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August 17, 2026

The Honorable Ron Wyden
Ranking Member
Senate Finance Committee
United States Senate
Washington, DC 20510

Members of the Drug Pricing Working Group
United States Senate
Washington, DC 20510

RE: Request for Information: Commonsense Policy Options to Lower Drug Prices for Patients

Dear Ranking Member Wyden and Members of the Drug Pricing Working Group:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to respond to the Senate Finance Committee Minority's Request for Information (RFI) on "Commonsense Policy Options to Lower Drug Prices for Patients". BIO shares the Committee's goal of ensuring that patients can afford and access the medicines prescribed by their healthcare providers. We welcome the Committee's focus on patient access and affordability and its examination of barriers that too often stand between patients and the therapies they need.

We have in front of us the opportunity not merely to make incremental changes, but to design a more forward-looking vision for the U.S. healthcare ecosystem that delivers both affordability and continues to lead the world in innovation. That principle guides BIO's response below.

The Biotechnology Innovation Organization (BIO) is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies, all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives.

Our members are advancing cell and gene therapies, precision medicines, and treatments for chronic and rare diseases that were unimaginable just a generation ago, helping to improve life expectancy and reduce disease. By helping people live longer, healthier lives, biopharmaceutical medicines deliver value that extends well beyond treating disease – contributing meaningfully to the nation's gains in longevity as just one example.[1]

[1] Frank R. Lichtenberg, The Effect of Pharmaceutical Innovation on Longevity, HEALTH ECON.& BIOECON. L. Rev. (2022), https://pubmed.ncbi.nlm.nih.gov/35344806/.

Yet too many patients cannot access the medicines their healthcare providers prescribe. Today, insurers, pharmacy benefit managers (PBMs), and other intermediaries have created a labyrinth of restrictions—including high cost-sharing requirements, utilization management restrictions, opaque rebate arrangements, and other administrative obstacles—that increase patient costs and delay their care.

At the same time, biotech innovation remains incredibly risky and difficult. Only about 10-12 percent of drugs entering human clinical trials ultimately reach patients [2], and the average cost of developing a new medicine now exceeds $2.6 billion. [3]

This is a pivotal moment for the United States. We are closer than ever to realizing a future in which medicines not only manage disease, but prevent illness, improve health, and provide cures. Sustaining America's world-leading biotechnology pipeline will require policymakers to ensure that policies intended to improve affordability strengthen, rather than weaken, the ecosystem that makes continued innovation possible.

BIO urges the Committee to pursue reforms that directly improve affordability and access for patients without importing foreign price-setting or imposing government price-setting policies that would reduce incentives for investment in new treatments. BIO strongly opposes price-setting approaches, including international reference pricing policies, which allow foreign governments and non-U.S. pricing systems to dictate the value of medicines in the United States. International reference pricing does not address the barriers patients face at the pharmacy counter. It does, however, jeopardize American patients' access to future treatments and cures.

Our more detailed comments follow, with summary highlights included at the beginning of each section.

Section I: Lowering Drug Prices

While BIO appreciates the Committee's focus on lowering costs for Americans, we are concerned with efforts that would expand government price-setting, including the Medicare Drug Price Negotiation Program (DPNP). **Alternatively, BIO welcomes the opportunity to work with the Committee on policies that will advance patient access to the medicines they need. Our recommendations flow from this overarching principle.** In summary:

- International reference pricing should not be included in the DPNP. The existing program – despite its significant faults – should remain grounded in

[2] Congressional Budget Office, Research and Development in the Pharmaceutical Industry, 5 (Apr. 8, 2021), https://www.cbo.gov/publication/57126.
[3] Deloitte, *Navigating the GLP-1 Boom: Measuring the Return from Pharmaceutical Innovation* (May 4, 2026), https://www.deloitte.com/us/en/Industries/life-sciences-health-care/perspectives/navigating-the-glp-boom.html.

U.S. market conditions and the quicker, more robust access we see here versus that in other countries.

- The DPNP should not be expanded. Within the next five years, 100 drugs in Medicare will already be subject to the DPNP. Further expansion of the program will only stifle drug development and severely limit the number of new drugs available to patients.

- Biologics and small molecule drugs should both have 13 years of protection from the DPNP. Shortening the protection period will undermine innovation and threaten U.S. leadership in biopharmaceutical development.

- Incentives to develop orphan drugs are essential to sustain and grow investment in this critical area of high, unmet need and must be preserved.

- Protections for small biotech companies from the DPNP should be extended to support small and emerging companies that drive early-stage innovation.

- Approaches that would re-base Medicare inflation penalties, expand inflation rebates to include MA units, or extend inflation rebates to the commercial market fail to address the high out-of-pocket costs patients face.

- A holistic consideration of a treatment's value to patients, families, and society should be the overarching principle when developing policies to provide sustainable access to novel, innovative, and transformative therapies.

Section 1: "Bolstering Medicare's Ability to Negotiate Lower Drug Prices"

BIO appreciates the Committee's commitment to lowering costs for patients. However, efforts to include misleading international pricing data, expand the number of drugs subject to negotiation, and shorten the timelines of the DPNP will severely impact patient access to treatments.

"Factoring International Pricing into Negotiation"

BIO Comment: BIO strongly opposes efforts to allow the Secretary to consider or implement international drug pricing data as a factor in any portion of the DPNP's negotiation process.

Importing international MFN pricing would not meaningfully lower what patients pay at the pharmacy counter. An analysis of the proposed Part B methodology found that only about 0.3% of fee-for-service beneficiaries would see any out-of-pocket change, because the large majority already hold supplemental coverage that offsets

Part B cost-sharing, even as manufacturers would face mandatory rebates on every eligible drug.[4]

It is additionally well established that importing arbitrary international government-set prices to the U.S. would have a deleterious impact on biotech innovation.[5] These effects have been and would be felt in long-term investment in biotech innovation and near-term ongoing investment decisions in current clinical research and development made by biopharmaceutical manufacturers.

BIO disagrees with the premise that drug price reductions will be absorbed by industry without adverse impacts to meaningful clinical innovation pipelines. Economic analysis repeatedly confirms this concern. A recent study by the University of Chicago evaluated the potential impact of Most Favored Nation (MFN) pricing on drug innovation and patient health by analyzing MFN pricing in Medicare and Medicaid. Researchers estimated that applying MFN standards to these markets, without assuming spillovers to others, would result in a nearly 48 percent reduction in U.S. R&D spending.[6] Over ten years, this trend is expected to cause the loss of 210 new drug approvals, 290 post-approval indications, and a total loss of 500 drugs.[7] This hit to innovation is associated with a loss of 516 million life years or 6.6 million lives lost globally.[8] Researchers also estimate manufacturers would limit their entry into countries with low prices to preserve U.S. prices.[9]

Beyond the risk that importing arbitrarily low, government-set prices would pose to biotech innovation, adopting such measures in the U.S. would specifically undercut U.S. leadership in the biotechnology sector, at a time when such leadership is already under threat by China.

The United Kingdom is an instructive example of how national policy decisions to artificially devalue innovation can impact national biotech innovation and investment. While the UK was once ranked just behind the U.S. as a global leader in biopharmaceutical research and life sciences, it has seen a marked decline in foreign direct investment into its life sciences sector in recent years, which industry analysts have attributed to an increasingly uncompetitive pricing and reimbursement environment. According to the Association of the British Pharmaceutical Industry, life sciences foreign direct investment into the UK was around 58 percent lower in 2023 than it was in 2017, and the UK's global ranking for life sciences investment fell from second place in 2017 and 2021 to seventh in

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[4] Avalere Health, *How MFN Pricing in Part B May Affect Beneficiary OOP Costs* (Jan. 21, 2026), https://advisory.avalerehealth.com/insights/how-mfn-pricing-in-part-b-may-affect-beneficiary-oop-costs
[5] Journal of Managed Care & Specialty Pharmacy (JMCP), International Reference Pricing of Pharmaceuticals in the United States: Implications for Potentially Curative Treatments (May 2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC10373031/#sec5
[6] The University of Chicago, The Impact on Patient Health of Most-Favored-Nation Pricing of Already Marketed Drugs (Sept. 29, 2025), https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2025/09/MFN-Impact-on-Patient-Health-Final-Sep-29.pdf
[7] Ibid.
[8] Ibid.
[9] Ibid.

2023.[10] This decline in investment has occurred alongside slowed growth in pharmaceutical R&D and a diminishing share of clinical trial activity in the UK, suggesting that pricing, access constraints, and relative reimbursement levels have begun to undermine the country's appeal as a location for innovative drug development (as well as early product launches).[11]

Further, BIO is concerned that incorporating foreign price data into the DPNP creates a false narrative and jeopardizes patient access to innovative medicines here in the U.S. Foreign prices are governed by price-setting that is frequently based on the use of the discriminatory quality-adjusted life years (QALYs). The federal government has recognized that QALYs are inherently discriminatory to patients with chronic disease and disability. In its November 2019 report on QALYs, the National Council on Disability (NCD) "found sufficient evidence of QALYs being discriminatory (or potentially discriminatory) to warrant concern."[12] It called on Congress to pass legislation prohibiting the use of QALYs in Medicare and Medicaid. In addition, it encouraged CMS to use alternative measurements of value when "the exact cost and benefits of a drug or treatment are not known."[13] Notably, Congress prohibited the use of QALYs as part of the IRA, and using foreign reference pricing in "Maximum Fair Price" (MFPs) would undermine congressional intent.[14]

The NCD report also notes that basing prices in the U.S. on foreign prices imports a discriminatory system and jeopardizes patient care.[15] Studies have shown that countries that use QALYs have severe restrictions on patient access to innovative medicines. For example, one study showed that between 2002 and 2014, 40 percent of medicines that treat rare diseases were rejected for coverage in the United Kingdom.[16]

An additional important consideration when considering importing foreign prices into the U.S. market is the prevalence of out-licensing agreements, particularly among small and mid-sized biotechnology companies. These agreements are often executed years before approval and serve as a critical financing mechanism that enables companies to fund clinical development and advance innovative therapies toward patients.[17]

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[10] Association of the British Pharmaceutical Industry (ABPI), *Creating the Conditions for Investment and Growth* (Sept. 10, 2025), https://www.abpi.org.uk/publications/creating-the-conditions-for-investment-and-growth/.
[11] Pharma Industry Says UK Pricing Revenue Unsustainable, Blocking Investments, *Reuters* (Mar. 20, 2025), https://www.reuters.com/business/healthcare-pharmaceuticals/pharma-industry-says-uk-pricing-revenue-unsustainable-blocking-investments-2025-03-20/.
[12] "Quality-Adjusted Life Years and the Devaluation of Life with Disability," National Council on Disability, November 6, 2019.
[13] Ibid.
[14] 42 U.S.C. § 1320f-3(e)(2)
[15] NCD, November 2019.
[16] 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/fulltex
[17] Eungdo Kim et al., *Factors Affecting Outbound Open Innovation Performance in Bio-Pharmaceutical Industry—Focus on Out-Licensing Deals*, 13 SUSTAINABILITY 4122 (2021), https://doi.org/10.3390/su13084122; *Kelchtermans et al., Do Licensors Learn from Out-Licensing? Empirical Evidence From the Pharmaceutical Industry*, 112 TECHNOVATION 102405 (2022), https://www.sciencedirect.com/science/article/abs/pii/S0166497221001863.

Out-licensing arrangements provide upfront capital in exchange for commercialization rights in foreign markets. As a result, the U.S. sponsor typically has little or no control over ex-U.S. pricing and, in many cases, limited visibility into those prices. This reality challenges the key assumption underlying international reference pricing policies -- that manufacturers can adjust prices across markets in response to U.S. pricing changes.

Where rights have been out-licensed, the connection between U.S. and ex-U.S. pricing may be highly attenuated or nonexistent. In such cases, policies that rely on international reference pricing may reduce revenues available to support future research and development without generating the corresponding changes in foreign market pricing that are central to the policy's rationale. Given the many emerging biotechnology companies that depend on out-licensing to finance innovation, this dynamic warrants careful consideration.

Beyond the implications for out-licensed products, incorporating these pricing metrics would have devastating impacts on access. A recent study found that patients in other countries have access to fewer than half the new medicines across major therapy areas and must wait almost three years for new medicines compared to three months for Americans.[18] Similarly, the European Federation of Pharmaceutical Industries and Association's Waiting to Access Innovative Therapies (WAIT) Indicator found that close to half of innovative medicines are not available to patients in Europe due to factors such as slow approval processes, misalignment on evidence requirements, and insufficient budgets.[19] In fact, the WAIT survey found it takes an average of 597 days from approval until a drug is available to patients in the European Union.[20] **Introducing international reference pricing into the DPNP's negotiation process will compound the already unprecedented uncertainty in pricing introduced by the IRA and perpetuate access issues for patients.**

"Negotiating Lower Prices on More Drugs" & "Delivering Lower Negotiated Drug Prices to Patients Faster"

BIO Comment: BIO opposes any expansion of the DPNP, including efforts to increase the number of drugs subject to the DPNP each year or by shortening the timeline for when drugs can be eligible for the DPNP. BIO believes it is misguided to expand the program while there has not been any demonstrable evidence of improving patient access. To ensure Medicare beneficiaries have access to innovative new medicines, the Committee should instead focus on ensuring that both small molecule

[18] Pharmaceutical Research and Manufacturers of America (PhRMA), Access to New Medicines Report (May 2026), https://cdn.aglty.io/phrma/Attachments/NewItems/PhRMA_OnePager_AccessToNewMedicinesReport_8.5x11_v3.2_Print%20(2)_20260512113247.pdf
[19] European Federation of Pharmaceutical Industries and Associations (EFPIA), EFPIA Patients W.A.I.T. Indicator 2025 Survey (2025), https://www.efpia.eu/media/mnfdwzax/efpia-patients-wait-indicator-2025.pdf
[20] Ibid.

drugs and biologics are not subject to the DPNP until 13 years post FDA approval. Shortening the timelines before drugs are subject to the DPNP will exacerbate the current crisis of innovation and assuredly threaten American leadership in biopharmaceutical development globally.

