PERSONALIZED MEDICINE COALITION

April 3, 2025

The Honorable John Joyce
U.S. House of Representatives
2102 Rayburn House Office Building
Washington, DC 20515

The Honorable Donald Davis
U.S. House of Representatives
1123 Longworth House Office Building
Washington, DC 20515

Re: Support for H.R. 1672, the *Maintaining Investments in New Innovations (MINI) Act*

Dear Representative Joyce and Representative Davis:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions from across the health care spectrum, thanks you for reintroducing H.R. 1672, the *Maintaining Investments in New Innovations (MINI) Act.* The *Inflation Reduction Act (IRA)* included policies intended to lower prescription drug costs for Medicare beneficiaries and reduce drug spending by the federal government. However, multiple studies demonstrate the potential for the *IRA* to result in fewer new therapies being developed to address current and future unmet needs. Due to smaller patient subpopulations, personalized medicines that address the root causes of disease can sometimes be expensive and risky to develop. Medicare's drug price negotiation program established by the *IRA* could have an outsized effect in discouraging the pharmaceutical industry from bringing additional personalized medicines to market. Bipartisan policy solutions like the *MINI Act* would forestall disruption to the innovation ecosystem that has allowed patients and providers to benefit from genetically targeted therapies. PMC supports this bill and urges Congress to swiftly advance it during the 119th Congress.

Personalized medicine is an evolving field in which physicians use diagnostic tests and individual details about a person's health 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. Personalized medicine is playing an important role in transforming care and patient outcomes for a range of serious and life-threatening diseases and conditions, helping to shift patient and provider experiences away from trial-and-error medicine and toward a more streamlined process for making clinical decisions.

Statement of Neutrality

PMC's members may present their own views on H.R. 1672, the *Maintaining Investments in New Innovations (MINI) Act*. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance and are not

intended to adversely impact the ability of individual PMC members, alone or in combination, to pursue separate positions with respect to the *MINI Act*.

Improving the Prospects for Genetically Targeted Therapies under the *IRA*

Personalized medicines now account for more than a quarter of the new therapies approved since 2015. They have comprised more than a third of new drug approvals for six of the last seven years.[i] Recent approvals have brought a record number of new treatments for rare genetic diseases and new ways to address certain cancers and other diseases, including Alzheimer's disease. Multiple analyses, including those from the Congressional Budget Office (CBO), have called attention to the potential consequences of the Medicare drug price negotiation program established by the *IRA*, such as canceled research and development and disincentives to invest in small-molecule medicines and therapeutic areas that require incremental innovation.[ii, iii, iv, v]

Under the *IRA*, drugs are eligible for Medicare negotiation nine years after approval by the U.S. Food and Drug Administration (FDA) versus 13 years for biologics. Genetically targeted therapies (GTTs) work by either delivering healthy copies of genes to target cells, permanently changing the genetic code, or manipulating gene expression. If a GTT silences a gene, it is regulated as a drug, but if a GTT adds to a gene, it is regulated by the FDA as a biologic. Despite differences in their pathways for regulatory approval, GTTs are similar in development time, therapeutic action, and complexity of manufacturing. As part of the Medicare drug price negotiation program, GTTs regulated as drugs would be negotiated after nine years, whereas GTTs regulated as biologics would be negotiated after 13 years. These different timelines under the *IRA* impose an artificial distinction that could lead to a lack of parity in the development of these novel therapies.

Of the dozen or so FDA-approved GTTs, all are personalized medicines. While only a limited number of GTTs are on the market now treating rare disease patients, the underlying technology is expected to generate novel therapies for non-rare diseases in the future. To ensure the even advancement of all GTTs in this promising area of personalized medicine, PMC supports the *MINI Act*, which would make statutory changes to the *IRA* so that all GTTs are treated as biologics that could be negotiated after 13 years.

Conclusion

To sustain progress in the development of groundbreaking personalized medicine treatments for the benefit of patients and health systems, Congress must support policies that encourage the advancement of the field. PMC would be pleased to serve as a resource for you and your staff to ensure that the *MINI Act* is signed into law this year. If you have any questions about the content of this letter, you can contact me at cbens@personalizedmedicinecoalition.org or David Davenport, PMC's Director of Public and Science Policy, at ddavenport@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

[i] Personalized Medicine Coalition. *Personalized Medicine at FDA: The Scope & Significance of Progress in 2023*. February 29, 2024. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2024/02/report-3.pdf (Accessed March 30, 2025).
[ii] Congressional Budget Office. C*BO's Simulation Model of New Drug Development: Working Paper 2021-09*. August 26, 2021. https://www.cbo.gov/publication/57010 (Accessed March 30,2025).
[iii] Vital Transformation. *Build Back Better Act: Total Market Impact of Price Controls in Medicare Parts D and B*. July 28, 2022. https://vitaltransformation.com/2022/07/build-back-better-act-total-market-impact-of-price-controls-in-medicare-parts-d-and-b/ (Accessed March 30, 2025).
[iv] Avalere. "Drug Pricing Bill Could Reduce Manufacturer Revenue by Over $450B." July 22, 2022. https://avalere.com/insights/drug-pricing-bill-could-reduce-manufacturer-revenue (Accessed March 30, 2025).
[v] O'Brien, John. "Branded Drug Report 2023: John O'Brien, NPC." *Chain Drug Review*. January 9, 2023. https://www.chaindrugreview.com/branded-drug-report-2023-john-obrien-npc/ (Accessed March 30, 2025).