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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Attorneys for Plaintiffs

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:

XAVIER BECERRA
United States Department of Health & Human Services
Office of the Secretary
200 Independence Avenue, S.W.
Washington, D.C. 20201

DANIEL J. BARRY
United States Department of Health and Human Services
Office of the General Counsel
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UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington D.C. 20201

DIANA ESPINOZA
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20852

HEALTH RESOURCES AND SERVICES ADMINISTRATION
5600 Fishers Lane
Rockville, MD 20852

United States Attorney General
United States Department of Justice
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United States District Attorney for the Southern District of Indiana
United States Attorney's Office
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Indianapolis, IN 46204

/s/ John C. O'Quinn
John C. O'Quinn

Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 17, 2021

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

Dear Mr. Asay:

The Health Resources and Services Administration (HRSA) has completed its review of Eli Lilly and Company's (Lilly) policy that places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. Lilly is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

Lilly purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, Lilly must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. Lilly must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from Lilly's policy. Lilly must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on Lilly's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that Lilly provide 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**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

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DANIEL J. BARRY,
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UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
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DIANA ESPINOSA,
in her official capacity as
Acting Administrator of HRSA
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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PLAINTIFFS' MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND TEMPORARY RESTRAINING ORDER

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

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INTRODUCTION

Three days ago, Defendant Diana Espinosa, Acting Administrator of Defendant HRSA, sent Plaintiffs ("Lilly") an extraordinary letter. The letter, sent in the middle of the agreed-upon briefing schedule for the parties' cross-motions for summary judgment about the meaning of the 340B statute, demands that Lilly capitulate to HRSA's position on that very question by June 1, or else face civil monetary penalties ("CMPs") or worse. *See* Ltr. from Diana Espinosa, Acting Adm'r, to Derek L. Asay (May 17, 2021) (Exh. A). That is, HRSA has threatened to impose massive penalties on Lilly if it continues the very position this action seeks to defend.

That is no exaggeration: The letter begins by notifying Lilly that "HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute," and then 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" (under which, as this Court is aware, Lilly continues to offer 100% of 340B discounts to 100% of covered entities, but will not provide discounts to contract pharmacies as a matter of course). *Id.* at 1-2 (emphasis added). The letter reminds Lilly that it "signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum" and that "Lilly is bound by the terms of the PPA." *Id.* at 1. It 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 Defendant HHS is sufficiently satisfied with "Lilly's willingness to comply with" HRSA's unilaterally imposed view of Lilly's "obligations under section 340B[.]" *Id.* at 1-2. And it concludes by "request[ing] 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.

In other words, Defendants just told Lilly—without even the faintest acknowledgment of this litigation—that unless Lilly accedes to the government's position on the ultimate legal issue in this case ***and*** begins paying substantial and irretrievable sums of money over to third-parties, the agency will drop the government hammer. The letter provides no legal explanation or justification for the arbitrary June 1 deadline for this demand. Nor is there one: The government's official (but non-credible) position is that the interpretation of the 340B statute on which the December 30, 2020 "Advisory Opinion" and, in turn, the May 17 letter rests has been clear and consistent since 1992—29 years ago, and 18 years before the legislative text upon which the government's position is supposedly based was added to the 340B statute. Nevertheless, the government suddenly decided ***this week*** that Lilly must accept the obligation to deliver discounted drugs to contract pharmacies by the very day the government's reply brief is due in this case (the government's reply is nominally due May 31, but that is Memorial Day).

Defendants' attempt to circumvent this litigation, and the briefing schedule they agreed to, could not be clearer. In its motion for summary judgment filed May 10, Lilly expressly urged the Court to decide this case on ***the very ground*** that would preclude the agency from carrying out the threats it made in the May 17 letter. Lilly argued that HRSA's December 30 Decision announcing Defendants' view that the 340B statute obligates manufacturers to deliver discounted drugs to an unlimited number of contract pharmacies constitutes a legislative rule that is inconsistent with the statute and wrongfully promulgated without notice and comment. Lilly has asked this Court to invalidate that Decision precisely because federal law does not authorize the contract pharmacy rule to which HRSA is committed. *See* Pls.' Combined Mem. in Supp. of Pls.' Cross-Mot. for Summ. J. and in Opp'n to Defs.' Mot. to Dismiss or, in the Alternative, for Summ. J., at 22-24, Dkt. 89 (May 10, 2021) ("Lilly MSJ"). Yet rather than wait for this Court's decision on that

question in the ordinary course, Defendants are now attempting to take matters into their own hands and prevent Lilly from seeing the end of its day in court. This Court should not countenance this interference with its proceedings, nor with the rights of the litigants who have come before it.

It is not difficult to guess the driving force behind this letter. At the hearing on Lilly's previous motion for a preliminary injunction, the government emphasized how responsive it was to political pressure from members of Congress to come down on drug manufacturers that disagreed with its interpretation of the statute. Official Reporter's Tr. of Oral Arg. on Mot. for Prelim. Inj. at 55:10-14 (Feb. 26, 2021) (Exh. B). So too now. Five days before HRSA sent its latest demand, HHS Secretary Becerra testified before Congress and, in response to House members urging him to take action against Lilly and other manufacturers, testified "We are on this one…. Everyone has to follow the law." Everyone, that is, except the Defendants—who now seek to derail this orderly (and expeditious) litigation, and instead preempt the decision pending before this Court. That has troubling implications for our system of justice, in which independent courts, not politically responsive executive agencies, ultimately arbitrate legal questions.

Lilly therefore moves for a preliminary injunction on its pending claims to bar Defendants from taking any adverse action against Lilly related to the 340B program based on Defendants' interpretation of the statute (as reflected in the December 30 Decision) until after this Court issues final judgment on Lilly's claims. Lilly further respectfully requests that the Court grant a temporary restraining order to the same effect in the interim to maintain the status quo while this Court resolves the present motion for a preliminary injunction.

Lilly does not seek this relief lightly. But given the government's unwillingness to play by the rules and its effort to circumvent the judicial process, Lilly is now left with no choice but to seek this Court's immediate intervention. Because Lilly is likely to prevail on its claims in

Counts I-IV of the First Amended Complaint (including the ultimately dispositive statutory-interpretation question, as well as its other challenges to the December 30 Decision, which for the first time announced the agency's rule on contract pharmacy sales) that have been briefed and are pending before this Court, because Lilly faces irreparable harm from the government's threatened actions, and because the balance of equities and public interest in due process and correct legal interpretation all favor injunctive relief pending resolution of the pending cross-motions for summary judgment, this Court should grant the present motion.

BACKGROUND

Through the December 30 Decision at the heart of this lawsuit, HHS is attempting to force Lilly to provide its products at steep discounts to for-profit pharmacies, while pretending that this novel obligation is actually not new at all, but rather has been in the 340B statute since it was first enacted in 1992. *See* Defs.' Mot. to Dismiss, or, in the Alternative, for Summ. J., at 14-21, 24-27, Dkt. 88 (Apr. 20, 2021) ("MTD/MSJ"). The December 30 Decision announces that "to the extent contract pharmacies are acting as agents of a covered entity, a drug manufacturer in the 340B Program is obligated to deliver its covered outpatient drugs to those contract pharmacies" and charge "no more than the 340B ceiling price for those drugs." ADVOP_1; *see also* ADVOP_8 (concluding that "manufacturers may not refuse to offer the ceiling price … even where [covered entities] use distribution systems involving contract pharmacies" and even when the covered entity does not itself place the order). On January 12, 2021, Lilly filed this lawsuit under the Administrative Procedure Act ("APA") seeking to set the December 30 Decision aside as impermissible under the statutory text, unconstitutional, irregularly promulgated without notice and comment, and arbitrary and capricious. Compl. for Decl. & Inj. Relief, Dkt. 1 (Jan. 12, 2021).

Lilly filed an amended complaint two weeks later, adding claims challenging HHS's separate 340B ADR Rule on a number of grounds. *See* First Amended Compl. for Decl. & Inj.

Relief ¶¶ 211-63, Dkt. 17 (Jan. 25, 2021); *see also id.* ¶¶ 164-210 (renewing claims challenging the December 30 Decision). Lilly also filed a motion for preliminary injunction relating solely to the ADR Rule, not the December 30 Decision. *See* Pls.' Mot. for Prelim. Inj., Dkt. 18 (Jan. 25, 2021). After briefing and oral argument, this Court granted Lilly's motion for preliminary injunction against the ADR Rule. Order Granting Pls.' Mot. for Prelim. Inj., Dkt. 81 (Mar. 16, 2021) ("ADR PI Op."). The Court found that Defendants' actions before belatedly promulgating the ADR Rule were "duplicitous[] and misleading—the antithesis of fair notice under the APA," and, "[a]ccordingly," concluded "that Plaintiffs have established with a fair likelihood of success that Defendants violated notice-and-comment rulemaking requirements under the APA" in promulgating the ADR Rule. *Id.* at 23. The Court further ruled that Lilly would "suffer irreparable injury for which there is no adequate remedy of law" by virtue of having been "'depriv[ed] of a procedural protection to which [Lilly is] entitled.'" *Id.* at 23, 25 (first alteration in original) (quoting *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 94 (D.C. Cir. 2002)); *see also* ADR PI Op. 25-26 ("[I]f the ADR Rule were permitted to go into effect and was later determined to have been promulgated without an adequate, fair opportunity for advance notice and comment, Plaintiffs would be deprived of their right, under the APA, to provide meaningful input into the agency's decision at a time when it is most likely to be carefully considered, a harm which the Court would be unable to fully remedy after the fact."). Finally, the Court found that "the balance of harms and the public interest factors weigh in favor of Plaintiffs." *Id.* at 27. The Court therefore entered an order preliminarily enjoining Defendants "from implementing or enforcing [the ADR Rule] against Plaintiffs" "until further order of this Court." Prelim. Inj., Dkt. 82 (Mar. 16, 2021).

