Submitted electronically

September 7, 2022

The Honorable Patty Murray
Chair
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

The Honorable Frank Pallone
Chair
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

Re: Reauthorization of FDA User Fee Programs

Dear Chairwoman Murray, Chairman Pallone, Ranking Member Burr, and Ranking Member McMorris Rodgers,

I am writing to express FasterCures' support for reauthorizing the FDA's user fee programs (PDUFA, MDUFA, GDUFA, and BsUFA). With the September 30, 2022 reauthorization deadline looming, the stalled user fee legislation package could have important ramifications for the FDA's ability to hire and retain necessary staff and to fulfill its organizational mandate in reviewing and approving essential medical products in a timely manner. As with previous iterations, this user fee reauthorization presents an opportunity to make crucial improvements to enhance FDA's capabilities. It is our hope that Congress will be able to agree upon bipartisan provisions that advance the user fee reauthorization legislation with critical new authorities for FDA before the programs are scheduled to expire at the end of September.

FasterCures, a center of the Milken Institute, is driven by a singular goal: to save lives by speeding scientific advancements to all patients. With an independent voice, FasterCures works to build a system that is effective, efficient, and driven by a clear vision: collaborating with our partners to build a patient-centric system where science is accelerated, unnecessary barriers are overcome, and lifesaving and life-enhancing treatments get to those who need them as rapidly and as safely as possible.

Since their introduction, FDA's user fee programs have helped expedite the development and availability of medical products for patients, especially those with cancer or those suffering from rare diseases for whom there are few or no treatment options. Previous user fee programs have enhanced efficiency across the FDA, facilitated timely communications between the FDA and product sponsors, and instituted benchmarks for review timelines that the FDA must meet. The current iteration of user fee reauthorization includes negotiated terms that build on this history to strengthen FDA's activities.

The user fee reauthorization is also an important opportunity to implement reforms at the FDA. FasterCures is an advocate for a stronger and more effective agency, and we encourage Congress to grant the FDA the authorities needed to enhance its capacity to fulfill its mandate. A priority for FasterCures—and one we hope will be addressed in the final user fee reauthorization legislation—is diversity in clinical trials. The COVID-19 pandemic underscored the need to ensure representativeness of diverse patient populations in research and offered valuable lessons and best practices for enhancing diversity in clinical trials. We hope that final authorization legislation will continue to bolster FDA's efforts in this area.

Additionally, efforts to expedite access to lifesaving drugs, such as the accelerated approval pathway, have been under scrutiny due to recent approvals. We strongly encourage Congress to continue to improve FDA's accelerated approval pathway so that it remains a mechanism for accelerating access to treatments for patients with serious conditions. We also support other provisions that will reauthorize programs, such as the orphan products grants program, and offer exemptions from certain requirements for devices designed to treat or diagnose rare diseases.

Thank you for your continued work to strengthen our nation's regulatory infrastructure and to ensure timely access to much-needed medical products. It is our hope that, in addition to reauthorizing the user fee programs, Congress will be able to prioritize the most pressing reforms needed to proceed quickly with reauthorizing the user fee programs. We remain committed to providing ongoing support as you continue in this process.

Sincerely,

Esther Krofah
Executive Vice President of Health
Executive Director, FasterCures and Center for Public Health
Milken Institute