Studies indicate that the DPNP's MFPs have created unintended consequences that have been devastating for patient access to critical treatments. PBMs have responded to the MFP changes by increasing patient cost-sharing by raising copays, increasing coinsurance, moving medicines to higher-cost tiers, as well as excluding certain drugs from formularies altogether.[21] Pharmacies have also reported huge financial losses from stocking MFP drugs, with 60.4 percent of independent pharmacies considering not stocking one or more of the first 10 drugs listed in the DPNP.[22] It is clear that the DPNP's MFP is creating detrimental unintended consequences to patient affordability and access that would be exacerbated by expansion of the DPNP.

The negative impact of the IRA on the American biopharmaceutical innovation pipeline is already being felt. Following the passage of the IRA, the National Pharmaceutical Council found the average monthly number of industry-sponsored trials on post-approval drugs dropped by 38.4 percent.[23] **Research by IQVIA found that if the IRA's price-setting process had been in effect from 2000 to 2020, 33 percent of subsequent drug approvals for biologic therapies and 34 percent of subsequent drug approvals for small molecule therapies may not have been achieved.[24]**

To ensure Medicare beneficiaries have access to innovative new medicines, the Committee should instead focus on fixing the "pill penalty." Currently, the IRA subjects small molecule drugs to the DPNP nine years after FDA approval. The IRA should be amended by ensuring that small molecule drugs have the same time period of protection as that of biologics – 13 years. **The nine-year window is particularly harmful for oncological, cardiovascular, and neurological diseases like Alzheimer's, which are often developed as small molecule drugs**.

Breakthroughs in mental health treatments have come from small molecule drugs' ability to cross the blood-brain barrier and the central nervous system.[25] Their size also allows medicines to reach targets within cells, allowing them to be uniquely

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[21] Ibid.
[22] National Community Pharmacists Association (NCPA), *NCPA to CMS: A Third of Independent Pharmacies Won't Carry Drugs in the Negotiated Price Program, and 60 Percent More Are Considering Dropping Out* (Jan. 27, 2025), https://ncpa.org/newsroom/news-releases/2025/01/27/ncpa-cms-third-independent-pharmacies-wont-carry-drugs-negotiated.
[23] Zheng, Patterson & Campbell, *The Inflation Reduction Act and Drug Development: Potential Early Signals of Impact on Post-Approval Clinical Trials* (Apr. 22, 2025), https://pmc.ncbi.nlm.nih.gov/articles/PMC12181196/.
[24] IQVIA Institute for Human Data Science, *Proliferation of Innovation Over Time: Frequency, Timing and Clinical Value of Expansions Post-Initial Approval* (Feb. 18, 2025), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/proliferation-of-innovation-over-time.
[25] PhRMA, *Small Molecule Medicines: Why They're Vital for Patients* (May 3, 2023), https://cdn.aglty.io/phrma/global/resources/import/pdfs/CR-Small%20Molecule%20White%20Paper-v7.pdf.

suited for cancer treatments.[26] However, despite small molecules having unique abilities to treat disease that many large molecule treatments do not, analysis of certain clinical trial data has found that, following the IRA, small molecule oncology drugs are already experiencing a disproportionately greater reduction in post-approval clinical trial initiations, compared with biologic drugs.[27]

Small molecule medicines frequently gain their most meaningful clinical advances in the years following initial approval, as researchers identify new indications, optimize dosing, and expand the patient populations who benefit.[28] But the current reality of price-setting just nine years after approval truncates this critical window of continued scientific development. One study found that for the top 30 small molecule drugs in Medicare Part D, additional indications were approved 7.5 years on average after a drug's initial approval.[29] This means that many of the additional approvals came after the seven-year trigger when the government price-setting process begins under the IRA. Faced with this reality, companies have little incentive to complete ongoing research and support for additional indications post-approval.

Investment in small molecule medicines is critical to lowering costs and improving patient access because pills do not require frequent doctor visits or specialized administration like large molecule treatments. **This is particularly important for rural and low-income patients who may have less access to health care facilities and may be more likely to skip treatments due to distance**.[30] Health care-adjacent expenses, such as transportation and lost earnings from taking time off work for appointments, are lowered for the patient and the health care system when a patient is able to take a pill in their home.[31]

Before the IRA, the introduction of generics for small molecule drugs typically led to very significant savings in the market, which can bring down overall costs. The United States has lower prices for unbranded generics, which account for 90 percent of U.S. prescription drug volume, compared with comparison countries, whose prescription drug landscape is composed of only 41 percent generics.[32] When comparing U.S. and international drug prices, the University of Chicago found that if

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[26] Ibid.
[27] Zheng, Hanke et al., *Early Impact of the Inflation Reduction Act on Small Molecule vs. Biologic Post-Approval Oncology Trials*, National Pharmaceutical Council (Sept. 3, 2025), https://www.npcnow.org/resources/early-impact-inflation-reduction-act-small-molecule-vs-biologic-post-approval-oncology.
[28] Saranraj & Usha Kiran, *Drug Repurposing: Clinical Practices and Regulatory Pathways* (Sept. 10, 2024), https://pmc.ncbi.nlm.nih.gov/articles/PMC12048090/.
[29] The American Journal of Managed Care (AJMC), Unintended Consequences of the Inflation Reduction Act: Clinical Development Toward Subsequent Indications (May 13, 2024), https://www.ajmc.com/view/unintended-consequences-of-the-inflation-reduction-act-clinical-development-toward-subsequent-indications
[30] Journal of the American Board of Family Medicine (JABFM), Primary Medication Adherence in a Rural Population: The Role of the Patient-Physician Relationship and Satisfaction with Care (Sept. 2006), https://www.jabfm.org/content/19/5/478
[31] The American Journal of Managed Care (AJMC), Opportunity Costs of Ambulatory Medical Care in the United States (Aug. 18, 2015), https://www.ajmc.com/view/opportunity-costs-of-ambulatory-medical-care-in-the-united-states
[32] Andrew W. Mulcahy, Daniel Schwam & Susan L. Lovejoy, *International Prescription Drug Price Comparisons: Estimates Using 2022 Data* (2024), RAND Corporation, https://www.rand.org/pubs/research_reports/RRA788-3.html

generic drug prices, use, and penetration were factored in, the United States would have lower drug prices than other, similar nations.[33] **While patients in the U.S. receive access to the most cutting-edge medical innovation in the world, they also benefit from generic competition once patents have expired.**

However, due to this 9-13 distortion, many investors will choose to focus on biologics, robbing patients of important new treatments long-term. **To ensure Medicare beneficiaries have access to innovative new medicines, the Committee should ensure that both small molecule drugs and biologics are not subject to the DPNP until 13 years post FDA approval.**

"Eliminating Blockbuster Bailouts"

The recent expansion of the Orphan Drug Exclusion (ODE) has been critical in improving incentives to seek additional orphan designations and ensuring access to more treatments for rare diseases and conditions.

BIO also urges the Committee to structure orphan drug development incentives to ensure our healthcare system is maximizing the potential clinical benefit of each new medication and ensuring patients with rare diseases have the broadest possible access to effective treatments. With only five percent of the more than 10,000 rare diseases having an FDA-approved treatment, there is a significant need to protect incentives to research and develop medicines targeting rare conditions.[34]

Proposals to roll back protections for orphan drug development fundamentally misunderstand the history of orphan drug development and the current challenges faced by firms working on medicines for rare diseases. Congress passed the Orphan Drug Act of 1983 (ODA) to stimulate the development of drugs for rare diseases.[35] By definition, an orphan condition is one affecting fewer than 200,000 in the U.S.[36] Before its passage, only 38 rare disease medicines had ever been approved in the history of the FDA.[37] Since then, over 900 drugs have been approved for over 400 rare diseases.[38] However, commercial-stage rare disease companies are more financially at risk because they invest far more in R&D (40%) than non-orphan peer companies (17%).[39] The Orphan Drug Act provided significant incentives to allow

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[33] Tomas J. Philipson, Deyu Zhang, and Qi Zhao, *Policy Brief: International Price Differences for Drug Prescriptions* (June 7, 2025), https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2025/06/Policy-Brief-International-Price-Differences-for-Drug-Prescriptions-June-7.docx.pdf.
[34] National Pharmaceutical Council, *Early Signals of the IRA on Orphan Drugs*, Policy & Evidence Brief (May 2025).
[35] Department of Health and Human Services, Office of Inspector General, *The Orphan Drug Act: Implementation and Impact*, OEI-09-00-00380 (May 2001), https://oig.hhs.gov/oei/reports/oei-09-00-00380.pdf.
[36] U.S. Food and Drug Administration, *Rare Diseases at FDA*, https://www.fda.gov/patients/rare-diseases-fda.
[37] Peter Saltonstall, Heidi Ross, and Paul T. Kim, *The Orphan Drug Act at 40: Legislative Triumph and the Challenges of Success* (2024), https://onlinelibrary.wiley.com/doi/abs/10.1111/1468-0009.12680?domain=author&token=RF6SMYYYHYEXARBG3KFG.
[38] Ibid.
[39] Neal Masia, *Rare Disease Companies in the Public Markets: Challenging Performance Against a Backdrop of Policy Uncertainty* (Oct. 2023), https://www.rarecoalition.com/wp-content/uploads/Health-Capital-Group-White-Paper-FINAL-1.pdf.

companies to continue to invest in these complex diseases, despite the high capital and often limited initial returns required to do so.

However, researchers have raised concerns that the loss of incentives around orphan drugs could roll back this progress. Under the Inflation Reduction Act (IRA), orphan drugs are exempted from Medicare price-setting, but the original exemption was limited to only those drugs that treated a single rare disease. Accordingly, this disincentivized researchers and investors from pursuing costly follow-on research to find new orphan designations and approvals because, if their efforts proved successful, the drug would no longer be exempt from government price-setting. A study by the National Pharmaceutical Council compared a pre-IRA period (2020-2021) to a post-IRA period (2022-2023), finding that, **following the passage of the IRA, the percentage of drugs with a first orphan designation that later received a second designation decreased by 48 percent**.[40] Recognizing that this exemption was too narrow, H.R. 1 amended the IRA to ensure orphan drugs treating one or more rare diseases or conditions are excluded from Medicare price negotiations. The legislation further clarified that the countdown to eligibility for price negotiation would only begin when an orphan drug loses this exclusion.

BIO appreciates the Committee's interest in ensuring that orphan drug incentives remain appropriately targeted. However, we have concerns that the $400 million Medicare spending threshold proposed in the No Big Blockbuster Bailouts Act may not accurately distinguish between traditional blockbuster products and therapies that continue to serve only rare disease populations. In rare disease, aggregate Medicare spending can reach significant levels even when a therapy treats a relatively small number of patients, reflecting the substantial scientific, clinical, and manufacturing challenges associated with developing treatments for rare conditions. As a result, an exclusively orphan therapy could exceed the proposed threshold while continuing to serve only a limited number of patients with rare diseases. BIO is concerned that this approach could inadvertently weaken incentives to pursue additional rare disease indications and may undermine some of the benefits Congress recently reinforced through the ORPHAN Cures Act.

BIO strongly opposes repealing important protections recently passed into law that amend the IRA's ODE and incentivize critical follow-on investment into rare disease drug development. **Efforts by the Committee to expand the number of orphan drugs eligible for negotiation and revert the expansion of the ODE would directly contradict the intended purpose of the ODA**, which is to encourage the development of drugs for rare diseases or conditions, including by providing incentives in the form of extended market exclusivity.

In pursuit of supporting affordability and access to treatments for patients with rare diseases and cancers through the lens of IRA negotiations, BIO also urges the Committee to extend the Small Biotech Exception past 2028.

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[40] "Early Signals of the IRA on Orphan Drugs". National Pharmaceutical Council Policy & Evidence Brief. May 2025.

A large number of innovative therapies in the U.S. market today are the result of discovery and development efforts from small and mid-sized biotechnology companies. Specifically, research shows that 55 percent of new medicines approved by the FDA between 2011 and 2020 were developed by firms with less than $500 million in annual revenue and 45 percent were fully discovered by small companies without academic or government transfer of intellectual property.[41] It often takes many of these small companies twenty or more years to achieve profitability, as it can take some small companies over fifteen years to achieve regulatory approval of their first marketed medicine. When the IRA was passed by Congress there was widespread recognition that pricing policy changes can have a disproportionate impact on small biotechnology companies that may be heavily, if not entirely reliant, on the revenue from one or two marketed medicines to sustain operations and advance additional clinical development programs. This recognition led to the establishment of multiple protections for small manufacturers within the IRA—including the Small Biotech Exception. The IRA Small Biotech Exception provides for a drug's exemption from negotiation if the medicine is less than one percent of Medicare Part B or Part D expenditures and it represents at least 80 percent of a company's total Part B or Part D spending, as is common for many small, emerging companies pursuing the development of novel therapies to treat rare and orphan diseases. At that time, Congress rightfully recognized that major pricing policy changes could have a significant and disproportionate impact on manufacturers lacking a diversified portfolio, constraining their future growth and in some cases threatening those companies' existence as independent enterprises.

While we applaud Congress' recognition of the need to protect small biotechnology firms through this and other protections in the IRA, unfortunately, the IRA Small Biotech Exception is set to expire in 2028, a change that will leave many small firms exposed to a dramatic change in their revenue levels, impacting their continued growth as independent companies and potentially leading to significant consolidation in the biopharmaceutical industry overall. **To preserve the important work of the small biotech segment of the industry, BIO strongly urges the Committee to take immediate action to extend the Small Biotech Exception prior to its expiration—and to provide for the exemption's evolution in a way that will allow additional small biotech companies to qualify in the future.**

Similarly, since small companies make a significant contribution to the R&D ecosystem, we urge the Committee to not only extend the IRA Small Biotech Exception beyond 2028, but to also look at extending, evolving, and establishing other IRA small manufacturer protections going forward to help preserve small biotechnology companies' ability to continue to make meaningful independent contributions to patient health in the future. Maintaining a vibrant small and mid-sized segment of our domestic biotechnology industry is essential to both ensuring that American patients have sustained access to a broad array of innovative

[41] Vital Transformation, *The US Ecosystem for Medicines: How New Drug Innovations Get to Patients* (Dec. 2022), https://vitaltransformation.com/2022/12/the-us-ecosystem-for-medicines-how-new-drug-innovations-get-to-patients/.

medicines and also to ensuring that the U.S. can retain its global leadership role in biomedical innovation, recognizing that other countries like China are rapidly accelerating efforts to claim global dominance in this endeavor.

