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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

BIOTECHNOLOGY INNOVATION ORGANIZATION et al.

*Plaintiffs,*

v.

ALEX M. AZAR, II et al.,

*Defendants.*

Civil Case No: 3:20-cv-08603-VC

**NOTICE OF MOTION AND MOTION FOR PRELIMINARY INJUNCTION**

Assigned to Hon. Vince Chhabria

Date: January 21, 2021
Time: 10:00 a.m.
Courtroom: 4, 17th Floor

**NOTICE OF MOTION AND MOTION**

TO ALL PARTIES AND THEIR COUNSEL: PLEASE TAKE NOTICE that at 10:00 a.m. on January 21, 2021, or as soon as the Court deems feasible[1] and as counsel may be heard at the United States District Court for the Northern District of California, Courtroom 4, 450 Golden Gate Avenue San Francisco, CA 94102, Biotechnology Innovation Organization ("BIO"), on behalf of itself and its members, California Life Sciences Association ("CLSA"), on behalf of itself and its members, and Biocom California ("Biocom"), on behalf of itself and its members (together, "Plaintiffs"), will, and hereby do, move for a preliminary injunction 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"), pursuant to the Administrative Procedure Act, 5 U.S.C. § 553(b), and the Medicare Act, 42 U.S.C. § 1395hh.

Plaintiffs respectfully ask this Court to enjoin an unlawful new rule, issued without notice and comment, by the United States Department of Health and Human Services ("HHS"). *See* Interim Final Rule, Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180 (Nov. 27, 2020) ("MFN Rule"). The MFN Rule drastically transforms the statutory mechanism that governs Medicare Part B reimbursements to doctors and hospitals for administering certain prescription drugs to patients, and adopts a scheme based on foreign pricing, in excess of HHS's regulatory and statutory authority. The MFN Rule will irreparably harm Plaintiffs' members, who include biotechnology companies that manufacture and sell drugs covered by the Rule. The public interest and balance of equities also weigh heavily in favor of an injunction, because the Rule will otherwise cause severe and irreparable harms to patients, doctors, and others throughout the healthcare system.

Plaintiffs' Motion is based upon this Notice of Motion and Motion; the Memorandum of Points and Authorities; the supporting declarations and exhibits filed concurrently herewith; the Complaint (ECF 1); and such further evidence and argument as the Court may consider.

[1] Plaintiffs have moved for an expedited briefing schedule (ECF 25) and seek a hearing as soon as the Court deems feasible following the filing of their reply brief.

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## INTRODUCTION AND STATEMENT OF ISSUES

Plaintiffs respectfully ask this Court to enjoin an unlawful new rule, issued without notice and comment, by the United States Department of Health and Human Services ("HHS"). *See* Interim Final Rule, Most Favored Nation (MFN) Model, 85 Fed. Reg. 76,180 (Nov. 27, 2020) ("MFN Rule"). The MFN Rule drastically transforms the statutory mechanism that governs Medicare Part B reimbursements to doctors and hospitals for administering certain prescription drugs to patients, and adopts a scheme based on foreign pricing, in excess of HHS's regulatory and statutory authority.

HHS acknowledges that the MFN Rule could inflict extreme financial hardship on various healthcare providers, 85 Fed. Reg. at 76,222, and cause certain patients to lose access to life-saving therapies, *id.* at 76,244. The agency's own estimates show that one in ten Medicare Part B patients could lose access to drugs covered by the MFN Rule in its first year of operation. *Id.* at 76,237–38. Yet, HHS gave its new Rule immediate effect, so that it will alter reimbursement payments as of January 1, 2021—*before the agency even receives*, much less *considers*, the comments it has solicited.

Thus, in addition to issuing a rule in excess of its statutory authority, HHS has violated the notice and comment requirements of the Administrative Procedure Act ("APA") and Medicare Act. And it has done so in an utterly reckless way. Nearly all of the 50 drugs covered by the MFN Rule are for critical or life-altering diseases. Thirty-eight are cutting-edge cancer treatments, without comparable substitutes. Others treat autoimmune diseases or rare conditions. They "have dramatically improved care for patients." Decl. of Dr. Michael Seiden ("Seiden Decl.") ¶ 21. The MFN Rule will make these vital drugs inaccessible to many patients almost immediately. "The lives of seniors battling cancer and other very serious diseases are at stake in less than 30 days." Igra Decl. Ex. 14 at 1.

The MFN Rule will also cause extreme hardship to doctors and hospitals. Decl. of Alexander Hardy ("Hardy Decl.") ¶ 27. Some may have to close due to the financial upheaval caused by the foreign-price-based reimbursements. *Id.*; *see also* 85 Fed. Reg. at 76,222. Others will be placed in the "impossible position" of not being able to provide their patients with the treatment they deem necessary in their best medical judgment. Seiden Decl. ¶¶ 20-21; Decl. of Madelaine Feldman ("Feldman Decl.") ¶ 11. Plaintiffs' members will suffer irreparable harms because they will need to either alter pricing for distributors or lose

market share. Either way, the result will be substantial revenue losses that threaten the financial foundation for their research and development for long-term life-saving medications, and could force workplace reductions, as well as the postponement or abandonment of ongoing trials of new, innovative treatments, including for COVID-19. Decl. Hardy Decl. ¶¶ 32, 35; Decl. of Michael S. Chen ("Chen Decl.") ¶¶ 24, 25.

