May 11, 2025

The Honorable Mike Johnson
Speaker
U.S. House of Representatives H-232
Washington, DC 20515

The Honorable John Thune
Majority Leader
United States Senate SD-511
Washington, DC 20510

The Honorable Steve Scalise
Majority Leader
266 Cannon House Office Building
Washington, DC 20515

The Honorable John Barrasso
Majority Whip
307 Dirksen Senate Office Building
Washington, DC 20510

RE: EPIC Act – Align MDPNP Eligibility for Small Molecule Drugs and Biologic Products

Dear Speaker Johnson, Majority Leader Thune, Rep. Scalise and Sen. Barrasso:

On behalf of the 64 undersigned organizations representing healthcare providers and the patients they serve, we urge you to align the Medicare Drug Price Negotiation Program (MDPNP) eligibility timelines for small molecule drugs and biologic products at 11 years post-FDA approval. On April 15, 2025, the President signed an Executive Order on drug prices calling on Congress to fix the "pill penalty." Furthermore, Sen. Tillis (R-NC) and Rep. Murphy (R-NC-03) have introduced legislation in the 119th Congress (S.832/H.R.1492) to address this disparity, the Ensuring Pathways to Innovative Cures (EPIC) Act. We strongly support these measures to ensure future access to new small molecule drugs, which will improve patient drug accessibility and affordability.

As health care provider and patient advocacy organizations, we understand the harsh realities at play when patients are unable to afford their prescription medications. We regularly work to try and find options that allow patients to maintain their treatment. Unfortunately, switching to a therapeutically equivalent drug with less patient cost-sharing is not always an available option for patients, who are beholden to the pharmacy benefit and formulary design dictated by their pharmacy benefit manager and health plan. When patients are unable to maintain their treatment plan, they may turn to medication rationing or forfeit their treatment all together. This can have serious consequences for patients with chronic conditions, leading to disease progression, decreased functionality and even hospitalization.

We recognize the mission of the Inflation Reduction Act (IRA) of 2022 to address patient drug affordability. However, we have remained consistently concerned that certain provisions of the law may actually exacerbate drug spending for both Medicare and its beneficiaries while reducing access to small molecule drugs.

The IRA provided that certain drugs were exempt from consideration under the Medicare Drug Price Negotiation Program (MDPNP), including small molecule drugs with less than seven years from their FDA-approval or licensure date and biologic products with less than 11 years. Small molecule drugs are chemically synthesized medications that are typically dispensed at a pharmacy to the patient in convenient forms, such as pills, syrups or capsules, for administration at home and without the assistance of a healthcare provider. Biologic products are complex medications derived from living organisms. Some biologics, such as insulin, can be self-administered by the patient in their own home. Other biologics, such as those for cancer, arthritis, osteoporosis, and multiple sclerosis (MS), are often administered via infusion by a health care provider at an outpatient clinic or provider's office. Both drug types serve an essential role in the

treatment of patients, and we encourage further research and development in both types of drugs to ensure future cures for conditions afflicting Americans across the country.

Unfortunately, the disparity in the eligibility timeline between small molecule drugs and biologic products within the IRA is already impacting investment in research and development. We remain concerned that pharmaceutical manufacturers and biotech investors may be less likely to invest in research and development for small molecule drugs if they know they have less time before MDPNP consideration. This could create a vacuum in research and development to treat more common chronic conditions, like hypertension, gastrointestinal disorders and chronic inflammation, which are often treated with small molecule drugs.

As healthcare provider and patient advocacy organizations, this is particularly troubling, as small molecule drugs are essential tools in helping patients with chronic conditions maintain independence and avoid more intensive in-office or facility-based care when it is not medically necessary. Reduced investment in small molecule drugs is also counterproductive to efforts aimed at supporting patients in self-managing their care and staying adherent to medication regimens—core goals of chronic disease management.

We recognize the essential value that both small molecule drugs and biologic products offer in treating patients, which is why we urge Congress to adopt policies that create parity for these drugs under the MDPNP. Policies that support research and development for both small molecule drugs and biologic products will help ensure a healthier tomorrow for Americans. We support the directives within the Executive Order to eliminate the "pill penalty" and encourage Congress to address this disparity by including the EPIC Act in reconciliation.

On behalf of the 64 undersigned healthcare provider and patient advocacy organizations, we appreciate your consideration, and we look forward to supporting efforts to advance this important policy priority. Please contact the Coalition of State Rheumatology Organizations (jfrasco@hhs.com) if we can help provide any additional information.

Sincerely,

Advocates for Compassionate Therapy Now
AiArthritis
Alabama Society for the Rheumatic Diseases
Alliance for Patient Access
Alliance for Safe Biologic Medicines
American Behcet's Disease Association
American Society of Plastic Surgeons
Arizona United Rheumatology Alliance
Arkansas Rheumatology Association
Association of Women in Rheumatology
Autoimmune Association
Biomarker Collaborative
California Rheumatology Alliance
Caring Ambassadors Program
CF United
Chronic Care Policy Alliance
Coalition of State Rheumatology Organizations
Coalition of Wisconsin Aging & Health Groups
Color of Gastrointestinal Illnesses
Community Liver Alliance

Dermatology Nurses' Association
Exon 20 Group
Florida Society of Rheumatology
Georgia Society of Rheumatology
Global Allergy & Airways Patient Platform
Hawaii Rheumatology Society
HIV+Hepatitis Policy Institute
Huntington's Disease Society of America
ICAN, International Cancer Advocacy Network
Infusion Access Foundation
International Bipolar Foundation
Kentuckiana Rheumatology Alliance
Let My Doctors Decide
Liver Coalition of California
Lupus and Allied Diseases Association, Inc.
Maryland Society for the Rheumatic Diseases
Massachusetts, Maine and New Hampshire Rheumatology Association
MET Crusaders
Michigan Rheumatism Society
MidWest Rheumatology Association
Mississippi Arthritis and Rheumatism Society
Nebraska Rheumatology Society
New York State Rheumatology Society
North Carolina Rheumatology Association
Patient Advocates United in San Diego County
PDL1 Amplifieds
Pennsylvania Rheumatology Society
Pharmacists United for Truth and Transparency
Rare Access Action Project
Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Association of Nevada
Rheumatology Society of New Mexico
South Carolina Rheumatism Society
Southern California Rheumatology Society
Spondylitis Association of America
State of Oklahoma Association of Rheumatology
State of Texas Association of Rheumatologists
Tennessee Rheumatology Society
The AIP BIPOC Network
The Bonnell Foundation: Living with cystic fibrosis
Virginia Society of Rheumatology
West Virginia State Rheumatology Society

CC: The Honorable Thom Tillis
The Honorable Greg Murphy, MD