December 8, 2025

The Honorable John Thune
Majority Leader
U.S. Senate
Washinton, D.C. 20510

The Honorable Chuck Schumer
Democratic Leader
U.S. Senate
Washington, D.C. 20510

The Honorable Mike Johnson
Speaker
U.S. House of Representatives
Washington, D.C. 20515

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

Dear Congressional Leaders:

On behalf of the Council of State Bioscience Associations (CSBA)—a national coalition of independent, state and territory-based organizations representing the full breadth of America's biotechnology ecosystem—we write to urge swift congressional action on three bipartisan, urgently needed policies that will strengthen the U.S. life sciences sector and improve patient access to affordable, life-changing therapies.

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]. Our member companies—many of them research-intensive, pre-revenue biotechnology innovators—are working every day to discover treatments and cures for diseases that currently have none. Their ability to continue taking scientific and financial risks depends heavily on clear, stable federal policy frameworks. Just as importantly, patients across the country depend on policymakers to ensure the affordability, accessibility, and timely development of new therapies.

Congress has a critical opportunity to advance reforms that directly help patients and promote the virtuous circle of biotech innovation. To support the ecosystem, we urge you to:

- Reauthorize the Rare Pediatric Disease Priority Review Voucher Program
- Extend the SBIR/STTR Programs
- Advance important PBM transparency reforms

[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

Reauthorize the Rare Pediatric Disease Priority Review Voucher Program
We strongly urge passage of the "*Mikaela Naylon Give Kids A Chance Act*" to ensure continuity of the FDA Rare Pediatric Disease Priority Review Voucher (RPD PRV) program. Nearly half of rare disease patients are children, yet therapeutic options remain extremely limited due to high development costs and small patient populations. The RPD PRV program has been one of the federal government's most effective tools for incentivizing the development of new pediatric rare disease therapies.

Since 2012, FDA has awarded 53 vouchers covering 39 rare pediatric diseases—36 of which previously had no approved treatments. These innovations have benefitted more than 200,000 vulnerable children. The program has enjoyed bipartisan support and has been successfully reauthorized twice. The successful PRV program, one that small biotech companies have incorporated into their financing strategies, and come to rely on since its inception, lapsed in December 2024. Without reauthorization, progress in drug development for children with rare diseases will slow and hope will diminish for families facing life-threatening rare conditions. We urge Congress to prevent any further interruption of this critical program.

Extend the SBIR/STTR Programs to Protect U.S. Innovation and Competitiveness
We also urge immediate action to extend the Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs which expired on September 30, 2025.

For more than four decades, SBIR and STTR have served as the largest and most reliable early-stage capital sources for R&D-intensive startups—particularly biotechnology companies working on high-risk, high-reward therapeutic innovations. Even a short lapse would have severe consequences for the nation's innovation capacity, undermining small business job creation, disrupting research pipelines, and delaying biomedical advances.

State governments recognize the high value of these programs: more than 28 states operate SBIR matching-grant initiatives that leverage federal funding and accelerate commercialization. Stability and continuation of SBIR/STTR are essential for maintaining U.S. leadership in biotechnology and ensuring that federal agencies and small businesses can plan effectively. Congress must extend the program immediately which will provide time to finalize a comprehensive reauthorization while protecting America's most productive early-stage innovation engine.

Advance PBM Transparency and Accountability Reforms
As Congress continues its work to improve health care access and affordability, we urge passage of comprehensive Pharmacy Benefit Manager (PBM) reforms. These reforms—agreed to by both chambers and nearly enacted last year—are overdue and urgently needed.

Three PBMs currently process almost 80% of prescription drug claims in the United States, creating a marketplace in which opaque contracting practices, spread pricing, rebate structures, and formulary design can drive up costs for patients and employers while limiting choice. For the tens of millions of Americans managing chronic or acute medical conditions, these practices translate into delays, denials, and unaffordable

out-of-pocket costs—even when employers already cover the majority of health care expenses.

The bipartisan package would take meaningful first steps toward restoring fairness and transparency by:

- Requiring full transparency into PBM practices, incentives, and financial arrangements;
- Banning spread pricing;
- Requiring 100% pass-through of rebates, fees, and discounts to plan sponsors and patients; and
- De-linking PBM compensation from drug prices.

These reforms would reduce perverse incentives, promote true market competition, and improve affordability for families nationwide. Congress came close to enacting these provisions last year; we urge you to finish that work now.

Across the country, biotechnology companies—large and small—are working to deliver the next generation of therapies, cures, and life-sustaining technologies. To succeed, they require federal policies that promote affordability, transparency, stability, and innovation. We urge Congress to swiftly pass these critical programs and deliver important reforms for patients and future biomedical innovation.

Thank you for your leadership and your continued commitment to advancing policies that support patients, strengthen American innovation, and maintain the United States' role as the global leader in biotechnology.

Sincerely,

AR - BIOArkansas
AZ - Arizona Bioindustry Association, Inc. (AZBio)
CA - Biocom California
CA - California Life Sciences
CA - SoCalBio
CO - Colorado BioScience Association
CT - BioCT
FL - BioFlorida
GA - Georgia Life Sciences
IA - Iowa Biotechnology Association
ID - Idaho Technology Council
IL - Illinois Biotechnology Innovation Organization, iBIO
IN - Indiana Life Sciences Association
KS - AdAstra Bio
KY - Kentucky Life Sciences Council
LA - Louisiana Bio
MA - MassBio
MD - Maryland Tech Council
MI - Michigan Biosciences Industry Association (MichBio)

MO - Missouri Biotechnology Association
MT - Montana Bioscience Alliance
NC - NCLifeSci
ND - Bioscience Association of North Dakota
NE - Bio Nebraska
NH – New Hampshire Life Sciences
NJ - BioNJ
NM - New Mexico Biotechnology & Biomedical Association
NV - Nevada Biotechnology & Health Science (NevBio)
NY - NewYorkBIO
OH - The Ohio Life Sciences Association
OK - Life Science Oklahoma
OR - Oregon Life Sciences
PA - Life Sciences PA
PR - INDUNIV Research Center, Inc./ BIO Puerto Rico
RI - RI Bio
SC - SCbio
SD - South Dakota Biotech
TN - Life Science TN
TX - Texas Healthcare & Bioscience Institute
TX - Texas Healthcare and Bioscience Institute
UT - BioUtah
VA - Virginia Biotechnology Association
WI - BioForward Wisconsin
WV - Bioscience Association of West Virginia