IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASSOCIATION OF COMMUNITY CANCER CENTERS, on behalf of itself and its members; GLOBAL COLON CANCER ASSOCIATION, on behalf of itself and its members; NATIONAL INFUSION CENTER ASSOCIATION, on behalf of itself and its members; and PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, on behalf of itself and its members,

Plaintiffs,

vs.

ALEX M. AZAR II, in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; SEEMA VERMA, in her official capacity of Administrator of the Centers for Medicare and Medicaid Services; CENTERS FOR MEDICARE AND MEDICAID SERVICES; BRAD SMITH, in his official capacity as the Director of the Center for Medicare and Medicaid Innovation; CENTER FOR MEDICARE AND MEDICAID INNOVATION,

Defendants.

CIV. NO. 1:20-cv-03531

ADMINISTRATIVE PROCEDURES ACT REVIEW OF AGENCY DECISION

COMPLAINT

Plaintiffs the Association of Community Cancer Centers; the Global Colon Cancer Association; the National Infusion Center Association; and the Pharmaceutical Research and Manufacturers of America allege as follows:

INTRODUCTION

1. For years, the Trump Administration urged major revisions to the Medicare Part B reimbursement system that would have substituted foreign price controls for the market-based approach adopted by Congress. The Administration recognized that such a fundamental change could be undertaken only by new legislation, and it urged Congress to act. But this summer, the President decided to proceed on his own initiative. "We've been waiting for Congress to take action for many decades to reduce drug prices," he announced. "I'm unwilling to wait any longer."[1] Lacking "any meaningful legislative support," the Trump Administration implemented administratively—without even going through standard notice-and-comment procedures—what it calls a "historic" and "transformative" effort to "completely restructure the prescription drug market, in terms of pricing and everything else."[2]

2. The Administration is only too right about that: Its new regulation will lead to delays and disruptions in drug access, jeopardizing critical care for millions of patients; by the Administration's own estimates, it will achieve much of its cost savings from "beneficiaries *not* accessing their drugs through the Medicare benefit, along with the associated lost utilization."[3] In

[1] *Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices* (July 24, 2020), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-signing-executive-orders-lowering-drug-prices (July 2020 White House Remarks).

[2] *Remarks by President Trump on Delivering Lower Prescription Drug Prices for All Americans* (Nov. 20, 2020), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-delivering-lower-prescription-drug-prices-americans (Nov. 2020 White House Remarks); July 2020 White House Remarks, *supra*, at note 1.

[3] Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180, 76,237 (Nov. 27, 2020) (MFN Rule) (emphasis added).

fact, the Administration has projected a 19% decline in utilization from lost access at non-340B providers.[4] The new regulation will also shortchange healthcare providers by reimbursing them a fraction of what they have already paid for critical medicines. And it will slash the funds available for pharmaceutical research and development, resulting in far fewer innovative medicines.

3. In this action, Plaintiffs challenge this overreach, which is unauthorized by statute and fundamentally inconsistent with our constitutional system of government. Under the Medicare statute—the approach duly approved by Congress and enacted into law—reimbursement for prescription drugs covered under the Part B program is based on average prices actually paid for drugs domestically. But the new regulation by the Centers for Medicare and Medicaid Services (CMS), known as the Most Favored Nation Rule (MFN Rule), implements a novel, mandatory, and nationwide payment scheme. Unlike a market-based approach, the Rule bases reimbursement on the lowest price available in any one of almost two dozen other countries—regardless of how those countries have chosen to structure their healthcare systems, the (dis)incentives they provide for pharmaceutical innovation, or the limitations they place on patients' ability to access these medications. By the President's own admission, the MFN Rule "will transform the way the U.S. government pays for drugs." Nov. 2020 White House Remarks, *supra*.

4. The Administration purports to derive the authority to supersede Congress's work from Section 1115A of the Social Security Act, as added by the Affordable Care Act. Yet Section 1115A does not grant CMS anything like the authority it would need to issue a regulation as far-ranging as the MFN Rule. Once described by four Supreme Court Justices as one of the more "minor" and "ancillary" provisions added by the Affordable Care Act, *NFIB v. Sebelius*, 567 U.S. 519, 704–05 (2012) (joint dissent), Section 1115A creates the "Center for Medicare and Medicaid

[4] MFN Rule, 85 Fed. Reg. at 76,237 tbl.11 (emphasis added).

Innovation" (CMMI), a sub-agency charged with "test[ing] innovative payment and service delivery models," 42 U.S.C. § 1315a(a)(1). By law, CMMI is authorized to test models that address "a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." *Id.* § 1315a(b)(2)(A). CMMI may waive parts of the Medicare statute and certain other parts of the Social Security Act during model tests, but only "as may be necessary" for the "sole[]" purpose of testing the model. *Id.* § 1315a(d)(1). If—and only if—an initial pilot test proves successful based on statutorily specified criteria and a certification from the CMS Chief Actuary, then CMMI may follow certain prescribed procedures to "expand . . . the duration and the scope of [the] model" to a second phase, including the option of "expand[ing] . . . the scope of a model" "on a nationwide basis." *Id.* § 1315a(c).

5. Or at least that is how the law is written—and how it was supposed to work. CMS is now attempting to use this modest "test" authority to "transform drug pricing forever." Nov. 2020 White House Remarks, *supra*. In doing so, CMS has far exceeded its statutory authority under Section 1115A. The MFN Rule is not an initial pilot "test." Nor does it "address a defined population" with identified "deficits in care"; indeed, it affirmatively harms patients in the short and long terms, securing its immediate cost savings in large part through the rationing of care. The Rule also skips the two-step statutory process of "test[ing]" and *then* "expan[sion]," 42 U.S.C. § 1315a(c), in favor of an immediate rollout in all 50 states and U.S. territories. With no control group, with "mandatory, nationwide participation," MFN Rule, 85 Fed. Reg. at 76,188, and with an immediate intended impact on the overwhelming majority of Medicare Part B drug spending, the MFN Rule lacks any pretense to being the sort of limited "test" of a Phase I "model" that Congress authorized under Section 1115A. The MFN Rule is instead among "the most far-reaching prescription drug reforms ever issued." July 2020 White House Remarks, *supra*.

6. CMS's interpretation of Section 1115A would arrogate virtually unlimited power to the agency to revise the Medicare program in its sole discretion. If CMS can launch comprehensive, nationwide models of its own design while waiving virtually all of Medicare Part B, nothing stops it from replacing any other part of Medicare—or even the whole thing. The damage to the separation of powers is manifest. CMS is claiming the authority to use the congressionally enacted Medicare statute as a suggestion, which it may keep, revise, or discard on its way to a healthcare system fully designed, implemented, and enforced in-house by the Executive Branch.

7. Compounding these harms, CMS has not permitted the public to have *any* real say in this "overhaul." CMS jettisoned the notice-and-comment process ordinarily required for rulemaking and instead issued the MFN Rule as an "interim final rule," effective immediately. Although the Administration has been considering proposals for basing Medicare reimbursements on international prices for almost three years, CMS attempts to justify this evasion of procedure by claiming that its hand was forced by the COVID-19 pandemic—an emergency so sudden that it apparently did not stir CMS to action at any point during the ten months since COVID-19 had been declared a public health emergency. By short-circuiting the notice-and-comment process, CMS deprived the public of the opportunity to point out the many shortcomings of the MFN Rule before it became effective, including how it will harm patients in both the short and long terms by reducing drug availability and development.

8. The MFN Rule is unlawful on several procedural and substantive grounds:

a. The MFN Rule does not qualify as a "test" of a "model" that addresses the "deficits in care" of "a defined population," but rather is, as the President acknowledged, a nationwide attempt to "completely restructure the prescription drug market, in terms of

pricing and everything else." July 2020 White House Remarks, *supra*. The Rule thus exceeds CMMI's limited regulatory authority under Section 1115A.

b. CMS nevertheless claims authority under Section 1115A to effectively repeal and replace key provisions of the Medicare statute, as well as other important provisions of the Social Security Act. But if Section 1115A in fact vested the agency with such expansive power, then Section 1115A would violate the Constitution's requirement of bicameralism and presentment.

c. If accepted, CMS's claim of authority under Section 1115A to overhaul the Medicare pricing system as the agency sees fit would also violate the Constitution's bar on the delegation of legislative power to the Executive Branch.

d. Congress committed the testing authority in Section 1115A to the *sole* discretion of the Secretary of Health and Human Services, but President Trump usurped that authority by commanding the Secretary to adopt the MFN Rule. The President may not ignore the statute and commandeer discretion that has been entrusted to another executive officer by directing that officer to reach a particular conclusion.

e. Because the MFN Rule was issued as an immediately effective interim final rule, without any notice or opportunity for public comment on a proposed rule, it violates the procedural safeguards of the Administrative Procedure Act (APA).

9. The MFN Rule will irreparably harm patients, care providers, physicians, pharmaceutical manufacturers, and the broader public interest in innovation and discovery in the pharmaceutical field. The Rule will significantly harm patients; shortchange physicians and other healthcare providers, resulting in reduced access to covered drugs; force pharmaceutical manufacturers to accept steep price reductions and potentially delay launches in certain markets,

further reducing patient access; and threaten long-term public health through cutbacks in research and development of new drugs.

10. For these reasons, and as explained below, Plaintiffs seek a preliminary and permanent injunction against the enforcement of the MFN Rule, including a temporary restraining order, a declaration that the MFN Rule is unconstitutional and invalid, and other appropriate relief.

JURISDICTION AND VENUE

11. This Court has jurisdiction pursuant to 28 U.S.C. § 1331 (action arising under the laws of the United States), *id.* § 1346 (United States as a defendant), and 5 U.S.C. §§ 701–06 (APA). An actual controversy exists between the parties within the meaning of 28 U.S.C. § 2201(a), and this Court may grant declaratory relief, injunctive relief, and other relief pursuant to 28 U.S.C. §§ 2201–02 and 5 U.S.C. §§ 705–06.

12. Although Congress has barred judicial review of some CMMI decisions, *see* 42 U.S.C. § 1315a(d)(2), such limitations do not apply to Plaintiffs' claims in this case, which involve constitutional challenges, the agency's authority to implement the MFN Rule, *see Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004) (such claims not barred by comparable provision), and the propriety of agency action without notice-and-comment rulemaking, *cf.* 42 U.S.C. § 1315a(d)(2) (not limiting such challenges).

13. Defendants' publication of the Rule in the Federal Register on November 27, 2020, constitutes a final agency action and is therefore judicially reviewable under the APA. 5 U.S.C. §§ 704, 706.

14. Venue is proper in this Court under 28 U.S.C. § 1391(e) because this action seeks relief against federal agencies and officials acting in their official capacities, some Defendants are

located in this district, and a substantial part of the events or omissions giving rise to the claim occurred in this district.

THE PARTIES

15. The Association of Community Cancer Centers (ACCC) is a non-profit corporation organized and existing under the laws of the State of California, with its headquarters located in Maryland. It is a community of more than 25,000 multidisciplinary practitioners and 2,100 cancer programs and practices nationwide, who together treat roughly 65% of the nation's cancer patients. Founded in 1974, ACCC brings together healthcare professionals across all disciplines in oncology to promote quality cancer care. Its members rely on ACCC for education and advocacy support in adapting and responding to complex changes and challenges in the delivery of quality cancer care. ACCC's members will be adversely affected by the MFN Rule because the Rule will reduce the rates at which many of the association's providers are reimbursed, forcing ACC's members to make cuts across departments and negatively impacting members' ability to serve patients.

16. The Global Colon Cancer Association (GCCA) is a non-profit corporation organized and existing under the laws of the State of Delaware, with its headquarters located in Pennsylvania. It acts as the voice for the millions of colon cancer patients worldwide by promoting access to quality medical treatments, advocating for patient-centered policy to ensure increased awareness and screening, and helping its member organizations collaborate and innovate. GCCA also supports the creation of new patient advocacy groups in developing areas that have no colon cancer organizations. The vision of GCCA is to create a global community in which people around the world can unite and battle this disease with one unified voice. Colon cancer patients participate directly in GCCA's activities. GCCA maintains a support community of 4,500 patients and caregivers, approximately half of whom are in the United States. And over 100 colon cancer

patients and survivors participated in GCCA's recent Global Colorectal Cancer Congress, an international gathering dedicated to advancing knowledge, research, and treatment of colorectal cancer. Numerous colon cancer patients rely on drugs covered under the MFN Rule and will be adversely affected by short-term changes in providers' prescribing practices in response to the Rule, as well as by lost longer-term opportunities for new and innovative colon cancer treatments.

17. The National Infusion Center Association (NICA) is a nonprofit corporation organized and existing under the laws of the State of Texas, with its headquarters located in Texas. It is the nation's voice for non-hospital, community-based infusion providers that offer a safe, more efficient, and more cost-effective alternative to hospital care settings for provider-administered medications. NICA's purpose is to ensure that patients can access safe, viable, and sustainable non-hospital healthcare delivery channels through which they can receive provider-administered medicines. Millions of patients rely on these medications to manage complex and chronic diseases, including autoimmune diseases like ulcerative colitis, multiple sclerosis, and lupus. NICA's efforts are focused on promoting patient safety and care quality, ensuring delivery-channel sustainability and expansion, buy-and-bill protection, and improving treatment adherence. It supports policies that improve drug affordability for beneficiaries, reduce disparities in quality of care and safety across care settings, and enable care delivery in the highest-quality, lowest-cost care setting. The MFN Rule will adversely affect many of NICA's infusion provider members by restricting and disrupting access for many of their Part B patients, reducing the rates at which the providers are reimbursed and threatening their ability to continue serving patients.

18. Pharmaceutical Research and Manufacturers of America (PhRMA) is a non-profit corporation organized and existing under the laws of the State of Delaware, with offices located in Washington, D.C. PhRMA 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. Since 2000, PhRMA members have invested approximately $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone. 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. PhRMA members sell 35 of the 50 drugs initially subject to MFN pricing, which will be reimbursed at international MFN prices well below the current Medicare Part B reimbursement price, and will be adversely affected by the MFN Rule. *See* MFN Rule, 85 Fed. Reg. at 76,194 tbl.2. A list of PhRMA members can be found at www.phrma.org.

