

**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, and May 19, 2021. ECF Nos. 59, 60, 62, 63.

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 (“Lilly”), Novartis Pharmaceuticals (“Novartis”), Novo Nordisk, Sanofi, and United Therapeutics regarding sales to 340B covered entities through contract pharmacy arrangements (“May 17 Letter”).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 restriction, 340B covered outpatient drugs at the 340B price to covered entities with contract pharmacy arrangements by June 1, 2021, to 340Bpricing@hrsa.gov.”

Several of the above pharmaceutical manufacturers have filed motions in their respective lawsuits against HHS to prevent enforcement of the May 17 Letter:

- On May 19, 2021, AstraZeneca submitted an emergency motion for administrative stay on HRSA’s June 1, 2021, deadline and, in the alternative, motion to expedite the U.S. District Court for the District of Delaware’s consideration of the parties’ cross-motions for summary judgement and HHS’s motion to dismiss. Emergency Motion for Administrative Stay and, in the Alternative, for Expedition, *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. May 19, 2021), ECF No. 66. The court denied AstraZeneca’s emergency motion for an administrative stay but granted the request for expedition and scheduled oral argument shortly thereafter. Oral Order. *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. May 24, 2021), ECF No. 71. On June 1, 2021,

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

- AstraZeneca reported to the court that HRSA had granted an extension to respond to the May 17 Letter until June 10, 2021. Letter to Leonard P. Stark from Daniel M. Silver, *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. June 1, 2021), ECF No. 77. On June 16, 2021 the *AstraZeneca* court issued an order denying in part and granting in part HHS's motion to dismiss. Order, *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. June 16, 2021), ECF No. 79. Motion to Dismiss for Failure to State a Claim, Motion to Dismiss for Lack of Jurisdiction Over the Subject Matter, Motion for Summary Judgment, *AstraZeneca Pharmaceuticals LP v. Becerra*, No. 1:21-cv-00027-LPS (D. Del. May 4, 2021), ECF No. 55. The Court found that the 340B statute is ambiguous and that HHS's OGC wrongly had concluded that its interpretation was compelled by the plain statutory text. Both AstraZeneca's and HHS's motions for summary judgment remain pending.
- On May 20, 2021, Lilly filed a motion for preliminary injunction and motion for temporary restraining order seeking to forestall its June 1, 2021 deadline to respond to the May 17 Letter. Motion for Preliminary Injunction and Motion for Temporary Restraining Order, *Eli Lilly & Co, et al v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. May 20, 2021), ECF No. 94. On May 27, 2021, the U.S. District Court for the Southern District of Indiana denied Lilly's motion for temporary restraining order but granted Lilly an extension to respond to the May 17 Letter until June 10, 2021. Minute Entry, *Eli Lilly & Co, et al v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. May 27, 2021), ECF No. 102. Lilly submitted its response to HRSA on June 10 and submitted the letter to the court on June 11. Notice of Filing of Response to May

17, 2021 HRSA Letter, *Eli Lilly & Co, et al v. Becerra*, No. 1:21-cv-00081-SEB-MJD (S.D. Ind. June 11, 2021), ECF No 115.

- On May 20, 2021, Sanofi filed a motion to expedite the U.S. District Court of the District of New Jersey's consideration of the parties' cross-motions for summary judgement and HHS's motion to dismiss, and for a temporary administrative stay on HRSA's June 1 deadline. Motion to Expedite and for a Temporary Administrative Stay, *Sanofi-Aventis U.S., LLC v. Becerra*, No. 3:21-cv-00634-FLW-LHG (D.N.J. May 20, 2021), ECF No. 72. On May 25, 2021, Sanofi filed an amended complaint challenging the May 17 Letter. Second Amended Complaint for Declaratory and Injunctive Relief, *Sanofi-Aventis U.S., LLC v. Becerra*, No. 3:21-cv-00634-FLW-LHG (D.N.J. May 25, 2021), ECF No. 78. On June 1, 2021, the court denied Sanofi's motion for an administrative stay. Order Denying Plaintiff's Motion for Administrative Stay, *Sanofi-Aventis U.S., LLC v. Becerra*, No. 3:21-cv-00634-FLW-LHG (D.N.J. June 1, 2021), ECF No. 83.
- On May 21, 2021, Novo Nordisk filed a motion to expedite the U.S. District Court of the District of New Jersey's consideration of the parties' cross-motions for summary judgement and HHS's motion to dismiss and for a temporary administrative stay on HRSA's June 1 deadline. Motion to Expedite and for a Temporary Administrative Stay, *Novo Nordisk Inc., et al v. Becerra*, No. 3:21-cv-00806-FLW-LHG (D.N.J. May 21, 2021), ECF No. 38. On May 25, 2021, Novo Nordisk filed an amended complaint challenging the May 17 Letter. Amended Complaint, *Novo Nordisk Inc., et al v. Becerra*, No. 3:21-cv-00806-FLW-LHG (D.N.J. May 25, 2021), ECF No. 40. On June 1, 2021, the court denied Novo Nordisk's motion for an administrative stay.

Order denying Plaintiff's Motion for an Administrative Stay, *Novo Nordisk Inc., et al v. Becerra*, No. 3:21-cv-00806-FLW-LHG (D.N.J. June 1, 2021), ECF No. 44.

- On May 31, 2021, Novartis filed suit in the U.S. District Court for the District of Columbia challenging HRSA's May 17 Letter. Complaint, *Novartis Pharmaceuticals Corp. v. Becerra*, 1:21-cv-01479-DLF (D.D.C. May 31, 2021), ECF No. 1. Novartis also filed a motion for preliminary injunction seeking to enjoin enforcement of the May 17 Letter. Motion for Preliminary Injunction, *Novartis Pharmaceuticals Corp. v. Becerra*, 1:21-cv-01479-DLF (D.D.C. June 2, 2021), ECF No. 5.

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. 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 the prior slate of appointments. On June 17, 2021 the Secretary signed the memorandum appointing ADR Board members.

The Parties agree that they should file a further joint status report on or before August 24, 2021.

June 18, 2021

Respectfully submitted,

/s/ Ronald S. Connelly

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