

Congress of the United States

Washington, D.C. 20515

January 28, 2022

Delivered via E-Mail

Dr. Janet Woodcock
Acting Commissioner
U.S. Food and Drug Administration
Department of Health and Human Services

Dear Acting Commissioner Woodcock,

We write today to request an update on the timeline for transmitting the Fiscal Years 2023-2027 commitment letter for the Medical Device User Fee Amendments (MDUFA) to Congress. Current law requires the Food and Drug Administration (FDA) to transmit the commitment letters to Congress on or before January 15, 2022. To date, we have not yet received the commitment letter for MDUFA.

We received the final commitment letters reflecting an agreement between FDA and the respective industries for the prescription drug, generic drug, and biosimilar user fee programs on January 12, 2022. We are reviewing each of these commitment letters and look forward to the upcoming process to evaluate each agreement and corresponding legislation.

It is important that Congress have sufficient time to review each commitment letter and to evaluate the agreements. The FDA and medical device industry's significant delay in transmitting the MDUFA commitment letter jeopardizes our ability to thoroughly review the commitments under the letter. We respectfully request a briefing with FDA and industry representatives, no later than Wednesday, February 9, to update us on the progress made toward reaching an agreement and the expected timeline under which the parties will be able to publish a draft agreement and transmit a final commitment letter to our respective committees.

We look forward to working with you as part of the medical product user fee reauthorization process.

Thank you for your attention to this matter.

Sincerely,



Patty Murray
Chair
U.S. Senate Committee on Health, Education,
Labor and Pensions



Frank Pallone, Jr.
Chairman
U.S. House Committee on
Energy and Commerce



Richard Burr
Ranking Member
U.S. Senate Committee on Health, Education,
Labor and Pensions



Cathy McMorris Rodgers
Republican Leader
U.S. House Committee on
Energy and Commerce

CC: Scott Whitaker, President and CEO, Advanced Medical Technology Association
Mark Leahey, President and CEO, Medical Device Manufacturers Association
Patrick Hope, Executive Chairman, Medical Imaging & Technology Alliance