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VIA ELECTRONIC FILING – http://www.regulations.gov

Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-5545-P
P.O. Box 80103
Baltimore, MD 21244-8013

Re: Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Proposed Rule

Dear Administrator Oz:

The Pharmaceutical Research and Manufacturers of America (PhRMA) submits these comments to the Centers for Medicare & Medicaid Services (CMS) on the Notice of Proposed Rulemaking ("Proposed Rule") for the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model (hereafter referred to as "GUARD").

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser-focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat, and cure disease. Over the last decade, PhRMA member companies have invested more than $850 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.[1]

PhRMA is deeply concerned that the GUARD Proposed Rule is not only illegal but also profoundly harmful to American patients. Our concern is based on the following reasons, which we elaborate on in more detail in our comment letter.

I. GUARD Exceeds CMS' Statutory Authority Under Section 1115A

A. GUARD is a mandatory funding mechanism, not a "test"

[1] PhRMA. (July 2025). 2025 PhRMA Annual Membership Survey. Available at: https://phrma.org/resources/2025-phrma-annual-membership-survey

For these reasons, and as detailed in later sections, CMS must reject the flawed policy reflected in GUARD and withdraw the Proposed Rule.

GUARD constitutes an unprecedented attempt to transform pharmaceutical pricing, violating the CMMI statute, appropriations laws, and the Constitution. First, GUARD would exceed the limited authority Congress provided in the Center for Medicare and Medicaid Innovation (CMMI) statute by enacting a mandatory, nationwide program that, in effect, imposes foreign reference pricing by compelling manufacturers to submit a rebate when U.S. prices exceed international reference prices. This

far exceeds multiple limits to CMMI authority, including that the proposal is a "test" of a "payment and service delivery model" that addresses a "defined population" with "deficits in care." Although CMS cites to "waiver" authority to justify the imposition of this new, additional rebate, waiver authority only permits CMS to refrain from enforcing current requirements – not to rewrite an underlying statute. CMS even claims that it is authorized to impose new civil monetary penalties, but imposing penalties is well beyond an agency's administrative powers. Second, by collecting rebates that would be deposited in Medicare's coffers, GUARD would violate federal appropriations law set forth in the Constitution and fiscal statutes. Finally, by interpreting its CMMI authority so expansively, CMS raises significant constitutional concerns, including separation of powers principles.

In addition, **GUARD will cause grave and irreparable harm to U.S. biopharmaceutical innovation, depriving patients of future cures and treatments.** Previously, President Trump has emphasized that his Administration would unleash the power of American innovation to cure cancer, Alzheimer's disease and other serious illnesses.[2] The Proposed Rule is entirely antithetical to this aim. It is well established that unilaterally imposed most favored nation (MFN) policies would have harmful impacts on biopharmaceutical investment and innovation, and American patients would pay the price.[3] In fact, analysis has shown that MFN pricing in Medicare and Medicaid would lead to a combined loss of 500 new treatments over 10 years, spanning both new drug approvals and approvals for new indications of existing drugs.[4] Five hundred fewer treatments for Americans with devastating, life-threatening diseases and chronic illnesses is too high a cost for this fundamentally unsound, likely illegal policy.

GUARD would hand global biopharmaceutical supremacy to China, a future about which Secretary Kennedy himself has warned.[5] As a result of its implementation of pro-innovation regulatory efficiencies and incentives, China is now on par with the U.S. in clinical trial activity and is rapidly advancing in the research and development of innovative medicines at a rate unmatched by any other country.[6,7] The surge in investment in biopharmaceutical research and development in China throughout the 21st century has been significant, increasing 2,600 percent (from $861.1 million to $23.6 billion) between 2000 and 2021.[8]

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[2] N.Y. Times. (July 2024). Read the Transcript of Donald J. Trumps Convention Speech. Available at: https://www.nytimes.com/2024/07/19/us/politics/trump-rnc-speech-transcript.html ("We will unleash the power of American innovation, and as we do, we will soon be on the verge of finding the cures to cancer, Alzheimer's disease and many other diseases.").

[3] *See, e.g.,* Matcha G. (May 2025). The Global Risks of America's "Most-Favored-Nation" Drug Pricing Policy. *The Petrie-Flom Center.* Available at: https://petrieflom.law.harvard.edu/2025/05/22/the-global-risks-of-americas-most-favored-nation-drug-pricing-policy/.

[4] Philipson T., et al. (September 2025). Policy Brief: The Impact on Patient Health of Most-Favored-Nation Pricing of Already Marketed Drugs. *University of Chicago*. Available at: https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2025/09/MFN-Impact-on-Patient-Health-Final-Sep-29.pdf.

[5] Pharmaceutical Technology. (January 2025). RFK Jr. Thrusts Domestic Manufacturing Agenda on Day 2 of Confirmation Hearings. Available at: https://www.pharmaceutical-technology.com/news/rfk-china-manufacturing-drug-concern/ ("If there is a pandemic, if there is a war or any conflict, China will now be able to ransom American health and that is not a good situation."); U.S. Department of Health and Human Services. (June 2025). HHS Testimony on The President's Fiscal Year 2026 Budget. Available at: https://www.hhs.gov/about/agencies/asl/testimony/2025/06/24/the-presidents-fiscal-year-2026-budget.html.

[6] Global Data. (2026). Contribution of Clinical Trials Worldwide. Available at: https://www.globaldata.com/health-economics/pharmatrends/

[7] Masson G. (July 2025). China biotechs 'reshaping' US biopharma as outlicensing deals rise 11%: Jefferies report. *FIERCE Pharma.* Available at: https://www.fiercebiotech.com/biotech/china-biotechs-reshaping-us-biopharma-outlicensing-deals-rise-11-jefferies-report

[8] OECD. (2025). Data Explorer Analytical Business Enterprise R&D by ISIC Rev.4 industry (ANBERD database).

As China stands poised to take over as the global leader in biopharmaceutical innovation, policies like GUARD would stifle critical American investments in our historically dominant innovation ecosystem.

GUARD would also produce a significant drag on U.S. infrastructure and employment. Mandatory MFN policies could imperil over $500 billion in recently announced capital investments across the sector. These investments will lead to over 100,000 new jobs. However, if expanded to all beneficiaries in Medicare Parts B and D, GUARD—and the Global Benchmark for Efficient Drug Pricing (GLOBE) NPRM, which imposes MFN pricing for Medicare Part B drugs—could eliminate approximately 337,000 American jobs in the biopharmaceutical industry and nearly 1.5 million jobs in total across the economy.[9] Even as articulated in the Proposed Rule, GUARD would materially disrupt the biopharmaceutical ecosystem.

Most alarming is that in exchange for extensive, sustained harm to American innovation and workers, GUARD fails to address any real shortcoming in the U.S. market. In fact, CMS willfully ignores the fact that the U.S. intellectual property system, which balances innovation and competition, leads to lower U.S. drug costs in the long term. CMS itself in the Proposed Rule recognizes that people in America pay *less* for generic medicines than people in other countries, a fact supported by recent analysis, which showed that in Medicare and Medicaid, prices of prescription fills in the U.S. are 18 percent lower than other countries when accounting for generic use.[10] In addition to lower drug costs over the long term, Americans have better and faster access to medicines relative to foreign counterparts, all while driving the global biopharmaceutical ecosystem.

And, as discussed at length below, **GUARD would do very little, if anything, to help seniors access their medicines.** CMS acknowledges that GUARD does not directly impact Part D enrollees' out-of-pocket costs and could even increase them. CMS fails to address the actual root causes of why patients struggle to access and afford their medicines, including insurers' vertical integration with pharmacy benefit managers (PBMs) and the use of aggressive tactics to deny coverage,[11] in addition to plans not using discounts and rebates to directly reduce beneficiary costs at the pharmacy counter.

The U.S. is already experiencing the negative impacts of policies that involve government price setting for medicines, particularly via President Biden's Inflation Reduction Act (IRA). Price setting under the IRA is increasing costs and reducing available therapy options for beneficiaries.[12] A majority of

[9] VitalTransformation. Most Favored Nation (MFN) Reference Pricing in Medicare: Impacts on Jobs, Innovation, and State Budgets. Available at: https://vitaltransformation.com/2025/09/most-favored-nation-mfn-reference-pricing-in-medicare-impacts-on-jobs-innovation-and-state-budgets/.

[10] Philipson T., Zhang D., Zhao Q. (June 2025). International Comparison of Prices for Drug Prescriptions. *University of Chicago.* Available at: 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 (compared to Canada, France, Germany, Japan and United Kingdom).

[11] PhRMA. (January 2026). Can't get your medicine? Don't count on your insurer. Available at: https://phrma.org/blog/can-t-get-your-medicine-don-t-count-on-your-insurer

[12] PhRMA. (August 2024). The Unintended Consequences of Government Price Setting in Medicare Part D. Available at: https://phrma.org/blog/the-unintended-consequences-of-government-price-setting-in-medicare-part-d (IRA's drug pricing provisions could increase out-of-pocket costs for 3.5 million Part D patients taking a medicine subject to a government-set price in 2026). *See also:* PhRMA. The Inflation Reduction Act and Medicare Drug Price "Negotiation." Available at: https://phrma.org/policy-issues/government-price-setting/inflation-reduction-act (The IRA will jeopardize critical post-approval research).

beneficiaries are enrolled in plans where their cost-sharing will increase for many price-set drugs in 2026 compared to before the IRA.[13]

Finally, in addition to our concerns with MFN-type policies conceptually, GUARD, as designed, is fundamentally and irreparably flawed. These infirmities include, but are not limited to:

- **CMS' own standard for "economically comparable" is rendered meaningless by the very market basket it constructed.** The market basket of countries used in the GUARD framework fails to meet CMS' own standard for "economic comparability." Many of the countries included in the market basket also rely on external reference pricing to set their domestic drug prices — meaning their prices are derived from the prices of other countries. Critically, some of those referenced countries would not themselves qualify under the GDP-based criteria CMS uses to define economic comparability. As a result, non-comparable price signals are effectively laundered into the benchmark through intermediary countries, rendering CMS' comparability standard entirely meaningless.
- **CMS penalizes manufacturers for prices they do not set and then admits the problem is too widespread to fix.** In many cases, the rights to manufacture and distribute a drug are divided between different entities in the United States and in foreign markets — meaning the U.S. manufacturer has no control over the pricing decisions made abroad. Yet CMS' framework would effectively penalize U.S. manufacturers for prices set by counterparts, a consequence the Agency itself acknowledges in the Proposed Rule without offering any meaningful resolution. Rather than addressing this inequity, CMS declines to provide an exemption, citing the breadth of its potential impact — an admission that the problem is not narrow or incidental, but widespread and structural.
- **CMS' static benchmark fails to capture real-world price changes, undermining the entire purpose of the so-called "test."** The proposal claims to offer manufacturers a choice between two different approaches to establishing an international benchmark price. However, in many cases, manufacturers may effectively not be able to select Method II due to a lack of required data, potentially because a different manufacturer holds the rights to distribute a drug outside the U.S., as mentioned above. But in Method I, CMS will use an international benchmark based on data from as early as January 1, 2024, and this benchmark will not change throughout the performance period. Thus, if companies were to increase ex-U.S. prices, there would be no impact on rebate liability, raising questions about what CMS would be "testing," and its ability to identify changes in behavior.

