MASSBIO

700 Technology Square, 5th Floor
Cambridge, MA 02139
617.674.5100 | massbio.org

February 23, 2026

Submitted electronically to Regulations.gov

Mehmet Oz, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-5545-P
P.O. Box 8013
Baltimore, MD 21244-8013

**RE: Global Benchmark for Efficient Drug Pricing (GLOBE) Model [CMS-5545-P]**

Dear Administrator Oz:

The Massachusetts Biotechnology Council ("MassBio") appreciates this opportunity to submit comments to the Centers for Medicare & Medicaid Services on the above-referenced proposed rule to implement price controls in Medicare, the GLOBE Model (referred to in this letter as "the Model").

MassBio represents the premier global life sciences and healthcare hub of Massachusetts, which has a vibrant biomedical research and development community that is a global leader for medical discovery and innovation. MassBio's 1,700+ member organizations are dedicated to preventing, treating, and curing diseases through transformative science and technology that brings value and hope to patients. MassBio's mission is to advance Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

While we support CMS's goals of increasing patient access and reducing foreign freeloading, we write to urge CMS not to move forward with the Model, which would significantly undermine incentives for lifesaving biotechnology innovation and potentially endanger patient access to future innovations without improving patients' ability to access medications. The Model also dramatically exceeds the statutory authority that the Center for Medicare and Medicaid Innovation (CMMI) has to test payment and service delivery models, using the guise of a "model" to import price controls that Congress has considered and declined to enact. Finally, the Model is most harmful in particular key areas of the biotechnology ecosystem, including smaller manufacturers, manufacturers that have out-licensing agreements in which they do not control sales or pricing of a product outside the United States, rare disease treatments, and cell and gene therapies.

We note that the concerns put forth in this letter do not cover the entire scope of potential policy and legal flaws that MassBio sees in the Model, but represent key reasons why CMS should withdraw the Model and instead work across stakeholders to identify alternative mechanisms to achieve the underlying policy aims through alternative means.

## I. The Model's Price Controls Will Undercut Patient Access and Biotechnology Innovation.

Introducing foreign pricing into the U.S. reimbursement system would bring to American patients all of the downsides that such pricing has produced in other countries: reduced patient access to medicines and reduced incentives to produce the next generation of cures.

It is well established that countries that adopt price control systems like those contemplated by the Model (which would rely on prices from such countries) have considerably slower and narrower access to pharmaceutical innovations than the United States. One analysis found that applying reference pricing across Medicare and Medicaid would reduce U.S. pharmaceutical revenues by 49 percent and global revenues by 31 percent, leading to a roughly 48 percent decline in R&D spending and, over a decade, about 210 fewer new drug approvals and approximately 500 total foregone approvals and new indications—while such a proposal would be broader than GLOBE, it reflects the well-documented, devastating impact that reference pricing can have on innovation.[1] Another analysis found similar effects on innovation from significant revenue reductions, projecting that a 10 percent decline in expected U.S. revenues leads to a 2.5 percent to 15 percent reduction in pharmaceutical innovation, including fewer clinical trials and new drug approvals.[2] When Congress considered legislation that would have limited pricing for prescription drugs to paying no more than 120 percent of what peer countries pay, the Congressional Budget Office projected that it would lead to fewer nearly 40 fewer medicines coming to market over the following decade because of reduced incentives for innovation.[3] An outside analysis of that legislative proposal found substantially larger impacts to innovation than the already significant impacts CBO estimated, projecting that 61 fewer medicines would have come to market in the prior decade under the legislation among small and emerging biotech firms, roughly a 90 percent reduction.[4]