With the ADR Rule preliminarily enjoined, this case then proceeded in the regular course (at least until Monday of this week) to dispositive briefing on both the December 30 Decision claims and the ADR Rule claims. The matters before the Court include the fundamental question of whether the 340B statute permits the government to ***require*** manufacturers such as Lilly to provide their products to so-called contract pharmacies at the steeply-discounted 340B prices. The government filed a motion to dismiss and for summary judgment on April 20. Remarkably, the government took the position in that brief that the December 30 Decision said nothing that the 1992 340B statute and the agency's own guidance documents from 1996 and 2010 did not already say, *see* MTD/MSJ 14-21, 24-27—quite a claim, since (A) the December 30 Decision relied on statutory "must offer" language that was not added to the 340B statute until ***after*** HHS issued its 2010 guidance, *see* Lilly MSJ 14-15; and (B) the "agency" theory at the heart of the December 30 Decision has no basis in the statutory text and no support in the administrative record in this case, *see id.* at 27-33.

On May 10, Lilly filed its own motion for summary judgment and opposition to the government's motion to dismiss. Lilly's motion explained that the December 30 Decision is a legislative rule illegally promulgated without notice and comment, because it commands parties using mandatory language, engrafts a requirement onto the 340B statute just like rulemaking would do, and attempts to create the legislative basis for an enforcement action that could not plausibly be maintained without the Decision. *See id.* at 12-19; *see also id.* at 19-22. As a result (and for other reasons), the December 30 Decision constitutes final agency action that can be challenged in federal court. While Defendants' failure to go through notice-and-comment rulemaking is fatal to the December 30 Decision and requires vacatur on its own, Lilly urged the Court to address the merits of the statutory question—*i.e.*, whether it is in fact true that Congress

has required Lilly to deliver discounted drugs to contract pharmacies—to avoid more wasteful trips around the agency merry-go-round. *See id.* at 22-24. Lilly also explained that because the December 30 Decision purports to force a classic A-to-B private wealth transfer and does not fit within even the most expansive definition of "public use" under the Fifth Amendment, it is an unconstitutional condition on Medicaid participation. *See id.* at 33-37. Finally, Lilly argued that the December 30 Decision is arbitrary and capricious because it fails to explain (indeed it denies the existence of) the agency's obvious change in position, does not substantiate the existence of "agency" relationships between contract pharmacies and 340B covered entities, and declines to account for who will ultimately keep the money it is taking from Lilly's pockets. *See id.* at 37-41.

Lilly expected, of course, that the government would respond to these arguments in its reply brief (nominally due May 31, though that is Memorial Day), and that Lilly would respond in due course in its own reply (due June 14). That is the briefing schedule to which the parties agreed and that the Court directed. *See* Order at 1, Dkt. 85 (Mar. 29, 2021).

But then, out of the blue, the government announced that it expects Lilly to capitulate to the government's interpretation of the statute by June 1—before briefing is even complete. On Monday, May 17, 2021, Defendant Diana Espinoza, the Acting Administrator of Defendant HRSA, dispatched a letter to a Lilly executive directly; the letter did not come through, or copy, Lilly's counsel in this litigation. The letter announces that "HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute," and 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." Exh. A at 1-2.

Strangely, the May 17 letter's explanation for this mandate differs even from the summary judgment brief ***the government just filed***. The letter claims to echo HHS's purportedly consistent position since 1996, *see id.* at 1, but unlike HHS's summary judgment brief, it relies only on statutory language added to the 340B statute by the 2010 Affordable Care Act, *see* Pub. L. No. 111-148, Title VII, § 7102(b), 124 Stat. 119, 827 (Mar. 23, 2010); it does not even cite the original 1992 "purchased by" language the government's brief in this Court relied on, *see* MTD/MSJ 22-25. Nor—unaccountably—does it say ***anything*** about the "agency" theory the December 30 Decision and Defendants' brief rely upon. The May 17 letter purports to require Lilly to deliver discounted drugs to contract pharmacies, period, whether they act as the covered entities' agents or not. *See* Exh. A at 1-2. HRSA's letter offers no explanation for departing from, or even evidence that HRSA is aware of, the brief that its lawyers just filed in this Court on these points.

Nor does the letter try to reconcile its categorical determination of overcharging and threat of CMPs with HRSA's prior pronouncements that the ADR process would serve as the mechanism through which HRSA and HHS would determine whether a particular contract pharmacy was sufficiently related to a covered entity for purposes of the program. That is remarkable, since the government could not have been clearer on this point at oral argument on Lilly's motion for a preliminary injunction against the ADR Rule. The government's unequivocal position was that although "the agency has determined that covered entities have a right generally to use contract pharmacy arrangements, the agency has not passed on the specifics of Lilly's new policy, ***because that belongs in the ADR***." Exh. B at 76:24–77:3 (emphasis added); *see also id.* at 77:4-10 ("[T]he panels are empowered to determine whether Lilly's policy comports with its obligations under the statute. That is all. And if the panel determines that Lilly's policy does not comply with the statute, it can refer its decision to HRSA for enforcement action. HRSA can consider whether to

impose penalties, sanctions, to refer the decision to the OIG for civil monetary penalties."). Indeed, the government went so far as to describe Lilly's lawsuit as "seeking to thwart" a determination of whether "Lilly's new policy" results in "overcharging." *Id.* at 76:23–77:3. Having been enjoined from pursuing its ADR process, the agency has now decided to "thwart" that process (and this lawsuit) itself.

The May 17 letter then goes on to levy a number of threats, both open and veiled, against Lilly. The letter reminds Lilly that it "signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum" and that "Lilly is bound by the terms of the PPA." Exh. A at 1. It 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 Defendant HHS is sufficiently satisfied with "Lilly's willingness to comply with" HRSA's unilaterally imposed view of Lilly's "obligations under section 340B[.]" *Id.* at 1-2. And it concludes by "request[ing]" (*i.e.*, demanding) "that Lilly provide 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. The letter cites no exigency or special reason for this deadline; it is just a fiat, backed by the threat of severe sanctions. The terms of that fiat are clear: "Surrender before you get a judicial decision or we will come after you for penalties and conclude that you have violated the PPA that allows you to participate in Medicaid at all."

While there is no actual exigency for such an extraordinary threat, the real-world impetus for it is not hard to guess. Just five days before sending the letter, HHS Secretary Xavier Becerra faced heated criticism from multiple members of Congress to "take swift enforcement action" against Lilly and others simply for following the law as written. *See* Tom Mirga, *Breaking: Becerra, on 340B Pricing Denials, Tells House Panel, "Everyone Has to Follow the Law,"* 340B

Report (May 12, 2021), https://bit.ly/3eYoDuA (Exh. C). Secretary Becerra responded in no uncertain terms: "We are on this one." *Id.* The hearing makes plain that the government's latest move was not predicated on neutral and detached legal reasoning, but was instead a deliberately calculated political attempt to assuage members of Congress and their constituents. This bow to political pressure over legal reasoning should come as no surprise, as the government has already (and repeatedly) made clear its willingness to placate the cries of political actors to "take action" against drug manufacturers. *See, e.g.*, Exh. B at 55:10-14 ("point[ing] out that after the changes instituted by Lilly and its peers"—*i.e.*, their decisions to continue giving massive discounts to for-profit retail pharmacies only if the for-profit pharmacies actually pass the discounts onto the eligible patients rather than pocket the money for themselves—"there has been a bipartisan outcry with two different letters written by the Secretary of HHS for more than 200 members of both parties in Congress urging former Secretary Azar to take action").

The present motion asks the Court to prevent such interference with this litigation and instead to preserve the status quo until the Court can resolve Lilly's lawsuit. The Court should enter a preliminary injunction on Lilly's claims challenging the December 30 Decision, barring Defendants (pending final resolution of this case) from taking any action against Lilly predicated on the interpretation of the 340B statute articulated in the December 30 Decision—including, but not limited to, obligating Lilly to deliver discounted 340B drugs to contract pharmacies, respect an unlimited number of contract pharmacy arrangements even when the covered entity has its own retail pharmacy, or imposing CMPs for the failure to do so. And, in the meantime, the Court

should enter a temporary restraining order to the same effect pending resolution of this preliminary injunction motion. [1]

LEGAL STANDARD

"To obtain a preliminary injunction, the moving party must demonstrate: (1) a reasonable likelihood of success on the merits; (2) no adequate remedy at law; (3) irreparable harm absent the injunction." ADR PI Op. 16 (citing *Planned Parenthood of Ind., Inc. v. Comm'r of Ind. State Dep't of Health*, 699 F.3d 962, 972 (7th Cir. 2012)). "If these threshold conditions are met, the Court must then assess the balance of the harm—the harm to Plaintiffs, if the injunction is not issued, against the harm to Defendants, if it is issued—and determine the effect of an injunction on the public interest." *Id.* at 17 (citing *Girl Scouts of Manitou Council, Inc. v. Girl Scouts of the United States, Inc.*, 549 F.3d 1079, 1086 (7th Cir. 2008)). The standard for temporary restraining orders—which are "designed to preserve the status quo until there is an opportunity to hold a hearing on the application for a preliminary injunction," 11A Wright & Miller, *Federal Practice & Procedure* § 2951 (3d ed., Apr. 2021 update), which may be granted ex parte, *see id.* § 2951-2952, and which may last no more than "14 days" "after entry," Fed. R. Civ. P. 65(b)(2)—is substantially the same. *See Baskin v. Bogan*, 12 F. Supp. 3d 1137, 1140 (S.D. Ind. 2014). Finally, as to requests for both preliminary injunctions and temporary restraining orders, "the more likely

[1] Lilly understands from counsel for the government that Defendants' position in response to this motion will be that Lilly must amend its complaint to separately challenge the May 17, 2021 letter. Lilly does not agree. The statutory basis for the May 17 letter rises and falls with the December 30 Decision, and the relief Lilly has sought in its summary judgment motion would preclude Defendants from carrying out their May 17 threats. Nonetheless, to the extent that the Court agrees with the government on that procedural point, Lilly respectfully requests that this motion also be treated as a motion for leave to file a Second Amended Complaint. If requested, Lilly will promptly file a Second Amended Complaint that will present challenges to the May 17 letter that are virtually indistinguishable from the ones in Counts I-IV. But in all events, with or without further amendment to the complaint, the government is not entitled to backfill its Administrative Record or otherwise to delay judgment day.

it is the plaintiff[s] will succeed on the merits, the less the balance of irreparable harms need weigh towards [their] side." *Whole Woman's Health All. v. Hill*, 388 F. Supp. 3d 1010, 1032 (S.D. Ind. 2019) (alterations in original) (quoting *Planned Parenthood of Wis., Inc. v. Van Hollen*, 738 F.3d 786, 795 (7th Cir. 2013)), *aff'd as modified*, 937 F.3d 864 (7th Cir. 2019).

