Biotechnology Innovation Organization
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February 9, 2026

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

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

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

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

Dear Mr. Thune, Mr. Schumer, Mr. Johnson, and Mr. Jeffries:

As President and CEO of the Biotechnology Innovation Organization (BIO), as a father and entrepreneur whose family is here today because of biotech innovation, and on behalf of the more than 1,000 innovative companies we represent, I write to express our significant concerns with the "Global Benchmark for Efficient Drug Pricing" (GLOBE) and "Guarding U.S. Medicare Against Rising Drug Costs" (GUARD) mandatory demonstration models recently released by the Center for Medicare and Medicaid Innovation (CMMI).

Though these "Most Favored Nation"-like models purport to make medicines more affordable for American patients – a worthy and necessary goal – the proposed demos will eviscerate the innovation pipeline and risk jeopardizing patient access to the next generation of medicines. **We respectfully implore Congress to urge CMS to rescind these models and to prevent any effort to codify Most Favored Nation policies into law.**

At a time when affordability is critical to Americans, we encourage you instead to pursue bipartisan legislative reforms to simplify the system and deliver more affordable medicines to patients without jeopardizing America's world-leading biotech industry and the millions of jobs and trillions in economic activity it supports.

Mandatory Demonstration Models & Their Impact
The GUARD and GLOBE mandatory demonstration models will upend many biotech companies and undermine America's biotech industry as a whole, especially threatening the small and mid-sized companies that develop over half of all new drugs. Many biotech innovators have only one or a small handful of products, while numerous others have only a single experimental therapy in development and bring in little to no revenue at all. This makes them especially reliant on private investment to survive.

The Real Story of the Biotech Innovation Revolution

The process of bringing a drug to market is fraught with risk and failure. As someone who has built multiple successful biotechs, I know that firsthand. Most experimental compounds never even make it out of the lab. Of the exceptionally promising ones that do enter clinical trials, nine in 10 fail to secure FDA approval. Developing a single new medicine often takes well over a decade and can cost north of $2B.

Unlike tech startups, which often achieve profitability in just two to three years, biotech profitability can take a decade or longer due to the lengthy, uncertain, and complex process for drug development and regulatory approval. In the meantime, entrepreneurs must scrap together funding to keep their efforts alive. Continued innovation depends on private investors willing to pursue high-risk research and a market that properly values their investment.

Blanket "Most Favored Nation"-style drug pricing policy would upend this risk-reward calculus. Importing the artificially low prices set by socialized health systems abroad through MFN-style proposals – be it in Medicare Part D, Part B, or Medicaid – would cut potential returns to a fraction of what is needed to justify sustained investment.

Particularly for small companies, many of which have less than a year of cash on hand, the GUARD and GLOBE demos – or codifying MFN pricing in any other way – would make it impossible to raise additional R&D funding and create a significant threat of insolvency. If MFN pricing had been in effect 25 years ago, I would not have been able to bring to market the enzyme therapy that has saved my children and countless others with Pompe disease.

The Engine of American Biotech Innovation Would Grind to a Halt Under MFN

The Trump Administration has wisely worked to negotiate agreements with some larger companies for portions of their product portfolios, exempting them from blanket MFN pricing. However, this one-off negotiating approach is ultimately unsustainable across the biotech industry. Small and mid-sized biotech firms lack the expansive drug portfolios to engage in similar negotiations, leaving them exposed to the significant financial risks of MFN policies such as GLOBE and GUARD. Further, due to the wide range of products these entrepreneurial companies offer and diseases they address, undermining their viability could have devastating consequences across the healthcare system, and American patients in both Medicaid and Medicare

If the GUARD and GLOBE models are implemented, small and mid-sized biotech firms will be forced to consider significant changes to their business – including cutting jobs, divesting medicines, or terminating research – that will adversely impact drug development. Patients will bear the ultimate cost.

European Prices Drove Innovation to the U.S. & The Impact on Patient Access

We have seen what happens when governments embrace price-setting schemes**.** In the 1970s, a handful of European countries accounted for 55% of newly developed medicines globally, while the United States accounted for just 31%. But as governments across Europe expanded various forms of direct and indirect price controls, fewer and fewer firms on the continent could justify risky research and development projects.

Between 2001 and 2010, the U.S. share of new drug approvals climbed to 57%, while France, Germany, Switzerland, and the United Kingdom collectively saw their share fall to 33%. In 2025, biopharmaceutical firms paused billions of dollars in investments in the UK because of untenable price controls – an issue only recently mitigated through the Trump Administration's negotiation of a U.S.-UK trade agreement.

Price controls exact an immense human toll, not just an economic one. European patients routinely wait years for treatments that Americans can access immediately. Sometimes, Europeans never gain access to these new therapies at all. Patients with chronic conditions, disabilities, and rare diseases are particularly vulnerable to these delays and denials – especially since many European health systems rely on discriminatory metrics such as the quality-adjusted life year (QALY), which often assign lower value to treatments for these kinds of conditions.

America's health care system is the global gold standard not only because it is so innovative, but because patients here have hope that patients in other places do not. There are better ways to improve affordability than copying foreign countries' flawed drug markets -- starting by simplifying the system to eliminate waste and abuse that inflates what American patients pay.

Simplify The System

We greatly appreciate the recent passage of bipartisan pharmacy benefit manager (PBM) reforms in the *Consolidated Appropriations Act of 2026* and urge Congress to go further to address the exploitative practices of middlemen. PBMs capture massive rebates from manufacturers while forcing patients to pay out-of-pocket for inflated list prices. PBMs push higher-cost drugs onto patients to maximize rebates and profits, even when less expensive, equally effective medicines are available.

Similarly, hospitals participating in the 340B Drug Pricing Program often pocket discounts rather than passing them to patients. Designed to help safety-net hospitals stretch limited resources and serve low-income patients, 340B has instead become a profit center for large hospital systems. A recent Senate Committee on Health, Education, Labor & Pensions (HELP) report documented how participating hospitals buy medicines at steep discounts, then charge patients full price and pocket the difference – without meaningfully expanding access to care. In 2024, drug purchases through the 340B program skyrocketed to $81.4 BILLION – more than Medicare Part D or Medicaid.

Additional PBM reforms in both Medicaid and the commercial market and restricting 340B eligibility to true safety-net hospitals would reduce patients' spending without destroying the broader biotech ecosystem that delivers lifesaving treatments to patients.

Trade Agreements Work
Finally, Congress should work with the Administration to address the global imbalance in drug pricing. Last fall, the Trump Administration made significant strides in combating foreign freeloading by negotiating a pharmaceutical trade agreement with the United Kingdom. Negotiating additional pharmaceutical-focused trade agreements to get other wealthy nations to contribute their fair share to drug development would reduce the burden on American patients to subsidize breakthroughs for the world.

BIO shares Congress and the Administration's goal of ensuring that patients can afford the medicines they need. However, blanket MFN policies such as the GLOBE and GUARD models would only deter investment, slow the development of new treatments, and ultimately deny patients access to the next generation of therapies. **We encourage Congress to advance policies that foster global support for innovation, rather than importing price controls that have proven to drive medical innovation away.** Together with smart reforms that benefit patients, we can ensure the United States remains the world leader in biomedical innovation.

We urge your support of policies to ensure the American innovation ecosystem remains at the forefront of medical discovery, and we stand ready to work with you to advance reforms that put American patients first.

Sincerely,

John F. Crowley
President and CEO
Biotechnology Innovation Organization (BIO)