UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

ELI LILLY AND COMPANY
Lilly Corporate Center
893 Delaware Street
Indianapolis, IN 46225,

and

LILLY USA, LLC
1500 South Harding Street
Indianapolis, IN 46221,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health & Human Services
Office of the Secretary
200 Independence Avenue, S.W.
Washington, D.C. 20201,

DANIEL J. BARRY, in his official capacity as Acting General Counsel of Health & Human Services
Office of the General Counsel
200 Independence Avenue, S.W.
Washington, D.C. 20201,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue, S.W.
Washington, D.C. 20201,

DIANA ESPINOSA, in her official capacity as Acting Administrator of the Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20852,

and

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

Defendants.

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

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PLAINTIFFS' COMBINED REPLY IN SUPPORT OF PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT AND REPLY IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Constitutional Provisions

Statutes

Rules

Regulations

Other Authorities

INTRODUCTION

The U.S. Department of Health & Human Services ("HHS") has now taken three unlawful actions seeking to compel Lilly to comply with extra-statutory requirements that the agency lacks authority to impose. In early December 2020, HHS rushed out a final Administrative Dispute Resolution ("ADR") rule without notice and comment. On December 30, the HHS general counsel issued an "Advisory Opinion" (again without notice and comment) announcing a new rule requiring manufacturers to deliver 340B-priced drugs to an unlimited number of contract pharmacies. And on May 17, 2021—while Lilly's challenges to the first two actions were pending before this Court—the Health Resources and Services Administration ("HRSA"), an operating agency within HHS, sidestepped the ADR Rule to "determine" unilaterally that Lilly's contract pharmacy policy violates the statute. These unlawful agency actions fly in the face of the reasoned decisionmaking that the APA requires, and they cannot be reconciled with either the 340B statute or the Constitution.[1]

Courts have already recognized the illegality of the government's first two attempts: This Court enjoined the ADR Rule in March given the agency's failure to proceed through notice and comment, Dkt. 81 ("PI Order") at 18-23; and Chief Judge Stark of the District of Delaware invalidated the December 30 Decision last month in *AstraZeneca*'s parallel case. *See AstraZeneca Pharms. LP v. Becerra*, 2021 WL 2458063, at *11-12 (D. Del. June 16, 2021). In response to the *AstraZeneca* decision, HHS withdrew its December 30 Decision, and it does not defend it further here. That means Lilly is entitled to judgment on its claims challenging the now-withdrawn Decision. It also means the focus of this case is now on the May 17 Determination, which the parties agree is final agency action. The

[1] One terminological note: We use the term "the agency" to refer interchangeably to HHS and HRSA. That is in keeping with HHS's own regulations, which—contrary to the government's claims—make clear that the HHS general counsel's office not only "[s]upervises all legal activities of the Department ***and its operating agencies***," HRSA included, but also "[f]urnishes all legal services and advice to … all offices, branches, or units of the Department in connection with the operations and administration of the Department and its programs, except with respect to functions expressly delegated by statute to the Inspector General." 86 Fed. Reg. 6,349, 6,351 (Jan. 21, 2021) (emphasis added).

question at the heart of the May 17 Determination is thus the central question currently before this Court: Does Lilly's policy comply with the statute? The answer to that question is straightforward: Yes. Lilly's policy, which is consistent with the agency's own prior guidance, fully complies with the 340B statute, which does not require manufacturers to deliver 340B drugs to contract pharmacies.

The 340B statute imposes a single obligation on manufacturers (and it does so indirectly). The very first provision in the statute, 42 U.S.C. § 256b(a)(1), provides that "[t]he [HHS] Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid … to the manufacturer for covered outpatient drugs … ***purchased by a covered entity*** … does not exceed [the ceiling price set by the Secretary], … and shall require that the manufacturer ***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." (Emphases added.) Lilly's policy fully complies with this obligation: Under its policy, Lilly will and does "offer" to "each covered entity" the ability to "purchase" "at or below the applicable ceiling price" all covered outpatient drugs that Lilly currently has on the market. The statute requires no more. In particular, the statute does not impose on manufacturers the additional obligation to transfer and deliver drugs to commercial pharmacies, which are ***not*** "covered entities." On the contrary, precisely because of the potential for abuse, the statute prohibits the transfer of drugs to third parties and prohibit third parties from participating in the 340B program. *See* 42 U.S.C. § 256b(a)(4), (a)(5)(B).

That should be the end of the matter. The text of the statute does not impose any obligation to deliver 340B drugs to contract pharmacies, and reading the statute's lack of any such obligation to allow the agency to impose one would be inconsistent with the statute's structure. The government's view also runs afoul of the "presum[ption] that Congress acts intentionally and purposely in the disparate inclusion or exclusion" of statutory language. *Russello v. United States*, 464 U.S. 16, 23 (1983). Congress expressly provided for contract pharmacy arrangements in a separate provision of ***the very***

same law that enacted the 340B statute, namely, the Veterans Health Care Act of 1992, but it did not do so for 340B. Congress's decision not to do so for 340B speaks volumes. If Congress wanted to require cooperation with contract pharmacies in the 340B program, it knew how to say so—"but it did not do so in the 340B statute." *AstraZeneca*, 2021 WL 2458063, at *10.

The government's construction fails for another reason: Congress must "speak clearly if it wishes to assign to an agency decisions of vast 'economic … significance,'" *Utility Air Reg. Gp. v. EPA*, 573 U.S. 302, 324 (2014), and the statute does not clearly require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies; indeed, the "clues" that "the statute offers" "militate ***against*** the [agency's] view." *AstraZeneca*, 2021 WL 2458063, at *11 (emphasis added). And there can be no question that the agency's position would have vast economic consequences. Contract pharmacy arrangements capture billions of dollars every year, VLTR_7936-47; *see* Dkt. 125 ("Reply") at 21, and much of that money goes into the pharmacies' coffers, ***not*** to covered entities (and certainly not to patients). Whether manufacturers must deliver discounted drugs to an unlimited number of contract pharmacies—under a statute that says nothing about any such obligation—is thus no minor "detail." Reply 13. Accordingly, the agency cannot impose on manufacturers the obligation to transfer and deliver discounted drugs to contract pharmacies, which are ***not*** covered entities.

In all events, even if the statute were not clear, the agency's actions would still violate the APA. First, the May 17 Determination fails to acknowledge, let alone explain, its changes in position on this issue. The letter says nothing about the limits the December 30 Decision placed on the contract-pharmacy-delivery obligation, and it denies what is clear for all to see (and what Chief Judge Stark expressly held): "[T]he government's position on drug manufacturers' obligations with respect to participation in the 340B Program has ***not*** remained constant but has, instead, materially shifted." *Id.* at *6. The government's willingness to shift theories (vainly in search of a justification for its actions) is something of a theme in this case—so much so that the Reply brief relies mainly on a

statutory provision that the May 17 Determination ***does not even mention***. Second, the May 17 Determination relies on the premise that the statute ***compels*** the agency's interpretation. But, as Chief Judge Stark held, the opposite is true: "the statutory language does not compel" the agency's position, *id.* at *11—and, under the APA, agency action must be invalidated when it is based on the unjustified assumption that it is merely enforcing Congress's judgment. Third, the agency failed to consider contract pharmacies' documented abuses of the 340B program and a number of other important aspects of the problem. Most glaringly, the agency opted to reach a final judgment about Lilly's policy using an admittedly one-sided process, listening only to covered entities' complaints and cutting Lilly out altogether. That is as arbitrary as it gets. The government now defends that choice only on the ground that Lilly could always tell its side of the story in ADR, but that is legally erroneous: ADR does not permit manufacturers to bring claims ***against the agency***. In any event, the existence of a separate ADR process does not excuse HRSA from the APA when it acts on its own.

Finally, the ADR Rule that the agency hastily issued late last year is fatally defective. As this Court previously concluded in granting Lilly's preliminary injunction motion, the ADR Rule was issued without notice and comment, in violation of the APA. The Rule also violates Article II of the Constitution under the Supreme Court's recent decision in *Arthrex* because it empowers ADR panelists to issue final decisions that cannot be reversed by the Secretary or any other principal officer, and it is further contrary to constitutional requirements under Article III and the APA.

For these reasons (and more), the Court should confirm that Lilly's policy does not violate the statute; set aside the May 17 Determination; set aside the ADR Rule; and enter judgment for Lilly.

BACKGROUND

Much has transpired since Lilly filed its motion for summary judgment. Given these new developments, Lilly provides the following additional background.

A. The 340B Program and the Relevant Provisions of the 340B Statute

The 340B program has grown substantially over the past decade, becoming the second-largest federal drug purchasing program, behind only Medicare Part D. Indeed, 40% of all hospitals are now recognized as covered entities under the 340B statute, as are more than 10,000 clinics and community health centers. The program was originally envisioned as a cost ***savings*** program through which covered entities could "help subsidize prescriptions for their lower income patients," 61 Fed. Reg. 43,549, 43,549 (Aug. 23, 1996), but HHS now treats it as a ***revenue***-stream entitlement, *see* Dkt. 88 (Defs.' MTD/MSJ) at 1, 13, 26, that allows covered entities to license their eligibility for discounts to massive retail pharmacy chains, which in turn ***profit*** off the program to the tune of hundreds of millions of dollars per year, *see* Walgreens Boots Alliance, Inc., Form 10-K, at 23 (Oct. 15, 2020), https://bit.ly/2MoLX9d (projecting that any curtailment of Walgreens' contract pharmacies' ability to participate in the 340B program "could also significantly reduce [***Walgreens'***] profitability").

The agency's willingness to allow the 340B program to be refashioned in this manner has no basis in the statute. Nothing in the statute even contemplates the use of contract pharmacies, let alone requires manufacturers to work through contract pharmacy arrangements or deliver 340B-priced drugs to an unlimited number of for-profit pharmacies whenever a covered entity so demands.

Two provisions of the 340B statute are central to this case: (1) the "purchased by" provision and (2) the "shall … offer" provision. Both are found in 42 U.S.C. § 256b(a)(1). The "purchased by" provision has been in the statute from the beginning. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967. This provision says, in relevant part, that "[t]he [HHS] Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid … to the manufacturer for covered outpatient drugs … ***purchased by a covered entity*** … does not exceed [the ceiling price for such drugs set by the Secretary]." 42 U.S.C. § 256b(a)(1) (emphasis added). The "shall … offer" provision was added to

the statute some 18 years later, as part of the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, § 7102(a), 124 Stat. 119 (2010). This provision commands the HHS Secretary, in his 340B agreements with manufacturers, to "require that the manufacturer ***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." 42 U.S.C. § 256b(a)(1) (emphasis added).

Neither provision says anything about delivery obligations or contract pharmacies. Nor does any other provision in the 340B statute. On the flip side, the statute explicitly prohibits covered entities from "resell[ing] or otherwise transfer[ring]" 340B drugs to anyone except their patients. *Id.* § 256b(a)(5)(B). This practice of sending 340B drugs to non–covered entities is known as diversion.

B. The Agency's Constantly Shifting Positions

As Chief Judge Stark held, HHS's position on contract pharmacies has "materially shifted" over time. *AstraZeneca*, 2021 WL 2458063, at *6. The agency has taken varying positions—announced in guidance, *faux* rulemaking efforts, and litigation—on the statutory source, if any, of manufacturers' purported obligation to deliver discounted drugs to contract pharmacies. Here is the recap:

1996 Guidance. In 1996, the agency issued an informal guidance document saying that each covered entity could use no more than one contract pharmacy, and only if the covered entity lacked an in-house dispensing pharmacy. 61 Fed. Reg. 43,549 (Aug. 23, 1996). The 1996 guidance did not conclude that the statute required manufacturers to deal with contract pharmacies, only that covered entities could use them (or, rather, could use "one pharmacy contractor per entity"). *Id.* at 43,555. The 1996 guidance also clarified that it "create[d] no new rights or duties." *Id.* at 43,550.

2010 Guidance. Next, in 2010, the agency departed from the 1996 guidance. The 2010 guidance told covered entities that they could use an unlimited number of contract pharmacies, even if they had an in-house dispensing pharmacy. 75 Fed. Reg. 10,272 (Mar. 5, 2010). The 2010 guidance was based on exactly the same statutory text as the 1996 guidance; it just announced a different

conclusion about what covered entities could do. *See* Reply 15. As in 1996, the agency did not say that the statute requires manufacturers to deal with contract pharmacies. The agency also clarified that it was imposing no "additional burdens upon manufacturers," 75 Fed. Reg. at 10,273, which means—as Chief Judge Stark noted—that the 2010 guidance could not have obligated manufacturers to deliver drugs to multiple contract pharmacies per covered entity, since no covered entity was even ***allowed*** to use multiple contract pharmacies pre-2010. *See AstraZeneca*, 2021 WL 2458063, at *6-7.

Even in loosening the reins on covered entities' ability to contract with outside pharmacies, the agency made clear that it expected guardrails to protect against diversion. The 2010 guidance explained that the following "elements" are "essential" to "contract pharmacy arrangements": (1) that "[t]he covered entity" would "purchase the drug," (2) that the covered entity would "***maintain title*** to the drug" until the pharmacy dispensed it, and (3) that "[t]he contract pharmacy" would "maintain a tracking system suitable to prevent diversion." 75 Fed. Reg. at 10,277-78 (emphasis added).

Agency Disclaimers of Authority to Require Contract Pharmacy Arrangements. Between 1992 (the inception of the 340B program) and 2020, the agency never once tried to penalize a manufacturer that declined to deliver discounted drugs to contract pharmacies or to work through an unlimited number of contract pharmacy arrangements. Nor did it ever claim that it could do so.

To the contrary, the agency ***specifically disclaimed the existence of any such authority***. Consistent with its prior guidance, *see* 61 Fed. Reg. at 43,550 (1996 guidance "create[d] no new rights or duties"); 75 Fed. Reg. at 10,273 (2010 guidance imposed no "additional burdens upon manufacturers"), HRSA told Lilly on June 11, 2020, that the 1996 and 2010 "contract pharmacy advice" were not "binding" on manufacturers. VLTR_7590. HRSA told a 340B-focused publication that "[t]he 2010 guidance … is not legally enforceable," and that it could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies. Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020); *see also Am. Hosp.*

Ass'n v. HHS, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021) (quoting HRSA email). And the agency persisted throughout 2020 in telling covered entities that although "HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy," it "has only limited ability to issue enforceable regulations" in light of what it then described as the lack of "authority" to so demand. *E.g.*, VLTR_3272, VLTR_3285, VLTR_4194. That explains why, even late last year, covered entities and contract pharmacies "underst[ood]" that HRSA "cannot require manufacturers to offer drugs at the 340B ceiling price to be shipped to contract pharmacies because the 2010 contract pharmacy guidance … is not legally enforceable." VLTR_3283.

