NATIONAL ASSOCIATION OF Manufacturers

February 23, 2026

The Honorable Mehmet Oz
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS Docket No. CMS-2025-1888: "Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model"

Dear Administrator Oz:

The National Association of Manufacturers (NAM) appreciates the opportunity to provide comments to the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) on the proposed Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model.

The NAM is the largest manufacturing association in the United States, representing manufacturers of every size, in every industrial sector, and in all 50 states. Small and medium-sized manufacturers make up the majority of manufacturing businesses in the United States and employ approximately 40% of the nearly 13 million manufacturing workers. Manufacturing contributes $2.94 trillion annually to the U.S. economy and accounts for nearly 53% of all private-sector research in the nation.

Biopharmaceutical companies are some of the most innovative manufacturers that discover and commercialize incredible new medicines to treat and cure challenging conditions. In fact, the average investment by a biopharmaceutical company to bring a medicine to market is approximately $2.3 billion[1] over 10 to 15 years.[2] Further, just 12% of the investigational drugs that enter a phase I clinical trial are ultimately approved by the FDA, meaning the other 88% fail along the way[3]—to say nothing of the hundreds of discoveries that never make it into clinical trials. This cycle of discovery and development makes biopharmaceutical manufacturers economic engines, accounting for $355 billion in value-added output to the U.S. economy in 2021 and supporting an additional 4.1 jobs for every person employed by a biopharmaceutical manufacturer.[4]

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[1] Deloitte. "Seize the digital momentum: Measuring the return from pharmaceutical innovation 2022" (January 2023). Available at https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf

[2] Pew Charitable Trusts. "From Lab Bench to Bedside: A Backgrounder on Drug Development" (March 2014). Available at https://www.pewtrusts.org/en/research-and-analysis/articles/2014/03/12/from-lab-bench-to-bedside-a-backgrounder-on-drug-development

[3] DiMasi, Joseph A., Grabowski, Henry G., and Hansen, Ronald W. "Innovation in the pharmaceutical industry: New estimates of R&D costs." J Health Econ. 2016; 47:20-33.

[4] National Association of Manufacturers. "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing" (October 2023). Available at https://documents.nam.org/COMM/NAM-Creating%20Cures,%20Saving%20Lives_FINAL3.pdf

The NAM appreciates CMS' focus on affordability; as employers, manufacturers are similarly concerned with the rising cost of health care. However, the NAM is concerned that the proposed GUARD model could impede life-saving innovation by importing flawed foreign pharmaceutical prices via international reference pricing. The proposed approach has significant potential to harm patients by reducing access to innovative treatments and cures; additionally, the GLOBE model exceeds the authority of the Center for Medicare and Medicaid Innovation (CMMI). Given the risks the proposed rule could pose for both manufacturers and patients, the NAM respectfully encourages CMS to reconsider and withdraw the proposed GLOBE model.

The GUARD Model Exceeds CMMI's Authority

Section 1115A of the Social Security Act defines CMMI's statutory authority to conduct tests of new health care payment and services delivery models with the express goals of improving patient care, lowering costs, and aligning patient systems to promote patient-centered practices. Under section 1115A, the models must apply to a specific health condition, care episode, provider type, community, or innovation within Medicare Advantage or Part D.[5] Specifically, section 1115A requires that models must address "a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."[6] Additionally, the statute requires CMS to study models that "reduce program costs…while preserving or enhancing the quality of care" for beneficiaries.

The proposed GUARD model does not meet either of these requirements; as such, the proposed rule exceeds CMMI's authority. It does not apply to a single health condition, care episode, provider type, or innovation that could be considered a "defined population". As described in the proposed rule, the GUARD model would apply to 25% of beneficiaries randomly selected by geography. The drugs selected for inclusion into the GUARD model fall within a broad set of therapeutic areas and appear to be selected, at least in part, because of their total spending within the Medicare Part D program rather than for patient impact, thus exceeding CMMI's scope.[7]

CMS has stated that manufacturer rebates the agency receives from GUARD will not directly impact Medicare beneficiaries' cost sharing. Instead, the agency claims cascading effects to patient care, which appear tenuous at best. In fact, the agency concedes that the model "does not directly impact Part D enrollees' out-of-pocket costs" and may actually increase costs over time.[8] With the model unable to deliver on CMMI's goals of improved care, lower costs, or patient-centered practices, it seems clear that the model does not fit within CMMI's scope of authority. The NAM is thus concerned about the proposal's potential cost—in the form of stifled innovation.

