IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, *Plaintiff*, v. ROBERT F. KENNEDY JR., in his official capacity as Secretary of Health and Human Services, *et al.*, *Defendants*.	Case No. 1:26-cv-03498-RCL

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE NATIONAL ASSOCIATION OF MANUFACTURERS AS *AMICI CURIAE* IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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IDENTITY AND INTEREST OF *AMICI CURIAE*[1]

The Chamber of Commerce of the United States of America is the world's largest business organization. As the nation's leading advocate for business, the Chamber represents companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the nation's business community.

The National Association of Manufacturers (NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs over 13 million men and women, contributes $2.9 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for 52% of all private-sector research and development in the nation. Biopharmaceutical manufacturers discover and bring to market innovative new medicines to prevent, treat and cure challenging diseases that make modern medicine possible. It is the strong position of the NAM and manufacturers across America that—to support the stability and productivity of the manufacturing workforce and preserve U.S. global competitiveness—a predictable reimbursement environment is essential to encourage sustained investment in research and development.

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[1] No counsel for any party authored this brief in whole or in part, and no entity or person, aside from *amici*, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief. The parties have consented to the filing of this brief.

INTRODUCTION

Amici share the government's goal of making sure that Medicare beneficiaries can afford the medicine they need. But GLOBE pursues that goal unlawfully and counterproductively. Centers for Medicare & Medicaid Services (CMS), Global Benchmark for Efficient Drug Pricing (GLOBE) Model, 91 Fed. Reg. 62936, 62946-47 (Oct. 2, 2026) ("GLOBE" or "Final Rule"). GLOBE puts patients and innovation at risk, and it threatens the conditions that have made the United States the world's leader in biopharmaceutical innovation. Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) well explains the several reasons why GLOBE is not authorized by the authority that Congress provided the Center for Medicare and Medicaid Innovation in section 1115A of the Social Security Act, 42 U.S.C. § 1315a, and why GLOBE poses serious constitutional questions. Rather than repeat those arguments, *amici* write to highlight two points that reflect the perspective of the broader business community that *amici* represent.

First, GLOBE is not just unlawful but affirmatively harmful. For decades, foreign countries free-rode on the American pharmaceutical industry by setting low prices that paid only enough to cover the marginal cost of production. Those foreign price controls were sustainable only because pricing in *American* markets permits pharmaceutical companies to recover their research and development costs and incentivizes the risk-taking needed to produce innovative breakthroughs. GLOBE's purportedly experimental pricing undermines that economic logic entirely. It slashes prices—and the incentive to innovate—in the United States yet does nothing to address under-pricing and free-riding abroad. As a result, if GLOBE is allowed to stand, innovation and investment will dry up, as drug manufacturers and investors receive the message that even life-saving breakthroughs may no longer generate a profitable return. Capital will move away from life-saving cures, fewer new treatments will reach American patients in need, and the United States

will cede ground to strategic competitors in the international competition to lead this critical sector of the global economy.

Second, GLOBE's legal logic lacks any limiting principle. The Final Rule asserts that section 1115A's testing authority authorizes CMS to modify "any mandatory monetary obligation that affects what Medicare ultimately pays for covered items and services." GLOBE, 91 Fed. Reg. at 62946-47. CMS is claiming authority to cut, significantly and by administrative fiat, the price the government pays for *anything* that Medicare covers—from pharmaceuticals to physician care, mental health services, medical devices, laboratory tests, and home health. Indeed, CMS claims that its limited "waiver" authority carries with it the right to replace Congress's detailed statutory pricing requirements with whatever alternative pricing regime CMS prefers in their place. Congress did not hide such a sweeping (and likely unconstitutional) power in the "mousehole" of section 1115A, and sanctioning such an expansion of administrative authority would have ripple effects throughout the administrative state and the American economy.

ARGUMENT

I. UPHOLDING THE GLOBE RULE WOULD STIFLE INNOVATION, LIMIT U.S. COMPETITIVENESS, AND HARM PATIENTS

A. The Economics of the American Pharmaceutical Industry

Medicare is the country's single largest purchaser of pharmaceuticals. U.S. Gov't Accountability Off., *Prescription Drug Spending*, https://tinyurl.com/4xz9z5tm. With certain exceptions, Medicare has historically reimbursed drug purchases using a formula, dictated by Congress, that is keyed to the prices that drug companies set in the open market. *See* 42 U.S.C. § 1395w-3a(b)(3). Congress's commitment to free-market drug pricing has powered a long-running explosion in pharmaceutical innovation for American patients, a field in which the United States leads the world. That success is not coincidental; it is the product of predictable economic

incentives. GLOBE upends those incentives entirely. If GLOBE is upheld, the direct and indirect impacts for innovation, competitiveness, and U.S. patients will be severe.[2]

Rational manufacturers invest in research and development only if they foresee a reasonable probability of generating a profit. In the pharmaceutical industry, whether a company can achieve profitability will depend on (among other things) the efficacy of the drug, its uniqueness in a competitive market, and the price the manufacturer will be able to charge. If the price cannot be set at a level that allows the manufacturer to recoup its costs, it will not have an incentive to make the investment. Thus, in a free market, manufacturers price drugs at a level that generates sales while also allowing the manufacturer to recoup its costs—which include not only the cost of producing each additional unit of the drug, but the research-and-development expenses that brought the drug to market to begin with.

