

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

ASTRAZENECA PHARMACEUTICALS LP,

*Plaintiff,*

v.

XAVIER BECERRA, in his official capacity  
as Secretary of the U.S. Department of Health  
and Human Services;

DANIEL J. BARRY, in his official capacity as  
Acting General Counsel of the U.S.  
Department of Health and Human Services;

DIANA ESPINOSA, in her official capacity as  
Acting Administrator of the Health Resources  
and Services Administration;

U.S. DEPARTMENT OF HEALTH AND  
HUMAN SERVICES; *and*

HEALTH RESOURCES AND SERVICES  
ADMINISTRATION,

*Defendants.*

C.A. No. 21-27 (LPS)

ADMINISTRATIVE PROCEDURE ACT  
REVIEW OF AGENCY DECISION

**PLAINTIFF'S EMERGENCY MOTION FOR ADMINISTRATIVE STAY  
AND, IN THE ALTERNATIVE, FOR EXPEDITION**

Plaintiff AstraZeneca Pharmaceuticals LP files this motion to raise with the Court a significant development relating to this litigation. As the Court is well aware, at the outset of this litigation the parties reached agreement on a stipulated schedule in lieu of proceeding on AstraZeneca's motion for a preliminary injunction. Briefing under the stipulated schedule will be complete on May 24, 2021, and oral argument is scheduled for June 9 on the parties' cross-motions for summary judgment and the government's motion to dismiss.

Earlier this week, Defendant Health Resources and Services Administration (HRSA) issued a letter asserting that AstraZeneca's contract pharmacy policy is unlawful and threatening to impose a variety of sanctions on AstraZeneca starting on June 1. As explained in further detail below, AstraZeneca respectfully submits that this development, which affects the circumstances under which the agreed-upon schedule was adopted, warrants a brief administrative stay to temporarily preserve the status quo until this Court has an opportunity to address the parties' respective dispositive motions. In the alternative, AstraZeneca requests that the Court expedite the current schedule to facilitate a swift resolution of the parties' dispute. In all events, AstraZeneca urges the Court not to allow this late-breaking development to delay the current schedule.

1. On May 17, 2021, AstraZeneca received a letter from Diana Espinosa, Acting Administrator of HRSA. The letter (attached as Exhibit 1) notifies AstraZeneca that HRSA has finished reviewing AstraZeneca's policy regarding contract pharmacy arrangements under the 340B Program, and that "HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute." Letter at 1.

For its conclusion that AstraZeneca's policy is unlawful, the letter articulates a justification that is at odds with any analysis previously issued by the agency. While the agency's Advisory Opinion had focused on the HHS Secretary's obligation, under the 340B statute, to enter into agreements requiring that 340B discounts are paid for drugs "purchased by a covered entity," the May 17 letter makes no mention of that requirement. Nor does the May 17 letter address the Advisory Opinion's position that 340B discounts must be provided for contract pharmacy sales "to the extent contract pharmacies are acting as agents of a covered entity." Advisory Op. at 1. Instead, the May 17 letter now seeks to ground AstraZeneca's obligation to offer discounts for contract pharmacy sales in the 340B statute's "must offer" provision, which the Advisory Opinion did not

analyze. Letter at 1. The May 17 letter also ties such obligation to the requirement that manufacturers “provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs,” *id.*, which is another argument not made in the Advisory Opinion.

The May 17 letter then declares that “AstraZeneca must [1] immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy,” [2] “credit or refund all covered entities for overcharges that have resulted from AstraZeneca’s policy,” and [3] “work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.” Letter at 2. The May 17 letter expresses HRSA’s intention, if AstraZeneca fails to comply with HRSA’s demands, to impose civil monetary penalties (CMPs) of up to \$5,883 per instance of noncompliance. Letter at 2 & n.3; *see* 42 U.S.C. § 256b(d)(1)(vi) (authorizing the imposition of civil monetary penalties for each instance of knowing and intentional overcharging of a covered entity). HRSA orders AstraZeneca to advise the agency of its plan to resume sales of 340B drugs to covered entities through contract pharmacy arrangements by June 1, 2021. Letter at 2.

