IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, *Plaintiff*, *v.* XAVIER BECERRA, DANIEL J. BARRY, DIANA ESPINOSA, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, and HEALTH RESOURCES AND SERVICES ADMINISTRATION, *Defendants*.	C.A. No. 21-27-LPS

JOINT STATUS REPORT

Undersigned counsel respectfully submit this joint status report pursuant to the Court's oral order at the hearing held on October 18, 2021 (D.I. 103). The Court directed the parties to inform the Court of "anything you want to tell me," including "your perspectives on the urgency" of a ruling on the pending cross-motions for summary judgment, as well as "any developments in the ADR process" or "any response to the inquiries that AstraZeneca has made." *Id.* at 95-96.

The parties' respective statements are set forth below:

1. **Plaintiff**

AstraZeneca respectfully urges the Court to facilitate resolution of the parties' dispute with the greatest expedition possible. Notwithstanding this Court's ruling that their view of the 340B statute is "legally flawed," D.I. 78 at 17, Defendants have resolved to press forward administratively on multiple fronts, threatening punitive and persistently accumulating sanctions

against AstraZeneca. The *only* thing that can keep Defendants from inflicting these harms is a ruling by this Court making clear that doing so would be inconsistent with the law.

ADR: As the Court is aware, four separate ADR petitions have been filed against AstraZeneca, which HRSA has now assigned to panels for formal proceedings. AstraZeneca believes that the ADR proceedings are unfair and legally faulty, including on multiple constitutional grounds. *See* 2d Am. Compl. (D.I. 86) at ¶¶ 117-131 (describing violations of the Appointments Clause and Article III). AstraZeneca is currently challenging the ADR process through a suit filed by Pharmaceutical Research and Manufacturers of America (PhRMA), of which AstraZeneca is a member. *See PhRMA* v. *Becerra*, No. 21-cv-198-PWG (D. Md.); *see also Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393 (S.D. Ind. Mar. 16, 2021) (agreeing with Eli Lilly that the ADR Rule violated the APA and preliminarily enjoining Defendants "from implementing or enforcing" the ADR Rule against Eli Lilly). In addition, as this Court has explained, ADR 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.

Upon being informed of the assignment of the four ADR petitions against it, AstraZeneca sent HRSA a letter inquiring about the composition of the panels and the deadlines (if any) for responding to the petitions, including the opportunity to seek a stay pending this Court's decision on the parties' fully briefed dispositive motions. As of the hearing held by this Court on October 18, AstraZeneca had not received a response. Following the hearing, AstraZeneca filed motions with HRSA to extend any responsive deadlines that may apply until after this Court's ruling.

On October 23, one of the ADR panels issued a scheduling order directing AstraZeneca to respond to the petition, move to dismiss, or seek a stay by November 21. The order also

indicated that the parties will be granted, as a matter of right, one 30-day extension. Should AstraZeneca seek and receive a 30-day extension of its initial deadline, its new deadline would be December 21.

Also on October 23, HRSA informed AstraZeneca that its extension motions had been "forwarded to" the other three ADR panels assigned to the petitions against it. AstraZeneca has received no further information about the relevant deadlines for responding to those petitions, however, nor any further response to its earlier inquiries regarding the composition of the panels and the opportunity to seek a stay pending this Court's ruling. As a consequence, if AstraZeneca's motions for an extension are not granted, AstraZeneca's responses to those three ADR petitions could be due as soon as November 4. *See* 85 Fed. Reg. at 80,639 (providing for a response deadline of 30 days from notification).

CMP: As the Court is also aware, on September 22, AstraZeneca received a letter from HRSA referring AstraZeneca to the agency's Office of the Inspector General (OIG) for proceedings to impose CMPs against AstraZeneca for its contract pharmacy policy. Following this Court's summary judgment hearing, and in light of the Court's order to file a joint status report, AstraZeneca reached out to counsel for Defendants with several questions regarding the CMP proceedings: Who within OIG is handling the proceedings; what is the current status and timeline for those proceedings; and will they proceed in advance of this Court's ruling on the parties' summary judgment motions?

Counsel for Defendants did not answer AstraZeneca's questions, but provided AstraZeneca with email addresses for two OIG officials to whom AstraZeneca's questions about the CMP proceedings could be directed. AstraZeneca emailed those officials with its questions on October 22. On October 25, an OIG official responded that they would be willing to meet but

"will not discuss specific issues related to eventual CMPL enforcement of this matter at this time."

Need for prompt decision: Throughout this litigation, AstraZeneca has proceeded with expedition commensurate with the harms presented as a result of Defendants' actions. AstraZeneca filed suit against the Advisory Opinion on January 12, less than two weeks after the Opinion was first issued. At the outset of the litigation, AstraZeneca initially moved for a preliminary injunction in view of the irreparable harms that it faced, but agreed to stay its motion in favor of expedited briefing and argument on the parties' cross-motions. D.I. 23 ¶ 7. When HRSA threatened to refer AstraZeneca for CMPs on May 17—shortly before this Court's scheduled hearing on the first round of fully briefed summary judgment motions—AstraZeneca filed an emergency motion for administrative stay or, in the alternative, for expedition. D.I. 66. This Court denied the stay but granted the request for expedition, accelerating the motions hearing by two weeks. D.I. 71. The Court then ruled on the parties' motions 20 days after the hearing. D.I. 78.