The implications for patient access from adopting foreign pricing are also clear: A 2025 analysis found that 110 new medicines that launched in the U.S. since 2020 are not available in Europe.[5] These deficits in access are prominent in areas where there has been particularly promising innovation and where innovation is needed most, too: A recent IQVIA report found that 38 percent of new oncology drugs launched in the United States are not yet available in Europe,[6] and access to cell and gene therapies has also been slower and more limited in Europe than the United States.[7] Worse, the new and unpredictable reimbursement cuts contemplated by the Model would come at a time when pharmaceutical reimbursement is already under pressure in the United States, with pharmaceutical CEOs and industry analysts noting that the pricing provisions of the Inflation Reduction Act has already led companies not to pursue specific investments.[8]

The United States continues to lead the world in biopharmaceutical innovation, providing not just fuel for our economy but also an asset to our national security. But new rivals—particularly China—have been gaining ground

---

[1] University of Chicago Initiative on Enabling Choice and Competition in Healthcare, *Policy Brief: The Impact on Patient Health of Most-Favored-Nation Pricing of Already Marketed Drugs* (Sept. 29, 2025), https://ecchc.economics.uchicago.edu/2025/09/29/policy-brief-the-impact-on-patient-health-of-most-favored-nation-pricing-of-already-marketed-drugs/.

[2] USC Schaeffer Center, *The Elasticity of Pharmaceutical Innovation: How Much Does Revenue Drive New Drug Development?* (Feb. 2025), https://schaeffer.usc.edu/research/the-elasticity-of-pharmaceutical-innovation-how-much-does-revenue-drive-new-drug-development/

[3] Congressional Budget Office & Joint Comm. on Taxation, *Letter to the Honorable Frank Pallone Jr., Chairman, Committee on Energy and Commerce, U.S. House of Representatives: Effects of Drug Price Negotiation Stemming from Title I of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare* (Oct. 11, 2019), available at https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf.

[4] Vital Transformation, *H.R. 3 and Reference Pricing: Total Market Impact* (Mar. 22, 2021), https://vitaltransformation.com/wp-content/uploads/2021/04/HR3_4.5.21_v10.1.pdf.

[5] Biotechnology Innovation Organization (BIO), *Putting Americans First: No Medicine Is More Expensive Than the One Patients Can't Access* (Sept. 12, 2025), https://bio.news/bios-view/putting-americans-first-no-medicine-is-more-expensive-than-the-one-patients-cant-access/.

[6] IQVIA Institute for Human Data Science, *Global Oncology Trends 2024: Outlook to 2028* (May 28, 2024), available at https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-oncology-trends-2024.

[7] Ctr. for Evidence-Based Value & Access Research (CEVR), *Variation in Market Access Decisions for Cell and Gene Therapies Across the United States, Canada, and Europe* (2025), available at https://cevr.tuftsmedicalcenter.org/publications/variation-in-market-access-decisions-for-cell-and-gene-therapies-across-the-united-states-canada-and-europe.

[8] *Drug Price Controls Mean Fewer Cures*, *Wall St. J.* (Aug. 14, 2024), https://www.wsj.com/opinion/inflation-reduction-act-drug-price-controls-james-foster-charles-river-laboratories-joe-biden-kamala-harris-0e3af291

in recent years,[9] and industry observers have noted that the Model would reduce U.S. competitiveness and hand an advantage to such competitors.[10] In order to sustain U.S. leadership in biotechnology, the federal government needs to be taking steps to support and protect the U.S. biotechnology economy, not introducing new uncertainty. The uncertainty of the Model would be particularly damaging given the diverse nature of the biotechnology economy in the U.S., exemplified here in Massachusetts, ranging from small firms researching pre-clinical or investigational drugs, to much larger manufacturers with which these smaller companies typically partner to commercialize their innovative products. No other country has such a dynamic, diverse biotechnology economy, and CMS should be considering ways to protect this leadership, rather than undermine it.