ARGUMENT

I. The May 17 Letter Confirms That Lilly Is Likely To Succeed On The Merits.

A. The May 17 Letter Confirms that the December 30 Decision Is a Final, Legislative Rule That Lilly Has Properly Challenged.

It was already clear that the December 30 Decision is a legislative rule properly subject to challenge in this Court, as Lilly previously explained at length in its summary judgment brief. *See* Lilly MSJ 12-19. The May 17 letter removes any potential doubt on that score.

"Legislative rules" are those that "create new law, rights, or duties." *Metro. Sch. Dist. of Wayne Twp., Marion Cnty. v. Davila*, 969 F.2d 485, 489-490 (7th Cir. 1992); *see also NRDC v. EPA*, 643 F.3d 311, 321 (D.C. Cir. 2011) ("[T]he inquiries into whether the agency action was final and whether the agency action was a rule were essentially the same."). Simply put, before the December 30 Decision, there was no basis for the government's now-articulated view that it could require manufacturers to provide discounts to an unlimited number of for-profit retail pharmacies, let alone to institute an enforcement action ***and impose CMPs***—which are available only for "knowing[] and intentional[]" violations of the statute, 42 U.S.C. § 256b(d)(1)(B)(vi)(III)—against a manufacturer that declined to honor an unlimited number of contract pharmacy arrangements as a matter of course (but still provides 340B discounts to 100% of covered entities).

After all, as recently as last summer, ***even HRSA*** acknowledged that it lacked authority to impose CMPs on manufacturers that decline to give contract pharmacies 340B discounts. On July

8, 2020, HRSA's Director of Communications wrote that "although the agency 'strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements,' 'HRSA's current authority to enforce certain 340B policies … is limited." *Am. Hosp. Ass'n v. HHS*, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021) (ellipsis in original) (quoting correspondence from HRSA Communications Director Martin Kramer). That same HRSA correspondence concluded that "HRSA is unable to develop enforceable policy" with respect to contract pharmacies, with the caveat that "HRSA is still considering this matter as raised by the actions of these manufacturers." Michelle Stein, *HRSA Urges Pharma To Continue 340B Discounts At Contract Pharmacies*, Pa. Office of Rural Health (Aug. 2020), https://bit.ly/3wnHDZz (quoting Kramer correspondence). HRSA's July 2020 communication was consistent with Defendants' oft-stated position that it lacked the ability to bring any type of enforcement action against manufacturers that declined to offer discounts to an unlimited number of contract pharmacies as a matter of course. Before issuing the December 30 Decision, HHS and HRSA said over and over again that they lacked the authority to compel manufacturers to provide 340B discounts on drugs dispensed by contract pharmacies. *See* Lilly MSJ 16-17 (detailing numerous statements to that effect from HRSA and HRSA officials).

Now, however, in the wake of the December 30 Decision, Defendants have no such compunctions, as evidenced by the May 17 letter. *See* Exh. A at 2 (threatening CMPs, which are available only for knowing and intentional violations of the statute, unless Lilly starts giving 340B discounts to an unlimited number of contract pharmacies). It is simply not credible that ***the 340B statute*** (which has been on the books for 29 years, and which has not been materially amended since 2010), rather than the December 30 Decision, forms the basis of HRSA's marked change in position. The December 30 Decision was, in fact, the culmination of Defendants' "consider[ation

of] this matter." Stein, *supra*. Indeed, the December 30 Decision is not just the font of HRSA's newfound regulatory boldness. It is a textbook legislative rule from which "legal consequences" are already beginning to "flow" (as evidenced by the May 17 letter), *see, e.g.*, *Sackett v. EPA*, 566 U.S. 120, 126 & n.2 (2012), and the reasoning of which the agency now treats as having "binding effect," *PhRMA v. HHS*, 138 F. Supp. 3d 31, 44 (D.D.C. 2015). In any event, imposing such an obligation, after years of telling everyone involved that Defendants lacked authority to do so, makes the December 30 Decision final agency action even if it is not a legislative rule. *See U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1813 (2016); *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997); *see also* Lilly MSJ 18-22. More than that, it is agency action that requires notice and comment (if it can happen at all without violating the statute and the Constitution). The December 30 Decision is thus final agency action properly subject to challenge now.

The May 17 letter also confirms that the government's statute of limitations defense (MTD/MSJ 17-21) is meritless. *See* Lilly MSJ 18-19. Not only does the letter demonstrate that the December 30 Decision is a legislative rule, but its content also belies the suggestion Lilly could have sued before now. In explaining what statutory language HRSA believes creates the obligation to deliver discounted drugs to an unlimited number of contract pharmacies, the May 17 letter cites only language that ***was not in the statute when HRSA issued its 1996 and 2010 contract pharmacy guidance documents***. The May 17 letter relies on the language in "Section 340B(a)(1) of the Public Health Service (PHS) Act requir[ing] that manufacturers 'shall … offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price,'" Exh. A at 1 (final alteration in original) (quoting 42 U.S.C. § 256b(a)(1)), which is the language interpreted in the December 30 Decision.

As Lilly has already pointed out, that language was not added to the statute until 14 years ***after*** HRSA "issue[d]" "its 1996 contract pharmacy guidance," *id.* *See* Lilly MSJ 14-15.

As originally enacted, Section 340B(a)(1) of the Public Health Service Act provided as follows:

> The Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this section, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

Pub. L. No. 102-585, Title VI, § 602(a), 106 Stat. 4943, 4967 (1992). The "must offer" language on which the government relies does not appear there for a reason: It was not added to the statute until 2010. The "must offer" provision codified HRSA's 1994 "non-discrimination" guidance, which was entirely distinct from HRSA's contract pharmacy guidance and which was intended solely to address situations in which manufacturers might seek to limit access to all 340B purchasers on the basis of a shortage or limitation on distribution. *See* HRSA, 340B Drug Pricing Program Notice Release No. 2011-1.1, *Clarification of Non-Discrimination Policy* (May 23, 2012), https://bit.ly/3406yGl; *see also* 59 Fed. Reg. 25,110 (May 13, 1994). Congress codified this requirement via the Affordable Care Act, which (among many other things) amended Section 340B(a)(1)'s existing language to add the word "outpatient" added between "covered" and "drugs" and specify the actual date of enactment, and then added the following sentence to the provision:

> Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered outpatient drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the "ceiling price"), and ***shall require that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price***.

Pub. L. No. 111-148, Title VII, § 7102(b), 124 Stat. 119, 827 (2010) (emphasis added). The bolded-and-italicized language (the "must offer" provision) is what the May 17 letter relies on.[2]

The government's suggestion that the statute of limitations extinguished Lilly's cause of action before the agency took any action based on this new language, and indeed before it existed, is absurd. And, to be clear, HRSA and HHS did not suddenly decide in 2010 that they could compel manufacturers to provide 340B discounts on drugs dispensed through contract pharmacies. On the contrary, as their many statements from just last summer make clear, *see* Lilly MSJ 16-17, HRSA and HHS clung to the ***opposite*** position all the way up until the December 30 Decision. In sum, at no time prior to December 30, 2020, could Lilly have brought this lawsuit which, in light of HRSA's extraordinary May 17 letter, is ripe and properly before this Court.

B. The May 17 Letter Confirms that Lilly Is Likely to Succeed in Showing that HHS's Interpretation of the 340B Statute is Contrary to Law.

1. HHS's Contract Pharmacy Rule is Contrary to the 340B Statute.

Nothing in the 340B statute requires manufacturers to deliver discounted drugs to contract pharmacies or to give pharmacies after-the-fact 340B discounts when they "replenish" their stores. *See generally* Br. of 340B Expert Aaron Vandervelde as Amicus Curiae in Support of Neither Party at 13-14, 16, Dkt. 92-1 (May 12, 2021) ("The prevailing replenishment model"—under which contract pharmacies "identif[y] 340B eligibility after the prescription has been dispensed to the patient and reimbursed by the payer"—not only "represent[s] a sizeable shift from how contract pharmacy arrangements were administered prior to the 2010 guidance," but has "turned 340B eligibility determination and inventory management into an accounting exercise that allow[s] …

[2] Consistent with the terms of that guidance and the statute, Lilly continues to offer all of its covered outpatient drugs at the 340B price to all covered entities. The government's position that the "must offer" provision means that Lilly must also give discounts to contract pharmacies cannot be reconciled with the reality that a statutory instruction that manufacturers must "offer to covered entities" simply does not mean that manufacturers also must offer to contract pharmacies.

enhanced profitability" for contract pharmacies.). The 340B statute requires manufacturers in the program to offer discounts to "each covered entity"—no less, but no more. *See* 42 U.S.C. § 256b(a)(1) ("requir[ing] that [each] manufacturer" that has entered into a PPA "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price"). And no one has ever claimed that contract pharmacies are covered entities. And of course they have not: The entities Congress defined to be covered entities are all "providers of safety net services to the poor," *PhRMA*, 138 F. Supp. 3d at 34, while most contract pharmacies are huge commercial enterprises that serve their shareholders and profit off of manufacturer discounts. *See* Lilly MSJ 24-27.