Ironically, HHS claims that the COVID-19 pandemic has caused an emergency situation that justifies its failure to provide notice and consider comments on its reckless new Rule. But the Trump Administration manufactured the "emergency" it is invoking as good cause to justify that action. It discussed the idea of tying Part B reimbursements to foreign drug pricing *for more than two year*s, and, in July 2020, promised to adopt such a policy unilaterally when Congress refused to act. Yet HHS did not issue the MFN Rule until late November, when it suddenly announced that the pandemic justified immediate issuance without notice and comment. *See* 85 Fed. Reg. at 76,249. This contention is baseless. An agency may not delay action until the last minute and then claim that an "emergency" excuses it from its notice-and-comment obligations. *California v. Azar*, 911 F.3d 558, 577 (9th Cir. 2018); *Chamber of Commerce v. Dep't of Homeland Sec.*, 2020 WL 7043877 (N.D. Cal. Dec. 1, 2020) (rejecting contention that pandemic excused compliance with notice-and-comment).

HHS's clear violation of the APA and Medicare Act warrants preliminary injunctive relief. The MFN Rule also should be preliminarily enjoined because it exceeds HHS's statutory authority. HHS promulgated the MFN Rule as an exercise of its authority under a statutory provision that allows it to "test" new payment and service delivery models. *See* 42 U.S.C. § 1315a. But this radical transformation of Part B drug spending is a far cry from the "testing" of a "model" contemplated by the statute.

Plaintiffs are likely to succeed on the merits of those arguments and issuance of a preliminary injunction is necessary to prevent immediate and irreparable harms to plaintiffs' members. The public interest also weighs heavily in favor of an injunction, because of the irreparable harm that will otherwise be suffered by patients, doctors, and throughout the healthcare system. A preliminary injunction is needed during the pendency of this litigation to maintain the *status quo* and adherence to the framework enacted by Congress that governs the complex Medicare Part B program, in which more than 50 million Americans

are enrolled.

## BACKGROUND AND STATEMENT OF FACTS

### A. MEDICARE PART B AND 42 U.S.C. § 1315A

The Medicare program provides health insurance to seniors and the disabled. Part B of Medicare covers, among other things, drugs administered in doctor's offices or hospital outpatient clinics (including similar facilities). *See* 42 U.S.C. §§ 1395k(a)(2)(B), 1395x(s)(2)(A)–(B). Part B reimburses doctors and hospitals for the drugs they administer to patients during those visits.

Congress based Part B reimbursement rates on the market price in the United States—in Medicare parlance, the "average sales price" ("ASP"). ASP "include[s] volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates" (other than rebates paid under the Medicaid Program). *See* 42 U.S.C. §§ 1395w-3a(b)(4), (b)(6), (c)(3); 42 C.F.R. § 414.804(a). Basing the Part B reimbursement rate on ASP helps ensure that Medicare receives the benefits of market-based discounts, while also supporting access to medicines and innovation in biotechnology. Medicare's base reimbursement rate for most Part B drugs and biologicals is set at 106% of the ASP. 42 U.S.C. § 1395w-3a(b)(1), (b)(8). This formula has been in place since 2005. 117 Stat. 2066, 2239.[2]

The statutory provision on which HHS purports to rely for the MFN Rule allows HHS to "test innovative payment and service delivery models to reduce program expenditures under [Medicare or Medicaid] while preserving or enhancing the quality of care furnished to individuals under such subchapters." 42 U.S.C. § 1315a(a)(1). HHS is given limited authority to waive certain Medicare provisions, including ASP, "solely" for the purpose of conducting such "tests." §§ 1315a(b)(1), (d)(1). HHS is authorized to test a model only if "there is evidence that [it] addresses a defined population for which there are deficits in care." § 1315a(b)(2)(A). HHS is required to "focus on models expected to reduce program costs under the applicable subchapter while preserving or enhancing the quality of care received by individuals receiving benefits under such subchapter." *Id.* Tests must proceed in two phases,

[2] Under the Budget Control Act of 2011, Part B reimbursement is subject to sequestration cuts that reduce payment for most Part B drugs to ASP plus 4.3 percent. Decl. of Naomi Igra ("Igra Decl.") Ex. 2 at 80 n.27.

and nationwide implementation is permitted only in the second phase and only after evaluation of the first phase. § 1315a(c).

### B. HHS'S ISSUANCE OF THE MFN RULE

The Trump Administration attempted to persuade Congress for more than two years that Medicare reimbursement rates should be tied to foreign drug prices. In January 2018, President Trump told Congress that he was directing his administration to make lowering drug prices "one of our top priorities" and that "[i]n many other countries, these drugs cost far less than what we pay in the United States." Igra Decl. Ex. 3 at 7.

Later in 2018, HHS issued an Advance Notice of Proposed Rulemaking ("ANPRM") that discussed adopting a different approach known as an "international price index" model for reimbursing Part B drugs. *See* Medicare Program; Int'l Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54,546 (Oct. 30, 2018). HHS stated that the notice was a "potential model" at the "concept design" stage, *id.* at 54,547–50, and that additional comments on the design would be invited "through notice and comment rulemaking," *id.* at 54,550. Comments on the ANPRM demonstrated the lack of statutory or regulatory support for the approach, and also identified significant policy shortcomings. Docket CMS-2018-0132, Index Price Concession Model/Most Favored Nation Model, https://beta.regulations.gov/docket/CMS-2018-0132. No further action was taken on the advanced notice; a proposed rule was never published. Igra Decl. Ex. 13.

In 2019 and 2020, President Trump pushed Congress to pass legislation to lower drug prices. Igra Decl. Ex. 4; *id.* at Ex. 5; *id.* at Ex. 6 at 1. Congress considered several bills that would have changed the statutory formula for Medicare drug pricing, but took no such action. The President then bypassed Congress and issued this MFN Rule.

#### 1. The September 30, 2020 Executive Order

On July 24, 2020, President Trump signed four Executive Orders regarding drug pricing. He stated that one of these orders would require the United States to "determine what other medically advanced nations pay for the most expensive drugs, and instead of paying the highest price, Medicare will pay the lowest price and so will lots of other U.S. buyers." Igra Decl. Ex. 6 at 6. The President did not mention

the pandemic as a basis for this order. The President never released this order to the public, stating instead that it would be held "until August 24th, [in] hop[e] that the pharmaceutical companies will come up with something that will substantially reduce drug prices." Igra Decl. Ex. 6 at 7.