19. Defendant Alex M. Azar II is the Secretary of the United States Department of Health and Human Services (HHS). He oversees, among other things, CMS and the Medicare program. He is sued in his official capacity.

20. Defendant HHS is an executive department of the United States Government headquartered in Washington, D.C., and is responsible for CMS and the Medicare program.

21. Defendant Seema Verma is the CMS Administrator. She administers the Medicare program on behalf of the Secretary and oversees CMMI's activities. She is sued in her official capacity.

22. Defendant CMS is an administrative agency within HHS that is headquartered in Baltimore County, MD, and that administers the Medicare program.

23. Defendant Brad Smith is the Director of CMMI and CMS Deputy Administrator. He is sued in his official capacity.

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

BACKGROUND

Pharmaceutical Innovation Thrives on Investment in Research and Development

25. PhRMA's members develop life-saving and life-enhancing medicines that are promoted, prescribed, and sold throughout the nation and the world. Between 2000 and 2019, the U.S. Food and Drug Administration (FDA) approved more than 600 new drugs. Asher Mullard, *2019 FDA Drug Approvals*, 19 Nature 79, 81 fig.1 (Feb. 2020), https://go.nature.com/3iFdP3E. PhRMA's members were responsible for much of this innovation, including nearly half of the novel drugs approved last year. *Id.* at 80–81 tbl.1.

26. As biopharmaceutical companies build on new technologies and advances in scientific knowledge, they continue to develop groundbreaking therapies to combat and potentially to cure devastating diseases afflicting patients. One of the most important priorities for PhRMA and its members right now is developing vaccines and treatments for COVID-19, the disease caused by a novel strain of coronavirus. As of November 2020, there were more than 1,680 clinical trials testing a variety of COVID-19 treatments and vaccines. PhRMA, *The Biopharmaceutical Industry Is Leading the Way in Developing New Vaccines and Treatments for COVID-19* 1 (Nov. 2, 2020), https://onphr.ma/35Up8la. The United States Government has chosen several of the most-promising vaccine candidates for Operation Warp Speed, a public–private partnership aimed at delivering 300 million doses of a safe and effective vaccine by January 2021. PhRMA is proud to count its members among four of the five teams originally chosen. *See* Noah Weiland & David

E. Sanger, *Trump Administration Selects Five Coronavirus Vaccine Candidates as Finalists*, N.Y. Times (last updated July 27, 2020), https://nyti.ms/3iTUGLF. Several members have already reported promising positive results for their COVID-19 vaccine candidates and have sought or plan to seek emergency use authorizations from the FDA. Noah Weiland & Katie Thomas, *Pfizer Applies for Emergency F.D.A. Approval for Covid-19 Vaccine*, N.Y. Times (Nov. 20, 2020), https://nyti.ms/2Kr8HUR.

27. Pharmaceutical researchers are also currently researching and developing a wide array of therapies for other life-threatening and debilitating diseases, including developing another vaccine to protect against the Ebola virus, homing in on a long-acting injectable capsid inhibitor to be used as an anti-retroviral treatment for HIV infections, and working on nearly 600 cutting-edge medicines to meet the unique needs of pediatric patients. *See* Am.'s Biopharmaceutical Cos., *Medicines in Development 2020 Report: Vaccines* 3 (Apr. 2020), https://onphr.ma/2Crvw7i; Am.'s Biopharmaceutical Cos., *Medicines in Development 2020 Report: Infectious Diseases* 3 (July 2020), https://onphr.ma/2FtCdqR; Am.'s Biopharmaceutical Cos., *Medicines in Development 2020 Report: Children* 1 (Jan. 2020), https://onphr.ma/2PSX4FN. Pharmaceutical companies are also working on more than 350 novel cell and gene therapies, including nearly 200 that treat cancer. *See* Am.'s Biopharmaceutical Cos., *Medicines in Development 2020 Update: Cell and Gene Therapy* 1–2 (Feb. 2020), https://onphr.ma/3fY6wSX. One of the most cutting-edge and promising areas of development is immuno-oncology, which aims to harness the body's immune system to fight cancer. *See* Sophie Carter & David E. Thurston, *Immuno-Oncology Agents for Cancer Therapy*, Pharm. J. (May 7, 2020), https://bit.ly/2VxzuBk. Recent discoveries and clinical advances in the area have already begun improving outcomes and survival rates for some patients, including those with skin, kidney, and lung cancer. *See id.* The objective is to

eventually replace chemotherapy as the first-line treatment for many cancers and thus help patients live longer, healthier lives. *See id.*

28. However, every life-saving or life-enhancing drug comes at a stunning development cost. On average, a manufacturer will spend nearly $3 billion developing one new medicine. *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://bit.ly/30UAIdg. Some pharmaceutical companies have invested an average of over $10 billion per new drug. Alexander Schuhmacher et al., *Changing R&D Models in Research-Based Pharmaceutical Companies*, 14 J. Translational Med., no. 105, 2016, at 3–4, https://bit.ly/2PWRKRC.

29. Funding the research and development of new life-saving and life-enhancing drugs is a constant gamble. Only one in 5,000 compounds that enter preclinical testing will achieve FDA approval for therapeutic use, a failure rate of 99.98%. Sandra Kraljevic et. al., *Accelerating Drug Discovery*, 5 Eur. Molecular Biology Org. Reps., no. 9, 2004, at 837, https://bit.ly/2Y2gwEK. Of the therapies that do reach market, merely one-third manage to even cover their cost of development, much less turn a significant profit. *See* Council of Econ. Advisers, *Funding the Global Benefits to Biopharmaceutical Innovation* 7 fig.3 (Feb. 2020), https://www.whitehouse.gov/wp-content/uploads/2020/02/Funding-the-Global-Benefits-to-Biopharmaceutical-Innovation.pdf (2020 CEA Report).

30. Moreover, the required investments in time and expense to research and develop innovative new drugs are continually increasing. Over the last 60 years, research and development costs in the pharmaceutical industry have increased 8.6% annually, even after adjusting for inflation. Schuhmacher et al., *supra*, at 3. One study found that from 2003 to 2013, the cost of developing a prescription drug that gains market approval soared 145%. *See* DiMasi et al., *supra*,

at 28. It now takes an average of ten to fifteen years to develop a new drug. *See id.* at 25–26. Some of the most important factors behind these increases are that clinical drug development takes more time as the necessary research grows more complicated, the drugs themselves (especially biologicals) are becoming more complex, and demands by regulatory authorities and payers are escalating. Schuhmacher et al., *supra*, at 4, 6.

31. Other factors have simultaneously reduced the returns on the drugs that *do* make it to market. For example, drug treatments are becoming increasingly personalized, taking into consideration a patient's "genetic, anatomical, and physiological characteristics," FDA, *Paving the Way for Personalized Medicine* 4 (Oct. 2013), https://www.fdanews.com/ext/resources/files/10/10-28-13-Personalized-Medicine.pdf, which both increases development costs and reduces the patient population that can defray those costs. These targeted drugs are often critical in treating serious but rare illnesses. Last year, FDA approved eleven personalized medicines with specific biological markers to help guide prescribers' decisions; the year before, it approved 25, which constituted 42% of all FDA-approved therapeutic products that year. Personalized Med. Coal., *Personalized Medicine at FDA: The Scope & Significance of Progress in 2019*, at 3,4 (2020), https://bit.ly/343D1N8; Mullard, *supra*, at 81 fig.1.

32. In short, the task facing most pharmaceutical companies is staggering. They must risk billions and billions of dollars researching compounds, only 0.02% of which will ever reach market, and only a further third of which will ever recoup development costs. Every year, the odds get longer.

33. Pharmaceutical companies must sustain these constant, high-risk gambles on only a single prospect—that, if a product reaches market and fills a dire patient need in the healthcare field, it will earn market-based returns.

Congress Has Established a Reimbursement System That Encourages Innovation

34. Congress has recognized both the critical need for robust medical research and the unique challenges facing the pharmaceutical industry. For that reason, it has enacted and refined a drug pricing system that creates incentives for continued investment in this area—specifically, a carefully calibrated regime that rewards innovators with certain exclusive rights and the opportunity for market-based returns.

35. Under the federal patent laws, innovation is rewarded primarily by granting a patent holder the exclusive right to make, use, and sell the patented invention for a limited period of time. 35 U.S.C. § 154. Most recently, Congress has concluded that patent holders are generally entitled to exclusive use of their inventions for up to twenty years from the application date—and possibly less, given the time necessary for clinical trials and the regulatory process. *Id.* During that period, federal law protects the patent by prohibiting patent infringement, defined as the unauthorized making, using, offering for sale, or selling of any patented invention within the United States. *Id.* § 271(a).

36. Congress has often fine-tuned the particular incentives offered by the patent system, including by supplementing the patent laws with laws applicable to pharmaceuticals specifically. In 1984, for example, Congress provided for the extension of the patent term of prescription drugs subject to FDA approval in the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 15 U.S.C. §§ 68b *et seq.*), popularly known as the Hatch-Waxman Act. As federal courts have observed, the public benefits significantly from these additional incentives to innovate. *See Glaxo, Inc. v. Novopharm, Ltd.*, 110 F. 3d 1562, 1568 (Fed. Cir. 1997); *Pfizer Inc. v. Dr. Reddy's Lab'ys, Ltd.*, 359 F.3d 1361, 1364 (Fed. Cir. 2004).

37. Congress has further adjusted incentives for research and development in the pharmaceutical field through subsequent supplemental legislation. In the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, for example, Congress permitted the FDA to award additional incentives, in the form of extended market exclusivity, for the development of pediatric medications. *See* 21 U.S.C. § 355a. Congress has also used market exclusivity to encourage investment in drugs for rare conditions or diseases in the Orphan Drug Act, Pub. L. 97-414, 96 Stat. 2049, and the amendments thereto. *See* 21 U.S.C. §§ 360aa–360dd.

38. That the patent laws are Congress's prerogative is clear from the Constitution itself. *See* U.S. Const. art. I, § 8, cl. 8. As the Supreme Court has recognized, "it is Congress that has been assigned the task of defining the scope of the limited monopoly that should be granted to authors or to inventors in order to give the public appropriate access to their work product." *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 429 (1984). And Congress has gone to extraordinary lengths to strike the proper balance of exclusivity and economic competition for patented prescription drugs.

39. Critically, the grant of the exclusive right to use and sell a product also conveys the right to sell the product at the market price that exclusivity permits, which gives patents their economic value and encourages invention. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1373 (Fed. Cir. 2007) ("Congress has decided that patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use."). The Supreme Court and Congress have long recognized that it is in large part the prospect of obtaining the exclusive rights to an invention for a limited period of time, and the corresponding opportunity to recoup initial outlays

and to profit during that period, that motivates inventors to risk the substantial sums of money on research and development that are often required. "Patents are designed to promote innovation by providing the right to exclude others from making, using, or selling an invention. They enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities." H.R. Rep. No. 98-857, pt. 1, at 17 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2650 (describing purpose of the patent extension contained in the Hatch-Waxman Act).

40. Congress has also repeatedly rejected proposed legislation that departs from this approach. In 2017, for example, a bill was proposed in the House of Representatives that would have tied the prices of certain drugs inside the United States to the prices at which those drugs were sold abroad—even though foreign prices are often subject to price controls imposed by governments less concerned with promoting pharmaceutical innovation. Medicare Drug Price Negotiation Act, H.R. 4138, 115th Cong. (2017); *see infra* ¶¶ 44–**Error! Reference source not found.**. But the bill never made it out of the House Subcommittee on Health. Similar bills also died in the Senate Committee on Finance in 2017 and the House Subcommittee on Health in 2018. *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). Most recently, the House of Representatives passed H.R. 3, which would have set a maximum price for certain drugs based on prices in certain foreign countries. *See* Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019). But the bill was dead on arrival in the Senate, in large part because of those "aggressive and controversial" provisions. Selena Simmons-Duffin, *The House Passed Its Prescription Drug Plan—Here's What's in It*, NPR (Dec. 12, 2019), https://n.pr/3qkm0XQ.

41. In contrast with these failed efforts, drug reimbursement under Medicare Part B broadly accords with Congress's longstanding policy encouraging innovation. Medicare Part B covers a wide range of healthcare services for its beneficiaries, including drugs administered by a physician. *See* 42 U.S.C. § 1395k(a)(1); *id*. § 1395x(s)(2)(A). Congress has sought to ensure that the costs of these drugs are reimbursed by Medicare at rates as close as possible to "the actual price paid by purchasers" in "real market transaction[s]." H.R. Rep. 108-178, pt. 2, at 194, 197–98 (2003). Congress has thus required Medicare Part B reimbursement rates for these drugs to reflect in most cases the "average sales price" methodology, which pays out the average sales price of the drug—a market-based price that reflects the weighted quarterly average of all manufacturer sales prices to customers for the drug or biological (with limited exceptions)—plus an add-on of 6% (4.3% under sequestration). That add-on serves as a handling fee to the provider, and it helps promote patient access to the drug by helping ensure that all providers (including small or rural providers that may pay higher-than-average drug prices) at least break even. *See* 42 U.S.C. § 1395w-3a. By basing Part B payments on market transactions, Congress provides pharmaceutical companies the opportunity to earn competitive returns that encourage and fund future innovation.

