U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20005

VIA CM/ECF

May 21, 2021

The Honorable Leonard P. Stark, Chief Judge
District of Delaware
J. Caleb Boggs Federal Building
844 N. King Street, Unit 26, Room 6124
Wilmington, DE 19801-3555

Re: *AstraZeneca Pharmaceuticals LP v. Becerra, et al.* (1:21-cv-00027-LPS)—Opposition to Emergency Motion for Administrative Stay or Expedition

Dear Chief Judge Stark:

Plaintiff AstraZeneca Pharmaceuticals ("Astra") has filed a purported emergency motion asking this Court to enjoin (under the guise of an "administrative stay") Astra's deadline to respond to a new agency action not challenged in Astra's complaint, not briefed by the parties, and thus not yet capable of resolution at the upcoming June 9, 2021 hearing. Despite its claims of exigent circumstances, Astra does not even attempt to identify authority for this Court to administratively "stay" Astra's deadline to respond to the agency (likely because no authority exists), nor does Astra attempt to brief the requirements that would be necessary for the Court to enjoin agency action (assuming claims challenging the new action were before the Court). Astra's request is procedurally improper, logically incoherent and should be denied. Should Astra wish to challenge the recent violation letter it received, it promptly should amend its complaint and the parties should submit short supplemental briefs of no more than 7-10 pages addressing the new claim(s).

As explained in Defendants' Motion to Dismiss or for Summary Judgment ("Mot."), ECF No. 56 at 6-8, the present dispute arose in mid-2020 when Astra and several other large, global pharmaceutical manufacturers abruptly upended the twenty-five year operation of the 340B Program. Specifically, Astra and its peers announced that no longer will they offer (or offer without manufacturer-imposed restrictions) access to discounted drugs for safety-net healthcare providers (called "covered entities") and their patients when the patients fill their prescriptions at outside, neighborhood pharmacies. These actions have increased profits for the drug makers, while dramatically curtailing much-needed funding for safety-net providers and, in some cases, forcing patients to pay more for medications or adjust their medication regimen. *Compare* Caprisecca Decl. ¶ 10 (admitting that Astra's policy has resulted in a significant reduction in the volume of 340B discounts it provides to covered entities: "a comparison between the volume of 340B discounts before and after our new policy" demonstrates Astra "could face hundreds of millions of dollars per month" in penalties) *with* Br. Amici Curiae, Nat'l Ass'n of Comm. Health Ctrs. *et al.*, ECF No. 59 at 10-19 (presenting evidence, supported with numerous declarations, of severe consequences to providers and patients accruing from the manufacturers' actions).

Astra admitted in its complaint that the Health Resources and Services Administration ("HRSA"), the component of the Department of Health and Human Services ("HHS") to which oversight and implementation of the 340B Program has been delegated, explicitly put Astra on notice eight months ago that the agency was "considering whether AstraZeneca's proposed policy constitutes a violation of the 340B statute and whether sanctions would apply," including "civil monetary penalties." *See* Am. Compl. ¶ 51 (citing Ex. D, Letter from Adm. Pedley, Sept. 2, 2020). HRSA further warned Astra that its new restrictions "could have the effect of severely limiting access" to drugs during a global pandemic. *Id.* Unfazed, Astra proceeded to implement its policy.

HRSA's review of Astra's policy culminated in a new agency action, in the form of a 340B-violation letter issued May 17, 2021. *See* Pl.'s Mot. for Adm. Stay ("Stay Mot.") Ex. 1. In that letter, HRSA's acting administrator informed Astra that the agency "has determined that AstraZeneca's actions have resulted in overcharges and are in direct violation of the 340B statute." *Id.* 1. The letter relies exclusively on statutory text to determine that the requirement that Astra honor covered entities' purchases "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and that "[n]othing … grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing." *Id.* HRSA directs Astra to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements," and confirms that civil monetary penalties (CMPs) may be imposed. Although the letter instructs Astra to "provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price" by June 1, 2021, that date is *not* tied to the potential imposition of CMPs. *Id.* 2. On the contrary, although "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies … may result in CMPs," HHS "will determine whether CMPs are warranted *based on AstraZeneca's willingness to comply with its obligations* under section 340B(a)(1)." *Id.* The letter thus makes clear that HHS has not made any determination as to whether sanctions are warranted at all but, should Astra continue to flout its 340B obligations, any such sanctions will not necessarily be limited to violations that occur after June 1.

