McCarter & English

Daniel M. Silver
Partner
T. 302-984-6331
F. 302-691-1260
dsilver@mccarter.com

McCarter & English, LLP
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, DE 19801-3717
www.mccarter.com

February 14, 2022

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 this Court of further developments relevant to the Court's disposition of the litigation.

As the Court is aware, several Administrative Dispute Resolution (ADR) petitions have been filed against AstraZeneca and have been assigned to panels for formal proceedings. On January 7, 2022, the parties filed a Joint Status Report informing the Court that AstraZeneca had sought to stay those ADR proceedings pending (*inter alia*) the decision in this case. The ADR petitioners opposed AstraZeneca's stay motions.

Today, February 14, an ADR panel denied AstraZeneca's stay motion, per the attached opinion. In so ruling, the panel stated that it "respects the role of Article III courts in our constitutional system and will abide by any orders issued by such courts," Op. at 3, but the panel expressly rejected AstraZeneca's argument that the panel should await this Court's decision on the parties' fully briefed summary judgment motions before engaging AstraZeneca in ADR proceedings. The panel ordered AstraZeneca to respond to the petition by March 13.

Respectfully, AstraZeneca continues to believe that an expeditious resolution of this matter is appropriate, and indeed, necessary in view of the progression of parallel proceedings.

Respectfully submitted,

/s/ Daniel M. Silver

Daniel M. Silver (#4758)

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

BEFORE THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADMINISTRATIVE DISPUTE RESOLUTION PANEL

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, *Petitioner*, v. SANOFI-AVENTIS U.S. LLC and ASTRAZENECA PLC, *Respondents*	No. 210112-2

DECISION ON MOTIONS TO STAY

On December 20, 2021, Respondents Sanofi-Aventis U.S. LLC (Sanofi) and AstraZeneca PLC separately moved this Panel to stay the proceedings in this administrative matter. Petitioner National Association of Community Health Centers (NACHC) filed an opposition to those motions on January 10, 2022, and the Respondents separately replied on January 24, 2022. The motions are, therefore, fully briefed.

For the reasons set forth below, this Panel respectfully denies the Sanofi and AstraZeneca motions.

A. Standard for Granting a Request to Stay Proceedings

In considering the Respondents' motions, the undersigned begin with the related propositions that the Administrative Dispute Resolution (ADR) regulation (ADR Rule or Rule) that establishes this Panel's authority and governs these proceedings is valid,[1] and that the Department of Health and Human Services (HHS) has an affirmative obligation to implement the Section 340B drug-discount program, *including an obligation to resolve certain disputes arising under that program*, on a rational, non-arbitrary, and nationwide basis.[2] It necessarily follows from those propositions that where a dispute, such as NACHC's petition, is presented to an ADR Panel, there is a presumption that the Panel will exercise its limited jurisdiction and issue a decision recommending resolution of that dispute.[3]

It is also true, however, that this Panel's conduct in this matter is governed, and constrained by, the Federal Rules of Civil Procedure. *See* 42 C.F.C. § 10.23(b). Applying those Rules to the instant setting, it is clear this Panel has broad discretion to stay proceedings pending before it. *See, e.g.*, *Clinton v. Jones*, 520 U.S. 681, 706 (1997); *Landis v. N. Am. Co*, 299 U.S. 248, 254 (1936).

As the Respondents point out, in exercising their discretion to stay proceedings, federal district courts "'weigh competing interests and maintain an even balance' between the court's

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[1] *See, e.g.*, *Citizens to Pres. Overton Park, Inc.* v. *Volpe*, 401 U.S. 402, 415 (1971); *Escobedo v. Green*, 602 F. Supp. 2d 244, 248 (D.D.C. 2009). *See also Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health and Human Res.*, -- F. Supp. 3d --, 2021 WL 5150464 (D.N.J. 2021) (upholding the ADR regulation in response to a challenge under the Constitution and the Administrative Procedure Act).

[2] *See Astra U.S.A., Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 120 (2011) (refusing to recognize a private right of action to enforce Section 340B pharmaceutical pricing agreements and noting that recognizing such a right would "undermine [HHS's] efforts to administer both Medicaid and [Section] 340B harmoniously and on a uniform, nationwide basis.").

[3] *Cf. Sanofi-Aventis U.S.*, 2021 WL at *28 (recognizing that an ADR Panel does not have the authority to impose remedies, but only to issue decisions that are subject to review by principal officers appointed under the Constitution's Appointments Clause).

interest in judicial economy and any possible hardship to the parties." *Belize Soc. Dev., Ltd. v. Gov't of Belize*, 668 F.3d 724, 732–33 (D.C. Cir. 2012) (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)). Federal courts also place upon the movant the burden of establishing the need for a stay. *U.S. S.E.C. v. Deloitte Touch Tohmatsu CPA, Ltd.*, 928 F. Supp. 2d 43, 47 (D.D.C. 2013).

The well-established, federal-court standard for granting a request to stay proceedings, however, does not translate verbatim to these proceedings. For one thing, federal courts are appropriately and understandably concerned with judicial economy and the expenditure of federal judicial resources. This Panel, however, sits in the Executive Branch. The interests this Panel must weigh, therefore, are not those of judicial economy or the appropriate use of judicial resources, but rather (1) HHS's interest in managing its resources, (2) HHS's interest in, and obligation to manage the 340B Program, and (3) any possible hardship to the parties.

B. Application of the Standard for a Stay of Proceedings

Having considered those interests, the undersigned conclude that the Respondents have not carried their burden to establish that a stay is appropriate.

