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Cecelia Schott, Pharm.D., M.B.A.
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Johnson & Johnson

Apostolia-Maria Tsimberidou, M.D., Ph.D.
M.D. Anderson Cancer Center, University of Texas

Michael Ybarra, M.D.
PhRMA

August 17, 2026

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Senator Catherine Cortez Masto
United States Senate
309 Hart Senate Office Building
Washington, D.C. 20510

Senator Peter Welch
United States Senate
115 Russell Senate Office Building
Washington, D.C. 20510

Senator Ruben Gallego
United States Senate
302 Hart Senate Office Building
Washington, D.C. 20510

RE: Response to Request for Information: Commonsense Policy Options to Lower Drug Prices for Patients

Dear Ranking Member Wyden, Senator Cortez Masto, Senator Welch, and Senator Gallego:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 150 institutions from across the health care spectrum, appreciates the opportunity to provide comments in response to the Senate Finance Committee Democrats' Request for Information (RFI) regarding policies to lower prescription drug costs while supporting continued biomedical innovation.[i] We share the Committee's commitment to improving patient access to medical care that is the most appropriate for their clinical situations and to reducing unnecessary barriers to medications prescribed by their healthcare providers. Personalized medicine-related developments at the U.S. Food and Drug Administration (FDA) show that scientific innovation continues to move the health system toward the utilization of individual patient information to improve patient outcomes and make clinical care more efficient. Policies that negatively impact investment in research and development ultimately delay or prevent future treatments for patients with cancer, rare diseases, neurodegenerative disorders, infectious diseases, and many other serious conditions. The most effective path forward for the Committee is one that addresses inefficiencies throughout the healthcare system, reduces patients' out-of-pocket costs, and preserves the incentives necessary to develop tomorrow's cures.

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. Personalized medicine is helping to shift the patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions, which leads to improved patient outcomes, a reduction in

unnecessary treatment costs, and better patient and provider satisfaction. PMC and its members are leading the way in personalized medicine and in developing evidence showing how patients and the health care system can benefit from appropriate testing and tailored treatment as soon as possible during their clinical experiences.

Statement of Neutrality

Many of PMC's members will present their own responses to the Senate Finance Committee Democrats' Request for Information (RFI) regarding policies to lower prescription drug costs for patients and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to RFI.

Section I: Lowering Drug Prices

PMC supports efforts to improve prescription drug affordability, however, reforms should recognize that reducing manufacturers' drug prices alone will not necessarily reduce the amount patients pay for their care. The Committee should pursue targeted reforms that lower out-of-pocket costs while preserving the innovation ecosystem responsible for developing future treatments and cures. We appreciate the Committee examining both affordability and innovation and respectfully offer the following comments.

Medicare Drug Price Negotiation Program (MDPNP)

Congress enacted the Inflation Reduction Act (IRA), which established a framework for addressing some aspects of drug affordability in Medicare. That framework reflects policy choices aimed at generating savings and introduced a discussion of timelines that are necessary to preserve innovation. PMC recognizes Congress' interest in evaluating the Medicare Drug Price Negotiation Program (MDPNP) established by the IRA including potential modifications to or expansion of the program. However, PMC is concerned about the long-term implications of the MDPNP as it has been currently implemented and for the unintended consequences changes to the program may have on patients and for biomedical innovation.

Fifteen years ago, personalized medicines represented less than 10 percent of new drug approvals. In 2025 personalized medicines accounted for more than one-third of all new drug approvals for the sixth consecutive year. Sixteen of the forty-six new molecular entities approved by the FDA last year were personalized medicines to treat individuals with certain cancers, rare, and chronic diseases.[ii] Research conducted after approval of a new drug is important for advancing personalized medicine. After initial approval of a drug by FDA, further research provides greater understanding of patients' responses to treatment based on results from molecular diagnostics. This research may lead to new or improved treatment indications that contribute to progress in personalized medicine. Over the past nine years, PMC has identified more than 130 expanded indications significant to advancing personalized medicine.[iii] Notably, these expanded indications have had an upward trend in the average time since a drug's initial approval. Since these expanded indications can increase the product's aggregated utilization and risk for earlier selection, the drug price negotiation program can alter manufacturers' decision-making for investing in researching new uses for a drug post approval, potentially affecting smaller patient subpopulations with serious conditions or unmet needs.

