Nos. 21-3128 & 21-3405

In The United States Court of Appeals for the Seventh Circuit

ELI LILLY AND COMPANY and LILLY USA, LLC,
Plaintiffs-Appellants-Cross-Appellees,

v.

XAVIER BECERRA, DANIEL J. BARRY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIANA ESPINOSA, AND HEALTH RESOURCES AND SERVICES ADMINISTRATION
Defendants-Appellees-Cross-Appellants.

On Appeal from the United States District Court
for the Southern District of Indiana, Indianapolis Division
Case No. 1:21-cv-00081-SEB-MJD
Honorable Sarah Evans Barker

OPENING BRIEF AND REQUIRED SHORT APPENDIX FOR PLAINTIFFS-APPELLANTS

Andrew A. Kassof, P.C.
Diana M. Watral, P.C.
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
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John C. O'Quinn, P.C.
Counsel of Record
Matthew S. Owen
Matthew D. Rowen
Megan L. McGlynn
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Washington, DC 20004
(202) 389-5000

Counsel for Appellants

May 25, 2022

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3128

Short Caption: Eli Lilly and Company et al v. Becerra et al

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party, amicus curiae, intervenor or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

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N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ John C. O'Quinn Date: January 20, 2022

Attorney's Printed Name: John C. O'Quinn

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☑ **No** ☐

Address: Kirkland & Ellis LLP, 1301 Pennsylvania Avenue, N.W., Washington, DC 20004

Phone Number: 202-389-5191 Fax Number: 202-389-5200

E-Mail Address: john.oquinn@kirkland.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3405

Short Caption: Eli Lilly and Company, et al v. HHS, et al

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Attorney's Signature: /s/ John C. O'Quinn Date: January 20, 2022

Attorney's Printed Name: John C. O'Quinn

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3128

Short Caption: Eli Lilly and Company et al v. Becerra et al

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N/A

Attorney's Signature: /s/ Matthew Owen Date: January 20, 2022

Attorney's Printed Name: Matthew Owen

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: Kirkland & Ellis LLP, 1301 Pennsylvania Avenue, N.W., Washington, DC 20004

Phone Number: 202-389-5943 Fax Number: 202-389-5200

E-Mail Address: matt.owen@kirkland.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3405

Short Caption: Eli Lilly and Company, et al v. HHS, et al

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Attorney's Signature: /s/ Matthew Owen Date: January 20, 2022

Attorney's Printed Name: Matthew Owen

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

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E-Mail Address: matt.owen@kirkland.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3128

Short Caption: Eli Lilly and Company et al v. Becerra et al

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Attorney's Signature: /s/ Matthew D. Rowen Date: January 20, 2022

Attorney's Printed Name: Matthew D. Rowen

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: Kirkland & Ellis LLP, 1301 Pennsylvania Avenue, N.W., Washington, DC 20004

Phone Number: 202-389-5931 Fax Number: 202-389-5200

E-Mail Address: matthew.rowen@kirkland.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3405

Short Caption: Eli Lilly and Company, et al v. HHS, et al

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Attorney's Signature: /s/ Matthew D. Rowen Date: January 20, 2022

Attorney's Printed Name: Matthew D. Rowen

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3128

Short Caption: Eli Lilly and Company et al v. Becerra et al

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Attorney's Signature: /s/ Megan McGlynn Date: January 20, 2022

Attorney's Printed Name: Megan McGlynn

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

Address: Kirkland & Ellis LLP, 1301 Pennsylvania Avenue, N.W., Washington, DC 20004

Phone Number: 202-389-3264 Fax Number: 202-389-5200

E-Mail Address: megan.mcglynn@kirkland.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-3405

Short Caption: Eli Lilly and Company, et al v. HHS, et al

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Attorney's Signature: /s/ Megan McGlynn Date: January 20, 2022

Attorney's Printed Name: Megan McGlynn

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

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Attorney's Signature: /s/ Andrew A. Kassof Date: January 20, 2022

Attorney's Printed Name: Andrew A. Kassof

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Phone Number: 312-862-2474 Fax Number: 312-862-2200

E-Mail Address: akassof@kirkland.com

APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

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Attorney's Printed Name: Andrew A. Kassof

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Attorney's Signature: /s/ Diana M. Watral Date: January 20, 2022

Attorney's Printed Name: Diana M. Watral

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Address: Kirkland & Ellis LLP, 300 North LaSalle, Chicago, IL 60654

Phone Number: 312-862-2772 Fax Number: 312-862-2200

E-Mail Address: diana.watral@kirkland.com

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Eli Lilly and Company; Lilly USA, LLC

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Kirkland & Ellis LLP

Faegre Drinker Biddle & Reach LLP

(3) If the party, amicus or intervenor is a corporation:

i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's, amicus' or intervenor's stock:

N/A

(4) Provide information required by FRAP 26.1(b) – Organizational Victims in Criminal Cases:

N/A

(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

N/A

Attorney's Signature: /s/ Diana M. Watral Date: January 20, 2022

Attorney's Printed Name: Diana M. Watral

Please indicate if you are *Counsel of Record* for the above listed parties pursuant to Circuit Rule 3(d). **Yes** ☐ **No** ☑

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STATEMENT REGARDING ORAL ARGUMENT

Appellants request oral argument because it would assist the Court in resolving this complex statutory interpretation case implicating the second-largest government drug-purchasing program. The government's authority to impose novel regulatory requirements on pharmaceutical manufacturers—on threat of severe civil monetary penalties and expulsion from the Medicare and Medicaid programs—has already sparked intractable disagreement across four district courts. The outcome of this appeal, and the appeals on the same question in other circuits, will have profound consequences for the integrity of the national healthcare system.

INTRODUCTION

This case concerns the 340B Drug Pricing Program, which requires pharmaceutical manufacturers to subsidize private parties called "covered entities" by mandating that manufacturers "offer" covered entities the opportunity to "purchase" their outpatient prescription drugs at steeply discounted rates. 42 U.S.C. §256b(a)(1). For obvious reasons, the universe of "covered entities" entitled to this private wealth transfer is narrowly circumscribed; perhaps most critically, no for-profit enterprise can be a "covered entity." For-profit enterprises thus have no legal basis to demand drugs at 340B prices. That includes pharmacy chains like Walgreens and CVS, which are colloquially referred to in this context as "contract pharmacies."

None of this is in dispute. The Department of Health and Human Services ("HHS") agrees that contract pharmacies are ineligible for 340B discounts and cannot force manufacturers to sell to them at 340B prices. Nevertheless, in 2020, HHS decided for the first time that the 340B statute requires manufacturers not just to *offer* their drugs *to covered entities* at discounted prices, but to *deliver* an unlimited number of discounted drugs *to contract pharmacies*, ostensibly on covered entities' behalf.

HHS's new position has no basis in the statutory text. The operative provision of the 340B statute, 42 U.S.C. §256b(a)(1), contains two relevant sentences: the "purchased by" sentence and the "offer" sentence. The former provides:

> The 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 [a set, steeply discounted price].

(Emphasis added.) The latter, which Congress added to the statute in 2010, provides:

> Each such agreement … 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.

(Emphasis added.) Neither sentence (nor any other part of Section 340B) says anything at all about delivery or sale to third parties besides covered entities—let alone mandates delivery to an unlimited number of third-party contract pharmacies.

HHS's novel interpretation also represents a severe departure from its longstanding views. For decades, HHS told regulated entities that manufacturers were under no statutory obligation to deliver 340B drugs to contract pharmacies. Then, after the Health Resources and Services Administration ("HRSA"), an HHS component, confirmed to Plaintiffs Eli Lilly and Company and Lilly USA, LLC (together, "Lilly") *in 2020* that it had no authority to require Lilly to deliver 340B drugs to contract pharmacies, Lilly announced that it would do so only under certain conditions. Yet on December 30, 2020, HHS released a so-called "Advisory Opinion" "conclud[ing]" that the statute's plain language "obligate[s]" "manufacturer[s] in the 340B Program … to deliver [their] covered outpatient drugs to … contract pharmacies and to charge … no more than the 340B ceiling price for those drugs." A.5. And on March 17, 2021, HRSA doubled down by sending Lilly a formal Violation Letter threatening crippling sanctions for Lilly's purported violation of the 340B statute.

That agency action is contrary to law. The 340B statute requires Lilly to offer its drugs to covered entities at discounted prices, and Lilly indisputably does so. The statute does not impose any additional obligation to deliver 340B drugs to contract

pharmacies—which are for-profit enterprises, not covered entities—and black-letter administrative law prohibits HHS from imposing such a requirement by fiat.

Lilly filed suit in 2021, challenging both the Advisory Opinion and ultimately the Violation Letter. The district court agreed with Lilly in part. The court vacated the Advisory Opinion as arbitrary and capricious because nothing in the statute actually requires manufacturers to deliver an unlimited number of 340B drugs to an unlimited number of contract pharmacies. Yet when the district court turned to the Violation Letter, it ruled that the 340B statute *does* require manufacturers to deliver 340B drugs to contract pharmacies and that HHS may enforce that rule against Lilly, on the theory that allowing manufacturers to impose *any* restrictions on their 340B offers to covered entities would "frustrate" what the court viewed as "the overarching" (but nowhere expressed) "purpose of the program." SA.43. Two other courts have since considered the same statutory provision and reached the opposite conclusion. *AstraZeneca Pharms. LP v. Becerra* ("*AstraZeneca II*"), 2022 WL 484587, at *7 (D. Del. Feb. 16, 2022) (Stark, J.); *Novartis Pharms. Corp. v. Espinosa*, 2021 WL 5161783, at *9 (D.D.C. Nov. 5, 2021) (Friedrich, J.).

The district court's (second) interpretation of the 340B statute is wrong as a matter of law. It is inconsistent with the plain text of the statute, upsets the delicate statutory balance Congress struck, and raises serious constitutional problems. It is also exactly backwards in treating congressional *silence* as restricting private parties' otherwise-lawful conduct with respect to their own property, rather than restricting the agency's authority to impose new rules upon them. That is no way to conduct

statutory interpretation, and this Court should reverse it. The Court should hold instead that Lilly complies with its statutory obligation by offering discounted drugs to covered entities at the ceiling price and that it has no further, unwritten obligation to deliver those drugs to for-profit contract pharmacies without restriction.

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. §1331 because Lilly challenged three final agency actions under the APA, 5 U.S.C. §§701-706.

This Court has jurisdiction under 28 U.S.C. §1291. On October 29, 2021, the district court entered a partial final judgment concerning Lilly's challenges to two of the three final agency actions. SA.66. On April 7, 2022, this Court remanded for the district court to clarify the nature of its partial judgment. Dkt.16. On April 14, the district court issued an amended partial final judgment under Rule 54(b) that specifically declared the rights and obligations of the parties and found that there was no just reason for delay in entering judgment. SA.70-71. The court specifically declared, adversely to Lilly, that the Violation Letter "does not exceed statutory authority" because the 340B statute "does not permit drug manufacturers … to impose unilateral extra-statutory restrictions on their offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements." SA.71.

Following the district court's initial judgment, Lilly timely filed a notice of appeal on November 10, 2021. R.146; *see* Fed. R. App. P. 4(a)(1)(A).[1] The claims that

[1] In its limited remand order, this Court explained that an "amended notice of appeal is unnecessary" and "the original appeal will come into force once a proper judgment has been entered." Dkt.16.1.

remain pending below relate to only one of the challenged agency actions and do not overlap with the claims resolved in the partial final judgment. *See* Dkt.9.15.[2]

STATEMENT OF THE ISSUE FOR REVIEW

Whether Section 340B, which requires pharmaceutical manufacturers to "offer" discounted drugs to covered entities, 42 U.S.C. §256b, also requires them to deliver discounted drugs to contract pharmacies without limitation.