## II. The Proposed Model Exceeds CMMI's Statutory Authority and Would Not Benefit Patient Care.

Beyond the significant damage the Model would do to biotechnology innovation and patient access, its attempt to create an international reference pricing system is also not within CMS' authority. CMMI's authorizing statute, section 1115A of the Social Security Act (42 U.S.C. 1315a), allows CMMI only to "to test innovative payment and service delivery models to reduce program expenditures," with such models necessarily "address[ing] a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." While CMMI is authorized to waive requirements of the Medicare statute, such waivers are permitted only "as necessary solely for purposes of" implementing a legitimate model test.

The Model is not a valid use of this authority because it is not a genuine "test" of the effect of a policy on expenditures and quality, does not address a defined population with deficits in care, and uses CMMI's waiver authority solely to establish an otherwise impermissible rebate rather than as necessary to test a true payment and service delivery model.

The Model is not a "test." Instead, it consists entirely in a post hoc manufacturer rebate, without altering provider incentives, or reforming care delivery in any discernible way. As a result, there is little reason to expect observable changes in clinical behavior or patient outcomes that could be meaningfully evaluated, and the effect on program spending is essentially a predictable result of arithmetic. A policy that simply mandates reduced net federal outlays through a greater rebate does not constitute a model "test" within the meaning of section 1115A.

The Model also does not address a defined beneficiary population with identified deficits of care. CMS describes the relevant beneficiary population as anyone who receives a drug subject to the Model. But prescription drug utilization is inherently dynamic and does not identify a stable or clinically coherent group of patients that could reasonable be considered "defined." Moreover, CMS has identified the potential deficits of care from the existence of high drug spending by Medicare. That is, instead of identifying shortcomings in care that drive poor outcomes or unnecessary spending, as the statute requires, CMS has simply inferred care deficits from federal spending levels alone, which are not necessarily even reflective of patient costs.

The Model also does nothing to address any deficits in care that the Medicare population faces. It is widely acknowledged, as CMS points out, that high cost-sharing can represent a barrier to care, and MassBio supports efforts to reduce cost-sharing so that patients can afford the medicines they need. In general, there are undoubtedly significant deficits in care in the Medicare population, some related to access to and adherence to medications. Many patients who need access to innovative medications—patients with serious mental illness or other serious conditions—often struggle with access to the therapy that works best for them and then maintain

---

[9] *See, e.g.,* Nicola Grassano et al., Exploring the Global Landscape of Biotech Innovation: Preliminary Insights from Patent Analysis, JRC Research Report JRC137266, Publications Office of the European Union (Mar. 20, 2024), https://publications.jrc.ec.europa.eu/repository/handle/JRC137266 ("The US are by far the country with the highest share of biotech patents, the EU is lagging behind (with an increasing gap with the US) , while China seem to have started catching up with the EU").

[10] *Trump Gives a Boost to China's Biotech Companies*, Wall St. J. (Dec. 31, 2025), https://www.wsj.com/opinion/donald-trump-drug-price-controls-most-favored-nation-cms-joe-biden-ed43a287.

adherence.[11] Access barriers that prevent patients from initiating or staying on guideline-directed therapy, such as formulary restrictions, are common and are consistently linked in the peer-reviewed literature to reduced adherence and worse downstream outcomes and higher medical costs and utilization.[12] But the Model does not address these real challenges—it would only undermine efforts to develop innovative treatments. While the Model claims to improve care through reduction in patient cost-sharing because beneficiary cost-sharing under the Model will be based on the post-rebate amount, the benefit here is not nearly as straightforward as CMS suggests. In Part B, just 13 percent of beneficiaries have only traditional Medicare and no form of supplemental coverage (such as Medigap, commercial insurance, or Medicaid), such that the vast majority of beneficiaries have coverage that substantially limits drug-related cost exposure and weakens any claim that drug spending itself constitutes a deficit in care.[13]

Finally, because there is no underlying payment and service delivery model to test, the Model oversteps CMMI's statutory authority through its design. As noted above, CMMI's authority is expressly limited to testing "payment and service delivery models." By contrast, the Model serves merely to transform the statutory Part B inflation rebate into a mechanism for importing foreign price controls without any predictable effect on care delivery. While CMMI does have the authority to waive requirements of the Medicare statute, to include requirements for the Part B inflation rebates, such waivers must be necessary solely for purposes of testing a payment and service delivery model. The "waiver" here serves merely to fundamentally alter the nature of the statutory rebate authority; it is not a waiver of requirements necessary to test a model. That is, the waiver effectively is the entire model, a framework inherently inconsistent with CMMI's statutory authority.