Price Controls Stifle Innovation and Impose Discriminatory Pricing Structures

The NAM supports the Trump Administration's goal of addressing uneven pricing structures that allow foreign governments to enjoy the benefits of U.S. biopharmaceutical development without

[5] 42 U.S.C. § 1315a

[6] 42 U.S.C. § 1315a(b)(2)(A)

[7] https://www.federalregister.gov/d/2025-23705/p-235

[8] Ibid.

paying their fair share for this innovation. While a significant share of U.S. pharmaceutical production is supported by export and global sales, foreign governments use price controls and reimbursement delays among other practices, to, in effect, discount the innovation in U.S.-manufactured pharmaceuticals. In response to USTR's request for comments regarding foreign nations freeloading on American-financed innovation, the NAM emphasized pharmaceutical manufacturers' role in the U.S. economy, domestic reforms that will help reduce health care costs, and ways to address unfair and discriminatory market access policies in foreign markets, without instituting harmful price controls.[9]

Impact on Innovation

The NAM has long been opposed to proposals, like the GUARD model, that would impose price controls on biopharmaceutical manufacturers. Price controls, and even the threat of price controls, stifle innovation and erode the United States' standing in biopharmaceutical research and product development. Further, shifting the balance of incentives away from innovation and R&D may ultimately harm patients. Price controls could also jeopardize the United States' leadership in biopharmaceutical innovation.

In addition to the value that pharmaceuticals deliver to patients, society, and the health care system, drug pricing also reflects the risks and costs inherent in drug innovation, including the investments required to bring a product to market through rigorous regulatory processes. Innovation in the pharmaceutical sector is a complex, lengthy, and cost-intensive process. R&D investments in the U.S. drive breakthrough discoveries and the development and commercialization of new drugs and therapies for Americans.

In the drive for continual innovation, pharmaceutical companies make up the largest share of all private-sector R&D in the nation, accounting for 36.1% of spending at $146.1 billion in 2023.[10, 11] It typically takes 10 to 15 years of research, clinical trials, and regulatory approval before a new drug can be brought to market.[12] The industry today invests 20 times more than it did in the 1980s; over the past 40 years, pharmaceutical R&D investment has compounded at over 9% a year.[13] In fact, when compared to other countries, U.S. business R&D expenditures are substantially more than R&D expenditures in other countries.

Importantly, pharmaceutical R&D efforts are tied to and bolstered by revenue for the manufacturers in the U.S. that are making these substantial investments. Reductions in revenue translate into reduced rates of innovative effort, which ultimately harms patients. The USC Schaeffer Center has estimated that for every 10% reduction in expected U.S. revenues, pharmaceutical innovation—such as clinical trial starts or new drug approvals—is expected to

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[9] Available at https://documents.nam.org/IEA/NAM%20USTR%20Drug%20Innovation%20Submission_Final%206.27.25.pdf

[10] U.S. Bureau of Economic Analysis, "Table 5.6.5. Private Fixed Investment in Intellectual Property Products by Type," U.S. Department of Commerce".

[11] National Association of Manufacturers, "Facts About Manufacturing".

[12] Derep, Maxime, N-Side, "What is the Average Time to Bring a Drug to Market in 2022?" 2022.

[13] National Association of Manufacturers (2023), "Creating Cures, Saving Lives: The Urgency of Strengthening U.S. Pharmaceutical Manufacturing".

ultimately fall by 2.5% to 15%.[14] This reduction is significant to the patients who would lose out on new and improved therapies that may no longer be researched and developed due to lack of revenue to do so.

Concerns with Foreign Reference Pricing

The GUARD model specifically uses foreign reference pricing to determine the prices to impose domestically. However, many foreign countries have government policies that fail to properly value innovation, including clawback and other revenue return mechanisms. These countries restrict patient access to innovative medicines by refusing to cover certain treatments they deem too expensive, actively harming their citizens. All of the countries referenced in the GLOBE model either directly or indirectly rely on quality-adjusted life years (QALYs) in their pricing schemes. Foreign countries use QALYs as a way to assign value to new treatments, but because QALYs assign lower numerical values to disabled or elderly patients, they can be discriminatory towards vulnerable populations while ignoring other elements that may matter to patients and caregivers. The U.S. has traditionally rejected such discriminatory pricing methods. Congress has expressly prohibited CMS from using these discriminatory metrics in pricing discussions in existing statutes. Using foreign reference pricing from countries that use QALYs to determine pricing within the GLOBE model would be in direct opposition to congressional intent.

For decades, some of the largest markets for U.S. innovative medicines, including Canada, Europe, Japan, and South Korea, have imposed discriminatory and nontransparent policies that undervalue American innovation, limiting the resources available to support U.S. R&D that leads to new and improved therapies for patients that need them. For example, Canada has removed the U.S. from its list of reference countries, resulting in cuts to the prices of patented biopharmaceutical products. Japan introduced off-year drug pricing revision resulting in continuous price reduction during patent periods. South Korea uses unreasonably low and outdated cost-effectiveness thresholds in its pricing assessments while imposing excessive and repeated price cuts that fail to recognize the value of patented pharmaceutical products.