STANDARD OF REVIEW

This Court "review[s] de novo a district court's grant of summary judgment." *Habitat Educ. Ctr., Inc. v. U.S. Forest Serv.*, 609 F.3d 897, 900 (7th Cir. 2010).

STATEMENT OF THE CASE

A. The 340B Drug Pricing Program

In 1992, Congress amended the Public Health Service Act to add Section 340B. *See* Veterans Health Care Act of 1992 ("VHCA"), Pub. L. No. 102-585, §602(a), 106 Stat. 4943, 4967 (codified as amended at 42 U.S.C. §256b). Section 340B requires manufacturers, as a condition of participation in Medicaid and Medicare Part B, to offer their drugs at heavy discounts to certain nonprofit healthcare providers called "covered entities." 42 U.S.C. §256b(a)(1); *see also id.* §§256b(a)(4), 1396r-8(a)(1), (5). Medicare and Medicaid are ubiquitous; "one way or another," they "touch[] the lives of nearly all Americans," *Azar v. Allina*, 139 S. Ct. 1804, 1808 (2019), and drugmakers have no real option but to participate in them (and, as a result, in the 340B program).

[2] Those claims relate to Lilly's challenge to a rule establishing Administrative Dispute Resolution procedures for the 340B program. *See* 85 Fed. Reg. 80,632-01 (Dec. 14, 2020). The district court preliminarily enjoined the rule, R.82, and the government did not appeal that injunction.

Section 340B operates through mandatory agreements between manufacturers and HHS. It requires that "[t]he 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 an amount" known as the ceiling price, which is set by a statutory formula. 42 U.S.C. §256b(a)(1); *see also id.* §256b(a)(2) (expounding the formula); *id.* §§256b(b)(1), 1396r-8(k)(2) (defining "covered outpatient drug" to include nearly all prescription drugs). The resulting "agreement[s]," known as Pharmaceutical Pricing Agreements, or PPAs, are not "transactional, bargained-for contracts"; rather, they "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113, 118 (2011). And the heavily-discounted statutory ceiling prices manufacturers must agree to charge covered entities are usually at least 20-50% lower than the market price, and sometimes as little as one penny per dose. SA.4; *see* U.S. Gov't Accountability Office ("GAO"), GAO-21-107, at 1 (Dec. 2020), https://bit.ly/3wl7UcA. The operative statutory language directs that PPAs "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).

No doubt because Section 340B requires drug companies to directly subsidize other private entities, Congress circumscribed the universe of covered entities and barred them from arbitraging 340B discounts. The statute defines the term "covered

entity" to mean only certain nonprofit healthcare providers that fit within one of fifteen specifically enumerated categories, such as rural referral centers and black-lung clinics. *Id.* §256b(a)(4). No for-profit enterprise can be a covered entity, so no for-profit enterprise is eligible to receive drugs at 340B prices.

Section 340B thus requires manufacturers to offer their prescription drugs to covered entities for purchase at a steep discount. It does not require manufacturers to accept *whatever* sale or delivery terms covered entities demand. Nor does it require manufacturers to make discounted sales to, or otherwise deal with, contract pharmacies (or any other for-profit entity). Rather, as the district court acknowledged, "[t]he 340B statute is silent as to contract pharmacy arrangements and drug manufacturers' delivery obligations." SA.41 (emphasis omitted).

That omission was not an oversight. Congress explicitly accounted for contract pharmacies in the very next provision of the statute that enacted Section 340B into law. Section 340B was enacted as §602 of the VHCA. The next section, §603, explicitly requires manufacturers to "make available for procurement" by certain federal agencies "each" of their "covered drug[s] … that [are] purchased under depot contracting systems," which include "a commercial entity operating under contract with [the procurer]"—*e.g.*, a contract pharmacy. 106 Stat. at 4967 (codified at 38 U.S.C. §8126(a), (h)(3)). Section 340B contains no such language.

Section 340B imposes severe consequences for violating its terms. A manufacturer that "knowingly and intentionally charges a covered entity" more than the ceiling price can face "civil monetary penalties" of up to $6,323 "for each instance

of overcharging." 42 U.S.C. §256b(d)(1)(B)(vi); *see also* 45 C.F.R. §102.3 (inflation-adjusted penalty). Knowing and intentional overcharging can also lead to termination of a manufacturer's PPA and thus debarment from Medicaid and Medicare Part B. *See* 42 U.S.C. §1396r-8(b)(4)(B). The statute also expressly prohibits covered entities from engaging in "diversion" by "resell[ing] or otherwise transfer[ring]" a covered drug to "a person who is not a patient of the entity," *id.* §256b(a)(5)(B), and from claiming "duplicate discounts or rebates" by requesting, *e.g.*, a Medicaid rebate for a drug a covered entity purchased at (or below) the 340B price, *id.* §256b(a)(5)(A)(i).

Congress did not give HHS the power to expand the list of covered entities that manufacturers must subsidize, enlarge manufacturers' obligations toward them, or otherwise fill gaps in the statute. Unlike with other programs, HHS lacks "broad rulemaking authority to carry out all the provisions of the 340B program." *PhRMA v. HHS*, 43 F. Supp. 3d 28, 42 (D.D.C. 2014); *see also* Mot. Hr'g Tr. 51:23-52:5, *AstraZeneca v. Becerra*, No. 21-cv-00027 (D. Del. Oct. 22, 2021), Dkt.103 (government conceding that HRSA "can't add to the statutory obligation" because "HRSA has not been expressly granted general rule making authority"); Gov't Br. 38, *Novartis Pharms. Corp. v. Johnson*, No. 21-5299 (D.C. Cir. May 9, 2022), Document #1946057 ("It is common ground that HHS has no rulemaking authority with respect to contract-pharmacy arrangements."). Instead, HHS's regulatory powers vis-à-vis 340B are "specifically limited" to three things. *PhRMA*, 43 F. Supp. 3d at 42. HHS may (1) establish an administrative process to resolve 340B price disputes between

manufacturers and covered entities, 42 U.S.C. §256b(d)(3)(A), (2) issue standards for calculating 340B ceiling prices, *id.* §256b(d)(1)(B)(i)(I), and (3) establish regulations regarding the imposition of civil monetary penalties, *id.* §256b(d)(1)(B)(vi)(I).

B. The Agency's Shifting Guidance

Since 1992, HHS (through HRSA) has issued several nonbinding "guidance documents" regarding the 340B program. As will be discussed, the agency's position in this case is that most of this guidance is—and was when promulgated—plainly wrong.

1994 Guidance. HRSA issued its initial program guidance just 18 months after Congress enacted Section 340B. 59 Fed. Reg. 25,110 (May 13, 1994). This initial guidance addressed basic issues of distribution. It clarified that if a "manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue," and that a covered entity may "use a purchasing agent without forfeiting its right to" 340B pricing, but only if the terms of the "arrangement" are "clearly defined" "in writing." *Id.* at 25,113. It also emphasized that while a covered entity's purchasing agent may initially "receive[] drug shipments" from a manufacturer or wholesaler without violating the statutory prohibition on diversion, all 340B drugs still must be "distribut[ed] *to the* [*covered*] *entity*" *itself* before they may be dispensed to patients. *Id.* (emphasis added). And it expressly permitted manufacturers to require covered entities to comply with "customary business practice[s], request standard information, [and] include other appropriate … provisions" in their contracts with covered entities. *Id.* at 25,114.

1996 Guidance. HRSA's next major guidance document addressed a related, but separate, issue: mechanisms for dispensing 340B drugs. 61 Fed. Reg. 43,549 (Aug. 23, 1996). It "became apparent" to the agency that "many covered entities … do not operate their own licensed pharmacies" and thus "depend upon outside pharmacy services" to dispense drugs to their patients. *Id.* at 43,549-50. A question arose as to how those covered entities could distribute 340B drugs without violating the prohibition on "diversion," *i.e.*, "resell[ing] or otherwise transfer[ring]" "any covered outpatient drug" purchased at the 340B price to "a person who is not a patient of the [covered] entity." 42 U.S.C. §256b(a)(5)(B). In response, HRSA announced that covered entities that lack "'in-house' pharmacy services" could contract with "*one*" outside pharmacy, which in turn could use "*only one* site … for the contracted service"—namely, dispensing prescription drugs to the covered entity's patients. 61 Fed. Reg. at 43,555 (emphases added); *see also id.* at 43,551 (rejecting objection that "[c]overed entities should be permitted to contract with more than one site and contractor"). But HRSA still emphasized that the covered entity would be responsible for any diversion because it "purchases the drug, retaining title, and directs shipment to its contractor." *Id.* at 43,553.

HRSA did not employ notice-and-comment procedures in issuing this guidance. *Id.* at 43,550. This was not a problem, HRSA claimed, because the guidance "create[d] no new law and create[d] no new rights or duties." *Id.* So while the 1996 guidance *permitted covered entities* without an in-house pharmacy to use at most one contract pharmacy without fear of being penalized for diversion, it did not *obligate*

manufacturers to deliver 340B drugs to any contract pharmacy. *See AstraZeneca II*, 2022 WL 484587, at *7 (1996 guidance "w[as] directed to covered entities"). Nor could it; as HRSA itself acknowledged, Section 340B "is silent as to permissible drug distribution systems," 61 Fed. Reg. at 43,549, and HRSA may not fill that silence by regulation, *see PhRMA*, 43 F. Supp. 3d at 42.

2010 Guidance. Fourteen years later, HRSA changed course. The agency issued new nonbinding guidance in 2010 that jettisoned both the one-contract-pharmacy-per-covered-entity restriction and the limitation that only covered entities without an in-house pharmacy could contract with an outside pharmacy in the first place. 75 Fed. Reg. 10,272 (Mar. 5, 2010). But even then, HRSA made clear that contract-pharmacy arrangements were still subject to meaningful constraints. The agency underscored that a covered entity could not simply authorize pharmacies to place 340B orders on its behalf. Instead, a covered entity was required (1) to make the "*purchase*"; (2) to "*maintain title*" to the drugs until they were dispensed; and, among other things, (3) to "*assume responsibility for establishing [the] price*" charged to their patients. *Id.* at 10,277 (emphases added).

As with the 1996 guidance, the 2010 guidance "w[as] directed to covered entities," *AstraZeneca II*, 2022 WL 484587, at *7, and did not go through notice and comment. Again, HRSA made clear that the guidance was "interpretive" only—and, therefore, that it "neither impose[d] additional burdens upon manufacturers, nor create[d] any new rights for covered entities under the law." 75 Fed. Reg. at 10,273.

C. Contract Pharmacies Flock to—and Warp—the 340B Program

Contract pharmacies flooded the program in the wake of the 2010 guidance. *See* PhRMA, *340B Contract Pharmacy 101*, at 8 (Sept. 2020), https://onphr.ma/391WMsW ("The number of contract pharmacy arrangements has grown by more than 4,000% since the 2010 guidance."); Karen Mulligan, Ph.D., *The 340B Drug Pricing Program: Background, Ongoing Challenges and Recent Developments*, Univ. of S. Cal. (Oct. 14, 2021), https://bit.ly/3FFSemV ("Estimated discounted purchases … have increased from about $4 billion per year in 2007-2009 to $38 billion in 2020."). Nearly 30,000 contract pharmacies—roughly half of the entire U.S. pharmacy industry—now participate in the program. Adam J. Fein, Ph.D., *340B Continues Its Unbridled Takeover of Pharmacies and PBMs*, Drug Channels (June 15, 2021), https://bit.ly/38TPJCs. Covered entities now often contract with for-profit pharmacies located more than *1,000 miles* away. GAO, GAO-18-480, at 23 (June 2018), https://bit.ly/3OY0Fj9.

