[PROPOSED LETTER BRIEF]

VIA ECF

The Honorable Paul W. Grimm
United States District Judge
District of Maryland
6500 Cherrywood Lane
Greenbelt, MD 20770

Re: *Pharmaceutical Research and Manufacturers of America v. Becerra, et al.*, No. 8:21-cv-00198-PWG (D. Md.)

Dear Judge Grimm:

Pursuant to permission granted by this Court, plaintiff Pharmaceutical Research and Manufacturers of America (PhRMA) submits this letter brief to apprise this Court of relevant developments pertaining to the Administrative Dispute Resolution Regulation (the ADR Rule), 85 Fed. Reg. 80,632 (Dec. 14, 2020), that PhRMA has challenged in this case, and to address certain rulings in another suit that involves some overlapping issues.

As PhRMA has noted, *see* Doc. 29 at 22 n.4, one court preliminarily enjoined use of the ADR Rule against one manufacturer after finding that the agency had likely violated its notice-and-comment obligations. *Eli Lilly & Co. v. Cochran*, 526 F. Supp. 3d 393, 407–08 (S.D. Ind. 2021). The *Lilly* Court later vacated an enforcement letter that the Health Resources and Services Administration (HRSA) had issued against Lilly under the 340B program, but did not further address the ADR Rule. *See Eli Lilly & Co. v. HHS*, No. 1:21-cv-00081, 2021 WL 5039566, at *1 n.1, *25–26 (S.D. Ind. Oct. 29, 2021). That case is on appeal. *See Eli Lilly & Co. v. HHS*, Nos. 21-3128, -3405 (7th Cir. Nov. 15 & Dec. 30, 2021).

After the conclusion of briefing in the present matter, the District of New Jersey rejected challenges to the ADR Rule brought by another manufacturer, including two challenges raised here: that Rule violates the Appointments Clause and that defendants failed to respond adequately to significant comments on the proposed rule. *Sanofi-Aventis U.S., LLC. v. HHS*, No. 3:21-cv-00634-FLW-LHG, 2021 WL 5150464 (D.N.J. Nov. 5, 2021). At the same time, the Court vacated enforcement letters that HRSA had issued to Sanofi and Novo Nordisk.[1] The parties' cross-appeals have been consolidated. *See Sanofi-Aventis U.S., LLC v. HHS*, Nos. 21-3167, -3379, -3168, -3380 (3d Cir. Dec. 29, 2021), ECF No. 3.

[1] Novo Nordisk's separate suit, *Novo Nordisk Inc. v. HHS*, No. 3:21-cv-00806-FLW-LHG (D.N.J.), did not challenge the ADR Rule but was consolidated with the *Sanofi* case.

Finally, in February, an ADR panel declined to stay proceedings against Novo Nordisk and AstraZeneca PLC in light of pending challenges to the ADR Rule, including those raised here, stating that the outcomes in the Third Circuit and in District Courts "in Delaware or Maryland" are "speculative." Decision on Motions to Stay at 5, *Nat'l Ass'n of Cmty. Health Ctrs. v. Sanofi-Aventis U.S., LLC*, No. 210112-2 (H.H.S. Feb. 11, 2022).[2]

Because the *Sanofi* Court has issued the only decision addressing the Appointments Clause and a failure-to-address-comments challenges that PhRMA has raised to the ADR Rule here, the balance of this submission addresses those rulings.

I. The Appointments Clause Ruling

As PhRMA has explained in its briefs to this Court, the ADR Rule violates the Appointments Clause because it empowers ADR Board members, who are inferior officers, "'to render a final decision on behalf of the United States' without any . . . review by their nominal superior or any other principal officer in the Executive Branch." *United States v. Arthrex, Inc.*, 141 S. Ct. 1970, 1981 (2021) (quoting *Edmond v. United States*, 520 U.S. 651, 665 (1997)). In its decision, the *Sanofi* Court rejected several of the theories that defendants advanced in that case (and have advanced here as well) to try to show that Board decisions are subject to meaningful review by the Secretary. Defendants claimed, for example, that the Rule did not "prohibit the Secretary from overturning a panel decision with which he disagrees." *See* Doc. 89 in *Sanofi*, No. 3:21-cv-00634 (D.N.J.), at 28; *see also* Doc. 31 in *PhRMA*, at 16 (claiming that "the Secretary freely may exercise discretionary review of panel decisions"). But the *Sanofi* Court recognized that the Secretary "has no power to revise or reverse" Board decisions "once rendered." *Sanofi*, 2021 WL 5150464, at *24. Defendants also claimed that the Secretary can exercise control over Board decisions by revoking his delegation of authority to the Board and deciding cases personally. *See* Doc. 62-1 in *Sanofi*, at 36; Doc. 26-1 in *PhRMA*, at 25. The *Sanofi* Court rejected these claims because the Secretary must adopt an ADR Rule, cannot rescind the current Rule without going through notice-and-comment rulemaking, and has no power under the current Rule to decide cases himself. *Sanofi*, 2021 WL 5150464, at *26 n.42.

