

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**
Southern Division

**ASSOCIATION OF COMMUNITY
CANCER CENTERS, et al.,**

Plaintiffs,

v.

Case No.: GJH-20-3531

**ALEX M. AZAR II, in his official capacity
as Secretary of the U.S. Department of
Health and Human Services, et al.,**

Defendants.

* * * * *

ORDER EXTENDING TEMPORARY RESTRAINING ORDER

At issue in this civil action is the Most Favored Nation (“MFN”) Rule—published by the Centers for Medicare and Medicaid Services (“CMS”), a division of the United States Department of Health and Human Services (“HHS”), on November 27, 2020—which requires reimbursements made for certain drugs covered by Medicare Part B to be based on the lowest price in a group of “most favored nations” rather than the average U.S. sales price. ECF No. 24. Plaintiffs in this civil action are organizations which represent members—including provider groups, doctors, patients, and pharmaceutical companies—that will be impacted should the MFN Rule be implemented. ECF No. 1 ¶¶ 15–18. Defendants are HHS; Alex M. Azar II, the Secretary of HHS; CMS; Seema Verma, the CMS Administrator; the Center for Medicare and Medicaid Innovation (“CMMI”); and Brad Smith, the Director of CMMI and the CMS Deputy Administrator. ECF No. 1 ¶¶ 19–24.

CMS initially intended the model underlying the MFN Rule to go into effect on January 1, 2021; Most Favored Nation (MFN) Model, 85 Fed. Reg. 76180 (Nov. 27, 2020) (to be codified at 42 C.F.R. pt. 513); however, Judge Catherine C. Blake of this Court issued a Temporary Restraining Order (“TRO”) on December 23, 2020, restraining Defendants from implementing, enforcing, or otherwise effecting the MFN Rule for a period of fourteen days. ECF No. 44. On December 28, 2020, in a parallel litigation challenging the MFN Rule, Judge Vince Chhabria of the United States District Court for the Northern District of California largely adopted Judge Blake’s reasoning and issued a nationwide preliminary injunction, enjoining Defendants from implementing the MFN Rule pending completion of the notice-and-comment procedures required by the Administrative Procedure Act (“APA”). *Cal. Life Scis. Ass’n v. Ctr. for Medicare & Medicaid Servs.*, No. 20-cv-08603-VC, 2020 WL 7696050 (N.D. Cal. 2020). Most recently, on December 30, 2020, Judge Kenneth Karas of the United States District Court for the Southern District of New York, also adopting Judge Blake’s reasoning, issued a more limited preliminary injunction, enjoining Defendants from applying the MFN Rule to EYLEA (afibercept) Injections, a drug manufactured by Regeneron—the Plaintiff in the New York litigation—and covered by the MFN Rule. ECF No. 51-1.

With the January 1 deadline looming, all three judges based their orders granting injunctive relief on Defendants’ failure to follow the notice-and-comment procedures required by the APA and declined, in each case, to evaluate the statutory and constitutional claims of the respective plaintiffs. ECF No. 43 at 11 n.9 (“The court does not today reach the plaintiffs’ arguments concerning the statutory authority of CMS or the constitutionality of the rule.”); ECF No. 51-1 at 12 (“In the interest of releasing this Opinion & Order expeditiously, the Court does not evaluate and takes no position on Plaintiff’s probability of success on its other claims.”); *Cal.*

Life Scis. Ass'n, 2020 WL 7696050 at *1 (“The motion for a preliminary injunction is granted based on the government’s failure to complete the notice and comment procedures required by the Administrative Procedure Act.”).

Plaintiffs in this action have raised both statutory and constitutional challenges to the MFN Rule in addition to their procedural challenge under the APA. In their Reply Memorandum, Plaintiffs indicated that they would submit a “more full rebuttal on the merits” in advance of a ruling on the Preliminary Injunction. ECF No. 35 at 22. The Court believes such a submission would be helpful at this juncture as the Court wishes to, at least, address the statutory issues presented by the Motion for Temporary Restraining Order and Preliminary Injunction, ECF No. 24, which have not previously been reached by any court.

In order to adequately consider these issues, pursuant to Fed. R. Civ. P. 65(b)(2), the Court extends the TRO issued on December 23, 2020 for an additional fourteen days. The Court finds that the opportunity to, at least, reach the statutory issues presented in this action provides good cause for the extension. This extension will not prejudice either party since Defendants are currently subject to the nationwide preliminary injunction issued by the Northern District of California, which vacates the MFN Rule pending completion of the notice-and comment-process. *Cal. Life Scis. Ass'n*, 2020 WL 7696050 at *2.

For the reasons stated above, it is ordered by the United States District Court for the District of Maryland that:

1. The Temporary Restraining Order issued in this civil action on December 23, 2020, ECF No. 44, is **EXTENDED** for another fourteen days until January 20, 2021, or until further Order from the Court; and
2. Plaintiffs **SHALL** submit additional briefing on their statutory challenges to the MFN Rule on or before January 11, 2021. Defendants may respond, if they choose, by January 15, 2021.

Dated: January 6, 2021

/s/

GEORGE J. HAZEL
United States District Judge