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September 24, 2021

VIA CM/ECF
The Honorable Leonard P. Stark
United States District Court for the 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.*, C.A. No. 21-27-LPS**

Dear Judge Stark:

We write on behalf of AstraZeneca to alert the Court to two important developments relevant to this Court's disposition of the litigation.

1. As the Court is aware, on May 17, 2021, the Health Resources and Services Administration (HRSA) sent a letter to AstraZeneca threatening to impose a variety of sanctions, including hundreds of millions of dollars per month in potential civil monetary penalties, if AstraZeneca failed to accede to HRSA's interpretation of the 340B statute. AstraZeneca moved for an administrative stay or expedition in light of the severe harms the May 17 letter threatened to impose. D.I. 66. As explained in the May 19 declaration submitted by Odalys Caprisecca, penalties for AstraZeneca's alleged violations of the 340B statute could amount to hundreds of millions of dollars in fines each month, in addition to reputational and other harm. Caprisecca Decl. ¶¶ 8-10, D.I. 66-1. The May 17 letter is the subject of fully briefed cross-motions for summary judgment currently pending before this Court, with a hearing scheduled for October 18.

The Court had originally scheduled the hearing for September 14, *see* D.I. 97, but had to reschedule due to a conflict, *see* D.I. 98. HRSA has chosen to escalate its actions against AstraZeneca during this brief delay: On September 22, AstraZeneca received a letter from HRSA referring AstraZeneca to the agency's Office of the Inspector General for AstraZeneca's "continued failure to provide the 340B price to covered entities utilizing contract pharmacies." Ex. A, Letter from Michelle Herzog, Acting Director, Office of Pharmacy Affairs, HRSA, to Odalys Caprisecca, Executive Director, US Strategic Price & Operations, AstraZeneca. Citing the May 17 letter, HRSA stated that it was initiating proceedings to impose civil monetary penalties against AstraZeneca for its "continued refusal to comply" with the agency's interpretation of the statute. *Id.* With HRSA's latest communication, the threat of serious harm to AstraZeneca that civil monetary penalties would impose is closer than ever.

This is now the second time that the agency has taken action to escalate sanctions against AstraZeneca, based on the agency's interpretation of the 340B statute, on the eve of proceedings in this Court to address that very interpretation. The May 17 letter itself was issued less than a month before a scheduled summary judgment hearing on the agency's Advisory Opinion, prompting this Court to expedite argument regarding the Opinion's legality. D.I. 71. This Court

subsequently ruled that the agency's analysis was "legally flawed," and that Section 340B "says nothing about the permissible role (if any) of contract pharmacies." D.I. 78 at 17-18. The agency then responded by withdrawing the Advisory Opinion and asking the Court to dismiss AstraZeneca's challenge to it as moot; instead, the Court granted judgment for AstraZeneca. D.I. 82, 83.

Now that the parties' cross-motions for summary judgment regarding the May 17 letter have been fully briefed and argument has been scheduled, HRSA has referred AstraZeneca for imposition of civil monetary penalties. HRSA has offered no explanation for why, more than four months after the May 17 letter, it has chosen this moment to take such a significant step. Nor has HRSA explained how AstraZeneca's policy could give rise to "knowing and intentional" violations of the statute, *see* 42 U.S.C. § 256b(d)(1)(B)(vi), in light of this Court's existing ruling on the merits, which its letter does not acknowledge.

AstraZeneca respectfully submits that HRSA's referral of AstraZeneca for imposition of civil monetary penalties at this time—while AstraZeneca is awaiting judicial resolution of the lawfulness of HRSA's violation determination—is inappropriate. The proper course is to await the outcome of this pending litigation before initiating any administrative proceedings for the imposition of civil monetary penalties. Notably, at a hearing on July 30, in a suit brought by Eli Lilly & Co. in the U.S. District Court for the Southern District of Indiana, the following exchange took place between the court and counsel for the government:

> THE COURT: So let me ask you a question about the enforcement process. So the enforcement letter basically asserts HHS's and HRSA's view of the violation. So how does Lilly contest that if it chooses to disagree?
>
> MS. TALMOR: Exactly as it has done, Your Honor. We have not moved to dismiss on the violation letter. We've only moved for summary judgment. So we're not arguing that it's not justiciable. So this process is playing out exactly as Congress intended.
>
> The agency charged with enforcement has found a violation. It has issued the equivalent of a cease and desist letter, and Lilly can challenge it in this court. So this is as Congress designed, and it's directly analogous to other agency enforcement scenarios as well.
>
> THE COURT: So the opposition to the quote, cease and desist order, end quote, is through judicial action?
>
> MS. TALMOR: Yes, Your Honor.

Trans. at 18-19, *Eli Lilly & Co. v. U.S. Dep't of Health & Human Servs.*, No. 21-cv-81 (S.D. Ind. July 30, 2021) (attached as Ex. B). The agency's decision to initiate parallel administrative proceedings subverts this orderly judicial process.

2. Separately, on September 2, the National Association of Community Health Centers served on AstraZeneca an amended petition for declaratory and injunctive relief in the agency's Administrative Dispute Resolution (ADR) process. *See* Ex. C. The same claims were originally brought against AstraZeneca, Sanofi, and Eli Lilly; the amended petition severs claims against Eli

Lilly—apparently because ADR proceedings against Eli Lilly remain enjoined by the U.S. District Court for the Southern District of Indiana. Assignment of the amended petition to an ADR panel could happen at any time. As this Court has recognized, such proceedings do not provide a meaningful venue for contesting Defendants' interpretation of the 340B statute: "If AstraZeneca (or another manufacturer) tries to raise the legal issue presented here in ADR proceedings, the result is preordained." D.I. 78 at 17.

* * *

These two developments signal that Defendants and covered entities are actively seeking sanctions against AstraZeneca for its contract pharmacy policy, notwithstanding the pendency of litigation in which AstraZeneca's compliance with the 340B statute is squarely before this Court, and notwithstanding this Court's ruling that the 340B statute does not obligate manufacturers to recognize unlimited contract pharmacy sales. AstraZeneca respectfully submits that these developments confirm the urgent need for expeditious resolution of this matter. Cognizant that the Court's schedule necessitated moving the hearing to October 18, AstraZeneca does not request that the hearing be expedited, but respectfully requests that the Court prioritize its resolution of the pending motions to avoid the need for preliminary injunction proceedings or further motion practice.

Respectfully submitted,

/s/ Daniel M. Silver

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cc: All Counsel of Record (via CM/ECF and E-Mail)