August 1, 2022

The Honorable Patty Murray
Chair
Committee on Health, Education, Labor & Pensions
United States Senate
Washington, D.C. 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor & Pensions
United States Senate
Washington, D.C. 20510

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

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

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

The XX undersigned organizations representing patients with rare diseases and other acute or chronic health conditions urge you to resume negotiations to develop a comprehensive FDA user fee package. Our organizations are deeply concerned about the impact that a delay in passage of this legislation will have on the FDA's ability to conduct the timely review of critical products that our patients need but believe there are other important policies that must be considered as part of the user feel reauthorization process and urge you to quickly develop robust, consensus legislation.

As you know, the Senate HELP Committee favorably reported the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act (S. 4348) out of Committee with a bipartisan 13-9 vote last month. In June, the U.S. House of Representatives considered and passed the Food and Drug Amendments of 2022 (H.R. 7667) with a bipartisan vote of 392-28. In addition to the provisions that would reauthorize FDA's user fee programs relating to prescription drugs, medical devices, biosimilars, and generic drugs, both the House and Senate bills contain additional provisions that would make necessary changes and improvements to the Federal Food, Drug, and Cosmetic Act that would ultimately benefit the patients our organizations represent. For example, both S. 4348 and H.R. 7667 would strengthen FDA's accelerated approval pathway to ensure that patients and their providers can continue to have confidence in the safety and effectiveness of drugs approved under the pathway. Furthermore, both S. 4348 and H.R. 7667 contain provisions to improve timely patient access to generic drugs and biosimilars.

Additionally, the House and the Senate bills each have distinct provisions that warrant cross-chamber consideration. For instance, H.R. 7667 includes provisions that would go a long way toward ensuring increased representation of diverse and underserved populations in the clinical trials supporting FDA-approved drugs and medical devices, but similar provisions are currently not in S. 4348. Conversely, S. 4348

includes provisions to improve FDA's oversight of the infant formula and medical food market to ensure continuous supplies of infant formula and medical foods are available that were not in the House-passed bill.

Our organizations strongly believe Congress should capitalize on the user fee reauthorization process to consider and enact the additional policies that would have little chance of passage as stand-alone bills, just as it has every five years since 1992. To pass a "clean" user fee package would be to walk away from an opportunity to make critical improvements in our nation's system for overseeing medical products. We urge you to immediately work together to blend your respective bills and continue Congress' longstanding tradition of passing strong, bipartisan FDA legislation to the benefit of all Americans.

For more information, please contact Heidi Ross, Vice President of Policy and Regulatory Affairs for the National Organization for Rare Disorders, at HRoss@rarediseases.org.

Thank you for your consideration,