Not coincidentally, the use of contract pharmacies has increased the risk of illegal diversion and incentivized profiteering. *See* GAO, GAO-11-836, at 28, 44 (Sept. 2011), https://bit.ly/3l3WzbE; HRSA, *340B Program Integrity, Audits of Covered Entity Results* (Apr. 2020), https://bit.ly/3fcAALF. Under the dominant model, known as "replenishment," covered entities and contract pharmacies work together to create a fictional regime in which covered entities claim that *they* purchase drugs, even though the drugs are controlled by contract pharmacies and dispensed without regard to whether the consumer is a covered entity's patient. Specifically, when a contract pharmacy is running low on a given drug, it (or an affiliate, but not the covered entity)

uses a covered entity's account to order more of the drugs at the 340B price; it asks for delivery to be made directly to it (not to the covered entity); and, once the shipment arrives, it merges the drugs into its general inventory. Covered entities do not take—and certainly do not "maintain," 75 Fed. Reg. at 10,277—title to the drugs. Thus, even if a pharmacy knows at the time of a sale that a patient is 340B eligible, it has no way of dispensing pills or vials that arrived in a 340B-priced shipment—which explains why contract pharmacies often no longer even try to determine whether a customer is 340B eligible. Instead, patients fill a prescription, are charged full price, and receive drugs out of a pharmacy's general inventory—and then, as the government itself admits, the pharmacy uses manipulable algorithms weeks later to estimate how many customers might have been 340B patients. *See* R.125-2 ¶¶5-11; *AstraZeneca Pharms. LP v. Becerra* ("*AstraZeneca I*"), 543 F. Supp. 3d 47, 61 n.19 (D. Del. 2021); HHS-OIG, OEI-05-13-00431, at 2-5 (Feb. 4, 2014), https://bit.ly/3eWKmBQ; Aharon Gal, *Examining Hospital Price Transparency, Drug Profits, and the 340B Program* 4, 14-15 (Sept. 2021), https://bit.ly/3yvdko4.

The resulting changes to the 340B program would shock the Congress that created it. What began as a small cost-savings program for safety-net providers is now the second-largest federal drug program, behind only Medicare Part D, and is expected to be the largest by 2026—all wrought by HRSA's nonbinding "guidance." *See* Alliance for Integrity and Reform of 340B, *The Impact of Growth in 340B Contract Pharmacy Arrangements—Six Years Later*, at 8 (Oct. 2020), https://bit.ly/33E5knv. Perversely, however, there is evidence that "as 340B revenue has expanded

exponentially, services provided to vulnerable populations have declined." William Smith & Josh Archambault, *340B Drug Discounts: An Increasingly Dysfunctional Federal Program*, Pioneer Health 5 (Mar. 2022), https://bit.ly/3MShVog. Indeed, one study found a negative correlation between "the ability of people suffering severe economic hardship to afford needed medicines and medical care" and "growth in the 340B program." *Id.*

Since "[i]t requires almost no imagination to appreciate how, with the significant expansion of the 340B Program and the proliferation of contract pharmacy arrangements, more opportunities for abuse … have arisen," SA.27, one would have expected federal regulators to redouble their oversight and enforcement efforts when HRSA loosened the contract-pharmacy reins in 2010. Remarkably, the opposite has happened: Federal oversight is now all but nonexistent. The GAO reported in December 2020 that *HRSA had ceased even trying to address the problem* because, in HRSA's view, "the 340B statute does not address contract pharmacy use." GAO-21-107, at 15-16. Perhaps unsurprisingly, one manufacturer reported that its 340B discounts increased by more than $1 billion—nearly 20%—from 2020 to 2021 alone. *See* Janssen Pharmaceutical, Inc., *The 2021 Janssen U.S. Transparency Report*, at 7 (2022), https://bit.ly/3vaXBYY. And as a recent industry report found and SEC filings confirm, Walgreens alone generates "hundreds of millions" of dollars in pure profit through its 340B contract-pharmacy arrangements. Raymond James, *340B Pharmacy Follow Up—Less Than $1.4B but Still Yuge*, at 1 (Sept. 9, 2020); *see also* Laura Joszt, *340B, Biosimilars, and More in the Future of Specialty Pharmacy* (May

4, 2022), https://bit.ly/399OKhD (five contract pharmacies "earn about $3.2 billion in gross profits from 340B"); Walgreens Boots Alliance, Inc., Form 10-K (Oct. 15, 2020), https://bit.ly/2MoLX9d (noting that "[c]hanges in pharmaceutical manufacturers' … distribution policies … in connection with the 340B drug pricing program[] could … significantly reduce [Walgreens'] profitability"); Rebecca Pifer, *Hospitals, PBMs Say Drugmaker Restrictions on 340B Discounts Stifling Finances*, HealthcareDive (May 5, 2020), https://bit.ly/3P9xmdF (reporting that CVS Health "said its 340B product lines were stagnant" after contract-pharmacy restrictions were imposed).

D. Lilly's Contract-Pharmacy Initiative and the Agency's Response

Against this backdrop, Lilly adopted a new 340B distribution initiative in 2020. Under this new initiative, Lilly would continue to offer (and authorize its wholesalers to offer) all covered entities the ability to purchase all covered outpatient drugs that Lilly manufactures at or below the 340B price and to deliver (and authorize its wholesalers to deliver) 340B drugs to any and all covered entities that order them. But Lilly (and its wholesalers) would not deliver 340B drugs to a contract pharmacy unless (1) a covered entity without an in-house pharmacy has designated the outside pharmacy as its sole contract pharmacy, or (2) the contract pharmacy is wholly owned by, or shares a corporate parent with, a covered entity. In addition, because Lilly—the world's first commercial manufacturer of insulin—is committed to insulin affordability, Lilly will deliver penny-priced insulin to multiple contract pharmacies as long as the covered entity agrees that *patients* will receive the full 340B discount,

that no payer is billed for the insulin, and that the covered entity provides documentation demonstrating compliance with the initiative.

Initially, HRSA acknowledged that Lilly had every right to adopt this initiative. Recognizing that its 1996 and 2010 "contract pharmacy *advice*"—HRSA's words in 2020—was "not binding" on manufacturers, HRSA accepted the initiative (despite "encourag[ing] Lilly to reconsider") and even posted Lilly's announcement of the initiative on the agency's website. AR.7589 (emphasis added).[3] This was as Lilly expected. From 340B's inception, the agency consistently took the view that it lacks authority to compel manufacturers to deliver 340B drugs to *any* contract pharmacies, let alone an unlimited number of them.[4] *See supra* pp.9-11.

The agency continued to espouse that view even after it posted Lilly's announcement. On July 8, 2020, HRSA's Communications Director wrote to a covered-entity trade group "that although the agency 'strongly encourages all manufacturers to sell 340B priced drugs to covered entities through contract pharmacy arrangements,'" it lacked the "authority to enforce" (or even impose) any such requirement. *Am. Hosp. Ass'n v. HHS*, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021) (quoting HRSA). HRSA told individual covered entities the same thing. *See, e.g.*, AR.3272; AR.3285; AR.4194. And HRSA told an industry news outlet that

[3] "AR" refers to the record compiled for the May 17 Violation Letter.

[4] Indeed, HRSA has repeatedly urged Congress to grant it "specific legislative authority to conduct rule making for all provisions in the 340B statute" precisely because its existing authority is so narrowly circumscribed. H. Comm. on Energy & Commerce, *Review of the 340B Drug Pricing Program* 27 (2018), https://bit.ly/3PcQBTy; *see also* GAO-21-107, at 35 ("HRSA has requested regulatory authority in every President's Budget since FY 2017.").

"[t]he 2010 guidance … is not legally enforceable" against manufacturers and that HRSA could not "compel[]" manufacturers "to provide 340B discounts on drugs dispensed by contract pharmacies." SA.10.

E. The Agency Issues, Then Withdraws, an "Advisory Opinion" Requiring Manufacturers to Deliver Drugs to an Unlimited Number of Contract Pharmacies

In the last days of the previous Administration, HRSA departed from all of its prior 340B interpretations. On December 30, 2020, HHS's General Counsel issued an "Advisory Opinion" that—for the first time, *see AstraZeneca I*, 543 F. Supp. 3d at 56—construed Section 340B to "obligate[]" each "manufacturer in the 340B Program … to deliver its covered outpatient drugs to … contract pharmacies and to charge … no more than the 340B ceiling price" whenever a pharmacy acts as a covered entity's "agent[]." A.5. This newly discovered obligation was limitless. According to the agency, Section 340B requires manufacturers to accommodate a demand for delivery to any number of contract pharmacies *anywhere*: "The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." A.7.

Remarkably, the Advisory Opinion pronounced that this obligation follows *unambiguously* from Section 340B's text. Without so much as mentioning the agency's many prior contrary statements, the Advisory Opinion declared that "the plain meaning of Section 340B requires manufacturers to sell covered drugs to covered entities at or below the ceiling price, independent of whether the entity opts to use contract pharmacies to dispense the drugs." A.6 (capitalization omitted). HHS relied principally on the first sentence of 42 U.S.C. §256b(a)(1), which states that "[t]he 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]." A.6 (emphasis in original). The Advisory Opinion also explicitly (and incorrectly) assumed—without explanation—that "the covered entity takes title" to 340B drugs even when a contract pharmacy places the order, receives shipment directly from the manufacturer or wholesaler, and commingles them in its general inventory. A.7. *But see supra* pp.12-13.

Because HHS's prior guidance recognized (indeed, required) contract-pharmacy limitations that the Advisory Opinion now calls illegal, the agency has been compelled to tell federal courts that its decades-long prior guidance must have been wrong—indeed, *unambiguously* wrong. *See* Oral Arg. Tr. 67:6-12, *AstraZeneca v. Becerra*, No. 21-cv-00027 (D. Del. May 28, 2021), Dkt.76 ("THE COURT: So [the] 1996 guidance, limiting it to one contract pharmacy was a wrong interpretation of the statute; correct? [GOVERNMENT COUNSEL]: Imposing that limitation is not consistent with the agency's understanding of the statute….").

Lilly immediately challenged the Advisory Opinion, "the first document in which HHS explicitly concluded that *drug manufacturers* are required by *statute* to provide 340B drugs to *multiple* contract pharmacies," *AstraZeneca I*, 543 F. Supp. 3d at 55-56, as substantively and procedurally defective, *see* R.1 ¶¶132-78. Lilly was not alone. In parallel litigation brought by another manufacturer, Judge Stark (then of the District of Delaware, now of the Federal Circuit) vacated the Advisory Opinion as arbitrary and capricious. *AstraZeneca I*, 543 F. Supp. 3d at 59-60. Judge Stark held

that the agency's position had "materially shifted" over time, that the Advisory Opinion failed to mention (let alone explain) the change, and that the Advisory Opinion was "based on the 'unjustified assumption' that Congress imposed [its] interpretation as a statutory requirement." *Id.* at 56, 61.

HHS withdrew the Advisory Opinion two days after Judge Stark's opinion. A.14. But that was not the end of the saga, or of Lilly's case.