Patients deserve to have access to affordable treatments now without compromising future innovations to create even better and more widely used treatments. **BIO welcomes the opportunity to work with the Committee on efforts to improve patient affordability and access to lifesaving treatments through thoughtful amendments to the IRA and related statute.** The U.S. has the most robust innovation ecosystem in the world that allows patients to get first-round access to treatments for some of medicine's most complex diseases. Reliance on misguided pricing structures and benchmarks in the absence of appropriate protections for small and mid-sized manufacturers will only harm patients in the long-term and compromise this critical pipeline of new medicines, particularly for rare disease patients, cancer patients, and even patients with chronic diseases for which treatments are lacking.

Section 2: "Enhancing Manufacturer Accountability for Price Gouging"

BIO Comment: **BIO does not support approaches that would re-base Medicare inflation penalties, expand inflation rebates to include MA units, or extend inflation rebates to the commercial market. Instead, we encourage the Committee to focus on reforms that directly lower patient costs (see comments in section II).**

Re-basing would create a retroactive, unpredictable penalty – effectively resetting the benchmark after the fact and turning a defined inflation policy into an open-ended penalty.

Such an approach would undermine predictability and compound the cumulative pressure companies already face through the Medicare DPNP, Part D redesign liabilities, Medicaid rebates, and growing 340B obligations. For biotechnology companies—particularly small and emerging companies and those focused on cures for rare disease—stable rules are essential. Drug development requires long-term investment decisions made years before a medicine reaches patients. A retroactive and continuously shifting benchmark would make it harder to plan, raise capital, and sustain investment in high-risk research.

Of additional concern, including Medicare Advantage (MA) units in the Part B rebate calculation would expand rebate liability without guaranteeing beneficiary savings. Counting MA units would increase federal rebate collections but would not ensure that beneficiaries see lower cost sharing, lower premiums, or improved access in their individual MA plan. Additionally, extending inflation rebates beyond the traditional Medicare fee-for-service program would create significant operational and administrative challenges for CMS and MA organizations. MA encounter data systems were not designed to support the drug-level inflation rebate calculations currently used in fee-for-service Medicare, and incorporating MA utilization into

rebate determinations would require CMS to establish new data collection, validation, reconciliation, and invoicing processes. These efforts would likely be resource-intensive, difficult to implement, and could increase the risk of calculation errors or payment disputes, particularly given the timing constraints associated with rebate invoicing and true-up calculations. **Congress should focus on other policies to help beneficiaries with their access barriers for Part B drugs, including banning the use of step therapy for Part B drugs for enrollees in Medicare Advantage**. MA beneficiaries should not face more restrictive access standards than beneficiaries in traditional Medicare.

Finally, we oppose expanding inflation rebates to the commercial market, as it would create a new federal price-setting system for private coverage. Further, it would layer new federal rebate obligations on top of existing commercial rebates, discounts, and negotiated arrangements. Such an approach would also present substantial operational and data challenges. Unlike Medicare fee-for-service, there is no single source of commercial claims data that could be used to calculate inflation-based rebates across the commercial market. Any such system would likely require the aggregation of data from multiple heterogeneous sources, creating significant data standardization, validation, and reconciliation challenges.

As noted throughout our comments, we believe the Committee should focus on direct ways to help patients with the access and affordability barriers they face rather than imposing additional, arbitrary price-setting mechanisms with no patient benefit.

Section 3: "Potential New Payment Models for Prescription Drugs"

BIO applauds the Committee's willingness to investigate new and creative ways to pay for prescription drugs to create a more efficient innovation ecosystem and affordable landscape for patients.

"Subscription Models"

BIO comment: BIO encourages the Committee to look more broadly at potential solutions to advance tools that will encourage the development of innovative approaches to payment and will ensure access to emerging and future treatments.

As new innovations in treatment provide new opportunities for patients with high unmet medical needs, existing outdated methods of reimbursement for such treatments have presented challenges for patients. While the current system has proven useful in reimbursing services used by high volumes of patients with low variation in cost per case, **BIO strongly supports policies that enable manufacturers and payers to voluntarily develop innovative payment and reimbursement arrangements aimed at increasing patient access.** Above all, any solutions to enhance access to novel, innovative therapies put forward by the Committee should place the health and wellbeing of patients first to ensure that

patients quickly receive the clinically appropriate care necessary for their condition. Patient-centered solutions should prioritize patient access and empower patients to improve their health and enhance their lives with the most appropriate and effective course of treatment for each patient's given condition.

While progress is being made, certain legal and regulatory barriers have unfortunately constrained more widespread adoption. Our legacy payment systems that emphasize volume over value have made it difficult for medical innovation that better cares for patients to receive payments that reflect added costs and mitigate financial losses for providers. Value-based contracting in healthcare has historically faced regulatory barriers under the federal Anti-Kickback Statute (AKS), which broadly prohibits offering or receiving remuneration to induce referrals for items or services reimbursed by federal health care programs.[42] The traditional AKS is broadly worded, criminalizing financial incentives that do not fit standard fee-for-service models, creating compliance uncertainty for innovative contracts. Additionally, the Medicaid Best Price requirements and dated price-reporting regulations make manufacturers reluctant to offer innovative rebates or outcomes-based pricing guarantees, as deep discounts can inadvertently trigger severe "best price" penalty liabilities.

Lawmakers must make necessary reforms to ensure that payment systems appropriately reflect advances in technology and provide adequate coverage across sites of care. Voluntary value-based, outcomes-based, indication-based, and other alternative payment arrangements offer important tools to support patient access, improve affordability, and align payment with clinical value. However, these models are not one-size-fits-all, and the appropriateness of any particular approach will depend on the characteristics of the therapy, patient population, existing coverage pathways, and the nature and duration of treatment. Policy frameworks should therefore preserve flexibility for manufacturers and payers to determine whether and how a particular arrangement is appropriate while maintaining appropriate safeguards for patient access. Importantly, new payment approaches should expand opportunities for patient access without inadvertently disrupting existing insurance coverage or continuity of care for patients who already receive treatment through those benefits.

Voluntary innovative payment models can play an important role in supporting affordability and access for certain therapies and patient populations, particularly where traditional reimbursement structures may not adequately account for the nature or timing of a therapy's clinical benefit. This may be especially relevant for certain transformative therapies, such as cell-based therapies.

"Addressing launch prices"

BIO Comment: To provide sustainable access to novel, innovative, and transformative therapies, a holistic consideration of a treatment's value to patients,

[42] Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1)-(2).

families, and society should be the overarching principle. An overt focus on price, including launch prices, does not address the value that an innovative therapy can have for an individual patient, especially those without alternative treatment options. **A launch-price focused policy also ignores the societal impact innovative therapies can have**, including increased productivity and decreased overall health costs due to fewer hospitalizations, surgical interventions, physician office visits, and other interactions with the healthcare system.

Significant breakthroughs in medical technology could not exist without the intensive research and development needed to bring forth treatments. In recent years, innovative treatments, including cell and gene therapies, that are under development have entered the market in significant numbers, highlighting new opportunities to build upon research and spur innovation. However, these exciting advancements do not arise without challenges. The expected cost to bring a new drug to market is estimated to range from less than $1 billion to more than $2 billion.[43] This estimate factors in the high-risk versus high-failure rate of clinical trials, with a success rate of only 7.9 percent.[44] This risk is compounded by the lengthy development process, which often takes a decade or more.[45] The cost of treatments should reflect a balance between ensuring high value to the patient and overall health care system and manufacturers' R&D costs.

The rhetoric that pharmaceutical companies, particularly biotechnology companies, can recoup R&D costs quickly after launch is far from the truth. With nearly 90 percent of all drugs entering clinical trials failing to receive FDA approval, the biopharma sector invests a huge component of its revenue in R&D – 50 percent more than the next closest sector.[46] The conservative estimate holds that roughly 139 drugs in the next ten years may never be developed due to current government price negotiations.[47] **If the United States desires to continue to be a leader in biopharmaceutical innovation while keeping treatments affordable and accessible, the Committee must ensure the U.S. regulatory environment promotes investment, not inhibits it by preventing the opportunity for investments to be recouped and then reinvested into the pipeline.**

Section II: Enhancing Prescription Drug Affordability

BIO appreciates the Committee's focus on lowering patient out-of-pocket costs. For patients, affordability is defined as whether the medicine prescribed by their physician is available when they need it, and whether the cost at the pharmacy

[43] Congressional Budget Office. Research and Development in the Pharmaceutical Industry. April 2021.
[44] Kim, Eungdo, et al. Factors Affecting Success of New Drug Clinical Trials. Ther Innov Regul Sci. 57(4):737-750. May 2023.
[45] Congressional Budget Office (2021). Op. cit.
[46] Biotechnology Innovation Organization (BIO) & Vital Transformation, *IRA's Impact on the U.S. Biopharma Ecosystem* (June 1, 2023), https://www.bio.org/sites/default/files/2023-06/IRA%E2%80%99s%20Impact%20on%20the%20US%20Biopharma%20Ecosystem.pdf.
[47] Ibid.

counter is manageable. Patient affordability will not be fully addressed unless policymakers confront a rebate system in need of reform and address plan and PBM practices that often prevent negotiated savings from reaching patients directly.

To support lowering patient out-of-pocket costs and enhancing prescription drug affordability, here are some of the most significant policy recommendations highlighted throughout this section:

- Support automatic enrollment in the Medicare Prescription Payment Plan (MPPP) for eligible beneficiaries to increase uptake and help patients "smooth" monthly prescription drug costs.

- Build on PBM reforms in the CAA of 2026 and extend to other markets and ensure rebates and discounts benefit patients directly.

- Maintain ASP+6 reimbursement for Medicare Part B medicines to preserve patient access to physician-administered therapies in community-based settings.

- Strengthen beneficiary and provider appeals processes by simplifying appeals, improving denial notices, and ensuring timely resolution.

- Establish clear step therapy exemption standards for patients facing clinical risks, treatment failures, contraindications, or other circumstances where delays are inappropriate.

- Eliminate step therapy for Part B drugs in Medicare Advantage.

- Ban copay accumulator and maximizer programs so all forms of copay assistance count toward patient deductibles and out-of-pocket obligations.

- Prohibit alternative funding programs (AFPs) that divert insured patients to charitable assistance programs and create treatment delays or access barriers.

Together, the policies outlined in Section II will directly benefit patients and do more to promote drug affordability than price-setting.

Section 1: "Lowering Patient Out-of-Pocket Costs"

"Out-of-Pocket Costs"

BIO Comment: BIO has long supported policies that limit patient out-of-pocket exposure and help patients manage prescription drug costs over time. The Medicare Part D out-of-pocket cap and the Medicare Prescription Payment Plan (MPPP) are important patient protections that can improve affordability and continuity of care. Recent evidence suggests that the Part D cap has meaningfully improved access to

medicines, including increased use of innovative medications after the cap was established.[48]

The MPPP is an important payment option that helps patients manage their monthly out-of-pocket (OOP) costs and access the care they need. However, enrollment data suggests that only a small number of beneficiaries who are likely to benefit from the program have enrolled.[49] Accordingly, BIO believes more needs to be done to facilitate the successful implementation of the MPPP, inform beneficiaries of this new option, and facilitate the selection of the MPPP by those who may benefit from the program. **As such, BIO recommends that the Committee support amending the Inflation Reduction Act (IRA) to allow for autoenrollment for Medicare beneficiaries in the MPPP.** This should be paired with enhanced education and awareness about the program as well.

BIO encourages the Committee to build on these patient-centered affordability protections while avoiding disease- or drug-specific caps that could unintentionally distort clinical decision-making or create inequities across patient populations. A broad monthly or annual cap that applies across the benefit is preferable to policies that pick specific categories of medicines for special treatment. This approach recognizes the reality that medicine evolves quickly. New therapies enter the market at a rapid pace, and patients with serious conditions often need access to diverse treatments over the course of their care.

BIO also encourages the Committee to examine options to limit out-of-pocket costs for patients in Traditional Medicare who receive physician-administered medicines under Part B, particularly those without supplemental coverage. Any Part B affordability reform should be designed to reduce patient financial burden without undermining sufficient provider reimbursement or shifting treatment to higher-cost settings.

At the same time, BIO urges the Committee to recognize that out-of-pocket caps alone cannot make medicines more affordable to patients if plans and PBMs continue to expose patients to high deductibles, coinsurance based on list prices, restrictive formularies, and utilization management barriers. **The patient-centered goal should be straightforward: patients should directly benefit from drug costs based on their negotiated savings, and patients should not be asked to subsidize the system through high cost-sharing at the point of care, a theme that will be further explored in later sections.[50]**

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[48]IQVIA Institute, *U.S. Medicine Use Trends 2026* (Apr. 28, 2026), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/us-medicine-use-trends-2026; USC Leonard D. Schaeffer Center for Health Policy & Economics, *Shifting Cost-Sharing Burden to Beneficiaries in Medicare Part D* (June 2025), https://schaeffer.usc.edu/research/cost-sharing-burden-medicare-part-d/.

[49] Avalere Health, *Early Enrollment Data Indicates More Beneficiaries Could Benefit from MPPP* (Apr. 23, 2025), https://advisory.avalerehealth.com/insights/early-enrollment-data-indicates-more-beneficiaries-could-benefit-from-mppp.