December 30 Decision. Everything suddenly changed on December 30, 2020, when the agency issued "Advisory Opinion 20-06." VLTR_8048-56. This December 30 Decision was "the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies." *AstraZeneca*, 2021 WL 2458063 at *6. In particular, it concluded 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 to charge … no more than the 340B ceiling price for those drugs." VLTR_8048 (emphasis added). In reaching that conclusion, the agency relied on both the "purchased by" provision and the "shall … offer" provision, *see* VLTR_8049; it explicitly stated that the obligation to deliver discounted drugs to contract pharmacies exists only "to the extent" that contract pharmacies act as "agents" of covered entities, *see* VLTR_8048; and it declared that its (new) interpretation of the statute was the only permissible reading, *see* VLTR_8050. On this last point, when the government was asked in *AstraZeneca* how it could reconcile the December 30 Decision with the 1996 guidance—which concluded that "[t]he statute is silent as to permissible drug distribution systems," and limited covered entities to one contract pharmacy apiece (and only in certain, limited circumstances), 61 Fed. Reg. at 43,549—the government did not even try to do so; it simply disclaimed the 1996 guidance as

wrong. *See* Hr'g Tr. 67:6-20, *AstraZeneca*, No. 21-cv-27 (D. Del. May 27, 2021), Dkt. 76 ("*AZ* Tr.").

Chief Judge Stark's Decision. Reviewing the agency's incorrect insistence that the 340B statute itself requires manufacturers to ship to an unlimited number of contract pharmacies, Chief Judge Stark held that the December 30 Decision is arbitrary and capricious. 2021 WL 2458063, at *10-11 (quoting *Am. Lung Ass'n v. EPA*, 985 F.3d 914, 944 (D.C. Cir. 2021)). In particular, Chief Judge Stark held that the December 30 Decision was final agency action; the agency's position has "materially shifted" over time; the Decision was "the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies," and the Decision "is based on the 'unjustified assumption' that Congress imposed [HRSA's] interpretation as a statutory requirement." *Id.* at *6-11. He accordingly "SET ASIDE and VACATED" the December 30 Decision. Mem. Order ¶ 4, *AstraZeneca*, No. 21-cv-27 (D. Del. June 30, 2021), Dkt. 83.

In a futile attempt to avoid an adverse judgment (a gambit rejected by Chief Judge Stark, who entered judgment for AstraZeneca, *see id.*), the agency has now purportedly withdrawn the December 30 Decision, while insisting that doing so changes nothing substantively. Dkts. 119, 119-1.

C. The Agency "Determines" that Lilly's Policy is Unlawful, Without Hearing from Lilly and in Direct Violation of the Government's Statements to this Court

In 2020, Lilly adopted a policy aimed at the root of the problem that the GAO itself had identified: the abusive and unaccountable use of contract pharmacies. *See, e.g.*, GAO, GAO-11-836, at 28 (Sept. 2011), https://bit.ly/2JvWKgJ (contract pharmacies "create[] more opportunities for drug diversion compared to in-house pharmacies"). Lilly's policy is simple. Lilly continues to offer each covered entity the ability to directly purchase all covered outpatient drugs that Lilly manufactures at or below the applicable 340B ceiling price. Lilly (or its wholesalers) will deliver to each covered entity that purchases 340B drugs from Lilly. But, consistent with the statute's restrictions on transferring 340B drugs, Lilly (and its wholesalers) ordinarily will ***not*** deliver 340B drugs to anyone else. Nonetheless, consistent with the agency's own 1996 guidance, Lilly will agree to deliver 340B drugs

to one contract pharmacy of the covered entity's choosing if the covered entity lacks an in-house dispensing pharmacy. Exh. A, Decl. of Heather Dixson, ¶ 5; *see id.* ¶ 13 (noting that Lilly has already done so for more than ***700*** covered entities since it announced its policy).[2] And if a covered entity wholly owns a contract pharmacy or shares a corporate parent, Lilly will treat the pharmacy as part of the covered entity for purposes of delivery. *Id.* ¶ 6. This policy fully complies with the 340B statute.

Despite awareness of Lilly's policy for nearly a year, it was only on May 17, 2021, in the midst of this litigation, that the agency announced that "HRSA ***has determined***," "[a]fter review of [Lilly's] policy and an analysis of the complaints HRSA has received from covered entities," "that Lilly's actions ***have resulted*** in overcharges and are ***in direct violation*** of the 340B statute." VLTR_3 (emphases added). The letter is nearly identical to the separate letters HRSA sent on the same day to five other manufacturers with similar policies. *See* VLTR_1-2 (AstraZeneca); VLTR_5-6 (Novartis); VLTR_7-8 (Novo Nordisk); VLTR_9-10 (Sanofi); VLTR_11-12 (United Therapeutics). The letters all announce a determination that is ***the culmination*** of the agency's decisionmaking process—not the commencement of it. Hence the letter Lilly received not only demands that Lilly "credit or refund all covered entities for overcharges that have resulted from Lilly's policy," but also orders Lilly to "offer[] its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements." VLTR_4. Lilly responded to the agency by explaining that its policy fully complies with the text, structure, and purpose of the 340B statute. *See* Dkt. 115, 115-1.

[2] Although the government contends that "Lilly's challenge … should be decided on the basis of the administrative record," Reply 21 n.10, the government filed its own extra-record declaration purportedly in response to an amicus brief. This Court can consider Ms. Dixson and Mr. Asay's declarations submitted with this brief, not only because the government has opened the door, but also because the "record may be supplemented to provide, for example, background information or evidence of whether all relevant factors were examined by an agency"—an acute consideration here given the administrative record's lack of evidence from manufacturers. *AT&T Info. Sys., Inc. v. GSA*, 810 F.2d 1233, 1236 (D.C. Cir. 1987); *see also Esch v. Yeutter*, 876 F.2d 976, 991-93 (D.C. Cir. 1989) ("Consideration of all relevant factors includes at least an effort to get both sides of the story").

The May 17 Determination[3] is most notable for what it does ***not*** contain. It does not mention the "purchased by" provision—which is what the Justice Department's Reply brief chiefly relies on to defend the agency now—even once. Instead, it relies solely on the 340B statute's "shall … offer" language, which (as noted) was added to the statute ***after*** HRSA's 2010 guidance. Moreover, the letter does not say that Lilly must deliver to contract pharmacies "to the extent" that a contract pharmacy acts as the "agent" of a covered entity, as the December 30 Decision held—even though the December 30 Decision is in the administrative record (which by definition discloses everything the agency considered in making its Determination), *see* VLTR_8048-55, and even though it was issued by the agency's chief legal officer, *see* footnote 1, *supra*, and had not yet been withdrawn. Instead, HRSA ignores and (silently) removes that "agency" limitation entirely. Nor does the May 17 Determination try to reconcile the agency's decision to make a final "determin[ation]" about Lilly's policy at all with the government's clear statement to this Court earlier in the case that "pass[ing] on the specifics of Lilly's new policy" is something "that belongs in the ADR." Dkt. 95-3 at 76:24–77:3.

Most importantly, the letter does not contain ***any*** of the extensive pseudo-findings made by

[3] The government does not dispute that the May 17 Determination is final agency action. Nor could it. To be final agency action, a determination "must [1] mark the 'consummation' of the agency's decisionmaking process" and "[2] be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *W. Ill. Home Health Care, Inc. v. Herman*, 150 F.3d 659, 662 (7th Cir. 1998) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)). And it is clear on the face of the letter Lilly received (1) that the agency's decisionmaking process vis-à-vis Lilly's policy is complete, *see* VLTR_3 ("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."), and (2) that legal consequences will flow directly from the Determination's issuance, *see* VLTR_4 ("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."). Indeed, the government refers to the correspondence Lilly received about the Determination as a "Violation Letter." Reply 12. It is final and reviewable now. *See, e.g.*, *Sackett v. EPA*, 566 U.S. 120, 126-27 (2012) (holding that an EPA order was final agency action, even though it included a proviso inviting regulated parties to "engage in informal discussion of [its] terms and requirements" with the EPA and purported to be non-final, because "'legal consequences'" flowed from the order's "issuance" and the order marked "the 'consummation' of the [agency's] decisionmaking process" (quoting *Bennett*, 520 U.S. at 178)).

its lawyers in the background section of the Reply brief. *Compare* Reply 2-11, *with* VLTR_3-4. HRSA did not identify any particular covered-entity complaint on which its "determination" was based—much less evaluate competing evidence, assess the validity of a covered entity's claims, or explain itself as the APA requires. And there is good reason that HRSA did not try: HRSA ignored Lilly's repeated attempts to discuss this issue with the agency. *See* Exhs. C-H. Lilly was never given a chance to see, let alone respond to, the covered-entity complaints that fill the administrative record before the agency rendered its *ex parte* determination. And, indeed, HRSA stuck to its approach of ignoring Lilly well past the point of absurdity: The administrative record shows that the agency reviewed the ***government's*** summary judgment brief in this case, but not Lilly's. *See* VLTR_8159-8227. HRSA did not attempt to justify its nakedly one-sided process—perhaps because it is unjustifiable.

D. The Reply Brief's Account of the Record is Irrelevant and Inaccurate

The government's Reply brief tries to supply the findings and reasoning unlawfully missing from its client-agency's official action. The Reply goes on at length about covered-entity allegations in the administrative record, advancing the Justice Department's own conclusions about what they show. That, of course, violates administrative law. *SEC v. Chenery*, 332 U.S. 194, 196 (1947).

In any event, while the government's reply tries to make the record seem overwhelming, in reality it mostly contains short, boilerplate complaints from covered entities that appear to have been coordinated by the agency's own outside vendor and supporting *amicus*. Almost all of the covered-entity complaints in the administrative record appear on the same form prepared by Apexus, HRSA's "340B Prime Vendor." *See* VLTR_110-6807. It also appears that the National Association of Community Health Centers—which filed a formal complaint against Lilly under the ADR Rule—helped orchestrate the coordinated submission of these complaints to HRSA. *See* VLTR_2272, 4929 (providing complaints "pre-populated with the drugs that are impacted by the actions taken by the three drug companies"). What is more, the forms the covered entities submitted almost all recite the

same complaint verbatim: "I am forced to pay WAC [wholesale acquisition cost] for [the drugs] for my contract pharmacies." *See, e.g.*, VLTR_279, 298, 1202, 1607, 1679, 1812, 1890, 1912, 6591.

Despite the government's bluster, many of these complaints do not even attempt to understand Lilly's policy. For example, many complaints claim that Lilly's entire product list was not available at 340B prices, even though they were—and even though those entities had never previously even tried to buy most of Lilly's products. *See, e.g.*, VLTR_488-95, 556-63, 765-72. The complaints also show that the complaining entities ***declined opportunities to purchase Lilly drugs at 340B prices***. Most of the government's cited complaints list insulin products Humulin and Humalog as drugs for which the covered were allegedly overcharged. *See, e.g.*, Reply 6-10. But Lilly made all of its Humulin and Humalog products available at the 340B price for covered entities to ship to as many contract pharmacies as they wanted, so long as the covered entities and the pharmacies made the drugs ***available to patients*** at the discounted price. Dixson Decl. ¶ 7. Apparently none of the covered entities whose complaints the government relies upon were willing to do that. *Id.* ¶ 12. The assertion that Lilly does not care about diabetes patients is thus more than a bit rich. The government also ignores that most of the complaining covered entities chose not to designate a contract pharmacy, even though Lilly did and does ship to one designated contract pharmacy per covered entity. *Id.* ¶¶ 10-13. Indeed, many of the covered entities the government highlights have continued to purchase drugs from Lilly ***at 340B prices*** since Lilly announced its policy, *id.* ¶ 11, and those that have not simply have declined to submit the paperwork necessary to access 340B prices via a single contract pharmacy.

Perhaps most telling of all, the complaints not only assume the answer to the statutory question before the Court—whether Lilly must deliver 340B drugs to an unlimited number of contract pharmacies—but fail to address ***how*** purchases would be made. These *ex parte* submissions do not show (nor does the government contend) that covered entities "maintain title" to drugs shipped to contract pharmacies under the standard replenishment model. Instead, the government's cited

examples simply show that someone ordered drugs, purportedly on behalf of covered entities, to replenish the general stocks of contract pharmacies—which, by nature of the fact that they are not dispensed specifically to 340B patients, means that they are ***not*** 340B drugs. *See* Dkt. 125-2 ("Pedley Decl.") ¶ 11; *see also id.* ¶ 5 (explaining that every drug dispensed by a contract pharmacy, whether to a covered entity's patient or not, "comes from the contract pharmacy's own inventory").

ARGUMENT

I. The May 17 Determination Is Contrary To Law.

The May 17 Determination is substantively defective. Because Lilly's policy—which materially tracks the 1996 guidance—complies with the terms of the 340B statute, the agency's determination that it does not is contrary to law. And because the agency's interpretation of the statute would amount to imposing an unconstitutional condition on Medicare and Medicaid participation—an uncompensated, *per se* taking via private wealth transfer—it is also contrary to constitutional right.

A. Lilly's Policy Fully Complies with the 340B Statute.

The question before the Court is whether Lilly's contract pharmacy policy complies with the 340B statute. *See* Reply 13 (noting that, "in its Violation Letter[,] HRSA made the specific determination ***that Lilly's policy violates the 340B statute***" (emphasis added)). The issue is thus not, as the Reply would have it, how Lilly interacted with any particular covered entity. It is whether Lilly's ***policy*** "violate[s] the statutory prohibition on overcharging covered entities." *Id.* Simply put, the answer to that question is "no." Lilly's policy is fully consistent with the statute.

First, Lilly's policy complies with the "shall … offer" provision because Lilly offers its drugs at or below the ceiling price to all covered entities that want them. That is all the statute requires. The "shall … offer" provision does not say anything about contract pharmacies or delivery obligations, and it does not require manufacturers to deliver drugs wherever a covered entity (let alone a third party purporting to speak for it) commands. Second, Lilly's policy complies with the "purchased by"

provision—which should not matter, since the agency did not rely on (or even mention) that provision in its May 17 Determination. But, in all events, transfers of discounted drugs to contract pharmacies are not "purchase[s] by a covered entity" as a matter of economic substance, legal form, or ordinary English, and neither Lilly nor the Court is required to pretend otherwise. The ***statute*** does not require Lilly to participate in what is—at best—an accounting fiction whereby covered entities nominally buy drugs that they never receive and never control, and that are not even dispensed to 340B patients.

1. Lilly's policy complies with the plain meaning of the "shall … offer" provision.

The agency's determination that Lilly's policy violates the 340B statute's "shall … offer" provision is wrong as a matter of law. Interpreting the 340B statute "starts with its text," not with non-binding agency guidance documents. *Milner v. Dep't of Navy*, 562 U.S. 562, 569 (2011). And the text of the "shall … offer" provision says that HHS "shall require that the manufacturer 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." 42 U.S.C. § 256b(a)(1); *see also* PPA § II.A. Notably, the provision does not dictate any term of the manufacturer's offer other than "price." Instead, it does only two things: It requires a manufacturer with a PPA to "offer" to "each covered entity" the ability to "purchase" "at or below the applicable ceiling price" all covered outpatient drugs that the manufacturer currently has on the market. And it clarifies that if a manufacturer removes one of its drugs from the market entirely, such that the drug is no longer "made available to any … purchaser at any price," then the manufacturer cannot be forced to sell "such drug" to covered entities just because "such drug" satisfies the statutory definition of a "covered outpatient drug."