In the December 30 Decision, HHS declared that it did not matter that contract pharmacies are not included in the statute, or that they are fundamentally unlike the safety-net providers that Congress did include, so long as they act as covered entities' ***agents*** (ostensibly when dispensing covered outpatient drugs to a covered entity's 340B-eligible patients). *See* ADVOP_1-8. As Lilly's summary judgment brief explained, the problems with that position are legion. It cannot be squared with the text and structure of the statute, which limits "agency" arrangements to three categories that do not include contract pharmacies. *See* Lilly MSJ 27-28 (discussing 42 U.S.C. § 256b(d)(1)(B)(v), (2)(B)(iv), and (3)(B)(vi)). It is contrary to the basic structure and purpose of the statute, which not only limits HHS/HRSA's regulatory authority to establishing an ADR process, creating a methodology for calculating ceiling prices, and doling out CMPs, *see* 42 U.S.C. § 256b(d)(1)(B)(vi), but also explicitly disallows arrangements under which covered entities join hands with outside enterprises to spread the wealth generated on the backs of manufacturer discounts, *see* Lilly MSJ 28-29 (discussing 42 U.S.C. § 256b(a)(5)(A)). It would also undermine the statute's goal of ensuring that the 340B program actually serves to benefit uninsured and

otherwise vulnerable patients, as opposed to diverting funds into the pockets of for-profit intermediaries. *See id.* at 29-31.

The bottom line is this: There is no reasonable interpretation of the statute under which manufacturers such as Lilly can be obligated to sell to contract pharmacies—as opposed to covered entities themselves. The plain language of the statute dictates that result; and the text, structure, and purpose of the statute defeat the government's "agency" theory as well. That is one of the key issues pending before this Court in Lilly's challenge to the December 30 Decision. Lilly thus respectfully requests injunctive relief to preclude the government from taking action inconsistent with the statute pending this Court's decision on the merits. *Cf. Sackett*, 566 U.S. at 126 & n.2.

2. HHS's Contract Pharmacy Rule is An Unconstitutional Condition and Fifth Amendment Taking.

Worse still, the obligation HHS seeks to impose via the December 30 Decision bears all the hallmarks of unconstitutional governmental coercion—the taking of private property without just compensation and for no public purpose. As Lilly has argued throughout these proceedings, requiring manufacturers to give 340B discounts to contract pharmacies would be tantamount to "a naked transfer of property from private party *A* to *B* solely for *B*'s private use and benefit," *Carole Media LLC v. N.J. Transit Corp.*, 550 F.3d 302, 311 (3d Cir. 2008), which is the classic form of an unconstitutional taking in violation of the Fifth Amendment, *see Kelo v. City of New London*, 545 U.S. 469, 477-78 (2005); *Reagan v. Farmers' Loan & Tr. Co.*, 154 U.S. 362, 399, 410 (1894); *Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) (op. of Chase, J.). The May 17 letter has made the problem even worse than it already was by jettisoning the purported limitation in the December 30 Decision that only those contract pharmacies that act as a covered entity's common-law agent are eligible to demand 340B-discounted product from manufacturers. Now, an even greater number of for-profit pharmacies can demand 340B discounts anytime, anywhere, so long as they

have a contract with a covered entity; and if Lilly refuses, it will be penalized and face potential expulsion from the program (***and*** Medicaid and Medicare). Even if the Court does not wish to decide whether that constitutes an outright taking or excessive fine, it is certainly close enough to the line to warrant application of the constitutional avoidance canon, *see INS v. St. Cyr*, 533 U.S. 289, 299-300 (2001); *United States v. Orona-Ibarra*, 831 F.3d 867, 876 (7th Cir. 2016).

The government's principal defense against this charge has been to claim that because Lilly's participation in the 340B program is nominally voluntary, Lilly cannot complain about the conditions imposed on that participation. *See, e.g.*, MTD/MSJ 30-32. In response, Lilly pointed out that the new conditions HHS and HRSA are trying to impose—give an unlimited number of for-profit businesses discounted product, no questions asked, or be subjected to crippling penalties and the potential expulsion from some of the largest government programs in existence—were certainly not the terms of the 340B program when Lilly signed its PPA. Imposing these onerous and constitutionally dubious conditions now is not just a classic bait and switch, but a textbook unconstitutional condition—"a gun to the head" in the guise of a mere "financial inducement," *NFIB v. Sebelius*, 567 U.S. 519, 581 (2012). *See* Lilly MSJ 35-37.

The May 17 letter makes Lilly even more likely to succeed on these claims than it already was. The letter specifically warns that HRSA believes Lilly will be in violation of its PPA unless it capitulates to HRSA's view of the 340B statute, *see* Exh. A at 1-2, and one remedy for such a violation is expulsion from the 340B program and from much of Medicare and Medicaid, *see* 42 U.S.C. § 1395r-8(a)(1); ADVOP_47, 50.

C. The May 17 Letter Confirms that Lilly is Likely to Succeed in Showing that the December 30 Decision is Arbitrary and Capricious.

The May 17 letter also confirms that the December 30 Decision is arbitrary and capricious. The crux of the December 30 Decision was the purported agency relationship between a covered

entity and a contract pharmacy. *See* ADVOP_1, 6; *see also* HHS, Press Release, *HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies* (Dec. 30, 2020), https://bit.ly/3bp6m7R ("Through the new advisory opinion, HHS has clarified that drug manufacturers must provide 340B discounts ***when a contract pharmacy is acting as an agent of a covered entity***." (emphasis added)). For all its (many) defects, the December 30 Decision thus at least purported to require an agency enforcer or an ADR panel to satisfy itself that a particular contract pharmacy's relationship with a covered entity amounted to common-law agency before determining that a manufacturer's refusal to deliver covered outpatient drugs at 340B ceiling prices to contract pharmacies resulted in overcharging and potentially justified CMPs.

The May 17 letter does away with all of that pretense. Although the letter reiterates the conclusion that manufacturers must sell to contract pharmacies at 340B prices, based on the government's view of the statute, ***not once*** does the letter mention common-law agency. Not once does it suggest that Lilly would have an opportunity to prove that a particular covered entity's relationship with a contract pharmacy actually did not satisfy the common-law agency requirement. Not once does it hint that the unadorned taking of private property will be limited to drugs dispensed by contract pharmacies that act as a covered entity's agent. And not once does it try to reconcile Defendants' categorical determination of overcharging, and their accompanying threat of CMPs, with HRSA's prior pronouncements that the ADR process would serve as the mechanism through which Defendants would make those determinations. *See supra* 8-9.

Instead, the May 17 letter sweeps with the broadest possible brush: "Lilly must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy," must "refund all covered entities for overcharges that have

resulted from Lilly's policy," must "restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements," and will be subjected to CMPs unless HHS is satisfied with "Lilly's willingness to comply with" Defendants' view of Lilly's "obligations under section 340B(a)(1)." Exh. A at 2.

The May 17 letter thus represents an out-and-out abandonment of the basic rationale of the December 30 Decision, but while retaining its ultimate conclusion that manufacturers must sell to contract pharmacies. As the letter makes plain, "HRSA ***has determined*** that Lilly's actions"—*i.e.*, the fact that Lilly has refused to deliver discounted product to contract pharmacies unless the covered entity lacks an in-house retail pharmacy, owns the contract pharmacy, or agrees to ensure that the entire 340B discount will be passed on to the 340B-eligible patients—"have resulted in overcharges and are in direct violation of the 340B statute." *Id.* at 1 (emphasis added). This new, mid-litigation "determin[ation]" did not (and could not) take account of whether any particular contract pharmacy to which Lilly has declined to deliver 340B-discounted product "without restriction" was acting at a covered entity's common-law agent. *Id.* at 2. Under the May 17 letter, Lilly must "restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements," full stop, or else be penalized to the tune of $5,883 "for each instance of overcharging." *Id.* at 2 & n.3.

The May 17 letter is thus tantamount to a concession that the December 30 Decision cannot stand. A "foundational principle" of administrative law instructs that "a court may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015). Here, that means that the common-law agency limitation is part and parcel with the December 30 Decision. But HRSA has now cast that common-law agency limitation aside. There is no way HHS/HRSA can defend the December 30 Decision now.

This "foundational principle" further confirms that Lilly is overwhelmingly likely to succeed on its APA challenges. Both the May 17 letter and the December 30 Decision take the position that the statutory "require[ment] that manufacturers 'shall … offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price'" means that manufacturers must "honor [340B] purchases regardless of the dispensing mechanism." Exh. A at 1 (quoting 42 U.S.C. § 256b(a)(1)); *see also* ADVOP_1-8. Both documents also claim that HRSA has taken this position "consistently since the issuance of its 1996 contract pharmacy guidance." Exh. A at 1; *see also* ADVOP_4. But as Lilly has already pointed out, the statutory language Defendants invoke was not in the 340B statute back in 1996. That means that Defendants' position ***must have*** changed since 1996, and it means they are acting arbitrarily in refusing to acknowledge, much less reasonably explain, their change in position.