Astra cannot shoe-horn review of this new agency action into its existing claims challenging a prior agency decision, and this Court should deny Astra's request for emergency relief, for several reasons.

First, Astra cannot obtain relief as to an agency action it has not even challenged—*especially* when it seeks to forestall enforcement of a statute Congress charged HHS with administering. Astra's operative complaint challenges legal advice from HHS's Office of General Counsel, which opined generally (and consistently with previous agency guidances) on what the 340B statute requires. That advice did not purport to analyze the legality of Astra's newly imposed restrictions; indeed, it did not itself impose any obligation on manufacturers and thus does not even constitute reviewable final agency action. Mot. 10-13. By contrast, the violation letter embodies a determination by a different entity altogether—HRSA, the component charged with enforcing Congress's mandate—that Astra's specific policy is unlawful and may result in sanctions. In its motion Astra completely ignores the fact (raised by undersigned counsel in the parties' meet and confer) that, should Astra wish to challenge the agency's determination, Astra must amend its complaint to set forth the legal theories on which it challenges HRSA's violation letter. *John Doe #1 v. Veneman*, 380 F.3d 807, 819 (5th Cir. 2004) (holding that enjoining agency decision not

challenged in complaint "exceed[s] the legal basis for judicial review under the APA" and "constitutes an impermissible advisory opinion"); *Trishan Air, Inc. v. Fed, Ins. Co.*, 635 F.3d 422, 435 (9th Cir. 2011) (holding claim not challenged in complaint is "not properly before the district court"). Astra cannot contend that review of the May 17th letter is somehow encompassed in its claims related to the General Counsel's advice, since Astra specifically has told this Court that "HRSA's letter reaches [its] position on the basis of new reasoning that appears nowhere in its Advisory Opinion (or any other prior statement of agency position)." *See* ECF No. 67, Letter Mot. for Admin. Stay, 1. Defendants disagree with Astra's characterization of the letter's position, but it is clear that the parties agree that HRSA's violation letter is not based on the Advisory Opinion. *See also* Stay Mot. ¶ 1 (claiming that HRSA's letter does not rely on 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'" and that it relies on a separate statutory phrase). Indeed, given Astra's assertion that "the letter articulates a justification that is at odds with any analysis previously issued by the agency," it is clear that—though the parties may differ on their views regarding the agency's consistency—Astra agrees with Defendants that the letter constitutes new action. And it is axiomatic that this Court lacks jurisdiction to award injunctive relief on the basis of a motion that "raises issues different from those presented in the complaint." *Sai v. Transp. Sec. Admin.*, 54 F. Supp. 3d 5, 9 (D.D.C. 2014); *see also Clay v. Okla. Dep't of Corr.*, No. CIV-12-1106-C, 2013 WL 3058122, at *2 (W.D. Okla. June 17, 2013) ("When the movant seeks intermediate relief beyond the claims in the complaint, the court is powerless to enter a preliminary injunction.").

Second, and relatedly, even were this Court to agree with Astra that the Advisory Opinion is reviewable *and* that it should be set aside, that would not resolve Astra's (as-yet unfiled) challenge to HRSA's letter. HRSA has made the specific determination that Astra is violating the 340B statute—something not encompassed within the General Counsel's advice. Stated plainly, HRSA's letter does not rely on the Advisory Opinion, and HRSA's actions to enforce the 340B statute would not be impeded by vacatur of the legal advice. This further demonstrates why Astra must file a claim challenging HRSA's letter and present argumentation on its merits should Astra wish to seek to forestall further enforcement.