The "shall … offer" language does not require Lilly to offer anything to or through contract pharmacies. As Lilly has explained, *see* Dkt. 89 (Lilly MSJ) at 24-27, contract pharmacies are not covered entities under the statute. The 340B statute sets out in exacting detail fifteen categories that qualify as covered entities, but it does not include contract pharmacies. *See* 42 U.S.C. § 256b(a)(4).

That omission is not the result of inadvertence. Congress added new healthcare providers to the list in 2010, *see* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 7101(a), 124 Stat. 119, 821-22 (2010) (codified as amended at 42 U.S.C. § 256b(a)(4)(M)-(O)) (adding certain "children's hospital[s]," "free-standing cancer hospital[s]," "critical access hospital[s]," and "community hospital[s]"), yet it has never added contract pharmacies. Indeed, Congress has never included any for-profit entity of any kind; even for-profit hospitals are excluded. Such particularization in defining who is (and is not) eligible to receive 340B "offer[s]" from manufacturers to "purchase" discounted drugs is strong evidence that Congress's omission of contract pharmacies was intentional.

Lilly's policy therefore complies with the "shall … offer" provision. Lilly will and does "offer each covered entity" the right to "purchase" "at or below the applicable ceiling price" all "covered outpatient drugs" Lilly produces. 42 U.S.C. § 256b(a)(1). The statute requires no more.[4]

The agency, however, accuses Lilly of violating the "shall … offer" provision, because it says that the provision contains an unstated restriction on how manufacturers must offer to ***deliver*** 340B-priced drugs. In particular, the agency contends that refusing to ***deliver*** discounted drugs ***to a contract pharmacy***, as opposed to only delivering to a covered entity directly (which Lilly consistently offers to do) somehow amounts to a refusal to ***offer*** the drugs to ***a covered entity***. *See* VLTR_3-4. Indeed, the agency appears to believe that the "shall … offer" language (impliedly) forbids manufacturers from having ***any*** terms or restrictions on how they arrange to deliver discounted drugs: According to the agency, a manufacturer cannot refuse to deliver drugs to "the lunar surface, low-earth orbit, or a neighborhood pharmacy" if a covered entity demands that it do so. VLTR_6834.[5]

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[4] Indeed, Lilly has continued to sell 340B drugs at or below 340B prices ***to a number of the covered entities the government highlights in the Reply brief***. *See* Dixson Decl. ¶ 11.

[5] Illustrating the absurdity of the government's view that if Lilly's offer to a covered entity has literally any terms and conditions, it no longer counts as an "offer" under the 340B statute, the Reply makes much of Lilly's alleged refusal to offer 340B discounts to PeaceHealth St. Joseph Medical Center. *See* Reply 4. In reality, the reason Lilly rejected St. Joseph's application to Lilly to designate a contract

To put it mildly, the agency's interpretation has no basis in the statute. "Statutory construction must begin with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Milner*, 562 U.S. at 569 (quoting *Park 'N Fly, Inc. v. Dollar Park & Fly, Inc.*, 469 U.S. 189, 194 (1985)). When Congress leaves a statutory term (such as "offer") undefined, courts must "give it its ordinary meaning." *Burrage v. United States*, 571 U.S. 204, 210 (2014); *see Taniguchi v. Kan Pac. Saipan, Ltd.*, 566 U.S. 560, 572 (2012) (relying on dictionaries to determine ordinary meaning). The ordinary meaning of "offer" does not carry with it any obligation to "deliver" to someone other than the purchaser. According to *Black's Law Dictionary* (11th ed. 2019), the term "offer" means: "**1.** The act or an instance of presenting something for acceptance," "**2.** A promise to do … some specified thing in the future, conditioned on an act … or return promise being given in exchange," and "**3.** A price at which one is ready to buy or sell; an amount of money that one is willing to pay or accept for something." *Merriam-Webster* is similar, defining the noun "offer" to mean "a price named by one proposing to buy" and the verb "to offer" to mean "to present for acceptance or rejection." "Offer," *Merriam-Webster*, https://bit.ly/2UvyPD0. In ordinary English, then, to say that a seller must "offer" a good to a particular buyer at a particular price does not tell you whether the seller must ship the good to the buyer directly, transfer it to a third party who is not the buyer, or (as the agency says) send it to the "lunar surface." VLTR_6834.

The same problem befalls the interpretation of the "shall … offer" provision advanced by the Reply brief, which (unlike the agency itself) describes the "shall … offer" provision as a nondiscrimination clause. The government now claims that because "Lilly places no delivery-location or dispensing-mechanism restrictions on full-priced sales—only covered entities' purchases," Reply 16, Lilly is violating the "shall … offer" provision by "discriminat[ing] against 340B purchases relative

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pharmacy was that St. Joseph ***crossed out*** the terms on Lilly's designation form that required covered entities and contract pharmacies to pledge not to take duplicate discounts. Dixson Decl. ¶ 11.

to commercial sales," Reply 17 n.6. But even if the Court could consider the *post hoc* rationalizations of DOJ lawyers in an APA case—which it cannot, *see Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983)—this argument would also fail, because it too contradicts the statutory text and is not supported by any facts. The statute does not say, "manufacturers cannot impose conditions on 340B purchases unless they impose the same conditions on non-340B purchases." All it says is that manufacturers must "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." 42 U.S.C. § 256b(a)(1). And that is exactly what Lilly does pursuant to its policy. In any case, the government's discrimination argument also fails on its own terms. Lilly is not refusing to do for covered entities what it does in its commercial sales; on the contrary, the replenishment model is something only 340B entities ask for at all. Treating different situations differently is not discrimination. And the government points to no evidence that Lilly is refusing to do something for covered entities that it, in fact, does in ordinary commercials sales; the statute does not impose special, additional obligations on manufacturers other than to "offer" the ceiling price.

In short, there is no textual basis in the statute for the intricate delivery obligations the agency has sought to engraft upon it through the December 30 Decision, violation letters, and court filings. And as Chief Judge Stark noted in the *AstraZeneca* case, that statutory silence is "a strong indication that the statute does not compel" ***either*** "any particular outcome with respect to covered entities' use of pharmacies" ***or*** any particular delivery requirement. 2021 WL 2458063, at *9.

2. Basic principles of statutory interpretation confirm Lilly's reading.

Five bedrock principles of statutory construction principles confirm that Lilly's interpretation, that it is not required to deliver 340B-priced drugs to contract pharmacies, is correct.

First, the government's interpretation runs afoul of the "presum[ption] that Congress acts intentionally and purposely in the disparate inclusion or exclusion" of statutory language. *Russello v.*

United States, 464 U.S. 16, 23 (1983). The government contends that Congress could not have meant "to detail the minutiae of how [340B] transactions are effectuated." Reply 13. But that is demonstrably false. In reality, Congress details these sorts of things ***all the time***, and it often does so in terms that embrace contract pharmacy arrangements. *See, e.g.*, 38 U.S.C. § 8126(a), (h)(3) (requiring manufacturers to "make available for procurement … each covered drug of the manufacturer … that is purchased under depot contracting systems," and defining "depot" to include "a commercial entity operating under contract with [the procurer]"); 42 U.S.C. § 1320a-7b(b)(3)(C) (allowing "entities who are furnishing services reimbursed under a Federal health care program" to pay "a person authorized to act as a purchasing agent" for certain purposes, provided "the person has a written contract" with the provider). Indeed, Congress explicitly provided for such arrangements in a separate provision of ***the very same law that enacted the 340B statute***, namely, the Veterans Health Care Act of 1992. *AstraZeneca*, 2021 WL 2458063, at *10. Congress's decision not to do so for 340B speaks volumes, and it cannot be disregarded. If Congress wanted to require cooperation with contract pharmacies in the 340B program, it knew how to say so—"but it did not do so in the 340B statute." *Id.*

Second, the government's position cannot be reconciled with the statute's structure. *See generally Beeler v. Saul*, 977 F.3d 577, 585 (7th Cir. 2020) (noting that "statutory interpretation 'calls on the judicial interpreter to consider the entire text, in view of its structure and the physical and logical relation of its many parts'" (quoting Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 167 (2012))). The 340B statute does not give covered entities *carte blanche* to demand drugs and then do with them whatever they wish. Quite the opposite. To ensure that 340B discounts are reserved only for the "providers of safety net services for the poor" set out in the statute (and thus their patients), *PhRMA v. HHS*, 138 F. Supp. 3d 31, 44 (D.D.C. 2015), Congress made explicit that covered entities may not transfer 340B drugs to anyone but their patients: Under 42 U.S.C. § 256b(a)(5)(B), "a covered entity shall not resell or otherwise transfer" 340B drugs to any "person

who is not a patient of the entity." And as the GAO has warned, contract pharmacy usage "creates more opportunities for drug diversion compared to in-house pharmacies." GAO-11-836, *supra*, at 28; *see also, e.g.*, HRSA, *340B Program Integrity, Audits of Covered Entity Results* (Apr. 2020), https://bit.ly/3fcAALF (similarly finding that contract pharmacies facilitate diversion).

It makes no sense to interpret the "shall … offer" provision to mandate the same kind of diversion the statute elsewhere prohibits. Yet the agency's interpretation allows covered entities to secure 340B discounts for "replenishment" drugs that are purportedly ordered on their behalf but delivered to contract pharmacies, and then dispensed to random, non-340B customers as part of a pharmacy's general inventory, with contract pharmacies profiting from it. That is plainly not what Congress meant by "offer," however much unappropriated "revenue" the agency's interpretation might generate for its favored stakeholders, *see* Reply 6-8. Indeed, if a manufacturer can be forced—based on the pretense of fleeting, nominal ownership by the covered entity—to transfer 340B drugs to third parties with no relationship to the covered entity other than a piece of paper (*i.e.*, a contract), then the statute's diversion restriction will be a dead letter. And, of course, federal agencies have no "right, in the guise of construction of an act, to either add words to or eliminate words from the language used by Congress." *GE Betz, Inc. v. Zee Co., Inc.*, 718 F.3d 615, 624-25 (7th Cir. 2013).

That is why the government is wrong to contend that "[i]f Lilly were correct that it only had to offer drugs to covered entities, … then by the same logic it could refuse to deliver drugs at all and force covered entities to physically pick up prescriptions from Lilly's warehouses." Reply 25. Lilly's policy (under which Lilly will deliver drugs to covered entities) does not impose that hypothetical restriction, which does not bear on the statutory-structure problem just discussed. But even if the Court thought that the statute is best read to require manufacturers to deliver 340B drugs directly ***to covered entities*** (rather than requiring covered entities to arrange transport), the statute still could not be read to require manufacturers to deliver directly ***to contract pharmacies***, which are ineligible

for discounts and which engage in diversion at outsized rates.

Third, the government's position violates the principle that Congress does not "hide elephants in mouseholes" or otherwise "alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001). Contrary to the government's say-so, the issue of whether manufacturers must accept an unlimited number of contract pharmacy relationships and deliver discounted drugs to an unlimited number of contract pharmacies is not some minor "detail." Reply 13. Even the government admits that contract pharmacy arrangements capture billions of dollars in discounts every year. VLTR_7936-47; *see* Reply 21. Construing the statute, which says nothing about any such obligation, to require manufacturers to work through contract pharmacy arrangements would thus have massive consequences in simple dollars-and-cents terms. It would also threaten to transform the program from one that ***reduces existing costs*** to help low-income patients and the healthcare providers that serve them, to one that instead ***generates new revenue*** for covered entities, and is material to for-profit pharmacies' bottom lines. *Compare* HHS-OIG, OEI-05-13-00431, at 2-5 (Feb. 4, 2014) (finding that patients "pay the full non-340B price for their prescription drugs at contract pharmacies," even when they are eligible for discounts), https://bit.ly/3eWKmBQ, *with* Raymond James, *340B Pharmacy Follow Up—Less Than $1.4B but Still Yuge*, at 1 (Sept. 9, 2020) (noting that Walgreens generated "hundreds of millions" in profits through 340B contract pharmacy arrangements). That is fatal to the government's position, for it is black-letter law that Congress must "speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'" *Utility Air Reg. Gp. v. EPA*, 573 U.S. 302, 324 (2014).

Fourth, the government's position is inconsistent with principles of lenity. The 340B statute authorizes, and the agency has threatened, penalties of nearly $6,000 ***per instance*** of what it now calls overcharging. VLTR_3-4; *see* 42 U.S.C. § 256b(d)(1)(B)(vi). As a result, the financial exposure Lilly faces from penalties under the agency's interpretation is massive. Principles of lenity require Congress

to speak more clearly before courts will construe silent or ambiguous statutory language to authorize such draconian results. *See Commissioner v. Acker*, 361 U.S. 87, 91 (1959) (holding, in a civil case, that "one 'is not to be subjected to a penalty unless the words of the statute plainly impose it'"); *Rand v. Commissioner*, 141 T.C. 376, 393 (2013) (applying rule of lenity to civil statute imposing tax penalties).

Fifth, the government's position is not supported by any clear evidence of legislative intent. The government insists that Congress must have meant to require manufacturers to deliver drugs to pharmacies of covered entities' choosing, because "Congress's intent was to provide access to discounted medications for safety-net providers." Reply 13. But "[n]o law 'pursues its purposes at all costs,'" *Hernandez v. Mesa*, 140 S. Ct. 735, 741-42 (2020), which means that "it frustrates rather than effectuates legislative intent simplistically to assume that whatever furthers the statute's primary objective must be the law," *Rodriguez v. United States*, 480 U.S. 522, 526 (1987) (per curiam). And, by itself, the bare intention to help covered entities financially does not answer the question of whether Congress meant to do so by reducing covered entities' costs for medication they purchase (Lilly's view), or by providing them with lucrative revenue streams at other private parties' expense they can market and split with the very for-profit retail pharmacies to whom they are not supposed to divert drugs (the government's position). In any case, abstract debates about how best to describe congressional purpose do not allow the agency to add terms to the law. Rather "a faithful agent must adhere to the product of the legislative process, not strain its language to account for abstract intention." Amy Coney Barrett, *Substantive Canons and Faithful Agency*, 90 B.U. L. Rev. 109, 124 (2010).[6]

[6] As Chief Judge Stark noted, "legislative history is of no greater assistance to the government." 2021 WL 2458063, at *10. Congress "specifically contemplated"—***but decided against***—"including language" in the 340B statute that would have expressly "referr[ed] to drugs 'purchased and dispensed by, or under a contract entered into for on-site pharmacy services with'" covered entities, which "suggests that Congress did not clearly intend to require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies." *Id.* (quoting S. Rep. No. 102-259, at 2 (1992)).

In short, Lilly's policy complies with the terms of the 340B statute, which does not require manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. The agency's May 17 Determination concluding the opposite is contrary to law and must be set aside.

B. The Government's Attempts to Re-imagine and Justify HRSA's Action Fail.

As explained above, the May 17 Determination is contrary to law because Lilly's policy does not violate the 340B statute. The government's strained efforts to resist that conclusion fail.

1. The government's defense of the agency's action violates *Chenery*.

At the outset, there is a basic problem with the government's defense of the May 17 Determination: That defense is based on grounds not relied on, much less explained, by the agency. But it is a "foundational principle" of administrative law 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). A court may neither "uphold [agency action] based on [the agency's] post hoc rationalization," *Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831, 839 (D.C. Cir. 2006), nor accept arguments made by the agency's lawyers but not the agency itself, *Phila. Gas Works v. FERC*, 989 F.2d 1246, 1250 (D.C. Cir. 1993). *See generally SEC v. Chenery Corp.*, 318 U.S. 80 (1943).

