

**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, June 3, 2022, and September 2, 2022. ECF Nos. 59, 60, 62, 63, 64, 65, 66, 67, 68, 69, 71.

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.* On November 30, 2022, the Secretary issued a notice of proposed rulemaking (NPRM) seeking comment on proposals to modify the ADR regulation currently in effect. 87 Fed. Reg. 73,516-27 (Nov. 30, 2022).

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. AstraZeneca has moved to stay those ADR petitions pending conclusion of district court litigation raising similar issues, and to date, the ADR panel assigned to Plaintiffs’ petition has not ruled on AstraZeneca’s request to stay those proceedings.

The Secretary also has taken action to enforce 340B program requirements against several pharmaceutical manufacturers, and litigation related to those enforcement steps is pending in several courts, including this one. *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.

DEFENDANTS' POSITION

On November 30, 2022, counsel for Defendants conveyed to counsel for Plaintiffs Defendants' position that this matter has long been moot and should be dismissed without prejudice, in light of the fact that the ADR Final Rule has been in effect for nearly two years and a proposal to revise that rule has been issued and is available for Plaintiffs to comment. Furthermore, Defendants' position is that no additional relief could be granted on Plaintiffs' Amended Complaint, that the Complaint should be voluntarily dismissed without prejudice, and, if Plaintiffs are unwilling to dismiss voluntarily, briefing should resume on Defendants' still-pending Motion to Dismiss. Defendants' counsel proposed a 15-day period for Plaintiffs to evaluate and respond to Defendants' position. After Plaintiffs' counsel informed Defendants' counsel that additional time is needed to evaluate these matters, Defendants agreed to Plaintiffs' counterproposal to request a 45-day stay, subject to the understanding that Defendants will not agree to request any further stays. Should Plaintiffs not agree to voluntarily dismiss before the next status report is due, Defendants intend to ask the Court to order Plaintiffs to promptly respond to the Motion to Dismiss Defendants filed on December 14, 2020.

PLAINTIFFS' POSITION

Plaintiffs' position is that this case is not moot. Plaintiffs' position is that they require additional time to assess the impact that the November 30, 2022, proposed rule may have on this case. The proposed regulation states: "If the 340B ADR Panel determines the specific issue that would be brought forth in a claim is the same as or similar to an issue that is pending in Federal

court, it will suspend review of the claim until such time the issue is no longer pending in Federal court.” 87 Fed. Reg. at 73,526 (42 C.F.R. § 10.23(a) (proposed)). Plaintiffs require additional time to assess whether the proposed rule, if finalized and applied retroactively, could impact the ADR claims brought by Little Rivers and FamilyCare. Accordingly, Plaintiffs requested that the parties jointly request the matter remain stayed for 45 days, at the conclusion of which Plaintiffs will decide how to proceed in this matter.

PARTIES’ POSITION

Accordingly, the parties jointly request that they file a status report by January 17, 2023. At that time, the parties may jointly stipulate dismissal or propose a schedule for completion of briefing on the parties’ pending motions.

December 1, 2022

Respectfully submitted,

/s/ Ronald S. Connelly
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