

**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-FYP

**JOINT STATUS REPORT**

On January 13, 2021, Plaintiffs, Ryan White Clinics for 340B Access, et al., and Defendants, Xavier Becerra, Secretary of Health and Human Services (the “Secretary”), 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 Joint Status Reports on February 16, 2021, March 23, 2021, April 19, 2021, May 19, 2021, June 18, 2021, August 24, 2021, October 25, 2021, January 3, 2022, March 4, 2022, and June 3, 2022. ECF Nos. 59, 60, 62, 63, 64, 65, 66, 67, 68, 69. The Parties agree that they should file a further joint status report in ninety days.

Plaintiffs filed this action on October 9, 2020, seeking orders directing the Secretary of Health and Human Services (“HHS”) to promulgate ADR regulations and to take enforcement action against certain pharmaceutical manufacturers that restricted or denied the sale of 340B

discounted drugs shipped to contract pharmacies. 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.*

As previously reported to the Court, Plaintiffs Little Rivers Health Care, Inc. (“Little Rivers”) and WomenCare, Inc., d/b/a FamilyCare Health Center (“FamilyCare”) have filed ADR petitions against AstraZeneca Pharmaceuticals LP (“AstraZeneca”). 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. HHS’s Health Resources and Services Administration (“HRSA”) informed Little Rivers and FamilyCare via separate emails that “HRSA has done an initial review of your petition and determined your petition is complete.” 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.” 42 C.F.R. § 10.21(f).

Litigation related to the Secretary’s efforts to enforce 340B program requirements against several pharmaceutical manufacturers is pending in several courts. *See Merck, Sharp & Dohme v. U.S. Dep’t of Health and Human Servs.*, No: 1:22-cv-01986-DLF (D.D.C. July 8, 2022), ECF 1; *Novartis Pharmaceuticals Corp. v. Espinosa*, 2021 WL 5161783 (D.D.C. Nov. 5, 2021), *appeal docketed*, No. 21-5299 (D.C. Cir. Dec. 30, 2021); *Sanofi-Aventis U.S., LLC v. Becerra*, 2021 WL 5150464 (D.N.J. Nov. 5, 2021), *appeal docketed*, No. 21-3168 (3rd Cir. Nov. 26, 2021); *Eli Lilly & Co. v. U.S. Dep’t of Health & Human Servs.*, 2021 WL 5039566 (S.D. Ind. Oct. 29, 2021), *appeal docketed*, No. 21-3128 (7th Cir. Nov. 15, 2021); *AstraZeneca Pharmaceuticals L.P. v. Becerra*, 2022 WL 484587 (D. Del. Feb. 16, 2022), *appeal docketed*, No. 22-1676 (3rd Cir. Apr. 15, 2022); *Boehringer Ingelheim Pharms., Inc. v. Becerra*, No. 1:21-

cv-02826-DLF (D.D.C. Dec. 9, 2021) (stayed), ECF 19.

On April 16, 2021, HRSA sent to the Office of the Secretary of HHS recommended new appointments to the ADR Board to correct for shortcomings in a prior slate of appointments. On June 17, 2021, the Secretary signed the memorandum appointing ADR Board members. On October 5, 2021, HHS appointed panels of ADR Board Members to adjudicate the Little Rivers and FamilyCare ADR petitions.

On January 3, 2022, AstraZeneca filed motions with the ADR panel requesting indefinite stays of the ADR proceedings pending the outcome of 340B-related district court litigation and the conclusion of any further ADR rulemaking proceeding by HHS. On January 24, 2022, Little Rivers and FamilyCare filed responses to AstraZeneca's motion for indefinite stay of ADR proceedings, and on February 7, 2021, AstraZeneca filed replies to those responses. In light of a decision issued by the U.S. District Court for the District of Delaware on February 16, 2022, in *AstraZeneca Pharmaceuticals L.P. v. Becerra*, the ADR Panel ordered Little Rivers, FamilyCare, and AstraZeneca to submit supplemental letter briefs limited to addressing what implications the *AstraZeneca* holding may have, if any, with respect to the panel's consideration of AstraZeneca's motion to stay. On March 2, 2022, each party filed their supplemental briefs. On August 10, 2022, Little Rivers and FamilyCare submitted a letter to the ADR Panel asking that the ADR Panel rule on AstraZeneca's Motion to Stay. On August 12, 2022, AstraZeneca filed a response. To date, the ADR Panel has not ruled on the motion to stay filed by AstraZeneca on January 3, 2022.

On December 10, 2021, the U.S. Office of Management and Budget updated its regulatory agenda, which included a notice that HRSA will propose a new ADR regulation. Off. of Mgmt. & Budget, Exec. Off. of the President, *340B Drug Pricing Program; Administrative*

*Dispute Resolution,*

<https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0906-AB28> (last visited September 1, 2022). The notice states that the proposed ADR regulation will present “new requirements and procedures for the 340B Program’s ADR process” and that it “better aligns with the President’s priorities on drug pricing, better reflects the current state of the 340B Program, and seeks to correct procedural deficiencies in the 340B ADR process.” *Id.* To date, HRSA has not proposed a new ADR regulation.

The Parties agree that they should file a further joint status report in ninety days.

September 2, 2022

Respectfully submitted,

/s/ Ronald S. Connelly

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