First, allowing the current proceedings to move forward will not unduly tax HHS's resources. Indeed, no Party has made any suggestion to the contrary, and the Panel is unpersuaded by the Respondents' discussion of judicial resources or judicial economy. Although this Panel respects the role of Article III courts in our constitutional system, will abide by any orders issued by such courts, and is sympathetic to the need, generally, to husband scarce federal resources, including the resources of the federal judiciary, the use of federal judicial resources is not something that this Panel should properly consider. Congress directed HHS to establish a dispute resolution process for specific issues arising in the 340B Program, an HHS

program. *See* 42 U.S.C. § 256(b)(d)(3)(A). HHS complied with that mandate by establishing the current ADR process within the Agency, *see* 85 Fed. Reg. 80,362 (Dec. 14, 2020), and by appointing this Panel to consider NACHC's petition. It is, therefore, HHS and Executive Branch resources that are relevant to a request to stay proceedings before this Panel. Consideration of those resources does not mandate a stay of these proceedings.

Second, neither the various pieces of litigation pending before the federal courts nor the possibility, or even the likelihood that HHS will choose to replace the current ADR Rule weigh in favor of a stay here.

The Supreme Court's decision in *Astra* is instructive on this point. In *Astra*, the Court addressed whether covered entities under the 340B Program have a right to sue in federal court as third-party beneficiaries of the pharmaceutical pricing agreements entered into between drug manufacturers and HHS. *See Astra*, 563 U.S. at 118. In declining to recognize such a right of action, the Court noted both that Congress "made HHS administrator of . . . the 340B Program," and that it is HHS's responsibility to administer that Program on a uniform, nationwide basis, subject, of course, "to judicial review under the [Administrative Procedure Act (APA)]." *Id.* at 120–22.

Nothing about HHS's administration of the 340B Program has fundamentally changed since *Astra* was decided. HHS, acting through the Secretary and the Health Resources and Services Administration, continues to be primarily responsible for administering the Program. And HHS's resolution of covered entities' complaints, including the one presented here, is still binding, "subject to judicial review under the APA." *Id.* at 122. The only thing that has changed is that HHS, consistent with express direction from Congress, has chosen to use the current ADR Rule and the Panels formed pursuant to that Rule, to help it execute that responsibility. Final

decisions by the Panels formed under the ADR Rule are subject, in the exercise of his sound discretion, to the Secretary's review and approval, or disapproval, and any final HHS actions with respect to the Program are still subject to review by a federal court under the APA.

Similarly, that the ADR Rule is currently being challenged in various federal courts does not change the fact that HHS is responsible in the first instance, as the Court in *Astra* recognized, for resolving covered entities' complaints, including the one brought by NACHC. It is true, as the Respondents point out, that the Court of Appeals for the Third Circuit could disagree with the district court in New Jersey and invalidate the ADR Rule, or that district courts in Delaware or Maryland could decide to invalidate the Rule. Those potential outcomes, however, are speculative. Moreover, as noted at the outset of this Order, this Panel operates consistent with two propositions, *viz*., (1) a presumption that the current ADR Rule is valid; and (2) that HHS, consistent with a mandate from Congress, has an affirmative obligation to implement the 340B Program, including an obligation to resolve certain disputes arising under that program.

That HHS may decide to replace the current ADR Rule with a new regulation also does not mandate a stay of these proceedings. First, there is potentially a long road between an agency's decision to announce rulemaking and the promulgation of a final rule. Indeed, the anfractuous procedural history of the current ADR Rule is a good example of the potential long and twisting path to a final rule. *See Sanofi-Aventis U.S., LLC*, 2021 WL 5150464 (D.N.J. 2021) (setting forth the decade-long history of the current ADR Rule). And, as the Parties well know, final rules are subject to challenge in the federal courts. Again, the current ADR Rule provides a clear example of the complex and protracted litigation that may ensue once a regulation becomes final. *Id*. (describing the multiple challenges to the ADR Rule). One need look no further than the Supreme Court's current docket to get a sense of the legal challenges that may await any

given agency action. In short, whether, when, and how the current ADR Rule may be replaced, as well as the outcome of any challenges to a new rule, are speculative. Given the presumptions identified above, the extant legal challenges to the ADR Rule and the potential that the Rule could be replaced are not sufficient reasons to stay these proceedings.

Finally, the respective hardships facing the parties do not counsel in favor of a stay. Absent a stay, the Respondents will presumably move to dismiss the petition and advance the same arguments they have made in other venues. Asking the Respondents to restate, in this venue, the same positions they have advanced elsewhere is not likely to be overly burdensome. Indeed, as NACHC points out in its response to the motions, being required to participate in a valid legal process, without more, is not the type of harm that typically justifies a stay. On the other hand, granting a stay is likely to cause hardship to NACHC's members. Accepting NACHC's representations as true, for purposes of resolving the current motions only, its members have, for over a year, suffered significant financial harm, including reducing clinical staff and curtailing services to patients. In light of these harms, the balance of hardships also weighs against granting the motions.

C. Conclusion

Until Congress changes the law, a court of competent jurisdiction enjoins either the ADR Rule or this Panel's activities, or HHS amends or replaces the ADR Rule, this Panel must assume it has a mandate to hear the petitions before it. Accordingly, and for the reasons set forth above, the motions for a stay are denied.

The Respondents are respectfully directed to file a response to the original petition, including any counterclaims or crossclaims permitted under Rule 13 of the Federal Rules of Civil Procedure, or an appropriate motion under Rule 12 of the Federal Rules of Civil Procedure, on or before 30 days after the date of this decision.

It is so ordered this 11th day of February 2022.

Glenn Clark
ADR Panel Member

Sean R. Keveney
ADR Panel Member

Timothy M. Lape -S5

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Date: 2022.02.11 11:44:59 -06'00'

Timothy Lape
ADR Panel Member