That forecloses the government's arguments on Reply. As the government notes, the May 17 Determination "relies on statutory text." Reply 2. But the only "statutory text" the agency cited is the "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.'" VLTR_3 (quoting 42 U.S.C. § 256b(d)(1)(A)). And, according to the brief the agency's lawyers have filed in this Court, that language ***does not address*** whether "'manufacturers must offer covered outpatient drugs' to covered entities … when they 'use purchasing agents or contract pharmacies'"; instead, they say it "speak[s] to a ***different*** obligation," namely, "that manufacturers must not discriminate against 340B purchases relative to commercial sales." Reply 17 n.6.

Because this is an APA case, that amounts to a confession of error. The government agrees that this case must "be decided on the basis ***of HRSA's reasoning in the Violation Letter*** and the administrative record supporting it." *Id.* at 12 (emphasis added). And the only "reasoning in the Violation Letter" that purportedly supports the agency's conclusion that Lilly is violating its statutory obligations is the bare assertion that the statute's "must offer" requirement—which the Reply now says "speak[s] to a ***different*** obligation," *id.* at 17 n.6—"is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs," VLTR_3. Indeed, even though the "shall … offer" provision is the only statutory text the agency invoked in its May 17 Determination, the government's Reply relegates it to an afterthought. The Reply instead chiefly discusses the "purchased by" language, and claims that Lilly's policy violates ***that*** provision. But an agency's lawyers are not permitted to defend its decisions on other grounds. The various new arguments the government makes in its Reply in support of HRSA's interpretation of the statute thus cannot save the agency action, because ***HRSA*** has not ***itself*** provided them.

2. The government's reliance on the "purchased by" language fails.

In any case, the government's arguments are wrong. Start with its claim that Lilly has somehow violated the 340B statute's "purchased by" provision. As Chief Judge Stark noted, the "purchased by" provision directly imposes an obligation ***only on the Secretary***, not on manufacturers. *AstraZeneca*, 2021 WL 2458063, at *9. Specifically, it directs the Secretary to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid … to the manufacturer for covered outpatient drugs … purchased by a covered entity … does not exceed [the ceiling price set by the Secretary]." 42 U.S.C. § 256b(a)(1).

The government cites no authority supporting its position that a covered entity's right to "purchase" drugs at a set price includes the right to demand delivery to wherever and to whomever the purchaser demands. That is because no such authority exists. Indeed, the law has long

distinguished between purchase-and-sale terms and delivery requirements. *See, e.g.*, *In re Valley Media, Inc.*, 226 F. App'x 120, 122-23 (3d Cir. 2007) (explaining that the term "'Delivery' has a well-defined meaning and common usage within the context of sales transactions under the UCC" that is different from the terms "sale" and "purchase"). When Congress directed manufacturers to "offer" their drugs to covered entities for purchase at 340B prices, it did not impose the additional (and far more onerous) obligation to facilitate delivery to contract pharmacies. That conscious decision should end the inquiry, for it is black-letter law that courts will not read a statute to intrude on private-property rights unless the statute "speak[s] directly" to the question. *United States v. Texas*, 507 U.S. 529, 534 (1993).

Statutory structure confirms that conclusion. As noted, the statute mandates that covered entities "shall not resell or otherwise transfer" 340B drugs "to a person who is not a patient of the entity." 42 U.S.C. § 256b(a)(5)(B). The statute also prohibits covered entities from receiving duplicate discounts. *Id.* § 256b(a)(5)(A)(i). And it requires HHS to "provide for improvements in compliance by covered entities … in order to prevent diversion" and duplicate discounting. *Id.* § 256b(d)(2)(A), (a)(5)(A)(ii). These provisions are all about preventing covered entities from allowing third parties to launder eligibility for discounts. It would make no sense to interpret the words "purchased by" in the same statute to embrace a replenishment model in which orders are placed by pharmacies or third party administrators—not covered entities—at a time of their choosing (not the covered entity's), delivered to pharmacies (not to the covered entity), and dispensed by pharmacies to any random patient (not just the covered entity's patients). The notion a covered entity is nominally making the purchase is at best an accounting fiction, *see* pp. 24-28, *infra*, and does nothing to reduce the covered entity's ***costs***. Courts do not endorse constructions that are "inconsisten[t] with the design and structure of the statute as a whole." *Univ. of Tex. Sw. Med. Ctr. v. Nassar*, 570 U.S. 338, 353 (2013).

3. The 340B statute does not require manufacturers to cooperate with the fictions of the "replenishment model."

More broadly, nothing in the 340B statute requires manufacturers to go along with the contract

pharmacy "replenishment" kabuki that has arisen in the last decade. Under the replenishment model, a contract pharmacy (or its vertically-integrated third-party administrator) places a 340B order, nominally on a covered entity's account, asking the manufacturer to have its distributor ship to the contract pharmacy new stock of drugs at or below the 340B ceiling price, after which the contract pharmacy alone decides how it is dispensed. Exh. B, Decl. of Derek Asay, ¶ 4. The covered entity never enters the picture. It does not physically receive the drugs; and it never has any practical control over them, either, because they are merged into the contract pharmacy's general inventory immediately after delivery. *Id.* ¶¶ 4-8. The covered entity's entire role completed the moment it enters into a contract with an outside retail pharmacy and authorizes the pharmacy to make purchases under the covered entity's 340B account, after which the contract pharmacy places orders for, and receives, 340B drugs based on algorithms the pharmacy and its third-party administrators develop. In short, regardless of whether it nominally takes title to replenishment drugs for a fleeting moment in time, the covered entity ultimately just licenses its statutory eligibility for 340B discounts—and, in doing so, effectively diverts 340B drugs—to dispensing pharmacies. And while the government accuses Lilly of mischaracterization in claiming that the agency would require Lilly to provide 340B drugs ***to contract pharmacies***, *see, e.g.*, Reply 54 n.25, there is no actual debate about this: Even ***HRSA's own declaration*** attests that that is exactly how the replenishment model works. *See* Pedley Decl. ¶ 5.

The "shall … offer" language cannot be read to require Lilly to embrace this scheme. Nothing in the text requires a manufacturer to offer to replenish contract pharmacies' inventory just because they previously dispensed non-340B drugs to an alleged 340B patient. In fact, the opposite is true: That provision could not be clearer that manufacturers must offer 340B prices to "***each covered entity***." 42 U.S.C. § 256b(a)(1) (emphasis added). The text does not say "each covered entity ***and their purchasing agents***." In fact, it explicitly distinguishes between "covered entit[ies]" and "other purchasers" when it comes to who is being "offer[red] … covered outpatient drugs for purchase." It

thus cannot reasonably be construed to require manufacturers to treat "other purchasers" ***as*** "***covered entit[ies]***" when it comes to manufacturers' requirement to "offer … each covered entity drugs for purchase at or below the [340B] price." And, as explained, when a contract pharmacy submits an order, no covered entity has asked for 340B drugs; only the pharmacy has—and, again, a contract pharmacy is not a covered entity. A manufacturer's decision not to treat replenishment orders as covered-entity purchases thus does not even implicate, let alone violate, the "shall … offer" provision.

The same is true of the "purchased by" provision (which the agency did not actually rely on). The ordinary meaning of "purchased by a covered entity," *id.*, does not encompass this scheme. The verb "to purchase" means "to obtain by paying money or its equivalent." "Purchase," *Merriam-Webster*, https://bit.ly/3jTZ1Ce. But, under the replenishment model, covered entities ***do not obtain drugs***—much less for their own use. Instead, a contract pharmacy looks over its records, decides that it previously dispensed drugs that could have been, but were not, ordered by a covered entity, and demands (ostensibly on behalf of a covered entity) that it ***directly receive*** drugs at 340B discount prices for its general inventory, which it will then dispense to non-340B patients. *See* Asay Decl. ¶¶ 5-12. The covered entity never takes possession of any of the replenishment stock.

No ordinary user of the English language would describe this contorted scenario as involving any "purchase by a covered entity." Indeed, we need not imagine what the hypothetically reasonable English speaker would think, because the administrative record here makes clear that ***even covered entities themselves*** view contract pharmacies as the true purchasers in these "replenishment" situations. *See, e.g.*, VLTR_5834 (covered entity complaining to HRSA that "Lilly stopped extending the 340B ceiling price on its drugs ***purchased through 340B contract pharmacies***.… Lilly has removed the 340B pricing from ***the 340B contract pharmacy accounts*** …." (emphases added)).

Those familiar with commercial law would reach the same conclusion. Under basic commercial law principles, "[g]oods must be both existing ***and identified*** before any interest in them

can pass." U.C.C. § 2-105(2) (emphasis added). Yet, under the replenishment model, 340B drugs are not identified ***to the covered entity*** (the alleged purchaser) until after they have been dispensed to a patient, at which point ***the patient***—not the covered entity—takes title. That means that, under the ordinary operation of law, the covered entity never maintains either possession or title; both go directly from the manufacturer (or distributor) to the pharmacy. And, under basic commercial law principles, that means that ***even when replenishment purchases are made in the covered entity's name or from its account***, such transactions are still not "purchase[s] by a covered entity."[7] What is more, even if a covered entity nominally acquires a financial interest in the drugs when the replenishment order is placed—at best a legal fiction—it certainly does not "***maintain*** title" to the replenishment stock, as was deemed "essential" in the 2010 guidance. *See* 75 Fed. Reg. at 10,277 (emphasis added).[8]

4. HHS's own regulations confirm that Lilly's policy is lawful.

The government finds no support for its position in HHS's "duly promulgated regulations." Reply 14. In fact, HHS regulations confirm that Lilly's policy is lawful.

The government first points to HHS's regulations on CMPs, but those regulations are affirmatively unhelpful to the government. The CMPs regulations impose on "[m]anufacturers … an

[7] To be sure, "title passes to the buyer at the time and place at which the seller completes his performance with reference to the physical delivery of the goods." U.C.C. § 2-401(2). But "identification is [] the earliest possible opportunity for title to pass." 3 *Anderson on the Uniform Commercial Code* § 2-401:52 (3d ed. 2020). And, as explained, when 340B drugs are sent directly to a pharmacy, they are shipped alongside all the other non-340B drugs that the pharmacy ordered to replenish its stock; and, once the drugs arrive, they are never separated out. Asay Decl. ¶¶ 4-11. The only time that the 340B drugs are identified as such is after they have been dispensed to a patient—and, even then, they are identified only algorithmically, not actually. *See id.* ¶¶ 6, 9.

[8] The government suggests that covered entities might be able to contract around these legal principles. But the task at hand is not to look for avenues for evasion; it is to determine what Congress meant by "purchased by a covered entity." And, in doing so, the Court "must take into account [the statute's] contemporary legal context," *Morse v. Republican Party of Virginia*, 517 U.S. 186, 230-31 (1996), and must "assume that our elected representatives, like other citizens, know the law," *Cannon v. Univ. of Chicago*, 441 U.S. 677, 696-97 (1979). The relevant law Congress is presumed to have known when it enacted this statute is the law of commercial transactions—and reasonable people with experience in that field would not treat replenishment orders as having been "purchased by a covered entity."

obligation to ensure that the 340B discount is provided through distribution arrangements ***made by the manufacturer***," 42 C.F.R. § 10.11(b)(2) (emphasis added), *i.e.,* Lilly's wholesalers, but impose no parallel requirement to honor distribution arrangements ***made by a covered entity***. *See also* 82 Fed. Reg. 1,210, 1,224 (Jan. 5, 2017) ("Manufacturers also have control over the distribution of covered outpatient drugs…."). The clear implication is that it is ***not*** a violation for a manufacturer to balk at covered-entity distribution arrangements, whether those arrangements purport to require delivery to "the lunar surface, low-earth orbit, or a neighborhood pharmacy." VLTR_6834. HHS also defines "overcharging" as "***any order*** for a covered outpatient drug … which results in a covered entity paying more than the ceiling price." 42 C.F.R. § 10.11(b) (emphasis added); *see also* 82 Fed. Reg. at 1,224 ("[I]t is the ***actual sale*** of the covered outpatient drug above the ceiling price by the manufacturers to the covered entity that is the subject of the overcharge." (emphasis added)). Again, that means that when there is no actual sale, there can be no "overcharge." As a result, when a covered entity decides not to buy 340B drugs from Lilly because of Lilly's policy of not delivering 340B drugs to contract pharmacies, Lilly's policy ***will not result in any overcharge***, because there is no order and no sale.[9]

The government fares no better by invoking HRSA's 1994 nondiscrimination guidance, which allowed covered entities to "use a purchasing agent" and purported to prohibit manufacturers from "placing restrictive conditions." *See* Reply 16-17. For one thing, the 1994 nondiscrimination guidance is never mentioned in the May 17 Determination. For another thing, the 1994 nondiscrimination guidance could not possibly have required manufacturers to deliver 340B drugs to unlimited numbers

[9] In its Reply, the government claims that "evidence of overcharge may include 'cases where refusal to sell at the 340B price has led to the purchase of the covered outpatient drug outside of the 340B Program.'" Reply 23 (citation omitted). That is not what the regulations say, which is perhaps why the agency itself did not advance this argument. The government presumably tries this argument out in its Reply so it can treat certain complaints in the administrative record showing that covered entities decided not to buy 340B drugs from Lilly, or could not buy through their preferred distribution model, as reflecting "overcharges." But they in fact do not, because they did not involve any "order" at all.

of contract pharmacies given that, until 2010, covered entities were only allowed to use at most ***one*** contract pharmacy. *See* 61 Fed. Reg. at 43,549-55 (1996 contract pharmacy guidance). And as Chief Judge Stark noted, limits on "what covered entities ***may*** do" vis-à-vis contract pharmacies necessarily affect "what drug manufacturers ***must*** do" vis-à-vis contract pharmacies. *AstraZeneca*, 2021 WL 2458063, at *6-7. The government's new spin on old, inapposite guidance is wrong.

As for the 2010 guidance, the agency made clear when it issued the guidance that it viewed as "essential" to "contract pharmacy arrangements" that (1) "[t]he covered entity" would "***purchase*** the drug," (2) the covered entity would "***maintain title*** to the drug" until the pharmacy dispensed it, and (3) "[t]he contract pharmacy" would "maintain a tracking system suitable to prevent diversion." 75 Fed. Reg. at 10,277-78 (emphases added). Under the replenishment model, however, those "essential" elements are gone. Indeed, even the government admits that replenishment stock is shipped directly to the contrary pharmacy from the manufacturer (or its distributor), "where it becomes neutral inventory" no different from non-340B stock. Reply 22; *see also* Pedley Decl. ¶ 5. Thus, covered entities certainly do not ***maintain*** title under the replenishment model, if they ever obtain title at all.

5. The government's latest interpretation is not entitled to deference.

For at least four reasons, the government is not entitled to *Skidmore* deference for its current interpretation of the 340B statute. First, the agency has not followed the required procedures to justify deference. *See Vulcan Constr. Materials, L.P. v. Fed. Mine Safety & Health Review Comm'n*, 700 F.3d 297, 315-16 (7th Cir. 2012) (declining to accord *Skidmore* deference to an agency position that had not been "subject to an outside vetting process such as public commentary"); pp. 43-45, *infra*.

