

**UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF COLUMBIA**

RYAN WHITE CLINICS
FOR 340B ACCESS, et al.,

Plaintiffs,

v.

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

Defendants.

Case No. 20-cv-2906-KBJ

JOINT STATUS REPORT

On January 13, 2021, Plaintiffs, Ryan White Clinics for 340B Access, et al., and Defendants, Xavier Becerra, et al., jointly moved to stay this case. ECF No. 58. The Parties sought a stay so that certain Plaintiffs could pursue claims in the 340B Administrative Dispute Resolution (“ADR”) process. ECF No. 58. On January 13, 2021, the Court granted the Parties’ motion and stayed this action. The Parties submitted a Joint Status Report on February 16, 2021. ECF No. 59. On March 10, 2021, the Court ordered the Parties to file a further joint status report on or before the earlier of April 19, 2021, or within five business days of the entry of any injunction of the ADR Rule. On March 16, 2021, the U.S. District Court for the Southern District of Indiana granted a motion by Eli Lilly & Co. (“Lilly”) to preliminarily enjoin the ADR rule as to Lilly. 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. Accordingly, the Parties are filing this status report in accordance with this Court’s March 10, 2021 order.

Plaintiffs filed this action on October 9, 2020, seeking, in part, an order directing the Secretary of Health and Human Services (“HHS”) to promulgate ADR regulations. ECF No. 1. The final ADR rule that Plaintiffs sought to compel was published in the Federal Register on December 14, 2020. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632 (Dec. 14, 2020) (“ADR Final Rule”). The ADR Final Rule became effective on January 13, 2021. *Id.*

In addition to Lilly, several other pharmaceutical manufacturers and a trade association of pharmaceutical manufacturers have filed separate suits against HHS and related federal defendants seeking to enjoin the ADR Final Rule and/or a separate Advisory Opinion issued on December 30, 2020 by HHS’s General Counsel concerning contract pharmacy arrangements under the 340B program. First Amended Complaint, *AstraZeneca Pharmaceuticals LP v Azar*, No. 1:21-cv-00027-LPS (D. Del. Feb. 12, 2021), ECF No. 13; Amended Complaint, *Sanofi-Aventis U.S., LLC v Azar*, No. 3:21-cv-00634-FLW-LHG (D.N.J. Feb. 2, 2021), ECF No. 17; Complaint, *Novo Nordisk Inc., et al v Azar*, No. 3:21-cv-00806-FLW-LHG (D.N.J. Jan. 15, 2021), ECF No. 1; Complaint, *PhRMA v Cochran*, No. 8:21-cv-00198-PWG (D. Md. Jan. 22, 2021), ECF No. 1.

On March 16, 2021, the court in *Eli Lilly & Co.* issued an order preliminarily enjoining Defendants from implementing or enforcing the ADR Final Rule against Lilly. 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. The court determined that, “at this early stage of the litigation,” Lilly had shown a likelihood of success on the merits on the question of whether HHS was required to engage in a new round of notice-and-comment procedures before issuing a final rule. *Id.* at 18, 23, ECF No. 81.

Three of the Plaintiffs in this case (Ryan White Clinics for 340B Access, Little Rivers Health Care, Inc. (“Little Rivers”), and WomenCare, Inc., dba FamilyCare Health Center (“FamilyCare”)) filed an amicus curiae brief jointly with the National Association of Community Health Centers (plaintiff in *National Association of Community Health Centers v. Azar*, 1:20-cv-03032-KBG) in support of the Defendants’ opposition to Lilly’s motion for preliminary injunction. Brief of Amici Curiae, *Eli Lilly & Co. v. Cochran*, 1:21-cv-00081-SEB-MJD (S.D. Ind. Mar. 9, 2021), ECF No. 75. The court considered the amicus curiae brief in reviewing the balance of equities and stated:

[T]he ADR process is still being finalized and we have been given no indication as to when the ADR Board will be named and ADR Panels will be assigned and begin the process of reviewing petitions. In these circumstances, where granting a preliminary injunction will put on hold a process that is not even currently operational, we find that the balance of harms and the public interest factors weigh in favor of Plaintiffs.

Preliminary Injunction and Order, *Eli Lilly & Co. v. Cochran*, 1:21-cv-00081-SEB-MJD, 27 (S.D. Ind. Mar. 16, 2021), ECF No. 81.

On February 4, 2021, Little Rivers filed an ADR petition against AstraZeneca Pharmaceuticals, LP (“AstraZeneca”). On February 4, 2021, Little Rivers sent the ADR petition to AstraZeneca via certified mail. *See* 42 C.F.R. § 10.21(a). Little Rivers’ counsel received confirmation that AstraZeneca received the petition via certified mail on February 8, 2021. On February 12, 2021, FamilyCare filed an ADR petition against AstraZeneca. On February 12, 2021, FamilyCare sent the ADR petition to AstraZeneca via certified mail. *Id.* FamilyCare’s counsel received confirmation that AstraZeneca received the petition via certified mail on February 15, 2021. The Little Rivers and FamilyCare ADR petitions contend that AstraZeneca has violated the 340B statute by declining to ship 340B discounted drugs to contract pharmacies. The ADR Final 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.” *Id.* § 10.21(f). The website for HHS’s Health Resources and Services Administration (“HRSA”) states, “Once the petition, including any supporting documentation, is received, HRSA reviews the petition for completeness and will notify the petitioner of whether the petition will move forward to the ADR Panel for review.” HRSA, *340B Administrative Dispute Resolution (ADR)*, <https://www.hrsa.gov/opa/340b-administrative-dispute-resolution> (last visited Mar. 22, 2021).

AstraZeneca has not responded to the Little Rivers or FamilyCare ADR petitions. Today, HRSA sent an email to Little Rivers’ counsel and one to FamilyCare’s counsel stating that, “HRSA has done an initial review of your petition and determined your petition is complete.”

The Parties agree that they should file a further joint status report on the earlier of April 19, 2021, or within five business days of the entry of any other injunction of the ADR Final Rule.

March 23, 2021

Respectfully submitted,

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