These operational deficiencies are just a few among many, and are distinct from the myriad policy and legal flaws outlined above and described further below. However, they are further evidence as to why GUARD is unworkable and must be withdrawn. **For these reasons, and as detailed in later sections, CMS must reject the flawed policy reflected in GUARD and withdraw the Proposed Rule.**

Recommended Action

We commend the Administration for promoting direct purchase programs that enable patients to bypass many of the barriers created by PBMs, and for its desire to make medicines more affordable for Americans. PhRMA has announced the launch of AmericasMedicines.com, a new website that will

[13] Internal analysis of 2026 Medicare Part D Formulary File data.

connect patients with manufacturer direct purchase programs.[14] These efforts reflect the growing recognition that PBMs and other middlemen receive massive rebates on medicines while charging patients the full price and imposing barriers to access. Direct purchase programs are convenient and for some patients, can save patients time and money, with no hidden markups or fees and transparent pricing for patients and businesses.

Further, the Trump Administration has frequently acknowledged the longstanding practice of foreign freeriding whereby other nations take advantage of American biopharmaceutical innovation without paying their fair share—which effectively imposes a 26 percent foreign freeriding "tax" on Americans.[15] Recent efforts by President Trump and the USTR to address foreign freeriding are welcomed. As previously noted, the U.S. invests significantly in R&D, and rather than resorting to harmful policies like GUARD that mandates MFN pricing, the Administration should continue working with Congress on market-based reforms that preserve U.S. leadership in biopharmaceutical innovation and expedited access for American patients to the world's most innovative medicines.

To avoid devastatingly hobbling the U.S. biopharmaceutical industry, the U.S. Department of Health and Human Services (HHS) should take steps to address the real market distortions in the system: PBMs and the 340B program. The U.S. is the only country in the world that allows entities like PBMs, insurers, and other intermediary entities to capture 50 percent of every dollar that patients spend on medicines.[16] PBM fees and rebates can exceed ex-U.S. drug prices by as much as 900 percent.[17] The 340B hospital markup program is also unique to the U.S., and allows tax-exempt hospitals and clinics to buy certain medicines for as little as a penny before substantially marking up the price, often by thousands of dollars; 340B markups can exceed drug prices abroad by as much as 700 percent. In both the 340B program and discounts achieved by PBMs, savings are often not shared with patients.[18] The Administration should continue to work with Congress to address these market distortions and lower costs for Americans and the health care system.

We strongly recommend that CMS and HHS refocus and redouble efforts to reform PBM practices and the 340B program, working with Congress as needed.

Further, to ease payment of monthly out-of-pocket costs for seniors under current Congressional authority, **CMS should continue to hold plans accountable to ensure seniors benefit from existing protections, including encouraging beneficiary awareness of and participation in the Medicare Prescription Payment Plan (MPPP) to "smooth" monthly costs.** As of mid-year 2025, only 0.6 percent

[14] PhRMA. (September 2025). PhRMA Announces Major Actions as Part of Industry's Commitment to American Patients and Workers. Available at: https://phrma.org/resources/phrma-announces-major-actions-as-part-of-industry-s-commitment-to-american-patients-and-workers
[15] No Patients Left Behind. (June 2025). Time to End Foreign Free Riding and Fix the Global Imbalance in Biomedical Innovation. Available at: https://www.linkedin.com/pulse/time-end-foreign-free-riding-fix-global-imbalance-k1huf/.
[16] BRG. (January 2025). The Pharmaceutical Supply Chain, 2013 – 2023. Available at: https://www.thinkbrg.com/insights/publications/the-pharmaceutical-supply-chain-2013-2023/
[17] Winegarden W. (June 2025). The 340B Discounts Hospitals Receive Will Often Exceed Total Drug Prices in Europe. *Pacific Research Institute.* Available at: https://www.pacificresearch.org/the-340b-discounts-hospitals-receive-will-often-exceed-total-drug-prices-in-europe/.
[18] *Ibid.*

of all Part D beneficiaries were signed up for MPPP, significantly lower than the estimated 15 percent of beneficiaries "likely to benefit" from the program.[19]

CMS should also hold plans accountable for increasingly aggressive utilization management approaches that restrict beneficiary access to medicines in clinically inappropriate ways. A recent IQVIA study found that Part D plans routinely deny access to prescribed medicine for patients with newly diagnosed chronic conditions: more than 70 percent of patients were initially denied in four of the five therapeutic areas IQVIA studied.[20] Published formularies do not tell the whole story—plans also restrict access through arduous layers of prior authorization procedures, step therapy requirements, and tiered cost-sharing, all of which can substantially interfere with patient access to clinically appropriate medicines.[21] This extends to price setting programs that already exist. **CMS should ensure plans are not enforcing barriers that could inappropriately steer patients away from selected drugs for which CMS has established a maximum fair price under the IRA.[22]**

We provide more detail on these arguments, as well as supporting evidence, in the following sections.

I. GUARD EXCEEDS CMS' STATUTORY AUTHORITY UNDER SECTION 1115A

GUARD is an unprecedented attempt to transform the market for pharmaceuticals that exceeds CMS' limited authority under Section 1115A of the Social Security Act in multiple, independent respects. At the outset, GUARD is not a "test" as required by the statute—nor does it meet the requirement that Phase I models address a "defined population" with "deficits in care." GUARD also does not meet Section 1115A's requirements to be a payment and service delivery model. Instead, GUARD is an impermissible sanction that violates the Administrative Procedure Act (APA), 5 U.S.C. § 558(b).

Additionally, CMS may not invoke Section 1115A(d)'s "waiver" authority to maintain the IRA's inflation rebate requirements while mandating additional MFN-based rebates; this is a statutory rewrite, not a waiver. Nor can CMS extend the IRA's civil monetary penalty provisions for failure to provide statutory inflation rebates to penalize nonpayment of GUARD's new, Agency-created "incremental rebates" as there is no clear congressional authorization for such an expansion.

A. GUARD is a mandatory funding mechanism, not a "test"

Section 1115A authorizes CMS "to test innovative payment and service delivery models" to reduce program expenditures "while preserving or enhancing the quality of care" furnished to Medicare and Medicaid beneficiaries.[23] The statute requires that Phase I models be a "test"—meaning that the Agency must identify a "research or experimental" goal "likely to yield useful information or demonstrate a novel

[19] Crum R. et al. (November 2025). The Medicare Prescription Payment Plan: Implementation in 2025 and Implications for 2026. *Milliman.* Available at: https://www.milliman.com/en/insight/medicare-prescription-payment-plan-2025-into-2026.
[20] IQVIA (June 2025). The Impact of Formulary Controls on Medicare Patients in Five Chronic Therapeutic Areas. Available at: https://www.iqvia.com/locations/united-states/library/white-papers/the-impact-of-formulary-controls-on-medicare-patients-in-five-chronic-therapeutic-areas
[21] American Cancer Society Cancer Action Network (May 2024). Step Therapy in Medicare Part D Oncology Drugs. Available at: https://www.fightcancer.org/policy-resources/step-therapy-medicare-part-d-oncology-drugs
[22] Centers for Medicare & Medicaid Services. (September 2025). Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028. Available at: https://www.cms.gov/files/document/ipay-2028-final-guidance.pdf
[23] Social Security Act (SSA) § 1115A(a)(1), (b)(2)(A).

approach to program administration."[24] GUARD does not fall within this definition. It is not an experiment. Instead, it will generate—with certainty—billions of dollars in forced, punishing rebates from manufacturers. An arrangement with preordained results—like GUARD—is not a genuine test. And CMS has failed to articulate any hypothesis for why the rebates mandated by GUARD could affect quality of care.

Courts applying analogous provisions have held that a "test," consistent with the term's ordinary meaning, does not include program changes that simply "save money" with "no research or experimental goal."[25] Section 1115A reinforces this plain-meaning limitation by using additional language that speaks in experimental terms. Under the statute, CMS may "test" models "to *determine the effect* of applying such models," and the Secretary is required to "conduct an *evaluation* of each model tested."[26] Thus, the Agency must proffer a hypothesis, conduct an experiment, and analyze the results.

Yet GUARD does not present an experimental intervention whose effects are unknown. It simply imposes rebates to punish manufacturers for differentials between foreign and domestic pricing. GUARD thus would establish, in effect, price controls that without question will increase government revenue, not an experiment.

Nor can GUARD be justified based on CMS' experimentation authority to "preserv[e] or enhanc[e] the quality of care."[27] That statutory language presupposes that CMS is testing whether expenditures can be reduced *without degrading quality* (and ideally while improving it). But CMS does not articulate any hypothesis about quality effects—positive, negative, or neutral—nor does it specify any mechanisms that would maintain or enhance quality under GUARD. Instead, CMS assumes that drugs with high costs result in high cost-sharing and low quality of care. However, CMS acknowledges that GUARD will not "directly impact enrollees' out-of-pocket" costs.[28] And CMS includes beneficiaries with low cost-sharing, such as low-income subsidy (LIS) beneficiaries or beneficiaries with zero cost-sharing due to hitting the catastrophic coverage limit. GUARD therefore does not meet the statutory requirement that a CMMI model be a genuine test of a research question where the answer is not preordained.[29]

GUARD also fails to fit within any ordinary understanding of the meaning of the word, "test," because CMS is imposing nationwide, mandatory price controls under the guise of a geographically limited rebate. As noted above, to test something means to "try," to "subject to a test," "a procedure for critical evaluation," a "trial."[30] Imposing price controls in a nationwide manner, however, and charging manufacturers 25 percent rebates based on such price controls, is hardly a mere "test." And, there is no question that GUARD is nationwide. While CMS attempts to frame GUARD as geographically limited –

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[24] *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994); *see Test*, MERRIAM-WEBSTER, merriam-webster.com/dictionary/test ("a critical examination, observation, or evaluation"; "the procedure of submitting a statement to such conditions or operations as will lead to its proof or disproof or to its acceptance or rejection"); *Test*, American Heritage Dictionary, https://www.ahdictionary.com/word/search.html?q=test ("[a] procedure for critical examination"; "[a] basis for evaluation or judgment").

[25] *Beno*, 30 F.3d at 1069; *see also Newton-Nations v. Betlach*, 660 F.3d 370, 380 (9th Cir. 2011) (requiring some "experimental value").

[26] SSA § 1115A(b)(2)(A), (4)(A) (emphasis added).

[27] SSA § 1115A(b)(2)(A).

[28] 90 Fed. Reg. 60338, 60411.

[29] *See also Beno*, 30 F.3d at 1069 ("The statute was not enacted to enable states to save money or to evade federal requirements but to 'test out new ideas and ways of dealing with the problems of public welfare recipients.'" (quoting S. Rep. No. 1589, 87th Cong., 2d Sess. 20, reprinted in 1962 U.S.C.C.A.N. 1943, 1961)).