Third, Astra has not even attempted to identify *any* statute, regulation, or Rule of Civil Procedure that would grant this Court authority to grant an "administrative stay" in these circumstances. Astra has not pointed to 5 U.S.C. § 705, and for good reason, since that provision only allows a court "to the extent necessary to prevent irreparable injury" to "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." A stay under § 705 also requires the movant to establish each of the four traditional preliminary-injunction factors. *See Colorado v. EPA*, 989 F.3d 874, 883 (10th Cir. 2021) (collecting authority). Astra does not seek to postpone the *effective* date of agency action (HRSA's letter already is in effect), it has not argued that it is irreparably harmed by HRSA's letter, nor has it attempted to meet the other injunction factors. Astra likewise does not point to any other source, or even caselaw, purporting to support its request for "an administrative stay." Moreover, the action it seeks to forestall is not even appropriate for such a stay. Although it casts its request as seeking postponement of "the date on which AstraZeneca's failure to comply will lead the agency to impose CMPs and potentially other serious consequences," Stay Mot. ¶ 3, the letter makes plain that the June 1 date is simply a deadline for

Astra to communicate to HRSA its plan to come back into compliance with its 340B obligations. *See* Stay Mot. ¶ 1 (acknowledging that "HRSA order[ed] AstraZeneca *to advise the agency of its plan* to resume sales of 340B drugs" by June 1). Contrary to Astra's portrayal, Stay Mot. ¶ 1, any subsequent decision by the agency to impose CMPs if Astra remains noncompliant are not tied to post-June 1 purchases—the letter takes no position on the time period for which CMPs may be imposed, if the agency decides to impose them. Defendants are unaware of, and Astra certainly has not provided, *any* authority suggesting this Court can issue an administrative stay of a deadline for a regulated entity to communicate with an agency regarding its statutory compliance, which is all the June 1 deadline entails.

Fourth, Astra essentially asks for equitable relief without endeavoring even to address the factors that would be necessary to support such a request. Astra claims that HRSA's letter "is at odds with any analysis previously issued by the agency," Stay Mot. ¶ 1, yet Astra's motion contains *not a word* addressing the likelihood of success on the merits of a challenge to this purportedly new rationale. Then again, given that Astra has no pending claims challenging the letter, it would be difficult for either party to brief the merits. Similarly, Astra speculates that HRSA's "threat" "has already caused harm" because it could result in "hundreds of millions of dollars in fines each month," *id.* ¶ 2, yet nowhere does Astra brief the irreparable-harm or balance-of-equities factors that would justify emergency relief. (Any claim of irreparable harm would be meritless at this point, given that the agency has not decided to impose CMPs, Astra would receive process before any sanctions were imposed, 42 C.F.R. § 10.11(a) (citing 42 C.F.R. Part 1003), any sanctions would be reviewable by a court, and the purported "hundreds of millions of dollars in fines each month" Astra faces stem entirely from its unilateral decision to alter the status quo and cut off access to discounted drugs for needy patients and providers. Indeed, given Astra's admission that its contract-pharmacy restrictions have resulted in a sufficiently large reduction in 340B discounts to warrant potentially "hundreds of millions of dollars per month" in penalties, exclusive of reimbursements to covered entities, Caprisecca Decl. ¶ 10, it is plain that any harm accruing to Astra is self-inflicted.) Equitable relief "is an extraordinary remedy never awarded as of right," and the movant bears a heavy burden. *Winter v. Nat. Res. Def. Council*, 555 U.S. 7, 24 (2008). Astra cannot obtain equitable relief (in the guise of a "stay") without establishing its entitlement.