[50]IQVIA Institute, *U.S. Medicine Use Trends 2026* (Apr. 28, 2026), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/us-medicine-use-trends-2026; USC Leonard D. Schaeffer Center for Health Policy & Economics, *Shifting Cost-Sharing Burden to Beneficiaries in Medicare Part D* (June 2025), https://schaeffer.usc.edu/research/cost-sharing-burden-medicare-part-d/.

"Improvements to Medicare Low-Income Assistance Programs"

BIO Comment: BIO supports efforts to improve affordability for low-income Medicare beneficiaries and encourages the Committee to consider policies that broaden access to the Part D Low-Income Subsidy program and simplify enrollment. Low-income patients are particularly vulnerable to treatment interruptions when out-of-pocket costs are unpredictable or unaffordable. More patients could get access to needed medicines by reducing administrative barriers to assistance and aligning eligibility rules across Medicare affordability programs.

"Distortions in Coinsurance & Deductibles"

BIO Comment: BIO appreciates the Committee's thoughtful examination of the factors that contribute to patient cost-sharing and prescription drug affordability. BIO shares the Committee's concern that patients often pay cost-sharing based on a price that does not reflect concessions, such as rebates or other discounts, negotiated after the point of sale. This is a central distortion in the prescription drug benefit. **Patients who need medicines should not be required to pay cost-sharing based on the undiscounted list price while PBMs, plans, or other intermediaries later receive rebates or fees that are not reflected in the patient's cost.**

BIO supports policies that ensure manufacturer rebates and other negotiated savings are used to lower patient out-of-pocket costs. The pharmacy benefit is unique because patients frequently pay cost-sharing based on an unnegotiated or list-price-based amount rather than the net price ultimately paid by the plan or PBM. This structure creates a "reverse insurance" dynamic in which patients with serious or chronic conditions who need medicines generate rebates that are used to subsidize premiums or other plan costs for the broader population, rather than reducing costs for the patients using the medicine.

The Committee is right to examine the increasing use of rebates as a percentage of overall drug spending in Medicare Part D and the shift from fixed copayments toward coinsurance. This trend is especially concerning because coinsurance exposes beneficiaries directly to list-price-based cost-sharing. One recent analysis found that standalone Part D plans' use of coinsurance for preferred branded drugs increased from 9.9 percent in 2020 to 71.9 percent in 2024.[51] Another study found that MA-PD average deductibles increased from $62 in 2024 to $224 in 2025, while the share of MA-PD enrollment in plans using coinsurance for preferred brand drugs rose from 2.6 percent to 27.5 percent.[52]

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[51]Erin Trish et al., *Cost Sharing for Preferred Branded Drugs in Medicare Part D*, 333 JAMA 1170-1172 (2025), https://jamanetwork.com/journals/jama/fullarticle/2830569.
[52]USC Leonard D. Schaeffer Center for Health Policy & Economics, Shifting Cost-Sharing Burden to Beneficiaries in Medicare Part D (June 2025), https://schaeffer.usc.edu/research/cost-sharing-burden-medicare-part-d/.

BIO supports policies that base patient cost-sharing on net price or otherwise ensure that negotiated savings are reflected at the point of sale. **In the absence of a comprehensive net price policy, the Committee should pursue oversight and program integrity safeguards to prevent PBMs and plans from penalizing manufacturers that lower list prices, including by excluding lower-list-price products from formularies, placing them on less favorable tiers, or subjecting them to additional utilization management requirements.** These dynamics undermine affordability, distort competition, and can leave patients paying more for the medicines their physicians prescribe.[53]

BIO also encourages the Committee to strengthen formulary oversight to ensure that lower-list-price medicines, biosimilars, and generics are not disadvantaged by incentives driven by intermediary extraction of value**. BIO has long supported a level playing field for biosimilars and innovator biologics, and believes formulary placement should be clinically appropriate, transparent, and designed to support patient access rather than maximize intermediary revenue.**

"Part D Market Impact"

BIO Comment: Enhancements to the Part D market ought to focus on improving accountability across the supply chain while ensuring that patients can access the medicines their providers determine are clinically appropriate. BIO believes that any evolutions to Part D should prioritize patient access to medications prescribed by their doctor. As such, BIO appreciates the Committee's recognition that efforts to lower patient out-of-pocket costs must be paired with careful attention to Part D market stability**. In particular, Congress should pursue policies that promote patient affordability while supporting a stable and competitive standalone Prescription Drug Plan (PDP) market**, especially as the Part D program continues to adjust to the significant changes made under the IRA.

BIO supports policies that preserve meaningful choice and ensure that Traditional Medicare remains a strong and reliable option for seniors and people with disabilities. At the same time, the Committee should be cautious about approaches that simply shift more liability onto manufacturers, particularly in the catastrophic phase, given the significant new liabilities already imposed under the IRA's Part D redesign and the effect those obligations can have on research and development of new medicines.

BIO urges the Committee to focus instead on plan and PBM accountability, bid oversight, transparency, and formulary protections. The Part D redesign already shifted substantial financial responsibility away from the federal government and

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[53]Federal Trade Commission, *Administrative Complaint, In the Matter of Caremark Rx, LLC, Express Scripts, Inc., and OptumRx, Inc.*, Docket No. 9437 (Sept. 20, 2024), https://www.ftc.gov/legal-library/browse/cases-proceedings/221-0114-caremark-rx-express-scripts-optumrx-matter; U.S. Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Apr. 9, 2019), https://www.finance.senate.gov/hearings/insulin-examining-the-factors-driving-the-rising-cost-of-a-century-old-drug.

toward plans and manufacturers. As plans continue to adjust to the redesigned benefit, recent analysis suggests that the market has experienced meaningful disruption. Avalere Health found that the standalone Prescription Drug Plan (PDP) market contracted further in 2026, with a 22 percent reduction in PDP options nationwide, while KFF has similarly documented shrinking plan availability and increasing enrollment concentration among a limited number of large plan sponsors.[54] Other analyses also indicate that Part D Market changes have contributed to market disruption, including plan exits, higher premiums, and greater enrollment concentration.[55] These trends underscore the need for careful oversight and stabilization policies that protect beneficiaries without compounding innovator manufacturer liability, given the economic realities of funding the cost of scientific research or otherwise weakening incentives for innovation.

Maintaining a stable Part D market will require policymakers to consider the financial pressures facing plans while protecting beneficiary access to care. With the administration's early termination of the Part D Premium Stabilization Demonstration, the Committee should consider establishing a durable stabilization mechanism that supports patient affordability and continued participation by standalone PDP sponsors.[56] CMS should also continue to monitor the implementation of the redesigned benefit and take steps to ensure that the changes do not create unintended consequences that harm beneficiaries through higher costs, reduced plan choice, or diminished access to needed medicines.

Further, BIO encourages the Committee to examine targeted reforms, stronger bid oversight, and improvements to risk adjustment and bid review. In particular, more accurate risk adjustment and enhanced CMS oversight of Part D bids could help ensure that plan payments better reflect the costs of covering higher-risk beneficiaries, reducing incentives for plans to respond to financial pressures through premium increases, market exits, narrower formularies, or more restrictive utilization management practices. Just as importantly, CMS should have the tools and authority necessary to prevent cost pressures from translating into restrictions on patient access to clinically appropriate medicines.

BIO opposes any expansion of manufacturer liability in the catastrophic phase, as there are other policy mechanisms that will truly stabilize the Part D Market. While manufacturers already shoulder significant responsibility under the redesigned benefit, many of the factors that shape patient access and affordability are driven by plan and PBM decisions, including formulary placement, utilization management, and benefit design. **A more patient-centered approach would focus on**

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[54] Avalere Health, *Part D Choices Continue to Shrink with Fewer PDPs in 2026* (Oct. 2, 2025), https://advisory.avalerehealth.com/insights/part-d-choices-continue-to-shrink-with-fewer-pdps-in-2026.; Juliette Cubanski & Anthony Damico, Kaiser Family Foundation, *Medicare Part D Enrollment, Premiums, and Cost Sharing in 2026* (June 11, 2026), https://www.kff.org/medicare/medicare-part-d-enrollment-premiums-and-cost-sharing-in-2026/.

[55] Health Affairs, *IRA Reforms To Medicare Part D Reinsurance Were Associated With Plan Exits And Higher Premiums, 2024-25* (July 7, 2026), https://www.healthaffairs.org/doi/10.1377/hlthaff.2025.01518.

[56] Centers for Medicare & Medicaid Services, Annual Release of Part D National Average Monthly Bid Amount and Other Part C & D Bid Information (July 28, 2026), https://www.cms.gov/files/document/july-28-2026-parts-c-d-announcement.pdf.

improving accountability of PBMs and other intermediaries while ensuring that patients can access the medicines their providers determine are clinically appropriate.

Section 2: "Addressing Perverse Dynamics in the Supply Chain"

BIO appreciates the Committee's interest in addressing inappropriate incentives in the prescription drug supply chain. For too long, PBMs and other intermediaries have operated with limited transparency and accountability while increasing the amount patients pay for their prescription drugs. BIO appreciates and applauds recent federal activity to reform PBMs, including the Consolidated Appropriations Act (CAA) of 2026[57], the Department of Labor's (DoL) proposed PBM disclosure rule[58], and the Centers for Medicare and Medicaid Services (CMS's) PBM compensation RFI[59]. Additionally, the Federal Trade Commission (FTC) publishing staff reports on PBM practices in July 2024[60] and January 2025[61], along with subsequent settlements with ESI and CVS, reflect growing recognition that PBM business practices raise costs, limit access, and undermine patient choice.

BIO supports reforms that make the prescription drug system work better for patients. That includes reducing incentives that can favor higher-cost medicines, ensuring that negotiated price concessions benefit patients, and addressing practices that may limit competition or influence treatment decisions without improving care. These reforms should apply consistently across markets to prevent PBMs from shifting revenue streams or restructuring business practices to evade regulation. BIO encourages the Committee to treat this work as the next phase of PBM reform. With the CAA, Congress has begun addressing rebate pass-through, transparency, and price-linked compensation, but additional reforms are needed to ensure PBMs return to their core role as administrators of the prescription drug benefit rather than financial intermediaries that profit from opacity.

To that end, BIO urges the Committee to focus on a set of key priorities, outlined in more detail throughout this section, to guide legislative PBM reform efforts:

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[57] Consolidated Appropriations Act, 2026, Pub. L. No. 119-75 (Feb. 3, 2026), https://www.govinfo.gov/app/details/PLAW-119publ75.
[58] Employee Benefits Security Administration, U.S. Department of Labor, *Improving Transparency Into Pharmacy Benefit Manager Fee Disclosure*, 91 Fed. Reg. 4348 (proposed Jan. 30, 2026), https://www.federalregister.gov/documents/2026/01/30/2026-01907/improving-transparency-into-pharmacy-benefit-manager-fee-disclosure.
[59] Centers for Medicare & Medicaid Services, Request for Information (RFI): Pharmacy Benefit Manager Compensation and Data Collection (June 18, 2026), https://www.federalregister.gov/documents/2026/06/18/2026-12344/request-for-information-rfi-pharmacy-benefit-manager-compensation-and-data-collection.
[60] Federal Trade Commission, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies*, Interim Staff Report (July 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf.
[61] Federal Trade Commission, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers* (Jan. 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

- Protecting patient choice and affordable and timely access to medicines, including preserving patient assistance programs;

- Reforming PBM compensation by requiring fees to be transparent, delinked from medicine prices and formulary placement, consistent with fair market value, and not contingent on business conducted with PBM affiliates;

- Refocusing PBMs on services that employers and plans actually need;

- Insulating clinical decision-making from rebate and fee incentives;

- Addressing vertical integration and associated value extraction enabled by self-dealing, including their ability to hide discounts in affiliated entities rather than lowering costs for patients, and restricting self-preferencing practices such as patient steering, differential reimbursement favoring affiliated pharmacies, specialty generic drug markups, spread pricing, and medical loss ratio (MLR) manipulation;[62]

- Expanding PBM transparency requirements needed to shine a light on, and hold PBMs accountable for, their abusive practices, including greater visibility into PBM fees, affiliated-entity transactions, pharmacy reimbursement practices, and the flow of rebates and discounts throughout the supply chain;

- Removing contractual barriers that prevent plans, employers, manufacturers, and patients from pursuing lower-cost options.

As the Committee considers PBM reforms writ large, BIO urges the Committee to design reforms that PBMs cannot circumvent. PBMs have repeatedly adapted their business models to preserve revenue when policymakers target a specific practice, including by shifting revenue generation activities from a scrutinized practice (e.g., rebate retention) to spread, administrative fees, data fees, GPO payments, private-label markups, post-adjudication pharmacy charges, and affiliate transfers.[63] **Reform should be functional rather than label-based: if an entity performs PBM-like services, receives PBM-related compensation, or benefits from PBM-controlled formulary, network, claims, or data decisions, it should then be subject to the same transparency, delinking, audit, anti-steering, and patient access standards.**

"Games & Abuses Due to Vertical Integration"

BIO Comment: BIO appreciates the Committee's focus on vertical integration across the prescription drug supply chain. The three largest PBMs are integrated with health plans, pharmacies, specialty pharmacies, rebate aggregators, and other

[62] Federal Trade Commission, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), https://www.ftc.gov/reports/pharmacy-benefit-managers-report.
[63] Nephron Research LLC, *Trends in Profitability and Compensation of PBMs and PBM Contracting Entities* (Sept. 18, 2023), https://nephronresearch.com/trends-in-profitability-and-compensation-of-pbms-and-pbm-contracting-entities/.

affiliated entities. Controlling 80 percent of all prescription volume, this gives these PBMs outsized influence over what medicines patients can access, what pharmacies patients may use, how formularies are designed, and where revenue is captured.[64] The FTC has found that consolidation and vertical integration allow the three large PBMs to exercise significant power over Americans' access to medicines and the prices they pay.[65]

BIO fully understands PBMs can play an important role in administering prescription drug benefits on behalf of employers, health plans, and other purchasers. Core PBM functions such as claims processing, pharmacy network administration, and drug price negotiation can help plans manage benefits efficiently and support patient access to needed medicines. BIO supports PBMs continuing to provide these core, essential services that sponsors and plans value. However, increasing vertical integration and consolidation have expanded the role of PBMs beyond these core administrative functions and created financial incentives that may not always align with the interests of patients or employers. **Congress should pursue reforms that preserve the legitimate services PBMs provide while refocusing them away from practices that maximize PBM profit at the expense of competition in the market or the benefit of patients and clients.**

Vertical integration has enabled outsized, anticompetitive market power that creates conflicts of interest when a PBM makes benefit design, formulary, network, or reimbursement decisions that financially benefit its affiliated entities. A vertically integrated PBM may have incentives to inappropriately steer patients to affiliated pharmacies, reimburse or offer contract terms to affiliated pharmacies that are more favorable than unaffiliated pharmacies, prefer products that generate higher rebates or margins, or route compensation through affiliated GPOs and rebate aggregators. **These practices—done under cloaks of opacity—restrict patient choice, limit competition, undermine independent pharmacies, and can ultimately raise costs for patients.**

BIO supports targeted reforms to address these conflicts. **The Committee should consider functional firewalls, anti-steering requirements, affiliate-neutrality standards, and data-use restrictions.** Moreover, PBMs should not be permitted to use claims, prescribing, pharmacy, or patient data obtained through benefit administration to steer patients or prescribers toward affiliated pharmacies or to advantage affiliated businesses. The Committee should also ensure that vertically integrated PBMs cannot leverage their ownership interests to distort pharmacy competition or patient choice.