F. The Agency Issues Lilly a Violation Letter Mid-Litigation

On May 17, 2021, while Lilly's case was still pending below, HRSA sent Lilly a Violation Letter announcing that, "[a]fter review of [Lilly's] policy and an analysis of the complaints HRSA has received from covered entities," the agency "ha[d] determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute." A.2. The Violation Letter concluded that "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." A.3. According to HRSA, although Lilly had charged covered entities no more than the ceiling price, Lilly must nevertheless refund covered entities for each alleged instance of overcharging or else face civil monetary penalties ("CMPs") and the potential termination of Lilly's PPA (and, with it, Lilly's ability to receive any coverage under Medicaid and Medicare Part B). A.3. (HRSA sent substantively identical letters to several other manufacturers

that had also limited their distribution of discounted drugs to contract pharmacies. *See* AR.1-2; AR.5-12.)[5]

The Violation Letter reached the same bottom-line position as the Advisory Opinion, but articulated a different reason for it. Whereas the Advisory Opinion relied principally on the first sentence of 42 U.S.C. §256b(a)(1) and the phrase "purchased by a covered entity" in particular, *see* A.6-7, the Violation Letter did not reference that provision at all. Instead, it purported to derive exactly the same statutory meaning from a *different* provision, added in 2010, that "requires that manufacturers 'shall … offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.'" A.2. Because the "shall offer" language is unqualified, the Violation Letter declared that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing," and doing so is therefore somehow unlawful. A.2.

After receiving the Violation Letter, Lilly amended its complaint to allege that the letter was contrary to Section 340B and the Fifth Amendment's Takings Clause, arbitrary and capricious, and unlawfully promulgated without public notice and comment. Lilly specifically sought a declaration that it has no statutory obligation to deliver discounted drugs to contract pharmacies without limitation.

[5] On September 22, 2021, HRSA referred Lilly to the Office of Inspector General ("OIG") for CMPs. R.143-1. OIG has taken no action to date.

G. The District Court's Decision

On October 29, 2021, the district court resolved the parties' cross-motions for summary judgment and the government's motion to dismiss.

The district court began by rejecting the government's procedural objections to Lilly's claims against the Advisory Opinion. The court first concluded that the agency's withdrawal of the Advisory Opinion did not moot Lilly's challenges because, as the May 17 Violation Letter made clear, "enforcement efforts directed toward drug manufacturers' policies regarding contract pharmacies will likely continue." SA.29. The court next concluded that the Advisory Opinion constituted final agency action ripe for adjudication, since it "clearly represent[s] 'a definitive pronouncement of [agency] policy,'" "advance[s] an interpretation the agency 'believes is the only permissible interpretation of the statute,'" and "treads new ground" different from any prior agency pronouncements. SA.31-32. Finally, the court ruled that Lilly's challenges were timely. Although the agency tried to claim that its new interpretation of Section 340B was not new at all (and therefore should have been challenged years ago), the court rejected that assertion as "disingenuous." SA.33.

The district court then ruled for Lilly on the merits of the Advisory Opinion. The court agreed with Judge Stark that "the Advisory Opinion is 'legally flawed'" because it is based on the "'unjustified assumption' that Congress imposed [HHS'] interpretation as a statutory requirement" when, in reality, Section 340B is "silen[t] both as to covered entities' entitlement to utilize unlimited contract pharmacy arrangements and as to any delivery obligations imposed on drug manufacturers." SA.34 (quoting *AstraZeneca I*, 543 F. Supp. 3d at 61). The court therefore ruled that

the Advisory Opinion is "arbitrary and capricious" and vacated and set it aside. SA.34-35.[6]

Turning to the Violation Letter, the district court ruled for each party in part. Despite agreeing that the Violation Letter is final agency action (because it determined Lilly's legal obligations and threatened severe consequences if Lilly did not acquiesce), the court found the Violation Letter to be only an interpretive rule and rejected Lilly's notice-and-comment claim. SA.36-37.

The district court agreed with Lilly that the Violation Letter was arbitrary and capricious. Along the lines Judge Stark explained in *AstraZeneca I*, the court found that the agency "failed even to acknowledge"—"much less provide 'good reasons' for"—its changed position as to its authority to enforce any delivery obligation on manufacturers. SA.57-58.

Nevertheless, the district court rejected Lilly's claim that the Violation Letter was contrary to Section 340B and specifically declared that Lilly's contract-pharmacy initiative violated the statute. SA.59, 71. Despite vacating the Advisory Opinion on the ground that Congress did not "impose[] [HHS'] interpretation as a statutory requirement," SA.34, despite reiterating that the statute is "silent as to contract pharmacy arrangements and drug manufacturers' *delivery* obligations," SA.41, and despite explicitly declining to endorse the agency's view that the statute "require[s]" "drug manufacturers … to deliver 340B drugs to an unlimited number of contract

[6] "[B]ecause the agency ha[d] already withdrawn the Advisory Opinion," the court did not address Lilly's other challenges or remand it to the agency. SA.61.

pharmacies," SA.45, the court concluded that the statute prohibits manufacturers from imposing *any* conditions on "the distribution of the drugs" and that it does so *unambiguously*, SA.46-47; *see also* SA.49 n.15 (declining to employ tools for interpreting ambiguous statutes).

The district court did not rely on any particular statutory text. It declared that Lilly's "construction of the 'shall … offer' provision to authorize its refusal to honor the 340B price for covered entities' purchases based solely on delivery location or dispensing mechanism … directly conflicts with the statutory requirement otherwise." SA.46. But the court never identified which textual provision (or provisions) purportedly create that "statutory requirement." Instead, it reasoned from abstract notions of legislative purpose. The court concluded that because Congress' intention in enacting Section 340B was to "create a comprehensive drug distribution scheme to enable safety net providers to purchase [discounted] drugs in a manner that ensures access to the discounted medications," the statute must be read to permit the agency to outlaw all manufacturer policies that "frustrate th[at] overarching purpose." SA.43. So even though the court acknowledged that Section 340B is "silent as to contract pharmacy arrangements and drug manufacturers' *delivery* obligations" and does not "require[]" "manufacturers … to deliver 340B drugs to an unlimited number of contract pharmacies," SA.41, 45, the court held that Lilly may not impose *any* delivery conditions on 340B orders and instead must honor *all* contract-pharmacy arrangements (despite the agency's decades-long position to the contrary). Similarly, despite "conced[ing]" that Lilly would face "significant financial"

consequences if forced to withdraw from the program, the court rejected Lilly's takings claim on the ground that Lilly had voluntarily chosen to participate in Medicaid and Medicare Part B, which require manufacturers to offer 340B subsidies to covered entities. SA.50-52.

It is from these adverse portions of the judgment that Lilly now appeals.[7]

SUMMARY OF ARGUMENT

Lilly complies with Section 340B because it offers discounted drugs to covered entities at the ceiling price. It has no additional statutory obligation to deliver (much less sell) discounted drugs in unlimited quantities to third-party contract pharmacies wherever they may be located across the country or, as the agency would have it, on the "lunar surface." A.7. That is clear on the face of the statute.

The Violation Letter purported to derive a prohibition on all delivery conditions from the statutory requirement to "offer" discounted drugs for "purchase" by covered entities. But no English speaker would interpret that language to include a requirement to deliver 340B drugs to for-profit contract pharmacies, *not* covered entities. And statutory structure confirms that if Congress wanted to require delivery to outside pharmacies, it knew how to do so—but did not. That is no doubt why even

[7] Following the district court's opinion, and cognizant of the potential for crippling civil monetary penalties, Lilly announced that it would expand its distribution initiative, pending this appeal, to permit 340B purchases through contract pharmacies if the covered entity agrees to furnish claims-level data associated with contract-pharmacy orders. *See* Eli Lilly and Co., Update to Eli Lilly and Company Contract Pharmacy Policy (Dec. 10, 2021), https://bit.ly/3wLVBHD; *see also Novartis*, 2021 WL 5161783, at *9 (concluding that a similar policy does not "violate Section 340B under the positions advanced in [a substantially identical] Violation Letter[]").

HHS long recognized (from 1992 until 2020) that manufacturers may impose delivery conditions on the sale of 340B drugs.

The district court correctly understood that the text did not support HRSA's interpretation; it vacated the Advisory Opinion for that very reason. But instead of following that reasoning to its logical conclusion and holding that Lilly had not violated the statute, the district court upended basic principles of statutory interpretation and administrative law to construe the statute against Lilly and reach what it thought to be better policy. In doing so, the court privileged purpose over text and inverted our system of limited government by suggesting that private companies may act only if Congress says so.

None of that is consistent with precedent or our constitutional system. Section 340B confers specifically limited regulatory authority on the Secretary to implement the program. That authority does not include the power to impose new obligations on manufacturers, expand the universe of covered entities, or fill in substantive gaps—*as the agency itself has conceded*. And it is a basic tenet of our constitutional system that agencies lack power to act unless specifically authorized by Congress.

The district court's atextual reading is all the more problematic here given the Takings Clause and unconstitutional-conditions implications of the government's position. The government may not, as the agency now demands, constitutionally compel private parties to transfer their wealth to other private parties. When Lilly first agreed to join the 340B program as a condition of participating in Medicaid and Medicare Part B, it would have been unthinkable that 340B would one day be larger

than every other federal drug program then in existence, or that manufacturers would be required to deliver discounted drugs to, much less subsidize, for-profit pharmacies. Now, because Medicaid and Medicare are practically inescapable for any manufacturer, it would be all but impossible for Lilly to extricate itself from the ever-expanding 340B program and defy the agency's command to give away its property on a massive scale—a demand that bears no nexus or proportionality to the "benefit" to which it is attached. Participation in 340B was supposed to be a way to help the Medicaid program on the margins; HHS's interpretation has made it *bigger* than Medicaid—all at the expense of manufacturers.

All of this explains why every court to consider this question has agreed that the agency erred when it interpreted Section 340B to unambiguously permit contract-pharmacy arrangements, *see infra* pp.43-44, and it explains why multiple district courts have now vacated substantially identical agency action aimed at other manufacturers. Judge Friedrich, of the U.S. District Court for the District of Columbia, expressly rejected the district court's analysis here, holding instead that "[n]either the 'Shall Offer' provision nor any other in Section 340B contains … clear language that forbids drug manufactures from imposing *any* additional conditions—no matter how minor—on covered entities that purchase drugs at 340B discount prices." *Novartis*, 2021 WL 5161783, at *7; *see also id.* at *7 n.4. And following his decision on the Advisory Opinion, Judge Stark vacated another violation letter on February 16, 2022, because it "rest[ed] on essentially the same flawed statutory

interpretation that [he had] already rejected." *AstraZeneca II*, 2022 WL 484587, at *6.

This Court too should reject the agency's atextual reasoning and reverse.

ARGUMENT

THE VIOLATION LETTER IS CONTRARY TO SECTION 340B.

Section 340B requires Lilly to offer discounted drugs to covered entities. No one contests that Lilly does so, and that should be the end of the case. The statute imposes no additional obligation on manufacturers to deliver or sell discounted drugs to non-covered entities. The Violation Letter's contrary determination has no support in the statutory text and is contrary to settled principles of statutory construction.

A. Lilly Complies With the Plain Text of Section 340B.

Interpretation of a statute "starts with its text," *Milner v. Dep't of Navy*, 562 U.S. 562, 569 (2011), and when the statute is clear, the interpretive exercise "ends there as well," *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 631 (2018). That foundational principle resolves this case. As the plain text of Section 340B makes clear, the only requirement the statute imposes on manufacturers is to offer covered entities the opportunity to purchase manufacturers' drugs at 340B-discounted prices. The statute does not impose an additional, orthogonal requirement to deliver 340B drugs to for-profit contract pharmacies whenever and wherever a covered entity demands.

