

**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, S.W.
Washington, D.C. 20201,

DANIEL J. BARRY, in his official capacity as
Acting 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,

DIANA ESPINOSA, in her official capacity as
Acting 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

Document Electronically Filed

**PLAINTIFFS' NOTICE TO THE
COURT**

Plaintiffs Eli Lilly and Co. and Lilly USA, LLC (collectively, “Lilly”) hereby give notice of the attached letter they received today, September 22, 2021, from Defendant Health Resources and Services Administration (“HRSA”). *See* Ex. A, Letter from M. Herzog to D. Asay (Sept. 22, 2021) (the “September 22 Letter”). The letter bears directly on the issues presented for this Court’s decision and confirms Lilly’s need for expedited or, in the alternative, preliminary injunctive relief, as sought in the pending motions.

On July 30, 2021, this Court held a consolidated hearing on the parties’ cross-motions for summary judgment and Lilly’s motion for a preliminary injunction. ECF No. 136. By agreement of the parties, the hearing focused on Lilly’s challenges to HRSA’s May 17, 2021 determination letter, in which HRSA concluded that Lilly’s 340B distribution policies violated the 340B statute. *See* Ex. B, July 30, 2021 Hr’g Tr. at 3. The Court agreed to prioritize decision on those issues first in order to help the parties advance the resolution of their ongoing dispute. *See id.* at 68. The Court’s decision on those matters remains pending.

On September 22, however—without waiting for the Court’s resolution of the pending motions—HRSA decided (again) to take matters into its own hands and publicly initiate civil monetary penalty (“CMP”) proceedings against Lilly. *See HRSA Refers Six Pharmaceutical Manufacturers to the Office of the Inspector General for Refusal to Comply with 340B Statute*, HRSA (Sept. 2021), <https://www.hrsa.gov/opa/index.html>. HRSA’s new letter confirms that its prior May 17 letter was an “instruct[ion]” to Lilly to abandon its position in this litigation and “immediately begin offering Lilly’s covered outpatient drugs at the 340B ceiling price to covered entities that dispense the discounted medications through their contract pharmacy arrangements.”

Ex. A at 1.¹ HRSA’s letter then announces that “[g]iven Lilly’s continued refusal to comply, HRSA has referred this issue to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule.” *Id.* (footnotes omitted) (citing 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. § 10.11(a)). CMPs, of course, are available only when a party acts *willfully*—that is, when it knows its conduct violates the law. 42 U.S.C. § 256b(d)(1)(B)(vi) (providing for CMPs only where manufacturer “knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price”). Remarkably, the September 22 Letter does not cite Chief Judge Stark’s June 16, 2021 opinion vacating the agency’s prior articulation of its statutory interpretation *on the very ground* that the statute does not unambiguously require what the agency says it does. *Astrazeneca Pharms. LP v. Becerra*, No. CV 21-27-LPS, 2021 WL 2458063, at *10-11 (D. Del. June 16, 2021).

Equally troubling, HRSA’s latest maneuver is inconsistent with the government’s representations to this Court. At the July 30 hearing, counsel for the government confirmed that *this lawsuit* was the proper way for Lilly to contest the May 17 determination:

THE COURT: So let me ask you a question about the enforcement process. So the enforcement letter basically asserts HHS’s and HRSA’s view of the violation. So how does Lilly contest that if it chooses to disagree?

MS. TALMOR: Exactly as it has done, Your Honor. We have not moved to dismiss on the violation letter. We’ve only moved for summary judgment. So we’re not arguing that it’s not justiciable. So this process is playing out exactly as Congress intended.

The agency charged with enforcement has found a violation. It has issued the equivalent of a cease and desist letter, and Lilly can

¹ As Lilly’s summary judgment brief explains, under its challenged policy, Lilly *does* offer 340B discounts to covered entities; what Lilly *does not* do is deliver discounted drugs to an unlimited number of contract pharmacies on demand. *See* Dkt. 129, Lilly Reply Br., at 9-10. The September 22 Letter, however, wrongly describes Lilly’s policy as a “continued failure to provide the 340B price to covered entities.” Ex. A at 1.

challenge it in this court. So this is as Congress designed, and it's directly analogous to other agency enforcement scenarios as well.

THE COURT: So the opposition to the quote, cease and desist order, end quote, is through judicial action?

MS. TALMOR: Yes, Your Honor.

Ex. B at 18:10-19:1. Now, however, HRSA's apparent view is that Lilly gets *no* opportunity to vindicate its statutory position in an orderly way; instead, Lilly must either capitulate before obtaining a judicial resolution or be subject to such penalties if it is wrong regardless of the proceedings pending before this Court.

The issuance of the September 22 letter bears directly on the issues presented for this Court's decision, and confirms Lilly's urgent need for this Court's resolution of those issues.

Dated: September 22, 2021

Respectfully submitted,

s/ John C. O'Quinn

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CERTIFICATE OF SERVICE

I hereby certify that on **September 22, 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/ John C. O'Quinn
John C. O'Quinn