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[64] Adam J. Fein, Ph.D., *The Top Pharmacy Benefit Managers of 2025: Market Share and Key Industry Developments* (Mar. 30, 2026), https://www.drugchannels.net/2026/03/the-top-pharmacy-benefit-managers-of.html.
[65]Federal Trade Commission, *Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies* (July 2024), https://www.ftc.gov/reports/pharmacy-benefit-managers-report; Federal Trade Commission, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers* (Jan. 2025), https://www.ftc.gov/reports/specialty-generic-drugs-growing-profit-center-vertically-integrated-pharmacy-benefit-managers.

More specific anti-steering safeguards are also needed. **PBMs should be prohibited from requiring or steering patients to use affiliated pharmacies when nonaffiliated in-network pharmacies are available.** Network and benefit design decisions should be based on objective cost, quality, safety, and access considerations rather than pharmacy ownership. PBMs also should apply the same contracting standards, participation criteria, reimbursement methodologies, and preferred-network opportunities to affiliated and nonaffiliated pharmacies. This includes retail, specialty, mail-order, delivery, and long-term care pharmacies. These protections would preserve patient choice while preventing vertically integrated PBMs from using network design to shift volume and revenue to their own corporate affiliates.

Vertical integration has also contributed to the consolidation of PBM functions that historically could be evaluated separately by plan sponsors. **BIO further recommends that Congress evaluate whether PBM services should be disaggregated so plan sponsors can separately select and audit the services they actually value, including claims processing and adjudication, drug price negotiation, and pharmacy network contracting.** Bundling these functions inside vertically integrated PBMs makes it harder for sponsors to understand true costs, compare vendors, and determine whether PBM decisions are improving patient affordability or simply preserving intermediary revenue.

Further, BIO also supports targeted structural reform of PBM-owned GPOs and rebate aggregators. These entities often serve as additional opaque contractual layers through which PBMs can flex even greater market power to extract rebates, administrative fees, and other compensation that can be routed without benefit to patients or the broader healthcare system. **BIO believes the Committee should prioritize divestiture or operational separation of PBM-owned "pharmacy GPOs" and rebate aggregators from PBMs. Unlike traditional healthcare GPOs, which aggregate purchasing volume to negotiate lower prices for providers, PBM-affiliated pharmacy GPOs primarily function as entities that negotiate and collect manufacturer fees, rebates, and other price concessions while reducing transparency for regulators, plan sponsors, and patients.** Any reforms should be carefully tailored to address these PBM-affiliated entities without disrupting legitimate provider-focused group purchasing organizations that help lower healthcare costs.

In addition, BIO supports consideration of pharmacy divestiture when paired with appropriate safeguards to protect patient access. Any effort to "break up" vertically integrated PBMs should serve to improve patient access, choice, and affordability for their prescription medication while creating more competition that allows independent pharmacies to operate on a level playing field. Unfortunately, due to abusive PBM practices, there has been a big drive in pharmacy closures over the past few years.[66] To address this disparity, BIO recommends pairing any structural separation requirement between pharmacies

[66] Rebecca Robbins, *Why Drugstores Are Closing Across America* (Oct. 19, 2024), https://www.nytimes.com/2024/10/19/business/drugstores-closing-pbm-pharmacy.html.

and PBMs with clear access guardrails, reasonable implementation timelines, as well as protections for patients using medicines that require specialized handling, storage, Risk Evaluation and Mitigation Strategies (REMS) compliance, patient support, or urgent shipment. Such safeguards should help ensure that divestiture does not inadvertently disrupt access for patients who rely on retail or specialty pharmacies for complex therapies.

Concerns about vertical integration also apply to PBM-owned private-label products. When PBM co-branding affiliates are involved in manufacturing, sourcing, marketing, or labeling arrangements, PBMs may have a financial incentive to favor those products through formulary placement, reimbursement policies, or network design. PBM private label drugs are discussed further in the section below.

With respect to the Committee's question about how CMS should consider margin for vertically integrated Part D sponsors, BIO supports requiring CMS to develop standards that account for margin accruing across affiliated entities, not merely margin reported at the plan sponsor level. If Medicare Part D subsidies are indirectly supporting inflated reimbursements to affiliated pharmacies or other internal transfers within a vertically integrated enterprise, CMS should have the data and authority necessary to identify and address those arrangements.[67] Such oversight should be paired with clear reporting requirements, audit rights, and safeguards to preserve patient access and pharmacy choice.

"PBM Private Label Drugs"

BIO Comment: BIO appreciates the Committee's examination of PBM-affiliated private label drugs. There are major risks to patients when PBMs own or control entities that label, price, license, or market generic or biosimilar medicines. BIO supports robust generic and biosimilar competition when it operates on a fair, transparent, and clinically appropriate basis. However, BIO is concerned that PBMs or their affiliates owning private label drugs can allow PBMs to self-preference their own products while harming competition. This allows them to capture margin that should instead benefit patients and payers. Further, systematic preferencing of PBM-affiliated biosimilars and other products threatens the competitive ecosystem by disincentivizing biosimilar manufacturers that are not contracted with PBMs from entering or staying in the market. If the three major PBMs that control 80% of the market each prefer their own private label biosimilar, there is little market share left for unaffiliated biosimilar manufacturers to compete.

Because these conflicts arise from common ownership and control backed by supra-competitive market shares, Congress should examine whether PBM-affiliated private label and co-branding entities should be prohibited from participating in Medicare Part D or otherwise divested from vertically integrated PBM conglomerates. PBMs should not simultaneously serve as formulary managers,

[67] Ed Silverman, State Audit of Medicaid Records Points to Methods Used by PBMs to Obscure Drug Costs (July 20, 2026), https://www.statnews.com/pharmalot/2026/07/20/iowa-medicaid-pbm-audit-circumvention-spread-pricing-ban/.

purchasing intermediaries, claims administrators, and manufacturers or marketers of products that directly compete for formulary placement and market share. Structural separation would reduce incentives for self-preferencing and help ensure that formulary and coverage decisions are made in the interest of patients, plan sponsors, and taxpayers rather than affiliated business lines.

BIO is concerned that PBMs may use their control over formularies, pharmacy networks, rebate contracting, claims adjudication, and patient steering to favor affiliated private label products regardless of whether those products offer the lowest net cost or best access for patients. When a PBM-affiliated private labeler can acquire a medicine at one price and charge a substantially higher price to plans, while also controlling formulary placement and pharmacy channel access, the risk of self-dealing is significant.[68]

If Congress does not pursue structural separation or ownership restrictions, this risk is especially acute where the same corporate enterprise can set the labeler's price, determine formulary status, control pharmacy channel access, and adjudicate claims. Congress should therefore require affiliate-neutral formulary standards for PBM private label drugs and should prohibit PBMs from excluding or disadvantaging clinically appropriate, lower-net-cost competing drugs.

BIO supports policies requiring PBMs to disclose any spread between a private labeler's acquisition cost and the prices charged to Part D plans, plan sponsors, and patients. BIO also encourages the Committee to consider cost-plus or acquisition-cost-based standards for PBM-owned private label drugs in Medicare Part D. This should be coupled with audit rights and regulator-facing reporting sufficient to detect self-preferencing and inflated markups. Any such policy should be carefully designed to prevent PBM abuse while preserving legitimate competition.

"PBM Gag Clauses"

BIO Comment: BIO appreciates the Committee's focus on PBM contract terms that restrict communication between relevant stakeholders, including plan sponsors or manufacturers. BIO has heard from its members about PBMs using their outsized market influence to enforce plan contract terms that may make the PBM the exclusive negotiator of drug pricing for a plan client, as well as manufacturer-PBM or manufacturer-GPO terms that may limit direct discussions between manufacturers and plans. These provisions limit competition across the marketplace and ultimately raise costs for all.

BIO supports regulating or prohibiting "exclusive negotiator," "non-solicitation," and similar gag clauses. This is especially necessary when

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[68]Federal Trade Commission, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers* (Jan. 2025); 46brooklyn, *How PBMs Can Use Private-Labelled Drug Products as a Great Escape from Anti-Steering Policies* (July 22, 2025); Adam J. Fein, *The Big Three PBMs' 2025 Formulary Exclusions: Humira, Stelara, Private Labels, and the Shaky Future for Pharmacy Biosimilars*, Drug Channels (Jan. 22, 2025).

they prevent plans, employers, or manufacturers from communicating about things such as pricing, value-based arrangements, or formulary alternatives. Congress has already recognized the harm caused by PBM gag clauses in the pharmacy context, including by prohibiting clauses that prevented pharmacists from informing patients about lower-cost options at the counter.[69] The same principle should apply more broadly: PBMs should not be able to use contract terms to block competition or prevent stakeholders from pursuing arrangements that could improve affordability and access.

At the same time, BIO recognizes that confidentiality may be appropriate for certain proprietary commercial terms. The goal should not be to eliminate legitimate confidentiality protections, but to prevent PBMs from using confidentiality as a shield for anticompetitive conduct or as a tool to preserve opaque revenue streams and other practices that effectively serve as an access barrier for patients.

A federal approach is particularly important because state PBM laws can face ERISA preemption questions when applied to self-funded employer plans. Congress should establish a uniform rule that prohibits PBMs and PBM-affiliated GPOs from using exclusive-negotiator, non-solicitation, nondisclosure, or similar provisions to prevent manufacturers, plans, employers, fiduciaries, auditors, or other appropriate parties from communicating about value-based arrangements, formulary alternatives, patient access, or lower-cost contracting options. Proprietary information can still be protected through tailored confidentiality standards.

"Increasing PBM Accountability for Rising Drug Costs"

BIO Comment: BIO agrees with the Committee that PBMs should be held more accountable, have meaningful incentives to manage drug spending, deliver lower costs for Medicare Part D plans, and deliver lower net costs for patients.

Beyond the points mentioned earlier in this section related to structural PBM policy reforms, **BIO supports shifting PBM accountability away from rebate maximization and toward measures that better reflect value for patients.** PBM performance should be evaluated based on net effective costs, patient affordability, access to medicines, and clinical appropriateness. PBMs should not be rewarded merely for generating larger rebates, especially if patients continue to face higher out-of-pocket costs.[70]

BIO also encourages the Committee to examine at-risk contracting models that hold PBMs financially accountable when the pharmacy trend exceeds reasonable expectations, provided such models are designed carefully to avoid creating perverse incentives to impose more restrictive utilization management or deny clinically appropriate care. **Any PBM accountability metric should be paired**

[69]Patient Right to Know Drug Prices Act, Pub. L. No. 115-263.
[70]Federal Trade Commission, *Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers* (Jan. 2025), https://www.ftc.gov/reports/specialty-generic-drugs-growing-profit-center-vertically-integrated-pharmacy-benefit-managers.

with patient access safeguards, transparency into formulary exclusions, utilization management, and reporting on denials, appeals, delays, and treatment abandonment.

"Pharmacy Dispensing Fees in Part D"

BIO Comment: BIO appreciates the Committee's recognition that pharmacy reimbursement can create unintended incentives throughout the supply chain. When pharmacies are undercompensated for the professional services associated with dispensing medicines, they may become more reliant on margins tied to ingredient costs or other spread-based revenue. This can contribute to higher costs and obscure the true cost of pharmacy services.

BIO supports transparent, predictable, and adequate pharmacy compensation that helps sustain patient access and reduces reliance on ingredient-cost spread. Any pharmacy compensation model should also reflect an absence of preference for an owned or affiliated pharmacy. These policies can also help preserve the retail, independent, specialty, long-term care, and other pharmacy channels that patients rely on. **BIO encourages the Committee to evaluate models that appropriately compensate pharmacies for services rendered while reducing incentives to generate revenue through inflated ingredient-cost reimbursement.**

Reasonable dispensing fees should be paired with affiliate-neutral reimbursement rules so PBMs cannot replace one spread-based revenue stream with another through differential treatment of affiliated pharmacies. At a minimum, PBMs should be required to disclose ingredient-cost reimbursement, dispensing fees, post-adjudication adjustments, and any pharmacy-facing fees in a manner that allows plan sponsors and regulators to compare affiliated and unaffiliated pharmacy compensation on an apples-to-apples basis.

"Addressing Price-Linked Compensation"

BIO Comment: BIO applauds Congress for taking meaningful bipartisan action in the Consolidated Appropriations Act of 2026 to prohibit PBM compensation from being tied to the price of a drug in Medicare Part D. **BIO recommends building on these reforms and applying similar principles across the commercial market.**

Delinking PBM compensation from drug price is a critical step toward addressing incentives that can lead PBMs to prefer higher-list-price products and extract fees or rebates in ways that do not benefit patients.