President Trump issued a new version of his order on September 13, stating "[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," defined as the price available "in a member country of the Organisation[sic] for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product." Exec. Order 13948, Lowering Drug Prices by Putting America First, § 2, 85 Fed. Reg. 59,649 (Sept. 23, 2020). It directed HHS to "immediately take appropriate steps to implement [a] 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.* § 3. The order made no mention of the pandemic.

HHS did not release its MFN Rule to the public until more than two months later, publishing it on November 27, 2020, as an interim final rule with immediate effect. 85 Fed. Reg. at 76,180. Far from characterizing it as a "test" of a "payment model," President Trump called an "unprecedented reform" "to end global freeloading," in which higher American drug prices "effectively subsidiz[e] socialism abroad." Igra Decl. Ex. 8 at 1–2. In discussing the Rule, the President once again did not mention the COVID-19 pandemic.

**2. Requirements of HHS's Most Favored Nation Rule**

Although HHS itself described the MFN Rule as a "test" of a "payment model" under 42 U.S.C. § 1315a, it provided that the "model" will apply in "all states and U.S. territories," 42 C.F.R. § 513.220, to all Part B patients who have Medicare as their primary payer and are not covered by other group health plans, *id.* §§ 513.2, 513.210(a). Participation in the "model" is mandatory for all Part B providers, with few exceptions, *see id.* §§ 513.100(b); 513.100(c). The purported "Phase I test" will last for 7 years, and the covered products account for approximately 75 percent of Part B's expenditures on separately payable drugs and biologics. 85 Fed. Reg. at 76,193; 42 C.F.R. § 513.1(c).

Doctors and hospitals who administer drugs subject to the MFN Rule will not be reimbursed based

on the rate formula set by Congress, but will instead receive an "MFN Drug Payment Amount" plus a flat "Alternative Add-On Payment." 42 C.F.R. § 513.210(a). The MFN Drug Payment Amount is based on the "MFN Price," which is derived quarterly for each drug "from the lowest GDP-adjusted country level price" prevailing among 22 other countries. *See* 85 Fed. Reg. at 76,196; 42 C.F.R. §§ 513.140(b)(1), 513.210. Subject to certain limitations, the MFN Drug Payment Amount will be 75% ASP and 25% MFN Price in the first year, 50% ASP and 50% MFN Price in the second year, 25% ASP and 75% MFN Price in the third year, and 100% MFN Price in subsequent years. 42 C.F.R. § 513.210(b)(8). The Alternative Add-On Payment is a flat payment per dose, calculated as 6.1224% of a volume-weighted average of historical ASPs for the 50 drugs initially subject to the MFN Rule. *See id.* § 513.220.

The MFN Rule applies, with certain exclusions, to the 50 Part B drugs for which Medicare spent the most money in 2019, *id.* § 513.130(a)(1), although "payments for Part B drugs account for only a small fraction of Medicare spending." Hardy Decl. ¶ 17. Drugs that enter the top 50 in later years and do not fall within an exclusion will be added to the list. 42 C.F.R. § 513.130(a)(2). Drugs are removed from the list only if they are removed from the market (or otherwise terminated from CMS's coding system) altogether. *Id.* § 513.130(a)(3).

**3. Impacts of HHS's Most Favored Nation Rule**

Congress's statutory framework uses ASP to base reimbursement on U.S. market forces. That ensures both that the Medicare Program gets the benefit of market-driven price reductions, and also that the reimbursement rate reflects the market-based prices necessary to support manufacturers' operations and ability to invest in developing new life-saving medicines. Decl. of Craig Garthwaite ("Garthwaite Decl.") ¶ 61.

The MFN Rule, however, replaces Congress's framework with foreign-based pricing that disrupts the balance Congress struck. Certain drugs are sold at lower prices in foreign countries than in the United States for reasons including "price controls imposed by foreign governments, comparatively weaker protections for intellectual property in those countries, or independent decisions by third parties licensed to distribute those drugs overseas." Hardy Decl. ¶ 20. For each listed drug, the MFN Rule will therefore inescapably reduce the Part B reimbursement rates.

HHS conceded that the MFN Rule could adversely affect doctors and hospitals and Medicare Part B patients, and that HHS was "unable to quantify these potential effects." 85 Fed. Reg. at 76,244. In fact, the reduced reimbursement payments that will become effective on January 1, 2021, will cause a host of immediate and severe disruptions. Most doctors and hospitals buy Medicare Part B drugs from distributors and administer them to their patients and then bill Medicare Part B for reimbursement afterwards. Under this "buy and bill" system, doctors and hospitals typically order drugs more than a month in advance, and in some cases under contracts that fix prices for a year or more. Seiden Decl. ¶¶ 11-12; Feldman Decl. ¶ 10. Under the statutory formula, they are reimbursed later at a rate that Congress provided to cover the cost they paid for the drug plus some of the overhead associated with their administering the drug to the patient. Seiden Decl. ¶¶ 11-14; Feldman Decl. ¶¶ 10-11. But under the MFN reimbursement rate, doctors and hospitals will lose money when they administer drugs to patients, because their Medicare Part B reimbursement will be lower than the price they paid for the drug. Seiden Decl. ¶¶ 13-14; Feldman Decl. ¶ 11. For some medical practices, the losses could pose threats to their economic survival. Seiden Decl. ¶¶ 14-15; Feldman Decl. ¶¶ 11-12. Some doctors and hospitals "will be forced by the MFN Rule to decline treatment for numerous Medicare patients beginning in January." Seiden Decl. ¶ 20. Others will "cease providing drugs covered by the MFN Rule to Medicare Part B patients," Feldman Decl. ¶ 12, despite the fact that such medications often "are far superior to," and "far more innovative and effective than[,] existing alternatives." Seiden Decl. ¶ 22.

