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
John C. O'Quinn, P.C.*
Matthew S. Owen*
Matthew D. Rowen*
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue N.W.
Washington, D.C. 20004
(202) 389-5000
john.oquinn@kirkland.com
matt.owen@kirkland.com
matthew.rowen@kirkland.com

Andrew A. Kassof, P.C.*
Diana M. Watral*
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-2000
andrew.kassof@kirkland.com
diana.watral@kirkland.com

* Admitted *pro hac vice*

Andrea Roberts Pierson
Brian J. Paul
Nicholas B. Alford
FAEGRE DRINKER BIDDLE & REATH LLP
300 N. Meridian Street, Suite 2500
Indianapolis, IN 46204
(317) 237-0300
andrea.pierson@faegredrinker.com
brian.paul@faegredrinker.com
nicholas.alford@faegredrinker.com

Attorneys for Plaintiffs

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

Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

September 22, 2021

Mr. Derek L. Asay
Senior Director, Government Strategy
Eli Lilly and Company
Lilly Corporate Center
893 Delaware Street
Indianapolis, Indiana 46285

Dear Mr. Asay:

By letter dated May 17, 2021, HRSA instructed Eli Lilly and Company (Lilly) to comply with its 340B statutory obligations and to 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. HRSA informed Lilly that continued failure to provide the 340B price to covered entities utilizing contract pharmacies could result in civil monetary penalties.

Given Lilly's continued refusal to comply,[1] 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.[2]

Sincerely,

/Michelle Herzog/

Michelle Herzog
Acting Director
Office of Pharmacy Affairs

[1] Lilly provided HRSA its basis for refusing to comply in a letter dated June 10, 2021.
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(a)

Exhibit B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, AND LILLY USA, LLC,	)	
Plaintiff,	)	CAUSE NO. 1:21-cv-81-SEB-MJD
	)	Indianapolis, Indiana
-v-	)	**July 30th**, 2021
	)	12:00 p.m.
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al,	)	
Defendants.	)	

Before the Honorable
SARAH EVANS BARKER, JUDGE

OFFICIAL REPORTER'S TRANSCRIPT OF
PRELIMINARY INJUNCTION AND CROSS-MOTIONS FOR SUMMARY JUDGMENT

Court Reporter: Laura Howie-Walters, FCRR/RPR/CSR
Official Court Reporter
United States District Court
Room 217
46 East Ohio Street
Indianapolis, Indiana 46204

PROCEEDINGS TAKEN BY MACHINE SHORTHAND
TRANSCRIPT PRODUCED BY ECLIPSE NT COMPUTER-AIDED TRANSCRIPTION

A P P E A R A N C E S

For Plaintiffs:

John C. O'Quinn, Esq.
Matthew S. Owen, Esq.
Andrea Butler, Esq.
KIRKLAND & ELLIS LLP
1301 Pennsylvania Avenue N.W.
Washington, DC 20004

and

Brian J. Paul
FAEGRE DRINKER BIDDLE & REATH LLP
300 North Meridian Street
Suite 2500
Indianapolis, IN 46204

For Defendants:

Kate Talmor, Esq.
Jody D. Lowenstein, Esq.
U.S. DEPARTMENT OF JUSTICE
1100 L Street NW
Washington, DC 20005

(Open court.)

THE COURT: Good morning again, although it's now afternoon, but greetings, all.

MS. TALMOR: Good afternoon.

MR. O'QUINN: Good afternoon, Your Honor.

Miss Harves, will you call the matter before the Court, please.

(Call to order of the Court)

All right. This matter's on the Court's calendar for oral argument on the parties' cross motions for summary judgment and the government's motion to dismiss.

We have had informal discussions this morning, and so it's my understanding that the parties have agreed to limit the scope of your arguments today. The issues that have been presented still are pending before the Court, but for purposes of today's hearing, the scope of your advocacy and remarks will be limited to the issues that you identified today.

So I'll try to catch the balls that you pitch to me as you're deciding which issues to raise. I'll hear -- they are cross motions obviously, so I'll here first from you, Miss Talmor, on behalf of the government, and then Mr. O'Quinn on behalf of Lilly, and then a rebuttal from you, Miss Talmor.

The way we'll allocate the time is 20 minutes to the government and 30 minutes to Lilly to handle the issues on the cross motions, and then ten minutes for rebuttal from the

access their medications, it clearly contravenes Congress's intent even without looking to the kind of outpouring of statements from Congress in the last six months confirming that point.

So on the interpretive point, there is no interpretive doctrine of which I'm aware where Congress is required to detail the minutiae of every aspect of a transaction. It's enough that Congress commanded that purchases don't exceed the ceiling price.

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 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.

THE COURT: Okay. So this would not be something -- we're not going to talk today about ADR too much, but it would not be something that would come within the ADR --

MS. TALMOR: No, Your Honor.

THE COURT: -- process?

MS. TALMOR: No, Your Honor. The ADR process allows covered entities and manufacturers to sue each other before the agency. It doesn't determine the agency's enforcement and it doesn't allow Lilly to challenge the agency's view.

THE COURT: Okay.

MS. TALMOR: So Lilly's counter argument that the statute requires it only to offer drugs is demonstrably wrong. So the Court cannot focus on a single phrase that manufacturers shall offer to the exclusion of necessary language in the same statutory subsection.

Now, we've explained in our briefs that the offer language Lilly relies on that manufacturers shall offer the drugs, that was added in 2010. It imposes a separate nondiscrimination requirement that manufacturers may not preference or prioritize commercial sales over 340B sales, say if there's a scarcity.

So we believe that Lilly also violates that provision because when a commercial purchaser buys Lilly's drugs, there are no restrictions on where those drugs are delivered, whether

THE COURT: Very good.

Okay. Thank you, lawyers, for honing your presentations and basically advancing these two really urgent issues for expedited priority consideration by the Court, and thereby allowing the other issues that you've raised to remain pending and not requiring the Court to specifically address the ADR and the constitutional issues in particular.

So I will play the cards that are laid and try to resolve these immediate issues on an expedited basis. Now "expedited" is in the eyes of the beholder. And from your point of view, I know you'd like me to rule from the bench, but not really. You don't really want me to rule from the bench because I have to march through it in a more cautious and deliberative way.

But I do give you my word that I'll try to get that done, and give you some guidance on these issues while reserving the other issues to see if we need to reconvene to address those.

So thank you for positioning the case in a way that's more manageable. And hopefully, based on these rulings, you'll get some indication of what level of controversy remains and also the relative importance of those issues to decide if, as we say around here, a full church wedding is necessary.

It's awfully nice to have you in court. I hope you have a good rest of your summer. Take your vaccines. Make