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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

BIOTECHNOLOGY INNOVATION ORGANIZATION; CALIFORNIA LIFE SCIENCES ASSOCIATION; and BIOCOM CALIFORNIA,

Plaintiffs,

Civil Case No: 20-cv-08603

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

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v.

ALEX M. AZAR, II, in his official capacity as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; SEEMA VERMA, in her official capacity as ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES; and THE CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

ADMINISTRATIVE PROCEDURE ACT CASE

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Plaintiff Biotechnology Innovation Organization ("BIO"), on behalf of itself and its members, plaintiff California Life Sciences Association ("CLSA"), on behalf of itself and its members, and plaintiff Biocom California ("Biocom"), on behalf of itself and its members (together, "Plaintiffs"), bring suit against Alex M. Azar, in his official capacity as the Secretary of the United States Department of Health and Human Services ("HHS"); HHS; Seema Verma, in her official capacity as the Administrator of the Centers for Medicare and Medicaid Services ("CMS"); and CMS (together, "Defendants"), and allege as follows:

INTRODUCTION

1. This lawsuit challenges HHS's issuance, during the final days of the Trump Administration, of a sweeping new rule that alters the statutorily prescribed method for determining reimbursement payments that healthcare providers receive for administering "the top 50" prescription medications to Medicare patients in hospital outpatient departments and other facilities.[1] This eleventh-hour rule was issued in clear violation of the notice-and-comment requirements of the Administrative Procedure Act ("APA"), and is substantively unlawful and *ultra vires*. The rule is an impermissible attempt by HHS to use its limited authority to "test" new payment "models" as a basis for completely rewriting the reimbursement formula Congress enacted.

2. Over two years ago, in October 2018, HHS announced that it might revise the reimbursement formula based on an "international pricing index." That idea was not set forth in a proposed rule, but rather in an advanced notice of proposed rulemaking. In November 2020, HHS issued a new and different reimbursement concept as an immediately effective interim final rule that will begin altering reimbursement payments as of January 1, 2021—*before the agency even receives*, much less *considers*, the comments it has solicited on this rule. That action clearly violates the APA.

3. HHS has rushed to put its new "Most Favored Nation" Rule ("MFN Rule") into effect despite its recognition that there is no "reliable precedent in the U.S. market" for its new reimbursement formula, and that there is "an unusually high degree of uncertainty" about the

[1] *See* Final Rule, Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180 (Nov. 27, 2020) (to be codified at 42 C.F.R. pt. 513) ("MFN Rule"); Fact Sheet: Most Favored Nation Model for Medicare Part B Drugs and Biologicals Interim Final Rule with Comment Period, CMS (Nov. 20, 2020), https://tinyurl.com/y65f3qr6.

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formula's potential impacts. 85 Fed. Reg. at 76,237. Indeed, HHS acknowledges that, as a result of the MFN Rule, some healthcare providers may suffer extreme financial hardship, *id.* at 76,222, and some Medicare patients may receive inferior therapies with "lower efficacy or greater risks," or end up "postponing or forgoing treatment" altogether. *Id.* at 76,244. The agency's own estimates show that, within three years, nearly one in five Medicare Part B patients may have *no* access to drugs covered by the MFN Rule, *id.* at 76,237–38, and that half of the projected savings to Medicare "would be due to lost utilization" of these drugs, *id.* at 76,239. In addition, the MFN Rule will deprive emerging biotechnology companies of their ability to attract crucial financing by seriously impacting their potential for market-based returns. Such decreases in investment will place critical research at risk, threatening the ability to develop innovative new drugs, especially for rare diseases.

4. HHS's purported justification for giving this unprecedented and harmful rule immediate effect is that economic disruptions caused by the COVID-19 pandemic have "given rise to an urgent need for swift action to reduce drug prices," and that implementation of its new reimbursement model will provide "immediate relief to Medicare beneficiaries." *Id.* at 76,249. This contention is baseless, and cannot justify dispensing with notice and comment on a new policy that the President has described as "transformative."[2] Indeed, the Administration has been pursuing similar measures for years and never previously asserted that they are a necessary response to the pandemic. The MFN Rule itself excludes from the new pricing structure all drugs authorized "to treat patients with suspected or confirmed COVID-19," 42 C.F.R. § 513.130(b)(ix), on the ground that applying the MFN Rule to COVID-19 drugs would impair the "rapid, widespread availability of such drugs in the U.S. to treat patients with suspected or confirmed COVID-19." 85 Fed. Reg. at 76,191. And this Court recently rejected a similar claim that the economic effects of pandemic allowed the outgoing Administration to make sweeping policy changes immediately effective without notice-and-comment. *Chamber of Commerce v. U.S. Dep't of Homeland Sec.*, No. 4:20-cv-7331, 2020 WL 7043877 (N.D. Cal. Dec. 1, 2020).

5. Further, the whole premise of the new Rule is that HHS is *testing* a new

[2] Remarks by President Trump at Signing of Executive Orders on Lowering Drug Prices, The White House, (July 24, 2020 from 3:45 PM ET to 4:28 PM ET), https://tinyurl.com/yxhpxvbs.

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reimbursement model that it believes will reduce drug prices. HHS cannot claim that it is testing a model to see *if* it reduces drug prices, then declare that the Rule should go into effect immediately because HHS knows that its model *will immediately* reduce drug prices. HHS certainly cannot make such a declaration in light of its admission that its unprecedented model involves "an unusually high degree of uncertainty," 85 Fed. Reg. at 76,237, and could end up harming—rather than helping—patients, by forcing them to accept riskier or less effective treatments or to forgo treatment during the COVID-19 pandemic. In fact, while HHS claims that implementing the MFN Rule as an interim final rule is necessary to ensure that the pandemic does not cause seniors to "stint[] on care," *id.* at 76,249, it admits that some of the savings it projects are "attributable to beneficiaries *not accessing their drugs through the Medicare benefit*," *id.* at 76,237 (emphasis added).

6. Although HHS's premature conclusions about the outcome of its purported test do not justify its failure to comply with the APA's notice-and-comment requirements, they confirm the other overarching flaw in its action—namely, that the MFN Rule is not a valid exercise of HHS's authority to test models. HHS has invoked a provision that allows it to "test" certain payment and patient care "models" on a "defined population," for which "there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures." *See* 42 U.S.C. § 1315a. HHS can expand a test if certain criteria are met, and must report the results of those tests so Congress can consider adopting models into law. *Id*. The MFN Rule plainly falls outside the ambit of this limited authority, and is instead an impermissible attempt to rewrite the "minutely detailed" reimbursement formula Congress enacted for Medicare Part B drugs. *Hays v. Sebelius*, 589 F.3d 1279, 1282 (D.C. Cir. 2009) (citation omitted).

7. The reimbursement formula Congress enacted for Medicare Part B drugs is based upon the competitive U.S. market for pharmaceutical products in order to ensure that healthcare providers do not lose money on the drugs that they administer to patients. In general, Medicare Part B covers medical services in the outpatient setting (*e.g.*, visits to a physician's office or a hospital outpatient facility). Pursuant to that coverage, Part B reimburses providers when they administer drugs to patients during those visits. These provider-administered drugs include many injectable and infusion products that treat serious or life-threatening diseases, like cancer, autoimmune conditions,

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