The APA requires agencies like HHS/HRSA to "articulate a satisfactory explanation for [their] action[s]." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The May 17 letter does not explain at all, must less satisfactorily, why the agency has jettisoned the "agency" theory on which its statutory interpretation previously rested. There are myriad possible explanations: Perhaps HRSA abandoned the common-law agency lynchpin of the December 30 Decision because it concluded that the 340B statute cannot support it. After all, the 340B statute allows three types of entities to act as a covered entity's agent, but does not extend that allowance to retailers, *see* 42 U.S.C. § 256b(d)(1)(B)(v), (d)(2)(B)(iv), (d)(3)(B)(vi) ("associations or organizations representing the interests of [] covered entities" "of which the covered entities are members," "wholesalers," and "distributors"). As a result, the statutory text cannot support the Decision's "agency" limitation, which HRSA and HHS appear to

have simply made up. Perhaps HRSA realized that the common-law agency limitation does not match up with the real world of contract pharmacy dispensing, under which demands for 340B drugs from manufacturers are made not by covered entities, but by contract pharmacies, ***after*** they have already dispensed a drug to an alleged patient of a covered entity. *See* HHS-OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 5 (Feb. 4, 2014), https://bit.ly/3eWKmBQ (explaining that, in the real world, contract pharmacies dispense drugs from their own supply and then request that the covered entity "replenish" their supply post hoc at 340B prices). Perhaps the new Administration decided that it wants to punish drug manufacturers for political reasons or that it wants to give a windfall to certain, more politically friendly businesses. Or perhaps HRSA abandoned the "agency" limitation for some other, equally unexplained reason. But whatever HRSA's reasons (if it even has reasons) for unceremoniously jettisoning the lynchpin of the December 30 Decision in the middle of briefing on whether the December 30 Decision is valid agency action consistent with the 340B statute and the APA, the May 17 letter proves that—yet again—Defendants' actions have been "duplicitous[] and misleading—the antithesis of fair notice under the APA." ADR PI Op. 22.

This is the paradigmatic case of arbitrary and capricious agency behavior.

D. Defendants' May 17 Letter Also Confirms that the Court Should Resolve the Merits of the Statutory Question, Not Just Remand for Notice and Comment.

While the May 17 letter lays bare the arbitrariness of the December 30 Decision, it also underscores why the Court should decide the merits of Lilly's ***statutory challenge*** to the December 30 Decision now. The question that runs through everything the government has done is whether HHS/HRSA can require manufacturers, as a condition of participation in the 340B program (and Medicaid and Medicare Part B), to deliver covered outpatient products to contract pharmacies at no more than the 340B ceiling prices, rather than simply vacating the December 30 Decision under

the APA and remanding to HHS/HRSA. To be sure, "[w]hen an agency commits a legal error, a court 'normally remand[s] … to the agency.'" *Conservation L. Found. v. Pritzker*, 37 F. Supp. 3d 254, 272 (D.D.C. 2014) (first alteration added) (quoting *Fogg v. Ashcroft*, 254 F.3d 103, 111 (D.C. Cir. 2001)). But "when 'the outcome of a new administrative proceeding is preordained,' a district court may forego the futile gesture of remand to the agency." *Berge v. United States*, 949 F. Supp. 2d 36, 43 (D.D.C. 2013) (quoting *A.L. Pharma, Inc. v. Shalala*, 62 F.3d 1484, 1489 (D.C. Cir. 1995)). "*Chenery* does not require that we convert judicial review of agency action into a ping-pong game.… It would be meaningless to remand" where "[t]here is not the slightest uncertainty as to the outcome of [an agency] proceeding." *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 766 n.6 (1969).

Here there is no doubt of the result on any remand. HHS and HRSA know what they think. They have made clear that (one way or another) they are going to treat the 340B statute as obligating manufacturers to deliver discounted drugs to an unlimited number of contract pharmacies. And their behavior to date also makes clear how they will deal with procedural niceties; if the Court vacates and remands, Defendants will simply come up with some new spin on the contract pharmacy issue, claim that it has always been their position, ignore their prior positions (and multiple changes of position), brush aside manufacturers' concerns about contract pharmacies' abuses, misconstrue the statute, and call it a day. At the end of all that, Lilly would be back before this Court litigating the same claims that the parties are currently briefing. If briefing goes badly for the agencies, they will try to forestall it with yet some other ***new*** interpretation (like the May 17 letter) and try to start the clock over again. "To remand would be an idle and useless formality," *id.*, and there is no reason for the Court to waste its own time or that of the parties by prolonging decision on the key statutory issue.

What is more, because the obligation Defendants seek to impose on Lilly and other manufacturers is contrary to the 340B statute ***as well as the Constitution***, no amount of procedure could possibly result in a valid rule that requires manufacturers to deliver discounted product to contract pharmacies. *See NRDC*, 643 F.3d at 322 ("Because [the agency's action] violates the statute[]," "nothing would be gained by postponing a decision on the merits" by vacating and allowing the agency to try again through notice-and-comment.); *Atl. City Elec. Co. v. FERC*, 295 F.3d 1, 8 (D.C. Cir. 2002) ("In the absence of statutory authorization for its act, an agency's action is plainly contrary to law and cannot stand.") (internal quotation marks omitted). On the flip side, without a decisive ruling on the statutory question, HRSA and HHS will continue trying to coerce Lilly (and other manufacturers) to conform to their view of the statute, which in turn will force Lilly (and other manufacturers) to seeking emergency relief yet again. The Court should rule on the merits of the statutory question, which is properly before it, in deciding Lilly's pending claims.

II. Lilly Will Suffer Irreparable Harm Absent An Injunction, Lilly Has No Adequate Remedy At Law, And The Balance Of Harms And The Public Interest Favor Lilly.

Lilly will suffer irreparable injury in the absence of an injunction. To start with the obvious, every dollar that Lilly is forced to refund as a result of Defendants' misguided contract pharmacy position will be irreparable injury by definition. *See* Exh. A at 1-2. And so will the cost of every discount that Lilly is forced to give to contract pharmacies going forward. Compliance with the government's demands, in order to avoid the threat of severe civil monetary penalties, will result in unrecoverable payments from Lilly to third parties. The effects of the government's coercion will be unreviewable—which is exactly why the government is trying to force Lilly to pay money to a favored political constituency ***before this Court rules***. That Hobson's choice is reason enough to grant the temporary relief Lilly seeks. "[E]conomic injury caused by federal agency action is unrecoverable because the APA's waiver of sovereign immunity does not extend

to damages claims." *District of Columbia v. U.S. Dep't of Agric.*, 444 F. Supp. 3d 1, 34 (D.D.C. 2020) (; *see* 5 U.S.C. § 702 (permitting judicial review of agency action under the APA only where the plaintiff is "seeking relief other than money damages"). And "where, as here, the plaintiff in question cannot recover damages from the defendant due to the defendant's sovereign immunity[,] any loss of income suffered by a plaintiff is irreparable per se." *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008); *accord Philip Morris USA, Inc. v. Scott*, 561 U.S. 1301, 1304 (2010) (Scalia, J., in chambers) ("If expenditures cannot be recouped, the resulting loss may be irreparable."). Indeed, the presence of "irreparable injury because the government is immune from damage suits" makes preliminary relief "clearly appropriate" when it is "coupled with [a] strong showing of likelihood of success on the merits," *Woerner v. U.S. Small Bus. Admin.*, 739 F. Supp. 641, 650 (D.D.C. 1990), as is the case here, *see supra* 12-23.

The fact that Lilly needs to seek such emergency relief in the midst of briefing cross-motions for summary judgment based on the government's demands is political overreach. After all, this case is poised to decide the critical statutory question. If the Court ultimately decides Lilly was required to extend 340B pricing to contract pharmacies, Lilly will comply with that decision. Conversely, if the Court ultimately decides manufacturers are ***not*** required to extend 340B pricing to contract pharmacies, then we surely expect the government will comply with ***that*** decision. But there is no explanation or justification for the government's attempt to make Lilly pay ***now***, other than to evade this Court's review and leave Lilly without recourse for such payments.

Beyond the matter of unrecoverable money, however, Lilly stands to lose constitutional and vital procedural protections if HHS is permitted to preempt this litigation as it proposes. Defendants are trying to coerce Lilly into giving away its property to other private parties (*i.e.*, contract pharmacies) not for any public purpose, but simply for the private gain of third parties.

"Most constitutional injury is presumed irreparable, with here-irrelevant exceptions for constitutional torts sufficiently analogous to common-law personal-injury claims." *Bernard v. Individual Members of Ind. Med. Licensing Bd.*, 392 F. Supp. 3d 935, 954-55 (S.D. Ind. 2019) (collecting cases); *see also, e.g.*, *Preston v. Thompson*, 589 F.2d 300, 303 n.3 (7th Cir. 1978) ("The existence of a continuing constitutional violation constitutes proof of an irreparable harm."); *Baskin v. Bogan*, 983 F. Supp. 2d 1021, 1028 (S.D. Ind. 2014) (same). A textbook private-use taking by the federal government is doubly irreparable in light of the United States' sovereign immunity. *Cf., e.g.*, *Pa. Prof. Liab. Joint Underwriting Ass'n v. Wolf*, 324 F. Supp. 3d 519, 540 (M.D. Pa. 2018) ("reject[ing] the [State's] eleventh hour suggestion that we allow the unconstitutional taking to occur and force the [plaintiff] to try its luck [seeking a refund] in state court," and holding that "declaratory and injunctive relief is the only way to ensure that the [plaintiff] does not suffer an irreparable injury"). The danger is heightened by the May 17 letter's threat that HHS will find Lilly in violation of its PPA (which means it will be at risk of debarment) if it does not immediately capitulate. Exh. A at 1.

Lilly has also "shown a likelihood of establishing that [its] procedural right to advance notice and comment was violated, depriving [it] of the protections afforded to [it] under the APA." ADR PI Op. 24. And as this Court recognized in its ADR opinion, "parties suffer actionable harm when they are 'depriv[ed] of a procedural protection to which [they are] entitled." *Id.* (alterations in original) (quoting *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 94 (D.C. Cir. 2002)); *see also ITServe Alliance, Inc. v. Scalia*, 2020 WL 7074391, at *11 (D.N.J. Dec. 3, 2020) ("[A] preliminary injunction may be issued solely on the grounds that a regulation was promulgated in a procedurally defective manner.").