In turn, patients may be forced to switch to outpatient care at hospitals that receive deeply discounted drug rates under a program known as "340B,"[3] to maintain treatment with one of the 50 listed medications. Requiring a shift to 340B institutions will limit access and will mean that many seniors battling cancer and other diseases will have to travel significant distances to receive care, *id.* Seiden Decl. ¶ 24, and immunocompromised seniors will be forced into contact with many more sick patients in the midst of a pandemic, Feldman Decl. ¶ 14.

Plaintiffs' members will experience serious harm and are significantly constrained in how they can

[3]Under the 340B program, pharmaceutical manufacturers participating in Medicaid must sell drugs at significant discounts to certain covered entities, such as Disproportionate Share Hospitals. *See* 42 U.S.C. § 256b.

respond to the new MFN reimbursement rate. If they maintain current prices, they will lose market share and revenues as providers stop prescribing and administering the covered drugs, which will have a dramatic adverse effect on manufacturers' research and development under this country's market structure that makes the United States the leading innovator and developer of new life-saving medications. *See, e.g.*, Hardy Decl. ¶¶ 9, 22, 30–35; Chen Decl. ¶¶ 2, 18, 19, 20. If, on the other hand, manufacturers align their prices with the MFN rate, that will also drive down revenues, and lead to similar adverse consequences. Chen Decl. ¶ 20.

Reductions to the Medicare reimbursement rate will also affect revenues beyond just Medicare Part B. It will reduce the amount distributors will agree to pay manufacturers for covered drugs, regardless of whether the drugs are ultimately administered to privately insured patients or those enrolled in Medicare Part B. Hardy Decl. ¶¶ 23, 24; Chen Decl. ¶ 19. Plaintiffs' members sell their products to distributors, who typically do not differentiate the price they pay manufacturers based on whether the particular vials are ultimately used to treat Medicare patients or privately insured patients. Hardy Decl. ¶¶ 24. Nor do manufacturers typically know, when they sell a certain quantity of drug to a distributor, exactly how much of that drug will be administered to privately insured versus Medicare patients. *Id.*; *see also* Garthwaite Decl. ¶ 141. The MFN Rule's disruption also could negatively affect revenues manufacturers receive under the Medicaid and 340B programs. *See* Hardy Decl. ¶¶ 25, 26. And it will reduce revenues by forcing Medicare Part B patients into 340B facilities, thereby increasing the amount of drugs for which manufacturers are required to provide 340B discounts. *Id.*

These effects mean that the MFN Rule will dramatically undermine the revenues that support manufacturers' research and development programs, which are what have led to the "far superior" therapies that are available to patients in the United States, Seiden Decl. ¶ 22, and often unavailable in foreign countries, Garthwaite Decl. ¶ 125; Hardy Decl. ¶¶ 10–11. They are also the programs that are working to develop therapies for COVID-19. Hardy Decl. ¶ 35.

### C. THE FAILURE TO AFFORD ADVANCE NOTICE AND COMMENT

HHS acknowledged, with great understatement, that there is "an unusually high degree of uncertainty" about the Rule's potential impacts. 85 Fed. Reg. at 76,237. Nevertheless, despite the

extensive disruption the MFN Rule will cause the complex, critical Medicare Part B program, HHS issued the Rule without prior notice or opportunity for any public comment. HHS provided a 60-day comment period that ends on January 26, 2021, but designated the MFN Rule as an "interim final rule" that is effective immediately and will start altering reimbursement rates on January 1, 2021, before the agency addresses any comments on the rule. 85 Fed. Reg. at 76,180. HHS contended that economic disruptions caused by the COVID-19 pandemic are impacting seniors' ability to afford co-payments on the covered drugs, and therefore that good cause existed to avoid following notice-and-comment requirements. *Id.* at 76,249.

### D. PRE-MOTION CONSULTATIONS WITH GOVERNMENT COUNSEL

Plaintiffs filed this suit on Friday, December 4th. On December 8th, plaintiffs' counsel advised government counsel that plaintiffs would seek injunctive relief unless the MFN Rule's effective date was delayed. The following day, government counsel advised that HHS was unwilling to do so.

## LEGAL STANDARD

"A plaintiff seeking a preliminary injunction must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The Ninth Circuit's "sliding scale" approach balances these elements. *Hernandez v. Sessions*, 872 F.3d 976, 990 (9th Cir. 2017). An agency's "decision not to follow the APA's notice and comment procedures" is reviewed *de novo* and without deference, because "complying with the notice and comment provisions when required by the APA is not a matter of agency choice." *Reno-Sparks Indian Colony v. EPA*, 336 F.3d 899, 909 n.11 (9th Cir. 2003) (quotation marks omitted); *see also Chamber of Commerce*, 2020 WL 7043877, at *6–7.

## ARGUMENT

### A. PLAINTIFFS ARE LIKELY TO SUCCEED ON THE MERITS

#### 1. The MFN Rule Violates APA and Medicare Act Rulemaking Requirements

The APA and the Medicare Act require an opportunity to comment on proposed rules before they are finalized, as well as a minimum 30 days' notice before a substantive rule becomes effective. 5 U.S.C.

§ 553(b)-(c), (d)(3); 42 U.S.C. §§ 1395hh(a)(1)-(2), (e)(1)(B)(ii). *See also Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1809 (2019) (Medicare notice-and-comment requirement is "a matter … of statutory duty").

