

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,
670 Maine Avenue, SW
Suite 1000
Washington, DC 20024,

Plaintiff,

v.

ROBERT F. KENNEDY JR., in his official
capacity as Secretary of Health and Human
Services,
200 Independence Avenue, SW
Washington, DC 20201,

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES,
200 Independence Avenue, SW
Washington, DC 20201,

MEHMET OZ, in his official capacity as
Administrator of the Centers for Medicare &
Medicaid Services,
7500 Security Boulevard
Baltimore, MD 21244,

CENTERS FOR MEDICARE & MEDICAID
SERVICES,
7500 Security Boulevard
Baltimore, MD 21244,

ABE SUTTON, in his official capacity as
Director of the Center for Medicare and
Medicaid Innovation,
7500 Security Boulevard
Baltimore, MD 21244, and

CENTER FOR MEDICARE AND MEDICAID
INNOVATION,
7500 Security Boulevard
Baltimore, MD 21244,

Defendants.

Case No. _____

**COMPLAINT FOR
DECLARATORY AND
INJUNCTIVE RELIEF**

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Plaintiff Pharmaceutical Research and Manufacturers of America brings this complaint for declaratory and injunctive relief against Defendants Robert F. Kennedy Jr., in his official capacity as Secretary of Health and Human Services; United States Department of Health and Human Services; Mehmet Oz, in his official capacity as Administrator of the Centers for Medicare & Medicaid Services; Centers for Medicare and Medicaid Services; Abe Sutton, in his official capacity as Director of the Center for Medicare and Medicaid Innovation; and Center for Medicare and Medicaid Innovation. Plaintiff alleges as follows:

INTRODUCTION

1. The question in this case is a recently recurring one: May a federal administrative agency claim a highly consequential power to transform a critical sector of the American economy without clear congressional authorization? Again and again, the Supreme Court has answered that question: No. *See, e.g., Learning Res., Inc. v. Trump*, 607 U.S. 229, 251 (2026); *Biden v. Nebraska*, 600 U.S. 477, 497 (2023); *West Virginia v. EPA*, 597 U.S. 697, 735 (2022).

2. Those precedents, and the “common sense” principle they embody, are fatal to the agency action challenged here. *Learning Res.*, 607 U.S. at 243 (opinion of Roberts, C.J.) (citation omitted). The Centers for Medicare & Medicaid Services (CMS) has issued a regulation—called Global Benchmark for Efficient Drug Pricing (GLOBE), 91 Fed. Reg. 62,936 (Oct. 2, 2026) (attached as Exhibit A)—that seeks to remake the Medicare program’s drug-pricing methodology. For decades, Congress has chosen to effectively price pharmaceuticals offered under Medicare Part B in general based on the “average sales price” of those drugs on the private market. In contrast, GLOBE would untether Medicare pricing from the statute and the American market, instead importing foreign price controls from 19 countries—Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands,

Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom—by effectively requiring drug manufacturers to charge only the prices paid in those nations. GLOBE would accomplish that objective by demanding that manufacturers pay “rebates” to CMS to lower their prices to a foreign-nation reference price.

3. GLOBE’s most-favored-nation (MFN) pricing idea is not new. Congress “is not unaware” of MFN pricing proposals; instead, it has “considered” numerous MFN bills in recent years. *Nebraska*, 600 U.S. at 503; *see, e.g.*, Medicare Drug Price Negotiation Act, H.R. 4138, 115th Cong. (2017). But each time, Congress “has chosen not to enact” MFN pricing in the Medicare program. *Nebraska*, 600 U.S. at 503. The first Trump Administration sought to effectuate a similar goal by regulation, only to have the rule quickly invalidated by three district courts. To prevent “the Executive seizing the power of the Legislature,” that same result is necessary here. *Id.*

4. Most fundamentally, CMS relies on an obscure statutory provision that does not authorize the agency’s aggressive overhaul of the Medicare program. CMS invokes Section 1115A of the Social Security Act, which authorizes a CMS sub-agency to “test innovative payment and service delivery models to reduce program expenditures.” 42 U.S.C. § 1315a(a)(1). As four Justices of the Supreme Court have observed, that provision is a “minor” and “ancillary” one. *NFIB v. Sebelius*, 567 U.S. 519, 704-05 (2012) (Scalia, Kennedy, Thomas, & Alito, JJ., dissenting). It grants CMS limited authority to experiment as to how payments and healthcare services are structured, and thus to “study . . . how to spend less government money.” *Id.* at 704. It does not provide carte blanche to rewrite the Medicare program to fit policy priorities that Congress has not authorized.

5. Numerous features of the statute, whether viewed individually or taken together, confirm that Section 1115A does not give CMS the authority to mandate precisely the sort of MFN policy that Congress has considered but chosen not to adopt. Section 1115A allows CMS to “test” how to “reduce program expenditures . . . while preserving or enhancing the quality of care”; it does not permit CMS to unilaterally impose a price-control policy that necessarily reduces the amount that manufacturers will receive. Section 1115A permits CMS to develop only “payment and service delivery models,” but GLOBE does not change how payments or healthcare services are structured under Medicare Part B—rather, it unilaterally requires manufacturers to pay rebates that push their products below the market-pricing baseline. Section 1115A requires CMS to “address” a “defined population” for which there are “deficits in care,” but GLOBE does not even purport to identify any actual deficits in care that the rule would address. And Section 1115A permits CMS to “waive” the requirements of the Medicare statute, but it does not grant the agency power to rewrite the statute by adding new and onerous obligations.

6. Fairly read, these provisions confer a more limited authority: CMS may test whether a different way of structuring payments or services would reduce program expenditures and thereby improve outcomes for a specific population with specific deficits in care. It may not, however, impose price controls that do not test anything about how restructuring payment affects expenditures and that affect an arbitrarily selected subset of Americans who use Part B drugs but who do not experience any particular deficits in their care.

7. If there were any doubt, the Supreme Court’s recent decisions applying the major questions doctrine doom CMS’s novel and sweeping assertion of authority. Because Congress does not “hide elephants in mouseholes,” *Whitman v. Am. Trucking Ass’n, Inc.*, 531 U.S. 457, 468 (2001), the Court has “long expressed reluctance to read into ambiguous statutory text

extraordinary delegations of Congress’s powers,” *Learning Res.*, 607 U.S. at 242 (opinion of Roberts, C.J.) (citation modified). Under that major questions principle, courts “expect Congress to speak clearly if it wishes to assign to an agency decisions of vast economic and political significance.” *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (internal quotation marks omitted). And when an agency “claim[s] to discover” a “newfound power in the vague language of an ancillary provision” of a statute, there is substantial reason to “hesitate before concluding that Congress meant to confer” the claimed authority. *West Virginia*, 597 U.S. at 724 (citation modified).

8. This case is a poster child for the major questions doctrine. Section 1115A is a vague and “ancillary” provision that has never before been understood to permit the imposition of price controls. *NFIB*, 567 U.S. at 705 (Scalia, Kennedy, Thomas, & Alito, JJ., dissenting). And GLOBE is a decision of “vast economic and political significance”: it upends the considered choices Congress has made in structuring our healthcare system, with hundreds of millions of dollars of immediate economic effects and billions more at stake in future years. Moreover, GLOBE is “unheralded”: except for the Administration’s prior failed effort to impose MFN pricing through Section 1115A, which courts swiftly invalidated and so cannot serve as precedent for this agency action, CMS has finalized no Section 1115A model remotely like GLOBE. Indeed, CMS itself admits that GLOBE “represents a novel application” of Section 1115A. 91 Fed. Reg. at 62,946. Thus, to the extent that the text of Section 1115A is “ambiguous,” the major questions doctrine would still require rejecting CMS’s attempt to shoehorn its MFN objectives into Section 1115A’s “modest words.” *West Virginia*, 597 U.S. at 723 (citation omitted).

9. GLOBE also violates other statutory requirements limiting CMS’s authority. Congress has prohibited CMS from using a discriminatory measure called “quality-adjusted life

years” (QALYs) to set reimbursements under the Medicare program, but GLOBE imports other countries’ QALY-based pricing methodology. And bedrock principles of appropriations law prohibit CMS from augmenting congressional appropriations by raising additional funds without statutory authority.

10. Any broader understanding of CMS’s authority would put Section 1115A in irreconcilable conflict with the Constitution. Article I’s Presentment Clause requires Congress, not agencies, to enact or repeal laws. And the nondelegation doctrine prohibits the Executive Branch from exercising the lawmaking power without direction from Congress. Both of those doctrines prohibit CMS from unilaterally repealing portions of the Medicare program—including Congress’s choice to set drug pricing using the average sales price, modified by congressionally chosen rebates—on the view that CMS knows better than the House and the Senate.

11. If allowed to move forward, GLOBE will work immediate and profound harms on American patients and American industry. America leads the world in access to lifesaving medicines. Patients in America have more options for pharmaceutical products than patients anywhere else across the globe. Most drugs and biological products are introduced into the United States prior to their launch in other developed nations. As a result, participants in Medicare, just like Americans with private insurance, can access a wider variety of drugs—and earlier than they could if they lived in other places.

12. That global pharmaceutical leadership rests on a critical feature of the American economy that GLOBE puts under threat: market-based pricing. Unlike the United States, other countries permit central planners to directly control which prescription drugs are available and at what price. And in other countries, bureaucrats decide which medicines are worth making available to the population, including based on those drugs’ costs. These decisions stifle

innovation by ensuring that the immense investments necessary to bring drugs to market will never be recouped. They therefore hurt individuals who reside in those countries by making it harder for them to access vital medicines. And they discriminate against elderly, disabled, and chronically ill people by valuing their lives less than the lives of younger and healthier individuals. The United States has chosen a different path, creating a robust market for drug products driven by the laws of supply and demand. The stability and predictability of market-based pricing is what drives American innovation and secures Americans the best patient outcomes.

13. GLOBE would upend that stability and predictability, harming seniors and imperiling our nation's global pharmaceutical leadership. MFN pricing would lead to the loss of hundreds of new treatments over the next decade, preventing both new drug approvals and approvals for new indications of existing drugs. The Council of Economic Advisers put the point best during the first Trump Administration: "Heavy-handed government intervention may reduce drug prices in the short term, but these savings are not worth the long-term cost of American patients losing access to new lifesaving treatments."¹

14. And there is substantial reason to doubt that GLOBE will do anything to help seniors access their medicines. The overwhelming majority of Medicare Part B recipients have supplemental insurance and so will not see any change to their out-of-pocket drug costs as a result of CMS's Rule. Nor will they see any non-trivial reduction to their Medicare premiums; on the contrary, CMS's own estimates suggest that beneficiaries will save only pennies every year. GLOBE thus imposes novel and disruptive price caps without achieving meaningful benefits to pharmaceutical affordability for seniors.

¹ Council of Econ. Advisers, *House Drug Pricing Bill Could Keep 100 Lifesaving Drugs from American Patients* (Dec. 3, 2019), <https://www.whitehouse.gov/articles/house-drug-pricing-bill-keep-100-lifesaving-drugs-american-patients>.

15. GLOBE would also stifle critical American investments in our innovation ecosystem. And it would cost American jobs in the biopharmaceutical industry, as well as across the American economy: Overwhelming evidence shows that pharmaceutical investment drops after countries impose price controls on medicines, which is how the United States supplanted Europe to lead the biopharmaceutical sector.

16. Finally, GLOBE would contravene American values. GLOBE would set pharmaceutical pricing by looking to the practices of countries that effectively ration healthcare based on statistical tools, like QALYs, that devalue the lives of seniors, people with disabilities, and the chronically ill. Again, Congress has expressly forbidden using this discriminatory metric to shape Medicare policy—yet GLOBE incorporates other countries’ contrary choice into the Medicare program.

17. The bottom line is this: Congress, not CMS, determines Medicare policy for American seniors. And Congress, unlike CMS, has decided that MFN-based price controls do not serve the national interest. Allowing CMS to override Congress’s choices in the name of “test[ing]” a “payment [or] service delivery model[.]” would be an unprecedented expansion of agency authority and an unacceptable diminution of Congress’s prerogative to make the laws. And CMS’s power grab would not end there. Future Administrations would have every incentive to use an unbounded Section 1115A power to advance their own health-policy priorities without legislative approval. Neither Section 1115A nor the Constitution permits that usurpation of the lawmaking role.

18. This Court should hold the GLOBE Rule unlawful and set it aside.

JURISDICTION AND VENUE

19. This Court has subject-matter jurisdiction because the claims arise under the Constitution and laws of the United States, 28 U.S.C. § 1331, and because the individual Defendants are United States officials, *id.* § 1346(a)(2).

20. This Court has authority to grant relief under the Administrative Procedure Act, 5 U.S.C. §§ 701-706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202. An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201.

21. The judicial-review limitation in 42 U.S.C. § 1315a(d)(2) does not preclude review of Plaintiff's claims in this case, which challenge Defendants' constitutional and statutory authority to issue the Rule. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004) ("If a no-review provision shields particular types of administrative action, a court . . . must determine whether the challenged agency action is of the sort shielded from review."); *Teva Pharmaceuticals USA, Inc. v. Kennedy*, 187 F.4th 587, 602 (D.C. Cir. 2026) ("An agency cannot expand a review bar simply by declaring its own conduct unreviewable.").

22. Defendants' publication of the Rule in the Federal Register on October 2, 2026, is a final agency action. *See* 5 U.S.C. § 704.

23. Venue is proper in this District because Plaintiff resides in this District, some Defendants are located in this District, and a substantial part of the events or omissions giving rise to the claims occurred in this District. 28 U.S.C. § 1391(e)(1).

PARTIES

24. Plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) is a nonprofit corporation organized and existing under the laws of the State of Delaware, with its headquarters located in Washington, DC. PhRMA serves as the research-based pharmaceutical

industry's principal policy advocate, representing its members' interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA is committed to advancing public policies that foster continued medical innovation and educating the public about the drug development and discovery process.

25. PhRMA's 34 members are the country's leading research-based pharmaceutical and biotechnology companies and are devoted to discovering and developing new medications that allow people to live longer, healthier, and more productive lives.² Over the last decade, PhRMA members have invested more than \$900 billion in the search for new treatments and cures, including \$110 billion in 2025 alone. Some of PhRMA's members sell drugs subject to GLOBE, such that the regulation will adversely affect them immediately. And other PhRMA members may fall within GLOBE's ambit in the future, as their drugs grow in market share or as CMS alters the scope of the program. And even if they do not sell Part B products subject to GLOBE, PhRMA's members strongly oppose CMS's efforts to mandate foreign drug pricing that displaces the United States' market-based approach.

26. Defendant Robert F. Kennedy Jr. is the Secretary of the United States Department of Health and Human Services (HHS). His responsibilities include overseeing the Centers for Medicare & Medicaid Services (CMS) and the Medicare program. He is sued in his official capacity.

27. Defendant HHS is an executive department of the United States Government that is headquartered in Washington, DC. It is responsible for CMS and the Medicare program.

² A list of PhRMA members can be found at <https://phrma.org/about#members>.