42. Overall, Congress's drug pricing system has helped the United States and its pharmaceutical industry become "central engines for developing new medical treatments and cures." 2020 CEA Report, *supra*, at 3. Today, the United States and its firms "fund[] about 44 percent of world medical research and development . . . , invest[] 75 percent of global medical venture capital, and hold[] the intellectual property rights for most new medicines." *Id.* In the 1970s, the United States was responsible for just 31% of new chemical entities produced by major nations; by the first decade of this century, however, over half of all such drugs were discovered

and developed in the United States. *See* Ross C. DeVol et al., Milken Inst., *The Global Biomedical Industry: Preserving U.S. Leadership* 5 (Sept. 2011), https://bit.ly/32QWP5C; *accord* Nam D. Pham & Mary Donovan, NDP Analytics, *Will US Leadership in Biopharmaceutical R&D Continue?* 3 (Nov. 2020), https://bit.ly/2URXajC.

Foreign Price Controls Stifle Pharmaceutical Innovation and Harm Patients

43. Congress and the Administration alike have recognized the key to the United States' success in pharmaceutical innovation—that such innovation requires "a portfolio approach in drug development decisions in which the whole portfolio must earn normal returns given the high failure rates of the various components." 2020 CEA Report, *supra*, at 5.

44. Other countries, especially in Europe, have structured their systems very differently. A reasonable prospect of "normal returns" to recoup up-front costs is generally not available in these countries, where price controls and other government interventions push the prices of drugs well below market prices. *See id.* at 8. Oftentimes, these interventions aim to price drugs as low as their marginal costs of production, which fail to account for the massive expenditures necessary to develop the drugs in the first place and often reflects different values regarding end-of-life care. These interventions are constantly increasing; for example, the Administration has observed that, between 2010 and 2011 alone, 23 countries implemented 89 different measures to artificially contain government spending on prescription drugs. U.S. Dep't of Health & Hum. Servs., *American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* 14 (May 2018), https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf (HHS Blueprint).

45. These sorts of foreign price control regimes—many of which rely on "external reference pricing," in which the price of a drug in one country is pegged to its price in other

countries—stymie innovation and harm patients. Over time, the increasing use of external reference price controls and other government interventions abroad has led to sharp drop-offs in pharmaceutical innovation. For example, in the mid-1980s, Europe outspent the United States on drug research and development by 24%. John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 4 (2008). By 2004, however, Europe trailed the United States by 15%, in large part because price controls had choked off its rate of R&D investment. *Id.* One analysis from President Trump's Council of Economic Advisers concluded that by 2017, foreign free-riding was depriving innovators of approximately $194 billion, or 42% of current global revenues. *See* 2020 CEA Report, *supra*, at 20. Since that phantom revenue never materialized to fund research and development, the "global result" was and continues to be "a slower pace of innovation, resulting in fewer potential new life-saving therapies for patients in all countries." *Id.*

46. Economists estimate that the costs of these lost opportunities are staggering. One 2018 study found that if foreign price controls were lifted in non-U.S. OECD countries, there would be anywhere between 8–13 new drugs introduced annually by 2030 and 28–44 new drugs annually by 2060. Taylor T. Schwartz et al., *The Impact of Lifting Government Price Controls on Global Pharmaceutical Innovation and Population Health*, ISPOR (May 2018), https://bit.ly/3ar7HJB. Concretely, that would increase the average life expectancy of a 45-year-old in 2014 by anywhere from 0.56 to 0.86 years. *Id*. In economic terms, that increase would represent $924 billion to $1.52 trillion in total value of lifetime welfare gains for that age cohort (or $41,000 to $67,000 per capita). *Id.*

47. Another study agreed, concluding that increasing European prices by only 20%—"just part of the total gap" in prices caused by European government interventions—"would result

in substantially more drug discovery worldwide." Dana Goldman & Darius Lakdawalla, Leonard D. Schaeffer Ctr. for Health Pol'y & Econ., Univ. of S. Cal., *The Global Burden of Medical Innovation* 4 (Jan. 2018), https://bit.ly/34dtzXR. Over the next 50 years, such a modest increase would lead to welfare gains of $10 trillion for Americans and $7.5 trillion for Europeans. *Id.*

48. Similarly, the Information Technology & Innovation Foundation, ranked as the top science and technology policy think tank in the world, *see* James G. McGann, Think Tanks & Civ. Soc'ys Program, Univ. of Pa., *2019 Global Go To Think Tank Index Report* 154 tbl.24 (June 18, 2020), https://bit.ly/3h8MoyP, has concluded that when it comes to pharmaceutical drugs, "an overwhelming body of academic research shows that price controls . . . significantly restrict the number of new drugs in the future." Joe Kennedy, *The Link Between Drug Prices and Research on the Next Generation of Cures*, Info. Tech. & Innovation Found. (Sept. 9, 2019), https://bit.ly/3fSIysc.

49. Price controls also prevent patients from accessing life-saving treatments and cures in a timely fashion—or sometimes at all. Nearly 90% of new medicines launched since 2011 are available in the United States. *See* PhRMA, *The United States vs. Other Countries: Availability of New Medicines Varies* (Nov. 2020), https://onphr.ma/36oGV3V. Germany comes in a distant second with 63% of new medicines available, and other countries perform even worse: 59% for the United Kingdom, 50% for France, and only 46% for Canada. *Id.* In the nineteen MFN Rule countries for which data are available, citizens on average have access to only 48% of new medicines. *See id.* And even the medicines that *do* become available in these countries arrive an average of fourteen months later than in the United States. *See id.* The Trump Administration has explained why: "Drug manufacturers usually pursue market access in the United States before other markets due to the higher prices in the United States" offered by the market-based pricing

system. Council of Econ. Advisers, *Reforming Biopharmaceutical Pricing at Home and Abroad* 13 (Feb. 2018), https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.

50. This pattern of reduced availability and delays holds true for medicines currently covered by Medicare Part B. On average, just 51% of new medicines covered by Medicare Part B that were launched since 2011 are currently available in the nineteen MFN Rule countries for which data are available, and those medicines arrived fourteen months later on average. *See* PhRMA, *The United States vs. Other Countries: Availability of Part B Medicines Varies* (Nov. 2020), https://onphr.ma/2HYdJYi (*Availability of Part B Medicines*). That finding is reinforced by HHS's own analysis, which shows that fewer than 5.4% of the medicines it examined were available in all 22 comparator OECD countries, nearly all of which have single-payer healthcare systems with government-imposed price controls. *See* U.S. Dep't of Health & Hum. Servs., *Medicare FFS Part B and International Drug Prices: A Comparison of the Top 50 Drugs* 11–12 & tbl.2 (Nov. 20, 2020), https://aspe.hhs.gov/system/files/pdf/264421/Part-B%20Drugs-International-Issue-Brief.pdf.

51. The Trump Administration has itself studied how price controls and other European-style government interventions affect pharmaceutical innovation, access to therapies, and healthcare outcomes. *See* Council of Econ. Advisers, *The Opportunity Costs of Socialism* (Oct. 2018), https://www.whitehouse.gov/wp-content/uploads/2018/10/The-Opportunity-Costs-of-Socialism.pdf (2018 CEA Report). The Administration's conclusion was stark, if predictable: "There is much theoretical and empirical economic analysis concluding that lowering prices for innovative industries often has short-run benefits that are dominated by long-run costs." *Id.* at 46. Specifically in the case of medical innovation, "evidence suggests that a 1 percent reduction in

market size," through measures such as price controls, "reduces innovation—defined as the number of new drugs launched—by as much as 4 percent." *Id.* at 47 (citation omitted). Surprising no one, the report concluded that "insufficient reimbursements to suppliers leads to a rationing of care," one reason why "European programs appear to deliver less healthcare to the elderly and result in worse health outcomes for them." *Id.* at 44–45.

The Trump Administration Decides to Supplant Congress's System with Executive Action

52. On October 30, 2018, CMS published an advance notice of proposed rulemaking. *See* Medicare Program; International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54,546 (Oct. 30, 2018) (Advance Notice). Citing concerns about the high prices paid for drugs under Medicare Part B relative to their costs in other countries, CMS's Advance Notice offered a so-called International Pricing Index (IPI) proposal as a potential solution. In effect, the IPI proposal would have imported foreign price controls into the United States. Rather than reimbursing for Medicare Part B drugs according to their average sales prices in the United States, Medicare would have instead paid a vendor based on an index of international prices from around the world.

53. By design, the IPI proposal was intended to prevent the market from setting prices for those drugs. Instead, if pharmaceutical manufacturers wanted their products to be reimbursed and thus available for patients, they would have needed to adhere to the government-mandated prices in sales to the IPI vendors. CMS reasoned that, in response to the incentives set up by the proposal, pharmaceutical manufacturers also "may seek to raise prices [abroad] or limit foreign sales." *Id.* at 54,557.

54. Comments on the Advance Notice were due to CMS by December 31, 2018. PhRMA, along with many others, submitted comments pointing out that the IPI proposal would

"significantly disrupt drug distribution and care management processes and have downstream impacts [on] physician reimbursement nationwide," ultimately resulting in substantial harm to "physician care quality, patient access to physicians and treatment options, and the continued research and development of innovative medicines." *See* PhRMA, Comment Letter on Advance Notice of Proposed Rulemaking Regarding International Pricing Index Model for Medicare Part B Drugs, at 2 (Dec. 31, 2018), https://onphr.ma/2E5I84m.

55. CMS took no public steps to adopt the IPI plan. Instead, President Trump urged legislative action. In his February 2019 State of the Union Address, President Trump "ask[ed] the Congress to pass legislation that finally takes on the problem of global freeloading." *President Donald J. Trump's State of the Union Address* (Feb. 5, 2019), https://www.whitehouse.gov/briefings-statements/president-donald-j-trumps-state-union-address-2.

56. By December 3, 2019, it seemed as if the Trump Administration had reversed its position entirely. At that time, the House of Representatives was debating H.R. 3, a bill that would have set a maximum price for certain drugs at 120% of the average of prices in Australia, Canada, France, Germany, Japan, and the United Kingdom. *See* Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019). H.R. 3 would also have established a "target price" of the lowest average price in any of those six countries and would have authorized large tax penalties against a pharmaceutical manufacturer that did not accept a price equal to or lower than that target price. *See id.*

57. On the eve of the vote, the Trump Administration released a statement in which it applauded the bill's "goal of lowering prices" but observed that "the threat it poses to continued medical innovation will harm American patients in ways that far outweigh any benefits." 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 (2019 CEA Analysis). The Administration conservatively estimated that H.R. 3 could lead to "a $75 billion to $200 billion reduction in research and development expenditures over the next decade," which would translate into "as many as 100 fewer drugs entering the United States market . . . , or about one-third of the total number of drugs expected to enter the market during that time." *Id.* By the Administration's estimate, that would "reduce Americans' average life expectancy by about four months—nearly one-quarter of the projected gains in life expectancy over the next decade." *Id.* Each year over the next decade, H.R. 3 would save the federal government an average of $34.5 billion, but it would cost the country anywhere from $375 billion to $1 trillion per year in health outcomes, far more "than H.R. 3's projected savings." *Id.*

58. The Trump Administration concluded by reiterating its "commitment to reducing drug prices through market-based mechanisms." *Id.* "Heavy-handed government intervention may reduce drug prices in the short term," the Administration stressed, "but these savings are not worth the long-term cost of American patients losing access to new lifesaving treatments." *Id.* For that reason, President Trump made clear that he was prepared to veto H.R. 3. *See* Exec. Off. of the President, Off. of Mgmt. & Budget, *Statement of Administration Policy: H.R. 3 – The Elijah E. Cummings Lower Drug Costs Now Act* (Dec. 10, 2019), https://www.whitehouse.gov/wp-content/uploads/2019/12/SAP_HR-3.pdf.

59. On July 24, 2020, however, President Trump changed course yet again. With great fanfare, he signed four executive orders with the stated intention of "massively lower[ing] prescription drug costs and increas[ing] Americans' access to life-saving medications." White House Fact Sheet, *President Donald J. Trump Is Taking Action to Lower Drug Costs and Ensure*

That Americans Have Access to Life-Saving Medications (July 24, 2020), https://www.whitehouse.gov/briefings-statements/president-donald-j-trump-taking-action-lower-drug-costs-ensure-americans-access-life-saving-medications (White House Fact Sheet).

60. One of the four orders was entitled "Lowering Drug Prices by Putting America First"—or at least so it appeared. Despite publicly signing the order on July 24, the President refused to make it available to anyone outside the government. The President indicated that he was withholding the signed order because the Administration planned to hold "talks" with pharmaceutical companies to reduce drug prices and negate the perceived need to put the order into effect, predicting that pharmaceutical companies would negotiate because the order would be "very tough" for them. July 2020 White House Remarks, *supra*.

61. On its website, the White House claimed that the withheld fourth order would institute a new and even more radical version of the IPI proposal by "ensur[ing] that the United States pays the lowest price available in economically comparable countries for Medicare Part B drugs," a scheme known as most-favored-nation pricing. White House Fact Sheet, *supra*. Even though President Trump described all four of the August 2020 orders signed as "sweeping," he singled out the MFN order as "transformative." July 2020 White House Remarks, *supra*. He described it as "bold," "sweeping," "big," "very big," "big stuff," "historic," and "very dramatic," underscoring that it was "the granddaddy" of "the most far-reaching prescription drug reforms ever issued." *Id.* He further promised that, along with the other three executive orders, the MFN order would "completely restructure the prescription drug market, in terms of pricing and everything else." *Id.*

62. President Trump warned that if he did not receive the concessions from pharmaceutical companies that he was demanding, he would release the MFN order exactly one

month later. Not until Sunday, September 13, 2020, did the President finally release the executive order. In it, he announced that "[i]t is the policy of the United States that the Medicare program should not pay more for costly Part B . . . prescription drugs or biological products than the most-favored-nation price." Exec. Order No. 13948 of September 13, 2020, 85 Fed. Reg. 59,649, 59,649 (Sept. 23, 2020) (MFN Executive Order). Based on that policy, the President directed Secretary Azar to take "steps to implement his rulemaking plan to test a payment model pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price." *Id.* The President also required Secretary Azar to "take appropriate steps to develop and implement a rulemaking plan[] [to test] a payment model pursuant to which Medicare would pay, for Part D prescription drugs or biological products . . . no more than the most-favored-nation price." *Id.* at 59,650.