[30] *Test*, American Heritage Dictionary, https://www.ahdictionary.com/word/search.html?q=test

including in the rebate calculation only the claims of beneficiaries residing in a random selection of specified "zip code tabulation areas" (ZCTAs) and referring to these beneficiaries as "GUARD Model beneficiaries"[31] – this is not a genuine geographic limitation. First, Part D plans would enroll a mixture of GUARD Model beneficiaries and non-model beneficiaries. Second, list pricing is at a nationwide level and rebating decisions are made at the plan level, not beneficiary by beneficiary or zip code by zip code. Manufacturers cannot alter prices only for the "GUARD Model beneficiaries." As such, downstream effects (such as changes in pricing or formulary tiering) would be nationwide or plan-wide.

CMS speculates in one portion of the preamble that manufacturers might lower U.S. list, launch or net prices in response to GUARD.[32] However, again, these responses would be nationwide (or plan-wide) – not limited to GUARD model beneficiaries. CMS' regulatory impact analysis also undermines such speculation. It concludes that manufacturers are unlikely to lower prices or increase rebates as a result of GUARD, stating: "Manufacturers could opt to change list prices in response to the model, but this will impact their pricing across the entire domestic market and would have unfavorable implications for inflation rebates outside of the model. Alternatively, manufacturers could increase rebates for Part D plan sponsors. . . . However, these rebates would be expected both inside and outside of the model in negotiations with large plan sponsors and would be difficult to remove once the model is over."[33]

The "limitation" to GUARD model beneficiaries thus serves no bona fide design purpose, and in operation would serve as no limitation at all. CMS could have simply used a multiplier (such as 25 percent) in lieu of counting the units of 25 percent of beneficiaries based on zip code residence. Such an across-the-board, nationwide multiplier would achieve the same result as CMS' proposed geographic limitation. GUARD should thus be understood as a nationwide, mandatory model, exceeding CMMI authority to merely engage in Phase I "tests."

B. GUARD does not meet the statutory preconditions for a Phase I test

Even if GUARD were a "test," Section 1115A authorizes CMS to conduct Phase I tests only under strict conditions established by Congress.[34] As relevant here, Phase I testing is permitted only "where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures."[35] GUARD does not meet these requirements.

First, GUARD does not identify a "defined population" characterized by "deficits in care." Instead, CMS selected 17 "top spending categories" for single source drugs and sole source biologics with more than $69 million in annual gross Medicare Part D spending and stated in a conclusory manner that there are "deficits in care" for those therapeutic categories.[36] Therapeutic categories, by definition, often include

[31] 90 Fed. Reg. at 60356.
[32] 90 Fed. Reg. at 60353.
[33] 90 Fed. Reg. at 60411. The Impact Analysis also assumes that "brown-bagging" could increase as a result of GUARD. We believe this assumption is incorrect, because beneficiaries cannot turn a Part D drug into a Part B drug solely by purchasing the drug and bringing it to a physician's office. *See* https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf at p. 58 (For drugs to be covered under Part B as "incident to" a physician's service "The charge, if any, for the drug or biological product must be included in the physician's bill and the cost of the drug or biological product must represent an expense to the physician.").
[34] SSA § 1115A(a)(1)).
[35] SSA § 1115A(b)(2)(A).
[36] 90 Fed. Reg. at 60352.

multiple drugs. Thus, reliance on "top spending categories" is wholly insufficient as a basis for defining a population with deficits of care than can be evaluated in a test. But CMS does not offer any evidence to indicate those specified drugs or categories align with conditions "for which there are deficits in care." Nor does CMS identify any particular deficit (*e.g.*, access barriers, underuse, adherence problems, or unmet clinical needs) that results in "poor clinical outcomes or potentially avoidable expenditures." To the contrary, as noted above, CMS includes in GUARD beneficiaries who receive significant assistance for cost-sharing, such as LIS beneficiaries, or beneficiaries in enhanced plans. Further, as discussed in section IV.B of this letter, what little explanation the Agency does offer for "deficits in care" rests on out-of-date studies that predate the start of affordability gains included in Part D redesign. Indeed, the Agency's own discussion illustrates that Medicare program spending—not deficits in care—was the sole selection criterion.

Second, even if CMS had adequately identified a defined population with "deficits in care," GUARD still fails the statutory requirements for a Phase I test because it does not "address" those deficits in the manner Section 1115A requires. CMS concedes that GUARD rebates do not "directly impact enrollees" and will not be "visible to beneficiaries at the point of sale."[37] Thus, to the degree other factors are creating "deficits of care" for Part D beneficiaries (e.g., plan formulary and UM policy) these are being ignored under GUARD. Moreover, by focusing on total gross costs to select therapeutic areas, CMS is choosing to price control, and thus damage innovation, for many of the most widely prescribed and effective drugs. CMS also proposes to include *all of* the six protected classes – and thus damage innovation for drugs used to treat vulnerable beneficiaries, such as those with epilepsy, mental illness, cancer, HIV-AIDS, and organ transplants.[38] Medicines not only save and improve the lives of millions of patients, but they also help control overall health care costs by preventing costly complications and replacing other medical interventions. Medicines enable better disease management and can avert the need for expensive emergency room visits, hospital stays, surgeries, and long-term care. Researchers estimate that medical breakthroughs to prevent and treat chronic disease could save 13.5 million lives and reduce health spending by $7 trillion over the next 15 years.[39] By harming innovation for widely prescribed drugs, innovative medicines, and drugs in all of the six protected classes, CMS would exacerbate – not address – deficits in care across the medical landscape.

Moreover, by tying the calculation of GUARD rebates to international prices, GUARD violates section 1182 of the Social Security Act because it would effectively utilize quality-adjusted life years (QALYs) or similar measures—imported from foreign countries—as a threshold to determine coverage, reimbursement, or incentive programs under Medicare, something CMS has repeatedly conceded it is prohibited from doing.[40]

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[37] 90 Fed. Reg. at 60352, 60411.
[38] PAN Foundation. Maintain the six protected classes in Medicare Part D formularies. Available at: https://www.panfoundation.org/our-positions/maintain-the-six-protected-classes-in-medicare-formularies/#:~:text=The%20six%20protected%20classes%20are,helpful%20articles%20to%20action%20alerts.
[39] PFCD. What is the Impact of Chronic Disease in the United States? Available at: https://12860544-bc49-4b5c-9d49-f592cc453792.usrfiles.com/ugd/128605_dcf1fd8434644230aaf899ed090179e2.pdf
[40] *See*, e.g., 89 Fed. Reg. 65724, 65744 (Aug. 12, 2024); 85 Fed. Reg. 54820, 54865 (Sept. 2, 2020).

C. GUARD exceeds CMS' statutory authority for and falls outside a Phase I Model

Numerous other features of the CMMI statute and the APA make clear that GUARD exceeds CMS' statutory authority.

Payment and service delivery model. GUARD exceeds CMS's statutory authority because it is not a "payment and service delivery model[]" authorized by Section 1115A. The term "[d]elivery" means "the act of conveying."[41] Thus, CMMI "payment and service delivery models" cannot change solely the payment amount but must test changes to *how* payment is delivered.[42]

GUARD, however, does not create an "alternative" method of payment; it simply seeks to manipulate domestic and international pricing through the imposition of mandatory, punishing rebates, in effect creating price controls on the biopharmaceutical industry. In contrast, in prior cases relying on the Phase I CMMI authority, CMS has altered the payment methodology by shifting from fee-for-service to bundled payment or by varying payment based upon certain quality metrics.[43] Because GUARD does not create an alternative payment methodology, it is not a "payment and service delivery model" and is not authorized under the CMMI statute.[44]

The GUARD rebates are unauthorized sanctions. The APA supports the conclusion that GUARD is not within CMMI authority for Phase I models, as the rebate is a sanction (which is defined to include both penalties and fines), requiring an express grant of authority. The APA states: "A sanction may not be imposed or a substantive rule or order issued except within jurisdiction delegated to the agency and as

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[41] *Delivery*, AMERICAN HERITAGE DICTIONARY, https://www.ahdictionary.com/word/search.html?q=delivery,); *see also Delivery*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/delivery ("the act or manner of delivering something").
[42] *See Paroline v. United States*, 572 U.S. 434, 447 (2014) ("When several words are followed by a clause which is applicable as much to the first and other words as to the last, the natural construction of the language demands that the clause be read as applicable to all.").
[43] For example, the Oncology Care Model provided for monthly payments to providers for coordinating episodes of oncology care and incentive payments tied to care improvements. While PhRMA questions CMS' authority to unilaterally impose mandatory models, even such prior models concerned payment delivery, not simply payment amount. For example, CMS' recent Transforming Episode Accountability Model tests an "episode-based payment approach in which ... hospitals ... receive a target price to cover all costs associated with the episode of care." CMS compares Medicare reimbursement under fee-for-service to episode-based payments. https://www.cms.gov/priorities/innovation/innovation-models/team-model. Other mandatory models are similar – using bundled, or episode-based payments or varying payment based on quality or performance indicators. *See e.g.,* Comprehensive Care for Joint Replacement Model, https://www.cms.gov/priorities/innovation/innovation-models/cjr; Radiation Oncology Model, https://www.cms.gov/priorities/innovation/innovation-models/radiation-oncology-model; and Increasing Organ Transplant Access Model https://www.cms.gov/priorities/innovation/innovation-models/iota.
[44] SSA § 1115A(b).

authorized by law."[45] Courts have recognized that an express grant of authority is required to promulgate sanctions[46]—and the CMMI statute does not contain the kind of clear statement that would suffice.[47]

Extends beyond Medicare. GUARD further exceeds CMMI authority, because it attempts to influence matters outside of the "care furnished to individuals" under Medicare,[48] and even outside of the United States. This is inconsistent with the statutory requirement to test payment and service delivery models "to determine the effect of applying such models under the applicable title [Medicare]."[49] Instead, GUARD would impose rebates in the U.S. that are increasingly more punishing the lower ex-U.S. prices are, an aspect CMS concedes is expected to incentivize manufacturers to increase prices abroad. This turns CMMI's model testing authority on its head—instead of testing the effect of applying a payment and service delivery model to Medicare, CMS seeks to use GUARD to apply changes outside of Medicare. For example, in the impact analysis, CMS states that manufacturers would likely "increase prices" in foreign countries as a result of the model[50] but controlling prices outside the United States or attempting to equalize U.S. pricing with foreign pricing is outside the scope of Medicare.

D. GUARD impermissibly rewrites, rather than "waives," the inflation rebate statute

The CMMI statute permits the Secretary to "waive" certain requirements in the Social Security Act "as may be necessary solely for the purposes of carrying out this section with respect to testing" Phase I models.[51] CMS invokes that waiver authority in an attempt to "modif[y]" the Part D inflation rebate provisions of the IRA.[52] But CMS effectuates this supposed waiver by adding—as a supplement to the existing inflation-driven IRA rebate—a new, foreign-pricing-based rebate.[53] And Section 1115A at most authorizes *waiving* otherwise-applicable requirements, not rewriting existing statutes.