The IRA already establishes an unequal timeline for negotiation. Small-molecule medicines become eligible for negotiation 9 years after approval, compared with 13 years for biologics. Multiple analyses, including those from the Congressional Budget Office (CBO), have called attention to the potential consequences of the MDPNP, such as canceled research and development and disincentives to invest in small-molecule medicines and therapeutic areas that require incremental innovation.[iv][v][vi] Legislators have also questioned CBO's initial analysis for underestimating such impacts of the program.[vii] After the IRA was enacted, capital markets began

pulling back from investments in small-molecule medicines in response to the law's shorter negotiation timeline. According to the Incubate Coalition, at least 44 research programs and 23 drugs that have been discontinued since the IRA was signed into law, many of which having a direct causation due to the uncertainty that the IRA has created.[viii] **Any efforts to further shorten the period before a medicine becomes eligible for Medicare negotiation would compound the IRA's effects on research and development, leaving less time for manufacturers to pursue additional indications, conduct post-approval studies, and develop improvements for patients. Specifically, reducing the biologics timeline to 9 years could produce a similar pullback in biologics investment and potentially drive some investors away from the biopharmaceutical therapeutics sector altogether.**

To date, the MDPNP has failed to achieve its primary goal of reducing actual out-of-pocket costs for average Americans. About two-thirds of Medicare Part D beneficiaries are enrolled in Part D plans where they pay more out of pocket for the IPAY 2026 MDPNP selected drugs than before the IRA.[ix] Instead, the MDPNP's implementation has begun yielding unintended consequences. The life sciences industry is characterized by high levels of scientific uncertainty, substantial capital investment, and lengthy development timelines. Bringing a single therapy from discovery to FDA approval often requires more than a decade of research and billions of dollars in investment, with only a small fraction of investigational products reaching patients.[x] Investors make funding decisions based upon the expected long-term value of successful therapies. Policies that significantly reduce the ability to sustain long-term biomedical research and development may discourage investment in the next generation of breakthrough medicines, particularly in scientifically challenging areas such as rare diseases, neurodegenerative disorders, oncology, and cell and gene therapies. **Expanding the MDPNP to a larger number of drugs before its full economic and clinical impacts are realized could permanently damage pipeline development in high-risk areas like oncology, rare diseases, and neurodegenerative disorders. The Committee should carefully evaluate the cumulative effects of the IRA before any proposed expansion of the MDPNP.**

International Reference Pricing ("Most Favored Nation")

International reference pricing systems, such as international price benchmarking methodologies which references prices in economically comparable countries, are built upon prices established by foreign governments that frequently rely on centralized price controls, delayed reimbursement decisions, restricted formularies, and limited patient access to innovative therapies. They have been described as a means of identifying lower-cost benchmarks, however, reliance on external price references will likely have downstream effects that are not closely aligned with individual patient needs or clinical circumstances.

In stark contrast to what American patients want, international reference pricing would interfere with achieving treatment value that matters to patients. Some patients will experience more or less benefit from a treatment than suggested by the averages reported within clinical trials and population-based data. For example, cancer is known to be a complex disease in which the same cancer type can behave differently in different patients. The consequence of these individual responses is that within a population of patients suffering from the same cancer, the mainstay therapy fails to achieve efficacy in many patients. Personalized medicine has driven significant improvements in survival rates in recent decades, but oncology has pronounced cross-country variability in the availability and timelines of patient access. Of the seventy-four cancer drugs launched between 2011 and 2018, 95 percent are available in the United States, compared with 74 percent in the United Kingdom and 49 percent in Japan.[xi]

Advances in pharmaceutical innovation over the past two decades have influenced how American patients perceive their health care. Personalized medicine approaches depend on the consideration of a patient's molecular and biological characteristics and also on individual values, clinical and economic circumstances, and the potential impact of a therapy for that patient over the long term. Fundamental patient values and

preferences, including the impact of treatment on quality of life, quantity vs. quality of time, functional ability related to illness or treatments, cost of supportive care, and other patient costs of treatment are weighed by patients and their caregivers. Access to appropriate therapy relies upon this type of individualized clinical decision making between patients and their providers.

