

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

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.

XAVIER BECERRA, in his official capacity
as Secretary of Health & Human Services,
Office of the Secretary
200 Independence Avenue, SW
Washington, D.C. 20201,

DANIEL J. BARRY, in his official capacity
as Principal Deputy General Counsel of Health
& Human Services
Office of the General Counsel
200 Independence Avenue, SW
Washington, D.C. 20201,

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

DIANA ESPINOSA, in her official capacity
as Principal Deputy 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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JOINT STATUS REPORT

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Undersigned counsel respectfully submit this joint status report pursuant to the Court's order of April 20, 2023. The parties have conferred and agree on the following:

1. Defendants have not promulgated or issued any revised or amended Administrative Dispute Resolution ("ADR") regulations since the issuance of the preliminary injunction in this case. Defendants, however, published a Notice of Proposed Rulemaking ("NPRM") to revise the current 340B ADR final rule issued on December 14, 2020. *See* 340B Drug Pricing Program; Administrative Dispute Resolution, 87 Fed. Reg. 73516 (Nov. 30, 2022) (proposing revisions to 42 C.F.R. §§ 10.3, 10.20-10.24). The public comment period on the NPRM closed on January 30, 2023, and the agency is working through the public comments that it received with the intent to issue a final rule in the future.

2. Given the pendency of the parties' cross-appeals and the agency's ongoing rulemaking process to revise the current 340B ADR final rule, the parties respectfully submit that this Court should not address the parties' cross-motions for summary judgment at this time. Awaiting the result of the cross-appeals and allowing the agency to complete its rulemaking process will conserve the Court's and the parties' time and resources.

The parties do not object to administratively closing the pending cross-motions for summary judgment on Plaintiffs' ADR claims, so long as (a) doing so does not serve to moot or vacate the Court's preliminary injunction nor convert the preliminary injunction into a permanent injunction, and (b) any party can request that the court reopen the pending cross-motions as to Plaintiffs' ADR claims at any point without having to file a new summary judgment motion.

Dated: May 11, 2023

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Deputy Assistant Attorney General

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/s/ Jody D. Lowenstein

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on **May 11, 2023**, 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/ John C. O'Quinn
John C. O'Quinn
Attorney for Plaintiffs