

**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, April 19, 2021, May 19, 2021, and June 18, 2021. ECF Nos. 59, 60, 62, 63, 64.

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 and FamilyCare have filed ADR petitions against 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). AstraZeneca has not responded to the Little Rivers or FamilyCare ADR petitions.

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. HHS has not yet 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”).<sup>1</sup> 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 restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract

---

<sup>1</sup> Available at <https://www.hrsa.gov/opa/program-integrity/index.html>.

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, et al 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., et al 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. Briefing has concluded on dispositive motions in all these cases except *United Therapeutics v. Becerra*, where it is scheduled to conclude by September 21, 2021.

The Parties agree that they should file a further joint status report on or before October 25, 2021.

August 24, 2021

Respectfully submitted,

/s/ Ronald S. Connelly  
Ronald S. Connelly  
D.C. Bar No. 488298  
POWERS PYLES SUTTER & VERVILLE, PC  
1501 M Street, N.W., 7th Floor  
Washington, DC 20005  
Tel. (202) 466-6550  
Fax (202) 785-1756  
[Ron.Connelly@PowersLaw.com](mailto:Ron.Connelly@PowersLaw.com)  
*Attorney for Plaintiffs*

BRIAN NETTER  
Deputy Assistant Attorney General

MICHELLE R. BENNETT  
Assistant Branch Director

/s/ Kate Talmor  
KATE TALMOR  
(Maryland Bar)  
Trial Attorney  
U.S. Department of Justice  
Civil Division, Federal Programs Branch  
1100 L Street, N.W.  
Washington, D.C. 20005  
(202) 305-5267  
kate.talmor@usdoj.gov  
*Attorneys for Defendants*