The ability to recover R&D costs is an essential incentive because R&D "is a long-term, high-risk, resource-intensive process." U.S. Chamber of Com., Patient Access Report 10 (2023), https://tinyurl.com/46a4bukt ("2023 Chamber Report"); *accord* Cong. Budget Off., No. 57025, Research and Development in the Pharmaceutical Industry 2 (2021), http://www.cbo.gov/publication/57025 ("CBO Report"). Indeed, it constitutes the "vast majority" of the cost of producing an innovative drug. Henry H. Gu, *The Hatch-Waxman Act and the Declaratory Judgment Action: Constitutional and Practical Implications*, 57 Rutgers L. Rev. 771, 798 (2005); *see also* 2023 Chamber Report 10 (estimating "it costs USD2.6 billion, on average, to develop a new drug"); CBO Report 2 ("estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug"); Olivier J. Wouters et al., *Estimated Research and*

[2] CMS has also proposed the Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, 90 Fed. Reg. 60338 (Dec. 23, 2025), which relies on a similarly startling assertion of authority.

Development Investment Needed to Bring a New Medicine to Market, 2009-2018, 323 JAMA 844 (2020).

One reason for the high cost of R&D is that the process of "[d]eveloping a new medicine can take a decade or more." 2023 Chamber Report 11; *accord* CBO Report 2; Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 21 (2016), https://bit.ly/30UAIdg. Another factor is the very high risk of failure: most potential drugs never make it to market at all. *See* U.S. Chamber of Com., The True Cost of Price Controls 10 (2024), https://tinyurl.com/bdcrdkxc ("2024 Chamber Study") ("On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and be approved by regulatory authorities."); NAM, Comments on Global Benchmark for Efficient Drug Pricing (GLOBE) Model 1 (Feb. 23, 2026) ("NAM Comments") ("just 12% of the investigational drugs that enter a phase I clinical trial are ultimately approved by the FDA"); Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837, 837 (2004) (most molecular entities that enter clinical trials never receive approval for patient use). The price of the rare drug that successfully runs that gauntlet and ultimately enters the market therefore must allow the manufacturer to recoup not only the cost of the years of work that allowed that particular product to come to market, but also the resources expended on the many projects that will never see fruition. *See* CBO Report 2.

One consequence of our (relatively) free-market health-care system is that American patients tend to pay more for treatment than citizens of many other countries. But that is because many countries—including at least some of those to which GLOBE pins its mandatory rebates—do *not* permit pricing that allows the recovery of R&D costs, linking their government-set prices instead to the small *marginal* cost of producing each additional unit of the drug. *See* Council of

Econ. Advisers, Reforming Biopharmaceutical Pricing at Home and Abroad 13-14 (2018), https://tinyurl.com/hwf62ts6 ("CEA Report"). The drugs that foreign countries pay for at unfairly low levels exist in the first place only because sales in the United States—at comparatively free-market prices—are far more likely to allow companies to recoup their costs and incentivize the R&D that leads to life-saving breakthroughs. *Cf.* NAM Comments 3. "*[O]nce a drug is already produced*," other countries may be able to get away with imposing low prices that exceed the marginal cost of production. CEA Report 14 (emphasis added); *see also* U.S. Chamber of Com., Comments on Proposed GLOBE and GUARD Rules 2-3 (Feb. 20, 2026), https://tinyurl.com/37vjp4d9 ("Chamber Comments").

By contrast, *before* a drug has been the subject of investment and clinical development, the incentives point the other way. If profitable pricing is unlikely in *any* jurisdiction, there is no incentive to pursue innovative breakthroughs at all, as the Council of Economic Advisers has also warned. Nothing in GLOBE suggests it is likely that other countries will choose to increase the prices their citizens pay for medicine (nor, certainly, could GLOBE require as much). And lowering the prices that Americans pay, *without also addressing* "free-riding abroad," "makes better health costlier in the future by curtailing innovation." CEA Report 5. GLOBE falls into that error and exposes the U.S. economy—and American patients—to these very risks.