To "waive" means "to refrain from pressing or enforcing."[54] Here, CMS is not refraining from pressing or enforcing the inflation rebate statute. The Part D inflation rebates authorized by Congress would continue to apply as enacted, and CMS is not declining to collect those rebates.[55] Rather, GUARD would simply layer on an *additional*, *separate* rebate obligation with no connection to domestic inflation. This new rebate cannot be described as a "waiver" of the existing rebate—no more than a lender's new monthly fee *in addition* to an existing fee could be described as a "waiver" of the existing fee—because *increasing*

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[45] 5 U.S.C. § 558(b). "'Sanction' includes the whole or a part of an agency . . . (C) imposition of penalty or fine." 5 U.S.C. § 551(10). *See also* 5 U.S.C. § 559 "Subsequent statute may not be held to supersede or modify this subchapter, except to the extent that it does so expressly."

[46] "Congress could not speak more clearly than it has in the text of the APA." *American Bus Ass'n v. Slater*, 231 F.3d 1, 6-7 (D.C. Cir. 2000). *See also Stanard v. Olesen*, 74 S. Ct. 768, 771 (1954) (describing section 558 as a "safeguard"); *Regents of Univ. Sys. of Ga. v. Carroll*, 338 U.S. 586, 599 (1950) (Federal Communications Commission could not exceed the only sanction authority Congress granted it: the refusal or revocation of a license); *Carpenter v. Mineta*, 432 F.3d 1029, 1033 (9th Cir. 2005) (Where statute did not explicitly delegate civil enforcement powers, it was reasonable to conclude the Agency lacked such authority).

[47] *See Gold Kist, Inc. v. USDA*, 741 F.2d 344, 348 (11th Cir. 1984), amended, 751 F.2d 1155 (11th Cir. 1985) ("Because section 1359(h) and (i) do not plainly impose a marketing penalty . . . the agency had no authority to impose such a penalty.").

[48] SSA § 1115A(a)(1).

[49] SSA § 1115A(b)(1).

[50] 90 Fed. Reg. at 60410.

[51] SSA § 1115A(d)(1).

[52] 90 Fed. Reg. at 60408.

[53] 90 Fed. Reg. at 60341.

[54] *Waive*, MERRIAM-WEBSTER, merriam-webster.com/dictionary/waive; *see also Waive*, AMERICAN HERITAGE DICTIONARY, https://www.ahdictionary.com/word/search.html?q=waive ("[t]o refrain from insisting or enforcing").

[55] 90 Fed. Reg. at 60341.

regulatory burdens is the opposite of *waiving* those burdens. If CMMI could claim to "waive" a calculation Congress mandated, keep those statutory rebates in place, and then add a different rebate regime on top, that would eviscerate any principled restraint against Section 1115A becoming a far-reaching authority to rewrite anything in the Medicare statute (and certain additional provisions), including the Medicare statute's most consequential pricing provisions.

The Supreme Court has squarely rejected this limitless theory of agency waiver authority. In *Biden v. Nebraska*, the Court evaluated an agency's claimed authority to "waive or modify" statutory provisions and held that such language does not confer "unlimited power to rewrite" a statute.[56] The Court recognized that an agency action that adds "new and substantially different provisions cannot be said to be a 'waiver' of the old in any meaningful sense," because it "not only nullifies existing provisions, but augments and expands them dramatically," effectively drafting "a new section … from scratch."[57]

The CMMI statute is even more limited than the statute in *Biden v. Nebraska*; it does not authorize modifications, only waivers. And CMS' interpretation embodied in GUARD suffers from the same fundamental defect that the Supreme Court identified in that case. GUARD does not suspend or relax the IRA inflation rebate requirements. In fact, it does not suspend or relax the statutory inflation rebate provisions at all; under GUARD, manufacturers would continue to provide the statutory inflation rebates. Rather, GUARD purports to rewrite the inflation rebate statute from the ground up by layering on an entirely new, foreign-pricing-based rebate scheme that Congress did not authorize. That "radically new text" cannot be justified through the waiver authority in Section 1115A(d), because it does not involve a waiver.[58]

E. CMS cannot extend CMP authority to new "incremental" rebates

CMS' proposal to extend the IRA inflation-rebate civil monetary penalty (CMP) regime to new "incremental" rebates[59] created by GUARD is another unauthorized rewrite of the statute. In Section 1860D-14B(e) of the Social Security Act, Congress expressly authorized CMP liability for a manufacturer's failure to provide statutory inflation rebates and set the CMP amount based on 125 percent of the unpaid inflation rebates. CMS cannot convert that targeted enforcement mechanism into a general-purpose penalty tool for CMS' new additional rebates.

CMS identifies no statutory basis for this expansion, and the expansion cannot be justified by CMMI's waiver authority. As noted, Section 1115A(d) authorizes only the waiver of certain otherwise-applicable statutory requirements "as may be necessary solely for the purposes of … testing" a Phase I model.[60] It does not authorize CMS to create new enforcement powers, much less to extend punitive CMP authority to obligations that Congress did not enact. Put simply, CMS' authority to waive elements of the inflation rebate statute for testing purposes does not suggest that CMS can create new rebates based on MFN pricing, call them "incremental inflation rebates," and then assess CMPs for failure to provide those new MFN rebates. Nor can such an expansion be described as a "waiver" of the CMP provisions in the

[56] 600 U.S. 477, 500-02 (2023).
[57] *Id.* at 498-99.
[58] *Cf. id.* at 498.
[59] 90 Fed. Reg. at 60386.
[60] SSA § 1115A(d)(1).

inflation rebate statute; *extending* a penalty to cover new conduct is not a "waiver" of that penalty in any sense of the word.

CMS also cannot rely on section 1128A(a)(8) of the Social Security Act to authorize the CMPs it proposes. That authority is delegated to the Office of the Inspector General,[61] and in any case does not include the 125 percent CMPs that CMS proposes. Section 1128A(a)(8) relates to making a false statement or providing a false record in connection with a claim to a federal health care program. Not providing a GUARD rebate would not be a false statement. Finally, as discussed in more detail above, CMS lacks the express congressional authority required under the APA, 5 U.S.C. § 558(b), for the civil monetary penalties it proposes for failure to pay the GUARD rebates.

F. CMS's interpretation of Section 1115A runs afoul of the major questions doctrine

The major questions doctrine forecloses CMS' interpretation of its statutory authority in multiple respects. The Supreme Court has recognized that agencies must identify "clear" congressional authorization when claiming the power to make decisions of "vast 'economic and political significance.'"[62] CMS has identified no such clear statutory command here. To the contrary, CMS seeks to use a narrow statutory authority to "waive" certain requirements "solely" to test a Phase I model as the launching pad for an economically transformative rebate scheme that substitutes foreign drug prices for those in the Medicare statute—in effect, imposing a price control—all under the guise of "waiving" inflation rebates. If Congress had intended to give CMS this sort of sweeping, economically transformative authority, it would have done so expressly—not through an oblique waiver provision or experimentation authority to "test payment and service delivery models."[63] CMS' expansive interpretation of its power is especially suspect given that Congress recently enacted a comprehensive drug pricing program in the IRA and considered—but did not adopt—MFN-style proposals.[64] That history underscores that GUARD raises major questions.

In addition, the statute does not authorize CMMI to make the consequential decision that participation in a model must be mandatory for specified individuals or entities.[65] To the contrary, section 1115A lacks any text clearly authorizing CMS to compel participation in payment and service delivery models, and the best reading of the statutory text and context is that the section precludes mandatory models.[66] Accordingly, the CMMI statute cannot properly be read as allowing CMMI to force individuals or entities to participate in a scheme that displaces the Medicare statute, as this would confer powers with vast

[61] 76 Fed. Reg. 13618 (March 14, 2011).
[62] *West Virginia v. EPA,* 597 U.S. 697, 716 (2022) (quoting *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014)).
[63] 42 U.S.C. § 1315a(b)(1); *see, e.g.*, *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 594 U.S. 758, 764 (2021).
[64] *See* H.R. 3, 116th Cong. § 101 (2020).
[65] One minor exception is SSA §1902(a)(84), stating that a state plan for medical assistance must "provide for implementation of the payment models specified by the Secretary under section 1115A(c) for implementation on a nationwide basis unless the State demonstrates to the satisfaction of the Secretary that implementation would not be administratively feasible or appropriate to the health care delivery system of the State." This provision reinforces that CMMI lacks general authority to make models mandatory and Congress instead provided authority for a mandatory model limited only to the case of certain state Medicaid plans.
[66] Neither section 1871 nor section 1102 of the Social Security Act provides requisite authority. These provisions, respectively, authorize CMS to promulgate regulations "necessary" to "carry out" the Medicare insurance program, or to provide for the "efficient administration of the functions with which" CMS is charged. The authority to "carry out" or "administer" other parts of the statute only allows CMS to promulgate regulations to implement mandatory provisions that lie elsewhere in the law – not convert voluntary testing authority into mandatory, legislative power.

economic and political significance on CMMI without clear congressional authorization for such an extraordinary power.

II. GUARD WOULD VIOLATE FEDERAL APPROPRIATIONS LAW

In addition to exceeding CMS' substantive authority under Section 1115A, GUARD independently violates principles of federal appropriations law set forth in the Constitution and fiscal statutes. Specifically, GUARD requires manufacturers to transfer funds to the Medicare Supplementary Medical Insurance (SMI) Trust Fund without statutory authorization, thereby augmenting Agency appropriations in violation of fiscal laws that CMS has no authority to waive.

An established principle of federal appropriations law—the anti-augmentation principle—generally forbids agencies from increasing or supplementing their congressionally appropriated funds using money obtained from outside sources unless Congress has expressly authorized them to do so.[67] This principle reflects the Constitution's allocation of appropriations authority to Congress alone.[68] It prevents agencies from circumventing that constitutional constraint by financing themselves through unauthorized collections.

The anti-augmentation principle is codified in several federal statutes, including the Miscellaneous Receipts Act[69] and the Anti-Deficiency Act.[70] Key here, the Miscellaneous Receipts Act requires that federal officials "receiving money for the Government from any source shall deposit the money in the Treasury as soon as practicable without deduction for any charge or claim."[71] The statute thus establishes a clear rule: when an agency receives funds, it must remit them to the Treasury's general fund unless Congress has specifically directed otherwise.[72] Violations of this rule are redressable in court.[73]

GUARD, by its terms, enables unlawful augmentation of the Agency's appropriated funds. The Medicare SMI Trust Fund is a congressional appropriation, fully subject to federal fiscal laws.[74] Yet, under GUARD, CMS would require manufacturers to provide new, MFN-level "incremental" rebates and would deposit those rebates directly into the Medicare SMI Trust Fund, not the Treasury's general fund. Those monetary transfers would thus augment the SMI Trust Fund appropriation—usurping Congress's exclusive power of the purse and squarely violating the Miscellaneous Receipts Act.

As explained above, nothing in the statutes CMS invokes authorizes this circumvention of federal appropriations law. Section 1115A empowers CMS to test payment and service delivery models and authorizes waivers of limited Social Security Act requirements in service of those tests. The statute does not authorize waivers of federal appropriations laws, grant CMS revenue-raising authority, or permit CMS to compel private entities to transfer money to the government outside of existing statutes. Nor can CMS rely on the existing IRA rebate provision that the Agency purports to "waive." That provision authorizes a specific rebate formula based on the extent to which a drug's price increases faster than inflation—not the new MFN pricing scheme CMS has proposed to institute in Medicare. And in any

[67] *See* 2 GAO, *Principles of Federal Appropriations Law* 6-162–63 (3d ed. 2006).
[68] U.S. Const. art. I, § 9, cl. 7.
[69] 31 U.S.C. § 3302(b).
[70] 31 U.S.C. §§ 1341–42.
[71] 31 U.S.C. § 3302(b).
[72] *See* 2 GAO, *supra*, at 6-166–67.
[73] *See Scheduled Airlines Traffic Offs., Inc. v. Dep't of Def.*, 87 F.3d 1356, 1361-62 (D.C. Cir. 1996).
[74] 2 GAO, *supra*, at 6-208.

event, Section 1115A's waiver authority is expressly limited to specified requirements of the Social Security Act; it does not extend to federal appropriations statutes such as the Miscellaneous Receipts Act or the Anti-Deficiency Act.

