

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

UNITED THERAPEUTICS CORPORATION,

Plaintiff,

v.

DIANA ESPINOSA, Acting Administrator of
U.S. Health Resources and Services
Administration, U.S. HEALTH RESOURCES
AND SERVICES ADMINISTRATION,
XAVIER BECERRA, Secretary of Health and
Human Services, and U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES,

Defendants.

Case No. 1:21-cv-1686 (DLF)

NOTICE OF DEFENDANTS' RECENT ENFORCEMENT REFERRAL

Plaintiff United Therapeutics Corporation (UT) hereby notifies the Court that on September 22, 2021, UT received the attached letter from Defendant U.S. Health Resources and Services Administration (HRSA). The letter announces that HRSA has referred UT to the U.S. Department of Health and Human Services' Office of Inspector General (OIG) for enforcement and imposition of civil monetary penalties, on the basis of HRSA's violation determination that is under review by this Court.

* * *

At the outset of this case, UT planned to move for a preliminary injunction to preserve the status quo and ensure effective judicial review of Defendants' violation determination. *See* Joint Mot. for Briefing Schedule, ECF No. 10 (referencing "Plaintiff's forthcoming motion for preliminary injunction"). But after this Court indicated that it was amenable to resolving the parties' cross-motions for summary judgment on an expedited schedule, UT concluded that it was

not necessary to seek emergency injunctive relief at that time. *See* Joint Notice at 1-2, ECF No. 13. UT noted, however, that “if it appears at some point during the expedited period in which cross motions are being resolved that the United States intends [to] take action against UT based on Defendants’ May 17, 2021 or May 28, 2021 letters, UT would anticipate seeking an emergency temporary restraining order.” *Id.*

Defendants’ decision to initiate enforcement action now—based on a determination that is under review by this Court—is unjustified, as demonstrated by the record and briefing in this case. It appears to be a transparent effort to pressure UT and warrants judicial intervention. But UT is aware of the Court’s orders and the parties’ filings in *Novartis Pharmaceuticals Corp. v. Espinosa*, No. 21-cv-1686-DLF, regarding an identical enforcement letter that HRSA issued to Novartis Pharmaceuticals Corporation. There, Defendants represented that “[t]he administrative process that OIG is required to follow before it may issue a final, effective decision imposing penalties . . . cannot be completed in the 19-day period between now and the October 12, 2021 motions hearing.” Defs.’ Response at 2, *Novartis*, ECF No. 27. Based on that representation, and because UT’s motion for summary judgment is scheduled to be heard October 12 alongside the motions in *Novartis*, UT will not seek emergency injunctive relief at this time. UT, however, reserves the right to seek emergency relief should Defendants’ representation turn out to be inaccurate.

Dated: September 24, 2021

Respectfully submitted,

/s/ Philip J. Perry

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