UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*, Defendants.	No. 20-CV-10488 (KMK) OPINION & ORDER

Appearances

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KENNETH M. KARAS, United States District Judge:

Regeneron Pharmaceuticals, Inc. ("Regeneron" or "Plaintiff") brings this Action seeking declaratory and injunctive relief against the United States Department of Health and Human Services ("HHS"), Alex M. Azar II, in his official capacity as Secretary of HHS ("Azar" or the "Secretary"), the Centers for Medicare & Medicaid Services ("CMS"), and Seema Verma, in her

official capacity as Administrator of CMS ("Verma" or the "Administrator"; collectively "Defendants"). Before the Court is an Order to Show Cause regarding Plaintiff's application for a preliminary injunction enjoining application of the Most Favored Nation Rule, 85 Fed. Reg. 76,180 ("MFN Rule"), to its drug EYLEA (aflibercept) Injection ("EYLEA"). (Order to Show Cause for Preliminary Injunction, Temporary Restraining Order, and Expedited Briefing Schedule ("OSC") (Dkt. No. 20).) For the reasons that follow, Plaintiff's application for a preliminary injunction is granted.

I. Background

On November 20, 2020, CMS released the Most Favored Nation ("MFN") Rule. Most Favored Nation Model, 85 Fed. Reg. 76,180 (Nov. 20, 2020) (to be codified at 42 C.F.R. pt. 513). "The MFN Model aims to take a global approach to calculating Medicare Part B drug payment amounts, by testing a new payment methodology that [1] takes into account the discounts that other countries enjoy [(the "MFN Price" component)]], and [2] pays providers and suppliers with a fixed add-on amount that does not reward the use of higher cost drugs [(the "alternative add-on payment" component)]." *Id.* at 76, 181. The MFN Rule was promulgated based on Section 1115A of the Social Security Act ("Section 1115A"), which allows CMS, through the Center for Medicare & Medicaid Innovation ("CMI") to "test payment and service delivery models." *Id.* at 76, 250; 42 U.S.C. § 1315a. This "test" will be in effect for seven years, with the MFN Price component phased in over the first three. 42 C.F.R. § 513.210(b)(8). Targeting some of Medicare Part B's top drug expenditures, the MFN Rule will apply to the top 50 drugs by aggregate allowed Medicare Part B charges (the "MFN Drugs"). *Id.* at § 513.130(a). Subject to certain exclusions, *id.* at § 513.130(b), participation is required for all providers and suppliers that submit a claim for an MFN Drug, *id.* at § 513.100(b). CMS did not follow notice

and comment procedures prior to promulgating the MFN Rule. *See* 5 U.S.C. § 553(b) & (c). Instead, it found that there was good cause to dispense with the notice and comment requirement of the Administrative Procedures Act ("APA"), supposedly due to the risks of high drug prices and the COVID-19 pandemic. 85 Fed. Reg. 76,248–76,249.

In announcing the MFN Rule, the President stated that it will "transform the way the U.S. government pays for drugs." 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/ ("MFN Announcement"). The President said that prior drug price reductions were "peanuts compared to what we've done with [most] favored nations," and that the MFN rule is "probably the biggest story that we've ever had relative to drug prices." *Id.* He further said "[n]obody has ever done this" and "there'll never be anything like this." *Id.* He indicated that "we're talking about savings of 50, 60, 70 percent, 80 percent." *Id.* Indeed, CMS estimates that the MFN Rule will save more than $85 billion for Medicare Part B, and $28.5 billion for beneficiaries. 85 Fed. Reg. 76,181.

