

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**

ELI LILLY AND COMPANY,
Lilly Corporate Center
893 Delaware Street
Indianapolis, IN 46225,

and

LILLY USA, LLC,
1500 South Harding Street
Indianapolis, IN 46221,

Plaintiffs,

v.

ALEX M. AZAR II, in his official capacity as
Secretary of Health & Human Services
Office of the Secretary
200 Independence Avenue, S.W.
Washington, D.C. 20201,

ROBERT P. CHARROW, in his official
capacity as General Counsel of
Health & Human Services
Office of the General Counsel
200 Independence Avenue, S.W.
Washington, D.C. 20201,

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, D.C. 20201,

THOMAS J. ENGELS, in his official capacity
as Administrator of the Health Resources and
Services Administration
5600 Fishers Lane
Rockville, MD 20852,

and

HEALTH RESOURCES AND SERVICES
ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20852,

Defendants.

No. 1:21-cv-81-SEB-MJD

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**PLAINTIFFS' MOTION TO
SCHEDULE ORAL ARGUMENT ON
PLAINTIFFS' CROSS-MOTION
FOR SUMMARY JUDGMENT AND
DEFENDANTS' MOTION TO
DISMISS OR, IN THE
ALTERNATIVE, FOR SUMMARY
JUDGMENT**

Pursuant to Local Rule 7-5(a), Plaintiffs request that the Court schedule oral argument on Plaintiffs' Cross-Motion for Summary Judgment, ECF No. 89, and Defendants' Motion to Dismiss or, in the alternative, for Summary Judgment, ECF No. 87.

As addressed in the parties' Joint Stipulation of Briefing Schedule, ECF No. 83, the parties have requested oral argument on these motions, and this Court, in turn, entered a briefing schedule for dispositive motions that provided for a "[h]earing on the parties' motions to be held at the Court's convenience" after the close of briefing. ECF No. 85 at 1. Plaintiffs hereby request that the Court schedule that hearing at its earliest convenience following the filing of Plaintiffs' reply (which will be no later than June 14).

As discussed in the parties' Joint Stipulation and at the preliminary injunction hearing, this action involves a number of complex constitutional and administrative-law issues. On January 12, 2021, Plaintiffs filed their Complaint. *See* ECF No. 1. The operative First Amended Complaint brings claims under Administrative Procedure Act ("APA") and constitutional claims against Defendants on the basis of two agency actions: the U.S. Department of Health and Human Services' ("HHS") Office of the General Counsel's December 30, 2020 advisory opinion ("December 30 Decision"), and HHS's rule on administrative dispute resolution for the 340B drug pricing program (the "ADR Rule"). *See* U.S. Dep't of Health & Human Servs. Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program* (Dec. 30, 2020), <https://bit.ly/357nqfk>; 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632-01 (Dec. 14, 2020). Plaintiffs filed a Motion for Preliminary Injunction on January 25, 2021, requesting that the ADR Rule be enjoined. *See* ECF No. 18. After full briefing and oral argument, the Court entered a preliminary injunction on March 16, 2021,

concluding that Defendants' promulgation of the ADR Rule likely violated the notice-and-comment requirements set forth in the APA. *See* ECF Nos. 81, 82.

These issues are related to those in other pending cases. In one action, in the U.S. District Court for the District of Columbia, the National Association of Community Health Centers filed a complaint against HHS requesting relief for failing to promulgate ADR regulations. *See* Compl., *Nat'l Assoc. of Comm'y Health Ctrs. v. Azar*, No. 1:20-cv-3032 (D.D.C.), ECF No. 1. The parties to that case jointly moved for a stay after HHS promulgated the ADR Rule at issue in the instant action, and the case has been stayed since January 7, 2021. *See* Joint Motion to Stay, *id.*, ECF No. 12. The parties to that case have been providing monthly status reports to the court, including updates on the progress of the instant action. *See, e.g.*, Joint Status Report, *id.*, ECF No. 14. In another action against HHS, filed by covered entities and their representatives in the U.S. District Court for the Northern District of California, the plaintiffs alleged that HHS had taken insufficient enforcement action against Lilly and other pharmaceutical manufacturers. *See* Compl., *Am. Hosp. Assoc. v. Dep't of Health & Human Servs.*, No. 4:20-cv-8806-YGR (N.D. Cal.), ECF No. 1. The court dismissed that action for lack of jurisdiction on February 17, 2021. *See* Order Granting Motion to Dismiss, *id.*, ECF No. 91.

Two other actions have been brought by pharmaceutical companies: AstraZeneca Pharmaceuticals LP ("AstraZeneca"), filed a complaint against HHS on January 12, 2021, in the U.S. District Court for the District of Delaware, and Sanofi-Aventis U.S., LLC filed a complaint against HHS on the same day in the U.S. District Court for the District of New Jersey. *See* *AstraZeneca Pharm. LP v. Azar*, No. 1:21-cv-27-LPS (D. Del.); *Sanofi-Aventis U.S., LLC v. U.S. Dep't of Health & Human Servs.*, No. 3:21-cv-634-FLW-LHG (D.N.J.). The complaints in those cases also allege claims against Defendants on the basis of the December 30 Decision and ADR

Rule. See First Amended Compl., *AstraZeneca*, No. 1:21-cv-27-LPS, ECF No. 13; Amended Compl., *Sanofi-Aventis*, No. 3:21-cv-634-FLW-LHG, ECF No. 17. In both of those cases there are also pending motions on similar issues. The *AstraZeneca* court set oral argument on the motions in its case for June 7, 2021. See Oral Order, *AstraZeneca*, No. 1:21-cv-27-LPS, ECF No. 53. Oral argument in the *Sanofi-Aventis* case is scheduled for June 21, 2021. See Order, *Sanofi-Aventis*, No. 3:21-cv-634-FLW-LHG, ECF No. 49.

In view of the important and complex issues raised in the instant action, the pendency of other related cases, and the Court's March 29, 2021 order that a hearing will be held, Plaintiffs respectfully request that the Court schedule oral argument at its earliest convenience following the completion of briefing in this case (which will be no later than June 14). Based on the preliminary injunction hearing, Plaintiffs estimate that the Court may wish to reserve at least one hour per side.

Dated: May 10, 2021

Respectfully submitted,

s/ Brian J. Paul

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CERTIFICATE OF SERVICE

I hereby certify that on **May 10, 2021**, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s/ Brian J. Paul
Brian J. Paul

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Defendants.

[PROPOSED] ORDER GRANTING MOTION TO SCHEDULE ORAL ARGUMENT

The Court orders as follows:

Upon consideration of Plaintiffs' Motion to Schedule Oral Argument on Plaintiffs' Cross-Motion for Summary Judgment and Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment, pursuant to Local Rule 7-5, the Court hereby GRANTS Plaintiffs' motion. Oral argument on the pending motions will be set for June ____, 2021 at _____ in Room 216 of the United States Courthouse in Indianapolis, Indiana. Each side shall have one hour to present argument.

IT IS SO ORDERED.

Dated: _____

Signed: _____

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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