Second, the agency's May 17 Determination is not adequately explained. The letter "is far from thorough"; it "made no effort to consider how its interpretation … harmonized (or failed to harmonize)" with the statute's other provisions. *Arobelidze v. Holder*, 653 F.3d 513, 520-21 (7th Cir. 2011) (declining to apply *Skidmore* deference to a paragraph-long statutory analysis); *OfficeMax, Inc. v.*

United States, 428 F.3d 583, 594 (6th Cir. 2005) (noting that the agency's "one-page analysis" of the relevant issue did "not contain the traditional hallmarks for receiving deference"); pp. 19-21, *supra*.

Third, the interpretation underlying the May 17 Determination is inconsistent with prior agency pronouncements. *See Arobelidze*, 653 F.3d at 520 ("To assess the persuasive power of the [agency's] decision, we examine," *inter alia*, "'its consistency with earlier and later pronouncements ….'" (quoting *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944))). The letter claims that it is fully consistent with the agency's prior pronouncements, VLTR_3, but that is false; the agency's position on the issue of manufacturers' obligations vis-à-vis contract pharmacies "has not remained constant but has, instead, evolved over time," *AstraZeneca*, 2021 WL 2458063, at *6. That "defeats any claim to *Skidmore* deference." *Horbeck Offshore Transp. LLC v. Coast Guard*, 424 F. Supp. 2d 37, 50 (D.D.C. 2006); *see, e.g.*, *Young v. UPS*, 135 S. Ct. 1338, 1352 (2015) (declining to apply *Skidmore* deference to an agency guideline that was inconsistent with the agency's prior positions).

Fourth, *Skidmore* affords an interpretation "respect" ***only*** "to the extent that [it has the] power to persuade," *Bailey v. Pregis Innovative Packaging, Inc.*, 600 F.3d 748, 751 (7th Cir. 2010), but the agency's interpretation is out of step with the statute's text and structure. *See Stapleton v. Advocate Health Care Net.*, 817 F.3d 517, 530 (7th Cir. 2016) (no deference where the agency interpretation "conflicts with the plain language of the statute"). The agency's position is not entitled to deference, and in any case cannot overcome the statute's plain meaning or displace the normal canons of statutory interpretation.

C. The Government's Position Cannot Be Reconciled with the Takings Clause.

The government's construction of the 340B statute also amounts to an unconstitutional condition, *i.e.*, an uncompensated taking in violation of the Fifth Amendment. The Takings Clause prohibits the government from taking private property for public use without just compensation. U.S. Const. amend. V. That prohibition applies regardless of whether the taking occurs via regulation or through an exercise of eminent domain. *Horne v. Dep't of Agric.*, 576 U.S. 350, 358 (2015); *Squires-*

Cannon v. Forest Preserve Dist. of Cook Cty., 897 F.3d 797, 798 (7th Cir. 2018).

The government's response misapprehends Lilly's claim and the Supreme Court's Takings jurisprudence. Despite the government's insistence, *see* Reply 31-33, the agency's position effectuates a *per se* taking, ***not*** a regulatory taking subject to the test in *Penn Central Transportation Co. v. City of New York*, 438 U.S. 104 (1978). As the Supreme Court reiterated just last month, *Penn Central* applies only when the government regulates how a property owner may use his own property. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021). When (as here) the government "take[s property] for itself ***or someone else***," "a per se taking has occurred, and *Penn Central* has no place"—even if (as here) the confiscation "arises from a regulation" rather than through an exercise of the eminent domain power. *Id.* (emphasis added). Here, the agency is not trying to tell Lilly how it may ***use*** its property; it is telling Lilly that it must ***give away*** its property (in the form of its drugs, at below-market discounted prices) for delivery to for-profit retail pharmacies. *Penn Central* therefore does not apply.

With that out of the way, it is plain that the agency's contract pharmacy mandate violates the Fifth Amendment. The government unabashedly argues that the 340B program does not merely reduce covered entity ***costs***, but is intended to generate operating "***revenue***" for the covered entities themselves at the expense of manufacturers. *See, e.g.*, Reply 6-7. That revenue-generating rationale should set off alarm bells. It contravenes a core tenant of Takings Clause jurisprudence—that the government should not be permitted to "forc[e] some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole." *Armstrong v. United States*, 364 U.S. 40, 49 (1960). Rather than ask Congress to raise taxes and appropriate funds to subsidize drug purchases, the agency finds it convenient to order Lilly to fund that subsidy itself. That is a taking.

The agency's mandate also runs afoul of the prohibition on takings for private use. The agency claims the right to force Lilly to give money (in the form of below-market prices) to for-profit retailers. That alone extinguishes the contention (at Reply 33) that the agency's action satisfies the Public Use

Clause, *see* U.S. Const. amend. V. After all, the government is not trying to take money or property from Lilly ***for itself***; it is trying to compel Lilly to give its property to other private enterprises. And the Public Use Clause is ***never*** satisfied when government action requires a private party to give its property to another private party, or when a taking benefits "a particular class of identifiable individuals" rather than the public at large. *Kelo v. City of New London*, 545 U.S. 469, 477 (2005).[10]

As a backstop, the government claims that Lilly has somehow consented to this taking, either directly or by participating in Medicare and Medicaid. *See* Reply 32-33. That is wrong.

First, the government claims that manufacturers "have been aware for decades" that they must provide 340B-discounted drugs to an unlimited number of contract pharmacies, and yet Lilly has still chosen to participate in the program. *Id.* at 32. That is demonstrably false. As Chief Judge Stark recognized, the December 30 Decision was "the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies." *AstraZeneca*, 2021 WL 2458063, at *6. Before that, the agency was on record that it could not "compel" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Mirga, *supra*; *see* Lilly MSJ 6-7. And before ***that***, covered entities could only use one contract pharmacy apiece. *See* 61 Fed. Reg. at 43,551-55 (1996 guidance); p. 6, *supra*.

That precludes the government's attempt to rely on *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984). *See* Reply 32 & n.12. For, as even the government admits, "the regulated entity in that case had been aware of the statutory obligation to relinquish its property in exchange for a valuable

[10] The Reply contends that the agency's mandate furthers the "objectives" of the statute. Reply 33. The GAO begs to differ. *See* GAO-20-108, at 5 (Dec. 2019), https://bit.ly/34Vj6zK (340B discounts often not passed onto patients); GAO-11-836, *supra*, at 28 (contract pharmacy usage "creates more opportunities for drug diversion compared to in-house pharmacies"). Leading researchers do too. *See, e.g.*, Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 N. End. J. Med. 539 (Feb. 8, 2018). But this dispute is ultimately irrelevant to Lilly's claim because, under the agency's determination, ***private parties*** receive the taken property—and "[n]o amount of compensation can authorize such action." *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 543 (2005).

government" benefit when it chose to opt in. *Id.* But the opposite is true here: It was not until ***last December***, decades after Lilly started participating in the 340B program, that HHS first publicly articulated the position that manufacturers are required to deliver discounted drugs to an unlimited number of contract pharmacies—and Lilly filed a lawsuit challenging the new requirement within weeks. That is the opposite of consent. *Monsanto* thus "provides [the agency] no refuge." *Id.*

Second, it makes no difference that Lilly is still participating in the 340B program despite the May 17 Determination letter's demands. The Supreme Court has made clear that the government may not treat a party's participation in a federal spending program as "voluntary" acquiescence in whatever coercive, unconstitutional conditions the government may attach to it. Rather, that is "economic dragooning" that leaves you with "no real option but to acquiesce" to the government's preferred policy. *NFIB v. Sebelius*, 567 U.S. 519, 582 (2012). That is exactly the case here: The agency is demanding that Lilly agree to provide massive 340B discounts on contract pharmacy sales, or else lose access to the Medicare and Medicaid programs that provide a sizable share of its revenues. *See generally Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019) (noting that "Medicare stands as the largest federal program after Social Security" and "spends about $700 billion annually to provide health insurance for nearly 60 million aged or disabled Americans, nearly one-fifth of the Nation's population"). Such a "financial 'inducement' … is much more than 'relatively mild encouragement'—it is a gun to the head." *NFIB*, 567 U.S. at 581. Indeed, it is much more significant than the financial threat in *NFIB*; if Lilly opted out of Medicaid, Medicare, and 340B, it would lose much more than the states stood to lose under the ACA (10% of their budgets). Nor is what "the government demands" of Lilly here remotely proportional to whatever minimal "social cost" might exist by virtue of Lilly's refusal to give for-profit contract pharmacies access to 340B discounts. *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606, 614 (2013); *see also Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987); *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994). The government cites nothing to the contrary.

And history confirms the point; after all, the 340B program operated without issue for decades before the agency reached its new contract-pharmacy-delivery-obligation interpretation.

The government's only response is to deny that any of those seminal cases—*NFIB, Nollan, Dolan,* and *Koontz*—applies here. That, too, is demonstrably wrong. As for *NFIB*, the government says it only applies to cases involving states seeking to protect their federalism interests. But *NFIB* never says that, and there is no reason to believe that the government is allowed to violate the constitutional rights of states but not of the people. Indeed, that is backwards: The point of federalism is to protect the individual liberties the Constitution secures. *See, e.g.*, *Bond v. United States*, 564 U.S. 211, 222 (2011). So, whether the affected party is a state seeking to protect its constitutional federalism interests or a business seeking to protect its constitutional property interests, the Constitution forbids the government from "using financial inducements to exert a 'power akin to undue influence'" just the same. *NFIB*, 567 U.S. at 577 (citation omitted). When "the total withdrawal of federal funding … would be ruinous," *NFIB* governs. *Doe v. Univ. of Sciences*, 961 F.3d 203, 213 (3d Cir. 2020).

The government next claims that *Koontz*, *Nollan*, and *Dolan* are inapplicable because (the government insists) "the Supreme Court has doctrinally delimited the applicability of these three decisions to 'the special context of exactions' in land-use permitting decisions." Reply 35 (quoting *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687, 702-03 (1999)). But if that were true, then the government would be able to impose unconstitutional conditions on all manner of federal benefits so long as they did not involve land-use exactions. As for the dicta in *City of Monterey* that the government cites, *see id.*, the Supreme Court's most recent ***holding*** on this issue makes clear that the government is wrong. Just last month, the Supreme Court applied the "framework" from *Nollan*, *Dolan*, and *Koontz* outside the land-use permitting context to "government health and safety inspection regimes." *Cedar Point*, 141 S. Ct. at 2079. Indeed, *Cedar Point* explicitly stated, in its reasoning, that the *Nollan-Dolan-Koontz* proportionality framework is relevant whenever the government's "grant of a

benefit" hinges on an appropriation of property, regardless of whether the benefit is "a permit, license, or registration," is "allowing access" to property, or is something else. *Id.* In all events, any doubt as to the applicability of this framework to the government's current attempt at economic coercion should be resolved in favor of Lilly—for as the Supreme Court recently reiterated, the "protection of property rights is 'necessary to preserve freedom.'" *Id.* at 2071.

With nowhere else to turn, the government is left to rely on *St. Francis Hospital Center v. Heckler*, 714 F.2d 872 (7th Cir. 1983). *See* Reply 32. But *St. Francis* is no help to the government, either. In fact, *St. Francis* ***does not even mention***, let alone apply, the unconstitutional conditions doctrine. *St. Francis* has nothing to say about this issue because it literally says nothing about it.

In sum: The agency's directive to Lilly to give its property away to other private parties through contract pharmacy arrangements is a taking. Lilly has never acquiesced in that taking, and the government cannot dragoon Lilly into doing so by threatening to exclude it from Medicare and Medicaid. At a minimum, the serious constitutional concerns raised by the agency's view counsel against adopting its interpretation without a clear mandate from Congress. Federal courts must "avoid an interpretation of a federal statute that engenders constitutional issues if a reasonable alternative interpretation poses no constitutional question." *Gomez v. United States*, 490 U.S. 858, 864 (1989); *see* Lilly MSJ 33. Here, that is a simple task, as Lilly's interpretation of the statute is unquestionably reasonable; indeed, a federal court has already held as much, *see AstraZeneca*, 2021 WL 2458063, at *8 n.14. This Court should therefore reject the May 17 Determination and set it aside as contrary to law.

II. The May 17 Determination Is Arbitrary And Capricious.

Even if the 340B statute could be construed to permit HHS to require manufacturers to deliver to contract pharmacies, the May 17 Determination would still be invalid under the APA because it is arbitrary and capricious. The May 17 Determination rests on the government's erroneous view that it extends a long-held and consistent agency position (it does not) and that the 340B statute's text

unambiguously requires the complicated contract pharmacy rules the agency now favors (it does not). Besides that, the agency resolved claims that covered entities have been overcharged without ever hearing from Lilly, despite explicitly telling this Court that such a determination should be made in ADR, and without considering a multitude of factors directly relevant to implementation of the 340B program. None of that is consistent with the APA's requirements.

A. HHS Failed to Acknowledge, Let Alone Explain, its Change in Position.

Under the APA, an agency must "display awareness that it ***is*** changing position" and "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *accord Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016). The agency failed to do so here. Chief Judge Stark correctly held that HHS's December 30 Decision was "the first document in which HHS explicitly concluded that ***drug manufacturers*** are required ***by statute*** to provide 340B drugs to ***multiple*** contract pharmacies." *AstraZeneca*, 2021 WL 2458063, at *6. Previously, the agency only ***permitted*** a ***single*** contract pharmacy per covered entity. The May 17 Determination nonetheless asserts that HRSA has been "consistent[] since the issuance of its 1996 contract pharmacy guidance." VLTR_3. That is false—and so is the Reply brief's repetition of the party line, *see, e.g.*, Reply 14, 15. Indeed, the fact that the government can only reconcile its current position with the 1996 guidance by saying that the latter was wrong—an extraordinary claim, since that guidance applied for 14 years—crystalizes that the government has changed positions. *See AZ* Tr. at 67:6-20.

The May 17 Determination also contradicts the agency's prior public pronouncements. For instance, HRSA told Lilly in writing in June 2020 that the 1996 and 2010 "contract pharmacy advice" were not "binding" on manufacturers. VLTR_7590. HRSA publicly reiterated that viewpoint one month later, telling a 340B-focused publication that "[t]he 2010 guidance … is not legally enforceable," and that it could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." Mirga, *supra*. And, as the administrative record reveals, the agency persisted

throughout 2020 in telling covered entities that although "HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy," it "has only limited ability to issue enforceable regulations" in light of what it then described as the lack of "authority" to so demand. *E.g.*, VLTR_3272, VLTR_3285, VLTR_4194; *see Am. Hosp. Ass'n v. HHS*, 2021 WL 616323, at *3 (quoting HRSA correspondence). The agency did not grapple with any of this in issuing the May 17 Determination; instead, it pretended that it does not exist.

