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 (KBJ)

JOINT STATUS REPORT

On December 17, 2020, the Parties jointly moved to stay this case. ECF No. 12. The stay was 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). The Court granted the Parties' motion. The Parties submitted Joint Status Reports on February 16, 2021 and April 19, 2021 advising the Court of relevant developments and requesting that the stay remain in place. ECF Nos. 13, 14. Pursuant to the Court's April 20, 2021 Minute Order, the parties respectfully submit this third Joint Status Report.

This case was filed on October 21, 2020, seeking the promulgation of ADR regulations. ECF No. 1. 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 Lilly and Company, Sanofi-Aventis U.S. LLC, and AstraZeneca

PLC (collectively, "the drug manufacturers") alleging ongoing and unlawful overcharging and seeking equitable relief.

On January 14, 2021, NACHC filed a motion in the ADR process seeking a preliminary injunction from the ADR Panel compelling the drug manufacturers' immediate compliance with their statutory obligation to offer FQHC covered entities covered outpatient drugs at or below 340B ceiling prices, regardless of whether those drugs are to be dispensed in-house or through a contract pharmacy.

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. The ADR Rule provides that, "[u]pon receipt of service of petition, the respondent must file with the 340B ADR Panel a written response to the Petition as set forth in Rule 12 or 56." 42 C.F.R. § 10.21(f). To date, the drug manufacturers have not submitted a response to either NACHC's petition or motion.

On March 16, 2021, the U.S. District Court for the Southern District of Indiana issued a 29-page 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. Given its observation that the "preliminary injunction will put on hold [an ADR] process that is not even

currently operational," the court found that the balance of harms and public interest factors weighed in favor of plaintiff Lilly. *Id*. at 27.[1]

On March 23, 2021, the Health Resources and Services Administration ("HRSA"), an HHS subcomponent 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." However, no ADR panelists have yet been appointed and no panel has been assigned to adjudicate NACHC's ADR petition or motion for immediate relief.

On May 17, 2021, HHS, through the Acting Administrator of HRSA, issued cease and desist letters to six drug manufacturers, including the three against whom NACHC has pending ADR claims. *See* HHS, HRSA, *340B Drug Pricing Program*, https://www.hrsa.gov/opa/index.html. Each letter provides, in substance, that "HRSA has determined that [drug manufacturer] policies that place restrictions on 340B Program pricing to covered entities that dispense medications through pharmacies under contract have resulted in overcharges and are in direct violation of the 340B statute." *Id.* The letters require that each drug manufacturer update HRSA by June 1, 2021 "on its plan to start selling, without restriction, covered outpatient drugs at the 340B discount price to covered entities that dispense medications through contract pharmacy arrangements." *See, e.g.,* Letter from Diana Espinosa, Acting Administrator, HRSA, to Derek L. Asay, Senior Director Government Strategy, Eli Lilly and

[1] As prior status reports have provided, Lilly's suit is one of several brought by drug manufacturers against HHS in district courts across the country. *See 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. Jan. 22, 2021). The cases challenge the ADR regulation, seek to enjoin enforcement of a December 30, 2020 HHS OGC Advisory Opinion, and/or challenge HHS guidelines related to manufacturers' audits of covered entities. HHS continues to vigorously defend each lawsuit.

Company (May 17, 2021), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hrsa-letter-eli-lilly-covered-entities.pdf.

In light of the foregoing, the parties propose the stay remain in effect through June 18, 2021, pending further pertinent developments. The Parties further propose that the next joint status report should be due no later than June 18, 2021, and will indicate proposed next steps for this matter.

Dated: May 19, 2021

Respectfully submitted,

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