28. Defendant Mehmet Oz is the CMS Administrator. He administers the Medicare program on behalf of the Secretary and oversees the activities of the Center for Medicare and Medicaid Innovation (CMMI). He is sued in his official capacity.

29. Defendant CMS is an administrative agency within HHS that is headquartered in Baltimore County, MD. It administers the Medicare program and is responsible for CMMI.

30. Defendant Abe Sutton is the Director of CMMI and the CMS Deputy Administrator. He is sued in his official capacity.

31. Defendant CMMI is a sub-agency within CMS that is also headquartered in Baltimore County, MD.

BACKGROUND

A. Because Pharmaceutical Innovation Requires Market-Based Returns, Foreign Price Controls Harm Patients By Deterring Innovation and Decreasing Access To New Drugs.

32. The pharmaceutical industry is dedicated to developing innovative drugs that make people healthier. Between 2020 and 2025, the Food and Drug Administration (FDA) approved 291 novel drugs developed by U.S. companies.³ These drugs included an antibody infusion therapy that slows cognitive decline in early-stage Alzheimer's patients; a novel treatment for children and adults with acute lymphoblastic leukemia; a non-insulin treatment for Type 2 diabetes that doubles as a treatment for obesity; a non-invasive inhibitor for metastatic lung cancer; a

³ FDA, *Novel Drug Approvals for 2025*, <https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2025> (last visited October 5, 2026); FDA, *Novel Drug Approvals for 2024*, <https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2024> (last visited October 5, 2026); FDA, *Novel Drug Approvals for 2023*, <https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2023> (last visited October 5, 2026); FDA, *Novel Drug Approvals for 2022*, <https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2022> (last visited October 5, 2026); FDA, *Novel Drug Approvals for 2021*, <https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2021> (last visited October 5, 2026); FDA, *Testimony of Patrizia Cavazzoni, The Path Forward: Advancing Treatments and Cures for Neurodegenerative Diseases* (July 29, 2021), <https://www.fda.gov/news-events/congressional-testimony/path-forward-advancing-treatments-and-cures-neurodegenerative-diseases-07292021>.

targeted treatment for a specific mutation of ALS; and a treatment for schizophrenia that disrupts symptoms without decreasing dopamine levels. Each of these drugs represents a major scientific breakthrough and will enable millions of people across the country to live longer, healthier lives.

33. Despite that historical success, developing even one new drug is exceedingly difficult. A central reason is that diseases emerge from extraordinarily complex biological systems involving many interacting molecules, cells, and tissues. Accordingly, it is impossible for even the best biotechnology researchers to craft a model of a disease that would allow them to identify a treatment with theory alone.⁴ Instead, they must form hypotheses about the biological mechanisms that cause the disease, identify thousands of possible molecules that could disrupt those mechanisms, and then test those molecules iteratively.

34. A second fundamental reason that drug development is difficult is that human health is at stake—thus, a drug may go on the market only after researchers prove to the FDA that the drug is safe and effective. Obtaining that proof requires a series of rigorous tests and trials, beginning with preclinical testing involving non-human subjects. *See* 21 C.F.R. § 312.23(a)(8). If preclinical testing for a particular drug is successful, the drug must go through three clinical trials of expanding scope and expense. *Id.* § 312.21. Only after those three trials are complete will the FDA consider approving the drug for widespread distribution. *Id.* § 314.50(f).

35. The combination of these processes—the iterative process of identifying treatments and the multi-phase trial process—means that bringing a drug to market consumes an immense amount of time and resources. Only 0.02% of drugs that enter preclinical testing eventually receive

⁴ *See* Jack W. Scannell et al., *Predictive Validity in Drug Discovery: What It Is, Why It Matters and How To Improve It*, 21 Nat. Rev. Drug. Discov. 915 (Oct. 2022).

FDA approval, and only 12% of drugs that enter clinical trials eventually receive FDA approval.⁵ The complete development and trial process for an approved drug often takes a decade or more.

36. As a result, the average cost of developing one new drug—which includes the costs of failed alternatives and the opportunity cost of committing capital that could be invested elsewhere—is roughly \$3 billion.⁶

37. Accordingly, pharmaceutical companies can afford to invest in research and development only when they expect to receive returns on the FDA-approved drugs that reach the market. “When the anticipation of future profits is higher, companies invest more in R&D and produce more new drugs.”⁷ By contrast, “if expectations about prices and profits were lower, companies would invest in less R&D.”⁸ Indeed, CMS acknowledges that “pharmaceutical R&D incentives are strongly shaped by expected commercial returns, patent and exclusivity rules, and risk-adjusted profitability.” 91 Fed. Reg. at 62,955. Critically, it is not enough for a pharmaceutical company to earn returns on a drug that merely cover the costs of that specific drug. Because the iterative nature of drug research and development requires companies to pursue many different paths at once, the “*whole portfolio* must earn normal returns given the high failure rates of the various components.”⁹

38. In other words, the continued production of new lifesaving drugs depends on the ability of pharmaceutical companies to accrue significant returns when those drugs reach the

⁵ Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps. 837 (2004), <https://pmc.ncbi.nlm.nih.gov/articles/PMC1299137/pdf/5-7400236.pdf>; Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (Apr. 2021), <https://www.cbo.gov/publication/57126>.

⁶ See Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. Health Econ. 20, 25-26 (2016), <https://pubmed.ncbi.nlm.nih.gov/26928437/>.

⁷ See Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (Apr. 2021), <https://www.cbo.gov/publication/57126>.

⁸ *Id.*

⁹ Council of Econ. Advisers, *Funding the Global Benefits to Biopharmaceutical Innovation* 5 (Feb. 2020), <https://www.govinfo.gov/content/pkg/GOVPUB-PREX6-PURL-gpo133193/pdf/GOVPUB-PREX6-PURL-gpo133193.pdf>.

market. In recognition of that fundamental principle, the U.S. government has historically allowed pharmaceutical companies that develop new treatments to charge market prices for their drugs. Congress has also prioritized patent rights in pharmaceuticals to ensure that drug manufacturers can “recover a portion of the market exclusivity lost during the lengthy process of development and FDA review.” *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997).

39. When creating the Medicare program, Congress likewise recognized the importance of predictable, market-based pricing for pharmaceuticals. The Medicare program establishes federally funded health insurance for individuals older than 65 (and certain disabled individuals under 65). The Medicare program has three parts, each of which establishes a specific health insurance plan: (1) Part A creates a plan, operated by CMS, that automatically covers most inpatient services for all Medicare beneficiaries, 42 U.S.C. §§ 1395c to 1395i-6; (2) Part B creates an optional plan, operated by CMS, that uses a mix of general revenues and premiums from enrollees to pay for essential outpatient services, including certain prescription drugs, 42 U.S.C. §§ 1395j to 1395w-6; and (3) Part D creates an optional plan, operated by private insurers, that covers a wide variety of outpatient prescription drugs, 42 U.S.C. § 1395w-101 to 1395w-154. As an alternative to the original Medicare program, Part C creates optional plans, operated by private insurers, that can offer the benefits of Parts A, B, and D. 42 U.S.C. §§ 1395w-21 to 1395w-29. Health care providers who provide products or services to Part A and Part B beneficiaries seek reimbursements directly from CMS, while providers for Part C and Part D beneficiaries seek reimbursements from the insurers that operate those plans.

40. As relevant here, Part B covers “medical and other health services,” 42 U.S.C. § 1395k(a)(1), which include “drugs and biologicals which are not usually self-administered by the patient” and are “furnished as an incident to a physician’s professional service,” *id.*

§ 1395x(s)(2)(A). Accordingly, Part B covers many of the innovative, complex biologics discussed above, including novel cancer treatments and immunotherapies.

41. Under Part B, healthcare providers that provide a covered drug or biologic to Part B beneficiaries typically may receive a reimbursement equal to 106% of the drug’s “average sales price.” *See* 42 U.S.C. §§ 1395w-3a, 1395u(o)(1)(C). The average sales price is determined based on the statute’s definition of “sales to all purchasers . . . in the United States,” with exceptions not relevant here. *Id.* § 1395w-3a(c)(1). In other words, the Medicare program allows manufacturers to receive roughly the rate they obtain elsewhere in the U.S. market.

42. This carefully calibrated pricing system has incentivized the pharmaceutical industry to invest hundreds of billions of dollars in research and development since 2020. From 2022 to 2024, U.S. biopharmaceutical companies reinvested roughly 33% of their revenue in research and development.¹⁰ By contrast, the most recent data show that companies in the semiconductor industry typically reinvest about 15% of their revenue in research and development; companies in the software industry typically reinvest about 20%; and companies in the aerospace and defense industries typically reinvest 4%.¹¹

43. The United States’ market-based approach to drug pricing is unique among developed countries, which strictly regulate drug prices—thereby disincentivizing research and development.¹² Of the 38 countries that belong to the Organisation for Economic Co-operation and Development (OECD), only the United States, Denmark, Germany, and the United Kingdom

¹⁰ Nam D. Pham et al., *Imbalance of Financial Risks and Economic Rewards in the U.S. Healthcare Supply Chain*, Pacific Research Inst. Ctr. for Med. Econ. and Innovation, 4 (Jan. 2026), https://www.pacificresearch.org/wp-content/uploads/2026/01/CMEI_HCSupplyChainFin_F_web.pdf.

¹¹ NYU Stern, *R&D Statistics by Sector* (Jan. 2026), https://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/R&D.html.

¹² Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (Apr. 2021), <https://www.cbo.gov/publication/57126>.

do not directly control the prices of prescription drugs when they enter the market.¹³ But those other three countries control drug prices through other mechanisms.

44. In the United Kingdom, for instance, the National Health Service (NHS) will pay for a drug only if the National Institute for Health and Care Excellence (NICE) determines that doing so “is a clinically and a cost-effective use of the health budget compared to other potential uses of that budget.”¹⁴ NICE makes such determinations by evaluating whether the drug’s price “can be justified in terms of changes in expected health effects,” as “expressed in terms of quality-adjusted life years” (QALYs).¹⁵ And NICE calculates QALYs by “estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality-of-life score (on a 0 to 1 scale).”¹⁶ In other words, drug prices in the United Kingdom—and the many other OECD countries that use QALYs—depend on the government’s determination that a specific drug will improve the quality of a specific patient’s life.

45. Many OECD countries peg their price controls to drug prices in other OECD countries. Indeed, “[w]ith the exception of Australia, Sweden, the United Kingdom, and the United States, all OECD countries use international benchmarking as one tool to regulate prices, at least in some market segments.”¹⁷ These “external reference pricing” policies create a

¹³ OECD, *Pharmaceutical Pricing Policies in a Global Market* (2008), https://www.oecd.org/content/dam/oecd/en/publications/reports/2008/09/pharmaceutical-pricing-policies-in-a-global-market_g1gh8df5/9789264044159-en.pdf.

¹⁴ NICE, *Changes to NICE Regulations: Cost-Effectiveness Threshold—Government Response* (Mar. 3, 2026), <https://www.gov.uk/government/consultations/changes-to-nice-regulations-cost-effectiveness-threshold/outcome/changes-to-nice-regulations-cost-effectiveness-threshold-government-response>.

¹⁵ NICE, *NICE Technology Appraisal and Highly Specialised Technologies Guidance: The Manual* (Mar. 31, 2026), <https://www.nice.org.uk/process/pmg36/chapter/economic-evaluation-2>.

¹⁶ NICE, *Glossary: Q*, <https://www.nice.org.uk/Glossary?letter=Q#QALY>.

¹⁷ OECD, *Pharmaceutical Innovation and Access to Medicines*, 37 (2018), https://www.oecd.org/content/dam/oecd/en/publications/reports/2018/11/pharmaceutical-innovation-and-access-to-medicines_g1g98d77/9789264307391-en.pdf.

significant risk of a “downward pricing spiral,” where a decrease in price in one country leads to a decrease in all others.¹⁸

46. These price controls have had devastating effects on drug innovation and access in OECD countries. In the mid-1980s, Europe outspent the United States on drug research and development by 24%.¹⁹ Today, after decades of price controls, Europe trails the United States by over 40%.²⁰ And that trend shows no signs of slowing down—as of 2023, 69% of growth in private research and development spending among OECD countries came from the U.S. pharmaceutical industry.²¹ That decrease in relative spending has corresponded to a relative decrease in clinical trials for new drugs, with Europe’s “share of trials decreasing from 18% in 2013, to 15% in 2018, to 9% in 2023.”²²

47. Economists estimate that this decrease in innovation has had—and will continue to have—significant negative effects on global health. One 2018 study found that if price controls were lifted in non-U.S. OECD countries, there would be anywhere between 8 to 13 new drugs introduced annually by 2030 and 28 to 44 new drugs annually by 2060.²³ Concretely, that would increase the average life expectancy of a 45-year-old by anywhere from 0.56 to 0.86 years. In

¹⁸ Euripid, *Guidance Document on External Reference Pricing (ERP)* 19 (July 2018), https://ppri.goeg.at/sites/ppri.goeg.at/files/inline-files/EURIPID_GuidanceDocument_V8.1_310718_5_0.pdf?

¹⁹ John A. Vernon et al., *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 4 (2008).

²⁰ Robert D. Atkinson, *China is Rapidly Becoming a Leader Innovator in Advanced Industries*, Information Technology & Innovation Foundation (Sep. 16, 2024), <https://itif.org/publications/2024/09/16/china-is-rapidly-becoming-a-leading-innovator-in-advanced-industries>.

²¹ OECD, *Health at a Glance 2023: OECD Indicators* (Nov. 7, 2023), https://www.oecd.org/en/publications/health-at-a-glance-2023_7a7afb35-en/full-report/pharmaceutical-research-and-development_6eb5e4b8.html.

²² Iqvia, *Assessing the clinical trial ecosystem in Europe* 13 (Oct. 2024), <https://www.efpia.eu/media/0ipkatpg/efpia-ct-report-embargoed-221024-final.pdf>.

²³ Taylor T. Schwartz et al., *The Impact of Lifting Government Price Controls on Global Pharmaceutical Innovation and Population Health*, ISPOR (May 2018), <https://www.ispor.org/heor-resources/presentations-database/presentation/ispor-2018/the-impact-of-lifting-government-price-controls-on-global-pharmaceutical-innovation-and-population-health>.

economic terms, that increase would represent \$924 billion to \$1.52 trillion in total value for that age cohort (or \$41,000 to \$67,000 per capita).²⁴

48. In addition to harming innovation, price controls in foreign OECD countries directly prevent patients from accessing new drugs when they need them. At the threshold, price controls and access limitations delay (or prevent) the launch of drugs in those countries. In 2022, for instance, “more than half of new drugs were launched first in the United States, and there was an average lag of about one year between launch in the United States and launch in other major OECD markets (Australia, Canada, France, Germany, Italy, Japan, and the United Kingdom).”²⁵ By the end of 2022, 74% of new drugs sold that year had launched in the United States; by contrast, only 52% had launched in Germany, only 43% had launched in the United Kingdom, only 34% had launched in France, and only 28% had launched in Canada.²⁶

49. Even after drugs are approved and launched, price controls further prevent patients from accessing them. For instance, a study of 173 innovative drugs approved by the European Commission between 2020 and 2023 found that, as of 2024, only 46% were “available” in Europe, *i.e.*, eligible for reimbursement, in at least one European country.²⁷ And only 29% were fully available in all European countries. The study also found that it took an average of 578 days for those drugs to become available after approval.²⁸

50. For all these reasons, U.S. policymakers have historically rejected efforts to impose drug price controls that reference prices in foreign countries. In 2017, for example, a bill was proposed in the House of Representatives that would have tied the prices of certain drugs inside

²⁴ *Id.*

²⁵ Andrew W. Mulcahy, *Comparing New Prescription Drug Availability and Launch Timing in the United States and Other OECD Countries*, RAND Corporation, at v (Feb. 1, 2024), https://www.rand.org/pubs/research_reports/RRA788-4.html.