HHS did not comply with these requirements, and cannot meet the "good cause" exception to justify its noncompliance. 5 U.S.C. § 553(b)(B); 42 U.S.C. § 1395hh(b)(2)(C) (citation omitted); s*ee Paulsen v. Daniels*, 413 F.3d 999, 1004–05 (9th Cir. 2005) (it "is antithetical to the structure and purpose of the APA for an agency to implement a rule first, and then seek comment later"). The good cause exception "is essentially an emergency procedure," *United States v. Valverde*, 628 F.3d 1159, 1165 (9th Cir. 2010), that is "narrowly construed" and "reluctantly countenanced," *California v. Azar*, 911 F.3d at 575, and usually reserved for situations where "delay would do real harm to life, property, or public safety." *E. Bay Sanctuary Covenant v. Trump*, 950 F.3d 1242, 1278 (9th Cir. 2020) (citation omitted).

HHS asserts that "good cause" exists here because "increases in Part B premiums and deductibles" from "rising spending on physician-administered drugs" could lead to "improper medication adherence or skipped treatment." 85 Fed. Reg. at 76,249. HHS also claims that the economic impacts of the COVID-19 pandemic, including "historic levels of unemployment," "rapidly exacerbated" these problems, creating "an urgent need" "for swift action to reduce drug prices." *Id*. These assertions are riddled with contradictions and come nowhere near "overcom[ing the] high bar" of showing "good cause." *Valverde*, 628 F.3d at 1164.

First, the agency's own delay defeats its claim of good cause. The Trump Administration pursued changes to the reimbursement formula for Medicare Part B drugs for over two years. *See supra* pp. 3–5. The President first signed an Executive Order directing HHS to implement his "Most Favored Nation" policy in July 2020, over four months before the MFN Rule was promulgated. HHS never explained why notice and an opportunity to comment could not be provided during this period.

The Ninth Circuit has repeatedly held that an agency may not delay action on known concerns and then claim that an "emergency" prevented it from following normal procedures. As in *California v. Azar* and *Valverde*, HHS cannot invoke the good cause exception after it "allowed . . . months to pass without action." *Azar*, 911 F.3d at 577 (nine month delay); *Valverde*, 628 F.3d at 1166 (seven month delay).

Indeed, this Court recently rejected a claim that economic conditions flowing from the COVID-19 pandemic provided "good cause" for dispensing with notice-and-comment where the agency had failed to act "for over six months." *Chamber of Commerce*, 2020 WL 7043877, at *8.

Second, the stated purpose of the MFN Rule—to conduct a "test" under the agency's testing authority, 42 U.S.C. § 1315a—is inconsistent on its face with HHS's attempt to invoke the good cause exception. HHS claims it is "testing a new payment methodology" that it "expect[s] . . . will lower beneficiary cost[s]." 85 Fed. Reg. at 76,181. But HHS elsewhere admits that the MFN Model "does not have a reliable precedent in the U.S. market," and that its foundational assumptions are subject to "an unusually high degree of uncertainty." *Id.* at 76,237. 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.

Third, HHS has shown no logical link between the COVID-19 pandemic and either the Rule itself or the decision to give the Rule immediate effect. As this Court recently explained, the question is not whether the "COVID-19 pandemic writ large" "qualifies as an emergency," but whether the agency can "demonstrate[] that the impact of the COVID-19 pandemic on [Part B patients] justified dispensing with the 'due deliberation' that normally accompanies rulemaking." *Chamber of Commerce*, 2020 WL 7043877, at *1. HHS does not contend that emergency *medical* needs related to the pandemic provide good cause for its action. In fact, the MFN Rule expressly *excludes* 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 Model" to COVID-19 drugs would impair the "rapid, widespread availability of such drugs in the U.S." 85 Fed. Reg. at 76,191. Thus, the fact that adults 65 or older comprise 8 out of 10 U.S. deaths from COVID-19, *id.* at 76,249, does not explain why it is necessary to rush implementation of a rule that will alter reimbursement rates for Medicare Part B drugs that are *not* used to treat COVID-19.

Nor is there any basis for the agency's claim that the MFN Rule must take immediate effect in order to address a sudden rise in spending on Part B medications. 85 Fed. Reg. at 76,249. According to its own data, a comparison of the first quarter 2019 Part B payment amounts with the last quarter of 2018 reveals that, on average, there was no change in payment amounts for the top 50 Part B drugs, and more

recent quarter-to-quarter comparisons show that, on average, payment amounts *decreased* from 0.4 percent to 3.2 percent for the top 50 drugs. CMS, 2020 ASP Drug Pricing Files (last modified Nov. 13, 2020), https://tinyurl.com/sp78dv6; CMS, 2019 ASP Drug Pricing Files (last modified June 1, 2020), https://tinyurl.com/y4dz5zwu.

Moreover, even if the cost of Part B drugs together with the pandemic could cause seniors to "stint[] on care," 85 Fed. Reg. at 76,249, HHS has not shown that the MFN Rule will address that problem. In fact, HHS elsewhere admits that, in its first year of operation, the MFN Rule itself may cause nearly 10% of Medicare beneficiaries to *lose* access to their Medicare Part B drugs, *id.* at 76,237, that the savings HHS projects are "attributable to beneficiaries *not accessing their drugs through the Medicare benefit*," *id.* (emphasis added), and that the "potential loss of access to certain drugs" may cause patients to incur "*additional medical expenses*" overall, *id.* at 76,247 (emphasis added). *See also supra* pp. 6–8 (discussing the Rule's numerous and immediate adverse impacts on care for Part B patients). As the Congressional Budget Office has noted, reduced access to prescription medicines can lead to increased expenditures in other areas of healthcare spending, such as hospitalizations. Igra Decl. Ex. 9 at 2-4. It makes little sense to focus on the costs of the covered medications in a vacuum, while ignoring the significant value and savings that are realized when prescription drugs are used effectively to prevent or shorten hospitalizations, to prevent disabilities or exacerbations of serious health conditions, and to help maintain individuals' health and well-being. *Id.*

HHS's assertions that immediate action is warranted because the pandemic has caused "historic levels of unemployment," and "we are currently seeing a new surge in COVID-19 cases that may lead to additional hardship" are similarly unsupported. 85 Fed. Reg. at 76,249. Most Medicare beneficiaries are retirees and have secondary insurance that may cover the co-payments for Part B drugs. For instance, in 2016, 81% of Medicare beneficiaries had supplemental insurance either through employer-sponsored insurance (30%), Medigap (29%), or Medicaid (22%). Garthwaite Decl. ¶ 146 n. 242. HHS acknowledges that there have been "positive economic and employment trends since the initial peak in April," 85 Fed. Reg. at 76,249, and the Administration has stated that "our economy is rebounding far beyond any expectations." Igra Decl. Ex. 10 at 5.