The MFN Rule Supplants Congress's Drug Pricing System with Foreign Price Controls

63. On November 20, 2020, President Trump held another press conference to tout "a very big announcement—the biggest ever, concerning drugs and drug pricing." Nov. 2020 White House Remarks, *supra*. He unveiled the "groundbreaking" MFN Rule, describing it as "probably the biggest story that we've ever had relative to drug prices. There's never been anything like this." *Id.* Secretary Azar agreed, declaring in a contemporaneous press release that the MFN Rule "will be the most significant single action any administration has ever taken to lower American drug costs." Press Release, Ctrs. for Medicare & Medicaid Servs., *Trump Administration Announces Prescription Drug Payment Model to Put American Patients First* (Nov. 20, 2020), https://www.cms.gov/newsroom/press-releases/trump-administration-announces-prescription-drug-payment-model-put-american-patients-first (2020 CMS Press Release).

64. Later that day, CMS issued the MFN Rule as an "interim final rule with comment period." On November 27, the MFN Rule went into effect after being published in the Federal Register, although it allowed the public to submit comments for consideration for the following 60 days. *See* MFN Rule, 85 Fed. Reg. at 76,180.

65. By any measure, the MFN Rule is far-reaching. It will run nationwide for an initial period of seven years starting on January 1, 2021, and ending on December 31, 2027.[5] *Id.* at 76,181. Over that time period, CMS will calculate a drug's "MFN Price" every quarter based on the lowest per capita, GDP-adjusted price of that drug in any OECD country with a purchasing power parity-adjusted GDP per capita that is at least 60% of the United States'. *See id.* at 76,196. Currently, that includes almost two dozen countries, including those with government-run, single-payer healthcare systems such as Canada and Sweden.[6] *Id.* at 76,200.

66. CMS will phase the MFN Price in during the first three years of the Rule. Over the first year, CMS will set reimbursement rates for each covered Medicare Part B drug at a weighted average of 25% of the MFN Price and 75% of the congressionally mandated average sales price of the drug. *Id.* at 76,205 tbl.5. CMS will rebalance the blended rate at 50-50% in the second year and 75-25% in the third year; in years four through seven, reimbursement rates will be set at 100% of the MFN Price.[7] *Id.*

[5] Even after the Rule ends, former participants must participate in monitoring activities for another two years. MFN Rule, 85 Fed. Reg. at 76,187.

[6] Based on available data, the Rule estimates that the MFN Price for the first quarter of 2021 will be based on drug pricing information from Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Netherlands, New Zealand, Norway, Spain, Sweden, Switzerland, and the United Kingdom. *See* 85 Fed. Reg. at 76,200.

[7] Furthermore, the MFN Rule will supplant the existing add-on payment of 6% of the average sales price with a flat per-dose add-on payment that is uniform across all drugs. *See* 85 Fed. Reg. at 76,216–17.

67. CMS will further pull the drug reimbursement rate downward if either the wholesale acquisition cost or the average sales price of a drug covered by the Rule rises faster than both inflation and the MFN Price. *See id.* at 76,213–15. That means that reimbursement could decline even more precipitously than by the stated MFN Rule percentage for any given year. It also means that the MFN Rule effectively regulates the prices of drugs sold *outside* the Medicare Part B regime, as the average sales price is a volume-weighted average of commercial prices.

68. The MFN Rule covers nearly twice as many drugs as the IPI proposal. The Rule will initially apply to the 50 single-source drugs and biologicals with the highest Part B spending, subject to certain narrow exclusions. *See id.* at 76,181. CMS estimates that in the first year, those 50 drugs will account for "approximately 75 percent of annual Medicare Part B drug allowed charges for separately payable drugs." *Id.* at 76,193. And that is only the beginning. Every year, CMS plans to extend the Rule to cover new drugs that rise to be among the top 50 drugs based on updated annual Medicare Part B spending. *Id.* at 76,192. Subject to narrow exceptions, drugs already covered by the Rule will remain covered, so the scope of drugs covered by the MFN Rule will only increase over time. *Id.*

69. Notably, however, the MFN Rule will *not* apply to any drugs with competition from generic drugs, regardless of the drug's price or the share of Medicare spending that it represents. *Id.* at 76,188–89. Whether patent rights for a drug have expired is thus a crucial factor in whether the MFN Rule applies to that drug.

70. In another notable exception, the MFN Rule will also not apply to any FDA-approved COVID-19 vaccine or drug used to treat the disease. *Id.* at 76,191. Although it cites COVID-19 as a justification for waiving the APA's notice-and-comment requirements, the Rule wholly exempts COVID-19 therapies themselves, explaining that such exclusions are necessary to

avoid the "risk of shortage[s]" caused by the Rule's disruption of market forces and to "minimize any potential for the MFN [Rule] to impact rapid, widespread availability of such drugs in the U.S. to treat patients with suspected or confirmed COVID-19." *Id.*

71. Finally, the MFN Rule will require mandatory participation from "a broad set of providers," *id.* at 76,187, including "all providers and suppliers that participate in the Medicare program and submit a separately payable claim for an MFN [Rule] drug," subject only to "limited exceptions," *id.* at 76,181. The MFN Rule will also apply across "all states and U.S. territories," with no geographic exceptions. *Id.* CMS explained in the MFN Rule that it did not "believe[]"the rule could "realize its full potential in spending reductions . . . without broad participation of Medicare participating providers and suppliers through a nationwide scope." *Id.* at 76,188. The MFN Rule operates by reducing the rate of reimbursement for drugs administered by Medicare providers in the outpatient setting, such as doctors, clinics, infusion centers, and hospitals. These providers typically purchase and administer the drugs they dispense to patients before receiving reimbursement. This approach, known as "buy and bill," puts providers at extraordinary financial risk. CMS acknowledges that under the Rule, "providers and suppliers will need to decide if the difference between the amount that Medicare will pay and the price that they must pay to purchase the drugs would allow them to continue offering the drugs." *Id.* at 76,236. In many cases, the Rule will force these providers to absorb losses for drugs that are purchased on the market but reimbursable only at the below-market MFN Rule reimbursement rates. CMS's own analysis suggests that providers will likely see payment cuts as a result. For example, in the fourth quarter of 2019, MFN prices averaged 65% below average sales prices. *See id.* at 76,236 tbl.9. Some specialties will be hit especially hard; CMS expects average reductions in add-on revenue of 10%

for infectious disease physicians, 13% for medical oncologists, and 21% for neurologists. *Id.* at 76,219 tbl.8.

72. But the MFN Rule's real target is a reduction in the prices at which drugs are sold by pharmaceutical manufacturers. The Rule explains that its objective is to force pharmaceutical "manufacturers to address the large difference between prices in the U.S. and in other countries," a goal the Rule repeatedly underscores. *Id.* at 76,213; *see, e.g.*, *id.* at 76,184 (referring to the impact on "a large set of manufacturers"); *id.* at 76,236 ("[M]anufacturers are expected to devote considerable resources to" "altering the availability and terms of their international prices."). President Trump emphasized the same point at the MFN order signing ceremony, noting that the Rule would be "very tough" for manufacturers. July 2020 White House Remarks, *supra*.

73. Significantly, patients will also be hurt by the MFN Rule. As the Administration has pointed out time and again, price controls harm patients by reducing access to life-saving and life-enhancing drugs. That is especially true in the context of non-hospital centers caring for patients in need of infused and injectable medications. Those patients suffer from some of the most complex, rare, and chronic diseases, including cancer, autoimmune disorders, and rheumatoid arthritis. Community-based infusion providers, which are frequently the lowest-cost care setting for patients with these illnesses, are often small businesses reliant on drug reimbursements to break even in treating their Medicare Part B patients. The MFN Rule will immediately imperil these providers' ability to care for patients, risking both disease flares that often become medical emergencies with lifelong repercussions and exponentially higher medical costs caused by disease undermanagement. In many cases, the MFN Rule will force community-based infusion providers to shutter their doors entirely.

74. In fact, the MFN Rule concedes that "beneficiaries may experience access to care impacts by . . . having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment." 85 Fed. Reg. at 76,244. CMS estimates that within the first three years of the Rule, there will be a drop of *nearly one-fifth* in the availability of covered Medicare Part B drugs. *Id.* at 76,237 tbl.11.

75. The MFN Rule will also harm patients by stifling the innovation that makes the discovery and development of those drugs possible. The Rule will decrease the funds available for pharmaceutical research and development, resulting in fewer new drugs. It will also lead to delays in access to even those drugs that are market-ready—which the Rule itself acknowledges and even cites as a reason for excluding COVID-related therapies.

76. In sum, the MFN Rule seeks to replace the set of carefully calibrated incentives Congress established for Medicare Part B pricing, *see supra* ¶ 41, with price controls devised in foreign capitals that reflect a very different balance between innovation and patient access.

The MFN Rule Exceeds CMS's Statutory Authority

77. The authority invoked by the MFN Rule, Social Security Act Section 1115A, authorizes CMMI "to test innovative payment and service delivery models." 42 U.S.C. § 1315a(a)(1). That testing authority is subject to narrow and strict requirements about what may be tested, how a test is evaluated, and under what circumstances a test can be expanded.

78. First, Section 1115A requires the Secretary to "select models to be tested from models 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). The Secretary must choose models that "reduce program costs" while also "preserving or enhancing the quality of care" for beneficiaries. *Id.*

79. Once such a model is chosen, the Secretary must follow a two-phase process under Section 1115A to test it and, if permitted by the statutory criteria, to expand it. In "phase I," CMMI tests the model to determine its effect "on program expenditures . . . and the quality of care." *Id.* § 1315a(b)(1). The Secretary may waive certain otherwise-applicable statutory requirements—including all those found in the Medicare statutes—but only "as may be necessary solely for purposes of" the test. *Id.* § 1315a(d)(1) (giving the Secretary the power to waive "requirements of subchapters XI and XVIII [of the Social Security Act] and of sections 1396a(a)(1), 1396a(a)(13), 1396b(m)(2)(A)(iii), and 1396u-4 (other than subsections (b)(1)(A) and (c)(5) of such section) of this title [Title 42]"). Notably, Section 1115A does not provide the Secretary with authority to waive the provisions of Title 5 of the U.S. Code, including specifically the provisions of the Administrative Procedure Act.

80. Each model tested in phase I receives an evaluation from the Secretary that includes "an analysis of . . . the quality of care furnished . . . [and] the changes in spending . . . by reason of the model." *Id.* § 1315a(b)(4)(A). If, "at any time after such testing has begun," the model is no longer expected (1) to improve the quality of care without increasing spending, (2) to reduce spending without reducing the quality of care, or (3) to simultaneously improve the quality of care *and* reduce spending, then the Secretary "shall terminate or modify the design and implementation" of the model. *Id.* § 1315a(b)(3)(B).

81. Based on the results of the phase I evaluation, CMMI may decide to move a model into "phase II." *Id.* § 1315a(c). Specifically, CMMI "may, through rulemaking, expand . . . the duration and the scope of a model that is being tested," which may include "implementation on a nationwide basis." *Id.* Such an expansion is permitted only if the Secretary determines that the expansion (1) is expected either to reduce spending without reducing the quality of care or to

improve the quality of patient care without increasing spending, and (2) "would not deny or limit the coverage or provision of benefits." *Id.* § 1315a(c). Furthermore, CMMI cannot expand the model unless the Chief Actuary of CMS first certifies that the expansion "would reduce (or would not result in any increase in) net program spending under applicable subchapters." *Id.* § 1315a(c)(2). Finally, Section 1115A does not authorize the Secretary to waive statutory requirements for a phase II expansion (as it does for a phase I test). In short, any program change given wide implementation under phase II expansion is subject to far stricter requirements than a test under the testing phase.

82. The MFN Rule is a far-reaching, comprehensive statutory overhaul rather than the "test" of a "model" that Section 1115A requires in phase I. That is by design—CMS has crafted the MFN Rule to maximize the percentage of Medicare Part B spending covered. It expects to cover drugs and biologicals "account[ing] for approximately 75 percent of annual Medicare Part B . . . charges." MFN Rule, 85 Fed. Reg. at 76,193. The objective is not to test a model but to achieve a certain outcome—to allow as many "eligible beneficiaries" as possible "to benefit from the cost-sharing reductions." *Id.* at 76,188. Indeed, the President has repeatedly touted the Rule as part of an effort to "completely restructure the prescription drug market, in terms of pricing and everything else." July 2020 White House Remarks, *supra*. CMS Administrator Verma agrees; she referred to even the Rule's more modest predecessor as "an overhaul of Medicare Part B drug pricing." Press Release, Ctrs. for Medicare & Medicaid Servs., *Remarks by Administrator Seema Verma at the Biopharma Congress* (Nov. 14, 2018), https://www.cms.gov/newsroom/press-releases/remarks-administrator-seema-verma-biopharma-congress (2018 CMS Press Release). Secretary Azar likewise called the MFN Rule "the most significant single action any administration has ever taken to lower American drug costs." 2020 CMS Press Release, *supra*.

83. These remarks reflect that the MFN Rule does not comport with the plain meaning of what it means to "test" a "model." "Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004) (citation omitted). The verb "test" refers to an effort to "try" something—as opposed to implementing it outright—on a limited basis for purposes of evaluating performance. *See Test, V.*, Oxford English Dictionary (2d ed. 1989), https://bit.ly/3as6yRV ("to try, put to the proof; to ascertain the existence, genuineness, or quality of"). The use of the word "model" reinforces this reading: It ordinarily refers to something performed on a small scale that serves as a demonstration to be evaluated and (if successful) potentially adopted more widely later.

84. The rest of the statute, through its two-phased approach, confirms this ordinary understanding of the words "test" and "model." Congress required the Secretary to evaluate "each model tested" in phase I, 42 U.S.C. § 1315a(b)(4)(A), making clear that the testing phase's *sole* objective is developing the evidence necessary to determine whether an expansion of the model into phase II would be appropriate. Only if that evaluation is positive (as determined by the specified statutory criteria) would the Secretary have the authority for a model's "implementation on a nationwide basis" in phase II. *Id.* § 1315a(c).