The Committee should aim to build on this progress by ensuring that the delinking policy is implemented robustly and cannot be evaded through affiliates, GPOs, rebate aggregators, data vendors, private labelers, or other entities operating under different corporate labels. BIO has encouraged CMS and the Department of Labor (DoL) to define PBMs, affiliates, and PBM services broadly enough to capture

entities that perform PBM functions or receive compensation connected to those functions, regardless of how those entities characterize themselves.

BIO is particularly concerned about PBM-owned GPOs and rebate aggregators, which may serve no patient-facing function while allowing compensation to be routed through separate entities that are difficult for outside stakeholders to evaluate. The Committee should ensure that price-linked compensation cannot continue simply because revenue is moved from the PBM to a different vertically integrated entity.

Congress should also anticipate that PBMs may respond to rebate and delinking reforms by increasing administrative, data, service, compliance, reconciliation, or other fees charged to manufacturers, pharmacies, plans, or affiliated entities. Those fees should be bona fide, fair-market-value payments for clearly defined services actually performed, not substitute revenue streams tied directly or indirectly to drug price, prescription volume, formulary placement, or patient steering. The Committee should require detailed reporting and audit rights sufficient to distinguish legitimate service fees from repackaged rebate, spread, GPO, or affiliate revenue. Unfortunately, BIO is concerned that PBMs are merely assessing new fees (e.g., ambiguous "data fees") to offset new requirements under the CAA and industry voluntary commitments. The reforms outlined in this response are necessary to ensure that PBMs are not burdening the healthcare system without providing value to warrant their high cost and the additional burdens they place on patients.

With respect to Medicare Part B reimbursement, BIO supports maintaining the ASP+6 methodology as a critical access protection for patients who depend on physician-administered therapies. ASP+6 helps ensure that smaller providers can administer complex therapies without being forced to refer patients to higher-cost hospital outpatient settings or discontinue offering certain treatments. The current methodology is essential in enabling the provision of drugs in outpatient centers of care and sustaining practice viability and patient access, particularly for smaller providers.

BIO notes that squaring support for PBM delinking with support for continuing ASP+6% in the outpatient setting means distinguishing between intermediary financial incentives and clinical practice overhead reimbursement. Critics of the ASP+6% reimbursement methodology for Medicare Part B drugs argue that a percentage-based add-on creates a financial incentive for providers to select higher-cost therapies over clinically equivalent lower-cost alternatives, since six percent of a larger acquisition cost yields a larger absolute payment. This critique conflates the existence of a percentage-based incentive with proof that the incentive dominates clinical decision-making, and the evidence does not support that conclusion. Physician-administered drugs in the buy-and-bill setting, unlike PBM-negotiated formulary placement, are prescribed under clinical protocols, payer prior authorization requirements, and increasingly under value-based and clinical pathway arrangements that constrain discretion far more tightly than a six percent margin can move. The 6% add-on was designed, and functions, as a proxy for the

real and variable costs of acquiring, storing, handling, and administering complex biologics and infused therapies, including products with short shelf lives, cold-chain requirements, and preparation waste that a flat fee cannot accurately capture across a heterogeneous product set. Moving to a flat-fee model for Part B drugs would undercompensate practices administering higher-cost, higher-complexity therapies relative to their actual overhead, accelerating consolidation of infusion services into hospital outpatient settings where reimbursement is materially higher, and reducing patient access to community-based and independent physician practice sites. The status quo formula is not without its critics, but the alternative solves an overstated problem by creating an understated one.

The case against percentage-based delinking in the PBM channel rests on a different footing entirely, because PBMs and administering providers occupy structurally different positions in the drug supply chain. A PBM does not take possession of, store, or administer a drug; it negotiates formulary placement and processes claims on behalf of a plan sponsor, and its percentage-of-price compensation is decoupled from any underlying cost of physical handling. Where ASP+6% ties payment to a documented, auditable cost basis, rebate- and spread-based PBM compensation ties payment to a number the PBM itself has significant leverage to inflate through formulary negotiation, creating an incentive to favor higher list-price products precisely because a larger percentage of a larger number benefits the intermediary rather than reimbursing a real cost. This is the incentive problem critics mistakenly locate in ASP+6%; it exists in the PBM channel in its purest, least justified form, because there is no offsetting overhead, storage, or clinical handling cost to legitimize it. Delinking PBM compensation from drug price, whether through flat administrative fees or other fixed-payment structures, removes a structural conflict of interest with no corresponding access or cost-recovery function lost, unlike a flat fee applied to provider reimbursement, which would strip away a legitimate proxy for real operational cost.

The distinction Congress should draw is not between percentage-based and flat-fee payment as a categorical matter, but between payment mechanisms that track a genuine, auditable cost function and those that do not. ASP+6% survives that test; PBM rebate and spread compensation does not.

"Inappropriate Pharmacy Rejections"

BIO Comment: BIO appreciates the Committee's attention to holding Part D plan sponsors and PBMs accountable for inappropriate pharmacy claim rejections, which are a direct and significant barrier to patient access. When a patient arrives at the pharmacy to fill a prescription their provider determined to be medically appropriate, a rejection can mean delay, confusion, abandonment, disease progression, and avoidable downstream health care utilization. These harms are particularly important for patients with serious conditions where timely treatment is critical.

BIO has repeatedly raised concerns that utilization management strategies such as prior authorization and step therapy can delay, disrupt, and prevent access to medically necessary prescription medicines.

Utilization management should be clinically appropriate, transparent, evidence-based, consistent with FDA labeling, and respectful of physician judgment. The data reinforces the urgency of this issue. The HHS Office of Inspector General found that Part D sponsors rejected millions of prescriptions at the pharmacy counter and that 73 percent of appealed rejections were overturned, suggesting that many rejected claims may have lacked sufficient clinical or programmatic justification.[71] In Medicare Advantage, KFF found that 80.7 percent of prior authorization denials were eventually overturned on appeal, but only 11.5 percent of denials were appealed at all, underscoring that many patients may never successfully navigate the appeals process even when a denial is ultimately reversible.[72]

The patient consequences of overaggressive utilization management are significant. **The American Medical Association found that 93 percent of physicians reported prior authorization caused care delays, 82 percent reported that prior authorization can lead to treatment abandonment, and nearly one-third reported that prior authorization had led to a serious adverse event for a patient.[73]** The Commonwealth Fund similarly found that among adults who experienced a prior authorization denial, 41 percent reported that the denial led to delayed care and 28 percent reported that a health problem worsened as a result.[74] These findings confirm that utilization management is not merely an administrative process. It can alter the course of care and lead to worse outcomes for patients.

Prescription drug-specific evidence points in the same direction. An IQVIA analysis found that more than half of Medicare Part D patients were initially denied coverage when attempting to fill a new prescription across five chronic therapeutic areas, with more than 70 percent of patients initially denied in four of the five areas analyzed. **Patients who ultimately overcame a rejection experienced average delays of 14 to 24 days, and some patients faced repeated rejections before gaining approval**. Most concerning, between 68 percent and 80 percent of patients who did not receive approval within a year for their originally prescribed medicine failed to initiate any new treatment in the same therapeutic area.[75] Another recent analysis found that nearly one-third of single-source branded

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[71]Suzanne Murrin, HHS Office of Inspector General, *Some Medicare Part D Beneficiaries Face Avoidable Extra Steps That Can Delay or Prevent Access to Prescribed Drugs* (Sept. 18, 2019), https://oig.hhs.gov/documents/evaluation/3141/OEI-09-16-00411-Complete%20Report.pdf.
[72]KFF, Medicare Advantage Insurers Made Nearly 53 Million Prior Authorization Determinations in 2024 (Jan. 2026), https://www.kff.org/medicare/issue-brief/medicare-advantage-insurers-made-nearly-53-million-prior-authorization-determinations-in-2024/.
[73]American Medical Association, *2024 AMA Prior Authorization Physician Survey* (2025), https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.
[74]Commonwealth Fund, *How Health Insurance Coverage Denials Affect Americans* (June 4, 2026), https://www.commonwealthfund.org/publications/surveys/2026/jun/how-health-insurance-coverage-denials-affect-americans-2025-affordability-survey.
[75]IQVIA Institute, *The Impact of Formulary Controls on Medicare Patients in Five Chronic Therapeutic Areas* (June 2025), https://www.iqvia.com/locations/united-states/library/white-papers/the-impact-of-formulary-controls-on-medicare-patients-in-five-chronic-therapeutic-areas.

prescriptions were rejected due to formulary exclusions or utilization management policies, and that many patients never received the intended medicine within 90 days.[76]

Step therapy raises similar concerns. BIO has previously explained that step therapy, often referred to as "fail first," can force patients to try one or more alternative therapies before they can access the treatment their provider prescribed. These policies are too often based on payer or PBM financial considerations rather than clinical appropriateness, and they can delay necessary treatment, lead to adverse health events, and increase overall health care spending. In a provider survey on Part B step therapy in Medicare Advantage, 94 percent of respondents said step therapy limits access to their preferred Part B treatments, 74 percent reported that step therapy protocols are not consistently based on established clinical guidelines, more than 60 percent described the burden on patients as high or extremely high, and 60 percent said patients often wait weeks to receive the originally prescribed therapy.[77]

BIO supports holding Part D plan sponsors and PBMs accountable for inappropriate pharmacy rejections. **The Committee should consider requiring greater transparency into rejection rates, reasons for rejection, appeal outcomes, time to resolution, repeated rejections, therapeutic area-level impacts, and whether patients ultimately initiate therapy.** Reporting should be detailed enough to identify plans or PBMs that disproportionately delay or deny access to clinically appropriate medicines.

BIO also supports incorporating patient access metrics into Medicare oversight tools, including potential Star Ratings measures or other accountability mechanisms related to inappropriate rejections. However, any metric should be carefully designed to avoid encouraging superficial compliance or gaming. The goal should be to measure whether patients actually receive clinically appropriate medicines in a timely manner, not merely whether plans process denials quickly.

The Committee should also strengthen beneficiary and provider appeal processes. Denials should include clear, specific, and actionable reasons; appeals should be simple and patient-friendly; plans should be required to assist beneficiaries and providers through the appeal process; and missed deadlines should result in automatic approval where appropriate. For step therapy, the Committee should ensure clear exceptions when a patient is stable on current therapy, has already failed a required therapy, faces risk of serious or irreversible harm, has a contraindication, or when the required step is inconsistent with FDA labeling or clinical guidelines. **BIO believes that policies such as those in the Safe Step Act (S. 2903) would go a long way to help beneficiaries.**

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[76]JAMA, *Formulary-Related Insurance Denials of Single-Source Branded Drugs in the United States* (July 9, 2026), https://jamanetwork.com/journals/jama/fullarticle/2851461.
[77]Avalere Health, *White Paper: Provider Survey on Part B Step Therapy in Medicare Advantage* (June 2025), https://advisory.avalerehealth.com/insights/white-paper-provider-survey-on-part-b-step-therapy-in-medicare-advantage.

BIO also urges Congress to strengthen clinical governance standards for formularies and utilization management. **PBMs should structurally separate clinical review from financial negotiations so that prior authorization, step therapy, formulary exclusions, and non-medical switching are not driven by rebate levels, affiliate margin, or GPO compensation.** Independent pharmacy and therapeutics processes should rely on clinical evidence, real-world outcomes, physician judgment, and patient-specific needs, with special attention to rare disease, oncology, cell and gene therapy, and other specialty medicines where delays or inappropriate switching can have serious consequences.

Furthermore, in the commercial market, PBMs use copay accumulators and maximizers, which prevent patients' third-party and charitable copay assistance from counting toward patient deductibles and out-of-pocket maximums. These programs harm patients by leaving them on the hook for their entire deductible or out-of-pocket maximum before they can access insurance benefits. Evidence from academic journals and other peer-reviewed studies shows these copay accumulators and maximizers are associated with reduced medication adherence, lower fill rates, and high risk of drug discontinuation or abandonment, consistent with evidence that sudden increases in out-of-pocket costs disrupt drug adherence and create financial strain.[78] **BIO encourages Congress to ban copay accumulators and maximizers to ensure that all forms of copay assistance count toward patients' out-of-pocket costs.**

Additionally, some PBMs and vendors in the commercial market are using so-called "alternative funding programs" (AFPs) that inappropriately tap charitable patient assistance programs for otherwise insured patients. AFPs inappropriately require insured, premium-paying patients to use charitable foundations, which is often an invasive and time-consuming process that requires the disclosure of financial and other information. AFPs can also lead to treatment delays and worsened health outcomes as patient assistance programs, charities, and foundations process applications and verify eligibility before assistance can be provided.
This all must occur while the patient waits for therapy. By contrast, a patient should be able to go to a pharmacy of their own choosing through their insurance and timely access needed therapy.[79]

Moreover, even as AFP create high hurdles for patients to access needed therapies, AFPs siphon resources from charitable foundations intended to benefit patients in need while the third-party vendor administering the AFP profiteers by taking a share of the "savings" accrued by improperly steering patients to patient assistance programs (PAPs). AFPs are also known to source prescriptions from unlicensed pharmacies outside of the United States.[80] **Given the discriminatory impacts**

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[78] Autumn D. Zuckerman, Megan P. Schneider & Stacie B. Dusetzina, "Health Insurer Strategies to Reduce Specialty Drug Spending: Copay Adjustment and Alternative Funding Programs," *JAMA Internal Medicine* 183, no. 7 (2023): 635-636, doi:10.1001/jamainternmed.2023.1829.
[79] William B. Wong et al., *A Descriptive Survey of Patient Experiences and Access to Specialty Medicines with Alternative Funding Programs*, *Journal of Managed Care & Specialty Pharmacy* (Oct. 29, 2024).
[80] Partnership for Safe Medicines, *Alternative Funding Programs: Offshoring Patients, Importing Risks*, https://www.safemedicines.org/2024/04/afps-offshoring-patients-importing-risks.html.

and significant harm that AFPs pose on patients, employer-sponsored coverage, and the healthcare system, BIO urges Congress to ban AFPs.