B. Upsetting Economic Preconditions to Innovation Will Lead to Predictable Harm

Without incentives to innovate, predictable results will follow. Innovation will slow—not only at larger well-known firms but also at smaller firms that rely most heavily on capital investments by outsiders and are least well positioned to absorb mandatory price reductions. *See* NAM Comments 5. Capital markets react strongly to policy risk; they withhold investment when returns are limited by rule or subject to intolerable uncertainty. If a federal agency can undo

Congress's pricing rules by fiat, the reliability of the American biopharmaceutical sector as an investment will suffer. Reduced investment in that critical sector will harm everyone else—not only businesses that depend on that sector, the workers whom they employ, and the economy as a whole, but countless individual patients, who will lose the life-saving benefits of innovative drugs that are not discovered.

Making the American pharmaceutical sector less attractive for investment will harm the United States' competitiveness and standing in the world. Investment will flow where returns appear most promising, and other competitors, particularly China, are seeking to displace the United States' historic leadership in the biopharmaceutical sector. *See* Chamber Comments 5.

Most importantly, and as experiences in foreign countries already show, patient care will suffer if U.S. innovation is stifled. Thanks to free-market pricing in the United States, manufacturers around the world often seek to serve U.S. patients "before other markets," providing Americans with "access to drugs sooner . . . compared to other developed countries." CEA Report 13; *see also* 2024 Chamber Study 11-12; Chamber Comments 3. According to a 2024 analysis by the Chamber, approximately 85% of the new drugs launched globally between 2012 and 2021 were available in the United States. By contrast, only 61% were available in Germany, 59% in the United Kingdom, and less than 50% in Canada, Spain, Australia, and South Korea. *See* 2024 Chamber Study 13-14 & fig.2; *accord* U.S. Dep't of Com., Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation 31 (2004), *archived in* WayBackMachine (Apr. 14, 2019), https://tinyurl.com/yknz5jbb ("recent research has suggested that foreign governments' price controls have delayed the launch of drugs in different markets, thereby adversely affecting patients' access to new medicines").

GLOBE and its underlying principles threaten to eliminate the conditions that have protected Americans' access to life-saving and life-enhancing care.

It is no answer to suggest, as the Final Rule does, that manufacturers can avoid these consequences by withdrawing from Medicare. *See* Final Rule, 91 Fed. Reg. at 62958 ("participation in the Medicare program, while practically significant for manufacturers of drugs covered by Medicare, is not legally compelled"). Medicare accounts for roughly a third of all U.S. prescription drug spending. *See* Cong. Rsch. Serv., No. R47872, Medicare Drug Price Negotiation Under the Inflation Reduction Act: Industry Responses and Potential Effects 1 (Dec. 8, 2023). Withdrawal from that market would be catastrophic for any company that attempted it—to say nothing of the harm it would inflict on patients no longer able to access critical medication through Medicare coverage. Indeed, because of the risk to patients, many members of *amici* would consider withdrawal to be not only commercially impracticable, but ethically unacceptable.

In the case of GLOBE, the pressure on manufacturers is especially severe, as the Final Rule focuses on Part B drugs that are subject to especially high Medicare spending. *See* Final Rule, 91 Fed. Reg. at 63098 (in-scope drugs limited to those with "spending greater than $100 million over a 12-month period"). Either the government knows that withdrawal is not a serious option for manufacturers—in which case its assurance of voluntariness is illusory—or it is genuinely contemplating the withdrawal from Medicare of companies that provide life-saving treatments. Either way, if GLOBE survives judicial review, harm to American patients will follow.

II. THE FINAL RULE'S INTERPRETATION OF SECTION 1115A HAS NO LIMITING PRINCIPLE

PhRMA well explains why the Final Rule cannot be considered a "test" and does not apply to a "payment [or] service delivery model[]" as Congress used those terms in section 1115A. *Amici* write to emphasize that the government's contrary reading is subject to no limiting principle.

For example, as PhRMA explains, section 1115A's reference to a "payment [or] service delivery model" is clearly a reference to *how* payment is structured and *how* services are delivered—not *how much* is paid under any particular model. The Final Rule argues that "the statute's broad reference to 'program expenditures' and 'program costs' supports an interpretation that encompasses any mandatory monetary obligation that affects what Medicare ultimately pays for covered items and services." Final Rule, 91 Fed. Reg. at 62946-47 (quoting section 1115A). That reading is extraordinarily broad and limited only by Medicare's coverage itself. *See Stewart v. Azar*, 366 F. Supp. 3d 125, 154 (D.D.C. 2019) (rejecting interpretation of statute that was "utterly unreasonable in its breadth" and "not subject to any kind of limiting principle" (internal quotation marks omitted)).[3]