85. Contrary to Congress's clear intention in Section 1115A, the MFN Rule is not a small-scale pilot program intended to test a hypothesis about an innovative Medicare pricing or delivery design before making recommendations to Congress for legislation. On day one, the MFN Rule institutes nationwide price controls for the overwhelming *majority* of Medicare Part B drug spending, and its reach only expands from there. By design, the MFN Rule is unprecedented in nature, scope, and financial impact.

86. The MFN regime is also mandatory. Out of more than 50 models proposed using Section 1115A, CMS has adopted only a handful that were mandatory, and each was estimated to be significantly more limited in its impact than the MFN Rule. For example, the Comprehensive Care for Joint Replacement Model, which gave acute care hospitals in certain selected geographic areas "retrospective bundled payments for episodes of care for lower extremity joint replacement . . . or reattachment of a lower extremity," was estimated to have only a modest financial impact on Medicare of $343 million over the initial planned expectancy of the model. *See* Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, 80 Fed. Reg. 73,274, 73,282 (Nov. 24, 2015); *see also* Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures, 85 Fed. Reg. 61,114, 61,348 (Sept. 29, 2020) (RO and ETC Models) (estimating $23 million and $230 million impacts for the mandatory Radiation Oncology and End-Stage Renal Disease Treatment Choices Models, respectively); "Medicare and Medicaid Programs; CY 2016 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; and Home Health Quality Reporting Requirements," 80 Fed. Reg. 68,623, 68,711 (Nov. 5, 2015) (estimating $380 million impact for the mandatory Home Health Value-Based Purchasing Model). By contrast, CMS estimates that the MFN Rule's impact will be $85.5 *billion—250 times larger*. *See* 85 Fed. Reg. at 76,238.

87. CMS also scaled down the mandatory scope of the joint replacement model from what it had initially planned, "making participation voluntary for all low volume and rural hospitals" and "reducing the number of mandatory geographic areas participating [in the model] from 67 areas to 34 areas." Press Release, Ctrs. for Medicare & Medicaid Servs., *CMS Finalizes Changes to the Comprehensive Care for Joint Replacement Model, Cancels Episode Payment*

Models and Cardiac Rehabilitation Incentive Payment Model (Nov. 30, 2017), https://www.cms.gov/newsroom/press-releases/cms-finalizes-changes-comprehensive-care-joint-replacement-model-cancels-episode-payment-models-and. And CMS simultaneously chose to cancel two other models—the Episode Payment Models and the Cardiac Rehabilitation Incentive Payment Model—that it had originally proposed making mandatory. *Id.* CMS explained that "[m]oving forward," it expected "to increase opportunities for providers to participate in voluntary initiatives rather than large mandatory bundled payment models." *Id.*

88. In addition, the MFN Rule does not address "a defined population for which there are deficits in care." 42 U.S.C. § 1315a(b)(2)(A). Far from focusing on "a defined population," the Rule targets the *entire* population of patients who will receive Medicare Part B drugs covered by the Rule. *See* 85 Fed. Reg. at 76,183. Nor does the MFN Rule identify any specific "deficits in care" that lead to either "poor clinical outcomes or potentially avoidable expenditures" for that broad population. 42 U.S.C. § 1315a(b)(2)(A). Instead, the model is simply aimed at reducing Medicare Part B costs generally.

89. Furthermore, the MFN Rule by design lacks *any* control group, which would be necessary for a true "test." *See* 85 Fed. Reg. at 76,232 (acknowledging that because the MFN Rule is "a nationwide, mandatory model," it lacks "an independent comparison group"). CMS has previously recognized that "the use of a comparison group not exposed to the intervention improves our ability to make causal inferences." RO and ETC Models, 85 Fed. Reg. at 61,140. CMS further acknowledges that a regime that controls pricing for the overwhelming majority of Medicare Part B drug expenditures made by the overwhelming majority of providers and suppliers will likely affect the few providers and suppliers *outside* of the regime, by reducing the average sales prices that ordinarily determine Medicare Part B drug payments. *See id.* at 76,229 ("[D]uring

the MFN [Rule], manufacturers' [average sales prices] for MFN [Rule] drugs could be higher or lower than they might be absent the [Rule] . . . ."); Advance Notice, 83 Fed. Reg. at 54,560. As a result, the MFN Rule may affect beneficiary care in those few settings outside of the Rule's formal scope, making changes in the quality of care resulting from the Rule nearly impossible to isolate and skewing CMS's "ability to make causal inferences." CMS admitted this serious methodological deficiency when it observed, even in conjunction with the abandoned IPI proposal, that "we may experience evaluation challenges with the comparison group[s] . . . not selected." *Id.* Not only did CMS refuse to correct this flaw by first experimenting with MFN pricing on a smaller scale, but it doubled down on the error, dramatically expanding the scope and duration of the rule from its earlier proposal to include practically all providers and suppliers along with a much higher percentage of Medicare Part B drug spending over seven years. Indeed, CMS confirmed that the MFN Rule had never been intended as a "test" at all when it justified that expansion by explaining that "a nationwide model geographic area allows all eligible beneficiaries . . . to benefit from the cost-sharing reductions under" the MFN Rule. 85 Fed. Reg. at 76,188.

90. The MFN Rule also turns Section 1115A's two-phase framework on its head. The statute requires that before a model can be "expanded" nationwide in phase II, it must first be "tested" on a small scale in phase I; evaluated by the Secretary; certified by the CMS Chief Actuary; and then subject to further determinations by the Secretary. 42 U.S.C. § 1315a(b)(4), (c). But the MFN Rule starts out as a broadly applicable rule that, because of the lack of a control group, cannot ever be meaningfully evaluated. If CMS can launch such a large-scale model under the "testing" phase, then it can circumvent the various congressionally established guardrails with respect to an expansion. But Section 1115A requires that the testing phase be distinct from the

expansion phase, including in scope, in order to give meaning to the two-phase process that the statute contemplates.

91. CMS's admission that the MFN Rule will lead to a massive reduction in the availability of covered Part B drugs further reinforces how far the Rule falls outside of CMS's statutory authority. Section 1115A directs the Secretary to test models "while preserving or enhancing the quality of care" for Medicare beneficiaries. 42 U.S.C. § 1315a(b)(2)(A). Having conceded that access to care will evaporate for nearly 20% of today's Medicare Part B covered drug availability, *see* MFN Rule, 85 Fed. Reg. at 76,237 tbl.11, CMS cannot now claim that this model will "preserve"—much less "enhance"—the quality of care for Medicare beneficiaries. Nor does the Rule honor Congress's exhortation that nothing in the provisions of the Affordable Care Act "shall result in a reduction of guaranteed benefits under" Medicare. Affordable Care Act, Pub. L. No. 111-148, § 3601(a), 124 Stat. 119, 538 (2010) (codified at 42 U.S.C. § 1395 note).

92. Section 1115A's grant of authority must also be read in light of the rest of the statutory scheme, including the set of incentives that Congress has carefully devised over many decades to encourage pharmaceutical innovation. Congress has repeatedly struck a different balance between access and innovation than many of the foreign nations included in the MFN basket—as is clear in Medicare Part B, the Affordable Care Act, the patent laws, and elsewhere. Section 1115A must be interpreted in that context; as the Supreme Court has long stressed, "where the legislation dealing with a particular subject consists of a system of related general provisions indicative of a settled policy, new enactments of a fragmentary nature on that subject are to be taken as intended to fit into the existing system and to be carried into effect conformably to it." *United States v. Jefferson Elec. Mfg. Co.*, 291 U.S. 386, 396 (1934).

93. CMS's contrary interpretation of the word "test" would grant it virtually unlimited power to revise the Medicare program however it pleases, especially combined with CMMI's waiver authority. *See Merck & Co. v. U.S. Dep't of Health & Hum. Servs.*, 962 F.3d 531, 541 (D.C. Cir. 2020) ("[T]he breadth of the Secretary's asserted authority is measured not only by the specific application at issue, but also by the implications of the authority claimed." (citation omitted)). During phase I, the Secretary may waive certain otherwise-applicable statutory requirements—including all those found in the Medicare statute—"as may be necessary solely for purposes of" the test. 42 U.S.C. § 1315a(d)(1). If CMS were right that Section 1115A authorizes it to launch large-scale, nationwide models while waiving as much of the Medicare statute as it wishes, then it is hard to see what could stop CMS from simply replacing the Medicare program wholesale.

94. Such vast authority would also raise several serious constitutional concerns, underscoring that Section 1115A's grant of authority is narrow. In addition to the problems associated with the Constitution's bicameralism-and-presentment requirement, *see infra* ¶¶ 100–108, and its bar on the delegation of legislative power, *see infra* ¶¶ 109–113, the MFN Rule arrogates to the Executive Branch Congress's exclusive authority under the Patent Clause and the Foreign Commerce Clause.

95. In effect, the MFN Rule imports foreign patent law into the United States, allowing foreign governments' judgments about the proper balance between innovation and price to supersede the balance struck by Congress pursuant to its exclusive authority under the Constitution. *See* U.S. Const. art. I, § 8, cl. 8. The effect is particularly egregious because the MFN Rule goes out of its way to exclude drugs that face competition from generic drugs—irrespective of whether those excluded drugs are more expensive or represent greater shares of

Medicare spending than the drugs that the Rule covers. *See* 85 Fed. Reg. at 76,188–89. As a result, the MFN Rule's applicability to a drug is, by design, tied to whether patent rights for the drug have expired. Yet nothing in Section 1115A gives CMS the authority to deprive pharmaceutical manufacturers of the economic benefits provided to them under federal patent law and supplemental legislation.

96. Similarly, the MFN Rule is an acknowledged attempt by the Administration and HHS to usurp Congress's "exclusive and plenary" power under the Foreign Commerce Clause by raising prices abroad. *Bd. of Trustees of Univ. of Ill. v. United States*, 289 U.S. 48, 56 (1933). Under the MFN Rule, CMS expects manufacturers "to devote considerable resources to" "altering the availability and terms of their international prices," 85 Fed. Reg. at 76,236, with the "likely result" of "increase[ing] observed prices in other countries," *id.* at 76,241. Or, as the President put it, "what's going to happen is their number will go up, our number will come very substantially down, and we'll all agree" on a price in the middle. July 2020 White House Remarks, *supra*. Secretary Azar agreed, explaining that the MFN Rule would "end foreign freeriding" by forcing "foreign socialist systems . . . to bear their fair share" of research and development costs. *Id.*

97. The Supreme Court has, under the analogous Interstate Commerce Clause, struck down similar attempts to control prices extraterritorially. Given Congress's constitutional authority over interstate commerce, a state "may not adopt legislation that has the practical effect of establishing 'a scale of prices for use in other states.'" *Healy v. Beer Inst., Inc.*, 491 U.S. 324, 336 (1989) (citation omitted). The same principle applies here: Only Congress has authority "[t]o regulate Commerce with foreign Nations," U.S. Const. art.1, § 8, cl. 3, and yet nothing in Section 1115A suggests that Congress delegated any part of its exclusive and plenary authority to CMS. Indeed, the MFN Rule is even *more* constitutionally problematic because it facially discriminates

against foreign commerce by applying solely to pharmaceutical manufacturers who sell drugs abroad but not to those who sell drugs exclusively in the United States. *See Healy*, 491 U.S. at 341.

98. There is no indication whatsoever that Congress intended to delegate to CMS this kind of vast authority over Medicare, federal patent law, and foreign commerce. But if Congress *had* intended such a delegation, it certainly would not have executed it through a short statutory provision authorizing an obscure sub-agency to test "innovative payment and service delivery models." *Id.* § 1315a(a)(1); *see Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress, we have held, does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

99. President Trump thus had it exactly right when he declared that "we're doing things that nobody thought could be done." July 2020 White House Remarks, *supra*.

The MFN Rule Violates the Presentment Clause

100. The Presentment Clause requires that "[e]very Bill which shall have passed the House of Representatives and the Senate, shall, before it become[s] a Law, be presented to the President of the United States; If he approve[s] he shall sign it, but if not he shall return it." U.S. Const. art. I, § 7, cl. 2. By contrast, "[t]here 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). In the face of that constitutional silence, the Supreme Court has interpreted the Presentment Clause to bar "unilateral [Executive] action that either repeals or amends parts of duly enacted statutes." *Id.* at 439.

101. Courts can determine whether the Executive Branch has enacted, repealed, or amended a statute by looking to the executive action's "legal and practical effect." *Id.* at 438.

102. For example, in *Clinton v. City of New York*, the Supreme Court reasoned that the President's cancellations of two budgetary provisions under the Line Item Veto Act had the "legal . . . effect" of amending the relevant statutes because the cancellations prevented the two provisions "from having legal force." *Id.* (citation omitted). Even though the "canceled provisions" still had "some continuing financial effect on the Government," the Court found that that effect was not relevant because the President had made the provisions "entirely inoperative as to appellees." *Id.* at 441.

103. Similarly, the Court found that the cancellations also had the "practical effect" of amending or partially repealing the relevant statutes. The Court reasoned that the President's cancellations were not in response to a contingent event that Congress had established as the trigger for the exercise of a statutory suspension power. *See id.* at 443–44. If they had been, the President would have been "executing the policy that Congress had embodied in the statute." *Id.* at 144. Instead, the President had effectively "reject[ed] the policy judgment made by Congress and rel[ied] on his own policy judgment." *Id.* The cancellations were thus "the functional equivalent of partial repeals of Acts of Congress." *Id.* Stepping back, the Court observed that "[w]hat has emerged in these cases from the President's exercise of his statutory cancellation powers . . . are truncated versions of two bills that passed both Houses of Congress. They are not the product of the 'finely wrought' procedure that the Framers designed" as the sole means for making law. *Id.* at 440.