In the same comments, the President indicated that the MFN Rule had been under consideration for at least two years. He stated that the MFN Rule "is something that has been talked about for many years, but nobody had the courage to do it." MFN Announcement. He also said that it "took a long time before we were able to do this because, statutorily, we had to go through a process." *Id.* He said the gap between U.S. and foreign prices has existed "for years," and "[w]e've been working on [the MFN Rule] for two years." *Id.* The Secretary echoed these comments, stating that he and the President "came up with the idea for Most Favored Nations status" at "the very first meeting we had in the Oval Office" after he became Secretary

in January 2018. *Id*. While the Secretary noted a recent application for approval of a vaccine, neither he nor the President discussed the role of the MFN Rule in responding to the COVID-19 pandemic. *Id*.

The regulatory record reflects this two-year history. On October 30, 2018, CMS issued an advance notice of proposed rulemaking (the "ANPRM"). Medicare Program; International Pricing Index Model for Medicare Part B Drugs, 83 Fed. Reg. 54,546 (Oct. 30, 2018). The ANPRM noted that U.S. drug acquisition costs exceed those of other developed countries, and that this leads to "unnecessary, potentially avoidable costs for Part B drugs." *Id*. at 54,550. It proposed an International Pricing Index model, which was to be tested in "selected geographic areas" pursuant to 42 U.S.C. § 1315a. *Id*. at 54,547. The ANPRM did not comply with the notice and comment requirements of 5 U.S.C. § 553(b) & (c). Instead, CMS promised that it "would implement [the model] through notice and comment rulemaking," *id*. at 54,550, and that "interested parties will also be provided an opportunity to comment on such information through subsequent proposed and final rulemaking documents," *id*. at 54,561.

On July 27, 2020, 21 months later, the President announced four executive orders focused on drug prices. *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/ ("Order Announcement"). The text of this Executive Order was released nearly two months later, on September 13, 2020. Exec. Order No. 13,948, Executive Order on Lowering Drug Prices by Putting America First (Sep. 13, 2020), https://www.whitehouse.gov/presidential-actions/executive-order-lowering-drug-prices-putting-america-first-2/ ("MFN Order"); *see also* Exec. Order No. 13,947, Lowering Drug Prices by Putting America First (July 24, 2020), https://www.govinfo.gov/content/pkg/DCPD-

202000674/html/DCPD-202000674.htm (noting the Sep. 13, 2020 release date for this Executive Order, which resembles and was superseded by the MFN Order). The MFN Order directed the Secretary to "immediately take appropriate 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*. It defined the "most-favored-nation price" as "the lowest price . . . for a pharmaceutical product that the drug manufacturer sells in a member country of the Organisation for Economic Co-operation and Development (OECD) that has a comparable per-capita gross domestic product." *Id*.

Plaintiff alleges, and Defendants do not refute, that EYLEA is among the 50 drugs covered by the MFN Rule, (Compl. ¶ 62 (Dkt. No. 1); Decl. of Richard O'Neal in Supp of Proposed OSC ("O'Neal Decl.") ¶ 16 (Dkt. Nos. 13)), and that the MFN Rule will reduce revenue from EYLEA and cause Plaintiff substantial financial harm, (O'Neal Decl. ¶¶ 21–33).

Plaintiff filed its Complaint on December 11, 2020. (Compl.). Since the MFN Rule will take effect on January 1, 2021, 42 C.F.R. § 513.1(c), Plaintiff immediately petitioned for emergency relief, including a preliminary injunction, (Proposed OSC (Dkt. No. 11); Decl. of Robert Allen in Supp. of OSC ("Allen Decl.") (Dkt. No. 12); O'Neal Decl.; Mem. of Law in Supp. of OSC ("Pl.'s Mem.") (Dkt. Nos. 14)).[1]

Also on December 11, 2020, the Court entered an Order to Show Cause, which established an expedited briefing schedule in light of the January 1 implementation date.

[1] Plaintiff also submitted a motion to seal portions of its memorandum and the O'Neal Declaration. (Not. of Pl.'s Mot. for Leave to File Under Seal (Dkt. No. 8); Decl. of Daniel Cellucci in Supp. of Pl.'s Mot for Leave to File Under Seal (Dkt. No. 9).)

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