Medicare covers a wide range of medical care—from drugs and medical equipment, to ambulance services, to mental health support. *See What Part B covers*, Medicare.gov, https://tinyurl.com/34hpn34t. *Amici*'s members provide and/or finance these services beyond prescription drugs in reliance on the payment schemes that Congress has legislated. The logic of the Final Rule would empower the Center for Medicare and Medicaid Innovation—a sub-agency within CMS, itself a sub-agency within the Department of Health and Human Services—to engage in unilateral administrative rate-setting for *all* of those services. It is inconceivable that Congress, in a little-known statute authorizing "test[s]" of experimental "models," gave away this sweeping authority. As PhRMA notes, if Congress sought to do so, that would raise serious constitutional concerns. The natural reading of the statute is that Congress did not.

[3] PhRMA is also correct in explaining that the Final Rule does not satisfy section 1115A's requirement that there be evidence that a model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. Here, as elsewhere, CMS's contrary interpretation rewrites the statute and erases the very limits that Congress wrote into CMS's authority under this provision. *See* Chamber Comments 6-8.

The Final Rule's interpretation of section 1115A makes particularly little sense in the context of prescription drug pricing, because *Congress itself* dictates the prices at which Medicare reimburses for prescription drugs. The U.S. Code is shot through with statutory formulae governing drug pricing. *See, e.g.*, *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 728 (2022) ("The Medicare statute meticulously lays out the formula that HHS must employ to set th[e] reimbursement rates" for covered prescription drugs). Congress's pricing frameworks reflect a wide range of policy choices that, as the foregoing demonstrates, *distinguish* the United States from other markets abroad—including, for example, its embrace of a largely free-market system and its rejection of benchmarks such as Quality-Adjusted-Life-Years (QALYs). *See* PhRMA Mot. 41-42.

For most medications, Medicare reimburses providers under a statutory formula, calculated by adding a small margin to the "Average Sales Price" paid to the manufacturer in the private market for the drug. 42 U.S.C. § 1395w-3a(b)(3); *see also* Budget Control Act of 2011, Pub. L. No. 112-25, § 301, 125 Stat. 240, 251-55. In setting that formula, Congress sought to link as closely as possible Medicare's price to "the actual price paid by purchasers" in "real market transaction[s]," H.R. Rep. No. 108-178, pt. 2, at 194, 197-98 (2003), to better reflect the market forces discussed above. CMS, however, does not share Congress's view about the merits of market-based pricing, so it now purports to do away with Congress's scheme and substitute a new and contrary scheme—and the logic of the Final Rule supplies no reason to think that GLOBE reflects the outer limit of the agency's ambition. The detailed rules legislated by Congress for pricing in Medicare are a wasted effort if CMS can unilaterally "waive" them and substitute whatever contrary pricing regime it prefers.

The Final Rule confirms these concerns and rejects any limiting principle. It reasons that agency imposition of most-favored-nation pricing is permissible because, "had Congress intended to foreclose this type of model testing, it could have done so expressly." Final Rule, 91 Fed. Reg. at 62953. The government's reading turns the separation of powers on its head. Agencies do not hold every power that Congress has not expressly withheld. On the contrary, "[a]gencies have only those powers given to them by Congress, and 'enabling legislation' is generally not an 'open book to which the agency may add pages and change the plot line.'" *West Virginia v. EPA*, 597 U.S. 697, 723 (2022) (brackets omitted) (quoting Ernest Gellhorn & Paul Verkuil, *Controlling* Chevron-*Based Delegations*, 20 Cardozo L. Rev. 989, 1011 (1999)); *Cent. United Life Ins. Co. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir. 2016) ("Agencies may act *only when and how* Congress lets them." (emphasis added)).

The implications of the government's asserted authority to take any action not "expressly" "foreclose[d]" would result in an upheaval of administrative law reaching far beyond GLOBE and the pharmaceutical industry. *Amici*'s members occupy a range of regulated industries throughout the American economy, and they rely on the well-settled constitutional and administrative-law doctrines that limit agency authority to the powers *affirmatively* granted by Congress.

In short, sanctioning the government's claimed power to "test" most-favored-nation pricing through GLOBE would in fact risk granting the government far broader power to impose price controls and otherwise to upend the American economy. The government's inability (or refusal) to identify a limit to the authority it claims under section 1115A supplies an additional reason to reject its interpretation of the statute and invalidate GLOBE. *See, e.g.*, *EPA v. Calumet Shreveport Refining, L.L.C.*, 145 S. Ct. 1735, 1748 (2025) (rejecting agency interpretation that "lacks any statutory limiting principle").

CONCLUSION

The Court should grant summary judgment in favor of Plaintiff and vacate GLOBE.

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Respectfully submitted,

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