IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS, Plaintiff, v. XAVIER BECERRA, Secretary of the United States Department of Health and Human Services, *et al.*, Defendants.	No. 1:20-cv-3032

JOINT STATUS REPORT

On January 7, 2021, the Court granted the Parties' joint motion to stay this case to permit Plaintiff National Association of Community Health Center ("NACHC")—on behalf of its covered entity members—to pursue claims in the 340B Administrative Dispute Resolution ("ADR") process established in the final ADR rule, 85 Fed. Reg. 80,632 (published Dec. 14, 2020, effective Jan. 13, 2021). Pursuant to the Court's October 26, 2021 Minute Order, the parties respectfully submit this eighth Joint Status Report.[1]

NACHC filed this case on October 21, 2020, seeking the promulgation of ADR regulations. ECF No. 1. Defendant HHS promulgated a final ADR Rule on December 14, 2020. On January 13, 2021, the first effective day of the ADR regulation, NACHC—on behalf of certain Federally-qualified health center (FQHC) members—filed a joint ADR claim against drug manufacturers Eli

[1] The Parties previously submitted Joint Status Reports on February 16, 2021, April 19, 2021, May 19, 2021, June 21, 2021, August 24, 2021, October 25, 2021, and January 3, 2022 advising the Court of relevant developments and requesting that the stay remain in place. ECF Nos. 13, 14, 15, 16, 17, 18, 19, 20.

Lilly and Company, Sanofi-Aventis U.S. LLC, and AstraZeneca PLC alleging ongoing and unlawful overcharging and seeking equitable relief. NACHC filed a preliminary injunction motion in the ADR process the following day. NACHC's initial petition and its motion for immediate equitable relief were served on the drug manufacturers by certified mail, as the ADR process requires.

On March 16, 2021, the U.S. District Court for the Southern District of Indiana issued an order granting Plaintiff Eli Lilly & Co.'s ("Lilly") motion to preliminarily enjoin the ADR rule, as to Lilly only, on procedural APA grounds. Preliminary Injunction and Order, *Eli Lilly & Co. v. Cochran*, 1:21-cv-00081-SEB-MJD (S.D. Ind. Mar. 16, 2021), ECF Nos. 81, 82. On March 23, 2021, the Health Resources and Services Administration ("HRSA"), an HHS operating division to which oversight of the 340B Program has been delegated, advised NACHC, through counsel, that "HRSA has done an initial review of your petition and determined your petition is complete."

On June 21, 2021, HHS Secretary Becerra signed a memorandum appointing ADR Board members pursuant to 42 C.F.R. § 10.20. On August 5, 2021, HRSA requested that NACHC separate its claims against Eli Lilly from its claims against AstraZeneca and Sanofi so that the 340B Panel could adjudicate the latter notwithstanding the preliminary injunction in *Eli Lilly v. Azar*. NACHC submitted amended petitions against AstraZeneca and Sanofi—and a separate, companion amended petition pertaining solely to its claims against Eli Lilly—on August 31, 2021.

On October 22, 2021, the ADR Panel assigned to adjudicate NACHC's petition issued an initial scheduling order directing Sanofi and AstraZeneca to respond to NACHC's petition within 30 days, but providing an additional 30-day extension of any deadline as of right.

On November 18, 2021, HRSA and HHS submitted to the Office of Management and Budget a new proposed rule titled "340B Drug Pricing Program; Administrative Dispute

Resolution" that "would replace the Administrative Dispute Resolution (ADR) final rule currently in effect." Proposed Rule Pending EO 12866 Regulatory Review, *340B Drug Pricing Program; Administrative Dispute Resolution*, RIN 0906-AB28.[2] The contents of the proposed rule are not yet publicly available.

As prior status reports have provided, Eli Lilly, Sanofi, AstraZeneca, and other drug manufacturers have sued HHS in district courts across the country, challenging HHS's various enforcement efforts[3] and the ADR Rule itself. *See, e.g., Eli Lilly v. Azar*, No. 1:21-cv-81 (S.D. Ind.) (filed Jan. 12, 2021); *Sanofi v. HHS*, No. 3:21-cv-634 (D. N.J.) (filed Jan. 12, 2021); *AstraZeneca v. Azar*, No. 21-cv-27 (D. De.) (filed Jan. 12, 2021); *Novo Nordisk Inc., et al v. Azar*, No. 3:21-cv-00806-FLW-LHG (D. N.J. Jan. 15, 2021); *PhRMA v. Cochran*, No. 8:21-cv-00198-PWG (D. Md.) (filed Jan. 22, 2021); *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-cv-01479 (D.D.C.) (filed May 31, 2021).

In the *Sanofi* and *Novo Nordisk* cases, the New Jersey district court issued a final judgment on November 5, 2021 upholding the ADR Rule, *inter alia. Sanofi v. HHS*, No. 3:21-cv-00634, 2021 WL 5150464, at *12–32, 42–43 (D.N.J. Nov. 5, 2021). Both sides have appealed the district court's judgment on various grounds. *Sanofi Aventis US LLC v. HHS*, No. 21-337 (3d Cir.) (filed Jan, 27, 2022). Sanofi's opening brief in that appeal is due on or before March 8, 2022; the Government's opening brief is due within thirty days of Sanofi's filing. *Id.* Dkt. No. 13-2.

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[2] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0906-AB28

[3] HHS's enforcement efforts, as described in prior joint status reports, included: (1) a December 30, 2020, HHS's General Counsel advisory opinion; and (2) six May 17, 2021 HRSA-issued enforcement letters including letter to the three manufacturers against whom NACHC has pending ADR claims. *See* HHS, HRSA, 340B Drug Pricing Program, https://www.hrsa.gov/opa/index.html.

In the *Eli Lilly* case, both Eli Lilly and the Government have appealed the Indiana district court's partial final judgment to the U.S. Court of Appeals for the Seventh Circuit. The Government has also appealed the D.C. District Court's decision in *Novartis Pharms. Corp. v. Espinosa*, No. 1:21-cv-01479, 2021 WL 5161783 (D.D.C. Nov. 5, 2021).

In *AstraZeneca*, following briefing and argument on cross-motions for summary judgment, the Delaware district court, on February 16, 2022, vacated and remanded HRSA's May 17 enforcement letter and ordered the parties to submit a joint report "setting out their proposal(s) for: (i) what relief the Court should grant [AstraZeneca] on the claims for relief in [AstraZeneca]'s second amended complaint. . . . and (ii) how, if at all, this case should now proceed." *AstraZeneca*, No. 1:21-cv-27 (D. Del.), ECF No. 113.

In *PhRMA*, dispositive motions were fully briefed as of October 12. *See PhRMA*, No. 8:21-cv-198 (D. Md.), ECF Nos. 26, 29, 31, 32.

On December 20, 2021, after availing itself of a 30-day extension as of right, Sanofi and AstraZeneca each filed motions to stay the ADR process pending resolution of their—and the other—federal court cases challenging the Government's authority to enforce 340B Program requirements, including all available appeals, *and* completion of rulemaking related to the proposed new ADR rule. NACHC opposed the motions. On February 11, 2022, the ADR Panel rejected the motions. Sanofi and AstraZeneca, after securing a two-week extension, must submit their responses in the ADR process on or before March 28, 2022.

In light of the foregoing, the parties propose the stay in this matter remain in effect through June 3, 2022, on which date an additional joint status report—which will indicate proposed next steps for this matter—will be due.

Dated: March 3, 2022

Respectfully submitted,

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