In Europe, countries use a variety of mechanisms that limit patient access to medicines, as well as aggressive cost-containment measures and revenue controls (based on arbitrary budget ceilings), such as outdated assessments, rebates, and industry clawbacks. Italy, for example, imposes discriminatory clawbacks on a select group of companies, many of them foreign owned, to address broader health care budgetary shortfalls. France layers price cuts, rebates, and industry-wide revenue clawbacks to achieve savings goals. Other nations limit the benefits of market exclusivity through protracted regulatory delays that lead to lost marketing time and access delays for patients. The UK maintains two pricing schemes: a voluntary scheme for branded medicine pricing and access (VPAG) as well as a similar statutory scheme, both of which have adversely impacted U.S. innovators.

President Trump is making progress, however, to address foreign penalties on innovation. The UK lowered the VPAG clawback for 2026 to 15% of revenue, a reduction from 23% in 2025, which was more than double the average rate of the last decade. The UK is also implementing a higher cost-effectiveness threshold for new products, ensuring innovative medicines are valued more appropriately moving forward. Manufacturers commend the Trump Administration for securing these changes and look forward to continued progress to address foreign freeloading.

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[14] USC Schaeffer Center white paper, "The Elasticity of Pharmaceutical Innovation: How Much Does Revenue Drive New Drug Development?" Feb. 18, 2025.

Instead of implementing domestic price controls that are tied to foreign markets that disincentivize innovation, the NAM encourages the Administration to leverage trade policy and current negotiations with U.S. trading partners to ensure that foreign countries adopt fair policies while also ensuring our trading partners adopt and enforce high intellectual property protections to protect R&D and innovation by manufacturers in the U.S.

This would include securing non-discriminatory and fair market access terms with our trading partners. This would level the playing field and ensure that U.S. patients are not bearing an unfair burden of funding global innovation, while also ensuring innovation continues so patients can access life-saving treatments and cures.

The GUARD Model will Disproportionately Impact Small and Medium-sized Manufacturers

The GUARD model would disproportionately impact small and medium-sized biopharmaceutical manufacturers that typically have concentrated commercial portfolios, sometimes with as few as one or two approved drugs. With small commercial portfolios, international reference pricing is particularly harmful to these manufacturers and could force them to make financial or business decisions that would limit patient access to these life-improving medicines.

Small and medium-sized biopharmaceutical manufacturers also rely on pre-approval out-licensing to secure needed funding for further product development. Manufacturers that have products in clinical trials and do not have commercial revenue will typically out-license foreign commercialization rights of the product with large pharmaceutical companies in order to secure survival financing to continue clinical development. Such agreements typically provide the licensors with upfront and milestone payments, while any royalty component from licensees is often modest or incidental. And in nearly all cases of this type of out-licensing, small or medium-sized manufacturers have no control over the prices that the licensee eventually charges in foreign markets.

These small and medium-sized companies are a critical part of the innovative biopharmaceutical ecosystem. International reference pricing could stifle their ability to develop incredible new and improved therapies because such pricing would hamstring their ability to recoup R&D expenses. This would devastate patients who would benefit from innovative new medicines. U.S. manufacturers strive to remain the leader in biopharmaceutical R&D to help patients. The proposed GLOBE model seriously threatens that objective.

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Manufacturers remain committed to finding solutions to lower health care costs, including through additional reforms to pharmacy benefit manager practices, reforms to the 340B program, and support for the U.S. Manufacturing Investment Accelerator Program.[15] Manufacturers are also dedicated to the innovation that leads to critical new medicines and to ensuring that patients can access them—in contrast to foreign countries where price controls stifle innovation and limit patient access to the latest treatments. The preservation of the Bayh-

[15] National Association of Manufacturers, U.S. Manufacturing Investment Accelerator Program. Available at https://nam.org/wp-content/uploads/securepdfs/2025/06/Manufacturing-Investment-Accelerator-Program-FINAL-DIGITAL.pdf

Dole Act and a fully resourced Food and Drug Administration help achieve those aims. The NAM looks forward to working with the Trump Administration to build on previous successes.

The NAM appreciates the opportunity to comment on this proposal and looks forward to working with CMS to ensure that innovators across our industry can continue to develop—and patients can continue to access—life-saving treatments and cures.

Sincerely,

Jess Wysocky
Director, Health Care Policy

Jake Kuhns
Vice President, Domestic Policy