Lilly also stands to suffer serious reputational injury from the government's unilateral and extrajudicial pronouncement that Lilly is acting in violation of its legal obligations (not to mention from the potential imposition of CMPs). Lilly is known for and proud of "its commitment to patient safety, patient care, and patient access, as well as its commitment to helping those most in need." Decl. of Leigh Ann Pusey (Exh. D) ¶ 4; *see also id.* ¶¶ 5-10. The May 17 letter has already cast a cloud over that hard-earned reputation. "Indeed, the government's suggestion that Lilly has engaged in conduct warranting penalties, as is already being reported in the press, is already damaging Lilly's reputation in the community and harming Lilly's reputation with its health-care partners and in the marketplace." *Id.* ¶ 29; *see id.* ¶ 27 (citing press reports reporting unequivocally "that Lilly is 'in violation' of the 340B statute and that Lilly 'face[s] possible financial repercussions, including civil monetary penalties for each overcharging incident' if it does not comply with HRSA's letter" (alteration in original) (quoting Jeff Legasse, *Six Drugmakers Are In Violation Of 340B Statute, Says HRSA*, Healthcare Finance (May 18, 2021), https://bit.ly/3u7qilU)). "Damage to Lilly's brand makes it more difficult for Lilly to recruit talent and to enter into, maintain, or grow relationships with various stakeholders that are necessary for discovering, developing, and delivering the world-class pharmaceuticals that patients need." *Id.* ¶ 30. Lilly thus stands to suffer textbook irreparable injury of multiple kinds absent the requested injunction—and, for the same reason, Lilly has no adequate remedy at law. *See generally* ADR PI Op. 23 ("[I]rreparable harm is 'probably the most common method of demonstrating that there is no adequate legal remedy.'" (quoting Wright & Miller, *supra*, § 2944)).

The balance of harms and the public interest, meanwhile, favor issuance of the injunction. Nothing bad will happen to the government if it is forced to wait for this Court's decision before penalizing manufacturers for disagreeing with its contract pharmacy position. Nor will any

covered entity or contract pharmacy be harmed by an order enjoining Defendants from taking action against Lilly during the pendency of these proceedings. If Defendants ultimately prevail on the statutory question in this litigation, they will be able to enforce the 340B statute as they construe it. And there is no harm to the government "when it is prevented from enforcing an unconstitutional [law]," *Joelner v. Vill. of Wash. Park*, 378 F.3d 613, 620 (7th Cir. 2004), and Defendants likewise will not be "harmed by having to conform to constitutional standards," *Does v. City of Indianapolis*, 2006 WL 2927598, at *11 (S.D. Ind. Oct. 5, 2006). Indeed, "[i]t is always in the public interest to prevent the violation of a party's constitutional rights." *G & V Lounge, Inc. v. Mich. Liquor Control Comm'n*, 23 F.3d 1071, 1079 (6th Cir. 1994); *accord ACLU v. Alvarez*, 679 F.3d 583, 590 (7th Cir. 2012); *see also, e.g.*, *Gov't Supp. Consolidating Servs., Inc. v. Bayh*, 734 F. Supp. 853, 865 (S.D. Ind. 1990) (granting preliminary injunction where irreparable economic harm and "possible violation of … constitutional rights" trumped harm to government).

On the flip side, assuming that Lilly prevails, the harms to Lilly's constitutional rights and the unrecoverable sums of money Lilly would be forced to hand over far outweigh any private economic concerns related to Lilly's alleged "overcharges" of contract pharmacies for covered outpatient drugs—all of which (unlike Lilly's injuries) can be remedied if Lilly does not ultimately prevail. *See Trust & Inv. Advisers, Inc. v. Hogsett*, 43 F.3d 290, 296-97 (7th Cir. 1994) (deprivation of constitutional rights outweighs lost revenue). That is more than enough to tilt the balance in Lilly's favor, particularly since Lilly is overwhelmingly likely to prevail on the merits of its challenges to the December 30 Decision. *See Cook Cnty. v. Wolf*, 962 F.3d 208, 234 (7th Cir. 2020) ("the more likely the plaintiff is to win, the less heavily need the balance of harms weigh in his favor").

Finally, given the government's mid-litigation effort to hijack these proceedings and force Lilly to submit to its position on the ultimate legal issue currently being briefed before this Court, an order maintaining the status quo and preventing further governmental efforts to usurp this Court's constitutional role (and flout Lilly's basic rights) would be in the public interest.

CONCLUSION

For the foregoing reasons, Lilly respectfully requests that the Court enter a preliminary injunction on Counts I-IV of Lilly's pending complaint, specifically enjoining Defendants from taking any adverse action against Lilly with regard to purported contract-pharmacy-related overcharges until this Court enters judgment on the issues currently being briefed in the parties' cross-motions. And because briefing on the injunction likely will take longer than the two weeks Defendants have given Lilly, *see* Exh. A at 2 (ordering Lilly to provide HRSA 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**")), Lilly further asks the Court to enter a temporary restraining order precluding Defendants from taking any such action against Lilly until this Court resolves Lilly's request for a preliminary injunction. In the alternative, Lilly requests that the Court vacate the current briefing schedule—under which the government's reply brief is due on May 31 and Lilly's is due on June 14, *see* Order at 1, Dkt. 85 (Mar. 29, 2021)—and replace it with an accelerated schedule that will allow the Court to resolve Lilly's pending claims before June 1.

Dated: May 20, 2021

Respectfully submitted,

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Attorneys for Plaintiffs

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

DANIEL J. BARRY
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DIANA ESPINOZA
Health Resources and Services Administration
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HEALTH RESOURCES AND SERVICES ADMINISTRATION
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United States Attorney General
United States Department of Justice
950 Pennsylvania Ave, N.W.
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United States District Attorney for the Southern District of Indiana
United States Attorney's Office
10 W Market Street, Suite 2100
Indianapolis, IN 46204

/s/ John C. O'Quinn
John C. O'Quinn

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 PRELIMINARY INJUNCTION

INDEX OF EXHIBITS

EXHIBIT	DESCRIPTION
Exhibit A	May 17, 2021 Letter from Diana Espinosa, Acting Administrator to Derek L. Asay
Exhibit B	Excerpt from February 26,2021 Official Reporter's Transcript of Oral Argument on Motion for Preliminary Injunction
Exhibit C	Tom Mirga, Breaking: Becerra, on 340B Pricing Denials, Tells House Panel, "Everyone Has to Follow the Law," 340B Report (May 12, 2021)
Exhibit D	Declaration of Leigh Ann Pusey

Exhibit A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration
Rockville, MD 20857

May 17, 2021

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

Dear Mr. Asay:

The Health Resources and Services Administration (HRSA) has completed its review of Eli Lilly and Company's (Lilly) policy that places restrictions on 340B pricing to covered entities that dispense medications through pharmacies under contract, unless the covered entity lacks an in-house pharmacy. After review of this policy and an analysis of the complaints HRSA has received from covered entities, HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute.

Section 340B(a)(1) of the Public Health Service (PHS) Act requires that manufacturers "shall…offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." This requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. Nothing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities. Section 340B(a)(1) of the PHS Act also requires manufacturers that have signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum to comply with these requirements. Lilly is bound by the terms of the PPA and must ensure that the 340B ceiling price is available to all covered entities.

Also consistent with section 340B(a)(1) of the PHS Act, manufacturers are expected to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs. This extends to the manner in which 340B drugs are made available to covered entities (e.g., access to 340B ceiling prices through wholesalers that make products available at non-340B ceiling prices).[1] The 340B Program Ceiling Price and Civil Monetary Penalties Final Rule (CMP final rule)[2] further specifies that a manufacturer's failure to provide 340B ceiling prices through the manufacturer's distribution agreements with wholesalers may violate a manufacturer's obligation under the 340B statute. HRSA has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor such purchases regardless of the dispensing mechanism.

[1] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017); 42 C.F.R. §10.11(b)(2)
[2] 82 Fed. Reg. 1210, 1230 (Jan. 5, 2017)

Lilly purports that the rationale for its restrictive action is to prevent diversion and duplicate discounts. The 340B statute provides a mechanism by which a manufacturer can address these concerns. Specifically, the manufacturer must (1) conduct an audit and (2) submit a claim through the Administrative Dispute Resolution process as described in section 340B(d)(3)(A) of the PHS Act. The 340B statute does not permit a manufacturer to impose industry-wide, universal restrictions.

For the reasons set forth above, Lilly must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements, regardless of whether they purchase through an in-house pharmacy. Lilly must comply with its 340B statutory obligations and the 340B Program's CMP final rule and credit or refund all covered entities for overcharges that have resulted from Lilly's policy. Lilly must work with all of its distribution/wholesale partners to ensure all impacted covered entities are contacted and efforts are made to pursue mutually agreed upon refund arrangements.

Continued failure to provide the 340B price to covered entities utilizing contract pharmacies, and the resultant charges to covered entities of more than the 340B ceiling price, may result in CMPs as described in the CMP final rule. The CMP final rule states that any manufacturer with a PPA that knowingly and intentionally charges a covered entity more than the ceiling price for a covered outpatient drug may be subject to a CMP not to exceed $5,000 for each instance of overcharging.[3] Assessed CMPs would be in addition to repayment for an instance of overcharging as required by section 340B(d)(1)(B)(ii) of the PHS Act. The Department of Health and Human Services will determine whether CMPs are warranted based on Lilly's willingness to comply with its obligations under section 340B(a)(1) of the PHS Act.

HRSA requests that Lilly provide 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**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

Diana Espinosa

Diana Espinosa
Acting Administrator

[3] Note, the Department of Health and Human Services publishes inflation-adjusted increases for various CMPs annually. The 2020 inflation adjusted penalty for 340B overcharging violations is $5,883. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020).

Exhibit B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, ET AL.,	)	
	)	
Plaintiff,	)	CAUSE NO.:
	)	1:21-C-00081-SEB/MJD
	)	Indianapolis, Indiana
-v-	)	**February 26th**, 2021
	)	10:15 a.m.
ALEX M. AZAR, II in his official capacity as Secretary of Health & Human Services, et al,	)	
	)	
Defendants.	)	

Before the Honorable
SARAH EVANS BARKER, JUDGE

OFFICIAL REPORTER'S TRANSCRIPT OF
MOTION FOR PRELIMINARY INJUNCTION

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 Eli Lilly:

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For Alex M. Azar, II:
(via video)

Kate Talmor, Esq.
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1100 L Street, NW
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and

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.

covered entities can use this program to raise money.

