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

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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EXHIBIT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 17, 2021

Ms. Odalys Caprisecca
Executive Director, US Strategic Price & Operations
AstraZeneca Pharmaceuticals, LP
1800 Concord Pike
Wilmington, DE 19803

Dear Ms. Caprisecca:

The Health Resources and Services Administration (HRSA) has completed its review of AstraZeneca Pharmaceuticals, LP's (AstraZeneca) policy that places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. AstraZeneca is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

AstraZeneca purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, AstraZeneca must 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. AstraZeneca must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from AstraZeneca's policy. AstraZeneca must 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.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on AstraZeneca's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that AstraZeneca provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

EXHIBIT 2

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* XAVIER BECERRA *et al.*, *Defendants*.	C.A. No. 21-27 (LPS)

DECLARATION OF ODALYS CAPRISECCA

Pursuant to 28 U.S.C. § 1746, I, Odalys Caprisecca, hereby declare and state as follows:

1. I am AstraZeneca's Executive Director for Strategic Pricing & Operations. In this capacity, I am responsible for US Pricing, Trade Operations, Contract Operations, and Government Reporting, which includes oversight of all federal programs such as the 340B program.

2. AstraZeneca is a proud participant in the 340B program. In 2020, for instance, AstraZeneca paid more than a billion dollars in discounts under the program to 340B program participants.

3. Since HRSA revised its contract pharmacy guidance in 2010 to authorize covered entities to contract with an unlimited number of independent pharmacies, we have become increasingly alarmed about the amount of duplicate discounting and drug diversion in connection with sales of our medicines under the 340B program. In the last several years, HRSA's audits of covered entities have identified significant non-compliance among contract pharmacies in particular. Last year, millions of dollars in inappropriate 340B discounts were identified based on

self-reported disclosures from covered entities—which the vast majority of participants in the program do not conduct.

4. At the same time, we have learned that contract pharmacies are earning substantial profit-margins on 340B discounted drugs that are not passed on to patients. Pharmacy profit margins on 340B brand name drugs are now a staggering 72%—more than triple regular margins—and generate hundreds of millions of dollars in profits each year. *See* Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program* 7 (Oct. 2020), https://bit.ly/3owtUwa. For example, Walgreens' SEC filings report that any pricing changes "in connection with the federal 340B drug pricing program[] could significantly reduce our profitability." *Walgreens Boots Alliance, Inc. Form 10-K* (Oct. 15, 2020), https://bit.ly/2MoLX9d.

5. In 2020, we changed our policy specifically to address program abuses. Our goal is to limit the potential for abuse in a manner that complies fully with the 340B statute, while at the same time enabling patients served by covered entities to continue to access our medicines. Under our new policy, effective October 1, 2020, a covered entity that maintains its own on-site pharmacy may obtain our medicines at 340B prices through the covered entity's on-site pharmacy. A covered entity that does not have an on-site pharmacy may recognize one contract pharmacy designated by the covered entity through which it may purchase our medicines at the 340B price. Under our revised policy, every 340B entity can purchase our medicines at the 340B price, either through its own in-house pharmacy or through its designated contract pharmacy. This is the same policy that HRSA had in place from 1996 through March 2010.

6. I understand that, on May 17, 2021, Diana Espinosa, Acting Administrator of HRSA, posted a letter on the HRSA website notifying 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."

7. The letter then directs 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." It does so with no discussion of AstraZeneca's actual policy, no acknowledgement that every covered entity can access our medicines through a pharmacy of its choice at the 340B price, and no analysis of the 340B statute supporting that an overcharge is occurring.

8. The letter also threatens that, if AstraZeneca fails to comply with HRSA's demands, HRSA may seek civil monetary penalties (CMPs) of up to $5,883 per instance of noncompliance. The letter orders AstraZeneca to advise the agency of our plan to resume sales of 340B drugs to covered entities through unlimited contract pharmacy arrangements by June 1, 2021.

9. To be clear, we do not agree with HRSA's characterization of our position. The HRSA letter is based on the incorrect premise "that AstraZeneca's actions have resulted in overcharges" to covered entities. AstraZeneca's policy as noted allows each covered entity to access our medicines through either their own in-house pharmacy or a contract pharmacy of their choice. Our policy in no way restricts any covered entity from purchasing any of our medicines at 340B prices, nor does our policy result in any overcharge to a covered entity. If HRSA follows through on any of the threats it makes in its letter, we will vigorously defend our position.

