

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

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

Plaintiffs,

v.

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

Defendants.

Civil Action No. 8:20-cv-03531-GJH

JOINT MOTION TO STAY

The parties, by their undersigned counsel, hereby jointly move the Court to stay this action as set forth below. In support of the motion, the parties further state as follows.

1. On November 27, 2020, the Centers for Medicare & Medicaid Services (CMS) published the Most Favored Nation Rule (MFN Interim Final Rule) as an interim final rule in the Federal Register. *See* 85 Fed. Reg. 76,180 (Nov. 27, 2020). The Rule seeks to tie drug reimbursement rates for certain drugs under Medicare Part B to the prices set in certain other countries over a seven-year period.

2. On December 4, Plaintiffs filed their Complaint, raising five challenges to the Rule, including that it was issued as an interim final rule in violation of the notice-and-comment provisions of the Administrative Procedure Act (APA).

3. On December 10, Plaintiffs filed a Motion for a Temporary Restraining Order and Preliminary Injunction. On December 15, pursuant to a court-ordered schedule, Defendants filed their Opposition, and the following day Plaintiffs filed their Reply.

4. Following a hearing, this Court issued a fourteen-day Temporary Restraining Order (TRO) on December 23 on the grounds that Plaintiffs were likely to succeed on the merits of their notice-and-comment challenge under the APA. *See* ECF No. 43.

5. On December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining Defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the APA. *See Cal. Life Scis. Ass'n v. Ctr. for Medicare & Medicaid Servs.*, No. 20-CV-8603, ECF No. 50 (N.D. Cal. Dec. 28, 2020). The California court based its order in large part on the reasoning in this Court's TRO. *See id.*

6. On January 6, this Court extended the TRO for another fourteen days, until January 20, 2021. It also ordered Plaintiffs to submit supplemental briefing on their statutory challenges to the MFN Rule on or before January 11, and Defendants to submit any response by January 15. Plaintiffs filed their supplemental briefing on January 11 as ordered.

7. Plaintiffs and Defendants have now reached an agreement to stay this litigation until a final rule based on the MFN Interim Final Rule is published in the Federal Register, based on the following conditions: (1) Defendants' agreement that they will not appeal the preliminary injunction issued by the Northern District of California; and (2) Defendants' agreement that the performance period for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. In the event that either of these two conditions is breached, the parties shall file a status report with the Court requesting that the Court lift the stay and establish a schedule for resolving Plaintiffs' Motion for Preliminary Injunction.

8. Plaintiffs and Defendants further agree to file a status report with the Court if Defendants rescind the MFN Interim Final Rule or otherwise determine that they no longer wish to proceed with the MFN Interim Final Rule.

9. Accordingly, the parties respectfully request that this Court enter the Proposed Order attached to this motion as Exhibit 1.

WHEREFORE, subject to the conditions contained herein, the parties respectfully request this Court to grant the Motion and stay the action.

DATED: January 13, 2021

Michele Sartori (Bar No. 26829)
E. Elizabeth Halpern***
Susan M. Cook***
HOGAN LOVELLS US LLP
555 Thirteenth Street, NW
Washington, DC 20004
(202) 637-5600
michele.sartori@hoganlovells.com
elizabeth.halpern@hoganlovells.com
susan.cook@hoganlovells.com

Counsel for Plaintiff Association of Community Cancer Centers

Andrew Zimmitti (Bar No. 18539)
Michael Kolber*
Adam Finkelstein***
MANATT, PHELPS & PHILLIPS LLP
1050 Connecticut Avenue, NW, Suite 600
Washington, DC 20036
(202) 585-6505
azimmitti@manatt.com
mkolber@manatt.com

Counsel for Plaintiff Global Colon Cancer Association

Respectfully submitted,

/s/ John P. Elwood
John P. Elwood*
Jeffrey L. Handwerker***
R. Stanton Jones (Bar No. 20690)
Allon Kedem*
Diana Sterk*
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Avenue, NW
Washington, DC 20001
(202) 942-5000
john.elwood@arnoldporter.com
jeffrey.handwerker@arnoldporter.com
stanton.jones@arnoldporter.com
allon.kedem@arnoldporter.com
diana.sterk@arnoldporter.com

Counsel for Plaintiff Pharmaceutical Research and Manufacturers of America

Timothy Cleveland*
Alethea Anne Swift*
CLEVELAND | TERRAZAS PLLC
303 Camp Craft Rd., Suite 325
Austin, TX 78746
(512) 689-8698
tcleveland@clevelandterrazas.com
aswift@clevelandterrazas.com

Benjamin H. Carney (Bar No. 27984)
GORDON, WOLF & CARNEY, CHTD.
100 W. Pennsylvania Avenue, Suite 100
Towson, MD 21204
(410) 825-2300
bcarney@gwcfirm.com

Counsel for Plaintiff National Infusion Center Association

* *Pro hac vice*

** *Pro hac vice* application forthcoming

*** Application for admission pending

DATED: January 13, 2021

Respectfully submitted,

JEFFREY BOSSERT CLARK
Acting Assistant Attorney General
Civil Division

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Rachael L. Westmoreland

Rachael L. Westmoreland
Alexandra R. Saslaw
Lisa N. Newman
Trial Attorneys
United States Department of Justice
Civil Division, Federal Programs Branch
P.O. Box 883
Washington, DC 20044
(202) 514-1280
rachael.westmoreland@usdoj.gov

Counsel for Defendants