**2. The Rule Exceeds HHS's Authority.**

Plaintiffs are also likely to succeed on the merits because the MFN Rule exceeds HHS's authority. As justification for its attempt to rewrite Medicare Act provisions governing payments for Part B drugs, HHS invokes 42 U.S.C. § 1315a(d)(1), which authorizes the Secretary to waive certain provisions of the Social Security Act "as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b)." *See* 85 Fed. Reg. at 76,230. Section 1315a provides no cover for the agency. The MFN Rule expressly states that it was adopted "*[i]n response to the September 13, 2020 Executive Order*," 85 Fed. Reg. at 76,182 (emphasis added), which announced that it was "the policy of the United States that the Medicare program should not pay more for costly Part B or Part D prescription drugs or biological products than the most-favored-nation price." Igra Decl. Ex. 7 at § 2. Thus, far from being a "test" of a new payment "model," the MFN Rule is clearly an attempt to rewrite the statutory formula in order to implement a new national policy that President Trump could not persuade Congress to pass – which is why HHS made the Rule mandatory for providers nationwide and estimates that it will affect more than $80 billion in Medicare spending over the next seven years, 85 Fed. Reg. at 76,181. The Rule is thus both *ultra vires* and "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

A comparison of the MFN Rule with the details of HHS's testing authority confirms this. Section 1315a(b)(2)(A) directs the Secretary to choose "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." A "defined population" thus must be a subset of Medicare beneficiaries incurring specific "deficits in care" or "potentially avoidable expenditures." A scheme that applies to every patient taking one of 50 or more drugs that constitute 75 percent of Medicare spending necessarily fails to "addres[s]" such a "defined population." Indeed, HHS's arrogation of authority flouts the common meaning of "model" as a "small scale" representation. Oxford English Dictionary Online (2020). It is difficult to fathom how the MFN Rule—which would encompass a significant and ever-growing majority of Part B drug spending—could possibly be a "model."

Similarly, the statute provides for a phased approach to tests: Models are "test[ed]" in "phase I," as a part of which HHS must analyze "the quality of care furnished under the model" and "the changes in

spending under [Medicare or Medicaid] by reason of the model." 42 U.S.C. § 1315a(b). HHS may "expand (including implementation on a nationwide basis) the duration and scope of a model that is being tested" only if, among other things, it "determines that such expansion is expected to … reduce spending under [the] applicable subchapter without reducing the quality of care; or … improve the quality of patient care without increasing spending." § 1315a(c)(1). This phased approach helps minimize the adverse effects from testing unsuccessful models. The MFN Rule short-circuits these requirements by immediately implementing a purported "model" on a mandatory nationwide basis. The statutory structure makes clear such mandatory nationwide "models" may be permissible (if at all) only as a "Phase II" *expansion* of a model that has already undergone initial testing and assessment, not in the initial *testing* phase.

As HHS admits, its nationwide "model" has no control group against which "test" results can be compared. 85 Fed. Reg. at 76,232. Accordingly, HHS must resort to complex statistical techniques, such as "interrupted time series," "segmented regression[s]," and "cluster-robust standard errors," to attempt to gauge the MFN Rule's impact. *Id.* at 76,233. Of course, the difficulty of disentangling the impacts of the Rule vis-à-vis other factors, in the midst of an ongoing pandemic, would only be a problem if HHS intended to "test" a "model," rather than implement a new nationwide policy.

It is implausible that Congress intended to entrust HHS with the authority the agency asserts here. If, under a proper interpretation of § 1315a, the MFN Rule is a valid "model," and nationwide implementation of that Rule is a valid "test," HHS would have near-boundless authority to ignore or rewrite the Medicare Act, and with it approximately $750 billion in annual spending. Igra Decl. Ex. 12. Nothing in § 1315a suggests that Congress intended to vest such awesome power in HHS. "Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions," or "hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). And courts have insisted that Congress "speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'" *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 324 (2014) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 129 (2000)). It defies that basic understanding to think that by enacting this "ancillary" and "minor provision" in the Affordable Care Act, *see NFIB v. Sebelius*, 567 U.S. 519, 705 (2012) (joint dissent), Congress intended to empower HHS to fundamentally

amend the Medicare Act.

HHS's contrary reading raises substantial constitutional concerns. Article I's Vesting Clause, U.S. Const. art. I, § 1, requires *at a bare minimum* that when Congress delegates authority to an agency, it supply the agency with an "intelligible principle to guide the delegee's use of discretion." *Gundy v. United States*, 139 S.Ct. 2116, 2123 (2019) (plurality op.); *id.* at 2139–41 (Gorsuch, J., dissenting). Reading § 1315a to authorize the Secretary to fundamentally rewrite the Medicare Act would raise substantial questions about the constitutionality of the statutory waiver authority. And for that reason, the statute should be fairly construed to avoid that question. *See Ashwander v. TVA*, 297 U.S. 288, 348 (1936) (Brandeis, J., concurring).