²⁶ *Id.* at 24.

²⁷ Iqvia, *EFPIA Patients W.A.I.T. Indicator 2024 Survey*, 5 (May 2025).

²⁸ *Id.* at 8.

the United States to the prices at which those drugs were sold abroad. Medicare Drug Price Negotiation Act, H.R. 4138, 115th Cong. (2017). But the bill never made it out of the House Subcommittee on Health. Numerous similar bills have also died in committee. *See* Medicare Drug Price Negotiation Act, S. 2011, 115th Cong. (2017); Medicare Negotiation and Competitive Licensing Act of 2018, H.R. 6505, 115th Cong. (2018); Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019).

51. Thus, when Congress sought to decrease drug prices through the Inflation Reduction Act of 2022 (IRA), Pub L. No. 117-169, 136 Stat. 1818, it opted not to pursue a program that would link Medicare prices to prices in foreign countries. Instead, that statute created two programs that deviate from market pricing in limited circumstances. The first is a rebate program “for certain drugs with prices increasing faster than inflation.” 42 U.S.C. § 1395w-3a(i). Under the program, if a drug’s average sales price increases faster than the rate of inflation in a given year, the company must pay a rebate to CMS that equals the difference between the average sales price and the price the drug would have been in a market where inflation was the only factor. *See id.* § 1395w-3a(i)(3). The second program is a so-called “negotiation” program, which directs CMS to annually select between 10 and 20 additional drugs each year and “achieve the lowest maximum fair price for each selected drug.” *Id.* § 1320f-3.

52. Price controls that reference foreign prices are a particularly bad fit for the United States because they incorporate inapplicable foreign rationing decisions that Congress would never directly approve. Specifically, many foreign countries impose price controls because the government has made an explicit decision to prioritize cost efficiency rather than health outcomes. For instance, as discussed, the United Kingdom’s NHS will pay for a drug only if it “is a clinically

and a cost-effective use of the health budget compared to other potential uses of that budget.”²⁹ Many other countries likewise delegate pricing decisions to centralized Health Technology Assessment (HTA) bodies that apply national evaluations of clinical evidence, cost-effectiveness, safety, and overall therapeutic benefit.³⁰

53. Many of these countries make these rationing decisions by relying on QALYs, a discriminatory methodology that is fundamentally inconsistent with American values.³¹ As discussed, foreign countries use QALYs to determine whether it is worth paying for a drug based on the effect the drug will have on a person or group’s length and quality of life.³² This methodology perpetuates discrimination against older adults and individuals with chronic conditions, disabilities, and people with rare diseases by assigning them lower scores and decreasing the likelihood that they will receive the treatments they need in the name of cost efficiency.³³ That kind of discriminatory rationing is inconsistent with the United States’ commitment to equal health outcomes for all Americans. And it further undermines the search for cures for chronic conditions, disabilities, and rare diseases. If the pharmaceutical industry cannot expect to receive returns for drugs provided to individuals with those conditions, it will not invest in discovering those treatments.

B. Courts Have Rejected Prior Efforts To Impose Foreign Price Controls By Executive Branch Fiat.

54. This is not the Executive Branch’s first attempt to impose MFN pricing without congressional approval. In July 2020, the President announced various Executive Orders relating

²⁹ NICE, *Changes to NICE Regulations*, *supra*.

³⁰ 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).

³¹ Julia Wahl et al., *QALY Use in Selected OECD Countries* Copenhagen Econ. (Feb. 2026), <https://copenhageneconomics.com/publication/qaly-use-in-oecd>.

³² NICE, *Glossary: Q*, <https://www.nice.org.uk/Glossary?letter=Q#QALY>.

³³ Gabriel Andrade, *Ethical Shortcomings of QALY: Discrimination Against Minorities in Public Health*, *Cambridge Quarterly of Healthcare Ethics* (Jan. 2024), <https://www.doi.org/10.1017/S0963180123000580>.

to drug costs, one of which aimed at bringing MFN pricing into the United States. At the signing ceremony, he stated that “we’ve been waiting for Congress to take action for many decades to reduce drug prices,” and that he was “unwilling to wait any longer.”³⁴

55. In November 2020, the President announced that he was directing HHS and CMS to impose a “Most Favored Nation rule,” which would “transform the way the U.S. government pays for drugs.”³⁵ “Medicare will now look at the price that other developed nations pay for their drugs,” he explained, “and instead of paying the highest price on that list—and we are substantially higher than any other country in the world—we will pay the lowest price.”³⁶

56. A week later, CMS issued an interim final rule that purported to impose most-favored nation pricing by altering the reimbursements available for 50 specified Medicare Part B drugs. CMS, Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180, 76,181 (Nov. 27, 2020). Relying on the same statutory authority invoked by CMS here—which is described further below—CMS purported to “waive” the statutory provision that tied reimbursements for those drugs to their average sales price. *Id.* at 76,258. CMS then provided that reimbursements for those drugs would instead be calculated using “drug pricing information” from a basket of OECD countries. *See id.* at 76,200.

57. The Most Favored Nation Rule never took effect. On December 23, 2020, a court in the District of Maryland entered a nationwide temporary restraining order that prohibited HHS and CMS from enforcing the rule. *Ass’n of Cmty. Cancer Ctrs. v. Azar*, 509 F. Supp. 3d 482, 488 (D. Md. 2020). The court reasoned that HHS and CMS had violated the Administrative Procedure

³⁴ White House, *Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices* (July 24, 2020), <https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-signing-executive-orders-lowering-drug-prices>.

³⁵ White House, *Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans* (Nov. 20, 2020), <https://trumpwhitehouse.archives.gov/briefings-statements/remarks-president-trump-delivering-lower-prescription-drug-prices-americans>.

³⁶ *Id.*

Act by failing to use the notice-and-comment rulemaking process, and that no “good cause” justified that failure. *See id.* at 494-96. The court also concluded that the plaintiffs—organizations which represented provider groups, doctors, patients, and pharmaceutical companies—would suffer irreparable harm from the rule, which “in its first year would reduce Medicare drug expenditures by nearly \$5 billion, and accordingly would drastically reduce revenues for providers, many of whom already operate on thin profit margins.” *Id.* at 499-500. Within a week, two other district courts issued similar orders. *See Cal. Life Scis. Ass’n v. CMS*, No. 20-cv-08603, 2020 WL 7696050, at *1 (N.D. Cal. Dec. 28, 2020); *Regeneron Pharms., Inc. v. HHS*, 510 F. Supp. 3d 29, 35 (S.D.N.Y. 2020). A year later, HHS and CMS rescinded the never-effective rule. CMS, Most Favored Nation (MFN) Model, 86 Fed. Reg. 73,986 (Dec. 29, 2021).

C. GLOBE Again Seeks To Import Foreign Price Controls Into the United States Without Congressional Approval.

58. The GLOBE Rule challenged here is the latest attempt to impermissibly import MFN pricing into the United States without Congress’s authorization. GLOBE purports to require pharmaceutical manufacturers participating in Medicare Part B to pay “rebates” to the government that effectively lower their drugs’ sales prices to the prices charged in foreign nations. CMS does not claim that Congress has directed the agency to upend the drug-pricing formulas in the Medicare statute. Instead, CMS asserts that a minor provision of the Patient Protection and Affordable Care Act (ACA) gives the agency vast and unreviewable authority to overhaul Congress’s considered choices about Medicare design. But the history of that section tells a different story: Except for the first unsuccessful attempt to mandate MFN pricing, there is no prior use of that statute of the nature and significance as this Rule. Numerous commenters thus explained to CMS the legal and policy problems with GLOBE, but the agency finalized the rule without meaningfully responding to those objections.

1. GLOBE’s operative provisions

59. If permitted to take effect, GLOBE would make sweeping changes to the Medicare Part B program. GLOBE announces classes of drugs whose manufacturers are required to participate in the so-called “model.” It then announces certain Medicare recipients’ claims (based on ZIP Code of residence) will be used for purposes of the “model.” Next, CMS calculates a price, based on foreign-drug pricing, for each covered drug. Finally, CMS requires manufacturers to pay a “rebate” down to that price; if the manufacturer fails to pay the rebate, CMS imposes crushing penalties for noncompliance. Put simply, GLOBE imposes foreign price controls under the guise of a rebate scheme.

60. GLOBE’s new pricing formula would apply to all Part B-covered drugs that meet four criteria, subject to limited exceptions. *First*, the drugs must be antigout agents, antineoplastics, blood products and modifiers, central nervous system agents, immunological agents, metabolic bone disease agents, or ophthalmic agents—categories that, as CMS explains, “include drugs used to treat cancer and related conditions, rheumatoid arthritis and other immune mediated conditions, and macular degeneration and other serious eye conditions.” 91 Fed. Reg. at 62,973. *Second*, the drugs must be “[s]ingle source drugs or sole source biological products,” meaning that there is no equivalent product sold or marketed in the United States. *Id.* at 63,104 (A “drug” and a “biological product” differ in that the former is chemically synthesized while the latter is isolated from natural sources.) *Third*, the drugs must result in Part B expenditures greater than a defined “minimum spend threshold over a 12-month period prior to the start of the applicable calendar quarter.” *Id.* The “minimum spend threshold” is set at \$100 million over a 12-month period ending 6 months prior to the start of the calendar quarter beginning April 1, 2027, and is subject to adjustments for inflation for future quarters. *Id.* And *fourth*, the drugs must not

be selected for the Medicare Drug Price Negotiation program that Congress authorized in the IRA. *Id.*

61. GLOBE’s coverage excludes three limited categories of Part B drugs that would otherwise meet those four criteria: (1) drugs that are exclusively approved to treat one or more rare diseases or conditions identified in Section 526 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bb; (2) cellular and gene therapy drugs that are listed on the FDA Approved Cellular and Gene Therapy Products website; and (3) plasma-derived drugs identified in 42 C.F.R. § 427.400. *See* 91 Fed. Reg. at 62,947.

62. GLOBE also refers to an additional, uncodified exclusion. Earlier this year, CMS launched the GENERating cost Reductions fOr U.S. Medicaid (GENEROUS) model, under which manufacturers could agree to MFN-style pricing in the Medicaid (not the Medicare) program in exchange for negotiated coverage criteria.³⁷ CMS states in the GLOBE rule that it “has determined that a manufacturer’s participation in the GLOBE Model could impact CMS’s ability to isolate the effects of the GENEROUS Model.” 91 Fed. Reg. at 63,070. It therefore announced that it “intends to use its authority” to waive GLOBE’s mandatory participation requirements for GENEROUS participants—even though it “decline[d] to codify manufacturer exemptions” on this basis. *Id.* In other words, CMS intends to exempt companies that made “voluntary MFN commitments,” *id.* at 63,082—but does not commit to binding itself to doing so in the future.

63. Manufacturers of drugs that meet CMS’s criteria and do not fall within an exclusion would be required to participate in GLOBE. The Rule explains that “mandatory participation is necessary” because “manufacturers would likely not volunteer to participate, given that the model’s rebate mechanism reduces their effective reimbursement.” 91 Fed. Reg. at 62,985; *see*

³⁷ CMMI, *GENEROUS (GENERating cost Reductions fOr U.S. Medicaid) Model*, <https://www.cms.gov/priorities/innovation/innovation-models/generous> (last visited October 5, 2026).

id. (“[T]he GLOBE Model would have few voluntary participants.”). Although CMS recognized that there are many drugs “where the U.S. manufacturer may not be the same entity that is responsible for sales in other countries,” it declined to alter the GLOBE Rule to permit such manufacturers to “qualify for a model exemption given their lack of responsibility for sales of drugs outside of the U.S.” *Id.* at 62,984.

64. GLOBE imposes CMS’s “model” on tens of millions of Medicare enrollees—approximately 25% of Medicare Part B fee-for-service beneficiaries. 91 Fed. Reg. at 62,938. Those covered beneficiaries are selected based on whether they live in a set of randomly chosen “ZIP Code Tabulation Areas.” *Id.* Like covered manufacturers, covered beneficiaries are not permitted to opt out of GLOBE, despite concerns raised by commenters that inclusion in GLOBE may adversely affect drug access. 91 Fed. Reg. at 63,066. Indeed, CMS will not even inform covered beneficiaries that they have been conscripted to participate in GLOBE. *Id.* at 63,065.

65. GLOBE would require CMS to calculate a reference price for all covered drugs purchased by covered participants based on “international drug pricing information.” 91 Fed. Reg. at 62,939. For that calculation, CMS looks to drug prices in 19 countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, France, Germany, Ireland, Israel, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, Switzerland, and the United Kingdom. *Id.*

66. CMS would calculate the foreign reference price for each drug using two separate methods. The first method would look to the lowest price in the 19 countries chosen by CMS, after adjusting for GDP. 91 Fed. Reg. at 62,939. The second method—which would be available only to those manufacturers that submit detailed, confidential data about the net pricing of their drugs abroad—would look to the weighted average of prices in comparator countries, again after

adjusting for GDP. *Id.* The higher of the two prices would be the relevant foreign reference price. *Id.* at 63,028.

67. CMS seeks to accomplish its MFN-pricing goals in the Medicare program through a system of “rebates” designed to ensure that manufacturers cannot recover more than the foreign reference price. 91 Fed. Reg. at 62,938. As already discussed, in enacting the IRA, Congress created an “inflation rebate” applicable to drugs whose prices rose faster than the rate of inflation. *See* 42 U.S.C. § 1395w-3a(i). GLOBE would replace that congressionally approved rebate calculation with an entirely different rebate calculation that is based on the delta between the foreign reference price and the statutory average sales price. 91 Fed. Reg. at 62,938. If, however, the inflation rebate is higher than the GLOBE-required rebate, then the inflation rebate would remain the operative rebate. *Id.*

68. GLOBE requires manufacturers to pay the foreign-pricing rebates to CMS on a quarterly basis, under pain of significant civil monetary penalties. *See* 91 Fed. Reg. at 63,058-59. CMS claims that, in the event of nonpayment of the GLOBE-required rebate, the “available civil money penalty [CMP] authority” that exists under the inflation-rebate statute would authorize the agency to impose penalties of “125 percent of the incremental GLOBE Model rebate amount . . . which would be in addition to any unpaid incremental GLOBE Model rebate amount due.” *Id.* at 63,058. In other words, CMS purports to redline a civil-penalty provision specific to a *statutory* rebate and turn it into a provision for GLOBE, which Congress did not enact.

