May 8, 2025

The Honorable Mike Johnson
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

The Honorable John Thune
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Hakeem Jeffries
Democratic Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Charles Schumer
Democratic Leader
U.S. Senate
Washington, DC 20510

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

The Council of State Bioscience Associations (CSBA) is a coalition of independent state and territory based non-profit trade associations, each of which advocates for public policies that support responsible development and delivery of innovative life-sustaining and life-saving biotechnology solutions. Convened by the Biotechnology Innovation Organization (BIO), CSBA's collective voice represents the true grassroots network of innovators, researchers, manufacturers, and accelerators across the country. According to a recent industry report, U.S. bioscience industry employment in 2023 reached 2.3 million jobs in more than 149,000 businesses across every state in the U.S. and Puerto Rico. The total economic impact of the bioscience industry on the U.S. economy, as measured by overall output, totaled $3.2 trillion dollars in 2023.[1]

The CSBA is deeply concerned that as Congress continues negotiations on a reconciliation package, reports have surfaced that proposals are being considered that would require biopharmaceutical companies to pay substantially higher rebates in Medicaid, either through an increase in the base rebate (currently 23.1%) or by requiring companies to pay the lowest global rate in Medicaid through a foreign reference pricing, which is also referred to as a "Most Favored Nation" (MFN) scheme.

Fundamentally, the CSBA is strongly opposed to any policies that would set reimbursement for pharmaceuticals in the U.S., including drugs delivered in Medicare and Medicaid, based on foreign reference prices, MFN, or other similar schemes. Any such proposals should be soundly rejected given the real and significant threats they pose to patient access and to our economic and national security.

[1] TEConomy/Biotechnology Innovation Organization. (2024). *The U.S. Bioscience Economy: Driving Economic Growth and Opportunity in States and Regions.* https://www.bio.org/csba-resources-and-reports

Adoption of foreign price control schemes ultimately means vulnerable patients have decreased access to medicines they need. Foreign countries that employ price control schemes and socialized medicine essentially discriminate against rare diseases and chronically ill patients by devaluing innovation and implementing excessive access restrictions. According to an IQVIA study, more than a hundred medicines approved in the United States over the past decade are unavailable to Europeans. A similar study found that between 2002 and 2014, 40% of medicines that treat rare diseases were rejected for coverage in the United Kingdom.[2] Ultimately, the use of foreign reference pricing/MFN schemes in the U.S. will result in these types of access restrictions in our own country.

Regarding the Medicaid program specifically, increased rebate requirements and foreign reference pricing schemes will jeopardize access to much needed medicines for the most vulnerable patients, including those battling pediatric cancer, life-threatening rare diseases, and chronic conditions.

Since its creation, the Medicaid Drug Rebate Program (MDRP) has helped bring hundreds of revolutionary therapies to underserved patients while maintaining incentives for continued research into new treatments and cures. The MDRP has guaranteed access to these therapies while ensuring the Medicaid program receives the lowest price offered by manufacturers throughout the U.S. However, efforts to increase the Medicaid rebate or use of international reference pricing or MFN-type approaches puts this carefully struck balance at risk.

In addition to having a devastating impact on American families, these proposals will have a chilling effect on research and development and continued investment in innovative therapies for vulnerable patients covered by the Medicaid program. In the U.S., the majority of new drug development is initiated at small, start-up biotech companies with little to no commercial revenue.

Companies already pay a significant share of prescription drug costs in the Medicaid program. In fact, Medicaid collects more in rebates than it spends on prescription drugs annually,[3] and many companies provide medicines to Medicaid beneficiaries for less than it costs them to produce their drugs. Rebates beyond current levels are unsustainable for most drug manufacturers, but small to mid-size companies focused on pediatric cancer, rare diseases and cell and gene therapy, and those that treat a high percentage of Medicaid patients would be disproportionately impacted. The consequences could be devastating and would extend far beyond Medicaid, dramatically increasing 340B costs to a program that is already skyrocketing and now stands as the second-largest federal pharmaceutical pricing program after Medicare.