Today, patients in the United States expect not only access to cutting-edge therapies but also meaningful involvement in decisions about their care. American patients consistently report valuing access to pharmaceuticals and the autonomy to choose, alongside their providers, from available treatment options that improve their lives and the lives of their loved ones. These perspectives highlight that patients in this country prioritize both faster access to effective treatment options and the long-term health benefits those medicines deliver. This combination of expectations for innovation and preferences for personal agency in treatment decisions is part of the American context. [xii]

Personalized medicine creates considerable benefits for patients and society since they are used in a manner that directs them toward patients who are most likely to benefit and away from those who are not. Foreign reference pricing heavily relies on Quality-Adjusted Life Years (QALYs). The QALY and other similar metrics do not sufficiently account for the broad heterogeneity of clinically relevant characteristics and preferences across patients and diseases, nor do they consider aspects of value defined by patients and their families. These measures rely on population averages that do not consider the heterogeneity of patient populations, even within the same condition. The QALY systematically undervalues the lives of disabled, chronically ill, and elderly people. The Committee prohibited the use of QALYs within the MDPNP, therefore, importing foreign metrics contradicts that original prohibition. **PMC opposes proposals to incorporate international reference pricing into Medicare or commercial drug pricing policy. The Committee should pursue domestic reforms that improve affordability through greater transparency, efficient regulation, and reductions in unnecessary administrative costs throughout the healthcare system.**

Section II: Enhancing Prescription Drug Affordability

PMC supports the Committee's goal of reducing patients' out-of-pocket costs and improving affordability. One of the most significant shortcomings of today's prescription drug benefit design is that many patients continue to pay cost-sharing based on a drug's list price rather than the substantially lower net price that is achieved after rebates and discounts. As a result, savings frequently remain within the supply chain instead of reducing patients' out-of-pocket expenses. This disconnect is particularly burdensome for patients with chronic diseases, rare diseases, and cancer, who often require specialty medicines associated with coinsurance rather than fixed copayments.

Ensuring Patients Benefit from Negotiated Discounts

Ensuring patients directly benefit from negotiated discounts would improve affordability without discouraging continued pharmaceutical innovation. The IRA made major changes to the Medicare Part D program, with policies impacting different stakeholders taking effect over several years. These changes included voluntary "smoothing," known as the Medicare Prescription Payment Plan (MPPP), to allow beneficiaries to spread their out-of-pocket Part D costs over the calendar year rather than paying directly at the pharmacy counter and an out-of-pocket cap for beneficiaries ($2,000 in 2025).

When someone opts into the MPPP, their plan will communicate that election to their chosen pharmacy as part of their payment transaction. At the point of sale, the person will not be charged. Instead, the plan will pay the beneficiary's cost-sharing obligation–deductible, coinsurance, or copay, depending on their plan details–to the pharmacy. Then, using a formula set forth in the IRA statute, the plan will send the beneficiary a monthly bill. The intention of MPPP is to help patients further in affording their prescriptions, but initial experiences with the

program show that only a small portion of Medicare beneficiaries with high drug costs have enrolled and there is still very little visibility into the implementation and use of the program. According to polling by the Partnership to Fight Chronic Disease, 74 percent of seniors have heard little to nothing about the MPPP, with nearly half knowing nothing at all. **The Committee should urge CMS to improve implementation of the MPPP by simplifying enrollment, making the program and its payment terms more transparent, and requiring Part D plans to conduct more effective outreach so that eligible beneficiaries understand and can readily access this important affordability option.**

Prior to lowering the out-of-pocket cap, the Medicare Part D program had no formal limit on beneficiary financial exposure. Beneficiaries no longer pay out-of-pocket after reaching the new cap. Part D plans are now liable for a larger share of total spending once beneficiaries hit their deductibles and catastrophic limit, including high spending beneficiaries. This lower liability is a benefit to patients and has had the greatest impact on affordability but now Part D cost sharing is beginning to shift from copay to coinsurance. The share of stand-alone Part D prescription drug plans using coinsurance, rather than a copay, for preferred branded drugs sharply increased from 9.9 percent in 2020 to 71.9 percent in 2024. Under coinsurance beneficiaries generally pay more because out-of-pocket spending is tied to list prices which do not reflect substantial manufacturer rebates. As a result, Medicare beneficiaries in stand-alone drug plans, which account for 43 percent of the Part D market will face higher costs.[xiii] **The Committee should evaluate policies that would better align patient cost-sharing with the actual net cost of medicines.**