69. Attempting to distance GLOBE from previous failed attempts to impose foreign price controls, CMS states that it “disagrees that the GLOBE Model imports foreign price-setting systems or foreign price controls into the Medicare program.” 91 Fed. Reg. at 62,955. Instead, CMS asserts, GLOBE merely requires the payment of rebates that are “informed by international

drug pricing information.” *Id.* That assertion ignores GLOBE’s mechanics, which use the rebates to reduce payments for drugs to the lowest or average (depending on the method chosen) price in the 19 foreign reference countries. Moreover, CMS’s characterization of GLOBE contradicts the Administration’s own description of its position: The 2026 Council of Economic Advisers Report—which CMS cites repeatedly to justify GLOBE, *see* 91 Fed. Reg. at 62,955 (“We direct the reader to the 2026 Council of Economic Advisers Report for a discussion of U.S. based drug pricing policy initiatives.”)—makes clear that the government’s core policy solution is “tying U.S. drug prices to international prices.”³⁸

70. GLOBE also contains a methodology for recalculating coinsurance obligations for covered drugs. 91 Fed. Reg. at 62,938. Where the foreign reference price is lower than the congressionally chosen price (taking into account the IRA’s inflation rebate), Medicare Part B fee-for-service beneficiaries would pay 20% of the foreign reference price. *Id.*

71. GLOBE’s purported coinsurance benefits are largely illusory. The vast majority—roughly 90%—of Medicare fee-for-service beneficiaries have supplemental coverage that leaves them with no or limited liability for out-of-pocket costs for their medicines.³⁹ Thus, one estimate indicates that only a minuscule fraction of Medicare fee-for-service beneficiaries would have their out-of-pocket costs reduced.⁴⁰

72. GLOBE is scheduled to take effect on November 30, 2026; its period for collection of “voluntary manufacturer-submitted international drug net pricing data” will begin on January 1, 2027. 91 Fed. Reg. at 62,936-37. Its “performance period” will run for five years, beginning

³⁸ The White House, Savings from Most-Favored-Nation Drug Pricing Policy (May 5, 2026), <https://www.whitehouse.gov/research/2026/05/savings-from-most-favored-nation-drug-pricing-policy>.

³⁹ Nancy Ochieng et al., *A Snapshot of Sources of Coverage Among Medicare Beneficiaries*, KFF (Dec. 19, 2025), <https://www.kff.org/medicare/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries>.

⁴⁰ Luke Frazier et al., *How MFN Pricing in Part B May Affect Beneficiary OOP Costs* (Jan. 21, 2026), <https://advisory.avalerehealth.com/insights/how-mfn-pricing-in-part-b-may-affect-beneficiary-oop-costs>.

on April 1, 2027, and running through 2032. *Id.* at 62,937. Because of lag time in calculating and receiving rebate payments, CMS anticipates that manufacturers will be paying GLOBE rebates through 2034. *Id.*

73. CMS estimates that the economic impact of GLOBE will be \$440 million over the seven-year payment period. 91 Fed. Reg. at 63,089 at tbl.13. That figure is sharply down from the \$11.9 billion that CMS estimated in its Notice of Proposed Rulemaking, *see* 90 Fed. Reg. at 60,313, largely because of the “assum[ption] that manufacturers that have signed GENEROUS Model participation agreements as of August 17, 2026 will have a waiver that waives the requirements of mandatory participation of manufacturers of GLOBE Model drugs and will therefore not participate in the GLOBE Model,” 91 Fed. Reg. at 63,072.

2. *GLOBE’s purported statutory authority*

74. CMS invokes a single statute to support these sweeping revisions to Medicare Part B: Section 1115A of the Social Security Act, 42 U.S.C. § 1315a.

75. Congress enacted Section 1115A as a “minor” and “ancillary” provision of the ACA. *NFIB v. Sebelius*, 567 U.S. 519, 704-05 (2012) (Scalia, Kennedy, Thomas, & Alito, JJ., dissenting). Its purpose is “the study of how to spend less government money.” *Id.* at 704.

76. The statute accomplishes that purpose by creating “within the Centers for Medicare & Medicaid Services a Center for Medicare and Medicaid Innovation.” 42 U.S.C. § 1315a(a)(1). CMMI is tasked to “test innovative payment and service delivery models to reduce program expenditures under the applicable subchapters”—meaning the Medicare and Medicaid programs—“while preserving or enhancing the quality of care furnished to individuals under such subchapters.” *Id.*

77. Section 1115A imposes numerous limitations on CMMI’s authority. Most obviously, CMMI’s powers are limited to “test[ing] innovative payment and service delivery

models to reduce program expenditures under” Medicare and Medicaid “while preserving or enhancing the quality of care furnished to individuals” under those programs. 42 U.S.C. § 1315a(a)(1). That language limits CMMI to conducting experiments (“tests”) to see how different ways of providing healthcare services and paying for those services (“innovative payment and service delivery models”) affect Medicare or Medicaid expenditures. The statute does not permit CMMI to try to save money in ways that do not involve testing innovative models for structuring payment and delivering healthcare or to generally refashion the Medicare and Medicaid programs.

78. The statute additionally imposes a two-phase procedure for testing payment and service delivery models.

79. In the first phase, CMMI must “select models to be tested” where 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.” 42 U.S.C. § 1315a(b)(2)(A). CMMI must “focus on models to reduce program costs under [Medicare or Medicaid] while preserving or enhancing the quality of care received by individuals receiving benefits under” those programs. *Id.* CMMI must then assess whether the models actually “improve the quality of care”; “reduce spending . . . without reducing the quality of care”; or “improve the quality of care and reduce spending.” *Id.* § 1315a(b)(3)(B). Unless the model satisfies one of those criteria, CMMI “shall terminate or modify” the model. *Id.*

80. Only if the model satisfies those criteria may CMMI put the model into the second phase. CMMI “may, through rulemaking, expand (including implementation on a nationwide basis) the duration and scope of a model” if it finds that doing so will “reduce spending . . . without reducing the quality of care” or “improve the quality of care without increasing spending.” 42

U.S.C. § 1315a(c)(1). CMMI may not expand a model unless it determines “that such expansion would not deny or limit the coverage or provision of benefits under [Medicare or Medicaid] for applicable individuals.” *Id.* § 1315a(c)(3).

81. As part of its testing of models, CMMI “may waive such requirements” of the statute (as well as portions of the Medicaid statute and certain provisions that generally grant authority to CMS) “as may be solely necessary for purposes of carrying out this section with respect to testing models” in the first phase. 42 U.S.C. § 1315a(d)(1). CMMI has no authority to add requirements to Medicare and Medicaid, nor is it authorized to waive Medicare and Medicaid provisions once a model enters the second phase.

3. *GLOBE’s dissimilarity to prior CMS models*

82. GLOBE has next to nothing in common with the rest of CMMI’s Section 1115A models—except, of course, for the 2020 MFN model that three courts quickly struck down.

83. The overwhelming majority of Section 1115A models are fully voluntary, meaning that participants have the choice to opt into CMMI’s test. *See* GAO-26-107953, *CMS Innovation Center: Obligations and Model Payments* 15 (Mar. 2026) (noting that, of active models, “22 models had voluntary participation and two had mandatory participation”). For example, the ACCESS Model allows “Medicare-enrolled care organizations” to opt into “Outcome-Aligned Payments” that reward “managing patients’ qualifying conditions.”⁴¹ Similarly, the Enhancing Oncology Model invites oncology providers to participate in an effort to improve quality and cost of care for “Medicare beneficiaries receiving systemic chemotherapy for seven specific cancers.”⁴² The model includes “two main payment structures”: one that provides a set amount per beneficiary

⁴¹ CMMI, *ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model*, <https://www.cms.gov/priorities/innovation/innovation-models/access> (last visited October 5, 2026).

⁴² CMMI, *EOM (Enhancing Oncology Model)*, <https://www.cms.gov/priorities/innovation/innovation-models/eom> (last visited October 5, 2026).

per month and one that increases or decreases reimbursements depending on whether the provider is able to hold total spending below a target amount.⁴³

84. Beyond GLOBE and the swiftly enjoined 2020 MFN rule, CMMI has finalized a mandatory model only seven times. And those other mandatory models have critical differences from GLOBE—differences that illustrate how GLOBE fails to satisfy the statutory requirements for mandatory models. Of particular significance, those models alter how payments to Medicare providers are structured by creating “two-sided risk arrangements” under which the providers receive a “positive payment adjustment” or a “negative risk adjustment” based on “performance.”⁴⁴ CMMI’s ASM Model creates incentives for care providers to intervene early to help patients avoid heart failure.⁴⁵ Its CJR Model provided that hospitals could “receive[] an additional payment from Medicare or . . . be[] required to repay Medicare for a portion” of previous payments, depending on the “quality” of their “performance” in providing coordinated care following joint-replacement surgery.⁴⁶ Its TEAM Model likewise allows hospitals to “earn a payment from CMS” or “owe CMS a repayment amount” based on post-surgery outcomes.⁴⁷ Two other models provide for “upside or downside risk” in relation to hospitals’ coordination of care for individuals with kidney disease.⁴⁸ A model that Congress ultimately prohibited from taking effect would have switched radiotherapy reimbursements from “fee-for-service payments” to “episode-based payments” to “incentivize[] physicians to deliver higher-value [radiotherapy]

⁴³ *Id.*

⁴⁴ CMMI, *ASM (Ambulatory Specialty Model)*, <https://www.cms.gov/priorities/innovation/innovation-models/asm> (last visited October 5, 2026).

⁴⁵ *Id.*

⁴⁶ CMMI, *CJR (Comprehensive Care for Joint Replacement) Model*, <https://www.cms.gov/priorities/innovation/innovation-models/cjr> (last visited October 5, 2026).

⁴⁷ CMMI, *TEAM (Transforming Episode Accountability Model)*, <https://www.cms.gov/priorities/innovation/innovation-models/team-model> (last visited October 5, 2026).

⁴⁸ CMMI, *IOTA (Increasing Organ Transplant Access) Model*, <https://www.cms.gov/priorities/innovation/innovation-models/iota> (last visited October 5, 2026); CMMI, *ESRD Treatment Choices (ETC) Model*, <https://www.cms.gov/priorities/innovation/innovation-models/esrd-treatment-choices-model> (last visited October 5, 2026).

care.”⁴⁹ And a final model provides for an “upward or downward” payment adjustment based on home healthcare agencies’ “quality performance.”⁵⁰

85. There is no regulatory antecedent (again, other than the swiftly enjoined 2020 MFN Rule) that mandates participation and necessarily reduces the amount of Medicare payments to participants, rather than altering payment structure to assess potential effects on program expenditures.

4. *GLOBE’s regulatory process*

86. CMS publicly announced GLOBE on December 21, 2025, and published a Notice of Proposed Rulemaking (NPRM) in the Federal Register two days later. *See* 90 Fed. Reg. at 60,244. CMS announced a 60-day period for comments on the NPRM. The same day, CMS announced a different NPRM, Guarding U.S. Medicare Against Rising Costs (GUARD), which would impose MFN pricing in Medicare Part D, but which CMS has not yet finalized. *See* 90 Fed. Reg. 60,338 (Dec. 23, 2025).

87. A diverse array of organizations and associations submitted comments opposing the GLOBE NPRM on the grounds that it exceeded CMS’s statutory authority and would hurt American patients, American businesses, and American global leadership.

88. Industry groups such as PhRMA, the Chamber of Commerce, and the National Association of Manufacturers explained that the rule would weaken the American economy. The Chamber of Commerce warned that “[w]eakening the incentive structure that has made the United States the world leader in medical innovation would have profound implications not only for American patients (and, indeed, patients around the world), but for U.S. economic security and

⁴⁹ CMMI, *Radiation Oncology Model*, <https://www.cms.gov/priorities/innovation/innovation-models/radiation-oncology-model> (last visited October 5, 2026).

⁵⁰ CMMI, *Home Health Value-Based Purchasing Model*, <https://www.cms.gov/priorities/innovation/innovation-models/home-health-value-based-purchasing-model> (last visited October 5, 2026).

national security.”⁵¹ The National Association of Manufacturers explained that GLOBE’s “[r]eductions in revenue” would “translate into reduced rates of innovative effort, which ultimately harms patients.”⁵² And PhRMA noted that “[m]andatory MFN policies could imperil over \$500 billion in recently announced capital investments across the sector.”⁵³

89. Associations of healthcare providers, including the American Hospital Association (AHA), the National Organization of Rheumatology Management (NORM), and the Coalition of State Rheumatology Organizations (CSRO), urged CMS to withdraw the GLOBE proposal because it would create harmful ripple effects in the healthcare market. The AHA expressed worry that GLOBE could “result[] in higher acquisition costs for hospitals.”⁵⁴ NORM noted its “concern[] that there could be unintentional ripple effects in the market that cause the manufacturer Average Sales Price (ASP) to drop, and thus provider administration fees to also drop.”⁵⁵ And CSRO shared the view that “these models could unintentionally harm patient access to essential medications.”⁵⁶

⁵¹ U.S. Chamber of Commerce, Comment on Proposed GLOBE and GUARD Rules, CMS-2025-1889-0033, at 5 (Feb. 20, 2026).

⁵² National Association of Manufacturers, Comment on Proposed Global Benchmark for Efficient Drug Pricing (GLOBE) Model, CMS-2025-1889-0059, 3-4 (Feb. 23, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0059>.

⁵³ Pharmaceutical Research and Manufacturers of America, Comment on Proposed Global Benchmark for Efficient Drug Pricing (GLOBE) Model, CMS-2025-1889-0105, at 4 (Feb. 23, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0105>.

⁵⁴ Am. Hosp. Ass’n, Comment on Proposed GLOBE Model, CMS-2025-1889-0080, 2 (Feb. 23, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0080>.

⁵⁵ Nat’l Org. of Rheumatology Mgmt., Comment on Proposed GLOBE and GUARD Models, CMS-2025-1889-0039, 1 (Feb. 20, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0039>.

⁵⁶ Coalition of State Rheumatology Organizations, Comment on Proposed Global Benchmark for Efficient Drug Pricing (GLOBE) Model and Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, CMS-2025-1889-0040, 1 (Jan. 29, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0040>.