2. At the outset of this litigation, AstraZeneca moved for a preliminary injunction in view of the irreparable harms that AstraZeneca faced from the agency’s position on the contract pharmacy dispute. AstraZeneca agreed to stay its motion in favor of expedited briefing and argument on cross-motions for summary judgment and the government’s motion to dismiss, but reserved its right to seek further relief in light of changed circumstances. *See* D.I. 23 ¶ 7. AstraZeneca respectfully submits that HRSA’s letter, including its threat to impose severe sanctions beginning June 1, now makes certain additional relief appropriate.

The May 17 letter has already caused harm to AstraZeneca and threatens further harm. As stated in the declaration of Odalys Caprisecca (attached as Exhibit 2), HRSA’s threat to impose

CMPs could amount to hundreds of millions of dollars in fines each month. Caprisecca Decl. ¶¶ 8-10. To be clear, AstraZeneca strongly disputes that HRSA has any basis for imposing CMPs on AstraZeneca as a result of its contract pharmacy policy, but the May 17 letter makes clear HRSA's contrary view. As a result, based on the volume of sales, AstraZeneca faces the threat of hundreds of millions of dollars in CMPs for *every month* that AstraZeneca retains its policy following June 1. *Id.* ¶ 10. And this threat, which was publicly posted on HRSA's website, is also causing AstraZeneca immediate and direct reputational harms, including among AstraZeneca's customers, covered entities, and investors. *Id.* ¶¶ 11-14. These reputational harms, including lost goodwill, will be difficult to remedy even if AstraZeneca is eventually successful in challenging HRSA's interpretation of Section 340B and overturning any CMPs imposed in the interim. *Id.* ¶ 14.

3. In view of the foregoing, AstraZeneca respectfully submits that the circumstances require action to forestall the serious consequences imposed by and threatened in the agency's letter. The May 17 letter identifies June 1 as the date on which AstraZeneca's failure to comply will lead the agency to impose CMPs and potentially other serious consequences. AstraZeneca is also concerned that the government may attempt to cite this last-minute letter as an excuse to delay or deviate from the current schedule.

AstraZeneca accordingly asks the Court to enter an administrative stay of the May 17 letter's June 1 deadline, to temporarily preserve the status quo until the Court has an opportunity to resolve the parties' cross-motions for summary judgment and the government's motion to dismiss. A two-week stay, with the possibility of renewal for an additional two weeks if necessary, would give the Court time to hear argument as currently scheduled on June 9, and to decide the case in due course. This short administrative stay should not burden the government, which has long known via this litigation (filed in January) of AstraZeneca's position on the Advisory Opinion, and yet published its letter only this week.

In the alternative, AstraZeneca asks the Court to accelerate the current schedule to facilitate resolution of the parties' dispute with the greatest expedition possible. Briefing on the parties' motions will be complete on May 24. AstraZeneca stands ready to present oral argument at any time to facilitate prompt resolution of this matter, preferably on or before June 1, or as soon as feasible thereafter, at the Court's discretion.

4. In an attempt to avoid the need for this motion, AstraZeneca contacted counsel for the government regarding whether the government would agree not to impose CMPs on AstraZeneca until after this Court has a chance to render its decision in this case. In the alternative, AstraZeneca asked whether the government would agree to extend the deadline for AstraZeneca to notify HRSA of its plan to resume sales of 340B drugs through contract pharmacies. The government declined both requests.

AstraZeneca and counsel for the government met and conferred regarding the present motion. The government stated that it opposes AstraZeneca's request and intends to respond in the time allotted under the Local Rules or as otherwise directed by the Court.

Dated: May 19, 2021

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Respectfully submitted,

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