104. Section 1115A, as noted, allows the Secretary to waive *any* provision of the Medicare statute, as well as other important provisions of the Social Security Act, in order to implement his desired models in phase I testing. *See* 42 U.S.C. § 1315a(d)(1). CMS has gone beyond its authority, however, by not just *suspending* the enforcement of the statutory drug pricing

scheme, but actually *replacing* it with an entirely new program of CMS's own making. That sweeping effort violates the Presentment Clause as interpreted by the Supreme Court. That Section 1115A's waiver authority was itself granted pursuant to a law passed in accordance with the Presentment Clause is immaterial. Even if Congress anticipated that the Executive Branch would use that waiver authority to override its laws, "Congress cannot alter the procedures set out in Article I, § 7, without amending the Constitution." *City of New York*, 524 U.S. at 446 (footnote omitted).

105. CMS's waivers in the MFN Rule have the "legal . . . effect" of amending the Medicare statutes in significant ways, including by repealing and replacing the average sales price methodology. Under the Rule's mandate, those provisions no longer have any "legal force or effect" for those providers covered by the Rule. CMS cannot argue in response that the provisions remain operative for other entities; whatever "continuing . . . effect" they have elsewhere, the waived provisions are "entirely inoperative" as to the physician practices and hospital outpatient departments covered by the Rule. *City of New York*, 524 U.S. at 441. In fact, CMS's actions are more patently unconstitutional than even the cancellations considered in *City of New York*. In that case, the President amended statutes solely by rendering two provisions inoperative. Here, not only has CMS rendered multiple provisions inoperative, but it has also replaced them with new provisions that create an entirely new legal system, with new legal obligations on third parties, that is nothing like what Congress contemplated.

106. CMS's waivers also have the "practical effect" of amending statutes that were duly enacted pursuant to the Presentment Clause. Each of the MFN Rule's waivers demolishes a cornerstone of the "finely wrought" Medicare Part B drug pricing system that Congress established. The MFN Rule is expressly framed as a rejection of the statutory scheme designed

by Congress, which CMS faults for allegedly "incentivizing avoidable costs and causing greater utilization of higher priced drugs." 85 Fed. Reg. at 76,235; *id.* at 76,180 ("Medicare pays substantially more" than other countries do "because [of] . . . the methodology in section 1847A of the Act."). And CMS did not overhaul Medicare Part B in response to a contingent, triggering event; rather, it simply "reject[ed] the policy judgment made by Congress" and instead "rel[ied] on [its] own policy judgment" to import the command pricing some foreign countries preferred. *City of New York*, 524 U.S. at 444; *see* MFN Executive Order, 85 Fed. Reg. at 59,649 (describing as the new "policy of the United States" that Medicare "should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price"). "It is not within the purview of the Agency, however—or of the courts for that matter—to alter, frustrate, or subvert congressional policy." *Miss. Poultry Ass'n, Inc. v. Madigan*, 992 F.2d 1359, 1365 (5th Cir.), *amended*, 9 F.3d 1113 (5th Cir. 1993), *aff'd on reh'g en banc*, 31 F.3d 293 (5th Cir. 1994). What has emerged from CMS's use of Section 1115A's waiver authority in the MFN Rule is not just a "truncated" version of the Medicare program, *City of New York*, 524 U.S. at 440, but an entirely different program altogether.

107. CMS's assertion of authority to rewrite the Medicare statute under Section 1115A is particularly indefensible: Section 1115A was added by the Affordable Care Act, which the Administration is currently urging the Supreme Court to strike down in its entirety. *See* Br. for the Federal Resp'ts at 13, 47, in *California v. Texas*, Nos. 19-840, 19-1019 (June 25, 2020). The Administration has not explained how its claim to unprecedentedly broad powers under Section 1115A—at the same time that it insists the provision is unenforceable under the Constitution—can be consistent with the President's responsibility to "take Care that the Laws be faithfully executed." U.S. Const. art. II, § 3, cl. 5.

108. Finally and in any event, the serious constitutional concerns raised by the MFN Rule's reliance on Section 1115A's waiver provision at a minimum affirm that CMS's authority under Section 1115A is narrow. *See Jennings v. Rodriguez*, 138 S. Ct. 830, 836 (2018).

The MFN Rule Violates the Non-Delegation Doctrine

109. Article I of the Constitution vests "[a]ll legislative Powers" in Congress, and the Supreme Court has held that Congress may not "abdicate or transfer to others the essential legislative functions with which it is thus vested." *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495, 529 (1935); *cf. INS v. Chadha*, 462 U.S. 919, 951 (1983) ("The Constitution sought to divide the delegated powers of the new federal government into three defined categories, legislative, executive and judicial, to assure, as nearly as possible, that each Branch of government would confine itself to its assigned responsibility.").

110. Congress runs afoul of this prohibition whenever it delegates expansive or significant policymaking authority to an administrative agency by statute without providing sufficiently clear guidelines for the agency to follow in using that power. Historically, courts have looked for "an intelligible principle" to guide the agency's exercise of authority. *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality op.) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)). Exactly how "intelligible" the principle must be depends on the delegation; "the degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Am. Trucking Ass'ns*, 531 U.S. at 475. Overall, delegations are permissible only "if Congress has made clear to the delegee 'the general policy' he must pursue and the 'boundaries of [his] authority.'" *Gundy*, 139 S. Ct. at 2129 (plurality op.) (quoting *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)).

111. If it were authorized by Section 1115A, the MFN Rule would result from an unconstitutional delegation of legislative power to the Executive Branch. Far from following any congressionally enacted "intelligible principle" to which the HHS Secretary was "directed to conform," *Gundy*, 139 S. Ct. at 2123 (plurality op.) (citation omitted), CMS used its purported authority to *repudiate* Congress's market-based approach to Medicare Part B drug pricing, the patent laws, and other legislation. The MFN Rule acknowledges as much, blaming the average sales price "methodology in section 1847A" for purportedly higher drug costs. 85 Fed. Reg. at 76,180. Indeed, the Administration has admitted that it is using Section 1115A's waiver authority not to execute Congress's "intelligible principle" but to override it with its own "policy." MFN Executive Order, 85 Fed. Reg. at 59,649. If Section 1115A allows the Administration to adopt and implement the MFN Rule, it means the provision provides CMS no intelligible principle to guide its decision-making process.

112. The President has admitted as much, saying that "we've been waiting for Congress to take action for many decades to reduce drug prices . . . [but] *I'm unwilling to wait any longer*." July 2020 White House Remarks, *supra* (emphasis added). Following the President's signing of the MFN Executive Order, the White House doubled down on that admission with a press release entitled "Congress Didn't Act on Prescription Drug Prices. So President Trump Did." *See Congress Didn't Act on Prescription Drug Prices. So President Trump Did.* (July 27, 2020), https://www.whitehouse.gov/articles/congress-didnt-act-on-prescription-drug-prices-so-president-trump-did; Nov. 2020 White House Remarks, *supra* ("[I]n the absence of any meaningful legislative support, this administration has delivered real, tangible results."). It is telling—and constitutionally fatal—that a "historic," "transformative," and "revolutionary" effort to "completely restructure the prescription drug market, in terms of pricing and everything else," July

2020 White House Remarks, *supra*; *Remarks by President Trump on Prescription Drug Prices*, (Oct. 25, 2018), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-prescription-drug-prices (2018 White House Remarks), is being designed, debated, and enacted not in the halls of Congress, but in the administrative offices of the Executive Branch.

113. Once again, the serious non-delegation concerns raised by the MFN Rule affirm, at minimum, that CMS's authority under Section 1115A is narrow. *See Jennings*, 138 S. Ct. at 836.

The President Unlawfully Directed the Secretary to Promulgate the MFN Rule

114. The Constitution gives Congress exclusive power to establish departments and agencies in the Executive Branch and to define the duties and functions of the officers who administer them. *See* U.S. Const. art. I, § 8, cl. 18. If Congress uses its power to entrust certain decision-making authority to the discretion of a particular officer, the President may not usurp that authority by directing how the officer must exercise it. To the contrary, officers whose duties are "prescribed by law" are "bound to execute them according to [their] *own* judgment," and "[t]hat judgment cannot lawfully be controlled by any other person"—not even the President. *United States ex rel. Stokes v. Kendall*, 26 F. Cas. 702, 752 (C.C.D.C. 1837), *aff'd*, 37 U.S. 524 (1838). Centuries of Executive Branch opinions have affirmed this rule, *see, e.g.*, Proposed Executive Order Entitled "Federal Regulation," 5 Op. O.L.C. 59, 62 (1981); Appeal of Illinois to the President, 11 Op. Att'y Gen. 14, 16–17 (1864); The President and Accounting Officers, 1 Op. Att'y Gen. 624, 625–26 (1823), which is also widely accepted among scholars, *see* Richard H. Pildes & Cass R. Sunstein, *Reinventing the Regulatory State*, 62 U. Chi. L. Rev. 1, 25 (1995). For that reason, Presidents have previously taken great care to frame their executive orders in ways that avoid directing subordinate officers to exercise their delegated authority in a particular way.

115. Besides the constitutional separation of powers, this also reflects fundamental principles of administrative law. Decision-makers in rulemaking proceedings must exercise their discretion in view of appropriate statutory considerations and public input, and they "violate the Due Process Clause and must be disqualified when they act with an 'unalterably closed mind' and are 'unwilling or unable' to rationally consider arguments." *Air Transp. Ass'n of Am., Inc. v. Nat'l Mediation Bd.*, 663 F.3d 476, 487 (D.C. Cir. 2011) (citation omitted); *see Ass'n of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170 (D.C. Cir. 1979) ("The 'unalterably closed mind' test is necessary to permit rulemakers to carry out their proper policy-based functions while disqualifying those unable to consider [public input] meaningfully . . . ."). If an executive officer has been directly ordered to promulgate a rule by the President, obviously that officer can no longer consider other alternatives rationally or public input meaningfully. And because the President is not subject to the notice-and-comment rulemaking process or any other APA-mandated procedures, *see Franklin v. Massachusetts*, 505 U.S. 788, 800–01 (1992), allowing the President to direct officers to issue rules would legitimize an end-run around the APA's procedural requirements.

116. Similarly, "[i]t is a 'foundational principle of administrative law' that judicial review of agency action is limited to 'the grounds that the agency invoked when it took the action.'" *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1907 (2020) (citation omitted); *see SEC v. Chenery Corp.*, 318 U.S. 80, 87–88 (1943). But meaningful judicial review of an officer's decision is not possible when the President has *directed* the officer to reach a particular conclusion: Either the court would have to review something *other than* the true ground for the officer's action (the presidential directive), or the court would be forced to conclude that the officer's decision depended on a factor (presidential command) neither authorized nor

contemplated by the statute. *See Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) ("[A]n agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider . . . ."). Either way, the officer's action would be unlawful.

117. Here, Congress was clear throughout Section 1115A that it was expressly delegating discretion over CMMI's testing authority solely to the HHS Secretary. Section 1115A requires "*[t]he Secretary* [to] select models to be tested from models where *the Secretary* determines that there is evidence that the model addresses a defined population." 42 U.S.C. § 1315a(b)(2)(A) (emphases added). It instructs "*[t]he Secretary* [to] focus on models" meeting certain requirements, *id.* (emphasis added), and gives "*the Secretary*" the power to choose the "geographic areas" in which testing occurs, *id.* § 1315a(a)(5) (emphasis added). It is "*[t]he Secretary*" who must "ensure that the [CMMI] is carrying out the duties described in this section," *id.* § 1315a(a)(2) (emphasis added), and "*[t]he Secretary*" who "shall conduct an evaluation of each model tested," *id.* § 1315a(b)(4)(A) (emphasis added), and "terminate or modify [its] design and implementation," *id.* § 1315a(b)(3)(B). All told, Section 1115A refers to "the Secretary" over twenty times. It mentions "the President" not once.

118. By contrast, the Affordable Care Act elsewhere often delegates decision-making authority directly to the President. *See, e.g.*, 42 U.S.C. § 280j note; *id.* § 300u-6 note; *id.* § 1397h(c)(5). Congress carefully distinguished among different officers of the Executive Branch when it conferred discretionary authority under the Act, and in Section 1115A it expressly insisted that the HHS Secretary, not the President, decide which "innovative payment and service delivery models" to test. 42 U.S.C. § 1315a(a)(1).

119. The President thus violated the text of the statute when he ordered the Secretary to use his authority under Section 1115A to promulgate the MFN Rule. The MFN Executive Order expressly directed the HHS Secretary "to implement his rulemaking plan to test a payment model pursuant to which Medicare would pay . . . no more than the most-favored-nation price." 85 Fed. Reg. at 59,649. In so doing, the order impermissibly overrode the Secretary's discretion about what type of payment model to test and, indeed, whether to test any payment model at all. Nor can there be any doubt that the MFN Rule was the product of the President's directive: The Secretary admitted as much when he acknowledged in the rule itself that CMS was "implement[ing] the MFN Model described in this" rule "*[i]n response to the September 13, 2020 Executive Order*." 85 Fed. Reg. at 76,182 (emphasis added).

The MFN Rule Violates the APA's Procedural Safeguards

120. The APA requires agencies to publish notice of all "proposed rule making" in the Federal Register, 5 U.S.C. § 553(b), and to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," *id.* § 553(c). The APA also generally requires "publication . . . of a substantive rule [to] be made not less than 30 days before its effective date." *Id.* § 553(d).

121. Such requirements "are not mere formalities" but rather "are basic to our system of administrative law." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2d Cir. 2018). They serve "the public interest by providing a forum for the robust debate of competing and frequently complicated policy considerations having far-reaching implications and, in so doing, foster reasoned decisionmaking." *Id.* They also "ensure[] fairness to affected parties[] and provide[] a well-developed record that enhances the quality of judicial review." *Sprint Corp. v. FCC*, 315 F.3d 369, 373 (D.C. Cir. 2003) (citation and quotation marks omitted).