The operative provision of the 340B statute, 42 U.S.C. §256b(a)(1), contains two sentences: the "purchased by" sentence and the "offer" sentence. The former, which has been in the statute since the beginning, provides:

> The 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].

(Emphasis added.) The latter, which Congress added to the statute in 2010, provides:

> Each such agreement … *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.) The latter is the only statutory provision the Violation Letter cites. *See* A.2-3.

Lilly complies with the "offer" provision. The key terms in that sentence—"offer," "purchase," and "price"—are well known to both lawyers and laymen. When Congress does not define a term, its plain meaning controls. *See HollyFrontier Cheyenne Ref., LLC v. Renewable Fuels Ass'n*, 141 S. Ct. 2172, 2176 (2021). To "offer" means "[t]o present for acceptance or rejection" and "[t]o present for sale." *Am. Heritage Dictionary of the English Language* 1255 (3d ed. 1992); *accord Random House Webster's Coll. Dictionary* 939 (1992). To "purchase" means "[t]o obtain in exchange for money or its equivalent; buy." *Am. Heritage Dictionary*, *supra*, at 1470; *accord Random House*, *supra*, at 1095. And "price" means "[t]he amount … of money … asked for or given in exchange for something else"; "[t]he cost at which something is obtained." *Am. Heritage Dictionary*, *supra*, at 1437. The provision thus obligates Lilly to present covered entities with the opportunity to buy Lilly's 340B-eligible drugs at a prescribed dollar amount. It does not demand more.

Lilly complies with that requirement because it offers all of its covered outpatient drugs at the ceiling price to all covered entities. Tellingly, not even the district court denied that. It rejected Lilly's statutory argument *not* because Lilly failed to make the required offers, but because the court thought Section 340B "does not permit drug manufacturers … to impose unilateral extra-statutory restrictions *on their offer* to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements." SA.59 (emphasis added).

There is no basis in the statutory text for the district court's posited prohibition on sale conditions not enumerated in the statute, much less conditions regarding the *delivery* of drugs. Nothing in the text of the "offer" provision says anything about delivery obligations to contract pharmacies or about navigating a covered entity's contract-pharmacy relationships at all; certainly it does not require delivery under circumstances tantamount to a direct sale, in which the *contract pharmacy*, rather than the covered entity, takes and maintains title to the drugs. It simply requires manufacturers to "offer" 340B drugs *to covered entities* at a certain price. And the "purchased by" provision in §256b(a)(1), which the Violation Letter does not cite, says nothing about delivery obligations either. That provision prescribes what "[*t*]*he Secretary* shall" do (namely, "enter into" PPAs setting the ceiling price of 340B drugs). 42 U.S.C. §256b(a)(1) (emphasis added).

No reasonable English speaker would interpret these provisions, which require manufacturers to offer specified goods for sale at a capped price to a specific class of buyers (*i.e.*, covered entities), to also mandate delivery to third parties—let alone to

empower the Secretary to impose such a mandate on his own. Nor does any other provision of the statute even arguably impose such a sweeping delivery requirement on manufacturers. *See, e.g.*, *id.* §256b(a)(2)-(3) (providing the inputs for calculating ceiling prices); *id.* §256b(a)(4) (defining "covered entity" to exclude any for-profit enterprise); *id.* §256b(a)(5) & (d)(2) (imposing requirements on covered entities); *id.* §256b(b) (defining terms); *id.* §256b(d) (imposing requirements on the Secretary).

The absence of language mandating delivery to contract pharmacies is no accident. As Judge Stark put it, "Congress knows how to write statutes that cover agents and contractors, but … did not do so in the 340B statute." *AstraZeneca I*, 543 F. Supp. 3d at 60. That cannot be an oversight, because Congress in fact did so in *the very next provision of the statute that enacted Section 340B into law*. Section 340B was enacted as §602 of the VHCA. *See* 106 Stat. at 4967. The immediately following provision requires manufacturers to "make available for procurement" by certain federal agencies "each covered drug of the manufacturer … that is purchased under depot contracting systems," which the statute defines to include "a commercial entity operating under contract with [the procurer]," *i.e.*, a contract pharmacy. 106 Stat. at 4967 (codified at 38 U.S.C. §8126(a), (h)(3)). In other words, Congress clearly provided for delivery to contract pharmacies. But not here. And when two provisions are enacted in the same statute, the "presum[ption] that Congress acts intentionally and purposely in the disparate inclusion or exclusion" of statutory language is at its zenith. *Russello v. United States*, 464 U.S. 16, 23 (1983). The government's

interpretation flatly contravenes that principle (in addition to flouting the statute's text and structure).

The *Russello* principle actually applies with even more force here. A second federal healthcare law explicitly authorizes "vendor[s] of goods or services" to pay "a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if … the person has a written contract, with each such individual or entity." 42 U.S.C. §1320a-7b(b)(3)(C). Taken together with §603 of the VHCA, that provision makes it abundantly clear that Section 340B's omission of similar language has meaning—and that neither the agency nor a court may, "in the guise of construction," read any such omitted language into Section 340B. *GE Betz, Inc. v. Zee Co.*, 718 F.3d 615, 624 (7th Cir. 2013); *see also Dole Food Co. v. Patrickson*, 538 U.S. 468, 476 (2003).

The familiar law of commercial contracts further confirms that words like "offer," "purchase," and "price" do not impliedly convey anything about delivery to third parties. *See Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991) ("Congress is understood to legislate against a background of common-law adjudicatory principles."). It is a basic principle of contract law that when a contract for the purchase of goods is silent as to delivery location, the seller is required to tender the goods at the *seller's* place of business, nowhere else. *See* 18 *Williston on Contracts* §52:4 (4th ed. 2021) (discussing the place of delivery under the Uniform Commercial Code, the Uniform Sales Act, and the common law); *see also, e.g.*, *Home Indem. Co. v. Twin City Fire Ins. Co.*, 474 F.2d 1081, 1084 (7th Cir. 1973)

(interpreting and applying the Uniform Commercial Code). Here, of course, Lilly does not require covered entities to pick up 340B drugs at its (or its wholesalers') warehouses; that is not the point. The point is that the words "offer" for "purchase" at a given "price" (elements of every sale-of-goods contract) do not, as the agency claims, imply that the seller will deliver the goods wherever the buyer desires—even the "lunar surface" or "low-earth orbit," as HHS suggested, A.R.8050—at whatever cost. In short, as Judge Stark recognized, "Congress could have explicitly stated that drug manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies," but did not. *AstraZeneca I*, 543 F. Supp. 3d at 60.

To be sure, one could imagine hypothetical delivery restrictions that *would* violate the "shall … offer" command. To take the agency's own example, if a manufacturer (rather than a covered entity) insisted on delivering drugs for pickup on the "lunar surface," A.7, or even some impossible-but-terrestrial location, that would violate the statute. But that is not because the condition concerns the place of delivery; it is because an offer to sell drugs only on the moon is not a "meaningful, *bona fide* offer[]" in the first place. *Novartis*, 2021 WL 5161783, at *6. To be clear, though, no one contends here that the delivery conditions *Lilly* imposed similarly render the underlying offer illusory or ingenuine. Nor could they, since Lilly's delivery conditions reflected *the agency's own 1996 guidance* and the way things actually worked for the majority of the program's existence.

In short, a statutory requirement to offer goods for sale does not mean that the seller cannot specify *any* other sales terms. Even HRSA appears to understand this

basic point outside the contract-pharmacy context. It has long recognized that the statutory requirement that manufacturers offer discounted drugs does not permit covered entities free reign to demand discounted drugs without limitation. In 1994, for example, HRSA issued guidance permitting manufacturers to require covered entities to comply with "customary business practice[s], request standard information, [and] include other appropriate … provisions" in their contracts with covered entities. 59 Fed. Reg. 25,114. HRSA offers no explanation for why *those* conditions are consistent with the obligation to "offer" discounted drugs, but contract-pharmacy limitations are not. *See Novartis*, 2021 WL 5161783, at *7.

The plain text thus resolves this case. Manufacturers' obligation to offer 340B pricing extends only to covered entities. *See, e.g.*, R.125.12-13. And under its distribution initiative, Lilly continues not only to offer every covered entity the ability to purchase Lilly's covered outpatient drugs at or below the 340B price, but to ensure the delivery of its covered drugs to every covered entity that orders them. The agency's determination that this policy violates Section 340B is therefore contrary to law.

B. Other Principles of Statutory Interpretation Confirm What the Plain Text Compels.

If the plain meaning of the text were not enough by itself, other basic principles of statutory interpretation and administrative law confirm that the agency's interpretation of Section 340B has no basis in law.

First, the agency's construction makes nonsense of the statute's structure. *See generally Beeler v. Saul*, 977 F.3d 577, 585 (7th Cir. 2020). Section 340B does not

give covered entities carte blanche to demand discounted drugs to do with as they wish. Quite the opposite. "The benefits of the 340B Program do not come without strings attached." *Novartis*, 2021 WL 5161783, at *1. Most notable, to ensure that 340B discounts (funded entirely by manufacturers) are reserved for the "providers of safety-net services" set out in the statute, *Astra*, 563 U.S. at 113, Congress made explicit that covered entities may not transfer 340B drugs *to anyone* but their "patients," *see* 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.").

It makes no sense to interpret 42 U.S.C. §256b(a)(1) to mandate, or at least closely approximate, the same kind of diversion that §256b(a)(5)(B) squarely prohibits. But that is what the agency's interpretation does, by condoning and enforcing the replenishment model. *See* R.125-2. Under that model, contract pharmacies (not covered entities) may purchase 340B drugs and incorporate those drugs into their general inventory. *See supra* pp.12-13; R.125-2 ¶11 (conceding that 340B drugs "become[] 'neutral inventory[]' and may be dispensed to any subsequent patient"). Thus, even if covered entities can be said to take title to the drugs at some point in this process, they certainly do not "maintain" it—as the agency's 2010 guidance required, 75 Fed. Reg. at 10,277, and the 1996 guidance assumed, 61 Fed. Reg. at 43,553. Then the drugs are dispensed to all comers at full price, without any prior determination about whether the customer is a 340B patient. R.125-2 ¶11. Thus, in the agency's view, §256b(a)(1) effectively permits what §256b(a)(5)(B) prohibits: the "transfer" of 340B drugs "to a person who is not a patient of [a covered]

entity." According to the agency, manufacturers must permit covered entities to "transfer" 340B drugs to contract pharmacies, which obtain complete control over the drugs after shipment, and contract pharmacies must then be permitted to again "transfer" the drugs to their customers. That interpretation, which would render the diversion prohibition a dead letter, makes nonsense of the statutory scheme.

Second, construing Section 340B to impliedly prohibit all conditions of 340B sales offers would violate the major-questions doctrine. "When an agency claims to discover in a long-extant statute an unheralded power to regulate a 'significant portion of the American economy,'" courts "typically greet its announcement with a measure of skepticism." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014); *accord NFIB v. OSHA*, 142 S. Ct. 661, 666 (2022) (per curiam).