III. GUARD RAISES SERIOUS CONSTITUTIONAL CONCERNS

Beyond the defects described above, GUARD raises significant constitutional concerns, including under the separation of powers and non-delegation doctrine, the Presentment Clause, and the Patent Clause. Under settled principles of constitutional avoidance, Section 1115A should be construed narrowly to avoid these serious questions.[75]

A. GUARD raises separation-of-powers and non-delegation concerns

CMS' interpretation of Section 1115A in GUARD would violate the separation of powers by vesting the Agency with legislative authority that the Constitution reserves to Congress alone. Article I provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States."[76] That assignment necessarily carries with it a bar on delegating Congress's lawmaking power to the Executive Branch. While Congress may authorize agencies to *implement* statutes, it must supply an "intelligible principle" that makes clear both the general policy the Agency must pursue and the boundaries of its authority, and it must provide sufficient standards to enable courts to determine whether the Agency has followed the law.[77]

If the CMMI statute in fact authorized GUARD, it would plainly violate these constitutional principles. Under CMS' reading, a model need not "test" a hypothesis; no concrete "deficits in care" need be identified that a model would address; and the statute's "waive[r]" authority becomes a power to rewrite statutes rather than waive certain requirements. Here, CMS' limitless reading would allow the Agency to, in effect, impose a sweeping price-control scheme via rebates that punish manufacturers for differentials between foreign and domestic pricing. Far from giving effect to an intelligible principle laid down by Congress, CMS' reading would permit it to rewrite the Medicare statute as the Agency sees fit. And these constitutional concerns would be exacerbated by an attempt to insulate aspects of GUARD from judicial review.[78] The availability of meaningful judicial review has long been recognized as a critical safeguard in delegation analysis, helping to ensure that agencies remain within the bounds Congress set.[79]

B. GUARD raises Presentment Clause concerns

CMS' interpretation of Section 1115A also violates the Presentment Clause, which forbids the Executive Branch from unilaterally amending, repealing, or nullifying duly enacted statutes. In *Clinton v. City of New York*, the Supreme Court applied the Presentment Clause to strike down the Line Item Veto Act, which authorized the President to "cancel in whole" certain spending and tax provisions after they had been enacted into law.[80] Because the Act empowered the President to effectuate "the functional equivalent of partial repeals of Acts of Congress" "for his own policy reasons, without observing the

[75] *See, e.g.*, *Zadvydas v. Davis*, 533 U.S. 678, 689 (2001).
[76] U.S. Const. art. I, § 1.
[77] *FCC v. Consumers' Rsch.*, 606 U.S. 656, 672 (2025).
[78] *See* SSA § 1115A(d); 90 Fed. Reg. at 60406.
[79] *See Am. Power & Light Co. v. SEC*, 329 U.S. 90, 106 (1946) ("The legislative policies and standards being clear, judicial review of the [agency action] safeguards against statutory or constitutional excesses.").
[80] *Clinton v. City of New York*, 524 U.S. 417, 439 (1998).

procedures set out in Article I, § 7," it violated the Presentment Clause.[81] As the Court explained, "[t]here is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes."[82]

CMS' interpretation of Section 1115A carries the same constitutional defect. Congress enacted the Medicare inflation rebate provisions as part of the IRA following extensive legislative debate, passage by both Houses of Congress, presentment to the President, and signature into law—the "single, finely wrought and exhaustively considered" process that the Presentment Clause requires.[83] Under GUARD, however, CMS purports to impose upon the statutorily-enacted rebate framework an entirely new rebate mechanism based on MFN prices—a mechanism that Congress recently considered and declined to adopt. That adulteration goes beyond mere implementation. In legal and practical effect, GUARD amends key aspects of the statutory scheme Congress enacted and supplants them with an Agency-designed policy of CMS' own making.

C. GUARD raises Patent Clause concerns

Finally, GUARD raises serious concerns under the Constitution's Patent Clause, which empowers Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[84] Through this Clause, the Constitution assigns to Congress—and Congress alone—the responsibility to design and calibrate the balance between innovation incentives and access to patented inventions, including innovative medicines.[85] Congress has exercised that authority by enacting a comprehensive patent framework that allows manufacturers, during the patent term, to price products at market rates, subject to competition and other constraints Congress has chosen to impose.

Courts have made clear that this balance may not be recalibrated without congressional authorization. In *Biotechnology Industry Organization v. District of Columbia*, the Federal Circuit held that only Congress may "re-balance the statutory framework of rewards and incentives" that underlies the federal patent system.[86] There, the court invalidated a pricing restriction on patented medicines because it interfered with the exclusivity and market-based returns that Congress deliberately secured through patent law.[87] That principle applies with even greater force here, where CMS proposes to override market prices derived from the U.S. patent system and replace them with prices imported from foreign patent regimes that reflect fundamentally different legal standards, economic assumptions, and innovation incentives. CMS even goes so far as to treat foreign analogue products in which a manufacturer may have no patent rights or any economic interest as interchangeable with U.S.-patented products for purposes of imposing rebate obligations. Section 1115A should not be read to endorse that override.

IV. GUARD WOULD NOT HELP SENIORS ACCESS OR AFFORD THEIR MEDICINES

[81] *Id.* at 444-45.
[82] *Id.* at 438.
[83] *Id.* at 439-40 (quotation omitted).
[84] U.S. Const. art. I, § 8, cl. 8.
[85] *Biotech. Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373-74 (Fed. Cir. 2007).
[86] *Id.*
[87] *Id.*

President Trump and his Administration have repeatedly publicly vowed to address consumer affordability.[88,89] However, rather than taking actual action to address affordability, CMS has chosen to impose a rebate based upon MFN reference pricing that will do nothing to improve, and potentially will harm, affordability for seniors. Further, as previously discussed in Section I.B, CMS justifies GUARD by claiming there are "deficits in care" for patients in Medicare related to beneficiary costs that are not supported by evidence or reality.

A. GUARD would have little, if any, beneficial impact on patient affordability

Recent changes to the Part D benefit, including the establishment of an annual maximum out-of-pocket cap and the (still underutilized) option for beneficiaries to pay out-of-pocket expenses monthly over the year rather than as they are incurred, represent substantial gains in patient affordability in Part D.[90] However, in its explanation for difficulty accessing and affording care, CMS seems to rely on an outdated framework, most predominantly on a pre-IRA analysis that does not take into account these benefit changes.

Furthermore, the Proposed Rule does not even attempt to help Part D beneficiaries access lower prices. Manufacturer payments of incremental MFN rebates are deposited in the Part D account of the Medicare SMI Trust Fund and do not impact patient out-of-pocket costs, Part D benefit paraments, or plan payments. In fact, the impact analysis included in the Proposed Rule projects that GUARD would actually increase beneficiary costs overall, including both cost-sharing and premiums.[91] These projections undermine CMS' baseless suggestion that GUARD would meaningfully address affordability issues for patients and illustrate CMS' willingness to risk the devastating consequences of its proposal in return for an illusory goal.[92]

B. The "deficits in care" CMS cites in GUARD are illusory

CMS frames the Proposed Rule on the premise that Medicare beneficiaries experience "deficits of care."[93]

The realities of the Part D benefit design make it immediately apparent why CMS's premise – that a "defined population" with "deficits of care" can be in any way meaningfully defined based on the gross prices of particular drugs in a way that allows for development of a valid test – immediately collapses of its own weight. Indeed, the very evidence the Agency cites argues against its premise. Instead of substantiating its premise, CMS turns to other factors in the current Part D benefit design, **relying largely on pre-Part D benefit redesign cost-sharing studies and proposing a GUARD design it concedes does not directly reduce beneficiaries' out-of-pocket costs**.

CMS states that the Agency selected the U.S. Pharmacopeia (USP) categories included in GUARD because "Medicare beneficiaries taking these drugs have conditions for which deficits in care exist and

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[88] BBC. (December 2025). Trump vows to make US affordable again, as Americans feel the pinch. Available at: https://www.bbc.com/news/articles/ckgl63lrpkmo
[89] White House. (November 2025). Day by day, President Trump is Making America Affordable Again! Available at: https://youtu.be/R5a9h_LP7uw
[90] 42 U.S.C. § 1395w-102 (2026).
[91] 90 Fed. Reg. at 60348.
[92] *Ibid.* at 60352.
[93] 90 Fed. Reg. 60352.

they represent a meaningful amount of spending under Part D."[94] To support this premise, CMS cites studies examining the relationship between Part D drug cost-sharing and utilization.[95] However, almost all of the cited studies predate the Part D benefit redesign's annual maximum out-of-pocket cap. A more complete literature review would have identified recent evidence that the cap on out-of-pocket costs is associated with increased access to prescribed medicines.[96] For example, the IRA out-of-pocket cap is expected to save asthma and COPD patients more than half a billion dollars each year in out-of-pocket costs, driving medication adherence and allowing them to live healthier lives.[97] Instead of the drastic proposals in this rule, which CMS admits "does not directly impact Part D enrollees' out-of-pocket costs for [GUARD Model drugs]," and could even increase patient out-of-pocket costs, CMS should instead work to improve the yet to-date underutilized Medicare Prescription Payment Program to make medicines even more affordable on a month-to-month basis below the annual cap by encouraging awareness and making election simpler, such as through a real-time point-of-sale election option.[98] While CMS makes unsupported assertions about "deficits in care" for patients based on assumed cost burdens, the proposed rule does not impact patient costs, and the Agency simultaneously discounts the fact that U.S. patients have uniquely benefitted from biopharmaceutical innovations. U.S. patients have the advantage of the fastest access in the world to breakthrough life-saving treatments, contributing to a 34 percent drop in cancer mortality between 1991 to 2022, and including advances in HIV and hepatitis C therapies, innovative statins and their generics, and revolutionary GLP-1 treatments.[99] These biopharmaceutical advancements vastly improve the lives of Americans and reduce spending on costly health care interventions and long-term health care.[100]

C. GUARD would not address the actual deficits in care seniors face

In the Proposed Rule, CMS initially cites concerns about beneficiary out-of-pocket costs that may produce deficits in care as the basis for GUARD. CMS then proceeds to propose a policy structured around the wholly unrelated collection of MFN-based rebates. While CMS acknowledges that GUARD rebates would have no direct effect on beneficiary cost-sharing[101], the Agency speculates about the potential for Part D cost sharing to be reduced if manufacturers were to respond to GUARD by lowering U.S. list prices. However, even CMS notes that this outcome is far from probable, and in even considering this outcome, CMS fails to appreciate that Part D is only one part of a highly complex, nationwide marketplace for medicines in which manufacturers and payers alike make sophisticated decisions based on a myriad of carefully calculated considerations. The near-total disconnect between the subject of the

