PERSONALIZED MEDICINE COALITION

July 7, 2022

The Honorable Charles Schumer
U.S. Senate
322 Hart Senate Office Building
Washington, DC 20515

The Honorable Mitch McConnell
U.S. Senate
317 Russell Senate Office Building
Washington, DC 20515

The Honorable Nancy Pelosi
U.S. House of Representatives
1236 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin McCarthy
U.S. House of Representatives
2468 Rayburn House Office Building
Washington, DC 20515

Re: Support for reauthorization of the U.S. Food and Drug Administration's Prescription Drug and Medical Device User Fee Programs

Dear Leader Schumer, Leader McConnell, Speaker Pelosi and Leader McCarthy:

On behalf of the Personalized Medicine Coalition (PMC), which represents more than 200 innovators, scientists, patients, providers, and payers to promote the understanding and adoption of personalized medicine concepts, services, and products for the benefit of patients and the health care system, I am writing to express our support for a swift conference on H.R.7667, the *Food and Drug Amendments of 2022*,[i] and S. 4348, the *Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022*,[ii] and passage of final legislation reauthorizing the collection of prescription drug and medical device user fees by August. Many of PMC's members will continue to present their own views on H.R. 7667 and S. 4348. PMC's support for continued action now is offered to avoid any lapse in funding for FDA employees and the activities they carry out so that the general concept of personalized medicine can advance.

We commend the bipartisan efforts thus far on H.R. 7667 and S. 4348. By reauthorizing the collection of prescription drug and medical device user fees at the FDA, H.R. 7667 and S. 4348 would provide critical funding to support the agency's drug, device, and biologic review programs. As you know, these user fee agreements must be reauthorized by Congress every five years, and the current authorization expires on October 1, 2022. Without continued funding, many FDA activities that support personalized medicine would stall.

Personalized medicine is an evolving field in which physicians use diagnostic tests to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Having a well-resourced, focused, and flexible FDA is essential to achieving PMC's mission of bringing forward the best treatment and prevention strategies for each patient. User fees supplement the agency's budget authority from Congress and ensure FDA has the resources and workforce needed to complete the timely evaluation of personalized medicine products while upholding the agency's high standards for ensuring safety and effectiveness.

PMC's analyses have shown that initiatives advanced by FDA in recent years have fostered many notable regulatory milestones. Personalized medicines have grown to account for more than a quarter of all new drugs approved by FDA each of the past seven years, including new personalized treatments helping transform care for molecularly selected subsets of patients with cancer as well as rare, common, and infectious diseases.[iii] In 2021, FDA also recognized the first tumor mutation database, which will allow test developers to use real-world data to support the clinical validity of new diagnostic tests, and approved several new diagnostic indications, which will allow for targeted treatment decisions for various health conditions. A well-resourced FDA will help innovators and physicians continue to develop safer, more efficacious treatment and prevention regimens based on the principles of patient-centered care.

As you also know, leading up to the reauthorization of these user fees for fiscal years (FYs) 2023 through 2027, FDA and negotiators from industry have agreed to a series of goals for medical product review and other important enhancements, which were transmitted to Congress earlier in 2022 as commitment letters for the *Prescription Drug User Fee Act (PDUFA) VII*[iv] and *Medical Device User Fee Act (MDUFA) V*.[v] After engaging for the better part of two years in the public stakeholder discussions to develop these commitment letters, we believe that the activities agreed to will advance personalized medicine and continue yielding benefits for a wide range of patients, including those currently underrepresented in clinical trials and with unmet medical needs.

In our previous statements on the commitment letters,[vi, vii] we commended multiple activities that would help ensure treatment and prevention strategies are delivered based on a person's biology, medical history, circumstances and values, including:

- targeted resources for staffing to support review of increasing cell and gene therapy applications;
- staffing to support the Center for Devices and Radiological Health's review activities;
- advancing the use of real-world evidence and digital health tools to inform regulatory decision-making;
- increasing diversity and patient engagement in research; and
- advancing decentralized clinical trials.

If you have any questions about the content of this letter, or if we can be of further assistance as Congress conferences the two bills, please contact me at cbens@personalizedmedicinecoalition.org or 202-499-0986, or David Davenport, PMC's Manager of Public Policy, at ddavenport@personalizedmedicinecoalition.org or 804-291-8572.

Sincerely yours,

Cynthia A. Bens
Senior Vice President, Public Policy

cc: Senator Patty Murray
Chair, Committee on Health, Education, Labor & Pensions
U.S. Senate

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

Congressman Frank Pallone
Chairman, Energy & Commerce Committee
U.S. House of Representatives

Congresswoman Cathy McMorris Rodgers
Ranking Member, Energy & Commerce Committee
U.S. House of Representatives

Congresswoman Anna Eshoo
Chairwoman, Energy & Commerce Health Subcommittee
U.S. House of Representatives

Congressman Brett Guthrie
Ranking Member, Energy & Commerce Health Subcommittee
U.S. House of Representatives

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[i] *Food and Drug Amendments of 2022, H.R. 7667.* 117th Congress, 2nd Session. May 13, 2022. https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/H7667-cpt_01_xml.pdf

[ii] *Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022, S. 4348.* 117th Congress, 2nd Session. June 14, 2022. https://www.help.senate.gov/imo/media/doc/FDASLA%20manager's%20amendment.pdf

[iii] Personalized Medicine Coalition. *Personalized Medicine at FDA: The Scope and Significance of Progress in 2021.* February 22, 2022. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/Personalized_Medicine_at_FDA_The_Scope_Significance_of_Progress_in_2021.pdf

[iv] U.S. Food and Drug Administration. *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027.* https://www.fda.gov/media/151712/download

[v] U.S. Food and Drug Administration. *Draft: MDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027.* https://www.fda.gov/media/157074/download

[vi] Personalized Medicine Coalition. *Remarks on Public Stakeholder Panel: FDA's Public Workshop on the Seventh Reauthorization of the Prescription Drug User Fee Act.* September 28, 2021. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PDUFA_VII_Goals_Letter_Comments_Docket_Submission_10.28.21.pdf

[vii] Personalized Medicine Coalition. *Comments on the Fifth Reauthorization of the Medical Device User Fee Act (MDUFA V).* April 21, 2022. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/MDUFA_V_comments_4.21.22.pdf