90. The good-government organization Citizens Against Government Waste attacked the proposal as “represent[ing] a profound expansion of federal power over healthcare policy through an agency that was never intended to serve as a substitute for Congress.”⁵⁷

91. Patient advocates like the American Cancer Society Cancer Action Network (ACS CAN), the Partnership To Improve Patient Care (PIPC), the Council for Affordable Health Coverage (CAHC), and the National Health Council (NHC) urged CMS not to implement GLOBE because it would prevent patients from accessing medically necessary drugs while failing to meaningfully reduce patient costs. ACS CAN stated that it “remains concerned that the proposed Model lacks sufficient patient-centered safeguards” and thus could harm “cancer patients who often rely on individualized treatment regimens.”⁵⁸ PIPC argued that “referenc[ing] discriminatory cost effectiveness standards like the quality-adjusted life year (QALY) used by many other countries is the wrong approach.”⁵⁹ CAHC observed that GLOBE’s purported coinsurance reduction “offers limited practical benefit given the prevalence of supplemental coverage among Part B beneficiaries,” and noted that GLOBE “does not include additional beneficiary protections, such as mandatory safeguards against access disruptions, enhanced transparency for patients, or targeted protections for beneficiaries who lack supplemental coverage.”⁶⁰ And NHC observed that GLOBE features “a design that prioritizes evaluation considerations over beneficiary choice in the face of acknowledged access risk.”⁶¹

⁵⁷ Citizens Against Gov’t Waste, Comment on Proposed GLOBE and GUARD Models, CMS-2025-1889-0029, 2 (Feb. 20, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0029>.

⁵⁸ Am. Cancer Soc’y Cancer Action Network, Comment on Proposed GLOBE Model, CMS-2025-1889-0104, 7 (Feb. 23, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0104>.

⁵⁹ P’ship to Improve Patient Care, Comment on Proposed GLOBE Model, CMS-2025-1889-0078, 1, 3 (Feb. 23, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0078> (citing 42 U.S.C. § 1320e).

⁶⁰ Coal. for Affordable Health Coverage, Comment on Proposed GLOBE Model, CMS-2025-1889-0155, 4 (Feb. 23, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0155>.

⁶¹ Nat’l Health Council, Comment on Proposed GLOBE Model, CMS-2025-1889-0151, 2 (Feb. 25, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0151>.

92. Undeterred, CMS announced the GLOBE Final Rule on September 30, 2026, and published it in the Federal Register on October 2, 2026. The Final Rule makes only modest modifications from the NPRM.

D. GLOBE Exceeds CMS’s Statutory Authority and Violates the Constitution.

93. GLOBE exceeds CMMI’s “minor” and “ancillary” authority under Section 1115A in multiple independent respects. *NFIB*, 567 U.S. at 704-05 (Scalia, Kennedy, Thomas, & Alito, JJ., dissenting). Section 1115A, as noted, directs CMMI to “test innovative payment and service delivery models to reduce program expenditures” under the Medicare and Medicaid programs “while preserving or enhancing the quality of care furnished to individuals under such subchapters.” 42 U.S.C. § 1315a(a)(1). But GLOBE does not qualify as a “test,” nor is it a “payment [or] service delivery model[]” within the meaning of the statute. *Id.* GLOBE also fails to meet the conditions for a Phase I test under Section 1115A. And it rewrites, rather than “waives,” provisions of the Medicare statute.

94. If any of these statutory questions were close, the major questions doctrine—which prohibits agencies from claiming newfound significant authority in ambiguous statutory language—would doom CMS’s novel effort to invoke Section 1115A to overhaul Medicare by effectively imposing price controls.

95. In addition to exceeding CMS’s statutory authority, GLOBE is contrary to law in two further respects: It violates Congress’s prohibition on the use of QALYs and defies federal appropriations law.

96. Finally, if CMS were correct that Section 1115A permitted it to rewrite the Medicare statute without congressional input, then the statute—and thus GLOBE—would violate the Constitution.

1. GLOBE is not a “test.”

97. GLOBE is not the kind of “test” permitted by Section 1115A. Under that section, CMMI may “test innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care” provided under Medicare. 42 U.S.C. § 1315a(a)(1); *see id.* § 1315a(b)(1) (requiring that CMS “determine the effect of applying such models . . . on program expenditures . . . and the quality of care”). The statute does not define the term “test,” so courts must look to its “ordinary meaning.” *Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560, 566 (2012). The relevant ordinary meaning of “test” requires some “research or experimental goal.” *Beno v. Shalala*, 30 F.3d 1057, 1069 (9th Cir. 1994). A “test” is a “basis for evaluation” or “critical examination.” *Test*, Merriam-Webster Dictionary Online, <https://www.merriam-webster.com/dictionary/test> (last accessed July 28, 2026); *see also Test*, American Heritage Dictionary (5th ed. 2022) (“[a] procedure for critical evaluation,” “a trial”). It follows that, in order to “test” whether an “innovative payment and service delivery model[]” will “reduce program expenditures,” there must be some question whether the model will in fact have that effect, 42 U.S.C. § 1315a(a)(1); if the result is already known, then there is no “research or experimental goal,” *Beno*, 30 F.3d at 1069, nor is there anything to “evaluate” or “examine.” In other words, unless there is uncertainty about whether a model will “reduce program expenditures,” the model is outside of CMS’s authority under Section 1115A.

98. GLOBE cannot satisfy that requirement. It will not “test” whether an “innovative payment and service delivery model[]” will “reduce program expenditures” because the results are preordained. 42 U.S.C. § 1315a(a)(1). Indeed, it is certain that GLOBE’s importation of foreign price controls will reduce government expenditures on the Medicare program through a mechanical application of the GLOBE “rebate” formula. 42 U.S.C. § 1315a(a)(1). There can thus

be no question of how GLOBE will affect “program expenditures.” It follows that GLOBE is not “test[ing]” a means of reducing expenditures within the meaning of Section 1115A. *Id.*

99. By way of analogy, if a family announced that it was planning to cut household expenditures by purchasing the exact same products at a lower price, that would not be a “test” of a new means of reducing household “expenditures.” So too here. CMS cannot disguise this price control scheme as a “test” when there is no question about the economic effects of GLOBE.

100. Other provisions of Section 1115A reinforce that plain-meaning limitation on CMMI’s authority by using additional language that speaks in experimental terms. CMS may “test” models “to determine the effect of applying such models . . . on program expenditures,” and the Secretary is required to “conduct an evaluation of each model tested.” 42 U.S.C. § 1315a(b)(1), (4)(A). Where, as here, the purported “model” simply lowers prices, there is no need to “determine the effect” of the model “on program expenditures.” *Id.* GLOBE is thus plainly at odds with the testing required under the statute.

101. Judicial decisions evaluating analogous provisions of Title 42 have likewise endorsed this understanding of “test.” They have held that the plain meaning of “test” does not include program changes that simply “save money” with “no research or experimental goal.” *Beno*, 30 F.3d at 1069 (interpreting 42 U.S.C. § 1315(a)); *see also Newton-Nations v. Betlach*, 660 F.3d 370, 380 (9th Cir. 2011) (requiring some “experimental value”). CMS’s model does not qualify as a “test” under this standard—and so it exceeds the agency’s authority under Section 1115A.

102. Agency practice, too, has long reflected this inherent limitation on CMMI’s authority under Section 1115A. As discussed earlier, there is no regulatory antecedent (except for the 2020 MFN rule that never took effect) that mandates participation and necessarily reduces

Medicare payments to participants. CMS’s statutory interpretation is thus both aberrant and wrong.

103. CMS claims that GLOBE “tests a specific, meaningful hypothesis” that tying mandatory rebates to the drug prices in other countries “will reduce Medicare program spending while preserving or enhancing the quality of care.” 91 Fed. Reg. at 63,081; *see id.* at 63,082 (asserting that GLOBE has a “testable hypothesis”). But the proposition that GLOBE will reduce Medicare program spending is not a genuine “hypothesis” because there is no uncertainty about whether it is true. It is a foregone conclusion that GLOBE will save CMS money by reducing the amount manufacturers are paid for providing Medicare Part B drugs. CMS admits as much, explaining that “manufacturers would likely not volunteer to participate, given that the model’s rebate mechanism reduces their effective reimbursement.” *Id.* at 62,985.

104. CMS also suggests it is an open question whether “prices for Part B rebatable drugs in reference countries are, on average, . . . lower than what Medicare pays,” creating doubt as to whether manufacturers will have to pay rebates. 91 Fed. Reg. at 63,081. But that assertion contradicts CMS’s unequivocal statements elsewhere in the rule that drug prices in the foreign reference countries are lower than they are in the United States. *See e.g., id.* at 62,944 (“U.S. prescription drug prices, particularly for U.S. originator drugs, exceed those found in other OECD countries.”); *see id.* at 62,937, 62,955 (similar).

105. CMS asserts that other effects of GLOBE—such as “the magnitude of any expenditure reduction” and “the behavioral responses of manufacturers and providers”—“remain uncertain.” 91 Fed. Reg. at 63,082. But the statute requires that there be uncertainty as to whether a model will “reduce program expenditures,” 42 U.S.C. § 1315a(a)(1)—uncertainty about the extent or manner of an inevitable reduction does not suffice. Moreover, CMS has undermined its

ability to assess anything about “magnitude” by exempting all GENEROUS participants from the requirement to participate in GLOBE.

106. Finally, CMS cannot save its flawed interpretation by claiming that GLOBE tests whether CMS can mandate rebates tied to foreign-drug pricing while “preserving or enhancing the quality of care.” 42 U.S.C. § 1315a(a)(1). Given the statute’s function—“the study of how to spend less government money,” *NFIB*, 567 U.S. at 704 (Scalia, Kennedy, Thomas, & Alito, JJ., dissenting)—the statute does not give CMS the freestanding authority to test how to preserve or enhance the quality of care. Instead, it makes that goal contingent on expenditure reduction: CMS must test whether a policy “reduce[s] program expenditures . . . *while* preserving or enhancing the quality of care.” Only tests about “program expenditures” are authorized under that text.

2. *GLOBE is not a “payment [or] service delivery model.”*

107. GLOBE exceeds CMMI’s authority under Section 1115A for an independent reason: It is not a “payment [or] service delivery model[.]” 42 U.S.C. § 1315a(a)(1). GLOBE does nothing to change how healthcare services are delivered and so cannot be a “service delivery model.” And while GLOBE mandates that manufacturers pay the government, it does not qualify as a “payment model.”⁶² As consistently understood throughout Section 1115A and other provisions of the U.S. Code, in judicial decisions, as a matter of plain meaning, and by CMS itself, “payment model” describes *how* payment is made—that is, it refers to the methodology or structure for making payments. GLOBE does not fit the bill because it does not experiment with an

⁶² In enacting Section 1115A, it is possible that Congress intended to authorize only “payment . . . delivery model[s]” rather than “payment model[s].” 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.”) (citation omitted). But that just reinforces that GLOBE does not fit the statutory text because GLOBE does not change the method by which payments are “deliver[ed]” by CMS.

innovative manner of structuring payments; it simply changes *how much* the government pays for drugs.

108. Section 1115A’s illustrative list of models demonstrates what the phrase “payment . . . model[]” means in context. That list includes models that shift from providing a fixed fee per service to overall payments that place the risk of inefficient practices on providers. *See, e.g.*, 42 U.S.C. §§ 1315a(b)(2)(B)(i)-(ii) (“models that transition primary care practices away from fee-for-service based reimbursement and toward comprehensive payment or salary-based payment” and “[c]ontracting directly with groups of providers . . . to promote . . . risk-based comprehensive payment or salary-based payment”). It also includes models that implement incentive payments, or adjust payments up or down based on outcomes or compliance with desired practices. *See, e.g., id.* at §§ 1315a(b)(2)(B)(vi), (xii) (“[v]arying payment to physicians who order advanced diagnostic imaging services . . . according to the physician’s adherence to appropriateness criteria” and “[a]ligning nationally recognized, evidence-based guidelines of cancer care with payment incentives”). As CMS acknowledges, none of the illustrative payment models involves direct changes to “drug pricing.” 91 Fed. Reg. at 62,953.

109. What those illustrative payment models have in common is that they involve changes to how payments are structured. Congress therefore anticipated that by developing “payment models,” CMS would experiment with the “how” of payment—primarily by encouraging providers to sign up for new and innovative payment formats that better align with preferred outcomes. There is no indication that Congress wanted CMS to use “payment models” to directly regulate the “how much” of payment—*i.e.*, the amount paid. CMS resists the relevance of the statute’s illustrative payment models on the ground that its authority is not limited to “the expressly enumerated model types.” 91 Fed. Reg. at 62,946. But CMS misses the point: CMS is

of course not limited to promulgating models identical to the listed examples, but those examples shed light on the permissible scope of the agency’s Section 1115A authority. GLOBE falls well outside of that scope.

110. Other provisions of the U.S. Code that use the term “payment model” confirm that a Section 1115A “payment model” is a method for structuring how payments are made. For example, 42 U.S.C. § 1395jjj provides that “accountable care organization[s]” (ACOs) will be paid “under the original Medicare fee-for-service program.” But it also gives the Secretary the “[o]ption to use other payment models” such as a “[p]artial capitation mode,” under which the “ACO is at financial risk for some, but not all, of the items and services” provided. *Id.* § 1395jjj(i). “Payment model” carries the same meaning in the Medicaid statutes. *See, e.g., id.* § 1395w-8(a) (requiring States to provide reports on the number of Medicaid beneficiaries who received “substance use disorder or mental health treatment” through a “fee-for-service payment model”).

111. Judicial decisions use the phrase “payment model” in the same way. For example, the Ninth Circuit has explained that “[t]raditional Medicare uses a fee-for-service payment model” but that “experts came to realize that this payment *structure* encourages healthcare providers to order more tests and procedures than medically necessary.” *United States ex rel. Anita Silingo v. WellPoint, Inc.*, 904 F.3d 667, 672 (9th Cir. 2018) (emphasis added); *see, e.g., FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 351 (3d Cir. 2016) (“Risk-based contracting is an alternative payment model to the traditional fee-for-service model in which healthcare providers bear some of the financial risk and upside in the cost of treatment.”); *Texas Tech Physicians Assocs. v. HHS*, 917 F.3d 837, 840 (5th Cir. 2019) (describing an “alternative payment model[]” under which “participating programs could earn monthly fees contingent on achieving cost savings of 5%”).

112. Plain meaning confirms that a “payment model” involves the “how” rather than the “how much” of payment. If a person’s hourly wages increase from \$15 to \$20, no one would say that her “payment model” has changed. But if the person goes from being paid a salary to being paid on a contingency basis, then the relevant “payment model” has been altered. Cases from outside the healthcare context confirm the point. *See, e.g., Reed v. Brex, Inc.*, 8 F. 4th 569, 579 (7th Cir. 2021) (noting that, under the Fair Labor Standards Act, employers may supplement “a commission-based payment model” with “periodic payments” like “advances”); *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1363 (Fed. Cir. 2008) (describing a “new payment model” for processing credit-card transactions that inserts a “financial processing entity” between customers and merchants).