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[94] *Ibid.* at 60351.
[95] *See Ibid.* at 60352.
[96] K Lin J., et al. (December 2025). Specialty Oral Anticancer Prescription Fill Rates After Medicare Part D Cost-Sharing Changes in 2024. *JAMA.* Available at: https://www.10.1001/jama.2025.22134.
Feller M., Madden R., Holcomb K. Part D Trend Insights: 2024 Trend Analysis Reveals Sharp Increase in Specialty Drug Utilization Among Non-Low Income Beneficiaries. *Milliman.* Available at: https://www.milliman.com/en/insight/part-d-trend-insights-analysis-specialty-drug-utilization.
[97] Mein et. al. (April 2025). Out-of-Pocket Prescription Drug Savings for Medicare Beneficiaries with Asthma and COPD Under the Inflation Reduction Act. *J Gen Intern Med*. Available at: https://pubmed.ncbi.nlm.nih.gov/39367288/
[98] *See* PhRMA comment letter on CY 2027 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Program Proposed Rule (CMS-4212-P). Submitted January 23, 2026.
[99] PhRMA. (February 2025). A New Era of Biopharmaceutical Innovation. Available at: https://innovation.org/wp-content/uploads/2025/02/PhRMA-InnovationReport.pdf.
[100] *Ibid.* (Every dollar invested in medicines generates roughly three times the impact on life expectancy compared to other kinds of medical care).
[101] 90 Fed. Reg. 60352

Proposed Rule (beneficiary costs that may produce deficits in care) and the proposed mechanism for GUARD (MFN-based rebates to CMS), together with the admission that GUARD will not improve beneficiary cost-sharing, reveal a serious lack of forethought and show that the record before CMS does not support its proposal.

Further, CMS' sole focus on out-of-pocket cost is shortsighted and fails to recognize the excessive barriers to timely access that Part D plans are currently imposing on seniors. For example, a recent IQVIA white paper found that over 70 percent of patients were initially denied coverage when trying to fill a new prescription for pulmonary arterial hypertension (PAH), multiple sclerosis (MS), immunology, and migraine medicines.[102] Ten to 19 percent of patients faced delays of five weeks or longer, and on average patients encountered two to three rejections before receiving approval – though some had to go through 11 or more.[103] These findings are confirmed in a recent survey of Medicare beneficiaries by the organization No Patient Left Behind (NPLB), which revealed that 30 percent of beneficiaries said their Part D plan initially denied access to medicines prescribed by their doctor, and among those, 40 percent had to use a medication that was not their physician's first choice, and 17 percent were unable to access any prescribed treatment at all.[104] These access concerns due to plan behavior even apply in the six protected classes, where one study found that plans require utilization management of drugs in the protected classes nearly 40 percent of the time, and the average Part D beneficiary was enrolled in a plan that places drugs from the protected classes on higher tiers (non-preferred or specialty) 64 percent of the time.[105] If CMS really wanted to address deficits in care, the Agency should focus on limiting these abusive plan behaviors that actually prevent seniors from accessing medically necessary therapies instead of the misguided GUARD policy, which will not help beneficiaries.

D. The highly speculative (if not unattainable) benefits of GUARD in no way justify its catastrophic impact on innovation and the U.S. economy

As discussed further in Sections V and VI, the tradeoffs imposed by GUARD are disproportionately negative. The proposed policies would impose significant long-term harms on pharmaceutical innovation, employment, and U.S. global competitiveness. When weighed against these harms, risks to innovation, employment, and affordability of critical medications, any limited benefits of the policy reflect a catastrophic cost-benefit ratio.[106] MFN-style frameworks fall short of addressing the real drivers of drug costs and deficits in care.[107] Critically, GUARD threatens pharmaceutical innovation, high-skilled employment, and global leadership for virtually no patient benefit.

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[102] IQVIA. (June 2025). The Impact of Formulary Controls on Medicare Patients in Five Chronic Therapeutic Areas. Available at: https://www.iqvia.com/locations/united-states/library/white-papers/the-impact-of-formulary-controls-on-medicare-patients-in-five-chronic-therapeutic-areas

[103] *Ibid*.

[104] No Patient Left Behind. (March 2025). Price Controls Hinder Treatment Access in Medicare Part D. Available at: https://www.nopatientleftbehind.org/resource-materials/price-controls-hinder-treatment-access-in-medicare-part-d.

[105] Medicare Part D's Six Protected Class Policy: Coverage Policies Create Access Challenges for Patients with Complex, Chronic Conditions. Partnership for Part D Access. Available at: https://www.partdpartnership.org/uploads/8/4/2/1/8421729/avalere_report_on_six_protected_classes_--_february_2021.pdf

[106] Matcha G. (May 2025). The Global Risks of America's "Most-Favored-Nation" Drug Pricing Policy. *The Petrie-Flom Center.* Available at: https://petrieflom.law.harvard.edu/2025/05/22/the-global-risks-of-americas-most-favored-nation-drug-pricing-policy/.

[107] *Ibid.*

V. GUARD WOULD IMPORT FLAWED PRICES THAT DEVALUE PATIENTS AND INNOVATION

GUARD presumes that foreign government drug prices are appropriate reference points, but these governments artificially suppress prices through controls and discriminatory valuation methods like QALYs, which devalue the lives of seniors, persons with disabilities, and the chronically ill. Whether relying on the QALY or other standards of comparative- and cost-effectiveness analysis, these systems result in restricted access to medicines compared to the U.S., where patients enjoy broader and faster access to innovative treatments. Tying rebates to MFN benchmarks would import these discriminatory frameworks and undermine American values of individual dignity, equal worth, early access to life-saving medicines, and individualized decision-making in health care.

A. GUARD incorrectly assumes that drug prices set by foreign governments are an appropriate reference point

Many foreign governments engage in unfair and non-reciprocal trade practices that undermine basic intellectual property protections and deny market access to U.S. innovators. Efforts by President Trump and USTR to eliminate foreign government acts, policies and practices that have "the effect of forcing American patients to pay for a disproportionate amount of global pharmaceutical research and development, including by suppressing the price of pharmaceutical products below fair market value in foreign countries," as envisioned in Section 3 of President Trump's May 12, 2025, Executive Order, are welcomed. However, while it is critical for the U.S. to address foreign freeriding, it would be a dire misstep to import the access-limiting values inherent in those countries' systems.

In many countries outside of the U.S., governments are the primary payer for medicines and effectively dictate the price of medicines, as well as the extent and timing of patient access to medicines. This position often results in U.S. trading partners failing to appropriately recognize the value of innovation in their pricing and reimbursement policies. Instead, they engage in actions that distort markets, artificially depressing prices for new medicines below what a competitive market would provide and delaying patient access to medicines.

Foreign governments increasingly employ a range of measures, including biased health technology assessments (HTA), mandatory price cuts and revenue clawbacks, international reference pricing, unreasonable reimbursement delays and erosion of intellectual property protections.[108] These measures often are layered to exert maximum pressure to artificially devalue the medical innovation that these countries receive. Government price controls and reimbursement delays are trade barriers that allow foreign governments to enjoy the benefits of U.S. biopharmaceutical development without paying their fair share for these innovations. In fact, the U.S. government has long recognized that foreign price controls on innovative medicines undermine biopharmaceutical innovation and limit patient access to medicines.[109]

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[108] *See* Pharmaceutical Research and Manufacturers of America. *Comment on Request for Comments Regarding Foreign Nations Freeloading on American-Financed Innovation*, Office of the U.S. Trade Representative, 90 Fed. Reg. 23105 (May 30, 2025). Available at: https://comments.ustr.gov/s/commentdetails?rid=VB9V88JYC6.

[109] U.S. Dep't of Commerce, Int'l Trade Admin. (December 2004). Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation. Available at https://web.archive.org/web/20190414170009/https://2016.trade.gov/td/health/DrugPricingStudy.pdf

In contrast to foreign governments that have employed price controls and other barriers to avoid contributing their fair share to the research and development of new medicines, the U.S. has long supported biopharmaceutical innovation through a system of robust intellectual property protections and market-based competition. Often, data that compares U.S. drug prices to foreign drug prices analyzes a relatively short time window. This data ignores the fact that over time, drugs in the U.S. often become less expensive than they are overseas, due to competition from generics and biosimilars. Taking into account the full spectrum of market prices including generics, U.S. prices for prescription medicines in Medicare and Medicaid are 18 percent lower than in five other developed countries.[110] Further, generic drugs represent a far greater share of prescribed medicines in the U.S. than in other countries. Approximately 90 percent of prescriptions filled in the U.S. are generic drugs, while in other Organisation for Economic Co-operation and Development (OECD) countries, generics comprise approximately 69 percent of prescriptions filled.[111]

Americans also have a significant advantage in access to innovative medicines relative to other countries, which would be compromised by MFN reference pricing.[112] Evidence has shown that in markets where the government sets prices for medicines, drug manufacturers cannot achieve adequate returns. This results in decreased availability of innovative medicines and extended periods of time before foreign citizens eventually can access medicines. In the U.S., for example, 87 percent of medicines launched are reimbursed. By contrast, in Australia only 25 percent and in Canada only 19 percent of those same medicines are available.[113] On average, OECD countries have access to 16 percent of new medicines launched within one year of global first launch, while by contrast, patients in the U.S. enjoy access to 78 percent of new medicines within one year.[114] This dramatic difference can prove a matter of life or death for patients with serious conditions, where every month of delay is consequential.

Physicians themselves implicitly acknowledge that government price setting restricts access to needed therapies. In a survey of U.K. doctors, half reported they had multiple patients traveling abroad due to unavailable or delayed treatments, and 82 percent agreed their patients would benefit from access to more innovative medicines.[115]

GUARD import discriminatory foreign pricing methodologies. By tying U.S. drug prices to foreign health systems, GUARD risks incorporating discriminatory metrics employed by these systems that conflict with American values and the U.S. health care system organized around these values. For example, many foreign countries rely on centralized HTA bodies that apply unified, national evaluations of clinical

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[110] Philipson T., Zhang D., Zhao Q. (June 2025). International Comparison of Prices for Drug Prescriptions. *University of Chicago.* Available at: 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 (compared to Canada, France, Germany, Japan and United Kingdom).

[111] *Ibid.*

[112] IQVIA Institute. (May 2025). America's Greatness in the Biopharmaceutical Sector. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/americas-greatness-in-the-biopharmaceutical-sector/iqvia-institute-greatness-in-biopharma-2025-web.pdf.

[113] *See* Pharmaceutical Research and Manufacturers of America. Comment on Request for Comments Regarding Foreign Nations Freeloading on American-Financed Innovation, Office of the U.S. Trade Representative, 90 Fed. Reg. 23105 (May 30, 2025). Available at: https://comments.ustr.gov/s/commentdetails?rid=VB9V88JYC6

[114] PhRMA. (April 2023). Global Access to New Medicines Report. Available at: https://cdn.aglty.io/phrma/global/blog/import/pdfs/2023-04-20-PhRMA-Global-Access-to-New-Medicines-Report-FINAL-1.pdf.