We are greatly concerned about the impact these proposals will have on patients with rare diseases and other serious, chronic conditions. Many of them have health coverage through Medicaid. They, and companies who work to develop treatments in these areas, would be disproportionately affected by these proposals. Just to cite a few examples:

[2] Mardiguian, S., Stefanidou, M., et al. "Trends and key decision drivers for rejecting an orphan drug submission across five different HTA agencies." Value in Health Journal. 2014. https://www.valueinhealthjournal.com/article/S1098-3015(14)03070-8/fulltext

[3] https://www.kff.org/medicaid/issue-brief/recent-trends-in-medicaid-outpatient-prescription-drugs-and-spending/

- More than 55,000 of the approximately 100,000 sickle cell disease (SCD) patients (approximately 55 percent) in the U.S. are enrolled in Medicaid;[4]
- More than 55 percent of children with cystic fibrosis are enrolled in Medicaid[5]
- Medicaid is the primary payor for 44 percent of MPS II patients, and the secondary payor for an additional 20 percent of patients.[6]

In summary, we urge you to reject any proposals that would increase Medicaid rebate levels or institute socialist foreign reference pricing schemes for our U.S. healthcare system. Rather than penalizing innovative companies that develop treatments for vulnerable patients, we should work together to find ways to ensure the U.S. maintains its strategic leadership in biopharmaceutical innovation and American patients have access to the best treatments available.

Thank you for your consideration. Please contact CSBA Executive Director, Patrick Plues at pplues@bio.org with any questions.

Sincerely,

AR- BIOArkansas

AZ- Arizona Bioindustry Association

CA- Biocom California

CA- Southern California Biomedical Council

CA- California Life Sciences

CO- Colorado BioScience Association

CT- BioCT

DE- Delaware BioScience Association

FL- BioFlorida

GA- Georgia Life Sciences

IA- Iowa Biotechnology Association

IL- Illinois Biotechnology Innovation Organization (iBIO)

IN- Indiana Life Sciences Association

KS- AdAstra BIO

KY- Kentucky Life Sciences Council

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[4] Shondelle M. Wilson-Frederick, PhD et al, Office of Minority Health, HHS, *Prevalence of Sickle Cell Disease Among Medicaid Beneficiaries in 2012*, Data Highlight No. 16 (June 2019), https://www.cms.gov/About-CMS/Agency-information/OMH/Downloads/Data-Highlight-16-Sickle-Cell-Disease.pdf

[5] Mariam Hassan et al, *The Burden of Cystic Fibrosis in the Medicaid Population*, 10 ClinicoEconomics & Outcomes Research 423, 424 (2018) https://pmc.ncbi.nlm.nih.gov/articles/PMC6065469/pdf/ceor-10-423.pdf

[6] Therese Conner et al, *An online survey of burden of illness in families with mucopolysaccharidosis type II children in the United States*, 21 Molecular Genetics & Metabolism Rep. at 2, Table 1 (2019), https://pmc.ncbi.nlm.nih.gov/articles/PMC6722252/pdf/main.pdf

LA- Louisiana BIO

MA- MassBio

MD- Maryland Tech Council

MI- Michigan Biosciences Industry Association (MichBio)

MN- Medical Alley

MO- Missouri Biotechnology Association

MT- Montana Bioscience Alliance

NC- North Carolina Life Sciences Association

ND- Bioscience Association of North Dakota

NE- Bio Nebraska

NJ- BioNJ

NM- NMBio

NY- NewYorkBIO

OH- Ohio Life Sciences Association

OK- Life Science Oklahoma

OR- Oregon Bioscience Association

PR- Industry University Research center Inc dba INDUNIV

SC- SCbio

SD- South Dakota Biotech

TN- Life Science TN

TX- Texas Healthcare & Bioscience Institute

UT- BioUtah

VA- Virginia Biotechnology Association

WA- Life Science Washington

WI- BioForward Wisconsin

WV- Bioscience Association of West Virginia