Finally, BIO urges the Committee to recognize that inappropriate pharmacy rejections are not merely administrative inconveniences. For patients, they can mean the difference between starting therapy and abandoning care altogether. Patient-centered affordability reform must therefore address both the amount a patient pays and whether the patient can actually obtain the medicine prescribed. Lower nominal cost-sharing is not meaningful if PBMs and plans retain the ability to block, delay, or redirect treatment for reasons unrelated to clinical appropriateness.

Section III: Bolstering Biopharmaceutical Innovation in the United States

Biopharmaceutical innovation has transformed the treatment of cancer, rare diseases, autoimmune disorders, infectious diseases, and countless other conditions affecting millions of Americans. Today, many diseases once considered life-threatening can now be managed as chronic conditions due in part to biopharmaceutical advancements. **Continued progress depends on a research ecosystem that supports scientific discovery, rewards risk-taking, and enables innovators to efficiently translate breakthrough science into therapies that reach patients.**

The United States remains the global leader in biomedical innovation, but that position should not be taken for granted. Other nations are making substantial investments designed to attract research activity, clinical trials, manufacturing, and capital. At the same time, drug development has become more expensive. As Congress considers ways to strengthen American competitiveness, policymakers should focus on creating an environment that allows scientific breakthroughs to move efficiently from laboratory discovery to patient care. **Patients benefit when the United States remains the best place in the world to discover, develop, manufacture, and commercialize new medicines.**

At a high level, BIO encourages the Committee to explore recommendations detailed in the Reagan-Udall report "Enhancing Early-Stage Drug Development in the United States". The full 18 recommendations outlined in that report were developed with thought-leader input, inclusive of FDA, and intended to ensure that the U.S. remains the preferred location for first-in-human studies, while preserving rigorous standards for patient safety and scientific integrity.[81]

More specifically, here is a summary of BIO's recommendations in Section III below:

- Continue to strengthen federal support for basic biomedical research through robust, predictable funding for NIH, academic research institutions, and

[81] Reagan-Udall Foundation for the FDA, *Enhancing Early-Stage Drug Development in the United States* (2026).

programs that advance foundational scientific discovery and help attract and retain world-class researchers.

- Expand investment in translational research by strengthening NIH, ARPA-H, and related initiatives that help bridge the "valley of death" between scientific discovery and clinical development.

- Create and scale biotechnology accelerators and commercialization programs that provide funding, infrastructure, technical expertise, and public-private collaboration to move promising discoveries from the laboratory toward patient-ready therapies.

- Increase incentives for high-risk science and emerging biotechnology companies through targeted funding, tax policies, and innovation programs that support early-stage development in areas of significant unmet medical need.

- Strengthen the U.S. clinical trial ecosystem by streamlining regulatory processes, expanding early-stage clinical trial capacity, reducing operational burdens, and improving patient participation and site activation.

- Invest in scientific talent development and recruitment through research training, workforce development, STEM education, and policies that help the United States attract, cultivate, and retain top scientific talent.

- Apply CHIPS and Science Act-style competitiveness policies to biotechnology by funding bioeconomy initiatives and incentivizing domestic biopharmaceutical manufacturing, contract development capacity, technology transfer, supply chain resilience, and U.S.-based investment to strengthen competitiveness against China.

Section 1: "Enhancing Investments in Drug Research and Development"

As the Committee understands well, federal support for biomedical research plays a foundational role in advancing medical innovation and improving patient outcomes. Federally funded research generates the scientific understanding that enables future drug development and creates the knowledge base upon which private-sector innovation depends.

"Basic Research"

BIO Comment: Basic research is particularly important because it often takes years, and sometimes decades, before scientific discoveries produce practical applications. Many of the therapies available today are rooted in research that began long before their eventual clinical development. **Public funding helps support areas characterized by scientific uncertainty, long timelines, and limited commercial incentives. Private investment often follows once the**

scientific foundation has been established, thereby turning novel concepts into actual medicines.

Federal support also strengthens the broader innovation ecosystem, especially for academia and smaller biotech innovators. NIH-funded research contributes not only to scientific discovery but also to workforce development, translational science, and the creation of new therapeutic opportunities that can attract private investment.[82] Stable and predictable funding helps ensure promising scientific work is able to continue, reduces uncertainty for research institutions, provides opportunities for biotechnology entrepreneurs, and strengthens America's long-term competitiveness in the life sciences.[83]

The United States has historically succeeded because of a public-private partnership model that combines strong federal investment in scientific research with a dynamic biotechnology sector capable of translating discovery into treatment. NIH supports the foundational scientific research that expands our understanding of biology and disease while biotechnology companies build on that foundation through the high-risk and resource-intensive process of developing, manufacturing, and delivering new medicines to patients. While both are necessary to deliver novel medicines, the risk and the extensive cost of later-stage research and development coupled with the significant cost of building world-class manufacturing make the private sector investment a powerful engine for the nation’s economy. These complementary roles have helped make the United States the global leader in biomedical innovation, creating not just medicines but high-quality jobs. Policies that support this partnership will help ensure that future breakthroughs continue to be discovered and developed in the United States.

“Translational Research”

BIO Comment: While the United States continues to produce world-class scientific discoveries, too many promising breakthroughs fail to advance from the laboratory into clinical development. Researchers often describe this challenge as the "valley of death," where scientific discoveries struggle to secure the expertise, infrastructure, and financing necessary to progress toward commercialization and patient use.[84]

The Committee should prioritize efforts that help bridge the gap between discovery and development. Translational science plays a critical role in moving innovations from the lab bench to the patient's bedside. Investments that improve translational research infrastructure can reduce development timelines. They also improve

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[82] Sandra Barbosu & Sarina Fereydooni, *How NIH-Funded Science Supports U.S. Biopharmaceutical Innovation*, Information Technology & Innovation Foundation (Dec. 15, 2025), https://itif.org/publications/2025/12/15/how-nih-funded-science-supports-us-biopharmaceutical-innovation/.
[83] National Cancer Institute, *How Gleevec Transformed Leukemia Treatment* (Apr. 11, 2018), https://www.cancer.gov/research/progress/discovery/gleevec.
[84] Maaike Everts & Mark Drew, *Successfully Navigating the Valley of Death: The Importance of Accelerators to Support Academic Drug Discovery and Development*, *Expert Opinion on Drug Discovery* 19, no. 2 (2024): 253-258, https://doi.org/10.1080/17460441.2023.2284824; Attila A. Seyhan, *Lost in Translation: The Valley of Death Across Preclinical and Clinical Divide*, *Translational Medicine Communications* 4, no. 18 (2019), https://doi.org/10.1186/s41231-019-0050-7.

capital efficiency and statistically increase the likelihood that promising therapies ultimately reach patients. **The Committee should prioritize translational mechanisms that are milestone-based, scientifically rigorous, and designed to leverage private, philanthropic, patient-organization, academic, and institutional investment.** Examples include proof-of-concept grants, translational matching programs, disease-focused research networks, biomarker and endpoint-development infrastructure, shared data platforms, and commercialization support for academic institutions.

Accelerator models should be defined broadly to include academic translational centers, nonprofit disease foundations, venture-backed incubators, public-private partnerships, therapeutic-development organizations, innovation hubs, and industry-sponsored collaboration platforms. The policy goal should be measurable progress toward patient benefit, not a narrow organizational form.

BIO supports expanding investment in translational research and strengthening programs that help move discoveries from bench to bedside. Translational science serves as the critical bridge between scientific discovery and clinical application. Investments in this area can improve development efficiency, reduce timelines, and increase the likelihood that promising scientific advances ultimately become therapies available to patients.[85]

The Committee should continue to explore opportunities to strengthen translational research infrastructure and support collaborative approaches that accelerate progress toward patients. **Investments that help overcome the barriers between scientific discovery and clinical development will improve patient outcomes while strengthening the United States' position as the global leader in biomedical innovation.**

BIO urges Congress to strengthen funding for both the NIH and the Advanced Research Projects Agency for Health (ARPA-H) as both agencies fund complementary basic, translational, and early-phase research in partnership with academia and industry. Their efforts drive an innovative research agenda that can help continue American competitiveness not just in the development of medicines but also in their manufacturing.

"Clinical Trials"

BIO Comment: Clinical development remains one of the most important determinants of whether scientific advances ultimately become therapies available to patients. Increasingly, however, sponsors are conducting more early-stage development activities outside the United States because of cost, complexity, and administrative burden.[86] This trend is concerning not only from a competitiveness standpoint but also because patients benefit when innovative research is conducted domestically.

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[85] Reagan-Udall Foundation for the FDA, *Enhancing Early-Stage Drug Development in the United States* (2026).
[86] Ibid.

The challenge facing the United States is not maintaining high standards. FDA remains the global gold standard for evaluating the safety and effectiveness of medical products. Rather, the challenge is ensuring that the American clinical development ecosystem is faster, more predictable, and more efficient while maintaining those standards.[87]

Drug development has become increasingly complex and expensive over time. Clinical trials have become more data-intensive and operationally challenging, yet overall clinical success rates have remained relatively stable. As a result, sponsors increasingly seek opportunities to conduct research in jurisdictions that offer greater cost and time efficiencies.[88]

Further, BIO supports efforts to modernize Investigational New Drug (IND) requirements and review processes. Existing requirements have evolved over time in ways that can increase complexity and create uncertainty for sponsors. Risk-proportionate approaches, better communication between sponsors and regulators, clearer expectations regarding required data, and more efficient review processes could reduce unnecessary delays while preserving patient protections.[89]

BIO also supports efforts to strengthen early-stage clinical trial infrastructure in the United States. Dedicated Phase I clinical trial capacity, streamlined site activation processes, expanded use of centralized review mechanisms, and stronger coordination among research sites could help reduce costs and shorten development timelines.[90] These reforms are particularly important for small biotechnology companies, which often operate with limited capital and must carefully manage development resources.

Congress should also clarify that reasonable reimbursement for costs associated with clinical-trial participation, including travel, lodging, meals, childcare, elder care, lost wages, technology, and internet access, does not violate Medicare, Medicaid, anti-kickback, or other program-integrity rules when appropriate safeguards are in place. Clear safe harbors or guidance would reduce financial barriers for patients while preserving protections against improper inducement. **A key way to support these efforts would be through passing the Clinical Trial Modernization Act (H.R. 3521 / S. 4440).**

Additional reforms should expand the number and diversity of U.S. trial sites, including community hospitals, integrated delivery networks, rural providers, physician practices, and health systems serving historically underrepresented populations. Broader use of single-IRB reliance, standardized contracting, harmonized administrative requirements, electronic consent, remote monitoring,

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[87] Biotechnology Innovation Organization, *Strategies for Enhancing FDA as Global Gold Standard* (Nov. 2025).
[88] Helen Dowden & Jamie Munro, *Trends in Clinical Success Rates and Therapeutic Focus*, *Nature Reviews Drug Discovery* 18, no. 7 (2019): 495-496, https://doi.org/10.1038/d41573-019-00074-z; Reagan-Udall Foundation for the FDA, *Enhancing Early-Stage Drug Development in the United States* (2026).
[89] Reagan-Udall Foundation for the FDA, *Enhancing Early-Stage Drug Development in the United States* (2026).
[90] Ibid.

telehealth-enabled participation, interoperable data systems, and appropriate use of real-world evidence can reduce start-up delays and improve evidence generation.

In addition, BIO recommends that the Committee prioritize policies that encourage greater use of modern clinical trial approaches. **Improved utilization of innovative trial designs, better incorporation of patient perspectives, expanded use of biomarkers and modern regulatory science tools, and improved FDA-sponsor engagement can make clinical development more efficient while maintaining scientific rigor.**

Furthermore, realizing the benefits of clinical trials in innovative treatments for rare diseases requires a strong innovation ecosystem capable of advancing promising discoveries into clinical development. Policies that improve capital formation, reduce unnecessary barriers to development, and strengthen the overall innovation ecosystem can help ensure that these companies continue serving as an important source of scientific progress and new therapies for patients. **To help bridge the gap between promising science and patient access, BIO supports biomedical accelerators, commercialization hubs, venture philanthropy initiatives, public-private translational research institutes, and similar collaborative models designed to help researchers advance promising discoveries toward commercialization.** These efforts can connect academic researchers, patient organizations, investors, biotechnology companies, and public partners in ways that reduce barriers to development and strengthen the innovation ecosystem.[91]

Federal policies can also help innovative companies make better use of the infrastructure, data, and expertise that already exist across the research ecosystem. **For many small and mid-sized biotech companies, building advanced laboratory space, manufacturing capacity, or clinical trial networks from scratch is simply not feasible.** Expanding access to federal laboratories and biobanks, along with regulatory science resources and clinical trial infrastructure, could help promising technologies move more efficiently from discovery to development. Clear, standardized partnership frameworks would make these collaborations easier to establish and scale.

Section 2: "Addressing Competition from China"

BIO appreciates the Committee taking threats to U.S. biotech leadership from the People's Republic of China ("China") seriously, as China has emerged as a major competitor in biotechnology innovation and clinical development. Through sustained investment in research infrastructure, manufacturing capacity, regulatory

[91] National Center for Advancing Translational Sciences, *Budget Overview* (Apr. 17, 2026), https://ncats.nih.gov/about/budget; Reagan-Udall Foundation for the FDA, *Enhancing Early-Stage Drug Development in the United States* (2026).

modernization, and talent development, China has significantly increased its role in the global life sciences ecosystem.[92]

"Boosting Domestic Clinical Trials"

BIO Comment: China has emerged as a major competitor in biotechnology innovation and clinical development. The challenge posed by China is not simply scientific. China increasingly competes on speed, operational efficiency, and development costs. In many cases, companies can initiate research activities more quickly and at lower cost than in the United States. These advantages have contributed to increasing clinical trial activity and investment flows abroad.[93]

The United States should respond by strengthening its own ecosystem. Across committees, Congress should focus on removing barriers that make research more difficult to conduct domestically. **Investments in clinical trial infrastructure, regulatory modernization, workforce development, and manufacturing capacity can make the United States more competitive while maintaining the scientific standards that distinguish FDA and the broader American system.**

America's advantage has always been its ability to innovate. **Policies that support innovation, accelerate development timelines, and strengthen domestic capabilities will do more to enhance U.S. leadership than efforts that simply seek to constrain competitors.**

One way the Committee can carry out this mission is by providing robust incentives for domestic R&D on orphan drugs. As such, BIO recommends that the Committee advance H.R.1414, Cameron's Law, which would fully restore the Orphan Drug Tax Credit (ODTC) from its post-Tax Cuts and Jobs Act (TCJA) rate of 25% back to its original pre-2017 level of 50% for qualified clinical testing expenses.