122. Congress has specifically stressed the importance of a robust period of notice and comment for considering changes to the Medicare system. The Supreme Court has explained that "Medicare touches the lives of nearly all Americans . . . as the largest federal program after Social Security." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Even "minor changes" to the way the program is administered "can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." *Id.* at 1816. "Recognizing this reality," *id.* at 1808, Congress doubled the standard 30-day comment period under the APA for any establishment of or change to a "substantive legal standard" affecting the payment for services under Medicare. *See* 42 U.S.C. § 1395hh(a)(2), (b)(1); *see also id.* § 1395hh(e)(1)(B)(i) (providing for a 30-day delay in effective date).

123. CMS admits that it failed to comply with the required APA procedures. Instead, it issued the MFN Rule as an interim final rule, benefitting from neither notice nor comment, with an effective date of November 27, 2020, the day of the Rule's publication in the Federal Register and only one week after it became public. 85 Fed. Reg. at 76,180.

124. CMS justifies its disregard of the APA's requirements by invoking the "good cause" exception, which allows agencies to dispense with notice-and-comment procedures only "when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B); *see id.* § 553(d)(3); 42 U.S.C. § 1395hh(b)(2)(C); *id.* § 1395hh(e)(1)(B)(ii). CMS claims that it faces such an emergency in this case because the problem of "high drug prices" has been "rapidly exacerbated" by the COVID-19 pandemic. MFN Rule, 85 Fed. Reg. at 76,249. CMS concludes that the "new surge

in COVID-19 cases . . . may lead to additional hardship and requires immediate action" to address "the particularly acute need for affordable Medicare Part B drugs." *Id.*

125. Contrary to CMS's claims, however, the "good cause" exception is not an "escape clause[]" to be "arbitrarily utilized at the agency's whim." *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012) (citation omitted). Instead, the exception "is to be narrowly construed and only reluctantly countenanced." *United States v. Ross*, 848 F.3d 1129, 1132 (D.C. Cir. 2017) (quotation marks and citation omitted). "[C]ircumstances justifying reliance on this exception are 'indeed rare' and will be accepted only after the court has 'examine[d] closely proffered rationales justifying the elimination of public procedures.'" *Council of the S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 580 (D.C. Cir. 1981) (citation omitted). Courts therefore generally restrict agencies' use of the "good cause" exception "to emergency situations," *Mack Trucks*, 682 F.3d at 93 (citation omitted), such as where a "delay would imminently threaten life or physical property" or risk "fiscal calamity," *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706–07 (D.C. Cir. 2014).

126. Here, CMS has not demonstrated anything approaching an "emergency situation." In fact, its lengthy delays belie the very notion. Secretary Azar has admitted that the MFN Rule was first discussed in *January 2018*—almost three years ago. *See* Nov. 2020 White House Remarks, *supra*; *see also Chamber of Commerce of the U.S. v. Dep't of Homeland Sec.*, No. 20-CV-07331, 2020 WL 7043877, at *8 (N.D. Cal. Dec. 1, 2020) (*Chamber of Commerce* Order) (rejecting pandemic as justification for proceeding by interim final rule and stating that "even if the problems [the Administration] purport[s] to solve with the Rule[] may have been exacerbated by the COVID-19 pandemic, [the Administration] do[es] not suggest they are new problems"). CMS first solicited comments on the IPI Advance Notice shortly before the midterm elections in

October 2018. It then failed to act on those comments at any point in the next *two years* by proceeding to issue a notice of proposed rulemaking as the APA requires.

127. In July 2019, long before the pandemic began, President Trump declared that the administration "very shortly" would be announcing a "favored nations" drug-pricing scheme "in the form of an executive order." *Remarks by President Trump Before Marine One Departure* (July 5, 2019), https://www.whitehouse.gov/briefings-statements/remarks-president-trump-marine-one-departure-51. The Administration did nothing for more than a year, however. On July 24, 2020—six months *after* Secretary Azar designated COVID-19 a Public Health Emergency, *see* Press Release, U.S. Dep't of Health & Hum. Servs., *Secretary Azar Declares Public Health Emergency for United States for 2019 Novel Coronavirus* (Jan. 31, 2020), https://www.hhs.gov/about/news/2020/01/31/secretary-azar-declares-public-health-emergency-us-2019-novel-coronavirus.html—President Trump finally announced an executive order that would require the Secretary to take steps to implement the MFN Rule. But it was still not until November 27, 2020—ten months after Secretary Azar's declaration of the COVID-19 public health emergency, and over *two years after* the issuance of the Advance Notice—that the Trump Administration finally issued the MFN Rule. During that time, the Administration issued several proposed rules unrelated to COVID-19, at least one of which expressly requested public comment on the impact of COVID-19. *See Chamber of Commerce* Order, *supra*, at *9.

128. Given its relaxed pace in issuing the MFN Rule, CMS cannot now demonstrate any sudden "emergency" that excuses the Administration's circumvention of the APA's notice-and-comment procedures. *See id.* at *8 (noting that delays of six months or more "have precluded reliance on the good cause exception"). As another district court recently stressed, "[t]he COVID-

19 pandemic is an event beyond [the Administration's] control, yet it was within [the Administration's] control to take action earlier than [it] did." *Id.* at *9.

129. CMS has also not explained how or why the MFN Rule will resolve the "emergency" that it claims to identify. Statements about the effect of COVID-19 on American public health generally do not demonstrate a dire emergency with respect to the specific Medicare Part B beneficiaries that the MFN Rule purports to affect. *See id.* at *10. CMS suggests that the Rule "will provide immediate relief to Medicare beneficiaries through reduced copays for MFN drugs due to lower drug payments." 85 Fed. Reg. at 76,249. That suggestion is overstated, though, because as the MFN Rule itself acknowledges, *see* 85 Fed. Reg. at 76,183 n.22, the vast majority of Medicare beneficiaries already have supplemental coverage to help cover out-of-pocket expenses. *See* Milena Sullivan et al., *International Price Index Model's Impact on Patients and Providers*, Avalere (Dec. 27, 2018), https://bit.ly/36bhym0 (estimating 87–90% of Medicare fee-for-service beneficiaries are enrolled in supplemental coverage to help defray out-of-pocket costs of Part B medicines).

130. In any event, if the objective were simply to reduce copays, CMS could have issued any number of other regulations that would have done that more directly and effectively, rather than remaking most of the Medicare Part B reimbursement system from scratch. Several of PhRMA's members, for example, have expanded their patient assistance programs to help patients afford and access their treatments in light of the pandemic. It simply is not credible that the *seven-year* MFN Rule "test" was designed to meet the emergency that CMS identifies. And indeed there is no suggestion that the MFN Rule is "intended to be a temporary solution until the 'emergency situation has been eased by [its] promulgation.'" *Chamber of Commerce* Order, *supra*, at *10 (citation omitted). If anything, the MFN Rule is likely to *exacerbate* the problem by substantially

slashing the reimbursement available to healthcare providers and suppliers at a time when they can least afford it.

131. Furthermore, CMS acknowledges that the MFN Rule may "impact [the] rapid, widespread availability" of drugs in the United States, including those used "to treat patients with suspected or confirmed COVID-19." 85 Fed. Reg. at 76,191. For that reason, it has exempted such drugs from the scope of the MFN Rule. The upshot is that CMS, allegedly in order to respond to the COVID-19 emergency, is issuing a rule that specifically *exempts* treatments for COVID-19.

The MFN Rule Irreparably Harms Patients, Providers, Manufacturers, and the Public

132. If the MFN Rule goes into effect, it will irreparably harm patients, providers, and pharmaceutical manufacturers in several independent ways; and it will significantly impair the broader public interest in innovation and discovery in the pharmaceutical field.

133. First, the MFN Rule will irreparably harm patient health outcomes in both the short and long terms. In the short term, "there is a public interest in . . . patients obtaining needed medications in a timely manner." *Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 230 (D.D.C. 2012). As already noted, CMS has admitted that the MFN Rule will result in shortages of drugs and delays in access—foreseeing that patients will "experience access to care impacts by . . . having to travel to seek care from an excluded provider, receiving an alternative therapy that may have lower efficacy or greater risks, or postponing or forgoing treatment." 85 Fed. Reg. at 76,244; *see supra* ¶ 73. Those harms will be felt acutely by the most vulnerable patients, who rely on the drugs subject to the MFN scheme to manage complex diseases like cancer and autoimmune disorders. These patients often require MFN-covered drugs because their conditions are unresponsive to, or difficult to treat with, other treatment modalities. Impeding access to these medications will immediately risk disease flares and progression, both of which may cause

irreparable damage. Nor will the harm be limited to Medicare Part B patients. If providers are subjected to untenable reimbursement cuts that jeopardize the economic viability of their practices, privately insured patients who rely on those providers for access to essential treatments will also experience care delays and disruption.

134. Consider a few examples. Pure Infusion Suites, a member of the National Infusion Center Association, is an infusion provider serving patients in Montana, Idaho, and Colorado. It offers affordable infusion therapies in safe, comfortable, non-hospital settings; but it will be forced to reduce or discontinue services to Part B patients when the MFN Rule's reimbursement rates take effect. Likewise, Utah-based Wasatch Infusion provides IV therapy for patients suffering from immune disorders and other conditions. The MFN Rule poses a significant and immediate threat to Wasatch's ability to continue providing this care in Utah communities.

135. Patients will also suffer as providers are forced to substitute less-effective drugs that are not subject to MFN pricing (and therefore have reimbursement rates that do not require the care provider to lose money on every treatment). *See* 85 Fed. Reg. at 76,236–37. Forcing patients to switch to less-effective medication for reasons unrelated to health or safety unnecessarily puts American lives at immediate risk. Indeed, avoiding these harmful effects is precisely why CMS carves out certain types of medicines from the Rule, including COVID-19 treatments and vaccines. *See id.* at 76,191.

136. Such harms are not hard to predict, considering that CMS has based the MFN Rule's reimbursement rates on prices in countries that already suffer from low access to and delays in the availability of new medicines. New medicines covered under Part B are widely available in the United States, but only 26% to 66% of those same medicines are available in the MFN Rule's reference countries; even then, their availability relative to the United States can be delayed by

over two years. *See Availability of Part B Medicines*, *supra*. These threats to access and availability are particularly harmful given that Part B drugs are often used to treat life-threatening conditions such as cancer, where even a short delay can meaningfully reduce the chance for survival.

137. In the long term, the public interest favors "promoting industry incentives to research and develop new drug treatments." *Mylan Lab'ys, Inc. v. Leavitt*, 484 F. Supp. 2d 109, 124 (D.D.C. 2007). But with less revenue under the MFN Rule, pharmaceutical manufacturers will have fewer funds to invest in new drugs. They will also have to allocate existing funds differently. Generally speaking, manufacturers make allocation decisions after analyzing the risks and benefits of directing resources to certain therapeutic areas or products. The MFN Rule substantially changes those incentives in a way that will decrease overall investment in Part B drugs, even in promising areas such as oncology. These issues are particularly acute for PhRMA members and other manufacturers whose current and pipeline portfolios include a large percentage of physician-administered drugs that fall within Part B. The inevitable consequences for patients will be severe.

138. Some numbers help illustrate the scale of these harms. CMS estimates that over seven years, the MFN Rule will produce $85.5 billion of savings for Medicare, along with $28.5 billion in savings for beneficiaries. 85 Fed. Reg. at 76,181. But CMS explained that these savings come in substantial part from "beneficiaries *not* accessing their drugs through the Medicare benefit, along with the associated lost utilization" of doing without needed prescriptions and treatments. *Id.* (emphasis added). The savings estimates also fail to account for additional costs of this forgone care, *id.*, but the Administration has provided an appraisal elsewhere: President Trump's Council of Economic Advisers scored a legislative proposal to implement a form of

reference pricing, H.R. 3, and concluded that it would cost the country anywhere from $375 billion to $1 trillion *per year* in health outcomes. *See* 2019 CEA Analysis, *supra*. And the MFN Rule, which imports price controls from almost four times as many "comparable" countries as H.R. 3 (22 as opposed to six), doubtless will be even more devastating to health outcomes.

139. Second, the Rule will inflict devastating economic losses on providers and pharmaceutical manufacturers and create substantial risks to patient care and health. Many of the members of the National Infusion Center Association, for example, are small businesses that rely on Medicare reimbursements to cover the cost of medications and thus cannot absorb the additional costs associated with the MFN Rule's reimbursement rates. These providers are the nation's lowest-cost care setting for medications that millions of Medicare beneficiaries rely on for efficient and cost-effective disease management, and a reduction in their reimbursement rates will pose a serious threat to their businesses. Providers will have no choice but to cease treating Part B patients, resulting in increased medical costs, emergency medical procedures, and in-patient hospital services for those patients. Members of the Association of Community Cancer Centers will likewise face serious costs and administrative burdens that will require them to limit services or send patients to other, less convenient locations for care. In some cases, the increased costs will be sufficient to put them out of business—as they are forced by the MFN Rule to absorb losses for drugs that are purchased on the market but reimbursable only at the below-market MFN Rule prices. *See supra* ¶ 71. CMS suggests that providers can avoid these harms by simply purchasing covered drugs at lower prices, but that ignores the existence of pre-negotiated contracts with wholesalers and Group Purchasing Organizations that cannot easily be revised, and that certainly cannot be renegotiated before the MFN Rule begins applying to reimbursement rates on January 1, 2021.

140. Members of the Association of Community Cancer Centers such as Maryland Oncology Hematology, a physician group practice serving most of Maryland, anticipate suffering significant revenue losses under the MFN Rule. For example, one of the drugs that would be reimbursed at MFN prices under the Rule is rituximab, an immunotherapy commonly used to treat Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia, among other conditions. In 2018, more than 70,000 Medicare beneficiaries received this drug. *See* Medicare Part B Drug Dashboard, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartB. Under the MFN Rule, reimbursement for a dose of rituximab for an average Non-Hodgkin's Lymphoma patient would be cut by $1,158, a 17.9% reduction from the average sales price-based reimbursement rate for January 1, 2021. *See* MFN Rule, 85 Fed. Reg. at 76,211 (Table 6); CMS January 2021 ASP Pricing File, https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/2021-asp-drug-pricing-files. These revenue losses will force providers to make painful cuts across departments, negatively affecting the services that can be made available to patients. These harms will be particularly hard-felt by providers operating in rural areas and those operating on already-thin margins, made even worse by increased operating costs and reductions in oncology patient volume during the COVID-19 pandemic. Providers will have to make difficult decisions about patient care, while cutting services to patients with significant healthcare needs.