**3. Section 1315a(d)(2) Is Inapplicable Here**

Although the statute precludes judicial review of six particular aspects of a testing model, *see* 42 U.S.C § 1315a(d)(2), it does not bar review of claims that HHS violated the APA and other procedural requirements in issuing regulations. *See McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 496 (1991) (similar provision did not apply to "procedural objections"); *E. Bay Sanctuary*, 950 F.3d at 1269 (interpreting similar "jurisdictional limitations" as "allowing collateral APA challenges"); *Yale New Haven Hosp. v. Azar*, 409 F. Supp. 3d 3, 15 (D. Conn. 2019) (judicial review bar does not preclude challenges that "seek[] review of the promulgation of . . . rules and policies … separate from the substance of any such rules or policies"). Indeed, none of the six prongs of the provision limiting judicial review of testing models refers in any way to the notice and comment requirements of the APA or Medicare Act, much less includes the kind of clear language necessary to override the APA and Medicare Act's express grant of authority for courts to determine whether an agency has acted "without observance of procedure required by law." 5 U.S.C. § 706(2)(D); *see Allina*, 139 S.Ct. at 1809.

In addition, judicial review is necessary to address HHS's unlawful, *ultra vires* agency action. Section 1315a(d)(2) does not bar review of whether the MFN Rule falls completely outside the scope of HHS's authority to test payment models. *Chamber of Commerce v. Reich*, 74 F.3d 1322, 1328 (D.C. Cir. 1996) ("When an executive acts *ultra vires*, courts are normally available to reestablish the limits on his authority." (quoting *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988)); *see also Bowen v. Mich.*

*Acad. of Family Physicians*, 476 U.S. 667, 680-81 & n.12 (1986) (reviewing "constitutional challenges to the Secretary's administration of Part B of the Medicare program."). Thus, while the statute largely precludes challenges to the specifics of *how* HHS exercises its testing authority, it does not bar claims that HHS has *exceeded* the scope of its authority in order to impermissibly rewrite the Medicare reimbursement framework. There is a "strong presumption that Congress intends judicial review of administrative action." *Bowen*, 476 U.S. at 670. That presumption is "particularly strong" when, as here, a plaintiff claims that "agency action [was] taken in excess of delegated authority." *Amgen, Inc. v. Smith*, 357 F.3d 103, 111–12 (D.C. Cir. 2004) (citing *Leedom v. Kyne*, 358 U.S. 184, 190 (1958)). Congress has not precluded review of *ultra vires* challenges. *See, e.g., Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1173 (D.C. Cir. 2003) ("the case law … is clear that judicial review is available when an agency acts *ultra vires*").

**B. PLAINTIFFS' MEMBERS WILL SUFFER IRREPARABLE HARM**

Absent an injunction, plaintiffs' members will be irreparably harmed in many ways.

First, plaintiffs' members suffer irreparable injury if they are deprived of their statutory right to comment, and to have the agency meaningfully consider those comments, before the MFN Rule begins altering reimbursement rates. This Court has acknowledged that "depriving" plaintiffs "of the opportunity to offer comments ... may constitute irreparable injury" where, as here, "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); *see also California v. HHS*, 281 F. Supp. 3d 806, 829–30 (N.D. Cal. 2017) (notice-and-comment violation results in a "procedural injury" that "may serve as the basis for a finding of irreparable harm"), *aff'd in part, vac'd in part on other grounds*, 911 F.3d 558 (9th Cir. 2018); *N. Mariana Islands v. United States*, 686 F. Supp. 2d 7, 18 (D.D.C. 2009) (loss of opportunity to comment is irreparable harm because "damage done by [the Government's] violation of the APA cannot be fully cured by remedial action.").

Plaintiffs' members will also suffer substantial economic harm because the MFN Rule will dramatically reduce manufacturer revenues. This decline will begin immediately, and will total "billions of dollars of revenue annually . . . . " Hardy Decl. ¶ 7; *see also* Chen Decl.¶ 20. This harm is irreparable

because the government's sovereign immunity bars recovery of these losses should plaintiffs ultimately prevail. *See E. Bay Sanctuary Covenant*, 950 F.3d at 1280 ("[W]here parties cannot typically recover monetary damages flowing from their injury—as is often the case in APA cases—economic harm can be considered irreparable."); *City & County of S.F.*, 2020 WL 7052286, at *14 (9th Cir. Dec. 2, 2020) ("There is no dispute that such economic harm is sufficient to constitute irreparable harm because of the unavailability of monetary damages").

Lost revenue will cause further irreparable harm because it will lead to less spending on research and development of new drugs. With less revenue, some of plaintiffs' members may quickly face the possibility of having to halt ongoing development efforts for innovative life-saving medicines or to postpone those already planned. Chen Decl. ¶¶ 21, 22; Hardy Decl. ¶ 32. Such disruptions are irreparable, because once a drug trial has been halted it may not be "possible to recruit patients" to restart the trial, and "clinical trial sites may no longer be available." Hardy Decl. ¶ 33. *See Am. Trucking Ass'ns, Inc. v. City of Los Angeles*, 559 F.3d 1046, 1058 (9th Cir. 2009) (inability to immediately unwind changes made constituted irreparable harm); *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1382–83 (Fed. Cir. 2006) (considering "the discontinuation of clinical trials" as a "factor in … establish[ing] irreparable harm"); *Nat'l Ass'n of Mfrs. v. U.S. Dep't of Homeland Sec.*, 2020 WL 5847503, at *14 (N.D. Cal. Oct. 1, 2020) (accepting injuries of, *inter alia*, "disruption of business operations" and "inability to make capital investments" as irreparable).

