

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

ELI LILLY AND COMPANY

Lilly Corporate Center
893 Delaware Street
Indianapolis, Indiana 46225

and

LILLY USA, LLC

1500 South Harding Street
Indianapolis, Indiana 46221,

Plaintiffs,

v.

**XAVIER BECERRA,
in his official capacity as Secretary of HHS**

Office of the Secretary
200 Independence Avenue, SW
Washington, D.C. 20201,

**DANIEL J. BARRY,
in his official capacity
as Acting General Counsel of HHS**

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 Acting Administrator of HRSA**

5600 Fishers Lane
Rockville, Maryland 20852,

and

**HEALTH RESOURCES AND SERVICES
ADMINISTRATION**

5600 Fishers Lane
Rockville, Maryland 20852,

Defendants.¹

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

Document Electronically Filed

¹ Pursuant to Rule 25(d), the identities of the individual-official defendants have been updated.

**PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION
AND A TEMPORARY RESTRAINING ORDER**

Pursuant to Federal Rule of Civil Procedure 65(a), Plaintiffs Eli Lilly and Company and Lilly USA, LLC (collectively, "Lilly") hereby move this Court for a preliminary injunction barring Defendants, as well as their officers, agents, employees, attorneys, and all persons in active concert or participation with them who receive actual notice of the Order, from taking any adverse action against Lilly related to the 340B drug pricing program based on Defendants' interpretation of the statute (as reflected in the December 30, 2020 Advisory Opinion), including actions described in the May 17, 2021 letter described below, until after this Court resolves and issues final judgment on Lilly's claims challenging the validity of the December 30, 2020 Advisory Opinion (Counts I-IV of Lilly's First Amended Complaint).

Lilly also respectfully moves this Court for a temporary restraining order to the same effect, to maintain the status quo while this Court resolves the present Motion for preliminary injunction.

Lilly files this Motion based on its receipt of a May 17, 2021 letter from the government which demands that "Lilly must *immediately* begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements" *and* must "credit or refund all covered entities for overcharges that have resulted from Lilly's policy." Ex. A at 1-2 (emphasis added). The letter further warns that "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies" will "result in CMPs" (which "would be in addition to repayment") unless Defendants are satisfied with "Lilly's willingness to comply with" the government's view of Lilly "obligations under section 340B[.]" *Id.* It concludes by requiring "that Lilly provide [Defendants with] an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by *June 1, 2021*," *id.* at 2 (emphasis added), in the midst of the

briefing on the cross-motions for summary judgment currently pending before this Court.

This Motion is based upon all the files, records, and proceedings herein, including the administrative record and the accompanying memorandum of law and supporting declaration, as well as any evidence that may be submitted at a hearing on the motion.

Lilly requests that the Court require no security because Defendants will suffer no injury from the issuance of a preliminary injunction or a temporary restraining order.

Lilly conferred with counsel for Defendants prior to filing this motion. Defendants oppose the relief requested and intend to respond. Lilly inquired with counsel for Defendants regarding whether the government would agree to either (a) extend the June 1 deadline that the government imposed for Lilly to respond to the government's May 17 letter, or (b) agree to withhold any action described in the May 17 letter, pending resolution of this case. The government declined those requests. This Motion follows.

Dated: May 20, 2021

Respectfully submitted,

s/ John C. O'Quinn

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CERTIFICATE OF SERVICE

I hereby certify that on **May 20, 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. I further certify that copies will be mailed by U.S. mail to the following addresses:

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