113. CMS itself has historically understood “payment model” in this way. A CMS slideshow from 2013 explained that “[a] payment model refers to the manner in which a payer reimburses providers.”⁶³ And the actual payment models CMS has finalized in the past are consistent with that definition. As described above, those models generally move payments towards incentive-based systems where—rather than receiving a flat fee per service—Medicare providers can receive a performance bonus (or a detriment) based on the quality of care provided. Those models test whether a change to “the manner in which [the] payer reimburses providers” might reduce program expenditures. GLOBE, by contrast, changes the amount rather than the manner of payment. CMS claims that GLOBE likewise involves “changes to payment incentives.” 91 Fed. Reg. at 62,945. But manufacturers cannot reduce or eliminate their payment obligation by improving their performance or patients’ quality of care. GLOBE therefore does not

⁶³ CMS, *Health Care Innovation Awards – Round Two: Payment Models* (July 11, 2013), <https://www.cms.gov/priorities/innovation/files/slides/hciatwopymtmdls.pdf>.

“incentivize” desired behavior through variable payments; it simply requires manufacturers to make payments tied to the external metric of drug prices in other countries.

114. Finally, this understanding of the statute accords with its central purpose to “study . . . how to spend less government money.” *NFIB*, 567 U.S. at 704 (Scalia, Kennedy, Thomas, & Alito, JJ., dissenting). Changing how payment is structured advances that goal by testing (as the incentive-system models do) whether that change could potentially save money. For instance, providing incentive payments *could* save money by reducing costly interventions down the road. Or it could cost the government money by increasing upfront payments with no change in expenditures on the backend. Simply ordering manufacturers to pay “rebates” to CMS, by contrast, does not aid in the “study” of how to spend less money—it simply spends less money. In this way, the statutory phrases “test” and “payment and service delivery models” work together to limit CMMI’s authority.

115. CMS’s contrary understanding of its Section 1115A authority is untenably broad. Under CMS’s view of “test” and “payment and service delivery model,” CMS could unilaterally lower the reimbursements that any healthcare provider receives under the Medicare statute, calling those reduced reimbursements an “alternative approach to calculating” provider-reimbursement rates. *See* 91 Fed. Reg. at 62,937. But under a proper understanding of the statute, that deviation from Congress’s reimbursement decisions would not be a “test” (because it would necessarily lower program expenditures) and would not be a “payment . . . model” (because it would not change how payments are structured).

3. ***GLOBE does not meet the conditions for a Phase I test.***

116. Even if GLOBE qualified as a “test” of a “payment [or] service delivery model,” Section 1115A authorizes CMS to conduct Phase I tests only under strict conditions. 42 U.S.C. § 1315a(b). 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.” *Id.* § 1315a(b)(2)(A). GLOBE exceeds that limited authority because it neither identifies any “defined population” nor addresses any “deficits in care.”

117. GLOBE does not address the needs of any “defined population” of Medicare recipients. It imposes the “model” on 25% of all Medicare beneficiaries who are enrolled in Part B and use traditional Medicare Part B as their primary payer. 91 Fed. Reg. at 63,103. Those individuals have nothing to set them apart from any other Medicare recipient beyond the fact of “random selection” based on ZIP code. *Id.* at 62,938. Indeed, CMS admits that it chose not to “[s]elect geographic areas with the populations most affected by affordability challenges or access barriers,” in order to ensure the beneficiaries were “randomiz[ed].” *Id.* at 62,980.

118. Nor does GLOBE identify any “deficits in care” for covered Medicare beneficiaries. GLOBE targets all Medicare Part B rebatable drugs that fall in seven drug classification categories and have particular characteristics, subject to limited exclusions. The classification categories include “drugs used to treat cancer and related conditions, rheumatoid arthritis and other immune mediated conditions, and macular degeneration and other serious eye conditions.” 91 Fed. Reg. 62,973. CMS included the drugs in those categories because they “were responsible for most [Medicare] Part B spending (91 percent)” in 2024; have more than \$100 million in annual Part B fee-for-service spending; and are single source drugs or sole source biologics. *Id.* at 62,965, 63,104.

119. CMS fails to connect those categories of drugs to any “deficit in care” for the covered Medicare beneficiaries. CMS asserts that it has “focused the model test on [drug classifications] that will target patients in therapeutic areas most likely to experience significant

financial burden due to high drug costs.” 91 Fed. Reg. at 62,980. And it claims that high drug costs can “result in poor clinical outcomes” due to “financial distress” or more limited access to treatments. *Id.* But those claims fail to reckon with the fact—which CMS acknowledges—that the vast majority of Medicare fee-for-service beneficiaries (around 90%) have supplemental coverage and thus no liability for out-of-pocket costs. *See* 91 Fed. Reg. at 63,091 (failing to contest that only “about 22,000 beneficiaries[] would see out-of-pocket changes”).⁶⁴ Cost-sharing liability is therefore not a meaningful factor in any deficits in care for these patients. And while CMS also asserts that GLOBE will lower Part B recipients’ premiums, it makes no effort to show that high premiums present a barrier to care under Part B—or that GLOBE will lower premiums by more than few cents for each beneficiary.

120. Finally, even if CMS had adequately identified a defined population with “deficits in care,” GLOBE still fails to meet the statutory requirements for a Phase I test because it does not “address[]” those deficits. 42 U.S.C. § 1315a(b)(2)(A). As noted, the vast majority of beneficiaries under GLOBE will have little to no reduction in out-of-pocket costs, since nearly all traditional Medicare beneficiaries have supplemental coverage and so do not pay Part B coinsurance. The possibility of out-of-pocket savings for beneficiaries is thus illusory. If anything, GLOBE’s price controls will exacerbate—not address—deficits in care, including by harming innovation for widely prescribed drugs and innovative medicines.

4. *GLOBE rewrites rather than “waives” the Medicare statute.*

121. GLOBE also exceeds CMMI’s limited “waiver” authority under the Medicare statute. Section 1115A(d)(1) 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

⁶⁴ *See also, e.g.,* PhRMA, Comment Letter on GLOBE Model, Dkt. No. 5545-P, at 17 & n.90 (Feb. 23, 2026).

to testing” Phase I models. 42 U.S.C. § 1315a(d)(1). CMS invokes that waiver provision as its authority for modifying the Part B inflation rebate provisions of the IRA. *See* 91 Fed. Reg. at 63,075. But GLOBE’s wholesale replacement of the IRA rebate scheme far exceeds any “waiver” authority.

122. To “waive” means to “mak[e] compliance no longer necessary.” *Biden v. Nebraska*, 600 U.S. 477, 497 (2023); *see also Waive*, American Heritage Dictionary, *supra* (“[t]o refrain from insisting on or enforcing”). So where, as here, a statute authorizes an agency to “waive . . . requirements” of a statutory scheme, 42 U.S.C. § 1315a(d)(1), the agency may not add “new and substantially different provisions” or otherwise rewrite the statute. *Biden*, 600 U.S. at 498. Instead, the statute authorizes the agency to “relax existing legal requirements.” *Id.*

123. GLOBE does not “waive” provisions of the IRA rebate program; it creates an entirely new statutory scheme. GLOBE replaces the Part B inflation rebate calculation authorized by Congress with a wholly new—and higher—rebate calculation based on foreign drug prices. That rebate scheme bears no relation to domestic inflation—the focal point of the Part B inflation rebate under the Inflation Reduction Act. It is, instead, crafted out of whole cloth.

124. In further violation of the limited “waiver” authority, GLOBE establishes a new enforcement regime, complete with civil penalties. *See* 91 Fed. Reg. at 63,116. GLOBE purports to authorize CMS to impose, among other sanctions, civil money penalties equal to 125% of the GLOBE rebate amount by importing the regulations governing the IRA’s rebate penalties and replacing any references to the inflation-rebate amount with references to the GLOBE rebate amount. *Id.*; *see* 42 C.F.R. § 427.600. No language from any statute authorizes those penalties: The IRA’s inflation-rebate penalties apply only when a manufacturer fails to comply “with the requirements under paragraph (1)(B)” of the statute, not with the requirements of GLOBE. 42

U.S.C. § 1395w-3a(i)(7). And while CMS further relies on the general “civil monetary penalty authority” under Section 1128A of the CMS statute, 91 Fed. Reg. at 63,116, that provision authorizes penalties only for the submission of “false record[s]” or “false and fraudulent claim[s].” 42 U.S.C. § 1320a-7a(a)(8). Moreover, that provision authorizes penalties of only \$100,000 per false statement—not 125% of the GLOBE amount. *Id.* There is no existing statutory authority to penalize any manufacturer who fails to comply with GLOBE—and the novel imposition of those penalties far exceeds any “waiver” authority.

125. Moreover, GLOBE does not even purport to “relax existing legal requirements” of the IRA. *Biden*, 600 U.S. at 498. As noted, if the inflation rebate is higher than the GLOBE-required rebate, then the inflation rebate will remain operative. 91 Fed. Reg. at 63,028. Thus, the rebate amount can never fall below what the IRA rebate program would have required prior to GLOBE’s comprehensive reconfiguration of it.

126. The Supreme Court’s decision in *Biden v. Nebraska* squarely forecloses CMS’s understanding of its Section 1115A waiver authority. There, the Court evaluated whether the Higher Education Relief Opportunities for Students Act of 2003 authorized the Secretary of Education to establish a student loan forgiveness program. *See id.* at 483. The Secretary invoked as the basis for his authority a provision of that Act which permitted him to “waive or modify” provisions “applicable to the student financial assistance programs under title IV of the [Education Act]” under certain circumstances. *Id.* at 494 (quoting 20 U.S.C. §1098bb(a)(1)). As relevant here, the Court rejected the Secretary’s argument that his authority to “waive” legal provisions enabled him to craft new provisions: “The addition of . . . new and substantially different provisions cannot be said to be a ‘waiver’ of the old in any meaningful sense.” *Id.* at 498. The Secretary’s “comprehensive debt cancellation plan” had not only “nullif[ied] existing provisions,

but augment[ed] and expand[ed] them dramatically.” *Id.* at 499. Such an “exhaustive rewriting of the statute” could not “fairly be called a waiver” (or even a modification). *Id.* at 499-500.

127. The Supreme Court’s reasoning is on all fours here. “What [GLOBE] has actually done is draft a new section of the [IRA] from scratch by ‘waiving’ provisions root and branch and then filling the empty space with radically new text.” *Id.* at 498. Section 1115A’s waiver provision does not grant that sweeping authority to remake the Medicare statute. CMS does not actually deny that GLOBE’s “rebate obligation is a novel addition rather than a relaxation of existing requirements”—it merely states that the statute allows it to waive requirements “to the extent necessary” and that its purported waivers are necessary for GLOBE to “function[] as designed.” 91 Fed. Reg. at 63,078. But the statutory phrase “to the extent necessary” is not a license to expand a limited authority to “waive” into the power to rewrite a statute however the agency deems “necessary.”

128. CMS further asserts that *Biden v. Nebraska*’s analysis of the statutory term “waive” does not apply here because Section 1115A “expressly authorizes” GLOBE. 91 Fed. Reg. at 63,078. But in *Nebraska*, the Supreme Court rejected the government’s similar claim that its student-loan-forgiveness program “operate[d] squarely within . . . express statutory parameters.” *Id.* at 63,078-79. Thus, under *Nebraska*, the plain meaning of statutory terms like “waive” prevails over an agency’s say-so.

5. The major questions doctrine confirms that GLOBE exceeds CMS’s authority under Section 1115A.

129. At the very least, CMS lacks the “clear congressional authorization” required to “restructure the American [drug] market” through GLOBE. *West Virginia v. EPA*, 597 U.S. 697, 724 (2022). The Supreme Court has “long expressed ‘reluctan[ce] to read into ambiguous statutory text’ extraordinary delegations of Congress’s powers.” *Learning Res., Inc.* U.S. at 242 (opinion

of Roberts, C.J.) (citation omitted). For instance, it has “declined to read authorization to ‘waive or modify’ statutory or regulatory provisions applicable to financial assistance programs as a delegation of power to cancel \$430 billion in student loan debt,” *id.* (citing *Biden v. Nebraska*, 600 U.S. 477 (2023)); “declined to read authorization to determine the ‘best system of emission reduction’ as a delegation of power to force a nationwide transition away from the use of coal,” *id.* at 242 (citing *West Virginia*, 597 U.S. at 732); and “declined to read authorization to ensure ‘safe and healthful working conditions’ as a delegation of power to impose a vaccine mandate on 84 million Americans,” *id.* (citing *NFIB v. OSHA*, 595 U.S. 109 (2022)). The lesson of those “‘major questions’ cases” is that the government may not “claim[] broad, expansive power on an uncertain statutory basis.” *Id.*

130. This is a major questions case. To start, whether the government has the authority to impose unilateral price controls on prescription drugs is a question of extreme “economic and political significance.” *Learning Res.*, 607 U.S. at 246 (opinion of Roberts, C.J.) (citation omitted). Even minor price controls on prescription drugs will influence multi-billion-dollar research and development decisions.⁶⁵ And the controls here are far from minor—as CMS acknowledges, GLOBE will decrease Medicare Part B spending by \$440 million over the next seven years. 91 Fed. Reg. at 63,089 tbl.13.

131. That figure, moreover, massively understates the economic impact of CMS’s claimed authority. In its proposed rule, CMS estimated that GLOBE would reduce Medicare Part B expenditures by roughly \$12 billion. 90 Fed. Reg. at 60,246. The agency arrived at a reduced figure in the final rule primarily by removing from its calculations the companies that CMS “intends to” exempt from GLOBE due to their participation in the GENEROUS model. 91 Fed.

⁶⁵ Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (Apr. 2021), <https://www.cbo.gov/publication/57126>.

Reg. at 63,070. But those exemptions are time-limited to GENEROUS’s five-year period ending in 2031—and they are not codified in the rule itself, such that CMS could seek to revoke them. *See id.* (“[W]e . . . decline to codify manufacturer exemptions from the GLOBE Model.”). CMS cannot escape the major questions doctrine by artificially deflating GLOBE’s initial price tag through ad hoc, discretionary exemptions. After all, the doctrine looks to the full implications of “the Government’s claimed authority,” not how the agency promises to use such authority for the time being. *West Virginia*, 597 U.S. at 728-29. Under CMS’s interpretation of Section 1115A, there is no meaningful limit on the economic magnitude of rebate obligations the agency could impose.

132. Nor is there any dispute that drug price controls have significant political salience. In this year’s State of the Union Address, President Trump touted that he “took prescription drugs, a very big part of health care, from the highest price in the entire world to the lowest.”⁶⁶ And he has reportedly encouraged members of his party to make drug prices a major part of their campaign strategy in the 2026 midterm elections.⁶⁷

133. Additionally, Congress has “considered and rejected” GLOBE’s foreign-pricing policy “multiple times.” *West Virginia*, 597 U.S. at 731; *see* Medicare Drug Price Negotiation Act, H.R. 4138, 115th Cong. (2017); Medicare Drug Price Negotiation Act, S. 2011, 115th Cong. (2017); Medicare Negotiation and Competitive Licensing Act of 2018, H.R. 6505, 115th Cong. (2018); Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019). After many years of debate over the best way to lower prescription drug prices, Congress enacted the IRA,

⁶⁶ Rebecca Robbins, *Trump Promised the ‘World’s Lowest’ Drug Prices. We Checked the Numbers*, N.Y. Times (Mar. 18, 2026), <https://www.nytimes.com/2026/03/18/world/europe/trumprx-drug-prices-really-cheapest-world-comparison.html>.