The Court nevertheless held that the ADR Rule does not violate the Appointments Clause. First, because panel decisions must be submitted to HRSA "'for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities,'" the Court ruled that the Secretary has an "unambiguous supervisory mechanism" — the power to ignore Board rulings. *Id.* at *25 (quoting 42 C.F.R. § 10.24(e)). Second, the *Sanofi* Court concluded that the Secretary has adequate supervisory power

[2] A copy of the ADR panel's decision was filed in *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. Feb. 14, 2022), and that copy is attached hereto as Exh. 1.

because his ability to remove members from service on the Board is the power to remove them from federal service entirely. *Id.* at *26–27. Neither theory is correct.

A. The "Discretion to Ignore" Theory. The *Sanofi* Court's first theory of effective oversight fails for two reasons. First, permitting the Secretary or HRSA to ignore Board decisions would be plainly inconsistent with the system of binding precedent required by the ADR Rule. *See* 42 C.F.R. § 10.24(c)&(d) (Board's decision is the "agency decision," and the agency decision "constitutes a final agency decision that is *precedential* … unless invalidated by an order of a court of competent jurisdiction") (emphasis added). The *Sanofi* Court itself recognized that non-enforcement "would appear to impact the precedential value of Board decisions." *Sanofi*, 2021 WL 5150464, at *25 n.41. In fact, "supervision" through non-enforcement would convert decisions that, by Rule, are to be precedential, into merely advisory rulings. Adopting such an approach would effectively rewrite the Rule without the notice and comment that the *Sanofi* Court recognized is required by law. *See id.* at *26 n.42 ("The Secretary . . . cannot [modify] the ADR Rule without complying with the APA's procedural requirements for new agency action, including notice and comment . . . .").

Second, an ADR scheme that confers completely standardless discretion on HRSA to ignore Board decisions would render the ADR process arbitrary and unlawful. Under this theory, HRSA could, without explanation, decline to enforce one Board decision and then, six months later, enforce a decision involving different parties but otherwise indistinguishable facts. Such a scheme would not only violate basic principles of due process, it would violate the statutory requirement that the ADR Rule establish "procedures as may be necessary to ensure that claims shall be resolved *fairly*." 42 U.S.C. § 256b(d)(3)(B)(ii) (emphasis added). Indeed, as the ADR panel recognized just months ago, the agency "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." *See* Exhibit 1 at 2 & n.2 (citing *Astra U.S.A., Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 120 (2011)) (emphases altered). A system involving unfettered discretion to ignore supposedly "precedential" decisions is the antithesis of a rational, non-arbitrary program.[3]

[3] The *Sanofi* Court also quoted a statement from the rulemaking proceeding in which HRSA noted that, for covered entity violations, it would leave the "*form of* enforcement … open" to afford "maximum flexibility in determining what is appropriate." *Sanofi*, 2021 WL 5150464, at *25 (quoting 85 Fed. Reg. 80,632, 80,642 (Dec. 14, 2020) (emphasis added)). But this is not an assertion, much less evidence, that HRSA has unfettered discretion to ignore some Board decisions while choosing to enforce others.

For these reasons, this Court should decline to adopt the *Sanofi* Court's theory that Board decisions are subject to meaningful review by a principal officer.[4]

B. The "Removal Power" Theory. The *Sanofi* Court also concluded that the Secretary's power to remove members from service on the Board weighed "decidedly in … favor" of the Rule's constitutionality. *Sanofi*, 2021 WL 5150464, at *27. This conclusion is also mistaken. In *Arthrex*, the Supreme Court ruled that Administrative Patent Judges (APJs), who could issue final decisions on certain matters of patent law, were not inferior officers simply because they could be removed from "judicial assignment without cause" and assigned to non-adjudicative tasks. 141 S. Ct. at 1982. The Court held that this form of removal power was insufficient because assigning APJs to "a different task going forward" was not a means of "countermanding the final decision already on the books." *Id.* And APJs were not subject to the meaningful control created "by the threat of removal from federal service entirely," because they enjoyed "for cause" civil service protections. *Id.* (citing 5 U.S.C. § 7513(a)).