Some plaintiffs' members also will lose market share, as doctors and hospitals who switch away from plaintiffs' members' medicines in early January may never switch back. Chen Decl. ¶ 21. In some instances, members' products are covered by the rule while similar competing products are not. Chen Decl.¶ 18. The rule will severely "degrade [the] competitive position" of these companies, by providing a strong financial incentive for physicians to switch to competitors' products. *Id*. Such "[l]oss of market share … may support a finding of irreparable harm." *Open Text, S.A. v. Box, Inc.*, 36 F. Supp. 3d 885, 906 (N.D. Cal. 2014)); *see also Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 67 (2d Cir. 2007) ("loss of current or future market share" constitutes irreparable harm); *Zeltiq Aesthetics, Inc. v. BTL Indus., Inc.*, 32 F. Supp. 3d 1088, 1104 (N.D. Cal. 2014) (same). The rule may also require plaintiffs' members

to restructure their workforces. Hardy Decl.¶ 34; Chen Decl. ¶ 21; *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d at 1382–83 ("reduction in workforce" is a factor showing irreparable harm).

The MFN Rule will cause irreparable harm with respect to plaintiffs' members' regulatory reporting obligations as well. They are required under the current framework to calculate and submit an ASP to CMS, with significant potential penalties for noncompliance. 42 U.S.C. § 1396r–8(b)(3)(A)(iii). However, the Rule would require exclusion of sales of covered drugs from the ASP calculation, but manufacturers lack the information needed to comply with this change. Garthwaite Decl. ¶ 141; Hardy Decl. ¶¶ 24, 36. Although plaintiffs' members would have an impossibility defense to any enforcement action, the legal uncertainty caused by the Rule, and the potentially wasted costs incurred to try to comply are irreparable harms. *A Woman's Friend Pregnancy Res. Clinic v. Harris*, 153 F. Supp. 3d 1168, 1215 (E.D. Cal. 2015) ("civil penalties" "constitute irreparable injury" where damages are "unrecoverable due to … sovereign immunity"), *vacated on other grounds by A Woman's Friend Pregnancy Res. Clinic v. Becerra*, 901 F. 3d 1166 (9th Cir. 2018).

### C. THE PUBLIC INTEREST AND BALANCE OF EQUITIES FAVOR AN INJUNCTION

Here, both the public interest and balance of equities interest weigh strongly in favor of granting plaintiffs' motion for a preliminary injunction. *See E. Bay Sanctuary Covenant*, 950 F.3d at 1271 (these factors "merge" "[w]hen the government is a party").

The public interest supports "preserv[ing] the status quo … pending a determination of the action on the merits." *L.A. Mem'l Coliseum Comm'n v. NFL*, 634 F.2d 1197, 1200 (9th Cir. 1980). That is particularly true here, where HHS's rush to implement its misguided MFN Rule will not only inflict irreparable harms on plaintiffs' members, but on patients and health care providers as well. The Rule will cause certain patients to receive inferior medical treatment or lose access to care altogether. Indeed, some healthcare providers have already ceased ordering covered medicines due to the Rule. *See supra* p. 7. "[T]he harm to patients will be immediate and irreparable," Garthwaite Decl. ¶ 124, particularly given that the majority of the covered medicines are cutting-edge treatments for life-threatening diseases such as cancer, and "are far superior to existing alternative treatments," Seiden Decl. ¶ 22. The rule will also harm the public interest by forcing patients to travel to hospitals to obtain medications, thus

"consolidat[ing] . . . larger numbers of patients into hospitals for treatments during the pandemic," including immune-compromised patients. Feldman Decl. ¶ 14. In the absence of a preliminary injunction, "the lives of seniors battling cancer and other very serious diseases are at stake in less than 30 days." Igra Decl. Ex. 14 at 1.

The rule will also cause severe financial hardship to various healthcare providers absent an injunction. Even if plaintiffs' members could immediately adjust their prices to the MFN reimbursement rate, in many cases healthcare providers are already bound by long-term price contracts with distributors. Garthwaite Decl. ¶ 113. These "potentially dire public health and fiscal consequences" of the MFN Rule—particularly in the midst of a pandemic—tilt the balance of equities and public interest strongly in favor of granting an injunction. *See Azar*, 911 F.3d at 582.

The public interest in research and development of innovative, life-saving medications will also be preserved through a preliminary injunction that maintains the status quo. Garthwaite Decl. ¶¶ 121, 140 (allowing MFN Rule to go into effect would "add to the uncertainties to the prospects of future investments in the biotech industry[,] chill investment" and threaten firm's ability to conduct research and development).

And "[t]he public interest is served by compliance with the APA" and Medicare Act's notice-and-comment requirements. *Azar*, 911 F.3d at 581–82 ; *Scholl v. Mnuchin*, 2020 WL 5702129, at *21 (N.D. Cal. Sept. 24, 2020). The APA and Medicare Act "reflect a judgment by Congress that the public interest is served by a careful and open review of the proposed administrative rules and regulations." *Azar*, 911 F.3d at 581–82. The value of such "careful and open review," *id*., is demonstrated by the consequences of its absence here: the agency's rush has produced a rule rife with misguided and ill-considered provisions that will seriously harm the very patients it was intended to help. *See* p. 18, *supra*; Garthwaite Decl. ¶¶ 120–134.

By contrast, HHS will not be harmed by a delay. "[P]ublic interest exists in ensuring that the government complies with its obligations under the law and follows its own procedures," *Medina v. U.S. Dep't of Homeland Sec.*, 313 F. Supp. 3d 1237, 1252 (W.D. Wash. 2018), and the Government "cannot suffer harm from an injunction that merely ends an unlawful practice or reads a statute as required to avoid

constitutional concerns," *Rodriguez v. Robbins*, 715 F.3d 1127, 1145 (9th Cir. 2013). And if HHS "is ultimately successful in defending the merits of the Rule, the harm will amount to no more than a temporary extension of the law previously in effect for decades." *City & County of San Francisco*, 2020 WL 7052286, at *14.

**CONCLUSION**

For the foregoing reasons, the Court should preliminarily enjoin defendants from implementing and enforcing the MFN Rule pending further proceedings on the merits.

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Respectfully submitted,

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