⁶⁷ Adam Cancryn, *Trump Wants To Focus on Health Care in the Midterms, Creating Headaches for the GOP*, CNN (Feb. 19, 2026), <https://www.cnn.com/2026/02/19/politics/midterm-elections-trump-health-care>.

which decisively rejected foreign-reference pricing and adopted the inflation-rebate and “negotiation” programs. *See* 42 U.S.C. § 1395w-3a(i)(3); *id.* § 1320f-3. CMS cannot unilaterally reopen that debate at this juncture: To the extent that MFN pricing in Medicare is constitutionally permissible at all, the choice to adopt that pricing scheme must come from Congress and not from the Executive Branch. CMS responds that GLOBE does not “implement the international reference pricing provisions that Congress considered and did not adopt in the context of the Negotiation Program.” 91 Fed. Reg. at 62,953. But the fact that GLOBE does not replicate the precise provisions that Congress declined to enact does not diminish the import of Congress’s rejection of the overall policy of foreign-reference pricing.

134. GLOBE is also an assertion of “‘unheralded’ regulatory power” that admits of no limiting principle. *West Virginia*, 597 U.S. at 723. CMS’s asserted use of the model authority is “unheralded” because—except for the invalidated 2020 IFR—the agency has never sought to use that authority to control drug prices directly. Indeed, CMS itself admits that GLOBE “represents a novel application of CMS Innovation Center authority under section 1115A of the Act.” 91 Fed. Reg. at 62,946; *see id.* at 63,079 (“We acknowledge that the GLOBE Model’s rebate structure represents a novel approach to drug pricing within the Medicare program.”). CMS asserts that GLOBE “is consistent with the manner in which [it] has exercised its section 1115A authority” in the past because it “test[s] an alternative approach to how Medicare pays for items and services.” *Id.* at 62,951. But again, GLOBE does not change *how* Medicare pays for drugs; it merely changes *how much* drug manufacturers must pay back to CMS.

135. Tellingly, GLOBE does not resemble any of CMS’s cited examples. For instance, by CMS’s own description, the Enhancing Oncology Model tested a shift from “fee-for-service reimbursement” for cancer care to “episode-based payment.” *Id.* By contrast, GLOBE alters only

the amount, not the structure, of payments. That is why, as CMS stated in announcing the final rule, GLOBE represents a “groundbreaking” use of Section 1115A.⁶⁸

136. For similar reasons, GLOBE would represent a “transformative expansion in [CMMI’s] regulatory authority,” *West Virginia*, 597 U.S. at 724 (citation omitted), turning it from a small sub-agency dedicated to scientific research to a powerful economic regulatory body on the level of the United Kingdom’s NHS. And if CMMI can impose price controls with reference to a basket of foreign prices—which are referenced nowhere in the statutory text—then there is no limit to what it could do to advance a future Administration’s healthcare priorities, regardless of whether those priorities are shared by the Legislative Branch.

137. CMS claims that GLOBE does not present a major question because it is “time-limited” to seven years and applies to only a subset of the Medicare population in certain geographic areas and a subset of Medicare Part B drugs. 91 Fed. Reg. at 62,952. None of those features take GLOBE outside the scope of the major questions doctrine.

138. To start, the Supreme Court has never suggested that agency action must last for an indefinite period of time to trigger the major questions doctrine. To the contrary, the Court has applied the doctrine to many policies that, like GLOBE, are of limited duration. The OSHA vaccine mandate was set to last for only six months. *See* 86 Fed. Reg. 61,402, 61,461(2021). The federal eviction moratorium was designed to expire after only four months. *See Alabama Ass’n of Realtors v. HHS*, 594 U.S. 758, 760 (2021); 85 Fed. Reg. 55, 292 (2020). And the student-loan-forgiveness plan called for a one-time cancellation of debt, not a permanent change to the student-borrower program. *Nebraska*, 600 U.S. at 488. These decisions make sense: The doctrine focuses

⁶⁸ CMS, Press Release, *CMS Finalizes New Mandatory Drug Payment Model to Deliver Lower Drug Prices for Beneficiaries in Original Medicare Part B* (Sept. 30, 2026), <https://www.cms.gov/newsroom/press-releases/cms-finalizes-new-mandatory-drug-payment-model-deliver-lower-drug-prices-beneficiaries-original>.

on “the Government’s claimed authority,” which is not tied to the term of a particular rule or policy. *West Virginia*, 597 U.S. at 728-29. And if CMS’s claimed authority is upheld by the courts, then the agency could attempt to expand GLOBE, including by seeking to revoke the exemptions it declined to codify and by exercising its authority to “expand (including implementation on a nationwide basis) the duration and the scope of a model.” 42 U.S.C. § 1315a(c); *see* 91 Fed. Reg. 49,570, 50,128 (CMS’s assertion that CMMI models need not have a “fixed end date”). The agency will have license to finalize the GUARD rule, which imports the same foreign-reference pricing into Medicare Part D. In short, upholding CMS’s authority would give the agency free rein to use Section 1115A to impose price controls throughout the Medicare program.

139. Likewise, GLOBE is not insulated from major questions treatment simply because it does not apply to *all* Medicare Part B beneficiaries or *all* Medicare Part B drugs. The OSHA vaccine mandate applied only to employers with at least 100 employees. 595 U.S. at 113. The student-loan-forgiveness plan applied to only a subset of student borrowers with incomes below a threshold with certain kinds of eligible loans. *Nebraska*, 600 U.S. at 488. Nonetheless, the Supreme Court subjected both policies to major questions scrutiny. And under CMS’s interpretation of the statute, nothing would stop the agency from imposing the same requirements with respect to *all* Medicare Part B enrollees and drugs.

140. Finally, CMS claims the doctrine is inapplicable because it “is not claiming power from vague or ancillary text.” 91 Fed. Reg. at 62,951. But “ancillary” is precisely how four Justices of the Supreme Court described Section 1115A. *NFIB v. Sebelius*, 567 U.S. 519, 704-05 (2012) (Scalia, Kennedy, Thomas, & Alito, JJ., dissenting).

141. Accordingly, even if Section 1115A could conceivably “be[] read to delegate the asserted power”—and it cannot—CMS lacks the necessary clear statutory authority to implement GLOBE. *Learning Res.*, 607 U.S. at 243 (opinion of Roberts, C.J.). As a matter of “common sense,” Congress could not possibly have intended to give CMS the authority to eviscerate market-based drug pricing with “vague language” like “test,” “model,” and “waive.” *Id.*

6. GLOBE violates Section 1182 of the Social Security Act.

142. GLOBE not only exceeds CMS’s statutory authority under Section 1115A, it also contravenes Section 1182(e) of the Social Security Act. That provision prohibits the Secretary of HHS from using QALYs or “similar measure[s] that discount[] the value of a life because of an individual’s disability” “as a threshold to determine coverage, reimbursement, or incentive programs” under Medicare. 42 U.S.C. § 1320e-1(e). CMS has repeatedly acknowledged that it is prohibited from relying on QALYs as a threshold to determine coverage, reimbursement, or incentive programs under Medicare. *See, e.g.*, 89 Fed. Reg. 65,724, 65,744 (Aug. 12, 2024).

143. Congress made this choice because the use of QALYs inherently devalues the lives of patients with disabilities and chronic illnesses. Countries that use the QALY methodology to make reimbursement decisions do so because they have determined that declining to treat patients with a lower “quality” of life—which in their view includes people with a disability or a chronic illness—is an effective way of saving money. That methodology upends “the equality of moral worth that characterizes truly democratic societies.”⁶⁹

144. GLOBE violates this prohibition on the use of QALYs in Medicare reimbursement calculations. Fifteen of the nineteen countries included in GLOBE’s MFN formula use QALYs,

⁶⁹ *See Andrade, supra.*

either formally or informally, to set reimbursement rates for pharmaceuticals.⁷⁰ In other words, they determine whether and on what terms a drug may be marketed based on how many QALYs the drug is likely to add to the overall population. Under that methodology, drugs that target conditions experienced by younger, otherwise-healthy people will be prioritized over drugs that target conditions that are more likely to be experienced by the elderly, disabled, or chronically ill.

145. GLOBE thus imports the use of QALYs from those countries through its rebate calculation formula—in contravention of 42 U.S.C. § 1320e-1(e)’s command that the United States will not subject our Nation’s seniors to QALY-based decisionmaking. And while CMS insists that GLOBE “does not establish a QALY based reimbursement formula,” but simply imports prices from countries that use the metric as an “input into an alternative rebate amount calculation,” 91 Fed. Reg. at 63,007, that argument does not withstand scrutiny: CMS, after all, “ha[s] no authority ‘to do indirectly what it could not do directly.’” *Pub. Utils. Comm’n of State of Cal. v. FERC*, 143 F.3d 610, 616 (D.C. Cir. 1998) (quoting *Altamont Gas Transmission Co. v. FERC*, 92 F.3d 1239, 1248 (D.C. Cir. 1996)).

146. Importantly, the remainder of GLOBE is not severable from the provisions that import the use of QALYs. A court will “sever . . . a portion of an administrative regulation only when [it] can say without any substantial doubt that the agency would have adopted the severed portion on its own,” such as when the provisions ‘operate[] entirely independently of one another.’” *Interstate Nat. Gas Ass’n of Am. v. Pipeline & Hazardous Materials Safety Admin.*, 114 F.4th 744, 753 (D.C. Cir. 2024) (alteration in original) (quoting *Am. Petrol. Inst. v. EPA*, 862 F.3d 50, 71 (D.C. Cir. 2017)). Here, GLOBE’s entire rebate regime depends on its rebate calculation formula,

⁷⁰ Julia Wahl et al., *QALY Use in Selected OECD Countries*, Copenhagen Economics, 3 & tbl.1, <https://copenhageneconomics.com/wp-content/uploads/2026/02/QALY-use-in-selected-OECD-countries-February-2026-1.pdf>.

which impermissibly uses foreign reference prices that hinge on QALYs. *See* 91 Fed. Reg. at 63,106, 63,110-11. Thus, no provision of GLOBE could “operate[] entirely independently” of the provisions setting forth that formula—indeed GLOBE could not function without a rebate calculation method. *Interstate Nat. Gas Ass’n of Am.*, 114 F.4th at 753 (citation omitted).

7. *GLOBE violates federal appropriations law.*

147. By augmenting CMS’s funds with its unauthorized rebates, GLOBE independently violates fundamental principles of federal appropriations law. At the heart of federal appropriations law is the Constitution’s Appropriations Clause, which provides that “No Money shall be drawn from the Treasury, but in Consequence of Appropriations made by Law.” U.S. Const. art. I, § 9, cl. 7. “Textually, the command is unmistakable—‘no money can be paid out of the Treasury unless it has been appropriated by an act of Congress.’” *CFPB v. Cmty. Fin. Servs. Ass’n of Am., Ltd.*, 601 U.S. 416, 425 (2024) (citation omitted).

148. Congress has implemented the Appropriations Clause with several related statutes that prohibit the government from using funds except those that Congress has specifically authorized through an appropriations law. First, a “person having custody or possession of public money, including a disbursing official having public money not for current expenditure, shall deposit the money without delay in the Treasury.” 31 U.S.C. § 3302(c)(1). Second, “[a]ppropriations shall be applied only to the objects for which the appropriations were made except as otherwise provided by law.” 31 U.S.C. § 3301(a). Third, officers and employees of the United States may not supplement their salary “from any source other than the Government of the United States.” 18 U.S.C. § 209. Taken together, these commands mean that “an agency may not augment its appropriations from outside sources without specific statutory authority.” GAO, 2 Principles of Federal Appropriations Law, at 6-162 (3d ed. Mar. 10, 2016).

149. GLOBE violates that fundamental anti-augmentation rule. It increases HHS's available funds by directing manufacturers to deposit rebates in CMS's Supplementary Medical Insurance (SMI) Trust Fund. 91 Fed. Reg. at 62,953. CMS claims that GLOBE does not violate anti-augmentation principles because the IRA directs that rebate payments be deposited in the SMI Trust Fund. *Id.* at 62,953-54. But the IRA authorizes only *inflation* rebate payments to be deposited in that account; it is not a license for CMS to demand and retain different rebate payments that Congress has not provided for. Because no Act of Congress authorizes CMS to collect or to fund its activities with GLOBE rebates—for purposes of administering the SMI Trust Fund or otherwise—depositing them in the SMI Trust Fund is an unauthorized augmentation of appropriations. If CMS wants more money for its activities, it must look to Congress, not to CMMI.

8. *CMS's unbounded assertion of authority would violate the Presentment Clause.*

150. If Section 1115A were construed to permit GLOBE, the statute would violate the Presentment Clause, which requires that “every Bill which shall have passed the House of Representatives and the Senate, shall, before it become a Law, be presented to the President of the United States.” U.S. Const. art. I, § 7, cl. 2. “By providing that no law could take effect without the concurrence of the prescribed majority of the Members of both Houses, the Framers reemphasized their belief . . . that legislation should not be enacted unless it has been carefully and fully considered by the Nation's elected officials.” *INS v. Chadha*, 462 U.S. 919, 948-49 (1983).

151. “Amendment and repeal of statutes, no less than enactment, must conform with” the Constitution's bicameralism and presentment requirements. *Chadha*, 462 U.S. at 954. “There is no provision in the Constitution that authorizes the President to enact, to amend, or to repeal statutes.” *Clinton v. City of New York*, 524 U.S. 417, 438 (1998). The Executive Branch thus may

not “effect the repeal of laws, for [its] own policy reasons, without observing the procedures set out in Article I, § 7.” *Id.* at 445.

152. In *Clinton*, the Supreme Court explained that these principles forbid the Executive Branch from exercising “discretionary authority” to “reject[] the policy judgment made by Congress and rely[] on [its] own policy judgment.” 524 U.S. at 441, 444. And although Congress might desire to transfer its power to alter statutes to the Executive, “Congress cannot alter the procedures set out in Article I, § 7 without violating the Constitution.” *Id.* at 446.

153. If Section 1115A authorized CMS to mandate participation in GLOBE, the statute would violate the Presentment Clause. CMS claims that GLOBE does not present any concerns under the Presentment Clause because the agency “is not enacting new legislation.” 91 Fed. Reg. at 62,948. But GLOBE would effectively rewrite and replace the Medicare statute in multiple respects. For dozens of manufacturers, GLOBE would replace Congress’s rebate calculation with a completely different formula of CMS’s own making. And GLOBE would impose civil monetary penalties that Congress has never authorized. The altered “version” of the Medicare statute that would emerge would not be “the product of the ‘finely wrought’ procedure that the Framers designed.” *Clinton*, 524 U.S. at 440.

154.

