lead longer, healthier, and more productive lives. SWHR thanks Congress for making the FDA Reauthorization Act of 2017 a legislative priority and for moving forward with its timely completion and unimpeded passage.

If you have questions, please contact Sarah Wells Kocsis, SWHR Vice President of Public Policy, at 202.496.5003 or swellskocsis@swhr.org.

Sincerely,



Amy M. Miller, PhD
President and Chief Executive Officer