

March 26, 2025

The Honorable John Thune
Senate Majority Leader
511 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Charles Schumer
Senate Minority Leader
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mike Johnson
Speaker of the House
568 Cannon House Office Building
Washington, DC 20515

The Honorable Hakeem Jeffries
House Minority Leader
2267 Rayburn House Office Building
Washington, DC 20515

RE: Prioritize Patient Engagement in Health Care Policymaking

Dear Majority Leader Thune, Speaker Johnson, Minority Leader Schumer, and Minority Leader Jeffries:

We, the undersigned organizations, collectively represent a diverse community of individuals including patients, survivors, and caregivers who are impacted by cancer and other complex conditions including autoimmune, cardiovascular, gastrointestinal, mental health and rheumatological illnesses. We are focused on bringing together patients and their loved ones, advocates, and policy experts to ensure that the patient voice plays an integral role in federal and state policymaking impacting health care access, patient experiences, and patient outcomes.

Over the last two years, the Cancer Support Community (CSC) – in close collaboration with patient advocacy, caregiver, and health care innovator communities – has facilitated important conversations about the impacts that health care policy changes will have on patients, survivors, and caregivers impacted by cancer and other complex and chronic conditions. While we commend the 118th Congress for their commitments to explore policy solutions that help patients access the treatments and care they need, critical work remains to ensure that no patient faces negative unintended consequences as a result of these legislative decisions.

It is critical to prioritize patient and caregiver perspectives and input when considering legislation to address access and affordability issues of potentially life-saving treatments. Recognizing the need for meaningful patient and caregiver engagement in policy decision-making, in 2024, CSC worked in collaboration with other health care stakeholder communities to establish a set of recommended principles for patient-centered engagement to guide and support the policymaking process. While the original set of principles was designed with a focus on the process that the Centers for Medicare and Medicaid Services (CMS) uses to implement the Medicare Drug Price Negotiation Program (MDPNP) within the Inflation Reduction Act (IRA), the principles were created to be applicable to all types of policy making that stands to impact patients – including by Congress.

As the 119th Congress considers policy solutions to make treatments more affordable and accessible for patients around the country, we urge you to prioritize a patient-centered approach to ensure that patient, survivor, and caregiver perspectives are considered and integrated into policies that stand to impact them most.

IRA Impact on Small Molecule Drugs

While we recognize that the intent of the IRA is to increase access to critical treatments for Medicare beneficiaries, we continue to have concerns about how this policy will actually impact patients and their ability to access necessary treatments. A crucial tenet of the law is the distinction in negotiation timelines between small and large molecule drugs. Small molecule drugs – often taken in pill form – are eligible for negotiation seven years after approval by the Food and Drug Administration (FDA) while large molecule drugs – often administered by a health care professional – are eligible for negotiation eleven years after approval by the FDA. Price controls would go into effect two years after negotiation eligibility at nine and thirteen years following FDA approval, respectively.

Notably, small molecule drugs have become a critical part of treatment regimens for cancer because they are the only molecule that can cross the blood-brain barrier and are more accessible for patients due to the cost and convenience of taking them at home. This is especially critical for Americans living in rural communities who face higher cancer rates than those living in suburban areas and, in general, have less access to health centers and pharmacies.¹ As designed, the IRA will disincentivize research and development into small molecule drugs due to the shorter timeframe before a drug is eligible for negotiation, potentially decreasing the number of current and future treatments available to patients.

Policy Solution to Fix an IRA Disincentive

The Ensuring Pathways to Innovative Cures (EPIC) Act ([H.R. 1492](#)), recently introduced by Representatives Greg Murphy (R-NC), Don Davis (D-NC), and Richard Hudson (R-NC), would eliminate the unnecessary distinction between small and large molecule drugs in the IRA, allowing both to be eligible for negotiation thirteen years after FDA approval.

Seven of the ten drugs selected for the first round of Medicare negotiations and 13 of the 15 drugs selected for the second round of Medicare negotiations are small molecule drugs.² Research predicts that this number will increase as negotiations continue and will negatively impact future innovation of these drugs.³ While the policy change in the EPIC Act may seem negligible, it would ensure that critical research and development resources – including from innovative biopharmaceutical companies in America – are not diverted away from small molecule drugs, especially for hard to treat cancers and other conditions that may not yet have an FDA-approved treatment option.

Over the last 40 years, the cancer death rate in America has declined by 33 percent thanks in part to advancements in innovations and the availability of more effective and more accessible treatment options for patients.⁴ We cannot take steps that will stunt the progress made in medical advancements, particularly for cancer and other difficult diagnoses. We must continue to ensure that all patients have access to the treatment best suited for them and prescribed by their trusted medical professionals, and that policies accurately reflect the needs and input of patients who will be most impacted by them.