The powers the agency claims here plainly fit that description. The delta between Lilly's view of the statute (broadly consistent with the 1996 guidance) and the agency's newfound view is the difference between a cost-savings program attached to Medicaid and a federal drug program *bigger* than Medicaid. And that still-growing federal program is funded entirely by HHS's decision, in ostensibly nonbinding guidance documents, to order private companies to give away their property on a massive scale, without the bother of congressional appropriations. 340B sales increased from $4 billion per year to nearly $40 billion per year following the agency's decision in 2010 to permit covered entities to use multiple contract pharmacies. *See supra* p.12. Yet no clear statutory statement justifies this fundamental change in the scope and effect of the program. *See NFIB*, 142 S. Ct. at

665 ("The question, then, is whether the Act plainly authorizes the Secretary's mandate."). Instead, HRSA can point only to the bare requirement to "offer" drugs to covered entities at or below the ceiling price. *See* 42 U.S.C. §256b(a)(1). That is a "wafer-thin reed on which to rest" HRSA's claim to such "unprecedented" power. *Alabama Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021) (per curiam). Congress, after all, "does not … hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

The political significance should not be discounted either. *See Alabama Ass'n of Realtors*, 141 S. Ct. at 2489 ("[Courts] expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance." (quotations omitted)). Unlike most federal programs, the government does not foot the bill for 340B discounts; manufacturers do. Any government action that expands manufacturers' obligations under 340B saves money for the federal fisc and saves the political branches from having to raise taxes or cut spending. And the government action here not only allows Washington to avoid bicameralism and presentment, but imposes new and expansive costs directly upon politically unpopular companies. Certainly in the absence of any clear congressional authority, HRSA should not be permitted to effectively raise funds at an unprecedented scale for a favored class of private entities at the expense of a disfavored class.

Third, the fact that the agency itself never before understood its authority under Section 340B to sweep so broadly is a "powerful indication" that the agency's new construction is wrong. *FTC v. Bunte Bros.*, 312 U.S. 349, 351 (1941); *see id.* at

352 ("[T]he want of assertion of power by those who presumably would be alert to exercise it" is "significant in determining whether such power was actually conferred."). As the district court explained, *see* SA.53-58, the agency took the position *for years* that it lacked the authority it now claims the statute unambiguously grants it. It "not only espoused the view that it lacked enforcement authority regarding contract pharmacy use, but also applied that view in practice in addressing covered entity compliance." SA.55. The agency consistently told covered entities—and Lilly—that it could not make manufacturers honor contract-pharmacy arrangements, *see supra* pp.9-11, 16-17, and even told the GAO that it saw no need to police contract-pharmacy abuses by covered entities because "the 340B statute does not address contract pharmacy use," GAO-21-107, at 15-16. The agency stuck to this view through the 2010s, and even for most of 2020. SA.53-55. Indeed, the agency has urged Congress for years to provide it with comprehensive rulemaking authority precisely because it understands its current authority to be limited. *See supra* p.16 n.4. Precedent and basic logic counsel against now accepting the agency's novel claim of power—and all the more so given the lack of text authorizing it.

Fourth, legislative history confirms that Congress never authorized the agency's interpretation. Of course, "ambiguous legislative history" cannot be used "to muddy clear statutory language." *Milner*, 562 U.S. at 572. But here, it confirms what the plain text says. The House Committee Report explains that Congress enacted Section 340B to address a possible manufacturer incentive to raise drug prices. Medicaid requires manufacturers to issue rebates based on the "best price" offered to

any other U.S. purchaser. H.R. Rep. No. 102-384(II) at 9 (1992). In 1992, Congress feared that manufacturers would raise the "best price" offered to "specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans" (*i.e.*, covered entities) in order to decrease any Medicaid rebate they might owe. *Id.* at *12. Congress therefore created the 340B program to "remove any disincentive that the Medicaid rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals" and to "enable [covered] entities to stretch scarce Federal resources as far as possible." *Id.* That limited intervention to prevent a "disincentive" and give covered entities "access to price reductions" is wholly inconsistent with the agency's newfound mandate that manufacturers subsidize an unlimited number of for-profit contract pharmacies without restriction. And of course, nothing in this history suggests Congress intended to comprehensively prohibit all terms of sales offers for 340B drugs.

Indeed, a draft bill suggests that Congress did not intend to extend the program to contract pharmacies at all. If enacted, this draft bill would have required discounts on drugs "purchased and dispensed by, or under a contract entered into for on-site pharmacy services with," covered entities (or "purchased or dispensed by any satellite entity" of covered entities). S. Rep. No. 102-259, at 1-2 (1992). Yet as Judge Stark explained, although Congress "specifically contemplated" language permitting contract-pharmacy relationships, it "chose not to include pharmacy services in the

version of the bill that it ultimately passed." *AstraZeneca I*, 543 F. Supp. 3d at 60; *see also AstraZeneca II*, 2022 WL 484587, at *6 & n.9.

C. The District Court's Contrary Conclusion is Indefensible.

In one part of its opinion, the district court evidently agreed that the agency's construction of the statute lacks support in the text. It vacated the December 2020 Advisory Opinion, in which the agency first construed Section 340B to "obligate[]" each "manufacturer in the 340B Program … to deliver [340B] drugs to … contract pharmacies," A.5, as arbitrary and capricious on the ground that Congress *did not* impose any such "requirement" in the statute, SA.34-35. And the court declined to endorse the agency's view that "the 340B statute" *itself* "require[s] drug manufacturers to deliver to an unlimited number of contract pharmacies." SA.48. Those conclusions were correct. It follows that because Congress did not require manufacturers to deliver 340B drugs to contract pharmacies, the agency was wrong to conclude that Lilly's policy violates a nonexistent statutory command.

The district court went astray by jettisoning statutory text in favor of an unbounded inquiry into what would further the statute's general purposes. Indeed, the district court appeared to believe Section 340B's purposes had been frustrated for the first 18 years of its existence. It reasoned that because allowing manufacturers to impose delivery conditions—even modest ones that are more contract-pharmacy-friendly than the agency even *permitted* from 1992 to 2010—would "frustrate Congress' manifest purpose" to "create a comprehensive drug distribution scheme to enable safety net providers to purchase … 340B drugs in a manner that ensures

access to the discounted medications," the agency must be able to prevent manufacturers from imposing all such conditions. SA.43, 47.

That is not how statutory interpretation or administrative law work. Courts are not free to hypothesize what they think Congress's animating purpose must be and then pursue that objective as far as possible, so that every statute becomes "a comprehensive … scheme." SA.43. Because "no legislation pursues its purposes at all costs," 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, 525-26 (1987) (per curiam). Indeed, because "pretty much everything Congress does" is "a result of compromise," *Abramski v. United States*, 573 U.S. 169, 186 (2014), imposing limits on how far one particular purpose will be carried "is the very essence of legislative choice," *Rodriguez*, 480 U.S. at 525-26. Congress makes law while balancing the interests of "highly interested parties," often with conflicting goals, "attempting to pull the provisions [of proposed legislation] in different directions." *Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 461 (2002). It is therefore error for a court to "rewrite" a statute "under the banner of speculation about what Congress might have done had it faced a question that, on everyone's account, it never faced." *Henson v. Santander Consumer USA Inc.*, 137 S. Ct. 1718, 1725 (2017). That is a job for Congress alone.

This bedrock principle compels reversal. Nothing in the text of the statute reflects a congressional judgment that Section 340B's private-wealth-transfer mandate requiring manufacturers to offer discounts to specified non-profits should

be extended to *also* encompass unlimited delivery to third parties. The statute thus cannot be construed to impose any such requirement.

Confirming that, elsewhere in its opinion the district court got this question right. In vacating the Advisory Opinion as arbitrary and capricious, the district court held (correctly) that nothing in the statute requires manufacturers to deliver 340B drugs to contract pharmacies. SA.34, 48. That should have been the end of the matter when it came to the Violation Letter too, for "no amount of policy-talk can overcome a plain statutory command." *Niz-Chavez v. Garland*, 141 S. Ct. 1474, 1486 (2021). Yet rather than follow that (correct) determination to its logical endpoint, the court simply declared, without identifying any textual support, that "Congress's use of broad language" and failure to "mention … where 340B drugs are to be delivered" "leave [no] room for drug manufacturers" to impose *any* conditions on 340B delivery. SA.43, 46-47. Tellingly, although the court decided that Lilly's policy "directly conflicts with the statutory requirement," SA.46, it never identified that "statutory requirement"—which should be no surprise, since a few pages earlier the court (correctly) acknowledged that *no such requirement exists, see* SA.34-35.

At the core of the district court's analysis is a fundamental mistake about the legal consequence of statutory silence. In this country, private parties do not typically need the government's express permission to do things with their property. It is instead *administrative agencies* like HHS that "ha[ve] no power to act" under our constitutional system "unless and until Congress confers power upon [them]." *Louisiana Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); *see also Merck Sharp*

& Dohme Corp. v. Albrecht, 139 S. Ct. 1668, 1679 (2019). Private parties are free to act (or decline to act) "unilateral[ly]," without government authorization, as long as their actions do not violate any validly enacted law. *Contra* SA.49, 59.

That is why the Supreme Court has "frequently cautioned that '[i]t is at best treacherous to find in congressional silence alone the adoption of a controlling rule of law.'" *United States v. Wells*, 519 U.S. 482, 496 (1997). This principle has special force here, as the Supreme Court has said that Congress must "speak directly" when it intends to interfere with common-law rights. *United States v. Texas*, 507 U.S. 529, 534 (1993). When the default is liberty, government cannot take that liberty away through bank-shot inferences. And it certainly cannot do so on pain of severe monetary penalties. After all, "one is not to be subjected to a penalty unless the words of the statute plainly impose it." *Comm'r v. Acker*, 361 U.S. 87, 91 (1959) (quotation omitted).

The district court thus got it backwards. Not only is there no text authorizing HRSA's newfound mandate, but HRSA *concededly* "can't add to the statutory obligation" Congress did enact because it lacks any general rulemaking authority. Mot. Hr'g Tr. 51:23-25, *AstraZeneca*, No. 21-cv-00027; *see also* Gov't Br. 2, 38, *Novartis*, No. 21-5299 (conceding same); *PhRMA*, 43 F. Supp. 3d at 42 (so holding). Yet the district court concluded that *because* Section 340B "specifically omit[s] any mention of where 340B drugs are to be delivered," SA.46, the agency *can* prohibit manufacturers from setting delivery conditions as "unilateral extra-statutory

restrictions," SA.49, 59. The opposite is true: Since delivery conditions are indeed "extra-statutory," HRSA *cannot* impose them on Lilly.

The Supreme Court's decision in *Christensen v. Harris County*, 529 U.S. 576, 587 (2000), confirms the point. There, the Department of Labor issued an opinion letter interpreting a statute to prohibit employers from compelling employees to use their accrued time off (instead of receiving monetary compensation). *Id.* at 578. The government argued that because "neither the statute nor the regulations *permit* an employer to require an employee to use accrued compensatory time," employers were prohibited from doing so. *Id.* at 588 (emphasis added). The Supreme Court rejected that extreme position as "exactly backwards." *Id.* Agencies may not infer from statutory silence an "implicit[]" prohibition on otherwise lawful practices. *Id.* at 582.

In any case, Congress's silence about contract pharmacies here is especially telling. According to HHS, the premise of the contract-pharmacy distribution scheme is that, so long as covered entities are nominally involved, (for-profit) contract pharmacies can obtain drug manufacturers' property, sell it for a profit, and keep the difference. *See generally* A.5-12. To put it mildly, that is a bit much for a supposed "inference from legislative silence"; indeed, as explained in Section E, *infra*, drawing such an inference would raise fairly obvious Takings Clause problems Congress presumably would wish to avoid.