Fifth, Astra's suggestion that its procedurally improper motion was somehow contemplated in the stipulated schedule is inaccurate. Astra claims that, "[a]t the outset of this litigation," it "moved for a preliminary injunction in view of the irreparable harms" it "faced from the agency's position on the contract pharmacy dispute," and that, after a schedule was set, it "reserved its right to seek further relief in light of changed circumstances." Stay Mot. ¶ 2. In reality, in pressing for expedition of the schedule for resolving this action (and over Defendants' objection, ECF No. 21), Astra reserved its "right to seek further acceleration of the schedule in the event that ADR [alternative dispute resolution] proceedings advance before resolution of" the case. *See* ECF No. 23 ¶ 7. No ADR proceedings have advanced against Astra to date. And Astra's unilateral contemplation of reviving its preliminary-injunction motion had those proceedings advanced does not grant Astra ground to ask this Court to forestall a new agency action without the benefit of briefing or an amended complaint.

Sixth, Astra's contention that an administrative stay is warranted "to temporarily preserve the status quo," Stay Mot. ¶ 3, strains credulity. The status quo was toppled less than a year ago

when Astra and its peers upended the twenty-five-year, settled operation of the 340B Program and began denying purchases by covered entities using contract pharmacies. And the June 1 deadline is simply an instruction for Astra to communicate to HRSA *its plan* to resume making sales to covered entities regardless of dispensing mechanism; communicating to the agency certainly won't upset any "status quo." Finally, there is no ground to stay that deadline to communicate with HRSA, given that resolution of Astra's challenge to the Advisory Opinion will not resolve any dispute over HRSA's authority to enforce the 340B statute against Astra based on what Astra characterizes as new rationales.

Seventh, Astra's "concern[] that the government may attempt to cite this last-minute letter as an excuse to delay or deviate from the current schedule," Stay Mot. ¶ 3, is disingenuous. It is Astra, not the government, seeking to deviate from the current schedule. More to the point, undersigned counsel informed counsel for Astra during the parties' meet-and-confer on the morning of Tuesday, May 18, of Defendants' position that, should Astra wish to challenge HRSA's letter, it should amend its complaint so that the parties could address the merits of any new claims. Undersigned counsel repeated that position the following day. But rather than amend its complaint to permit expeditious briefing of any new claims *within the schedule already agreed to by the parties and set by the Court*, Astra insisted on wasting several business days by filing its procedurally baseless "emergency motion" on the misguided impression that the legality of HRSA's letter somehow presently is before the Court. It is not, and Astra promptly should amend its complaint if it wishes to ensure prompt resolution of any new claims. Regardless, any delay cannot be attributed to the government.

Eighth, Astra's assertion that a "short administrative stay should not burden the government, which has long known via this litigation … of AstraZeneca's position … and yet published its letter only this week," Stay Mot. ¶ 3, is specious. It is Astra that admittedly has known since September 2, 2020, that HRSA actively was investigating whether Astra's policy was unlawful and whether sanctions would apply, Am. Compl. ¶ 51, yet Astra proceeded with its restrictions. The fact that Astra tried to preempt HRSA's administrative process by filing suit to challenge the Advisory Opinion issued by a different HHS component, reiterating the agency's consistent statutory interpretation, does not now allow Astra to leapfrog the procedural hurdle of actually challenging the agency action it wants this Court to "stay."

In conclusion, Defendants respectfully suggest that this Court lacks authority to administratively stay HRSA's instruction for Astra to submit a proposal to come back into statutory compliance, and that, even if there were a statutory or procedural basis for such a stay, Astra would not be entitled to any relief due to its failure to brief the factors that would be necessary to support it. Moreover, no claims regarding HRSA's violation letter are pending before the Court and its legality could not be resolved through the current briefing. Should Astra wish to challenge HRSA's violation letter, Defendants respectfully suggest that it should be ordered to amend its complaint adding new claim(s) regarding this agency action, and the parties should be permitted to submit short supplemental briefs addressing those claim(s). Finally, Defendants do not yet take a position on the proper timeframe for the parties to address any new claims by Astra because it is not yet known what those claims would consist of or how promptly Astra might amend its complaint.

Respectfully,

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