¹ Cancer Epidemiol Biomarkers Prev: [Rural-Urban Cancer Incidence and Trends in the United States, 2000 to 2019](#) (August 2024)

² Managed Healthcare Executive: [Trump Impact on Medicare Drug Price Negotiations Uncertain](#) (January 2025)

³ Charles River Associates: [Impact of Medicare Price “Negotiation” Program on small and large molecule medicines](#) (May 2024)

⁴ American Cancer Society: [Cancer Statistics, 2023](#) (January 2023)

We urge you to prioritize patient-centered engagement as you craft health care policies in the 119th Congress and ensure that no patient will face unintended consequences as a result of health care policy changes.

Thank you for your continued dedication to addressing patient access and affordability issues. If you have any questions or if our organization can be a resource to you, please contact Daneen Sekoni at dsekoni@cancersupportcommunity.org.

Sincerely,

Cancer Support Community
Cancer Support Community Arizona
Cancer Support Community Iowa & NW Illinois
Cancer Support Community San Francisco Bay Area
Cancer Support Community South Bay
Gilda's Club Chicago
Gilda's Club Kentuckiana
Gilda's Club Madison Wisconsin

ADAP Advocacy
AiArthritis
Aimed Alliance
Allergy and Asthma Network (AAN)
Alliance for Aging Research
Alliance for Patient Access
Alliance for Women's Health and Prevention
American Urological Association (AUA)
Autoimmune Association
Biomarker Collaborative
Brem Foundation to Defeat Breast Cancer
CancerCare
Caregiver Action Network
Caring Ambassadors Program
Cervivor, Inc.
Chronic Care Policy Alliance
Coalition of State Rheumatology Organizations
Color of Gastrointestinal Illnesses (COGI)
Community Access National Network
Community Liver Alliance
Depression and Bipolar Support Alliance
Exon 20 Group
FORCE: Facing Our Risk of Cancer Empowered
Global Coalition on Aging Alliance for Health Innovation
GO2 for Lung Cancer
Headache and Migraine Policy Forum
HealthTree Foundation
HealthyWomen
Heart Valve Voice U.S.

ICAN, International Cancer Advocacy Network
International Myeloma Foundation
LUNgevity Foundation
Lupus and Allied Diseases Association, Inc.
Mental Health America
MET Crusaders
National Alliance for Caregiving
National Consumers League
National Minority Quality Forum
National Patient Advocate Foundation
Ovarian Cancer Research Alliance
Partnership to Fight Chronic Disease
Patients Rising
PDL1 Amplifieds
PlusInc
Pulmonary Hypertension Association
RetireSafe
Rural Minds
StopAfib.org, Division of the American Foundation for Women's Health
The ALS Association
The Mended Hearts, Inc.
Tigerlily Foundation
TOUCH The Black Breast Cancer Alliance
Young Survival Coalition

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Principles for Patient-Centered Engagement When Implementing the Medicare Drug Price Negotiation Program (MDPNP)

- **Engage patient advocacy organizations, patients, and caregivers** in structured, meaningful ways throughout the MDPNP process.
- **Define clinical benefit** to prioritize evaluations around endpoints, patient reported outcomes, patient experience data including impact on quality of life, and preferences that matter most to patients living with cancer and other complex conditions. This includes both qualitative and quantitative measures such as clinical endpoints, patient preference data/models, patient reported outcomes, and social impacts.
- **Develop critical infrastructure** necessary to educate the patient community and facilitate meaningful feedback that prioritizes patient definitions of value, including feedback on the evidence being considered by CMS and whether it reflects patient experiences and preferred outcomes.
- **Refer to patient navigators** to provide information to patients about the impact of these policies and to receive feedback from patients, with an explicit goal to identify any changes in utilization management practices as a result of IRA implementation.

- **Develop a monitoring and evaluation platform** and reporting framework surrounding the MDPNP and its impacts on patients to support continuous improvement in ongoing implementation.
- **Collect and report specifically on access challenges facing patients** as a result of the IRA to allow for continuous improvement of the MDPNP process and lessen the unintended consequences of this process on patients.
- **Collect and incorporate meaningful data and real-world evidence** that amplifies patient values and input within the MDPNP implementation process, including patient reported outcomes, patient experience data, impact to quality of life, and models that capture the dynamic and varied preferences of patients.
- **Prioritize outreach to patients, people with disabilities, and people living in rural communities** to ensure that the MDPNP supports all patient populations and does not threaten health care access.
- **Consider the groups and populations that have not already engaged** in defining patient-focused clinical benefit and impact of the MDPNP process and determine how best to activate those individuals.

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