NATIONAL TAXPAYERS UNION

May 9, 2022

The Honorable Anna Eshoo
Chair, House Energy and Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone
Chair, House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Brett Guthrie
Ranking Member, House Energy and Commerce Subcommittee on Health
2322-A Rayburn House Office Building
Washington, D.C. 20515

The Honorable Cathy McMorris Rodgers
Ranking Member, House Committee on Energy and Commerce
2322-A Rayburn House Office Building
Washington, D.C. 20515

Dear Subcommittee Chair Eshoo, Subcommittee Ranking Member Guthrie, Chair Pallone, and Ranking Member McMorris Rodgers:

On behalf of National Taxpayers Union (NTU), the nation's oldest taxpayer advocacy organization, we write to you on the reauthorization of user fee agreements at the Food and Drug Administration (FDA). NTU is urging lawmakers in your Subcommittee and Committee, and on the Senate Health, Education, Labor, and Pensions (HELP) Committee, to expeditiously advance reauthorization of the user fee agreements in line with the commitment letters already agreed to by FDA and industry stakeholders. These user fee agreements are an ongoing testament to the effectiveness of public-private partnerships in delivering safe, effective, and even life-saving products and devices to U.S. consumers, and parochial, extraneous interests should not delay their timely and clean reauthorization.

As you well know, Congress faces a September 30 deadline to reauthorize four user fee agreements between the FDA, pharmaceutical manufacturers, and medical device manufacturers: the seventh iteration of the Prescription Drug User Fee Agreement (PDUFA VII), the fifth iteration of the Medical Device User Fee Agreement (MDUFA V), and the third iterations of the Generic Drug User Fee Agreement (GDUFA III) and the Biosimilars User Fee Agreement (BsUFA III). For years, and decades in the case of PDUFA and MDUFA, these user fee agreements have supplemented discretionary appropriations to the FDA, enabling the agency to review and approve drugs faster and more effectively than in years prior.

NTU offers few perspectives in this communication on the policies that the FDA and the industry have agreed to for PDUFA VII, MDUFA V, GDUFA III, and BsUFA III, nor do we currently have strongly-held views on the policy provisions attached to your legislation, the "Food and Drug Amendments of 2022." Our expertise in the health policy space centers on pricing, payment, and health coverage matters, not on public health or medical product approvals.

However, as a taxpayer advocacy organization, we strongly believe that taxpayers – and all American consumers – have an important stake in a timely and friction-free reauthorization of the FDA's user fee agreements. To the extent that these user fee agreements help the FDA review and approve drug and device applications more quickly and effectively, the agreements will bring more innovative and life-saving products directly to the health care system in the years ahead. Prescription drugs and medical devices that help Americans better manage their health could help them avoid more expensive interventions – such as hospital stays – that collectively burden individuals, families, and the nation's federal- and state-funded health programs.[1] Generic prescription drugs and biosimilars that create market competition for treatments can drive down costs for consumers and taxpayers, much as the Hatch-Waxman Act has been credited with greatly increasing the proportion of U.S. prescriptions written for generics over the past four decades.[2]

To that end, we reiterate our request that the FDA user fee reauthorization process proceed in a speedy, efficient, and predictable manner for the stakeholders most affected. As you know, the agreements reached by industry and the FDA were carefully negotiated and crafted over the course of months, if not years. For decades, these agreements have been a collaborative product between the public and the private sectors. While attaching narrow reforms to user fee reauthorization may occasionally be desirable – and, indeed, each reauthorization of a user fee agreement has included agency reforms already agreed to by the FDA and industry stakeholders – your reauthorization this year should avoid major changes or additions that could delay the reauthorization process or turn it into a partisan political football. The burden of proof should be on the lawmakers proposing major attachments to the user fee agreements to account for why such proposals are necessary, urgent, capable of bipartisan support, and specifically relevant to user fee reauthorization.

If you have any questions or wish to discuss NTU's stake in the FDA user fee reauthorization process further, we are at your service.

Sincerely,

Andrew Lautz
Director of Federal Policy, National Taxpayers Union

CC: Members of the House Energy and Commerce Subcommittee on Health
Members of the House Committee on Energy and Commerce
The Honorable Patty Murray, Chair, Senate Health, Education, Labor, and Pensions (HELP) Committee
The Honorable Richard Burr, Ranking Member, Senate HELP Committee
Members of the Senate Committee on Health, Education, Labor, and Pensions

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[1] The Congressional Budget Office (CBO) authored a report in 2012 that discussed the effect of prescription drug use on other medical spending in greater detail. CBO wrote, in part: "...a 1 percent increase in the number of prescriptions filled by beneficiaries would cause Medicare's spending on medical services to fall by roughly one-fifth of 1 percent." For more, see: CBO. "Offsetting Effects of Prescription Drug Use on Medicare's Spending for Medical Services." November 2012. Retrieved from: https://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf (Accessed April 29, 2022.)

[2] For more, see: Sepp, Pete. "Hatch-Waxman Drug Patent Law Meets Middle Age – and Taxpayers Can Celebrate." NTU, April 1, 2019. Retrieved from: https://www.ntu.org/publications/detail/hatch-waxman-drug-patent-law-meets-middle-age-and-taxpayers-can-celebrate