

**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.

**NORRIS COCHRAN, in his official
capacity as Acting 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.

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

Document Electronically Filed

**REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR LEAVE TO FILE
NOTICE OF SUPPLEMENTAL AUTHORITY**

Plaintiffs Eli Lilly and Company and Lilly USA, Inc., (collectively “Lilly”) submit this brief reply to the government’s Opposition to Lilly’s Motion for Leave to File Supplemental Authority (hereinafter “Opp’n”). The government oddly asserts that the *Manufacturer Audit Guidelines and Dispute Resolution Process*, 61 Fed. Reg. 65,406-01 (Dec. 12, 1996), “do[] not provide any available method to resolve” disputes between manufacturers and covered entities under the 340B statute. Opp’n 1. In reality, however, these guidelines have provided a method to resolve countless disputes between manufacturers and covered entities over the past 25 years.

Indeed, while the government uses its Opposition as a means of casting aspersions on Lilly, claiming, *e.g.*, that “there is strong reason to believe that Lilly would *not* participate in the voluntary dispute-resolution process,” Opp’n 1-2, the fact of the matter is that the 1996 guidelines have provided the framework under which Lilly has accommodated literally *hundreds* of requests since last September alone to have Lilly ship 340B-discounted product to a single contract pharmacy of the covered entity’s choosing because they lacked an in-house pharmacy. *See* Exh. A. ¶ 7. In so doing, Lilly held telephonic discussions with dozens of covered entities, in several cases leading to resolution of any dispute. *See id.* ¶ 8.

Thus, the notion that Lilly has “demonstrated [a] refusal to engage with covered entities to resolve the contract-pharmacy dispute” (Opp’n 2) is a fiction, plain and simple. To take just one example, “the Pascua Yaqui Tribe sent Lilly a letter on January 19, 2021, outlining its disagreements with Lilly’s contract pharmacy distribution program. That very same day, Lilly granted the Pascua Yaqui Tribe ... an exception because it did not operate an in-house pharmacy. Lilly made the exception effective September 1, 2020, meaning that the Pascua Yaqui Tribe could identify retroactively which orders it should receive at the 340B price.” Ex. A ¶ 9.

Finally, it is more than a little ironic for the government to oppose taking judicial notice of a regulation that HHS itself issued 25 years ago and has never been withdrawn, while simultaneously asking the Court to take judicial notice of letters from members of Congress seeking to pressure HHS to take enforcement action against Lilly and other manufacturers. *See* Defs.' Request for Judicial Notice, Dkt. 69. Whatever the propriety of the government's position, it undoubtedly demonstrates the wisdom of the Founders of our Constitution in having issues such as this decided by neutral arbiters with life tenure, lest the political winds of the day drive the decision in private-party disputes over monetary damages and equitable relief.

Dated: March 9, 2021

Respectfully submitted,

s/ John C. O'Quinn

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Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on **March 9, 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, P.C.

Exhibit A

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DECLARATION OF DEREK L. ASAY

I, Derek L. Asay, declare and state as follows:

1. I am Senior Director, Government Strategy, Federal Accounts and Quality at Eli Lilly and Company (“Lilly”).
2. Before Lilly introduced its current contract pharmacy distribution policies, for years Lilly communicated with covered entities to identify and resolve 340B pricing issues, including 340B duplicate discounts, sales to ineligible patients, and other program integrity issues.
3. Since it introduced its contract pharmacy distribution program, Lilly has been communicating with covered entities to resolve disputes related to Lilly’s 340B distribution policies, including by holding discussions with covered entities to address concerns and facilitate approved exceptions for eligible contract pharmacy locations.
4. Beginning July 1, 2020, Lilly announced that, for three formulations of Cialis®, it would provide 340B discounts only to covered entities and their registered child sites, but not contract pharmacies unless the covered entity did not operate an in-house pharmacy—in which case it would allow the covered entity to designate one contract pharmacy to dispense Cialis.
5. Then, on September 1, 2020, Lilly announced that it would extend this distribution program to cover all Lilly products. Lilly also announced that it would voluntarily provide 340B discounts on Lilly outpatient drug products to certain contract pharmacies. First, as described above, Lilly allows covered entities without an in-house pharmacy to designate one contract pharmacy to continue dispensing drugs on its behalf. Second, Lilly will honor 340B discounted prices for all contract pharmacies purchasing certain Lilly insulin products, provided the covered entity agrees, *inter alia*, that the contract pharmacy will pass on the entire 340B discount to the patient purchasing insulin at the pharmacy counter.

6. Since then, after discussions with covered entities, Lilly has added two more voluntary exceptions. First, Lilly allows covered entities to utilize an unlimited number of contract pharmacies if those pharmacies and the eligible 340B covered entity are wholly owned by the same common parent entity. Second, Lilly expanded the exception for no in-house pharmacy to include covered entities that have an in-house pharmacy, but that do not dispense retail outpatient prescriptions.

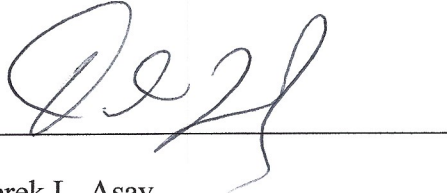
7. As of March 9, 2021, Lilly has approved exceptions for 554 covered entities that have invoked Lilly's exception for entities without an in-house (or in-house retail) pharmacy; 81 covered entities that have invoked Lilly's wholly-owned contract pharmacy exception; and 4 covered entities that have invoked Lilly's insulin product exceptions. In total, Lilly has approved 639 exceptions from entities located across 45 different states.

8. Since September 2020, Lilly has held telephonic discussions with at least 59 different covered entities to review and explain Lilly's contract pharmacy distribution policies and exceptions. Several of these conversations have allowed Lilly and the covered entity to resolve disputes about a contract pharmacy's eligibility.

9. Lilly has also approved exceptions in response to written communications from covered entities. For instance, the Pascua Yaqui Tribe sent Lilly a letter on January 19, 2021 outlining its disagreements with Lilly's contract pharmacy distribution program. That very same day, Lilly granted the Pascua Yaqui Tribe (and 3 child site locations) an exception because it did not operate an in-house pharmacy. Lilly made the exception effective September 1, 2020, meaning that the Pascua Yaqui Tribe could identify retroactively which orders it should receive at the 340B price. Lilly has not received any other communications from the Pascua Yaqui Tribe following the approval of the contract pharmacy exception.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: March 9, 2021

A handwritten signature in black ink, appearing to read "Derek L. Asay", is written over a solid horizontal line. The signature is cursive and stylized.

Derek L. Asay