The May 17 Determination also abandons the position that the agency had announced just months before, in the December 30 Decision. The December 30 Decision stated that participating manufacturers are obligated to provide 340B discounts only "***to the extent***" that a contract pharmacy is acting as an agent of the covered entity. VLTR_8048 (emphasis added). The May 17 Determination does away with all of that, with no explanation. The government now tries to reconcile that by insisting that the December 30 Decision included a discussion of agency relationships "merely as an example" and only "to creat[e] a helpful analogy to rebut manufacturers' claims of diversion, not a prerequisite to the application of statutory requirements." Reply 28. Nonsense: The core reasoning of the December 30 Decision was "that the covered entity and contract pharmacy are not distinct, but function as principal-agent." VLTR_8048; *see also* VLTR_8049-55.

When an agency adopts a position that is "radically different" from the agency's previous views, the APA requires the agency to "show that there are good reasons for the new policy." *Cook Cty. v. Wolf*, 962 F.3d 208, 230 (7th Cir. 2020). Because the agency failed to do so, or even to acknowledge the change, the May 17 Determination must be set aside.

B. HHS Erroneously Concluded that the 340B Statute Unambiguously Compels its Latest Interpretation.

Agency action "must be declared invalid, even though the agency might be able to adopt the regulation in the exercise of its discretion, if it was not based on the agency's own judgment but rather on the unjustified assumption that it was Congress' judgment that such a regulation is desirable or

required." *Am. Lung Ass'n*, 985 F.3d at 944. That dooms the May 17 Determination, which, just like the agency's December 30 Decision before it, "is based on the 'unjustified assumption' that Congress imposed [HRSA's] interpretation as a statutory requirement." *AstraZeneca*, 2021 WL 2458063, at *11; *see also* Reply 31, 37 (again claiming that the text unambiguously compels the government's view). Accordingly, even if the Court believes that the 340B statute is "ambiguous with respect to the central issue in this case" (namely, whether "drug manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies") ***and*** that the agency's "current interpretation of the statute is permissible," 2021 WL 2458063, at *9, *11, the Court ***still*** must set the May 17 Determination aside.

There is actually a deeper problem here. In December 2020, the GAO issued a report noting that HRSA had declined to address the problem of covered-entity diversion via their contract pharmacy partners ***because, in HRSA's own view, "the 340B statute does not address contract pharmacy use and, therefore, there may not have been a clear statutory violation***" by the covered entity. GAO, GAO-21-107, at 15-16, https://bit.ly/3hfFVD8 (emphasis added); *see also id.* ("HRSA did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other measures as set forth in guidance ***because the 340B statute does not address contract pharmacy use***." (emphasis added)). The May 17 Determination is thus flatly inconsistent with what HRSA told the GAO just last year. Worse, the GAO report reveals that the agency is trying to have it both ways: It simply cannot be the case that covered entities get a free pass to engage in diversion, "because the 340B statute does not address contract pharmacy use," *id.*, but manufacturers are required to deliver to an unlimited number of contract pharmacies, because the statute unambiguously requires that result, *see* Reply 31 (arguing that "the 340B statute offers but 'one plausible construction,'—that drug makers must sell 340B-discounted drugs to covered entities irrespective of their method of distribution" (citation omitted)). The agency may believe that it has *carte blanche* to interpret the statute however it wishes, even in contradictory ways, based on its

interests at the moment, but the statute is not a mere nose of wax to be twisted this way and that. The APA makes clear that neither Lilly nor this Court is required to acquiesce in such an approach.

C. The Agency Failed to Consider Important Aspects of the Problem.

The APA also requires an agency to "examine the relevant data," *Sparre v. U.S. Dep't of Labor*, 924 F.3d 398, 402 (7th Cir. 2019), consider important aspects of the problem its regulations implicate or create, and "articulate a satisfactory explanation for its action." *State Farm*, 463 U.S. at 43. The agency failed to do so here on a number of fronts. First, the agency did not address the known abuses of contract pharmacies or the lack of oversight by covered entities. It made no mention of the HHS-OIG report that found (a) that "most covered entities … do not conduct all of the oversight activities recommended by HRSA," which leads to "vulnerabilities to the 340B Program," and (b) that, as things stand now, contract pharmacies receive discounts on drugs that are not even dispensed to 340B patients. VLTR_7968, 7979. Worse still, the agency completely ignored the GAO's findings that "HRSA's oversight of the 340B program is inadequate to provide reasonable assurance that covered entities … are in compliance with program requirements." GAO-11-836, *supra*, at 1. That same report found that the use of contract pharmacies "may result in a greater risk of drug diversion," and that the "self-policing" scheme allowed by HRSA did not provide adequate oversight. *Id.* at 28. Lilly has regularly cited this report, *see, e.g.*, Lilly MSJ 29, yet it does not appear in the administrative record—and "an agency's refusal to consider evidence bearing on the issue before it constitutes arbitrary agency action within the meaning of § 706." *Butte Cty. v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010).

Second, the government relies heavily on the now-25-year-old finding that most 340B entities did not have in-house pharmacies in 1996. *See, e.g.*, Reply 25, 38-39. But that finding has never been updated, and we know that it cannot still be true, given that many covered entities continue today to buy 340B drugs directly from Lilly. *See* Dixson Decl. ¶ 11. What is more, the agency previously believed that this fact justified a one-contract-pharmacy-per-covered-entity policy for 14 years; it has

never explained why the same finding, even if it is still true (which, again, it almost certainly is not), now ***requires*** manufacturers to deliver to an unlimited number of contract pharmacies.

Third, the administrative record lacks ***even a single contract*** between a covered entity and a pharmacy setting forth which one takes title (and when), or even who actually pays for them. That means the agency has no idea whether covered entities ever take title, much less maintain it, or are actually doing anything else they claim. It also means that the agency does not, and cannot, know whether the complaints in the administrative record reflect arrangements in which covered entities actually (or even nominally) purchase drugs and contract pharmacies merely dispense them. Nor can the agency have any factual basis for the bald, unsubstantiated assertion that contract pharmacy fees are "reasonable," Reply 24, which seems dubious in light of the contract pharmacies' own SEC filings, *see, e.g.*, Walgreens 10-K, *supra*, at 23. That might explain why the government cites ***nothing*** to support that claim (and does not even try to describe how much the fees are, what makes them reasonable, or how their size furthers the purpose of the statute). Nor does the May 17 Determination (or the Reply) offer any facts or even reasoning to substantiate the assertion that "Lilly's 'pass on the entire discount' restriction [for insulins] is not reasonable or workable in practice." Reply 23-24. For good reason: That assertion is false. Lilly manages to sell these products for a penny; the least a for-profit contract pharmacy could do is pass that discount along. Had the agency said anything about this, it could not have reasonably called pass-ons "unworkable" for a for-profit pharmacy and "mandatory" for Lilly. (Naturally, the agency failed to mention this issue at all, which itself was arbitrary and capricious.)

To be sure, the government's brief discusses some evidence in the agency's cherry-picked record. But most of what the government highlights is irrelevant to the legal issue before the Court. For instance, the government now states that "HRSA relied on clear evidence of the harm to covered entities and their patients in issuing the Violation Letter." Reply 28. But the fact that covered entities make less money under Lilly's policy has nothing to do with whether Lilly's policy violates the statute.

Relying on such evidence would thus be arbitrary and capricious by itself. Furthermore, the covered entity complaints the Reply repeatedly invokes (*e.g.*, VLTR_1335, 1460, 1607, 3116, 3316, 5834, 6645) merely reiterate the agency's own interpretative position; they provide no independent reason why Lilly's policy supposedly violates the law. The unsurprising fact that covered entities and contract pharmacies agree with HRSA has no bearing on whether Lilly's policy is unlawful under the statute—and the inclusion of complaints reiterating the government's position does nothing to change that.

Fourth, the agency failed to grapple with the reality that "large numbers of low-income patients" do not receive any discounts when they acquire drugs through contract pharmacies, H.R. Rep. No. 102-384, at 9, and that "uninsured patients" instead "pay the full non-340B price for their prescription drugs at contract pharmacies," even when they are eligible for 340B discounts and even when the contract pharmacy is purporting to act as a covered entity's common-law agent, HHS-OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 4, 2014), https://bit.ly/3eWKmBQ. Again, Lilly has raised these points before, but the agency made no mention of any of this in its letter; nor did it try to reconcile its approach with these well-documented abuses. Nor did it respond to objections about how the use of contract pharmacies has resulted in massive, unchecked, and unprincipled growth in the 340B program—or how increased contract pharmacy usage has increased diversion and has literally diverted money away from needy patients to retail pharmacy chains, which is obviously not what Congress had in mind when it created this program. *See, e.g.*, Walgreens 10-K, *supra*, at 23 (projecting that reduction in contract pharmacies' ability to participate in 340B "could also significantly reduce our profitability"); *see also* Raymond James, *supra*, at 1 (Walgreens generated profits "in the hundreds of millions" through 340B contract pharmacy arrangements); Ltr. from U.S. Sen. C. Grassley to G. Wasson (July 31, 2013) (noting the same). Instead, the agency ignored all of these concerns. The APA demands far more.

Fifth, HRSA failed to consider Lilly's side of the story. The government previously promised

the Court that it would: At oral argument on Lilly's PI motion challenging the ADR Rule, the government made clear 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***." Dkt. 95-3 at 76:24–77:3 (emphasis added). Yet, rather than wait for (a properly promulgated) ADR Rule, HRSA decided to act instead as prosecutor, judge, and executioner via the May 17 Determination, passing judgment "on the specifics of Lilly's new policy" all by itself, ***without ever hearing from Lilly***. That is the definition of "capricious."[11]

The administrative record shows the agency relied on coordinated, boilerplate covered entity complaints that misunderstood Lilly's policy, without seeking Lilly's response (or even giving it notice). *See* Background § D, *supra*. Among other things, HRSA essentially relied on half of its enjoined ADR process—the complaints—in making its unilateral determination, but with no opportunity for Lilly to respond. *See, e.g.*, VLTR_6807-7575. That means that covered entities received the benefit of a sympathetic adjudicator, but Lilly received no procedural safeguards (not even those of the defective ADR process). Indeed, the covered-entity complaints the government cites in its Reply seem to have been solicited by the agency. *See, e.g.*, VLTR_7884-7924 (meeting materials showing that HRSA met with covered entities and contract pharmacy groups, but not manufacturers); VLTR_1458 (covered entity telling HRSA "[w]e appreciate everything you are doing to help us and hope that this documentation is useful"). That should be shocking—as should the fact that ***the agency asked a covered entity lobbyist for guidance on 340B enforcement***, *see* VLTR_7923-24[12]—but it is difficult to call it surprising. HRSA has favored the interests of contract pharmacies from the get-go,

[11] The agency's refusal to hear from Lilly actually went deeper. Lilly tried for months to get a meeting with the agency to discuss 340B issues, *see* Exhs. C-H (correspondence), but the agency rebuffed Lilly.
[12] On April 29, 2021, agency officials asked for the lobbyist's "views" "[o]n contract pharmacies"; she responded (in person) by "[a]sking HHS to send letters to companies to cease [and] desist" their policies. VLTR_7924. On May 17, 2021—less than three weeks later—the agency did exactly that.

and it has bowed to political pressure at every turn. *See, e.g.*, VLTR_7660-62, 7675-76 (letters from Congress urging enforcement); Dkt. 95-4 (HHS Secretary Becerra promising Congress to "take swift enforcement action" against, *e.g.*, Lilly); *cf. Pillsbury Co. v. FTC*, 354 F.2d 952 (5th Cir. 1966) (holding that congressional interference with agency decisional process violated plaintiff's right to due process).

The Justice Department's only defense of this *ex parte* mode of adjudication offered in Reply is legally erroneous. The Reply claims that the agency had no obligation to hear from Lilly before making a final "determination" about its guilt because Lilly should air its side of the story in the ADR process. Reply 27. That is wrong as a matter of fact: The May 17 Determination does not purport to give Lilly any wiggle room to fight it out with covered entities in ADR (under a new, properly promulgated Rule); instead, it explicitly instructs Lilly to immediately "credit or refund all covered entities for overcharges that have resulted from Lilly's policy." VLTR_4. It is also wrong as a matter of law: Even if the ADR Rule were not enjoined, Lilly could not bring an ADR claim against the agency to challenge HRSA's determination that Lilly's policy is invalid, because ADR does not permit manufacturers to bring claims ***against the agency***; it only covers disputes between manufacturers and covered entities against one another. *See* 42 C.F.R. §§ 10.21-10.24. In any event, the government's justification smacks of retaliation against Lilly for seeking an injunction of its defective ADR process.

Simply put, the process Lilly received cannot even be called inadequate; it was trial *in absentia*, in which the verdict was preordained. It would be hard to conceive of more arbitrary agency action.

Indeed, nothing the agency has done in this matter is consistent with administrative law. As discussed above, the 340B statute itself does not contain the contract pharmacy mandates that HRSA favors, much less unambiguously. If the agency wanted to decide, as a general matter, that drug manufacturers "are required to deliver 340B drugs to an unlimited number of contract pharmacies," *AstraZeneca*, 2021 WL 2458063, at *9, then it needed to proceed via notice-and-comment rulemaking, which "is mandatory" when an agency seeks "to impose legally binding obligations … on regulated

parties … that would be the basis for an enforcement action." *Hoctor v. U.S. Dep't of Agric.*, 82 F.3d 165, 169 (7th Cir. 1996); *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014). Perhaps the agency failed to do so because Congress "granted HHS … specifically limited" "rulemaking authority," which does not encompass imposing new obligations on manufacturers. *PhRMA v. HHS*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014); *see also id.* ("HHS has not been granted broad rulemaking authority to carry out all the provisions of the 340B program."). In the alternative, if the agency wanted to decide that Lilly's policy in particular is inconsistent with what the statute ***now*** says, then it needed to comply with the APA's requirements for formal adjudications. *See Pension Ben. Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 655 (1990) (formal adjudications require "that parties be given notice of 'the matters of fact and law asserted,' § 554(b)(3), an opportunity for 'the submission and consideration of facts [and] arguments,' § 554(c)(1), and an opportunity to submit 'proposed findings and conclusions' or 'exceptions,' § 557(c)[]"). But that would require the agency to listen to both sides—and, here, it refused even to include Lilly's briefs before this Court as part of its administrative record, while including its own. *See* p. 12, *supra*. That says it all. The agency's behavior represents the paradigmatic case of arbitrary behavior that the APA was designed to control. This Court should set the May 17 Determination aside and require the agency to abide by regular order and the rule of law.

III. The ADR Rule Is Procedurally And Substantively Defective.

A. The ADR Rule Needed to Proceed via Notice and Comment, But Did Not.

The ADR Rule violates the APA's notice-and-comment requirements in two ways.