* * *

All of that explains why every court to consider this question (including the district court) has agreed that the statute is "silent on what role (if any) contract

pharmacies play in Congress' discount drug scheme," and held that the agency erred when it interpreted the text to "unambiguously permit[] contract pharmacy arrangements." *Sanofi-Aventis U.S., LLC v. HHS*, 2021 WL 5150464, at *35-36 (D.N.J. Nov. 5, 2021); *see also* SA.45, 59; *Novartis*, 2021 WL 5161783, at *6; *AstraZeneca II*, 2022 WL 484587, at *6. And although one district judge agreed with Judge Barker that Section 340B contains unstated prohibitions on sales conditions, *see Sanofi-Aventis*, 2021 WL 5150464, at *37 (reasoning based on "Congressional intent" after "start[ing] with the legislative history"), two other district courts correctly held that substantially identical violation letters sent to other manufacturers are inconsistent with text, structure, and basic principles of interpretation.[8]

"Most important[]" to Judge Stark was the fact that "the text of 42 U.S.C. §256b(a) never mentions pharmacies." *AstraZeneca II*, 2022 WL 484587, at *6. That "omission" is "a 'strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies,'" and is all the more "notable" given that "another provision in §256b explicitly refers to certain affiliates of covered entities," *id.*; *see also* 42 U.S.C. §256b(d)(3)(B)(vi). "When a statute does not include even a single reference to the pertinent word (e.g., 'pharmacy'), it is highly unlikely (if not impossible) that the statute conveys a single, clear, and unambiguous

[8] All of these decisions are now on appeal before the Third and D.C. Circuits. *See AstraZeneca Pharms. LP v. Becerra*, No. 22-1676 (3d Cir. filed Apr. 15, 2022); *Novartis Pharms. Corp. v. Johnson*, No. 21-5299 (D.C. Cir. filed Dec. 30, 2021); *Sanofi-Aventis U.S., LLC v. HHS*, No. 21-3167 (3d Cir. filed Nov. 26, 2021).

directive with respect to that word." *AstraZeneca I*, 543 F. Supp. 3d at 59. Judge Stark found it hard "to imagine that 'Congress enumerated 15 types of covered entities with a high degree of precision,' and then intended to impliedly sweep in sales implicating contract pharmacies." *AstraZeneca II*, 2022 WL 484587, at *6.

Judge Friedrich also rejected HRSA's position (and expressly disagreed with the district court below, *Novartis*, 2021 WL 5161783, at *7 n.4). She explained that Section 340B is "silent as to what distribution requests *manufacturers* must accept." *Id.* at *6. The statute, she concluded, requires only that manufacturers "present their drugs to covered entities." *Id.* "Section 340B's 'Shall Offer' provision … requires manufacturers to offer their drugs to covered entities at the discounted price if they offer them to other purchasers," and the ordinary meaning of "offer" is "'presenting something for acceptance.'" *Id.* (quoting *Black's Law Dictionary* (11th ed. 2019)). Furthermore, neither the "must offer" provision nor "any other language in Section 340B" requires that manufacturers' offers to covered entities must be *unconditional*. *Id.* at *6-7, *9. The agency's "interpretation," Judge Friedrich concluded, "stretches the 'Shall Offer' provision beyond its plain meaning." *Id.* at *6.

This Court should hold the same.

D. Government Counsel's Post Hoc Arguments are Meritless.

In violation of basic administrative law principles, *see SEC v. Chenery Corp.*, 318 U.S. 80, 95 (1943); *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 224 (2016), HHS's lawyers also advanced several post hoc rationalizations for the Violation Letter. None can save the Violation Letter.

1. The government argued below that the *other* operative sentence in 42 U.S.C. §256b(a)(1)—"The Secretary shall enter into an agreement with each manufacturer … 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]"—"plainly requires manufacturers to *sell* discounted drugs *to covered entities*" "regardless how they dispense those drugs." R.125.15. But that provision directly imposes an obligation only *on the Secretary*, not on manufacturers. *AstraZeneca I*, 543 F. Supp. 3d at 59. And to the extent it (indirectly) contemplates required action by manufacturers, it requires only that manufacturers make their drugs available to be "purchased by" covered entities at or below the ceiling price. *See* 42 U.S.C. §256b(a)(1). No person would understand a requirement to make drugs available for purchase by *X* to mean the seller must deliver the drugs to *Y*. Put simply, the "purchased by" sentence does not carry a deliver-wherever-told requirement any more than the "offer" sentence does.

2. The government also offered the district court a new theory of the "offer" sentence not mentioned in the Violation Letter; this second post-hoc theory fails too. The government argued that the "offer" sentence in 42 U.S.C. §256b(a)(1) imposes an "*additional* requirement that manufacturers cannot discriminate by treating commercial purchases more favorably than 340B purchases," which it argued Lilly's 340B distribution initiative violates because "Lilly places no delivery-location or dispensing-mechanism restrictions on full-priced sales." R.125.15-16. But the statute says no such thing. "Congress knows full well how to forbid discrimination,"

Novartis, 2021 WL 5161783, at *7, usually by employing (what else) some form of the word "discriminate," *e.g.* 42 U.S.C. §300gg-5(a); *id.* §2000e-2(a). Section 340B does not. It says only 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). In any case, Lilly's initiative does not violate any invisible nondiscrimination requirement. "Discrimination consists of treating like cases differently." *NLRB v. Collier*, 553 F.2d 425, 428 (5th Cir. 1977). The agency has pointed to no evidence that Lilly is refusing to do something for covered entities that it does in ordinary commercial sales. (No such evidence exists.) And while it is true that Lilly's policy is 340B-specific—*i.e.*, it does not apply to purchasers other than covered entities or to drugs not sold at 340B prices—that is simply because no one but covered entities is eligible for federally mandated discounts, licenses their eligibility for discounts to for-profit retailers, or uses the replenishment-model accounting trick. Lilly's policy treats *different* situations differently. That is not discrimination.

E. The Agency's Atextual Construction Violates the Canon of Constitutional Avoidance.

To make matters worse, the agency's position also runs headlong into the Takings Clause and the unconstitutional-conditions doctrine. The Takings Clause provides that the government may not "take[]" "private property … for public use, without just compensation." U.S. Const. amend. V. Nor may the government effectively accomplish the same by "characteriz[ing]" a taking "as part of a … voluntary exchange" when it is not in fact "voluntary." *Horne v. Dep't of Agric.*,

576 U.S. 350, 366 (2015). The government may not "hold hostage" the right to do business in a particular industry only "to be ransomed by the waiver of constitutional protection." *Id.* Likewise, the unconstitutional-conditions doctrine "vindicates the Constitution's enumerated rights," including property rights, "by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). In the property-rights context, in particular, courts generally ensure that the government has not unlawfully coerced a private party into giving up a constitutional right by demanding at least a "'nexus' and 'rough proportionality'" between the government's demands and any "social costs." *Id.* at 605-06; *see also Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2079 (2021).

Here, the Takings Clause and the unconstitutional-conditions doctrine bar HRSA from commanding Lilly to give away its property in the form of drugs priced well below market value to an ever-growing number of for-profit contract pharmacies. To begin with the basics, it is beyond dispute that the Takings Clause bars the government from directly compelling Lilly to give its property to another third party without just compensation. It makes no difference that Lilly's drugs are personal rather than real property, *Horne*, 576 U.S. at 358; that Lilly still receives *some* payment for its drugs, *id.* at 363; *Cedar Point*, 141 S. Ct. at 2073; that the government would be ordering Lilly to transfer its property to "a particular class" of private parties (*i.e.*, covered entities) rather than the government itself, *Kelo v. City of New London*, 545 U.S. 469, 477 (2005); or that the government's command would come

"garbed as a regulation," *Cedar Point*, 141 S. Ct. at 2072. The government would still be "physically tak[ing] [Lilly's] property for … someone else." *Id.*

Nor can the government impose the same private-wealth-transfer mandate as a "condition" of drugmakers' nominally voluntary participation in Medicare and Medicaid. *Horne* proves the point. There, the Supreme Court held that the government could not demand that raisin growers submit to an uncompensated taking as the price of "participat[ing] in the raisin market." 576 U.S. at 365. The Court explained that what the government described as a "voluntary" exchange was not voluntary at all because the government may not force industry participants to choose between their industry and their constitutional rights. "[P]roperty rights 'cannot be so easily manipulated'" with a "voluntary" label. *Id.*

Even in the Spending Clause context, the Supreme Court has made clear that the Constitution forbids the government from "using financial inducements to exert a 'power akin to undue influence.'" *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012). Thus, the government may not use the carrot-and-stick component of its Spending Clause power to impose onerous conditions of participation to which private parties have "no real option but to acquiesce," *id.* at 582, and courts may not blindly treat a private party's participation in a federal spending program as acquiescence in whatever coercive conditions the government may attach to it.

That is why it is no response to say, as the district court did, *see* SA.50, that Lilly "chose" to participate in the 340B program. True, Lilly agreed thirty years ago to participate in a limited program to help subsidize the care of disadvantaged

populations in exchange for Medicare and Medicaid reimbursements. But the program at that time benefited only nonprofit entities that served communities, not shareholders. The terms of the bargain have materially changed since then. Now, the program requires Lilly to subsidize for-profit companies who serve shareholders, not communities, and those same for-profit companies have contributed to exponential growth in the 340B program. It would have been unthinkable in 1992 that the program—which, again, is funded *entirely by manufacturers*—would one day be larger than nearly all other federal drug programs, *including Medicaid*. Lilly certainly could not have anticipated such transformational changes. Until a year ago, the agency *itself* disavowed any authority to require manufacturers to subsidize contract pharmacies' profits—let alone to penalize manufacturers that decline to the potential tune of millions of dollars.

Nor can Lilly reasonably walk away at this point. Medicaid alone reimbursed outpatient pharmaceutical manufacturers a total of over $66 billion in 2019 alone. Medicaid & CHIP Payment & Access Comm'n, *Report to Congress on Medicaid and CHIP* 3 (June 2021), https://bit.ly/3lmc0Mf; *see also Allina*, 139 S. Ct. at 1808 ("One way or another, Medicare touches the lives of nearly all Americans."). Lilly, like all participating manufacturers, now relies on its substantial Medicaid and Medicare payments and has relied upon them for decades. In *NFIB*, the Supreme Court held that sovereign States could not "defend their prerogatives by … not yielding" when Congress changed the terms of its Medicaid bargain and offered them the "choice" of either relinquishing the entirety of their Medicaid funds or expanding their Medicaid

programs. *See* 567 U.S. at 581-82. If the threat of losing Medicaid funds is coercive of sovereign states, it is surely coercive of private companies. As in *NFIB*, the government's command backed by threat of debarment is nothing less than "economic dragooning" equivalent to "a gun to the head." *Id.* at 581-82; *see also Horne*, 576 U.S. at 366; *Doe v. Univ. of Sciences*, 961 F.3d 203, 213 (3d Cir. 2020).

In any event, even if manufacturers' overall participation in the 340B program were not coerced, the government's proposed delivery requirement would still count as an unconstitutional condition because it flunks the nexus and proportionality test applied to exactions of private property. *See generally Cedar Point*, 141 S. Ct. at 2079. As a general matter, the "government may require property owners to cede a right of access as a condition of receiving certain benefits" only if the condition exacted from the property owner has "an 'essential nexus' and 'rough proportionality'" to the underlying government interest prompting the exaction. *Id.* (quoting *Dolan v. City of Tigard*, 512 U.S. 374, 386, 391 (1994)). In *Nollan v. California Coastal Commission*, 483 U.S. 825 (1987), for example, the Supreme Court held that, while the government could prevent a beachfront landowner from constructing a house on his own property to protect the public's ability "to see the beach," it could *not* condition a construction permit on requiring the landowner to grant a public easement across his land, *id.* at 837. Because the condition did not "further the end advanced as the justification" for the permit, it amounted to "an out-and-out plan of extortion." *Id.*

The government's interpretation of Section 340B here transforms and enlarges manufacturers' obligations beyond the bounds of the nexus and proportionality test.

