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, 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, and October 25, 2021. ECF Nos. 59, 60, 62, 63, 64, 65, 66.

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).

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 May 17, 2021, HRSA sent letters to pharmaceutical manufacturers AstraZeneca, Lilly USA, LLC ("Lilly"), Novartis Pharmaceuticals ("Novartis"), Novo Nordisk, Sanofi, and United Therapeutics regarding sales to 340B covered entities through contract pharmacy arrangements ("May 17 Letters").[1] Each of these manufacturers has implemented policies either refusing or restricting sales of drugs at 340B discounts when shipped to contract pharmacies. HRSA required that each manufacturer "provide an update on its plan to restart selling, without

[1] *Available at* https://www.hrsa.gov/opa/program-integrity/index.html.

restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by June 1, 2021, to 340Bpricing@hrsa.gov."

The above pharmaceutical manufacturers have filed lawsuits against HHS to prevent enforcement of the May 17 Letters. Second Amended Complaint, *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. July 9, 2021), ECF No. 86; Second Amended Complaint, *Eli Lilly & Co. v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. May 27, 2021), ECF No. 103; Second Amended Complaint, *Sanofi-Aventis U.S., LLC v. Becerra*, No. 3:21-cv-00634-FLW-LHG (D.N.J. May 25, 2021), ECF No. 78; Amended Complaint, *Novo Nordisk Inc. v. Becerra*, No. 3:21-cv-00806-FLW-LHG (D.N.J. May 21, 2021), ECF No. 40; Complaint, *Novartis Pharmaceuticals Corp. v. Becerra*, 1:21-cv-01479-DLF (D.D.C. May 31, 2021), ECF No. 1; Complaint, *United Therapeutics v. Becerra*, 1:21-cv-1686-DLF (D.D.C. June 23, 2021), ECF No. 1. The district courts have issued decisions in each case except *AstraZeneca Pharmaceuticals LP v. Becerra*, and the parties have appealed those decisions. *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).

On October 20, 2021, AstraZeneca filed motions in the Little Rivers and FamilyCare ADR proceedings to extend AstraZeneca's obligation to respond to the ADR petitions until the U.S. District Court for the District of Delaware rules on cross motions for summary judgment in *AstraZeneca Pharmaceuticals L.P. v. Becerra*, No. 1:21-cv-00027 (D. Del.). On October 21, 2021, Little Rivers and FamilyCare opposed AstraZeneca's motions. On November 1, 2021, the

ADR Panel issued initial scheduling orders directing AstraZeneca to respond to the petitions, move to stay proceedings, or file "an appropriate motion under rule 12 of the Federal Rules of Civil Procedure on or before 30 days after the date of this Order." The order also stated that "[e]ither party will be granted, as a matter of right, one 30-day extension of any of the deadlines set forth above." On November 30, 2021, AstraZeneca filed motions with the ADR panel for 30-day extensions of the deadlines set in the ADR Panel's November 1, 2021, scheduling orders. And on January 3, 2022, AstraZeneca filed motions with the ADR panel requesting indefinite stays of the ADR proceedings pending the outcome of the 340B-related district court litigation referenced above and the conclusion of any further rulemaking proceeding by HHS.

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 Jan. 3, 2021). 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.*

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

January 3, 2022

Respectfully submitted,

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