[115] Part B Access for Seniors and Physician Coalition. Available at: https://www.congress.gov/117/meeting/house/112551/documents/HHRG-117-IF14-20210504-SD084.pdf.

evidence, cost-effectiveness, safety, and overall therapeutic benefit.[116] These assessments form the basis for national decisions on coverage, reimbursement, and drug pricing.[117] By linking U.S. drug prices to prices based directly or indirectly on these assessments, GUARD would effectively import the pricing methodologies (and values they reflect) that are used in these countries.

This concern is heightened by the fact that all 19 GUARD reference countries use the QALY, an HTA tool that places a numerical value on patients' lives, either formally or informally.[118] This stands in stark contrast to the U.S., where use of QALYs in Medicare is expressly prohibited by law, as they have the effect of devaluing the lives of seniors, the disabled and chronically ill. As a result of foreign reliance on QALY-based HTA, any MFN policy is inevitably anchored to discriminatory QALY-based valuations.

A QALY seeks to quantify the value of a person or group's health by assigning a numerical value based on both the length and quality of life that is achieved through use of a particular treatment or intervention.[119] However, this methodology perpetuates discrimination against individuals with chronic conditions, disabilities, rare diseases, and older adults by assigning lower values to individuals with illnesses or impairments.[120] QALY metrics assume that certain individuals, by virtue of having a disability or illness, experience lower well-being, making treatments for those populations more likely to be deemed not cost-effective at any price compared to treatments for non-disabled individuals.[121] For example, in the United Kingdom, a patient with arthritis is worth only 50 percent of a person who is "young and in perfect health," while in Canada a patient with COPD is worth less than two thirds of someone who is deemed to be perfectly healthy.[122] Therefore, QALYs inherently devalue the lives of people with disabilities and chronic illnesses and restrict access to needed treatments for patients that rely on them.[123]

Importing foreign price controls through an international benchmarking mechanism would, in effect, delegate U.S. health-care decision-making to foreign governments whose health-economic evaluations run counter to U.S. law and ethical standards. Such judgments conflict with fundamental American values that affirm individual dignity and equal worth in every individual. In fact, Congress has explicitly stated that CMS cannot use:

> "comparative clinical effective research...in determining coverage, reimbursement, or incentive programs…in a manner that precludes, or with the intent to discourage, an individual from

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[116] *See* Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU, 2021 O.J. (L 458).
[117] European Medicines Agency. Health Technology Assessment Bodies. Available at: https://www.ema.europa.eu/en/partners-networks/health-technology-assessment-bodies.
[118] Wahl, Julia, et al. (February 2026). QALY Use in Selected OECD Countries. *Copenhagen Economics*. Available at: https://copenhageneconomics.com/publication/qaly-use-in-oecd
[119] National Institute for Health and Care Excellence. Glossary. Available at: https://www.nice.org.uk/glossary?letter=q#:~:text=One%20quality%2Dadjusted%20life%20year,a%200%20to%201%20scale
[120] Andrade G. (January 2024). Ethical Shortcomings of QALY: Discrimination Against Minorities in Public Health. *Cambridge Quarterly of Healthcare Ethics*. Available at: https://www.doi.org/10.1017/S0963180123000580.
[121] *See* Klimchak A., et al. (December 2024). Discriminatory Properties of the Quality-Adjusted Life Year Based Cost-Effectiveness Analyses for Patients with Disabilities: A Duchenne Muscular Dystrophy Case Study. *Value in Health*. Available at: https://doi.org/10.1016/j.jval.2024.07.008.
[122] Value Our Health. What is Your Life Worth Around the World? Available at: https://valueourhealth.org/voh-world-map/
[123] Mosquera J. (February 2023). QALYs, Disability Discrimination, and the Role of Adaptation in the Capacity to Recover: The Patient-Sensitive Health-Related Quality of Life Account. *Cambridge Quarterly of Healthcare Ethics*. https://www.doi.org/10.1017/S0963180122000330.

> choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability."[124]

The same section of the law further states:

> "The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under subchapter XVIII."

Further, whether based on the QALY or other standards of comparative clinical and cost-effectiveness, such determinations run counter to the importance of individualized doctor-patient decision-making. Instead, in the name of utilitarian cost-containment and budget management, national policies grounded in these standards have the effect of tying doctors' and patients' hands and preventing the tailoring of care to an individual's needs and preferences. In fact, U.S. physicians have overwhelmingly rejected such intrusions into medical decision-making.[125] Surveys show near unanimous opposition among U.S. physicians to negative German HTA assessments of COPD and diabetes therapies, reflecting deep concern that such centralized systems undervalue treatments for chronic diseases and impede individualized medical judgment.[126]

Public opposition toward QALY-based pricing is broad. Voters have expressed concerns that MFN-style policies could lead to restricted access to care, diminish the value placed on the lives of seniors and people with disabilities, and allow the government to play a larger role in medical decisions.[127] These concerns reflect deeply held American values rooted in individual freedom, the integrity of the doctor-patient relationship, and the need to limit government control over personal health care decisions.

CMS must ensure that health policy decisions value the lives of all patients equally, rather than embed a discriminatory framework that arbitrarily and unfairly undervalues certain lives.

VI. GUARD WOULD UNDERMINE U.S. COMPETITIVENESS AND SHIFT GLOBAL INNOVATION LEADERSHIP TO CHINA

The GUARD Proposed Rule and its MFN-style policies pose very real threats to the viability of the U.S. life sciences industry on a number of fronts, including the potential to cripple investment in biopharmaceutical R&D and quell future advances in innovative new medicines.

A. GUARD threatens the viability of U.S. life sciences industry

The impact of reduced investment in American biopharmaceutical innovation that would occur as a result of MFN pricing policies is sobering. As previously noted, it is well established that the MFN reference pricing proposed in GUARD would have harmful impacts on biopharmaceutical investment and innovation, and American patients would pay the price. Reductions in revenue have a direct relationship to launched drugs, as a 2015 paper found that it requires $2.6 billion of additional biopharmaceutical

[124] 42 U.S.C. § 1320e-1(d).
[125] Let My Doctors Decide Action Network. (September 2025). Survey Shows Vast Majority of U.S. Doctors Place Higher Value on Medicines vs. German Health Authorities. Available at: https://www.actionforpatients.org/post/survey-shows-vast-majority-of-u-s-doctors-place-higher-value-on-medicines-vs-german-health-authori.
[126] *Ibid.*
[127] Survivors for Solutions. (September 2025). Most Favored Nation & QALY Survey Memo. Available at: https://survivorsforsolutions.org/news-and-updates/most-favored-nation-amp-qaly-survey-memo.

revenue to lead to one new drug approval.[128] As a result of expected reductions in revenue, broad MFN pricing in Medicare and Medicaid would lead to a combined loss of 500 new treatments over 10 years, spanning both new drug approvals and approvals for new indications of existing drugs.[129]

Not only does this pose enormous harm to patients, but it directly contradicts, and even makes impossible, President Trump's promise to "get the cure to cancer, Alzheimer's, and so many other things"[130] by crippling the innovation engine that develops breakthrough therapies to realize these cures. As a result, patients will have to wait longer for potential new treatment options for devastating and life-threatening conditions.

Unilaterally imposed, GUARD would be catastrophic for the scientific innovation ecosystem, including small-to-midsize and early-stage companies. These firms often have highly concentrated portfolios –with only one or a few approved and marketed medicines – making it impossible to absorb the revenue shock of MFN pricing. MFN pricing has been estimated to reduce the number of medicines developed by these firms by up to 90 percent – 61 fewer medicines over 10 years.[131] This is particularly risky given these firms often invest in the areas in which patients have the fewest treatment options and the greatest unmet needs: rare diseases, oncology, and neurology.[132] Undermining incentives to seek new treatment options for a wide range of diseases is especially devastating for patients with one of the 95 percent of rare diseases that currently have no U.S. Food and Drug Administration (FDA)-approved treatment.[133]

The innovation ecosystem requires the contribution of small, emerging, and large companies to function. Companies often rely on both outside venture capital (VC) and the corporate VC of other biopharma companies, as well as direct partnerships, to fund their R&D. That investment only comes if there is a prospect of earning a return commensurate with the high risks and high rate of failure involved in bringing new treatments to market.[134] On average it takes ten to 15 years to bring a new medicine to patients, and only 12 percent of potential medicines that enter clinical trials are successfully approved by the FDA.[135]

Biopharmaceutical companies take this risk despite only generating a 10.3 percent profit rate (returns relative to investments) between 2022 and 2024. By contrast, PBMs, insurers and wholesalers earned a 41 percent profit rate during this period, four times more than biopharmaceutical companies.[136] At the same time, biopharmaceutical companies invested 33.2 percent of their sales back into R&D activities

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[128] Dubois P. (October 2015). Market size and pharmaceutical innovation. *The Rand Journal of Economics*. Available at: https://onlinelibrary.wiley.com/doi/full/10.1111/1756-2171.12113.
[129] Philipson T., et al. (September 2025). Policy Brief: The Impact on Patient Health of Most-Favored-Nation Pricing of Already Marketed Drugs. *University of Chicago*. Available at: https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2025/09/MFN-Impact-on-Patient-Health-Final-Sep-29.pdf.
[130] N.Y. Times. (July 2024). Read the Transcript of Donald J. Trump Speech. Available at: https://www.nytimes.com/2024/07/19/us/politics/trump-rnc-speech-transcript.html.
[131] VitalTransformation. H.R. 3 and Reference Pricing. Total Market Impact. Available at: https://vitaltransformation.com/2021/03/5984/.
[132] *Ibid.*
[133] National Organization for Rare Diseases. (2019). Rare Disease Day: Frequently Asked Questions. Available at: https://rarediseases.org/wp-content/uploads/2019/01/RDD-FAQ-2019.pdf
[134] Stanford, J. (July 2020). Price Controls Would Throttle Biomedical Innovation, *The Wall Street Journal*. Available at: https://www.wsj.com/articles/price-controls-would-throttle-biomedical-innovation-11593625880
[135] DiMasi, J. A., Grabowski, H. G., & Hansen, R. W. (2016). Innovation in the pharmaceutical industry: new estimates of R&D costs. *Journal of health economics*, *47*, 20-33.
[136] Pham, N.D., Pipes, S., Winegarden, W. (2026) Imbalance of Financial Risks and Economic Rewards in the U.S. Healthcare Supply Chain. https://www.pacificresearch.org/wp-content/uploads/2026/01/CMEI_HCSupplyChainFin_F_web.pdf

compared to the 3.8 percent average for all U.S. health care companies and the mere 0.1 percent invested by health care support services such as PBMs, insurers and wholesalers.[137] This is because these middlemen, whose business model relies on administrative tasks like claims processing and formulary management, earn higher returns with less capital investment and risk, while biopharmaceutical companies invest billions of dollars in the search for new treatments and cures.