Second, counsel for Eli Lilly pointed to OIG reports and other documents that they say show that there is rampant abuse in the contract pharmacy program. What this does is really demonstrate that Lilly and other manufacturers are trying to change the settled operation of the program. And there are proper mechanisms for them to seek to effect change in the program if they truly believe there are problems with it, but not through kind of back door extra-statutory means. And so I'd like to point out that after the changes instituted by Lilly and its peers, there has been a bipartisan outcry with two different letters written by the Secretary of HHS for more than 200 members of both parties in Congress urging former Secretary Azar to take action.

There also was a letter written by a large group of bipartisan state Attorneys General across the country basically agreeing with the opinions set forth in the advisory opinion and also urging the former secretary to take action.

So the proper way --

THE COURT: Wait, wait, take what kind of action?

MS. TALMOR: I do not have those documents in front of me. I do believe that what they urged the secretary was to take action to reign in the changes by drugmakers. Both the letter from the lawmakers and from the State Attorneys General emphasize that covered entities have relied on these

THE COURT: So if the panel decided to award damages to one of the parties in the ADR process, that decision could be pursued further through the Administrative Procedures Act steps?

MS. TALMOR: There are two pieces to the answer. A decision can absolutely be appealed under the Administrative Procedures Act, but I think that it is a misnomer to say the panel awards money damages. That's the remedy's point that Lilly is misportraying.

I'd like to talk about the claims presented to the ADR panel. I think that will clear this up. The ADR panel can --

THE COURT: Slow down. Slow down. Slow down.

MS. TALMOR: Thank you. A claim for overcharging, which is relevant here, or duplicate discounting or diversion. Those are the only claims the ADR can hear, and they have to be brought by a covered entity or a manufacturer. No contract pharmacies are involved.

Now, the claims that are pending before the ADR now, the claims that Lilly is seeking to thwart in this motion are claims by covered entities that Lilly is overcharging by unlawfully restricting their ability to buy discounted drugs.

What the panels are charged with doing is very similar, the same, as what other agencies do. They can determine statutory compliance. So while the agency has determined that covered entities have a right generally to use

contract pharmacy arrangements, the agency has not passed on the specifics of Lilly's new policy, because that belongs in the ADR.

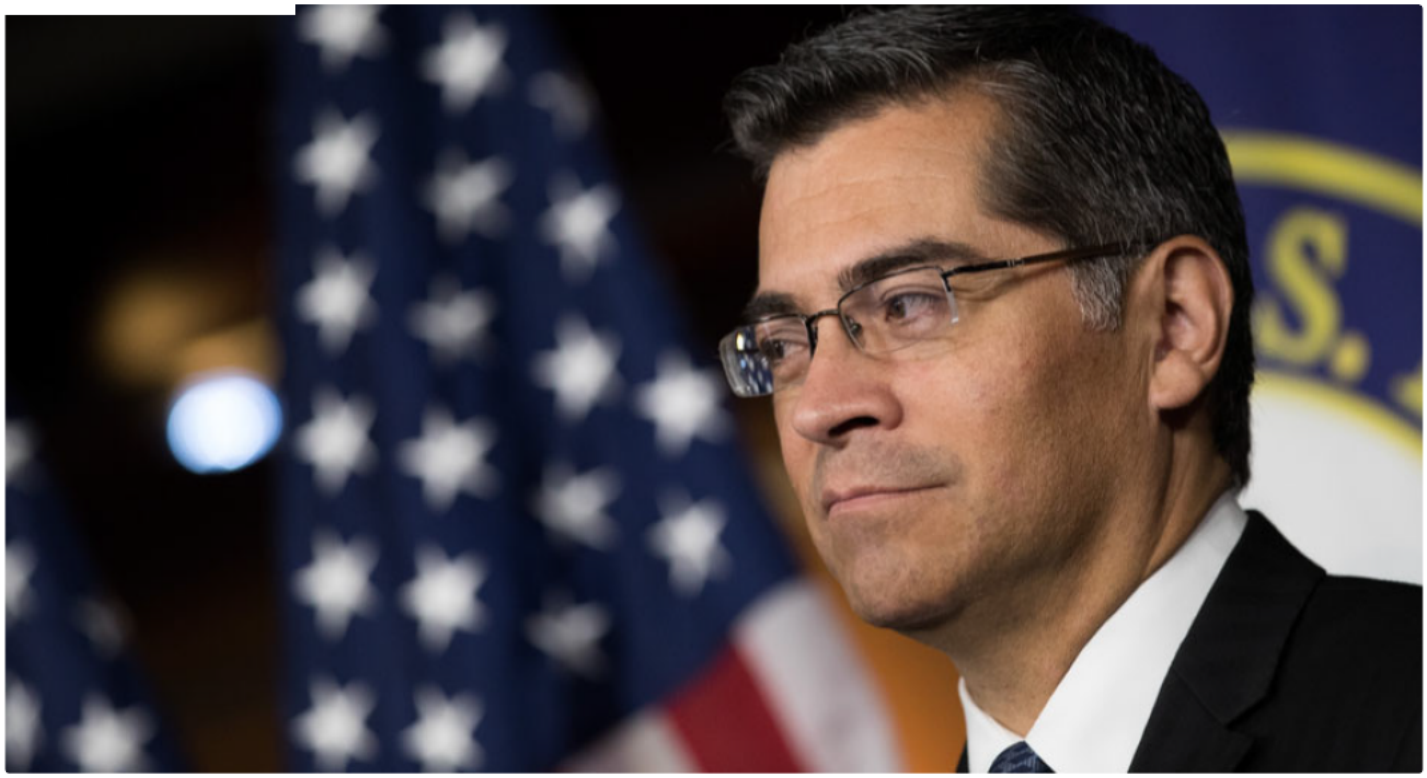
So the panels are empowered to determine whether Lilly's policy comports with its obligations under the statute. That is all. And if the panel determines that Lilly's policy does not comply with the statute, it can refer its decision to HRSA for enforcement action. HRSA can consider whether to impose penalties, sanctions, to refer the decision to the OIG for civil monetary penalties.

Meanwhile, if Lilly is the subject of an adverse decision, it can seek APA review of the determination of statutory compliance. So the panel does not award, you know, money damages the way that Lilly portrays because the rule requires the panel to refer its decision to HRSA.

However, I think it is critical to note that there's nothing unusual in an agency imposing fines or restitution, any type of award like that. We provided a very small sample in our brief of other agency contacts where the agency orders coming out of an adjudication are much more sweeping than what's presented here.

So just to touch on those, the Federal Trade Commission issued cease and desist orders that very much resemble injunction. The Securities and Exchange Commission issued injunction, including exclusion orders which bar an

Exhibit C



HHS Secretary Xavier Becerra told a House committee today "We are on this one" in reference to drug companies denying 340B pricing on their products.

Breaking: Becerra, on 340B Pricing Denials, Tells House Panel, "Everyone Has to Follow the Law"

In Breaking, Federal, Legislative May 12, 2021 Tom Mirga

U.S. Health and Human Services (HHS) Secretary Xavier Becerra told a member of Congress during a hearing this morning "We are on this one" when asked about six drug manufacturers' denials of 340B drug discounts when covered entities use contract pharmacies to dispense the products.

Becerra was testifying before the House Energy and Commerce Health Subcommittee about his department's budget request for the fiscal year that starts in October. Rep. Peter Welch (D-Vt.) said to him, "Six pharma companies, I believe illegally, are not passing on the discounts required under the 340B program."

"Is it your intention to enforce continued access to the discounts for community hospitals and community health centers?" Welch asked.

Sec. Becerra: "We are on this one, as we know that vulnerable populations are at risk. And so, everyone, I've been saying all along: We have to follow the law, and everyone has to follow the law."

During a Senate hearing in February, in response to a question about the depth of his knowledge about 340B, Becerra similarly said, "What we must do is make sure that the law is followed.... The first thing we have to do is enforce the laws we have in place."

The drug companies denying 340B pricing on drugs shipped to contract pharmacies, or imposing conditions on 340B pricing, are Eli Lilly, AstraZeneca, Sanofi, Novartis, Novo Nordisk, and United Therapeutics.

Also during today's House hearing, Rep. Doris Matsui (D-Calif.) told Becerra, indicating she did not expect a reply: "I want to take a minute to raise an issue I know you are familiar with—the ongoing actions of drug companies that have chosen to rewrite the 340B program to deny discounts dispensed through covered entities' contract pharmacies. As you know, HHS has issued an advisory panel (presumably Rep. Matsui meant to say advisory opinion) concluding that these actions are illegal. Yet drug companies have made clear they do not intend to comply with the law. I along with over 220 of my House colleagues wrote a letter to you earlier this year outlining our strong opposition to these actions. 340B is essential to providing access to care to low-income and rural patients. I encourage you to take swift enforcement action to put a stop to these efforts to undermine the program."

Rep. Angie Craig (D-Minn.) likewise said to Becerra, "I want to note the importance of the 340B program, how important it is to providing access to care for low-income and rural patients in my district. I encourage you to take swift action to protect that vital program."

The E&C Committee held several contentious hearings about the 340B program in recent years, most of them when Republicans were the majority party, during which witnesses were asked sharp questions by members.

Exhibit D

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.

DECLARATION OF LEIGH ANN PUSEY

I, Leigh Ann Pusey, declare and state as follows:

1. I am Senior Vice President, Corporate Affairs and Communications ("SVP"), at Eli Lilly and Company ("Lilly"), one of the leading pharmaceutical manufacturers in the world.

