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 Joint Status Reports on February 16, 2021, March 23, 2021, and April 19, 2021. ECF Nos. 59, 60, 62.

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 May 17, 2021, HHS's Health Resources and Services Administration ("HRSA") sent letters to pharmaceutical manufacturers AstraZeneca, Lilly USA, LLC, Novartis Pharmaceuticals, Novo Nordisk, Sanofi, and United Therapeutics regarding sales to 340B covered entities through contract pharmacy arrangements.[1] Each of these manufacturers has implemented policies either refusing or restricting sales of drugs at 340B discounts when shipped to contract pharmacies. HRSA's letters state that the obligation of a pharmaceutical manufacturer to offer covered entities drugs at or below the 340B ceiling prices "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." The HRSA letters direct each manufacturer to "work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements." The letters inform the manufacturers that "continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs [civil monetary penalties] as described in the CMP final rule." HRSA required that each manufacturer "provide an update on its plan to restart selling, without restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by June 1, 2021, to 340Bpricing@hrsa.gov." To date, the manufacturers have not yet responded.

On February 4, 2021, Plaintiff Little Rivers filed an ADR petition against AstraZeneca

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

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, Plaintiff 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.

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. The preliminary injunction by the *Lilly* court does not prevent ADR from proceeding as to AstraZeneca or any other manufacturer.

On March 23, 2021, HRSA sent an email to Little Rivers' counsel and to FamilyCare's counsel stating 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). AstraZeneca has not responded to the Little Rivers or FamilyCare ADR petitions.

On Jan 21, 2021, notice of the appointment of ADR Board members was briefly posted for public inspection, but it was later removed before publication in the Federal Register. 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 the prior slate of appointments.

HHS has not yet appointed ADR Board members.

The Parties agree that they should file a further joint status report on or before June 18, 2021.

May 19, 2021

Respectfully submitted,

/s/ Ronald S. Connelly
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