## III. International Reference Pricing Would Be Especially Damaging to Key Elements of the Biotech Ecosystem.

Beyond fundamental flaws in the Model outlined above, the Model would also have especially devastating effects on particular elements of the biotechnology ecosystem, including small and medium-sized biotechnology companies, companies that have out-licensed their products and have no control over foreign pricing, and efforts to develop particularly high-risk innovation areas such as rare disease treatments, and cell and gene therapies.

The most prominent example of this is the effect the Model would have on small and medium-sized biotechnology companies, which are crucial both to a robust, innovative pipeline of new therapies and to U.S. competitiveness in biotechnology. CMS recognizes that the Model may have particular effects on smaller biotech companies, soliciting comment on "adjustments to the GLOBE Model that could be considered" in the context of minimizing the effect on small entities as well as "other factors that could be considered to mitigate the impact on small manufacturers."[14] Without engaging in substantial analysis of the effects of the model on small biotech companies, CMS simply proposes to exclude products with less than $100 million in annual Medicare spending. Small biotechnology companies are the least well-equipped to handle the costs of new pricing uncertainty, while it is widely acknowledged that these companies themselves are responsible for the majority of novel new drugs.[15] Smaller companies often may have only one product that is covered by Medicare that accounts for the bulk of their revenue, and arbitrarily and suddenly reducing payment for that product could be financially ruinous for such companies. Meanwhile, small, pre-revenue companies—80 percent of MassBio pharmaceutical member

---

[11] See, e.g., Lars Osterberg & Terrence Blaschke, Adherence to Medication, 353 *N. Engl. J. Med.* 487 (2005), https://www.nejm.org/doi/full/10.1056/NEJMra050100.

[12] See, e.g., Laura E. Happe et al., A Systematic Literature Review Assessing the Directional Impact of Managed Care Formulary Restrictions on Medication Adherence, Clinical Outcomes, Economic Outcomes, and Health Care Resource Utilization, 20 *J. Managed Care Pharmacy* 677 (2014), https://pubmed.ncbi.nlm.nih.gov/24967521/.

[13] *A Snapshot of Sources of Coverage Among Medicare Beneficiaries*, Kaiser Fam. Found. (Dec. 19, 2025), https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries.

[14] 90 Fed. Reg. at 60,320.

[15] *See, e.g.,* IQVIA Inst. for Human Data Sci., *Emerging Biopharma's Contribution to Innovation* (June 4, 2019), https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/emerging-biopharma-contribution-to-innovation ("Emerging biopharma companies are responsible for a record 65% of the molecules in the R&D pipeline without a larger company involved").

companies have fewer than 50 employees—rely on the prospect of reliable reimbursement for their products in order to secure investment, and the Model would inject new, significant uncertainty into the risks already inherent to such investments.

Smaller biotechnology companies would also suffer particularly concentrated harms because CMS fails to address situations where companies have out-licensed their products outside of the United States and do not control ex-U.S. prices. CMS notes that it "considered an application process through which a manufacturer could qualify for a model exemption given their lack of responsibility for sales of drugs outside of the U.S.," but expresses concern that manufacturers might "transfer[] responsibilities to other entities to avoid model participation."[16] This issue poses a fundamental challenge to the proposed reference pricing framework, because part of the goal of such a framework is to provide support for upward pricing pressure outside of the United States to avoid dramatic reductions in the revenue available to fuel future research and development. If manufacturers do not control pricing outside the United States, the policy cannot achieve this goal.