The *Sanofi* Court mistakenly equated removal from the Board with "removal from federal service entirely." It stated that "[o]nly removal *from the Board* matters in the sense of the Constitution because officers are appointed *to federal service* in the first instance as Board members, notwithstanding their other government employment, and can only be terminated from federal service *entirely*, *i.e.*, as Board members, if they are dismissed in that capacity." *Sanofi*, 2021 WL 5150464, at *27 (emphases in original) (footnote omitted); *see also id.* at *27 n. 44 ("[i]t is not relevant whether Board members' other government positions are protected with for-cause removal, so long as their Board member service is not"). But this is clearly not what the Supreme Court meant in *Arthrex*. There, the Court contrasted "the threat of removal from federal service entirely"—which was a form of effective control – with "removing an APJ 'from his judicial assignment without cause'" and "reassigning [him] to a different task going forward"—which was not. *Arthrex*, 141 S. Ct. at 1982. Removing an individual from service as a Board member but permitting her to continue to work as an employee of HHS is directly analogous to removing an APJ from his judicial assignment and reassigning him to a different task. *Arthrex* thus makes clear that removal from the ADR Board is not an effective form of control.

B. The Overlapping APA Challenge

The *Sanofi* Court also rejected the argument that, in issuing the ADR Rule, HRSA failed to respond to comments concerning the need for modification of the audit

[4] The *Sanofi* Court also suggested that, if necessary, it would "sever the finality provision in the 340B statute rather than hold the entire regime unconstitutional." *Sanofi*, 2021 WL 5150464, at *24 n.40. But it is the rule, not the statute, that empowers the Board to issue final decisions without review by a superior officer, and principles of administrative review bar courts from re-writing invalid agency rules. *See* Doc. 32 in *PhRMA*, at 3–4.

guidelines. The *Sanofi* Court ruled that HRSA had responded to Sanofi's comment by stating that updated audit guidelines were unnecessary, that Sanofi's comments did not raise a significant problem with the ADR Rule itself, and that, in all events, Sanofi had no right to forestall a rulemaking on the ADR process and require HRSA to address a different issue. *Sanofi*, 2021 WL 5150464, at *20. These conclusions are also incorrect.

First, HRSA's *ipse dixit* assertion that updated audit guidelines were not "needed to finalize the ADR process," 85 Fed. Reg. at 80,633, is not a meaningful or adequate response. It does not show that HRSA "'adequately analyze[d] . . . the consequences' of its actions," *Casa de Md., Inc. v. Wolf*, 486 F. Supp. 3d 928, 961 (D. Md. 2020), or "enable a reviewing court" to understand "why the agency reacted . . . the way it did." *South Carolina ex rel. Tindal v. Block*, 717 F.2d 874, 886 (4th Cir. 1983). Second, the burdens that the audit guidelines impose are a significant problem with the ADR process, because an audit of a covered entity is a pre-condition to manufacturer use of that process; indeed, this is why HRSA solicited comments on the issue. *See* Doc. 32 in *PhRMA*, at 14–18. And, because of the statutorily-driven relationship between the guidelines and manufacturer use of the ADR process, the comments that manufacturers submitted on this topic were not an improper request that HRSA forestall a rulemaking on the ADR process to address a different issue. They were a request that HRSA address a problem *with the ADR process*, a problem that was caused by the audit guidelines that process incorporates. *See id.*

* * *

Accordingly, PhRMA respectfully submits that this Court should decline to follow the foregoing rulings by the *Sanofi* Court.[5]

Date: ____, 2022

Respectfully submitted,

/s/ Sujit Raman
Sujit Raman (Bar No. 28907)
Joseph R. Guerra (*pro hac vice*)
sujit.raman@sidley.com
jguerra@sidley.com
Sidley Austin LLP
1501 K Street, N.W.
Washington, D.C. 20005
Telephone: 202-736-8000
Facsimile: 202-736-8711

Attorneys for Plaintiff Pharmaceutical Research and Manufacturers of America

[5] PhRMA notes that Sanofi has appealed the decision entered against it, but its opening brief in the Third Circuit did not address the rulings discussed in this letter.

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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Timothy Lape
ADR Panel Member