10. However, HRSA's threats, in and of themselves, pose significant and in many ways unquantifiable harms to AstraZeneca. If HRSA follows through on any of its demands, we fail to see how we can effectively remedy the harms that would occur. First, and most obviously, civil monetary penalties are an extremely harsh sanction. According to HRSA's letter, they could amount to as much as $5,883 per instance that the government believes we sold our product to a covered entity at an incorrect price. Although AstraZeneca disputes that it *ever* overcharges a covered entity for 340B drugs, or that such overcharges occur under its contract pharmacy policy, HRSA clearly disagrees. Given the sheer number of 340B sales that we make every year, this could amount to hundreds of millions of dollars in potential penalties *every month* under a broad interpretation of HRSA's threat. For example, based on a comparison between the volume of 340B discounts before and after our new policy came into effect, AstraZeneca estimates that it could face hundreds of millions of dollars per month in CMPs (which does not include potential reimbursement requests from covered entities). The imposition of a penalty of such size, even if we could ultimately reverse it later on, will cause reputational injuries to our company.

11. Moreover, HRSA's letter, which was posted publicly on HRSA's website, is also adversely affecting our business relationships and causing reputational harm, including among our customers, covered entities, and investors. As a result of HRSA's letter, AstraZeneca's covered entity customers and investors have the impression—in our view, mistakenly—that AstraZeneca is *knowingly and intentionally* violating Section 340B and overcharging for 340B covered medications.

12. Our customer-facing teams have received multiple requests and inquiries from customers seeking a response to the demands in HRSA's letter. We have also received inquiries

from investors arguing that AstraZeneca is violating Section 340B at the expense of covered entities.

13. HRSA's claims have also been the subject of media scrutiny. I am aware of at least 14 national media and trade press organizations that have written articles covering HRSA's letter to AstraZeneca in just the two days since HRSA posted it online. *See, e.g.*, FDA News, *HHS Threatens Six Drugmakers with Legal Action for Withholding 340B Discounts* (May 19, 2021); Kaiser Health News, *Six Drugmakers Warned to Reinstate 340B Discounts to Contract Pharmacies* (May 18, 2021); Bloomberg Law, *Eli Lilly, Sanofi Breached Federal Law by Curbing Drug Discounts* (May 17, 2021).

14. Even if AstraZeneca is eventually successful in challenging HRSA's interpretation of Section 340B and overturning any CMPs imposed in the interim, the lost goodwill and reputational harm caused by HRSA's letter will be difficult to restore.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 19, 2021.

DocuSigned by:

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Odalys Caprisecca

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

RULE 7.1.1 CERTIFICATION

Pursuant to D. Del. L.R. 7.1.1, the undersigned counsel hereby certifies that counsel for Plaintiff conferred with counsel for Defendants by teleconference regarding the relief sought in the foregoing motion and that the parties were unable to reach agreement on the relief sought therein.

Dated: May 19, 2021

Respectfully submitted,

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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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

[PROPOSED] ORDER GRANTING PLAINTIFF'S MOTION FOR ADMINISTRATIVE STAY AND, IN THE ALTERNATIVE, FOR EXPEDITION

The Court having considered Plaintiff AstraZeneca Pharmaceuticals LP's Emergency Motion for Administrative Stay and, in the Alternative, for Expedition (the "Motion"), the relevant papers and submissions, and any opposition thereto,

IT IS HEREBY ORDERED, this _____ day of _____, 2021, that AstraZeneca's Motion is GRANTED.

A stay shall be in effect until June 9, 2021, during which, Health Resources and Services

Administration (HRSA) shall not impose any civil monetary penalties on AstraZeneca for failure to "[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." HRSA's request that AstraZeneca provide an "update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by June 1, 2021," shall also be stayed until June 9, 2021. The Court shall decide the June 9, 2021, hearing whether a further stay is necessary at that time.

[**Alternative Relief:** The hearing scheduled for June 9, 2021 is hereby rescheduled. The Court shall hear argument on the parties' cross-motions on May __, 2021 at ____.]

_____
CHIEF UNITED STATES DISTRICT JUDGE