## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS,

Plaintiff,

v.

No. 1:20-cv-3032

XAVIER BECERRA, Secretary of the United States Department of Health and Human Services, *et al.*,

Defendants.

## **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 Centers ("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 June 6, 2021 Minute Order, the parties respectfully submit this ninth Joint Status Report. <sup>1</sup>

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

<sup>&</sup>lt;sup>1</sup> 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, January 3, 2022, March 3, 2022, and June 3, 2002, advising the Court of relevant developments and requesting that the stay remain in place. ECF Nos. 13, 14, 15, 16, 17, 18, 19, 20, 21, 22. The Court, based on the parties' proposal, ordered this status report to be filed on or before September 3, 2022. Because the parties inadvertently suggested a Saturday filing date, and counsel for Defendants was on vacation the entire preceding week, the parties submit this report on the next business day following the Labor Day holiday.

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 Lilly and Company,<sup>2</sup> Sanofi-Aventis U.S. LLC, and AstraZeneca PLC alleging ongoing and unlawful overcharging and seeking equitable relief. As relayed in prior status reports, NACHC's ADR claim has continued to move through the process established in the final ADR Rule.

Specifically, on March 28, 2022, following the ADR Panel's rejection of two manufacturers' motions to stay the ADR process pending resolution of all available appeals in their separate federal court cases described in prior status reports, the manufacturers moved to dismiss NACHC's ADR petition. Briefing on the motions was completed on July 1, 2022.

In light of the foregoing, the parties propose the stay in this matter remain in effect through December 5, 2022, on which date an additional joint status report—which will indicate proposed next steps for this matter—will be due.

Dated: September 6, 2022

Respectfully submitted,

s/Rosie Dawn Griffin
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<sup>&</sup>lt;sup>2</sup> As reported in previous status reports, operation of the ADR Rule has been enjoined as to Eli Lilly, *see Eli Lilly et al. v. Becerra et al.*, Order on Preliminary Injunction, ECF 82, Case No. 1:21-cv-00081-SEB-MJD (S.D. Ind. March 16, 2021). NACHC's ADR claim accordingly is moving through the ADR process only as to respondents Sanofi-Aventis U.S. LLC and AstraZeneca PLC.

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s/ Kate Talmor
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