141. PhRMA members will be adversely affected by the MFN Rule because they sell 35 of the 50 drugs that are initially subject to MFN pricing and that will be reimbursed at rates well below the current Medicare Part B reimbursement rate. *See* MFN Rule, 85 Fed. Reg. at 76,194 (Table 2). PhRMA's members will lose substantial amounts of revenue; forgo unquantifiable investment and research opportunities; be forced to alter their business arrangements, including

through potential layoffs; and confront a fundamentally unfair competitive landscape, where manufacturers of covered drugs are forced to adopt below-market prices while manufacturers of alternative treatments are not. *See supra* ¶¶ 42–51. CMS presumes that pharmaceutical manufacturers will avoid many of these harms by negotiating higher prices abroad, but in reality manufacturers have little to no power over foreign prices precisely because so many MFN countries utilize non-negotiable price controls. Nor can manufacturers make up the loss in revenue in other market sectors, such as the commercial market, because the MFN Rule includes penalties to prevent manufacturers from doing so. *See* 85 Fed. Reg. at 76,213–15.

142. "[E]conomic damages may constitute irreparable harm where no remedy is available at the conclusion of litigation." *Mountain Valley Pipeline, LLC v. W. Pocahontas Props. Ltd. P'ship*, 918 F.3d 353, 366 (4th Cir. 2019); *see Philip Morris USA Inc. v. Scott*, 561 U.S. 1301, 1304 (2010) (Scalia, J., in chambers); *Multi-Channel TV Cable Co. v. Charlottesville Quality Cable Operating Co.*, 22 F.3d 546, 551 (4th Cir. 1994) ("Generally, 'irreparable injury is suffered when monetary damages are difficult to ascertain or are inadequate.'" (citation omitted)). Here, that is true three times over. The APA does not waive the federal government's sovereign immunity for damages claims, so providers and pharmaceutical manufacturers will be unable to recover any economic losses caused by the Rule's revisions to Congress's reimbursement scheme. *See Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, No. 20-CV-1630, 2020 WL 5232076, at *40 (D.D.C. Sept. 2, 2020); *Lawrence & Mem'l Hosp. v. Sebelius*, 986 F. Supp. 2d 124, 133 n.3 (D. Conn. 2013) (Medicare reimbursements). The losses at issue are also sufficiently large that, even apart from the sovereign immunity barrier, they qualify as irreparable harm in themselves. *Par Pharms., Inc. v. TWI Pharms., Inc.*, 2014 WL 3956024, at *3 (D. Md. Aug. 12, 2014). And finally, the loss of market share, jobs, innovations, and business opportunities

cannot be reversed or adequately recompensed through litigation. Each of these circumstances has been deemed sufficient to establish irreparable harm. *See Roche Diagnostics Corp. v. Med. Automation Sys., Inc.*, 646 F.3d 424, 427 (7th Cir. 2011); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1381 (Fed. Cir. 2006).

143. Third, the MFN Rule will also irreparably harm pharmaceutical manufacturers, patients, and providers by depriving them of their procedural right to notice and comment under the APA. The "depriv[ation] of the opportunity to offer comments" on a rule "may constitute irreparable injury while a rule promulgated in violation of [the APA] is in effect, provided that plaintiffs suffer some additional concrete harm as well." *E. Bay Sanctuary Covenant v. Trump*, 349 F. Supp. 3d 838, 865 (N.D. Cal. 2018), *aff'd*, 950 F.3d 1242 (9th Cir. 2020). In other words, so long as a prospective commenter has a cognizable interest "at stake," such as "fiscal interests," the "procedural injury" stemming from a notice-and-comment violation "may serve as a basis for a finding of irreparable harm." *California v. Health & Hum. Servs.*, 281 F. Supp. 3d 806, 829–30 (N.D. Cal. 2017), *aff'd in part, vacated in part on other grounds, remanded sub nom. California v. Azar*, 911 F.3d 558 (9th Cir. 2018). An affected party thus suffers irreparable harm where a rule improperly promulgated without notice and comment "will dramatically alter" a "complex and far-reaching regulatory regime" and the affected party has articulated "meaningful concerns." *Northern Mariana Islands v. United States*, 686 F. Supp. 2d 7, 17–18 (D.D.C. 2009).

144. Here, it would be an understatement to suggest that the MFN Rule—an overhaul of the Medicare Part B drug reimbursement system involving (at minimum) over $100 billion—"will dramatically alter" a "complex and far-reaching regulatory regime." It is even more of an understatement to suggest that Plaintiffs here have "meaningful concerns" about the manner in

which this unlawful usurpation of Congress's prerogatives is being rushed through and the harms it will cause to them and others.

145. Fourth, the MFN Rule will also irreparably harm pharmaceutical manufacturers, patients, and providers by depriving them of their constitutional rights. Courts recognize that "a prospective violation of a constitutional right constitutes irreparable injury for purposes of seeking equitable relief." *Karem v. Trump*, 960 F.3d 656, 667 (D.C. Cir. 2020) (cleaned up). Indeed, "[w]hen an alleged deprivation of a constitutional right is involved, . . . most courts hold that no further showing of irreparable injury is necessary." 11 A Charles Alan Wright et al., *Federal Practice & Procedure* § 2948.1 (3d ed. 2005) (footnote omitted). Here, the MFN Rule is unconstitutional on multiple levels—it violates the bicameralism-and-presentment requirement, improperly delegates legislative power to the Executive Branch, and encroaches on Congress's exclusive power over patents and foreign commerce.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The MFN Rule Was Issued Without Observance of Procedure Required by 5 U.S.C. § 553)

146. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

147. The APA provides that courts must "hold unlawful and set aside agency action" that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

148. The APA requires agencies to publish notice of all "proposed rule making" in the Federal Register, *id.* § 553(b), and to "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments," *id.* § 553(c). Likewise, the Social Security Act requires the HHS Secretary, before issuing the relevant types of regulations

"in final form," to "provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. § 1395hh(b)(1).

149. The APA also generally requires "publication . . . of a substantive rule [to] be made not less than 30 days before its effective date." 5 U.S.C. § 553(d). Similarly, the Social Security Act requires that relevant regulations "not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be," the regulation. 42 U.S.C. § 1395hh(e)(1)(B)(i).

150. The MFN Rule was not adopted through the required notice-and-comment procedure, nor did it provide for the required 30-day delay in effective date. There is no "good cause" that waives either requirement. The Rule was therefore promulgated "without observance of procedure required by law" and must be set aside under 5 U.S.C. § 706(2)(D).

SECOND CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The MFN Rule Exceeds CMS's Statutory Authority Under 42 U.S.C. § 1315a)

151. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

152. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law" or is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C).

153. Independent of the APA, courts have a duty to set aside agency action that is *ultra vires*. *See Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1173 (D.C. Cir. 2003).

154. The MFN Rule violates clear statutory limits on CMS's authority to "test payment and service delivery models in accordance with selection criteria." 42 U.S.C. § 1315a(b)(1). The MFN Rule is not a "test of a "model," but rather—in the Administration's own description of the Rule's more modest predecessor—"an overhaul of Medicare Part B drug pricing," 2018 CMS

Press Release, *supra*, that will "completely restructure the prescription drug market, in terms of pricing and everything else," July 2020 White House Remarks, *supra*. By its own terms, the MFN Rule will directly alter federal reimbursement for three-fourths of all Medicare Part B drug spending pursuant to a "policy" at odds with the one Congress established. The Rule by design has no control group, and it circumvents numerous congressionally established guardrails that are intended to govern a model's "expansion" and "implementation on a nationwide basis" once it has succeeded on a smaller scale. *Id.* § 1315a(c).

155. The MFN Rule is also not "in accordance with selection criteria," *id.* § 1315a(b)(1), because the Secretary has not determined and cannot determine "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). Instead of addressing a "defined population," the MFN Rule targets the entire population of patients who will receive a covered drug. 85 Fed. Reg. at 76,183. The MFN Rule also has not identified any specific "deficits in care" leading to either "poor clinical outcomes or potentially avoidable expenditures" for that broad population. Nor does the rule "preserv[e] or enhanc[e] the quality of care" enjoyed by Medicare beneficiaries. 42 U.S.C. § 1315a(b)(2)(A).

156. The MFN Rule is therefore "not in accordance with law," it is "in excess of statutory jurisdiction, authority, or limitations," and it must be set aside under 5 U.S.C. § 706(2)(A), (C). The MFN Rule is also *ultra vires*.

THIRD CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The MFN Rule Is Not in Accordance with Art. I, § 7 of the U.S. Constitution)

157. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

158. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law" or "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(A), (B).

159. Even apart from the APA, courts must set aside agency action that violates the Constitution. *See Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 491 n.2 (2010).

160. The Presentment Clause requires that "[e]very 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; If he approve he shall sign it, but if not he shall return it." U.S. Const. art. I, § 7, cl. 2. The Clause bars "unilateral [Executive] action that either repeals or amends parts of duly enacted statutes." *City of New York*, 524 U.S. at 439.

161. CMS has interpreted its waiver authority under Section 1115A to allow it to repeal part of the congressionally enacted Medicare statute and to replace that repealed portion with a massive new statutory regime of its own making.

162. If CMS's interpretation is correct, then the MFN Rule violates the Presentment Clause. CMS's waivers in the MFN Rule have the "legal . . . effect" of making numerous provisions in the Medicare statutes "entirely inoperative" and without "legal force." *Id.* at 438, 441. In so doing, the waivers also have the "practical effect" of "rejecting the policy judgment made by Congress." *Id.* at 444. Compounding the constitutional problem, CMS has not just suspended enforcement of particular provisions, but instead has replaced the superseded statutory provisions with entirely new requirements that reflect CMS's "own policy judgment." *Id.* at 438, 444. By creating a new system with new obligations, CMS is impermissibly arrogating the lawmaking process to itself.

163. The MFN Rule is therefore "not in accordance with law" and must be set aside.

FOURTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The MFN Rule Is Not in Accordance with Art. I, § 1 of the U.S. Constitution)

164. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

165. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law" or "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(A), (B).

166. Even apart from the APA, courts must set aside agency action that violates the Constitution. *See Free Enter. Fund*, 561 U.S. at 491 n.2.

167. The Constitution vests "[a]ll legislative Powers . . . in [the] Congress of the United States." U.S. Const. art. I, § 1. The Supreme Court has interpreted this language to bar the delegation of "the essential legislative functions with which it is thus vested." *A.L.A. Schechter Poultry*, 295 U.S. at 529.

168. CMS has interpreted its authority under Section 1115A to allow it to repeal as much of the congressionally enacted Medicare statute as it wishes and to replace that repealed portion with a new regime of its own making.

169. If CMS's interpretation is correct, then the MFN Rule is the result of an unconstitutional delegation of the legislative power to the Executive Branch. CMS issued the Rule because the President was "unwilling to wait any longer" for "Congress to take action . . . to reduce drug prices." July 2020 White House Remarks, *supra*. The Rule does not execute congressional policy, but overrides it; it does not fill in statutory blanks, but erases entire swaths of the Medicare program. It is, by the President's own acknowledgment, "revolutionary." 2018 White House Remarks, *supra*.

170. The MFN Rule is therefore "not in accordance with law" and must be set aside.

FIFTH CLAIM FOR RELIEF

(Declaratory/Injunctive Relief – The MFN Rule Is the Result of an Unauthorized Presidential Directive)

171. Plaintiffs reallege and incorporate by reference all prior and subsequent paragraphs.

172. The APA requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law" or is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C); *see id.* § 706(2)(B).

173. The Constitution confers upon Congress the power to establish departments and agencies in the Executive Branch and to define the duties and functions of the officers who administer them. *See* U.S. Const. art. I, § 8, cl. 18. Once Congress has done so, the President has no legal power to direct how those officers must exercise their prescribed authority. *See* Presidential Authority to Direct Departments and Agencies to Withhold Expenditures From Appropriations Made, 1 Op. O.L.C. Supp. 12, 12 (1937).

174. Here, Section 1115A expressly assigns the Secretary of Health and Human Services sole discretion over CMMI's testing authority. Yet President Trump directed the HHS Secretary in the MFN Executive Order to "implement" the MFN Rule. 85 Fed. Reg. at 59,649. In so doing, the President usurped the Secretary's authority to make that decision for himself. In fact, the MFN Rule itself acknowledges that it is being implemented "*[i]n response to the September 13, 2020 Executive Order*." 85 Fed. Reg. at 76,182 (emphasis added).

175. Because the Rule was issued pursuant to an unauthorized presidential command rather than the Secretary's exercise of discretion, it was "not in accordance with law" and was "in excess of statutory jurisdiction, authority, or limitations."

PRAYER FOR RELIEF

NOW, THEREFORE, Plaintiffs request a judgment in their favor against Defendants as follows:

1. Declare that the MFN Rule is not in accordance with law, is unconstitutional, is without observance of procedure required by law, and is invalid;
2. Set aside and vacate the MFN Rule;
3. Issue preliminary and permanent injunctive relief, including a temporary restraining order, without bond, preventing Defendants from implementing or enforcing the MFN Rule, or requiring them to complete notice-and-comment rulemaking before putting any such rule into effect;
4. Award Plaintiff reasonable attorneys' fees and costs, plus interest accruing thereon, under the Equal Access to Justice Act, 28 U.S.C. § 2412; and
5. Grant such other and further relief as the Court may deem appropriate.

DATED: December 4, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed. R. Civ. P. 4.

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