2. In my role as SVP, I oversee Lilly's corporate affairs office, which includes, among other things, our offices of global corporate responsibility, global government affairs, global public policy and public affairs, global communications, and corporate branding, and which works to communicate the values that the company stands for, the principles that guide the company, and what differentiates the company in the marketplace. In my role as an Executive Committee member and as SVP, I have a keen interest in preserving our corporate reputation and enhancing our corporate brand, which, among other things, allows us to compete for top talent and enter into, maintain, or grow external relationships with key stakeholders that are vital to Lilly's purpose—uniting caring with discovery to create medicines that make life better for people around the world.

3. Since 1876, Eli Lilly and Company has been a leading corporate citizen and, in the years ahead, we intend to build on this proud tradition. We seek to discover and develop innovative medicines that address some of the world's greatest health challenges. We are also committed to operating our business ethically and responsibly, finding sustainable solutions that improve access to medicines and health care, and supporting the communities in which we operate through our corporate responsibility efforts

4. Lilly is known for its commitment to patient safety, patient care, and patient access, as well as its commitment to helping those most in need.

5. That reputation is well deserved. For example, Lilly has initiated numerous programs to help patients—particularly uninsured patients, senior citizens covered by Medicare

Part D, and patients with high-deductible plans—reduce out-of-pocket expenses for prescription medications.

6. With respect to insulin affordability specifically, Lilly has introduced various affordability solutions such as -- automatic discounts at the pharmacy counter, co-pay cards, unbranded insulins at half off the list price, and donations to charities where people struggling financially can get their insulin for free. And in September, we committed long-term to our $35 co-pay card, originally introduced to support those impacted by COVID-19, as an ongoing savings option for everyone else who needs help. Through this program, a monthly prescription of Lilly insulin can be purchased for $35 by anyone who is uninsured or has commercial insurance. Lilly also recently began participating in the CMS Innovation Center's Medicare Part D insulin cost sharing program, making affordable insulin available for patients covered by Medicare Part D. The net effect of all of these solutions is that today, anyone using Lilly insulin – regardless of their insurance status – can now enroll to buy their monthly prescription for $35. In 2019 alone, we estimated that these insulin affordability solutions helped up to 20,000 patients per month.

7. Separate and apart from its efforts to make prescription medications more affordable for Americans, Lilly donates substantial sums to the Lilly Cares program, an independent 501(c)(3) that provides up to a one-year supply of Lilly medications for free to low-income patients with no insurance, Medicare Part D, and in some instances commercial insurance. Lilly also launched the Lilly Foundation in 1968, which is dedicated to improving global health for people living in communities with limited resources. The Foundation provides support for Lilly 30x30, the company's initiative to improve health care for 30 million people annually by 2030. And Lilly has created the Lilly Global Giving Web site, through which employees can find and support projects around the world in the areas of health, hunger, education, and the

environment, and under which employees who donate $25 or more to projects featured on the site will have their donations matched by the Lilly Foundation, up to a total of $1 million a year.

8. Furthermore, early in the pandemic, Lilly developed, at its own expense, a highly accurate COVID-19 test that it administered for free to front-line healthcare workers and first responders in Indiana. Lilly has also devised and made available ventilator splitters that allowed ventilators to serve two patients at once. Serving its core mission, Lilly has invested hundreds of millions of dollars developing COVID-19 treatments—including monoclonal neutralizing antibody treatments and repurposing another molecule to treat COVID-19-induced acute respiratory distress syndrome—which resulted in the FDA granting emergency use authorizations for those treatments. In addition, Lilly has donated COVID-19 therapies to Direct Relief, enabling the humanitarian organization to provide COVID-19 therapies at no cost to low- and lower-middle-income countries most heavily impacted by the pandemic. And Lilly recently committed $5 million to Direct Relief's Fund for Health Equity to help improve health in underserved communities.

9. Those are just some of the many reasons why the Ethisphere Institute named Lilly as one of the World's Most Ethical Companies in 2017, 2018, and 2019.

10. Consistent with its efforts to ensure that patients have meaningful access to prescription medications, Lilly participates in the 340B drug pricing program, under which Lilly offers its prescription drug products at steep discounts to "covered entities," which serve the needy.

11. Unfortunately, for-profit retail pharmacies have increasingly siphoned from patients and safety-net providers the cost savings that Lilly's 340B discounts generate.

12. That is why, among other reasons, Lilly announced changes to its distribution plan in the summer of 2020 with respect to covered entities that utilize contract pharmacies to dispense 340B drugs.

13. Effective July 1, 2020, Lilly instructed its wholesale partners to provide 340B discounts exclusively to covered entities and their child sites—and not to contract pharmacies—for certain formulations of Cialis® (tadalafil). Lilly would still provide discounts to contract pharmacies to the extent they were designated by covered entities without an in-house pharmacy of their own (provided that each covered entity designated only a single external contract pharmacy). Lilly limited its July 2020 plan to those Cialis® products indicated for erectile dysfunction and for which a generic formulation was available.

14. On September 1, 2020, after rolling out the transition for Cialis® products, Lilly extended its distribution plan to all of Lilly's covered outpatient drugs under the 340B program.

15. Under that approach, Lilly continues to offer all covered outpatient drugs to all covered entities at (or below) the ceiling price, and even continues to allow contract pharmacies to dispense its 340B product when a covered entity lacks the capacity to dispense prescription medicines itself.

16. Furthermore, reflecting Lilly's commitment to making insulin products affordable, and following on the heels of an Executive Order issued by the President on July 24, 2020, Lilly made an exception for insulin patients, under which any contract pharmacies may dispense insulin to 340B patients so long as the contract pharmacy agrees to pass on the entire 340B discount—in this case, one-penny-per-milliliter prices—to the patient.

17. Lilly first notified the Health Resources and Services Administration ("HRSA")—the component of HHS responsible for overseeing the 340B program—in May 2020 that it intended to implement the Cialis® distribution plan effective July 1, 2020.

18. HRSA responded on June 11, 2020, that "contract pharmacies" "are not independent covered entities" and that its "contract pharmacy advice" was "guidance" and "not binding regulations."

19. HRSA sent a second letter on June 18, 2020, telling Lilly that it "look[ed] forward to receiving" Lilly's manufacturer notice announcing its Cialis® distribution plan for posting on the HRSA website.

20. On August 19, 2020, Lilly informed HRSA that it would extend its new distribution plan to include all of Lilly's covered outpatient drugs under the 340B program (*i.e.*, not just Cialis), by "discontinu[ing] [its] practice of voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products."

21. On August 26, 2020, HRSA sent Lilly a letter that suddenly changed course. HRSA now stated that it was "considering whether your new proposed policy constitutes a violation of section 340B and whether sanctions apply," including, but "not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256(d)(1)(B)(vi)."

22. Almost nine months later, on May 17, 2021, Lilly received a letter from Diana Espinoza, the Acting Administrator of HRSA, stating that "HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute."

23. The letter directs Lilly to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements" and "credit or refund all covered entities for overcharges that have resulted from Lilly's policy."

24. The letter further notes that "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies" will "result in CMPs [civil monetary penalties]" of more than $5,000 per violation, which "would be in addition to repayment."

25. The letter reminds Lilly that it "is bound by the terms of the" pharmaceutical pricing agreement ("PPA") it signed upon entering the 340B program. That PPA allows HHS to terminate Lilly's participation in the program if Lilly does not comply with the program's obligations.

26. The letter gives Lilly until June 1, 2021, "to provide 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."

27. The letter generated immediate and widespread press coverage impugning the reputation of Lilly. Articles reported as a matter of fact that Lilly is "in violation" of the 340B statute and that Lilly "face[s] possible financial repercussions, including civil monetary penalties for each overcharging incident" if it does not comply with HRSA's letter. *E.g.*, Jeff Legasse, *Six Drugmakers Are In Violation Of 340B Statute, Says HRSA*, Healthcare Finance (May 18, 2021), https://bit.ly/3u7qilU; Kathy Kelly, *340B Fight Escalates As Biden Administration Seeks Refunds From Manufacturers, Threatens Them With Fines*, Pink Sheet Daily (May 20, 2021), https://bit.ly/33XE9Rn. Press releases further described Lilly's actions as "dangerous" and declared that HRSA's "aggressive action" of threatening CMPs was "necessary" to prevent Lilly's allegedly "illegal[]" actions. *E.g.*, Kristen Coppock, *HRSA Finds 6 Pharmaceutical Manufacturers in Violation of 340B Requirements*, Pharmacy Times (May 17, 2021), https://bit.ly/2Scd8He.

28. This press coverage did not mention the ongoing litigation between Lilly and the government. Nor did it mention that a federal district court was currently in the process of deciding

the precise legal question addressed in, and purportedly resolved by, HRSA's letter. Instead, reports declared simply that HRSA's "letters appear to bring an end to an escalating feud between drugmakers and hospitals that started back in July 2020," Robert King, *HRSA Demands 6 Drugmakers Stop Cutting Off Sales Of 340B Drugs To Contract Pharmacies*, Fierce Healthcare (May 17, 2021), https://bit.ly/3fsXoHI, and that the Biden Administration had expressed its "legal view[]" that Lilly's violation warranted CMPs, Gina Shaw, *HRSA Orders Drug Manufacturers to Pay 340B Contract Pharmacies*, Pharm. Prac. News (May 18, 2021), https://bit.ly/3f5tzhe.

29. Any public assertion by the government that Lilly has knowingly or willfully violated its 340B obligations would plainly be injurious to Lilly's hard-earned reputation and corporate goodwill. Indeed, the government's suggestion that Lilly has engaged in conduct warranting penalties, as is already being reported in the press, is already damaging Lilly's reputation in the community and harming Lilly's reputation with its health-care partners and in the marketplace.

30. Damage to Lilly's brand makes it more difficult for Lilly to recruit talent and to enter into, maintain, or grow relationships with various stakeholders that are necessary for discovering, developing, and delivering the world-class pharmaceuticals that patients need.

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

Executed on: May 20, 2021

/s/ Leigh Ann Pusey .

Leigh Ann Pusey