AstraZeneca had hoped and expected that this Court's ruling—which, among other things, observed that Defendants' position was "legally flawed," D.I. 78 at 17—would cause Defendants to alter their conduct in conformity with the principles articulated by this Court. Instead, Defendants have escalated their efforts to punish AstraZeneca for its contract pharmacy policy. As counsel for Defendants have repeatedly made clear, Defendants will press forward unless and until this Court definitively rules on the meaning of the 340B statute in a way that precludes further administrative action. 1st Summ. J. Hr'g Tr. (D.I. 76) at 84, 109; 2d Summ. J. Hr'g Tr. (D.I. 103) at 69-71.

The ongoing administrative proceedings (CMP and ADR) threaten to inflict imminent harm on AstraZeneca. For every month that AstraZeneca does not acquiesce to Defendants' erroneous view of the 340B statute, it risks hundreds of millions of dollars in CMPs. *See* D.I. 66 at 4 (citing Caprisecca Decl. ¶¶ 8-10). These threatened penalties will continue to accumulate pending this Court's decision: As this Court aptly explained, the propriety of CMPs "ultimately [depends on] whoever wins on the statutory interpretation," because in the wake of that ruling, "either there is going to be a basis for penalties or there isn't." 1st Summ. J. Hr'g Tr. (D.I. 76) at 100. And AstraZeneca simultaneously faces an unconstitutionally structured ADR process, in which "the result is preordained," D.I. 78 at 17, which is a form of irreparable harm in itself. Indeed, given the "important individual liberty interests" protected by separation-of-powers principles, the Third Circuit has held that such a structural violation is "presumed" to cause constitutional harm to the litigant, such that an immediate "hearing on the merits is favored." *Cirko ex rel. Cirko v. Comm'r of Soc. Sec.*, 948 F.3d 148, 154-55 (3d Cir. 2020). In addition, Defendants' administrative actions—which incorrectly accuse AstraZeneca of violating its statutory obligations—have caused and will continue to cause significant "damage to [AstraZeneca's] reputation, which constitutes irreparable injury that is difficult to quantify" or to correct through litigation. *Ferring Pharm., Inc. v. Watson Pharm., Inc.*, 765 F.3d 205, 212 (3d Cir. 2014); *see* D.I. 66 at 4 (summarizing declaration describing "reputational harms, including among AstraZeneca's customers, covered entities, and investors").

For the foregoing reasons, AstraZeneca respectfully asks the Court to rule on the parties' motions as expeditiously as possible. Despite its diligent efforts over the past year, AstraZeneca remains in an administrative vacuum on multiple fronts, with no clear timetable for resolution

and no assurance that the agency will respect this Court's ruling. Absent relief from this Court, AstraZeneca has nowhere else to turn.

2. **Defendants**

As mentioned above, today an employee of HHS's Office of Inspector General responded to Plaintiff's email posing questions regarding HRSA's CMP referral. OIG's response read, in full: "OIG is available to speak with you and will attempt to answer any questions you have; however, we will not discuss specific issues related to eventual CMPL enforcement of this matter at this time. Please contact Susan Gillin and me directly with all issues related to this matter."

In this report Plaintiff argues that it faces irreparable harm due to the unconstitutional nature of the administrative process, yet Plaintiff has not challenged the ADR Rule either on constitutional or any other grounds, nor is any motion for relief from those proceedings pending.

As Plaintiff mentions above, on October 22, 2021, one of the ADR panels assigned to review a petition pending against AstraZeneca entered an initial scheduling order. Not only did that order grant Plaintiff 30 days from its issuance to file a response, plus the ability to obtain an additional 30-day extension as of right (meaning that, as a practical matter, no response is due until December 21, 2021), the scheduling order specifically contemplated that Plaintiff's response can take the form of "a motion to stay the proceedings in this matter" or a motion to dismiss under Federal Rule of Civil Procedure 12. Should Plaintiff file such a motion, the petitioner will have 21 days to respond, and Plaintiff will have an additional 14 days to reply in support of its motion. Although the panels assigned to review the other three petitions pending against Plaintiff have not yet entered a scheduling order, there is no reason to believe that Plaintiff will need to respond to those proceedings significantly more quickly than the

proceeding in which a scheduling order has been entered.

Although Defendants do not believe that the ADR proceedings necessitate a quick ruling from this Court, Defendants respectfully request an expeditious ruling from this Court due to the continuing overcharges and accruing harms caused by Plaintiff's unlawful refusal to honor its statutory obligations. As discussed at the hearing on October 18, 2021, HRSA's most-recent data show that Plaintiff is continuing to sell 340B drugs directly to covered entities in their 340B accounts at full commercial pricing (wholesale acquisition cost). In August 2021 alone, HRSA documented $2.5 million in overcharges, specifically on AstraZeneca's drugs, to covered entities directly in their 340B accounts. These continuing overcharges threaten the viability of resource-strapped safety-net providers, as documented in the administrative record. Defendants respectfully contend that an expedited ruling is preferable so that covered entities can once again access the discounts they have received for decades and to which they are statutorily entitled.

Dated: October 25, 2021

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