First, this Court has already found that "a withdrawal of the NPRM was effected, thus requiring the agency to have engaged in notice-and-comment procedures before promulgating the final ADR Rule, which it failed to do." PI Order 23. That conclusion was and remains correct. In violation of the APA's demand for "fair notice," the agency "effectively communicated a withdrawal of the proposed rule to the public" "through [its] actions and statements." *Id.* at 21 (quotation marks

omitted). The agency removed the NPRM from the Unified Agenda on August 1, 2017, "without any explanatory comment." *Id.* at 9. That may have been enough on its own to necessitate another round of notice and comment if the government wanted to issue a new ADR Rule, because it meant that the NPRM was publicly declared a "Completed Action," *see* HHS/HRSA, *View Rule, RIN: 0906-AA90* (Spring 2017), https://bit.ly/2ZydLLo, which is a status reserved for "rulemakings that are being Withdrawn or ending their lifecycle with a regulatory action that completes the rulemaking," HHS/HRSA, *About the Unified Agenda*, https://bit.ly/2OYh3FZ. But there is far more here than just the NPRM's removal from the Unified Agenda. "More than two and a half years of agency silence regarding any pending ADR rulemaking followed the NPRM's removal from the Unified Agenda." PI Order 22. The next thing the public heard was a statement from a HRSA official in March 2020 "that, absent additional congressional authority, there were no plans to engage in rulemaking with regard to the ADR process." *Id.* "Approximately nine more months of silence ensued." *Id.* HHS then issued its "'surprise edict' in December 2020 that a final ADR Rule was being promulgated." *Id.* Finally, the new Rule "was given a different RIN from the NPRM." *Id.*; *compare* 81 Fed. Reg. 53,381 , *with* 85 Fed. Reg. 80,632. "Considering these actions and circumstances together, the agency's message regarding the ongoing rulemaking related to the ADR Rule was ambiguous, confusing, duplicitous, and misleading—the antithesis of fair notice under the APA." PI Order 23. That means that the government was required to proceed anew through notice and comment before it could issue a final Rule. But "it failed to do" so. *Id.* The ADR Rule therefore must be set aside under the APA.

The government's Reply offers no new arguments to contest that conclusion beyond those the Court has already rejected. Just like at the PI stage, the government cannot "point[the Court] to any case law, provision in the APA, or regulation of the Office of the Federal Register which requires notice of the withdrawal of an NPRM to be published in the Federal Register to be considered effective." *Id.* at 21. That is because no such authority exists. Indeed, since the Court issued its PI

Order, the government has not cited a single new case on this issue other than *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519 (1978), which, as Lilly has already explained, underscores why the ADR Rule is invalid. *See* Lilly MSJ 42-43. In short, the Court was right when it entered a preliminary injunction, and nothing has changed in the interim. The Court should enter final judgment for Lilly.

Second, even if the NPRM had not been withdrawn, a new round of notice and comment would still be required because the final Rule is not a logical outgrowth of it. The government claims that all an agency must do to satisfy the logical outgrowth requirement is provide regulated parties with "notice of the topics" that the final rule will "cover[]." Reply 51. That is not the law. In reality, a final rule fails the logical outgrowth test if it "deviates too sharply from the proposal," because, in such a case, "affected parties will be deprived of notice and an opportunity to respond to the proposal." *Public Citizen, Inc. v. Mineta*, 427 F. Supp. 2d 7, 14 (D.D.C. 2006). Here, prior to the "surprise edict" in December 2020, the agency gave no notice that ADR would authorize money damages on top of refunds (and CMPs); the NPRM did not provide for money actions at all. But the final Rule authorizes aggrieved parties to file "***action**[**s**] **for monetary damages***" on top of seeking refunds. 42 C.F.R. § 10.21(a) (emphasis added); *see also, e.g.*, *id.* § 10.21(f). Nor did the NPRM provide any notice that ADR panels could issue injunctions, or that their decisions would be "precedential." *See* Lilly MSJ 44-45. The final Rule thus fails the logical outgrowth test. For as even the (sole) case the government cites on this issue makes clear, "a rule will be invalidated if no notice was given of an issue addressed by the final rules." *Am. Med. Ass'n v. United States*, 887 F.2d 760, 768 (7th Cir. 1989).

For those reasons, and for the reasons explained in Lilly's preliminary injunction briefing, *see* Dkt. 19 at 15-31, the Court should enter final judgment for Lilly on its claim that the ADR Rule was issued in violation of the APA's notice-and-comment rules; issue an order setting the ADR Rule aside under the APA; and permanently enjoin the government from enforcing the Rule against Lilly.

B. The ADR Rule Violates Article II.

In *United States v. Arthrex, Inc.*, the Supreme Court reaffirmed that Article II is violated when Executive Branch officers who were not properly appointed to a principal office "have the 'power to render a final decision on behalf of the United States.'" 141 S. Ct. 1970, 1981 (2021) (quoting *Edmond v. United States*, 520 U.S. 651, 665 (1997)). That decision requires invalidation of the ADR Rule.

The constitutional problem in *Arthrex* concerned administrative patent judges ("APJs"), who have even ***less*** independent authority than ADR panels do now. The *inter partes* review process administered by APJs begins when a private party files "a petition to institute an inter partes review of the patent," 35 U.S.C. § 311(a); the patent holder files a response, *see id.* § 313; a three-APJ panel, comprised entirely of Executive Branch officials appointed in the manner of inferior officers (*i.e.*, by a principal officer, not by the President), reviews the claims, *id.* § 6(c); and, at the end, the APJ panel issues a decision on IPR similar to an ADR panel decision, *see* 37 C.F.R. § 42.71. But, ***unlike*** here, the three-APJ panel decision is not always the Executive Branch's final word; rather, the statute at issue in *Arthrex* explicitly authorizes the "Patent Trial and Appeal Board" ("PTAB"), an Executive Branch entity, to "rehear[]" APJ panel decisions. 35 U.S.C. § 6(c); *see also* 37 C.F.R. § 42.71. *Arthrex* nevertheless held that this scheme violates Article II. *See* 141 S. Ct. at 1981.

The ADR system is on all fours with the scheme invalidated in *Arthrex*, except that ADR is worse. Just like APJs, ADR Board members are Executive Branch officers subject to the Appointments Clause. Just as the Commerce Secretary appoints APJs, the HHS Secretary appoints ADR Board members. *See* 86 Fed. Reg. 33,317-01 (June 2021). And just as APJs are empowered to issue "final" "decision[s]" on IPR claims when they sit in three-member panels, 37 C.F.R. § 42.71(c), ADR Board members are empowered to render final decisions on ADR claims when they sit as three-member panels: "[T]he decision of a majority of the [three-member] 340B ADR Panel[]" "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by

an order of a court of competent jurisdiction." 42 C.F.R. § 10.24(b)-(d); *see* 42 U.S.C. § 256b(d)(3)(C). Thus, in both cases, lower-level Executive Branch officials were given power to render final decisions without the review of any Senate-confirmed principal officer who can ***reverse*** that decision before it becomes final. Indeed, the ADR Rule gives the panel members' nominal superior even ***less*** of a role than the scheme in *Arthrex* did; unlike there, the 340B statute does not authorize internal Executive Branch rehearing, period. Instead, only "a court of competent jurisdiction" can review the merits of ADR panel decisions. 42 U.S.C. § 256b(d)(3)(C). That violates Article II under *Arthrex*.

Rather than accept its recent loss and move on, the government contorts the plain text of the 340B statute and the ADR Rule in a futile attempt to distinguish *Arthrex*. It then turns to relitigating *Arthrex* in this Court, repeating the same arguments the Supreme Court just rejected.

1. The government's defense depends on the premise that "the Secretary freely may exercise discretionary review of panel decisions." Reply 42. The government repeats this assertion over and over. *See, e.g.*, *id.* at 41, 45. It is wrong. Under the unambiguous terms of the statute and the ADR Rule, the Secretary has no authority to review the merits of ADR panel decisions; the administrative resolution of ADR claims is ***final*** when a three-member panel issues its decision. The 340B statute could not be clearer on this point: "The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." 42 U.S.C. § 256b(d)(3)(C). The Rule defines "[t]he agency decision" to mean "the decision of a majority of the 340B ADR Panel[]," and it provides that that "agency decision" not only is "final," but will be "precedential and binding on the parties involved ***unless invalidated by an order of a court of competent jurisdiction***." 42 C.F.R. § 10.24(c), (d) (emphasis added); *see, e.g.*, *id.* § 10.21(b) (discussing "the 340B ADR Panel's final agency decision"). Neither one says that ADR panel decisions are final "unless invalidated by a court of competent jurisdiction ***or by the Secretary***."

Despite this clear text, the government now contends that a separate provision of the 340B statute, 42 U.S.C. § 256b(d)(3)(B)(i), implicitly permits the Secretary to do what § 256b(d)(3)(C) and the ADR Rule unambiguously prohibit. *See* Reply 41-45. Not so. All § 256b(d)(3)(B)(i) says is: "Regulations promulgated by the Secretary [about ADR] shall—(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving [ADR] claims." It does not say a word about finality or the Secretary's supposed ability to review ADR panel decisions. In contrast, § 256b(d)(3)(C)—titled "Finality of administrative resolution"—could not be clearer that the only entity that can "invalidate[]" an ADR panel decision is "a court of competent jurisdiction."

Simply put, there is not one iota of textual support for the government's assertion that "the Secretary freely may exercise discretionary review of panel decisions." Reply 42. Nor is there any "ambiguity" on this point; the Secretary has no "authority to reverse the decisions" of ADR panels on the merits. *See id.* at 42 n.19, 43. To be sure, the Rule allows HRSA to take "appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities" once "[t]he 340B ADR Panel [has] submit[ted] the final agency decision to all parties, and to HRSA." 42 C.F.R. § 10.24(e). But that just proves Lilly's point: Under the statute and Rule, no principal officer has any role until ***after*** a panel has already "final[ly]" decided an ADR claim—and even then, his only role is to effectuate a remedy; he cannot review, revise, or reverse the panel decisions on the merits. Just as in *Arthrex*, then, these "restrictions on the [Secretary]" unconstitutionally "insulate the decisions of [ADR panels] from … direction and supervision." *Arthrex*, 141 S. Ct. at 1988 (op. of Roberts, C.J.).

2. The government next tries re-waging the battle it just lost by repeating the same arguments *Arthrex* rejected. The government claims that any Article II problem here is cured by the fact that the Secretary "may freely remove ADR Board members at will." Reply 43. The government said the same thing in *Arthrex*, too: It said there was no Article II problem because "the [PTO]

Director may respond after the fact by removing an APJ 'from his judicial assignment without cause' and refusing to designate that APJ on future PTAB panels." 141 S. Ct. at 1982 (majority op.). The Supreme Court disagreed. "Even assuming that" the Director could remove APJs without cause, the Article II problem would stay the same, because "reassigning an APJ to a different task going forward gives the Director no means of countermanding the final decision already on the books." *Id.* The analysis here is the same: Even if the Secretary has plenary authority to remove ADR Board members, he still has "no means of countermanding [a] final decision" issued by an ADR panel, *id.*, because only "a court of competent jurisdiction" can do so, 42 U.S.C. § 256b(d)(3)(C); *accord* 42 C.F.R. § 10.24(d). The Secretary thus cannot use his ***removal*** authority vis-à-vis ADR Board members, however powerful it may be, to solve the Article II problem with his lack of ***review*** authority.

Arthrex leaves no room for doubt on this score; it rejected as constitutionally inadequate even stronger "indirect" means of influencing APJs decisions. The government argued in *Arthrex* that the Director of the PTO (a principal officer) had sufficient supervisory authority over the work of the APJs by virtue of his power to decide who would sit on rehearing panels. The Supreme Court disagreed. The Court did not dispute that the Director could use his authority over the PTAB to "stack" rehearing panels "with additional APJs assumed to be more amenable to his preferences," or even that he could "assemble an entirely new panel consisting of himself and two other officers appointed by the Secretary … to decide whether to overturn a decision and reach a different outcome binding on future panels." *Arthrex*, 141 S. Ct. at 1981. But such a roundabout means of supervision "is not the solution." *Id.* What matters under Article II is whether a principal officer who is directly accountable to the President can "take responsibility for the ultimate decision" issued on behalf of the United States. *Id.* Thus, the mere fact that a principal officer could engage in "machinations" to generate his desired outcome after a panel has issued its decision does not solve the problem, because the initial, final decision was still rendered by officers not subject to direct supervision. *Id.* at 1982.

So too here. Regardless of the Secretary's authority to fire ADR Board members after the fact or to tinker with the remedy under 42 C.F.R. § 10.24(e), *see* p. 50, *supra*, "the buck stops with the [ADR Board members], not with the Secretary," "[i]n all the ways that matter to the parties who appear before the [ADR panel]," because it is the panel decision that "final[ly]" resolves the rights at issue in ADR claims, and it is the panel decision that "bind[s]" the parties involved. 141 S. Ct. at 1982. As in *Arthrex*, ADR Board members "exercise power that conflicts with the design of the Appointments Clause," *id.*, and their authority to finally decide claims that may be invalidated only by an Article III court "is incompatible with their appointment by the Secretary to an inferior office," *id.* at 1985.

3. That leaves only the question of remedy, *i.e.*, "the appropriate way to resolve this dispute given this violation of the Appointments Clause." *Id.* at 1986 (op. of Roberts, C.J.). In *Arthrex*, a majority held that the statutory restriction on the Director's ability to review APJ-panel decisions was unconstitutional, and a different majority held that the proper remedy for that constitutional violation was to hold the offending part of the statute "unenforceable as applied to the Director insofar as it prevents the Director from reviewing the decisions of the PTAB on his own." *Id.* at 1987 (op. of Roberts, C.J.); *see id.* at 1997 (op. of Breyer, J.) ("agree[ing] with [that] remedial holding").

But this case does not require complicated severance analysis into what Congress would choose; the required remedy is straightforward and prescribed by law. As the government notes, *see* Reply 42 n.19, Lilly's challenge is to the ADR Rule, a regulation. And the APA prescribes the remedy when it comes to regulations that are "contrary to constitutional right, power, privilege, or immunity"; in such a case, a "reviewing court ***shall*** … hold [the regulation] unlawful and set [it] aside." 5 U.S.C. § 706(2). The Court should therefore set aside the ADR Rule as contrary to constitutional right.

C. The ADR Rule Violates Article III.

The ADR Rule also violates Article III. "When a suit is made of the stuff of the traditional actions at common law tried by the courts at Westminster in 1789 … the responsibility for deciding

that suit rests with Article III judges in Article III courts." *Stern v. Marshall*, 564 U.S. 462, 484 (2011). The quintessential "traditional actions at common law" were suits between private parties for money damages. And yet rather than leave such quintessential private-party disputes where they belong—with the courts—the ADR Rule assigns them to Executive Branch policy officials, vesting "340B ADR Panel[s]" with exclusive original "jurisdiction" over any "action" for "monetary damages or equitable relief" brought by a "covered entity" claiming that it "has been overcharged" by a manufacturer. 42 C.F.R. § 10.21(a)-(c). This end-run violates the Constitution.

1. On its face, the ADR Rule authorizes Executive Branch employees to decide traditional private lawsuits. Despite previously fighting tooth-and-nail about "the scope of the Board's remedial powers," *see, e.g.*, Dkt. 32 (Defs.' PI Opp.) at 19-22, the government no longer contests that ADR panels can award "damages," *see* Reply 45. That is wise, as the ADR Rule could not be clearer: "The 340B ADR Panel shall have jurisdiction to entertain any petition where ***the damages sought*** exceed $25,000 … provided the petition asserts claims of the type set forth [in § 10.21(c)]." 42 C.F.R. § 10.21(b); *see also id.* § 10.21(a) ("action for monetary damages"); *id.* § 10.21(f) ("proceeding for damages"). The Rule is not quite as explicit when it comes to injunctions, but it authorizes "equitable relief" without qualification, and the quintessential form of equitable relief ***is an injunction***—not, as the government claims, something that "resemble[s] a cease-and-desist demand." Reply 52.

