PERSONALIZED MEDICINE COALITION

April 3, 2025

The Honorable Thomas Tillis
U.S. Senate
113 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ted Budd
U.S. Senate
354 Russell Senate Office Building
Washington, DC 20510

The Honorable Marsha Blackburn
U.S. Senate
357 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Steve Daines
U.S. Senate
320 Hart Senate Office Building
Washington, DC 20510

RE: Support for S. 832, the *Ensuring Pathways to Innovative Cures (EPIC) Act*

Dear Senator Tillis, Senator Budd, Senator Blackburn, and Senator Daines:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions from across the health care spectrum, thanks you for reintroducing S.832, the *Ensuring Pathways to Innovative Cures (EPIC) 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 small-molecule personalized medicines to market or seeking expanded indications for small-molecule drugs. We believe policy solutions like the *EPIC Act* would forestall disruption to the innovative ecosystem that has allowed patients and providers to benefit from personalized medicine. 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.

Personalized Medicine Coalition
personalizedmedicinecoalition.org
1710 Rhode Island Ave., NW, Suite 700
Washington, DC 20036
P: 202.589.1770
F: 202.589.1778

Statement of Neutrality

PMC's members may present their own views on S.832, the *Ensuring Pathways to Innovative Cures (EPIC) 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 *EPIC Act*.

Improving the Prospects for Small-molecule Personalized Medicines

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*, small-molecule drugs are eligible for Medicare negotiation nine years after approval by the U.S. Food and Drug Administration (FDA) versus 13 years for biologics, or large-molecule, products. Implementation of these differential timelines will disincentivize investment in small-molecule over large-molecule drugs. One analysis estimates 79 fewer small-molecule drugs and 188 fewer indications coming to market over the next 20 years.[vi] These dynamics may impact the growing pipelines of personalized medicines available to patients, including patients from communities already experiencing disproportionately high incidence and mortality rates from diseases like cancer.

Many targeted cancer therapies that deliver personalized medicine to patients are small-molecule drugs.[vii] Small-molecule drugs comprise 70 percent of the drugs already selected for negotiation by Medicare, and small-molecule oncology therapies are expected to be predominantly affected during the Medicare drug price negotiation program's first few negotiation cycles. Small molecules can be as difficult to discover and manufacture as biologics and share similar risk. The calculus for funding their development is essentially the same as biologics, and they merit the same incentives. To reduce the impact of differential timelines for drugs and biologics on clinical development for small molecules and patients who need these critical therapies, the *EPIC Act*, would establish equal timelines for the negotiation of both drugs and biologics at 13 years.

Conclusion

To sustain progress in the development of groundbreaking personalized medicines 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 *EPIC 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).
[vi] Bedard, Philippe L. et al., "Small Molecules, Big Impact: 20 Years of Targeted Therapy in Oncology," *The Lancet*. Vol. 395 (10229): 1078-88. March 28, 2020. https://doi.org/10.1016/S0140-6736(20)30164-1 (Accessed March 30, 2025).
[vii] Philipson, Tomas J. et al. *Policy Brief: The Potentially Larger Than Predicted Impact of the IRA on Small Molecule R&D and Patient Health*. The University of Chicago. June 25, 2024. https://ecchc.economics.uchicago.edu/files/2024/06/Small-Molecule-Paper-20240625.pdf (Accessed March 30, 2025).