Reforming Utilization Management Practices

PMC previously shared concerns with CMS and with the Committee that the MDPNP could narrow patients' access to existing treatment options in personalized medicine. Utilization management practices, such as prior authorization and step therapy, create difficulties for patient access to the latest treatments and standards of care informed by personalized medicine approaches.[xiv] [xv] CMS expressed concerns that plans may be incentivized to disadvantage selected drugs with utilization management that is not based on medical appropriateness, potentially exacerbating an already growing trend in the use of step therapy and its embedding in prior authorization requirements.[xvi] [xvii] [xviii] Despite these warnings, cost control measures such as narrowed formularies and utilization management are further impeding patient access. In 2025 nearly half of all attempts to fill a new branded medication in Medicare Part D were initially denied coverage.[xix]

PMC shares the Committee's interest in evaluating utilization management practices, including prior authorization, step therapy, and formulary exclusions. Overly burdensome or poorly designed utilization management requirements can delay medically necessary treatment, interrupt continuity of care, increase administrative burdens on providers, and worsen patient outcomes. In 2025 four of five therapeutic areas for chronic conditions, including immunology and multiple sclerosis, seventy percent of new-to-brand attempts were initially rejected.[xx] Patients with serious, progressive, or life-threatening conditions often cannot afford unnecessary treatment delays while navigating repeated prior authorization requirements or multiple rounds of step therapy. **The Committee should support meaningful utilization management reform by including clear exception processes and enforceable timelines, so that these tools protect clinical appropriateness rather than simply shifting costs onto patients. Furthermore, because negotiated drugs are being offered to plans at a lower price, negotiated drugs should not face additional cost-control practices that could limit eligible patient access to them. Patients who are stable on their current medications should be able to maintain access to these medications whether they are negotiated or non-negotiated drugs.**

<u>Section III: Bolstering Biomedical Innovation in the United States</u>

The United States is the global leader in biomedical research and development because it has cultivated an ecosystem that enables scientific discovery to progress from the laboratory to patients. This ecosystem includes

federally funded basic research, biopharmaceutical manufacturers, academic medical centers, contract research organizations, clinical investigators, and advanced manufacturers. Policies that reduce investment in biomedical research ultimately affect patients that would benefit from promising discoveries leading to approved therapies.

Strengthening Federal Research Partnerships

The National Institutes of Health (NIH) provides foundational research that enables many scientific discoveries later advanced by industry, while the FDA provides the scientific expertise necessary to evaluate the safety and effectiveness of new medical products. Federally funded biomedical research provides the scientific foundation that fuels private sector innovation by supporting high-risk, early-stage research and stimulating private sector investment, enabling companies to pursue resource-intensive clinical development programs and secure the significant capital required to bring new therapies to patients.

PMC joins the research community in urging the Committee to avoid far-reaching policies that would allow political appointees to exert greater political influence over how federal research grants are awarded and managed across the government, such as the recent proposed rule from the Office of Management and Budget *Regulation for Federal Financial Assistance*.[xxi] [xxii] The rule would expand political discretion in funding decisions, increase authority to suspend or terminate grants, and impose broad restrictions on international collaboration. Such policies would threaten the longstanding partnership between the federal government and the research community by discouraging private industry and academic institutions from pursuing federal research support and introducing greater uncertainty into the research funding landscape. This uncertainty may discourage future investment in biomedical innovation, disrupt the development of new therapies, and delay patients' access to life-saving treatments.

Federal research funding works best when it is predictable, transparent, and grounded in scientific merit. Certainty and continuity within the research system support long-term clinical research activities. **PMC strongly supports robust and sustained funding for NIH, FDA, and other federal agencies as well as policies that preserve our research grant system and contribute to biomedical innovation. Continued investment in these institutions strengthens public-private partnerships, accelerates scientific discovery, and helps maintain the United States' global leadership in medical research. Congress should also continue supporting initiatives that modernize clinical trials, expand the use of innovative trial designs, improve patient recruitment, and strengthen the domestic clinical research infrastructure. These efforts can reduce development costs, improve trial efficiency, and bring new therapies to patients more quickly while maintaining FDA's rigorous standards for safety and effectiveness.**

Conclusion

Thank you for the opportunity to comment on the RFI. PMC looks forward to working with your colleagues on the Committee to advance balanced reforms that promote patient affordability and sustain innovation in personalized medicine. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

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