9. *CMS’s unbounded assertion of authority would violate the nondelegation doctrine.*

155. Finally, if Section 1115A authorized GLOBE, then the statute would violate the nondelegation doctrine, which “bars Congress from transferring its legislative power to another branch of Government.” *Gundy v. United States*, 588 U.S. 128, 132 (2019) (plurality opinion). The Constitution provides that “[a]ll legislative powers herein granted shall be vested in a

Congress of the United States.” U.S. Const. art. I, § 1. “Th[e] text permits no delegation of those powers.” *Whitman v. Am. Trucking Ass’n*s, 531 U.S. 457, 472 (2001).

156. Under the Supreme Court’s nondelegation-doctrine case law, a statutory delegation is permissible only if Congress has made clear “the general policy” that the Executive Branch must pursue and delineated the “boundaries of this delegated authority.” *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946). “[T]he degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred.” *Am. Trucking*, 531 U.S. at 475.

157. If Section 1115A authorized CMS to mandate participation in GLOBE, the statute would violate the nondelegation doctrine. By using Section 1115A to unilaterally overhaul the Medicare program, CMS has defied the policies that Congress set in enacting the relevant statutes. CMS asserts that there is no nondelegation problem here because Section 1115A contains a “detailed, purpose-specific statutory framework” setting out “a robust intelligible principle” to limit the agency’s discretion. 91 Fed. Reg. at 62,948-49. But if interpreted to permit GLOBE, those statutory constraints would provide an “intelligible principle” in name only. *Am. Trucking*, 531 U.S. at 474. CMS claims the authority to reinterpret statutory terms like “test” and “payment model” to undo Congress’s choices in favor of its own policy preferences—and Congress has not delineated the boundaries of delegated authority as the Constitution requires if the agency is free to readjust those boundaries at will.

E. GLOBE Risks Serious Harm to Plaintiff, Patients, and Our Nation’s Leadership in Pharmaceutical Innovation.

158. If GLOBE goes into effect, it will inflict severe and irreparable harm on Plaintiff. The damage will not be borne by manufacturers alone: Patients will suffer too, as will the United States’ leadership in pharmaceutical innovation and discovery.

159. Importing foreign price controls will fundamentally alter the United States' market-based system for pharmaceutical development, inflicting devastating economic losses on manufacturers. As already explained, it takes over a decade to bring a new drug to market, and companies incur \$3 billion in costs to do so. Pharmaceutical companies thus take on significant risks to bring these new medicines to market.

160. A company's capacity to make those investments in R&D often bears a direct link to past revenue.⁷¹ Indeed, between 2022 and 2024, pharmaceutical manufacturers invested over 33% of their sales back into R&D activities.⁷²

161. Artificially reducing drug prices by importing foreign price controls will thus inflict disproportionate harm on manufacturers—and their ability to invest in life-saving drugs going forward. Mandating MFN policies could threaten over \$500 billion in capital investments.⁷³ And 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. Because VC funding can easily be redirected to other sectors, reducing the ability for VC capital to achieve a return on investment in new drugs will reduce availability of capital in the sector—making it difficult, if not impossible, for manufacturers to raise sufficient funding.⁷⁴

162. PhRMA members, in particular, will suffer acute and irreparable harm if GLOBE goes into effect. Because Medicare is such a large share of the United States market, manufacturers

⁷¹ See Destrina Grace Simanjuntak and Raymond R. Tjandrawinata, *Impact of Profitability, R&D Intensity, and Cash Flow on R&D Expenditure in Pharmaceutical Companies* (working paper, Social Science Research Network, April 29, 2011), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1824267.

⁷² Pham, N.D., et al., *Imbalance of Financial Risks and Economic Rewards in the U.S. Healthcare Supply Chain*, Pacific Research Inst. 4 (Jan. 2026), https://www.pacificresearch.org/wp-content/uploads/2026/01/CMEI_HCSupplyChainFin_F_web.pdf.

⁷³ Pharmaceutical Research and Manufacturers of America, Comment on Proposed Global Benchmark for Efficient Drug Pricing (GLOBE) Model, CMS-2025-1889-0105, 4 (Feb. 23, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0105>.

⁷⁴ See *id.* at 23.

will not be able to walk away from Medicare Part B simply because of GLOBE’s price controls. They are therefore likely to lose substantial amounts of revenue; forgo unquantifiable investment and research opportunities; and be forced to alter their business arrangements, including through potential layoffs. The considerable impact on revenue will also force PhRMA members to reallocate R&D funding—imperiling their ability to bring new, life-saving drugs to market.

163. The resulting harm to patients will be severe. As detailed above, price controls in foreign OECD countries have prevented patients from accessing critical new drugs when they need them. And studies have 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.⁷⁵

164. Academic studies, moreover, consistently demonstrate that a reduction in current drug prices and resulting revenues leads to a decrease in future research and the number of new drug discoveries. One study, for instance, found that a price cut of 40% to 45% would reduce the number of new development projects by 50% to 60%.⁷⁶ Another study found that a 1% reduction in pharmaceutical industry revenue leads on average to a corresponding 1.54% decrease in R&D investment.⁷⁷ And numerous other studies have reached similar conclusions.⁷⁸

165. The threat to oncology medicines, and the cancer patients that rely on them, is particularly striking. Estimates show that implementing mandatory MFN pricing would lead to a

⁷⁵ See Philipson T., et al., *Policy Brief: The Impact on Patient Health of Most-Favored-Nation Pricing of Already Marketed Drugs*, Univ. Chicago, 2 (Sep. 2025), <https://bpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2025/09/MFN-Impact-on-Patient-Health-Final-Sep-29.pdf>.

⁷⁶ Thomas A. Abbott & John A. Vernon, *The Cost of U.S. Pharmaceutical Price Reductions: A Financial Simulation Model of R&D Decisions*, NBER Working Paper No. 11114, at 24 (Feb. 2005), <https://www.nber.org/papers/w11114>.

⁷⁷ See Tomas J. Philipson & Troy Durie, *Issue Brief: The Impact of HR 5376 on Biopharmaceutical Innovation and Patient Health*, Univ. Chicago (Nov. 9, 2021) <https://cpb-us-w2.wpmucdn.com/voices.uchicago.edu/dist/d/3128/files/2021/08/Issue-Brief-Drug-Pricing-in-HR-5376-11.30.pdf>

⁷⁸ See Information Technology & Innovation Foundation, Comments in the Matter of: Proposed Global Benchmark for Efficient Drug Pricing (“GLOBE”) Model, CMS-5545-P, 6 (Feb. 23, 2026) (collecting academic studies).

50% to 84% decline in new cancer drug launches.⁷⁹ That decline would impact an estimated 2.4 million people in the United States, even just looking exclusively at the impact of MFN pricing on Medicare.⁸⁰ Other studies have similarly found that even a 10% decrease in cancer drug prices would likely cause a 5.3% decline in chemotherapy regimens for treating a cancer site.⁸¹ And oncology is just one example where rapid development and commercialization of new pharmaceutical products—including specialty medicines and biologics—is vital to saving lives.

166. The importation of QALY measures—which discriminate against individuals with chronic conditions, disabilities, and rare diseases, and which all 19 GLOBE reference countries use—will also directly harm patients. As explained above, QALY measures not only devalue the lives of those individuals but also restrict patient access to vital treatments.

167. Finally, GLOBE poses a serious risk to the United States’ global leadership in pharmaceutical innovation. The United States is home to 70% of the world’s mature, late-stage biotech R&D activity.⁸² And as of 2024, it maintained the largest share of global drugs in development.⁸³

168. But China is steadily advancing. In 2024, China had already captured a 20% share of drugs in development worldwide, and its compound annual growth rate for drugs in its pipeline

⁷⁹ See Bowen, H.P., et al., *The Impact of MFN on Oncology and Hematology Treatments*, MedRxiv, 6 (Feb. 20, 2026), <https://www.medrxiv.org/content/10.64898/2026.02.19.26346624v1.full.pdf>.

⁸⁰ *Id.* at 3.

⁸¹ Frank R. Lichtenberg, *Importation and Innovation*, NBER Working Paper No. 12539, 2, 11, 15 (Sep. 2006), <https://www.nber.org/papers/w12539>.

⁸² See Pharmaceutical Research and Manufacturers of America, Comment on Proposed Global Benchmark for Efficient Drug Pricing (GLOBE) Model, CMS-2025-1889-0105, 26 & n.147 (Feb. 23, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0105>.

⁸³ See Global Data, *China’s Evolution in Global Drug Development and Clinical Trials: Strategic Intelligence* (Oct. 6, 2025) <https://www.globaldata.com/store/report/china-drug-development-clinical-trials-theme-analysis/>.

between 2015 and 2024 was 22%.⁸⁴ China has also seen significant growth in clinical trial starts.⁸⁵ The United States is thus at a crucial juncture in global competition for pharmaceutical leadership.

169. GLOBE would stifle investment in American pharmaceutical innovation at the very worst moment—creating the opportunity for China to overtake the United States. Artificially suppressed revenues and uncertainty in the market caused by GLOBE will dry up investments available for R&D in the United States. And importing foreign price controls will devastate the United States’ 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. Studies have estimated that MFN pricing will reduce the number of medicines developed by these firms by up to 90%—61 fewer medicines over 10 years.⁸⁶ The fallout of such a catastrophic decline in drug development by these firms will be felt most acutely by patients who already face serious barriers to accessing effective treatment—including people with rare diseases, cancer, and neurological disorders, which small-and-midsize companies often seek to combat.⁸⁷

170. The United States’ globally dominant pharmaceutical industry is also one of our nation’s biggest employers. It supports nearly five million jobs across the U.S. economy and generates \$1.65 trillion in direct and indirect economic output annually.⁸⁸ Implementing MFN

⁸⁴ *See id.*

⁸⁵ *See* Pharmaceutical Research and Manufacturers of America, Comment on Proposed Global Benchmark for Efficient Drug Pricing (GLOBE) Model, CMS-2025-1889-0105, 26 & n.140 (Feb. 23, 2026), <https://www.regulations.gov/comment/CMS-2025-1889-0105>.

⁸⁶ *See* Vital Transformation, *H.R. 3 and Reference Pricing. Total Market Impact*, <https://vitaltransformation.com/2021/03/5984/>.

⁸⁷ *See id.*

⁸⁸ *See* PhRMA, Teconomy Partners LLC, *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates* 2, 20 (May 2024), <https://cdn.aglty.io/phrma/policy-issues/research-ecosystem/economy/The-Econ-Impact-of-US-Biopharma-Industry-2024-Report.pdf>.

pricing across beneficiaries in Medicare Parts B and D would, in turn, eliminate an estimated 337,000 biopharma industry jobs and nearly 1.5 million jobs in total across U.S. businesses.⁸⁹

171. CMS barely disputes that GLOBE will reduce biopharmaceutical innovation and diminish patient access to lifesaving drugs. Instead, CMS asserts that GLOBE will not “materially” reduce innovation or diminish access and claims that the *degree* of harm will not be as significant as GLOBE’s critics predict. 91 Fed. Reg. at 62,954. For instance, it emphasizes that GLOBE “reaches only drugs exceeding \$100 million in [Original Medicare] Part B allowed charges over a 12-month period—a threshold reflecting substantial market penetration.” *Id.* But that analysis entirely ignores the downstream effects on *future* lifesaving medications, which may never come to market if companies cannot benefit from the United States’ predictable market-based environment. Similarly, CMS insists that commentators overstate GLOBE’s potential harm to innovation because their “analyses . . . may not fully account for the range of ways in which manufacturers may adapt to changing market conditions . . . through partnerships, portfolio management, operational efficiencies, and other strategies to sustain R&D activities.” *Id.* But in a field of research where every marginal dollar is essential, CMS’s assurances that researchers will learn to make their limited resources go further is cold comfort.

172. GLOBE thus poses grave threats to the United States’ longstanding supremacy in pharmaceutical innovation—and would inflict corresponding harms on the countless American patients and workers who depend on that leadership.

⁸⁹ See Vital Transformation, *Most Favored Nation (MFN) Reference Pricing in Medicare, Impact on Jobs, Innovation, and States Budgets*, 9 (Sep. 30, 2025), https://vitaltransformation.com/wp-content/uploads/2025/09/MFN-Building-Blocks-Public-v6_9.29.25.pdf.

CAUSES OF ACTION

COUNT I:

GLOBE Is Contrary To Law

(Administrative Procedure Act—Against All Defendants)

173. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs as if fully set forth herein.

174. The Administrative Procedure Act provides that a reviewing court may “hold unlawful and set aside agency action” that is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right,” as well as agency action that is “not in accordance with law.” 5 U.S.C. § 706(2)(A), (C).

175. GLOBE exceeds CMS’s statutory authority under Section 1115A for multiple independent reasons. It does not “test” anything about “program expenditures.” It does not qualify as an “innovative payment [or] service delivery model[.]” It does not “address” the “deficits of care” of a “defined population.” And GLOBE does not “waive” provisions of the Medicare statute, but instead entirely rewrites them.

176. The major questions doctrine resolves any doubt that GLOBE is not authorized by Section 1115A. That doctrine requires CMS to point to clear congressional authorization for any policy of vast economic and political significance. GLOBE is unquestionably economically and politically significant—it wades into a set of drug-pricing questions that Congress frequently debates, and it has \$440 million in economic impact. Yet Congress has not given CMS clear authority to effectuate MFN-style drug pricing in the Medicare program.

177. GLOBE also violates other statutory provisions. Congress has forbidden CMS from using QALYs to determine Medicare payments, but GLOBE effectively imports QALY-based pricing methodologies into the United States. And Congress has forbidden CMS from

augmenting its own appropriations, but GLOBE enriches CMS without proper statutory authorization.

178. Because GLOBE exceeds CMS’s statutory authority and is contrary to law, the proper remedy is to set GLOBE aside in full. *See, e.g., Bridgeport Hosp. v. Becerra*, 108 F.4th 882, 884, 890 (D.C. Cir. 2024).

COUNT II:
GLOBE Violates the Constitution
(Administrative Procedure Act—Against All Defendants)

179. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs as if fully set forth herein.

180. The Administrative Procedure Act provides that a reviewing court may “hold unlawful and set aside agency action” that is “contrary to constitutional right, power, privilege, or immunity.” 5 U.S.C. § 706(2)(B).

181. For the reason described above, interpreting Section 1115A to permit GLOBE would render the statute unconstitutional under both the Presentment Clause and the nondelegation doctrine.

182. At a minimum, the Court should avoid an interpretation of Section 1115A that “raises serious constitutional doubts.” *Clark v. Martinez*, 543 U.S. 371, 381 (2005).

183. Because GLOBE exceeds the constitutional bounds of CMS’s authority, the proper remedy is to set GLOBE aside in full.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court provide the following relief:

- A. Declare that the Rule is not in accordance with law, contrary to constitutional right, and in excess of statutory authority;
- B. Hold unlawful and set aside the Rule, *see* 5 U.S.C. § 706(2);
- C. Postpone the effective date of the Rule, *see* 5 U.S.C. § 705;
- D. Grant preliminary and permanent injunctive relief, including a temporary restraining order, preventing Defendants from implementing or enforcing the Rule; and
- E. Grant such other relief as the Court deems just and proper.

Dated: October 7, 2026

Respectfully submitted,

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