MFN will lead to reduced investment in critical R&D pipelines by both companies and outside investors. Importantly, VC funding is mobile and can easily be redirected to other sectors, so reducing the ability for VC capital to achieve a return on investment in new drugs will reduce availability of capital in the sector. The forced rebates – that are in effect government price controls – established through GUARD could therefore make it impossible to raise additional VC funding and could push many companies to insolvency. As recently as last year, a significant number of small biotechnology companies faced financial instability, with 39 percent reported to have less than one year of cash to sustain operations.[138] When combined with the effects of MFN on large biopharmaceutical companies, these policies would lead to a significant disruption and loss of capital for the entire R&D ecosystem, resulting in fewer treatment options for patients.

B. GUARD would harm the U.S. economy and workers

GUARD would have a direct impact not only on scientific development and innovation, but on American lives themselves. It is estimated that over almost 20 years, MFN-style pricing would result in 167 to 342 fewer new drug approvals, and a staggering 160 to 326 million life-years lost.[139] It further has the potential to devastate not only the country's workforce, but its economy.

The biopharmaceutical industry is currently one of the biggest employers and investors in U.S. R&D. It supports nearly five million jobs across the U.S. economy, has $1.65 trillion in direct and indirect economic impact, and comprises more than 1,500 manufacturing facilities across the country.[140] With the institution of MFN reference pricing across all beneficiaries in Medicare Parts B and D, it is estimated that approximately 337,000 biopharma industry jobs and nearly 1.5 million jobs in total across the economy would be eliminated.[141] It further imperils over $500 billion in announced capital investments, which were designed to grow advanced manufacturing capabilities in the U.S.[142] These are losses we simply cannot afford.

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[137] *Ibid.*
[138] Ural, A. (October 2025). The Biotech Landscape in 2025 and Beyond: Is a Rebound in the Making or Not? Available at: https://www.dcatvci.org/features/the-biotech-landscape-in-2025-and-beyond-is-a-rebound-in-the-making-or-not/
[139] Philipson, T., Durie T. (September 2021). The Evidence Base on the Impact Controls on Medial Innovation. *University of Chicago.* https://bfi.uchicago.edu/working-paper/the-evidence-base-on-the-impact-of-price-controls-on-medical-innovation/.
[140] PhRMA, Teconomy Partners LLC. (May 2024). The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates. Available at: https://cdn.aglty.io/phrma/policy-issues/research-ecosystem/economy/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf.
[141] Vital Transformation. (2025). Most Favored Nation (MFN) Reference Pricing in Medicare Impacts on Jobs, Innovation, and State Budgets. Available at: https://vitaltransformation.com/2025/09/most-favored-nation-mfn-reference-pricing-in-medicare-impacts-on-jobs-innovation-and-state-budgets/
[142] PhRMA. (September 2025). PhRMA Announces Major Actions as Part of Industry's Commitment to American Patients and Workers. Available at: https://phrma.org/resources/phrma-announces-major-actions-as-part-of-industry-s-commitment-to-american-patients-and-workers

Perhaps the starkest example of the harmful impact of price controls on investment is the collapse of Europe's life sciences sector some 40 years ago, and the steep decline of the United Kingdom's in more recent years.

When the continent adopted price controls, the biopharmaceutical industry moved swiftly to the U.S.,[143] which had recently passed pro-innovation policies.[144] In 1986, European biopharmaceutical R&D investment was 24 percent higher than in the U.S.; currently, decades after price controls were put in place, Europe's R&D investment trails the U.S. by over 40 percent.[145]

In the United Kingdom, in part because of the countries' increasing price drug rebates and revenue clawbacks, investment in pharmaceutical R&D fell by nearly £100 million in 2023 alone. Since 2018, U.K. pharmaceutical R&D investment has underperformed globally; in 2020, U.K. growth fell to 1.9 percent per year, far short of the global average of 6.6 percent annual growth.[146] Further, life sciences foreign direct investment fell 58 percent between 2017 and 2023.[147]

This market impact should serve as a cautionary tale for the U.S., emphasizing the need for market-based reimbursement for valuable medicines that keep pace with and define scientific and medical innovation. America is grounded in the principles of innovation and prosperity, and federal policy should value innovation and growth appropriately, rather than repeating Europe's mistakes and undoing the shift toward American pharmaceutical industry dominance.

C. GUARD would mean ceding the U.S.' global innovation leadership to China

MFN pricing policies have the potential to undermine America's remaining advantages in global biopharmaceutical innovation by reducing investment in key drivers of future innovation while China accelerates its innovation engine and brings greater efficiency to its regulatory processes. The past decade has illustrated that China can be a globally competitive producer of technologically complex goods, including telecom equipment, computers, and satellites.[148] This strength is not accidental, but rather the result of deliberate, strategic planning, including the "Made in China 2025" program. As an ambitious industrial policy that strives to decrease foreign dependence and increase independent innovation capabilities through the R&D of high-end machine tools and key components, China's strategy specifically targets the biopharmaceutical industry as a key sector for growth.[149]

This growth is already evident. China's biopharmaceutical industry growth rate is faster than any other country, resulting in a surge in the volume and quality of biotech-related scientific publications, a rise in the number of novel Chinese drugs and out-licensing deals from Chinese biotech companies (particularly

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[143] *See, e.g.*, Golec, J., Vernon, J. European Pharmaceutical Price Regulation, Firm Profitability, and R&D Spending. *National Bureau of Economic Research.* Available at: https://www.nber.org/system/files/working_papers/w12676/w12676.pdf.
[144] Bayh–Dole Act enacted Dec. 12, 1980 (Public Law 96-517); Orphan Drug Act enacted Jan. 4, 1983 (Public Law 97-414).
[145] Atkinson R. (September 2024). China is Rapidly Becoming a Leader Innovator in Advanced Industries. *Information Technology & Innovation Foundation.* Available at: https://itif.org/publications/2024/09/16/china-is-rapidly-becoming-a-leading-innovator-in-advanced-industries/.
[146] ABPI. (September 2025). UK Tumbles Down Global Rankings for Pharma Investment and Research. Available at: https://www.abpi.org.uk/media/news/2025/september/uk-tumbles-down-global-rankings-for-pharma-investment-and-research/.
[147] *Ibid*.
[148] VitalTransformation. H.R. 3 and Reference Pricing. Total Market Impact. Available at: https://vitaltransformation.com/2021/03/5984/.
[149] China is Rapidly Becoming a Leader Innovator in Advanced Industries. *Information Technology & Innovation Foundation.* Available at: https://itif.org/publications/2024/09/16/china-is-rapidly-becoming-a-leading-innovator-in-advanced-industries/.

in oncology) and an increase in clinical trials taking place in the country.[150] If this trajectory continues, China is poised to outpace and surpass the U.S. across many critical biotech R&D metrics.

As an example, Chinese biopharmaceutical progress is particularly evident in the rise in China-headquartered companies' clinical trial starts. While in 2014 China had only five percent of total trial starts worldwide, it now has 30 percent of them – rapidly approaching the U.S. level of 35 percent.[151] This is a significant and sobering trend, reflecting not only the country's increased capacity, but its growing sophistication in drug development.

With respect to R&D investment in the biopharmaceutical industry, China is growing nearly three times faster than the United States. From 2000 to 2021, China's R&D investment increased 2,600 percent, and its global share of industrial R&D grew from three to 13 percent.[152] This represents a fundamental shift in where the world's innovation resources are deployed.

While the U.S. maintained the largest share of global drugs in development at 40 percent in 2024, China represented 20 percent, and France, Germany, Italy, Spain, and the U.K. represented a combined 11 percent, highlighting China's growing prominence in R&D activity worldwide.[153] In particular, China has steadily advanced in first in class innovation drug development, with its pipeline showing a compound annual growth rate of 22 percent between 2015 and 2024.[154] As China's investments and influence in the global biopharmaceutical sector grow, the U.S.' leading position wanes: From 2023 to 2024, the licensing value of cancer drugs owned and developed by Chinese biopharmaceutical companies increased 24 percent to $33 billion, while the value from U.S. companies fell 24 percent to $35 billion. [155] Collectively, these statistics represent groundbreaking levels of innovation and investment by Chinese-led companies enabled by pro-growth policies.

It's not only science in which China is investing: the country is also investing heavily in its workforce. As of 2020, China graduated over 100,000 more STEM students than the U.S., consistently outscoring American students in math and science tests and building the foundation for long-term industry leadership.[156,157]

Although China poses a significant risk to U.S. biopharmaceutical supremacy, America still maintains significant advantages as the home to 70 percent of mature, late-stage biotech R&D activity.[158]

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[150] *Ibid*.
[151] IQVIA. (March 2025). Global Trends in R&D 2025. Available at: https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/global-trends-in-r-and-d-2025.
[152] Internal PhRMA analysis of data from the OECD Data Explorer, Analytical Business Enterprise R&D by ISIC Rev.4 Industry (ANBERD database), accessed March 2025.
[153] GlobalData. (2025). China's Evolution in Global Drug Development and Clinical Trials: Strategic Intelligence. Available at: https://www.globaldata.com/store/report/china-drug-development-clinical-trials-theme-analysis/
[154] *Ibid.*
[155] GlobalData. (2025). T-Cell Immunotherapy Landscape – Comprehensive Analysis of Current Drugs and Dynamics. Available at: https://www.globaldata.com/store/report/t-cell-immunotherapy-theme-analysis/?utm_source=cision&utm_medium=press-release&utm_campaign=gd_pr_pharma_tcell_immunotherapy&CampaignValue=701Ti00000PW9l0IAD
[156] Neufeld J. (March 2022). STEM immigration is critical to American national security. *Institute for Progress.* Available at: https://ifp.org/stem-immigration-is-critical-to-american-national-security/
[157] World Population Review. (2025). Programme for International Student Assessment (PISA) Scores by Country 2025. Available at: https://worldpopulationreview.com/country-rankings/pisa-scores-by-country#what-is-pisa-why-does-it-matter
[158] *Ibid.*

MFN reference pricing has the potential to destroy these remaining advantages by reducing investment in new industry partnerships and emerging companies – key sources of future innovation. The question is no longer whether China can compete – it has demonstrated that it can and does. If the United States adopts these harmful and misguided policies, it will all but ensure that America falls behind.

We are at a critical juncture in global competition for biopharmaceutical leadership, and Secretary Kennedy has framed U.S. scientific competitiveness as a national interest tied to national security.[159] Adopting mandatory MFN reference pricing through the Proposed Rule would be unilaterally disarming, threatening the very interests our government seeks to protect. These misguided pricing policies would pull capital out of American biotech innovation at the exact moment when China is accelerating investments in pursuit of being a global leader, contrary to the Administration's stated domestic and international agenda. They also fail to address real problems with the U.S. health care system that create barriers to medicines for consumers.

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PhRMA appreciates the opportunity to comment on the GUARD Proposed Rule. Please do not hesitate to contact Elizabeth Carpenter (ECarpenter@phrma.org) or Jim Stansel (JStansel@phrma.org) if we can provide additional information or answer any questions related to our comments.

Sincerely,

/s/

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Elizabeth Carpenter

Executive Vice President, Policy & Research

/s/

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Jim Stansel

Executive Vice President and General Counsel

[159] U.S. Department of Health and Human Services. (June 2025). HHS Testimony on The President's Fiscal Year 2026 Budget. Available at: https://www.hhs.gov/about/agencies/asl/testimony/2025/06/24/the-presidents-fiscal-year-2026-budget.html.