That is enough to illustrate the Article III problem. The Rule undisputedly authorizes Executive Branch policy officials to compel private parties to give their property to other private parties. Under the Constitution, the power to authorize the deprivation of private property is precisely what demarcates the exclusive province of the Article III courts. *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 275 (1856). And in our system of government, no one can "confer the Government's 'judicial Power' on entities outside Article III." *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1372-73 (2018) (quoting *Stern*, 564 U.S. at 484). Because

that is exactly what the ADR Rule does, it is inconsistent with Article III.

2. This case does not fit within any exception to that general constitutional principle.

First, ADR panel members are not "adjuncts" to an Article III court. *See generally Crowell v. Benson*, 285 U.S. 22, 51-52 (1932). Unlike magistrate judges, *see* 28 U.S.C. § 636(b)(1), ADR panels are not mere factfinders, and they do not issue mere legal recommendations. Rather, their decisions are "final," they are "precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction," 42 C.F.R. § 10.24(b)-(d), and they resolve "action[s] for monetary damages" between private parties, *id.* § 10.21(a); *see also id.* § 10.21(b)-(f). The ADR Rule thus finds no refuge in the doctrinal safe harbor allowing "executive officials" to "find[] facts, or apply[] law to those facts, ***so long as*** [***they***] ***do***[] ***not authorize the deprivation of life, liberty, or property***." William Baude, *Adjudication Outside Article III*, 133 Harv. L. Rev. 1511, 1542 (2020) (emphasis added).

The fact that Article III courts can "invalidate[]" ADR panel decisions on appeal, 42 U.S.C. § 256b(d)(3)(C), makes no constitutional difference. That is because, unlike in *Crowell v. Benson*, here, an Article III court may review ADR panel decisions ***only*** under the sort of "deferential standard" that the Supreme Court "found lacking in *Northern Pipeline*." *CFTC v. Schor*, 478 U.S. 833, 853 (1986); *see N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 82 (1982); *see also* Lilly MSJ 54. Unlike in those other cases, no Article III court can take a fresh look at the issues ADR panels finally resolve in damages actions. "The judicial Power" therefore cannot be said to rest where it belongs.

Second, this case does not fit within the public rights doctrine. The government contends that ADR "involve[s]" nothing more than "the adjudication of entirely ***new*** rights, created by Congress." Reply 46. That is wrong. The right to sell one's property at the prevailing market price—along with the right ***not*** to give it to someone else below cost, *i.e.*, the right to exclude—is one of the most basic private rights in existence. Indeed, "the free use, enjoyment, and disposal of all [one's] acquisitions, without any control or diminution," 4 William Blackstone, *Commentaries* 129 (expounding

"right of private property"), was one of the three "core private rights" at common law. Caleb Nelson, *Adjudication in the Political Branches*, 107 Colum. L. Rev. 559, 618 (2007). The fact that ADR panels can issue "final" adjudications depriving Lilly of its core private rights is the Article III problem.

That problem is not cured just because covered entities' ADR ***claims*** for "overcharging" exist only as a result of the 340B statute. The government asserts that what matters for Article III is "***the nature of the claim asserted***," not the nature of the ***rights*** being adjudicated. Reply 46.[13] But, as Justice Breyer lamented in his *Stern* dissent, the Supreme Court has squarely rejected that argument. 564 U.S. at 513 (Breyer, J., dissenting) (arguing in defeat that "[t]he presence of 'private rights' [should] not automatically determine the outcome of the question"). And for good reason: If all newly created federal ***claims*** could be resolved by Executive Branch policy officials without any direct Article III involvement and without regard to what ***rights*** might be at stake (particularly for the defendants) in such proceedings, "then Article III would be transformed from the guardian of individual liberty and separation of powers we have long recognized into mere wishful thinking." *Stern*, 564 U.S. at 495 (majority op.). That is why the public rights doctrine is the public ***rights*** doctrine, not the public ***claims*** doctrine. In sum, the fact that "the novel claims for 'overcharging,' 'diversion,' and 'duplicate discounting'" here exist only because of the 340B statute, Reply 47, is no answer to the problem.

Nor can *Thomas v. Union Carbide Agricultural Products Co.*, 473 U.S. 568 (1985), aid the government. In *Union Carbide*, neither party in the non–Article III adjudication had ***any*** private rights at stake; rather, each party's rights were entirely created by Congress, *see* Lilly MSJ 54-55 (so explaining). That made *Union Carbide* the prototypical ***public*** rights case. *See Oil States*, 138 S. Ct. at

[13] The government creatively re-imagines *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33 (1989), as having held that "Article III resolution" (as opposed to adjudication by a bankruptcy court) was required "because the statutory ***cause of action*** effectively supplanted and resembled a pre-existing common-law action," ***not*** because the ***rights*** at issue were private rights. Reply 46 (emphasis added). That is not what *Granfinanciera* held. *See* 492 U.S. at 54-55 ("[I]f [a] right neither belongs to nor exists against the Federal Government, then it must be adjudicated by an Article III court."); Lilly MSJ 55-56.

1375 (public rights are "'derived altogether' from statutes"). And it explains why *Union Carbide* does not control here: Far from being a right that "the political branches could act on their own to abrogate," Nelson, *supra*, at 570 (defining public rights), the right not to be forced to give discounts to private parties long predated the 340B statute and persists intact despite it. In fact, it is exactly the sort of core private right that is, and always has been, protected by Article III.

Third, "consent" does not cure the Article III violation either. Because the government does not dispute that, *see* Reply 49 n.23, Lilly rests on the arguments it previously made, *see* Lilly MSJ 57.

3. Finally, the government's reliance on *Astra* fails. The government insists that, "in light of the Supreme Court's holding [in *Astra*] that [340B overcharging] claims cannot be heard in federal court," a ruling here in favor of Lilly would mean that such claims "cannot be heard in any forum, thus negating the will of Congress to create a remedy for claims of 'overcharging.'" Reply 49. That misunderstands both Article III doctrine and Lilly's claim under it. As explained, it has been the law of the land for nearly a century that agency adjudicators can find facts and issue recommendations of law, even in private-rights disputes, "so long as [they] do[] not authorize the deprivation of life, liberty, or property." Baude, *supra*, at 1542; *see Crowell*, 285 U.S. at 51-52. The problem here is with the ADR Rule, not Congress' design. The ADR Rule authorizes money damages and injunctions; the statute contemplates only quasi-restitutionary remedies. The ADR Rule empowers Executive Branch policy officials to "finally" decide these claims; the statute says nothing about who will constitute the Board. Perhaps a different ADR regulation could satisfy Article III and not lead to the "untenable result" the government posits. Reply 49. But the ADR Rule the agency hastily promulgated, in response to pressure from covered entities, is the only one we have. And, as explained, it violates Article III.

At a minimum, these constitutional defects should lead the Court to hold that the ADR Rule exceeds the scope of the agency's "statutory … authority." 5 U.S.C. § 706(2)(C). The statute authorizes the agency to create regulations that provide for "appropriate … remedies." 42 U.S.C.

§ 256b(d)(3)(A). A remedy that conflicts with the Constitution is not, and cannot be, "appropriate."

D. The ADR Rule is Arbitrary, Capricious, and Beyond the Agency's Authority.

The ADR Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," and must be set aside on that basis too. *See* 5 U.S.C. § 706(2)(A).

First, the Rule's choice of biased agency officials rather than neutral ALJs is neither reasonable nor reasonably explained. ADR entails hearing evidence, making credibility determinations, applying the Federal Rules of Civil Procedure and Evidence, interpreting legal texts (both statutory and contractual), and issuing decisions on the facts and the law. These are the tasks of judges; none of that has anything to do with specialized agency expertise. Yet the government has never tried to explain why it chose to eschew ALJs, who engage in this sort of decisionmaking every day in their ordinary work, in favor of policy officials from the agency. That is arbitrary and capricious—for, under the APA, an agency's exercise of discretion must be both "reasonable and reasonably explained," *Stovic v. R.R. Ret. Bd.*, 826 F.3d 500, 506 (D.C. Cir. 2016), and this is neither.

In its Reply, the government claims this argument is inconsistent with Lilly's position on Article II, but the government misunderstands both arguments. Lilly does not contend that "the Appointments Clause is violated if the Secretary ***cannot*** remove Board members." Reply 52. Lilly's Article II argument is not about removal; it is about review. Under the Appointments Clause, the Secretary must be able to directly overrule Board members' decisions before they become final, whether or not he can remove them. *Arthrex*, 141 S. Ct. at 1982; *see, e.g.*, Dkt. 103 (2d Am. Compl.) ¶¶ 230-33. The ***APA*** problem has nothing to do with that. The APA problem is that ADR panels are staffed with agency employees that are nearly guaranteed to exhibit more bias than ALJs. The ADR Board has two members from the HHS Office of General Counsel (which issued the December 30 Decision), two members from HRSA (the agency whose head made the May 17 Determination), and two members from the Centers for Medicare & Medicaid Services (another component of HHS).

That means that—unless this Court holds that the 340B statute cannot be read to require manufacturers to give 340B discounts to or through contract pharmacies, *see* Argument § I, *supra*—a majority of every ADR panel will be pre-committed to the view that refusing to fill replenishment orders at the ceiling price is a statutory violation. ***That*** deck-stacking, plus the fact that the agency did not explain why it chose this structure in lieu of ALJs, is why the Rule is arbitrary and capricious.

Second, the Rule fails to rectify—and, worse still, fails even to acknowledge—the serious constitutional concerns that Lilly and others have raised. *See* Lilly MSJ 57-58. The government says that these constitutional concerns were raised too late, *see* Reply 52, but, as Lilly has already explained, *see* Lilly MSJ 58, that is just not true. Indeed, even the government concedes that Lilly "***did*** raise concerns regarding the 'impartiality and accountability' of ADR panelists." Reply 52. And while Lilly may not have used the language of the Appointments Clause *en haec verba* when it submitted its comments, accountability ***is*** the watchword of Appointments Clause concerns. *See, e.g.*, *Arthrex*, 141 S. Ct. at 1982 (explaining why roundabout, after-the-fact means of indirect supervision "blur the lines of accountability demanded by the Appointments Clause"). The problem in *Arthrex*, after all, was that APJs exercise power that conflicts with the design of the Appointments Clause "'***to preserve political accountability***.'" *Id.* (emphasis added) (quoting *Edmond*, 520 U.S. at 663). In any case, the Federal Circuit invalidated the APJ system in *Arthrex* on Article II grounds all the way back in October 2019, *see* 941 F.3d 1320, which was well before the ADR Rule was promulgated without warning.

As for Lilly's Article III concerns, the availability of "monetary damages" and "equitable relief"—two of the principal bases for Lilly's Article III claim—appeared ***for the first time in the final Rule***; the original NPRM gave no hint that it would authorize ADR panels to issue such classic judicial remedies on top of refunds (and on top of any CMPs the agency may impose), *see* p. 47, *supra*. The government does not explain how Lilly was supposed to predict that the agency would resurrect a discarded NPRM and then enact this sea-change without notice and comment.

Third, the Rule fails to address manufacturers' concerns about the effect on manufacturers of HHS's onerous and outdated auditing guidelines. *See AstraZeneca*, 2021 WL 2458063, at *7 n.12 (noting that this is a "serious concern[]"). Manufacturers like Lilly raised this issue when the NPRM was under review, but the final Rule brushed these concerns aside. *See id.* Remarkably, the government has done it again: Lilly raised this deficiency in its MSJ (at 60), but the government does not say a single word about it in its Reply. Ignoring "an important aspect of the problem" is the hallmark of arbitrary agency action. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2384 (2020).

IV. The Court Should Enter Judgment For Lilly On Its December 30 Decision Claims.

The government makes no arguments in defense of the December 30 Decision or in response to the arguments Lilly raised against it in its summary judgment motion. The Court should therefore grant Lilly's summary judgment for Lilly's on Counts I-IV. As Lilly explained, *see* Lilly MSJ 11-41, its claims are justiciable, and the Decision is both substantively and procedurally invalid. In particular, as Chief Judge Stark held in the *AstraZeneca* case, the Decision violates the APA because, contrary to HHS's claim, the 340B statute does not "mandate[] [the Decision's] conclusion regarding covered entities' permissible use of an unlimited number of contract pharmacies." 2021 WL 2458063, at *8.

For a brief moment, the government asserted that Lilly's December 30 Decision claims were mooted by its gambit of attempting to withdraw the Decision after Chief Judge Stark ruled it was illegal but before he could enter final judgment. Dkt. 119 at 1. On reply, the government has abandoned this argument—or at least acts as if no one heard it say the word "moot." That is wise. The government would bear a "heavy burden of persuading the court that there is no reasonable expectation that the challenged conduct will reappear in the future." *Pleasureland Museum, Inc. v. Beutter*, 288 F.3d 988, 999 (7th Cir. 2002). And HHS's withdrawal gives no indication that the policy has been permanently jettisoned or that the agency has made any attempt to "sincerely self-correct[] the practice at issue." *Freedom from Religion Found. v. Concord Cmty. Sch.*, 885 F.3d 1038, 1051 (7th Cir. 2018). Instead,

HRSA disputed the reasoning in Chief Judge Stark's opinion and asserted that the withdrawal was happening only to "prevent litigation confusion." Dkt. 119-1. Indeed, it presents the paradigmatic example of an agency "ceas[ing] a challenged practice to thwart the lawsuit," leaving it free to "return to old tricks once the coast is clear." *Kikumura v. Turner*, 28 F.3d 592, 597 (7th Cir. 1994).

V. The Court Should Consolidate Or Grant The Motion For Preliminary Injunction.

This case comes to the court on cross-motions for summary judgment and Lilly's motion for a preliminary injunction against enforcement of the May 17 Determination. To the extent the Court is inclined to treat both sets of motions together, it can and should consolidate them under Federal Rule of Civil Procedure 65(a)(2). That said, because the agency has refused to agree not to take action against Lilly while this case is pending, Lilly renews its claim that the Court should enter a preliminary injunction barring the agency from taking enforcement action against Lilly consistent with the May 17 Determination during the pendency of these proceedings. Each injunction factor points in Lilly's favor. First, Lilly is likely to succeed on the merits of its claims, as explained. Second, if Lilly is forced to comply with the agency's demands while the issues remain pending but then Lilly ultimately prevails on the merits, Lilly will have suffered textbook irreparable injury in the form of unrecoverable money (both refunds given to covered entities and penalties paid to the agency), plus lost procedural protections and harm to reputation—and "irreparable harm is 'probably the most common method of demonstrating that there is no adequate legal remedy.'" PI Order 23. Third, the balance of interests favor an injunction as well, because even if the Court ultimately rules for the government on the merits (which it shouldn't), an interim injunction will not have caused any irreparable harm to the government ***or to any covered entity***, since Lilly will pay all money it is ordered to pay if this Court rules for the government and that ruling is affirmed on appeal. *See* Dkt. 95 (Lilly PI Mem.) at 28-29.

CONCLUSION

The Court should grant judgment for Lilly on all of its claims.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on **July 14, 2021,** a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ John C. O'Quinn
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