"Scientific Talent"

BIO Comment: The greatest strength of the American biotechnology ecosystem is its scientific workforce, led by the NIH and industry. Researchers, clinicians, entrepreneurs, engineers, and innovators drive the discoveries that ultimately improve patient outcomes and strengthen the nation's economy.

Maintaining U.S. leadership therefore requires continued investment in scientific talent. Research institutions, training programs, federal research funding, and opportunities for scientific advancement all contribute to the development of the next generation of innovators.

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[92] National Security Commission on Emerging Biotechnology, *Final Report* (2025).
[93] Anirudh Roy Popli et al., *The Emerging Epicenter: Asia's Role in Biopharma's Future*, McKinsey & Company (Jan. 7, 2026); IQVIA Institute, *Global R&D Trends 2026*.

Funding instability and administrative uncertainty can discourage researchers from entering or remaining in biomedical careers. Over time, these trends can weaken the talent pipeline that supports innovation and reduce America's ability to compete globally.[94]

The Committee should continue supporting policies that strengthen scientific education, research training, workforce development, and recruitment of top scientific talent.[95] Long-term leadership in biotechnology will depend on maintaining a workforce capable of advancing the next generation of scientific discoveries and medical breakthroughs.

Congress should invest across the full biomedical talent pipeline, from STEM education and undergraduate research to graduate training, postdoctoral support, physician-scientist pathways, early-career investigator awards, mid-career retention, and advanced technical workforce development. Expanded loan-repayment authority, bridge funding, biomedical research fellowships, and public-private training partnerships can help reduce the financial and career uncertainty that causes promising scientists to leave research careers.

Workforce policy should also anticipate emerging needs in artificial intelligence, machine learning, computational biology, genomics, precision medicine, advanced manufacturing, cell and gene therapy, digital health, regulatory science, and real-world evidence.

"Lessons from the Inflation Reduction Act and CHIPS and Science Act"

BIO Comment: The entire U.S. biotechnology ecosystem – including contract manufacturers and other service providers – is critical for American competitiveness in biotechnology and contributes to Americans having access to the most advanced medical therapies, supports high-quality American jobs, and drives exports for economic growth. Policy interventions informed by approaches in the CHIPS and Science Act for advancing domestic semiconductor manufacturing could help boost domestic biopharmaceutical innovation. Furthermore, the CHIPS and Science Act authorized many activities in the biosciences under *Title IV—Bioeconomy Research and Developmen*t; however, appropriations were not allocated to support those authorizations and the outlined National Engineering Biology Research and Development Initiative has not been implemented by Executive branch Departments and Agencies. Such an initiative would have broad impacts across different sectors of the bioeconomy, including in the human health sector, and would help the U.S. maintain an innovative science lead over international competitors like China. **The Committee has an opportunity to both propose helpful new policy measures to support domestic biopharmaceutical**

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[94] Max Kozlov et al., *U.S. Science After a Year of Trump*, *Nature* (Jan. 22, 2026); Aatish Bhatia et al., *The U.S. Is Funding Fewer Grants in Every Area of Science and Medicine*, *New York Times*.
[95] Jeremy Neufeld, *STEM Immigration Is Critical to American National Security*, Institute for Progress (Mar. 30, 2022), https://ifp.org/stem-immigration-is-critical-to-american-national-security/.

manufacturing and advocate for appropriations for and implementation of the *CHIPS and Science Act* biosciences provisions.

Biotech companies increasingly rely on contract manufacturers and other service providers as strategic partners that provide the physical infrastructure, expertise, and regulatory know-how needed to develop and manufacture complex therapies. Contract service providers support every stage of product lifecycle—from early research and clinical trials to commercial-scale production—allowing biotech firms to focus on innovation without having to build costly facilities or hire specialized staff. Their role is especially critical for small to mid-size companies that lack the resources to build and manage in-house manufacturing capabilities.

Growing and maintaining sufficient contract manufacturing capacity and expertise within the United States is essential to ensuring the rapid, reliable, and secure delivery of medicines to patients. We continue to hear from members, however, that limited capacity and capabilities among U.S.-based service providers constrain their manufacturing options. Strengthening domestic capacity alongside existing partnerships with manufacturers in allied nations would enhance supply chain resilience, flexibility, and patient access.

For many advanced therapies, including biologics, cell and gene therapies, and rare disease treatments, supply chains are highly complex and often require specialized handling, cold-chain logistics, and tight coordination between manufacturers, providers, and distributors. For other therapies, like radiological therapies, the half-life of the therapy necessitates proximal localization to the patient. **Locating manufacturing closer to patients can reduce logistical risks and improve the resilience of product delivery.**

Domestic manufacturing also generates substantial economic benefits for the United States. Biopharmaceutical manufacturing supports high-skilled, high-wage jobs, strengthens regional innovation clusters, and creates significant economic activity through suppliers and related industries across the country. **Industry analyses show that the biopharmaceutical sector and its supply chain contribute hundreds of billions of dollars in economic output and support millions of American jobs.**

Finally, expanding U.S.-based contract manufacturing capacity, coupled with partnerships with trusted allies and partners to complement existing domestic capacity, can reduce risks associated with a primary reliance on Chinese contract manufacturers. Manufacturing a biotechnology product requires sponsors to transfer detailed information, such as cell lines, production processes, analytical methods, and manufacturing know-how to their contract partner. This dependence creates potential business risks for U.S. innovators, including the loss or misappropriation of valuable intellectual property and proprietary manufacturing know-how. **It also has broader implications for the U.S. biotechnology ecosystem, as the transfer of technical expertise, workforce skills, and advanced manufacturing capabilities can accelerate the development of**

competing capabilities abroad and further strengthen China's position in strategically important sectors.

Over time, this process helps develop technical expertise, workforce capabilities, and manufacturing knowledge within the recipient ecosystem. In addition, heavy reliance on Chinese manufacturing capacity creates potential national security and supply chain vulnerabilities. Should geopolitical tensions escalate, China could restrict access to critical manufacturing services, materials, or supply chains for strategic or political reasons, potentially disrupting the development and production of medicines relied upon by American patients. A 2024 BIO survey found that 79% of respondent companies have at least one contract/product with a China-based or China-owned contract development or manufacturing partner, and that they will need up to eight years to switch manufacturing partners without additional government support.[96] **Such high utilization of China-based Contract Development and Manufacturing Organizations (CDMOs) by U.S. biotechnology companies presents potential threats to intellectual property and proprietary know-how, threatens to undermine U.S. biotechnology leadership by bolstering China's biotechnology ecosystem, and could jeopardize patient access if China chooses to leverage medical supply chains for political purposes.**

As service providers, contract manufacturers are not well positioned to quickly scale up without support. Infrastructure and supply chain investment, financial incentives, and workforce development programs are critical areas where government can assist. Success means American biotechnology companies choosing American -based contract manufacturers for developing new products and shifting existing product manufacturing back onshore, as available and complemented through partnership with trusted allies and partners versus strategic competitors.

The Committee should consider the following non-exhaustive menu of policy options for strengthening the U.S. contract manufacturing ecosystem, many of which mirror approaches in the CHIPS and Science Act for advancing domestic semiconductor manufacturing:

- *Incentivize transfer of life sciences technology to the U.S.* Incentives should be provided for biotech companies to choose U.S. contract manufacturers or move existing contract pipelines to the U.S.. **Incentives could include targeted tax credits for the incremental costs of transferring technology from one facility to another, access to other forms of capital, patent term extensions, additional exclusivity, federal procurement commitments, etc.** Technology transfers between facilities, including from international facilities to the U.S., require significant spend, such as on production batches, equipment upgrades, labor, validation, and

[96] Biotechnology Innovation Organization, *BIO survey reveals dependence on Chinese biomanufacturing, indicating up to 8 years needed to change partners* (9 May 2024); https://www.bio.org/bio-news/bio-survey-reveals-dependence-chinese-biomanufacturing

regulatory documentation. Incentives reduce barriers to commercialization, encourage U.S. domestic scaling, and derisk capital commitment from investors.

- *Launch translational programs for biotechnology that leverage government guarantees to attract private investment and reward technology adoption and innovative facilities.* **Expand government-backed grant and credit tool programs tailored to biotechnology manufacturing projects.** These could include structures like credit guarantees, flexible/convertible loan instruments, specialized mechanisms (e.g., U.S. International Development Finance Corporation (DFC)/Defense Production Act (DPA), etc.) Biomanufacturing requires significant upfront investment. Federal guarantees reduce capital costs, attract private investment, and accelerate growth in this strategic sector. Provide funding and tax incentives for adoption of advanced technologies (e.g., continuous processing, AI-driven quality systems) and support direct funding for pilot-scale (i.e., low production volume) facilities in emerging modalities such as cell and gene therapy or mRNA. Cutting-edge technologies and early-scale capacity are essential for efficient production and rapid translation of scientific breakthroughs. Public support builds resilience and positions the U.S. as a global leader.

- *Incentivize servicing low-volume contracts.* **Apply preferential tax rates for contract manufacturers serving low-volume contracts or orphan sponsors.** Implement accelerated depreciation for qualifying capital expenditures and expand interest deductibility for biotech infrastructure investments. These policies reduce cost barriers, improve cash flow, and make it financially attractive to prioritize smaller U.S. innovators while expanding domestic capacity.

- *Lower barriers to making capital-intensive investments.* Offer financial incentives, such as tax credits, targeted grants, or partial loan forgiveness for capital-intensive investment. These could include greenfield facility builds, buildouts of existing sites, purchasing of specialized equipment and upstream materials, etc. Greenfield builds, site expansions, and capital investments carry high upfront risk but deliver resilient, future-ready facilities. Incentives de-risk private investment and anchor long-term capacity in the U.S.

- *Encourage integrated end-to-end facilities.* **Explicitly reward fully integrated contract manufacturing campuses that bring end-to-end capabilities (from the creation of drug substance through to final drug product) under one roof.** Incentives may include preferential tax treatment and grants. End-to-end integration reduces friction, eliminates the need for tech transfer across multiple contract manufacturers, lowers regulatory burden, and strengthens supply chain security. End-to-end models speed time-to-market and increase U.S. competitiveness.

- *Ensure manufacturing equipment and raw materials are available.* Establish funding mechanisms and tax credits for upstream suppliers of critical

biotechnology equipment and materials, including raw inputs, prioritizing domestic production. **Reliable access to specialized equipment and inputs is essential. Domestic support reduces reliance on international vendors, secures U.S. supply chains, and ensures timely access to essential equipment.**

- *Prioritize long-lead equipment and materials.* Create a National Strategic Biomanufacturing Priority List for long-lead equipment and critical materials, with incentives for domestic sourcing and priority procurement under federal oversight. Key equipment often has 18–24 month lead times. Federal prioritization shortens timelines and strengthens long-term security.

- *Encourage public-private manufacturing clusters.* **Promote development of regional contract manufacturer-anchored biotechnology manufacturing clusters through incentives for shared infrastructure, workforce, and collaborative innovation.** Clusters lower capital burdens, foster collaboration, and strengthen regional economies through localized supplier networks and talent pools. They accelerate product development by providing shared access to advanced facilities, expertise, and supply chains.

- *Facilitate access to land and infrastructure.* **Work with state and local governments to offer land grants, infrastructure support, and site development incentives in underutilized industrial or economic development zones.** Subsidizing land and infrastructure attracts biotech investment, creates jobs, and revitalizes regions while aligning with national innovation goals.

Supporting contract manufacturers for biotechnology products is not just a strategic choice—it's a national imperative. A strong contract manufacturing ecosystem directly correlates to a strong biotechnology ecosystem—creating high-quality American jobs, driving exports that fuel economic growth, and securing our health supply chains to ensure that Americans have access to critical medicines when they need them.

Conclusion

BIO appreciates the Committee's efforts to ensure lower costs and improve access for patients. Prescription drug affordability and patient access are closely linked. Patients should be able to obtain the medicines they need at a cost they can afford, and meaningful progress will require policies that address the factors driving out-of-pocket costs and barriers to treatment.

However, for patients who rely on medicines to treat serious and life-threatening illnesses, affordability cannot be separated from access. **Policies that simply shift costs within the system without addressing PBM practices, utilization**

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management barriers, and rebate-driven distortions will fall short of delivering meaningful improvements for patients.

BIO urges the Committee to prioritize reforms that improve patient affordability while preserving access to medically necessary therapies and supporting continued United States leadership in biomedical innovation.

BIO looks forward to working with the Committee to advance patient-centered policies that improve affordability and strengthen access for patients. If you have any questions about our recommendations or would like to discuss anything further, please reach out to Lizzy Fox (lfox@bio.org).

Sincerely,

/s/

Joseph B. Franklin
Chief Legal and Policy Officer
Biotechnology Innovation Organization

/s/

Aiken Hackett
Executive Vice President, Federal Government Relations
Biotechnology Innovation Organization

CC:

The Honorable Catherine Cortez Masto
The Honorable Peter Welch
The Honorable Ruben Gallego
The Honorable Mark Kelley
The Honorable Tammy Baldwin
The Honorable Maggie Hassan
The Honorable Jeff Merkley
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The Honorable Tammy Duckworth
The Honorable Richard Blumenthal