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

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