CMS' concern that manufacturers may use out-licensing agreements as a way to escape rebates under the Model is also misplaced. Rather than serving as a mechanism to evade international pricing regimes out-licensing decisions are driven by bona fide market considerations, and have in many cases been put in place well before the Model's announcement. These arrangements are particularly critical for smaller biotechnology companies because out-licensing agreements are often an essential form of financing for such companies, providing capital during the years in which such companies engage in pre-revenue R&D and enabling these companies' products to generate revenue in foreign markets without such companies' having the global capabilities of the largest manufacturers.

The model would also be especially devastating to efforts to develop drugs for rare diseases. Efforts to develop drugs to treat rare conditions—often classified as "orphan drugs"—have long benefited from distinct statutory and policy frameworks that reflect their specialized role in the drug development ecosystem, including differentiated treatment under FDA authorities and the Inflation Reduction Act's drug price negotiation provisions, recently strengthened by Congress. Yet this longstanding policy priority and statutory differentiation are not meaningfully addressed in the proposed rule. Failure to account for orphan drugs would not only materially reduce incentives for continued innovation in rare diseases, but would also result in the use of international pricing information that is both limited and distortive. International reference data for orphan drugs are often sparse because peer countries are less likely to cover such products, and such products are less likely to be approved in markets outside the United States in the first place.[17] As a result, reliance on international pricing benchmarks would disproportionately and inaccurately understate the value of orphan drug products, contrary to the framework Congress has established.

The Model would also have particularly damaging effects on efforts to develop cell and gene therapy products (CGTs). CMS acknowledges that such products may be inappropriate for inclusion in the Model based on "supply chain criteria" or "other factors that warrant their inclusion or exclusion."[18] CMS is correct to recognize that CGTs present special considerations that make them ill-suited for inclusion in GLOBE or any similar proposal. Cell and gene therapies rely on highly specialized and often individualized manufacturing processes and use cases that frequently involve a single administration or a limited course of therapy. Pricing arrangements for these products often reflect these unique circumstances, and may include individualized pricing or outcomes-based or alternative payment structures. Applying standardized rebates derived from international reference prices would be poorly aligned with these characteristics and would risk destabilizing existing payment arrangements. At the same time, similar to challenges around orphan drug pricing, access to CGTs has been significantly narrower in countries outside the United States, reflecting both the dangers that foreign drug pricing systems pose to patient access and the likelihood that foreign pricing data on these products will be unreliable.

---

[16] 90 Fed. Reg. at 60,274.

[17] V. Giannuzzi et al., *Orphan medicinal products in Europe and United States to 2015: a comparison of designations, approvals and marketed indications*, 5 *Orphanet J. Rare Diseases* 94, 94–95 (2017) (noting 415 U.S. orphan products covering 521 indications vs. 133 EU products covering 179 indications).

[18] 90 Fed. Reg. 60,274.

## IV. Conclusion

While MassBio shares CMS' goal of increasing patient access to innovative medicines and reducing foreign freeloading, the proposed Model would undermine rather than advance these goals.

The proposed Model would significantly undermine incentives for innovation in the United States and put patient access to the latest innovations at risk, without meaningfully increasing patient access or reducing patient costs. The Model also dramatically oversteps CMS' statutory authority to test payment and service delivery models and would not produce a meaningful test of payment reforms. The Model would be especially devastating to small biotechnology companies, companies without control over international pricing of their products, rare disease drugs, and cell and gene therapy products.

MassBio thanks CMS for your consideration of our comments. Please don't hesitate to contact me at (617) 674-5148 or kendalle.oconnell@massbio.org if you have any questions or would like any additional information to consider our comments.

Sincerely,

Kendalle Burlin O'Connell
CEO & President
Massachusetts Biotechnology Council (MassBio)