

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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NOVARTIS PHARMACEUTICALS))	
CORPORATION,))	
))	
<i>Plaintiff,</i>))	
))	
v.))	Civil Action No. 1:21-cv-01479
))	
DIANA ESPINOSA,))	
in her official capacity as))	
ACTING ADMINISTRATOR, HEALTH))	
RESOURCES AND SERVICES))	
ADMINISTRATION))	
))	
and))	
))	
XAVIER BECERRA,))	
in his official capacity as SECRETARY,))	
UNITED STATES DEPARTMENT OF))	
HEALTH AND HUMAN SERVICES,))	
))	
<i>Defendants.</i>))	
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JOINT RESPONSE TO COURT’S JULY 9 MINUTE ORDER

This Court issued a minute order seeking the parties’ position on two issues: [1] whether the parties consent to consideration of the plaintiffs' motions for a preliminary injunction with an expedited ruling on the parties' cross-motions for summary judgment, and [2] if so, whether the current briefing schedules should be modified.

As for question [1], Novartis and the Government both consent to consideration of Novartis’s preliminary-injunction motion with an expedited ruling on the cross-motions for summary judgment.

As for question [2], the parties’ positions are as set forth below:

Novartis' Position:

The briefing in Novartis's case is nearly complete, and a hearing had been set for July 28. Novartis's contract pharmacy policy is already in place. Our understanding is that United Therapeutics' contract pharmacy policy, which is substantively different from that of Novartis, is not scheduled to become fully operational until September 2021. *See* United Therapeutics Complaint ¶ 77. Although there is some overlap in the statutory arguments made by each of the manufacturers, their arbitrary-and-capricious arguments are quite different due to the unique nature of their individual contract pharmacy policies. In Novartis' view, any efficiencies gained from coordinating argument therefore are outweighed by the differences in the status and substance of plaintiffs' policies and the briefing posture.

If the Court is nonetheless inclined to consolidate the two lawsuits and hold a joint merits hearing, Novartis would strongly prefer that a hearing be set on September 8, and at the latest by mid-September, in order to further prompt resolution of the lawsuit.

Defendants' Position:

Defendants agree with the Court's determination that the parties' motions in the above-captioned matter and the forthcoming motions in *United Therapeutics Corp. v. Espinosa*, 1:21-cv-1686-DLF (D.D.C.), can be resolved most efficiently if the Court were to consider these motions simultaneously. In both cases, the plaintiffs raise closely related challenges under the Administrative Procedures Act, 5 U.S.C. § 706, to set aside similar determinations made by the Health Resources and Services Administration regarding the plaintiffs' obligations under the 340B statute. And in both cases, the Court must review the same administrative record and consider the same statutory question that is essential to resolving the plaintiffs' claims. Defendants therefore anticipate that their arguments in support of their motions for summary judgment and in opposition

to the plaintiffs' cross-motions for summary judgment will substantially overlap. Defendants also respectfully suggest that resolution of the statutory and administrative law issues raised by the parties' motions will not turn on the specific details of each plaintiff's policy.

Therefore, in the interest of an efficient and expeditious resolution of this case and the *United Therapeutics* case, Defendants respectfully request that the Court set a hearing to jointly consider the motions submitted by the parties in both cases at a date and time most convenient to the Court after the current briefing schedule in *United Therapeutics* is completed. If the Court intends to hold a joint hearing, Defendants request that the hearing currently set in this matter for July 28, 2021, be vacated. In Defendants' view, no further modification of the current briefing schedule in this case appears warranted.

Additionally, Defendants request that their obligation to answer Plaintiff's complaint be stayed until after the Court resolves the parties' cross-motions for summary judgment, if necessary.

Respectfully submitted,

/s/ Catherine E. Stetson

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