As for nexus: Section 340B was designed to help needy patients that otherwise rely on Medicaid by granting covered entities that serve them access to discounted drugs. Whether that discount is passed on to patients or applied to reduce the costs of the facilities that serve them, the benefit exacted from participating manufacturers at least has a tight nexus to the program and its beneficiaries. But there is no "essential nexus" between the 340B program and allowing *for-profit commercial pharmacies* both *to profit* from the sale of manufacturers' drugs (while patients pay full retail price) *and to increase the rate of fraud* in the program. *See supra* pp.12-15. As for proportionality: The government's ever-expanding view of manufacturers' obligations has transformed the 340B program from an aid to Medicaid into something even larger than Medicaid—and indeed, larger than every federal drug program except Medicare Part D (which did not exist when Section 340B was enacted). Whatever close cases the proportionality test may sometimes present, this is not one of them.

At a minimum, the fact that the agency's construction raises these serious constitutional concerns means that it cannot be upheld under the principle of constitutional avoidance. Federal courts must "avoid an interpretation of a federal statute that engenders constitutional issues if a reasonable alternative interpretation" (which Lilly's plainly is) "poses no constitutional question." *Gomez v. United States*, 490 U.S. 858, 864 (1989). Here, it is not just that Congress *presumptively would* wish to avoid these private-wealth-transfer concerns; Congress *explicitly did* try to avoid them: It narrowly defined the universe of "covered entities"

to include only nonprofits, and it prohibited both diversion of 340B benefits and the taking of duplicate discounts. 42 U.S.C. §256b(a)(4), (5)(A)-(B); *see Novartis*, 2021 WL 5161783, at *5. Those provisions appropriately confine the benefit exacted from manufacturers to proportional limits. *See id.* at *1. The Congress that enacted those limits should not be presumed to have also intended a construction of Section 340B that obliterates them and simultaneously raises constitutional problems.

CONCLUSION

The judgment should be reversed in part and the case remanded with instructions to declare that Lilly's contract-pharmacy initiative does not violate the statute.

Respectfully submitted.

May 25, 2022

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CERTIFICATE OF COMPLIANCE
WITH TYPE-VOLUME LIMITATION

1. This brief complies with the type-volume limitation of 7th Circuit Rule 28.1 because, according to the "word count" function of Microsoft Word 2016, it contains 13,897 words, excluding the parts of the brief exempted from the word count by Federal Rule of Appellate Procedure 32(f).

2. This brief, which has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 12-point Century Schoolbook font, complies with the typeface and typestyle requirements of Federal Rules of Appellate Procedure 32(a)(5) and 32(a)(6).

May 25, 2022

s/ John C. O'Quinn, P.C.
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CERTIFICATE OF SERVICE

I hereby certify that on May 25, 2022, 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, P.C.
John C. O'Quinn, P.C.

REQUIRED SHORT APPENDIX

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 1:21-cv-00081-SEB-MJD
	)	
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.	)	
	)	
Defendants.	)	

ORDER

This cause is before the Court on a virtual cornucopia of claims: Defendants' Motion to Dismiss, or in the alternative, for Summary Judgment [Dkt. 87], filed on April 19, 2021; and Plaintiffs' Cross Motion for Summary Judgment [Dkt. 89] and Motion for Preliminary Injunction [Dkt. 94], filed on May 10, 2021 and May 20, 2021, respectively. Plaintiffs Eli Lilly and Company and Lilly USA, LLC (collectively, "Plaintiffs" or "Lilly") have brought this action against Defendants United States Department of Health and Human Services ("HHS"), Health Resources and Services Administration ("HRSA"), Diana Espinoza, in her official capacity as Acting Administrator of HRSA, Xavier Becerra, in his official capacity as Secretary of HHS, and Daniel J. Barry, in his official capacity as Acting General Counsel of HHS (collectively, "Defendants") under the Administrative Procedures Act ("APA"), challenging various agency actions involving the 340B Drug Pricing Program ("340B Program"), which Congress created in 1992 to

expand low-income Americans' access to affordable prescription medicines. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967.

Currently before us for decision are Plaintiffs' various legal challenges to a December 30, 2020 Advisory Opinion ("Advisory Opinion") released by HHS's Office of the General Counsel and a May 17, 2021 enforcement letter ("May 17 Letter") from HRSA, both relating to drug manufacturers' obligations under the 340B statute when dealing with covered entities that dispense medications through contract pharmacy arrangements.[1] Plaintiffs seek a judgment declaring that in issuing the Advisory Opinion and the May 17 Letter Defendants violated the APA by having been issued without Defendants following the required procedures, exceeding the agency's statutory authority, violating the Constitution, and by being arbitrary and capricious or otherwise not in accordance with law. Plaintiffs seek to have their implementation and/or enforcement enjoined. Plaintiffs also seek a declaratory judgment holding that Defendants lack the lawful authority to require Lilly to offer or provide 340B discounts to contract pharmacies.

On July 30, 2021, the Court conducted a hearing at which oral arguments were made on the pending motion for preliminary injunctive relief, directed at enforcement of

[1] Lilly has also challenged in this lawsuit Defendants' December 14, 2020 Administrative Dispute Resolution Regulation published at 85 Fed. Reg. 80,632 and codified at 42 C.F.R. §§ 10.20-24 (the "ADR Rule"), which sets forth the administrative dispute resolution process for certain disputes regarding the 340B Program. Pursuant to our prior ruling, Defendants are currently enjoined from enforcing the ADR Rule as to Lilly. The parties have agreed that a final decision on the merits of this claim can be issued by separate order at a later date. Accordingly, we do not address the ADR Rule in this entry.

the May 17 Letter, and the cross-motions for summary judgment as to all Plaintiffs' claims related to the Advisory Opinion and the May 17 Letter. Pursuant to Federal Rule of Civil Procedure 65(a)(2), we now hereby consolidate our ruling on the preliminary injunction with our ruling on summary judgment. Having carefully reviewed and considered the parties' written briefs and oral arguments, the administrative record, and the applicable legal principles, we hold, for the reasons detailed below, that the Advisory Opinion is invalid under the APA as arbitrary and capricious, and that the May 17 Letter while not contrary to law, unconstitutional, or violative of notice and comment procedures, is likewise arbitrary and capricious and thus violative of the APA, warranting an order setting aside and vacating their findings and directives and remanding the May 17 Letter to the agency for further consideration/action consistent with the opinions explicated here.

Factual Background

Background of the 340B Drug Pricing Program

Plaintiffs' lawsuit arose under the 340B Drug Price Program ("340B Program"), a drug-pricing discount regime established by Congress in 1992 within the Public Health Service Act, *see* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 (codified as amended at 42 U.S.C. § 256b), and administered by the Secretary of Health and Human Services ("HHS"), which requires, as a condition of Plaintiffs' participation in Medicaid and Medicare Part B,[2] that pharmaceutical

[2] Technically speaking, pharmaceutical manufacturers are free to opt out of participation in the 340B Program. However, if they do, they cannot receive coverage of or reimbursement for their

manufacturers such as Plaintiffs sell their outpatient drugs at a heavily discounted price to "covered entities," which are defined by statute to include 15 enumerated types of public and not-for-profit hospitals, community centers, and other federally funded clinics serving low-income patients. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992), *codified at* § 340B Public Health Service Act, 42 U.S.C. § 256b (1992). More specifically, all pharmaceutical manufacturers participating in the 340B Program 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). The resulting 340B "ceiling prices," which are calculated according to a prescribed statutory formula, *see id.* § 256b(a)(1), (a)(4), (b)(1), are significantly lower than the amount(s) other purchasers would pay and, in some cases, are as low as one penny per pill. These drug pricing discounts are intended to "enable [covered entities] to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384, pt. 2 at 12 (1992) (conf. report). Although not required, covered entities are permitted to pass the savings along to uninsured and underinsured patients to subsidize the costs of what would otherwise be cost prohibitive rates for medications.

products under Medicaid and Medicare Part B. If they opt out of participation in the 340B Program, they stand to lose "billions of dollars in revenue" annually from drug coverage in federal health-insurance programs. Am. Compl. ¶ 157.

To participate in the 340B Program, manufacturers are required to sign a form contract with HHS known as the Pharmaceutical Pricing Agreement ("PPA"), which incorporates the statutory obligations of the 340B Program and expresses the manufacturers' agreement to abide by those obligations. *See* 42 U.S.C. § 1396r-8(a)(1), (5). If at some point the government determines that a drug manufacturer has failed to comply with its 340B Program obligations, the manufacturer's PPA can be terminated, thereby preventing the manufacturer from receiving coverage for its drugs under Medicare and Medicaid. *See id.* § 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412–65,413 (Dec. 12, 1996); PPA §§ IV(c), VI(c).

Under the 340B Program, covered entities are prohibited from requesting "duplicate discounts or rebates," which means that covered entities may not request both a 340B discount and a Medicaid rebate for the same drug. 42 U.S.C. § 256b(a)(5)(A). Covered entities are also prohibited from engaging in "diversion," which is defined by statute as the practice of "resell[ing] or otherwise transfer[ring]" a covered outpatient drug "to a person who is not a patient of the entity." *Id.* § 256b(a)(5)(B).

HRSA's 1994 Final 340B Program Guidelines

In 1994, following a notice and comment period, HRSA issued "final program guidelines" for the 340B program which provided that "manufacturers must offer outpatient drugs at or below the section 340B discount prices," and "[i]f the manufacturer's drugs are available to covered entities through wholesalers, the discount must be made available through that avenue." 59 Fed. Reg. 25,113. The 1994 guidelines further provided that "[m]anufacturers may not single out covered entities from their

other customers for restrictive conditions that would undermine the statutory objective," (*id.* at 25,111–112), and "must not place limitations on the transactions (e.g., minimum purchase amounts) which would have the effect of discouraging entities from participating in the discount program." *Id.* at 25,113. In response to a comment urging the agency not to require manufacturers to honor contract-pharmacy sales, HRSA acknowledged that "[i]t is a customary business practice for manufacturers to sell to intermediaries as well as directly to the entity," that entities "often use … contract pharmacies," and that, "[b]y placing such limitations on sales transactions, manufacturers could be discouraging entities from participating in the program." *Id.* at 25,111.

HHS's 1996 Advisory Opinion Regarding Contract Pharmacies

During the first few years of operation of the 340B Program, it became clear that fewer than five percent of the covered entities who were statutorily eligible to participate in the 340B Program actually operated in-house pharmacies. Instead, the vast majority of such providers relied on distribution arrangements with outside pharmacies, called "contract pharmacies," to dispense prescriptions to patients. *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549-01, 43,550 (Aug. 23, 1996) (hereinafter "1996 Guidance"). Covered entities participating in the 340B Program who did not operate in-house pharmacies thus began relying on contract pharmacies to take delivery from manufacturers of 340B drugs purchased by the covered entity in order to dispense those drugs to the covered entities' low-income patients. *Id.* at 43,549.

Acknowledging this practice, and recognizing that, because "covered entities provide medical care for many individuals and families with incomes well below 200% of the Federal poverty level and subsidize prescription drugs for many of their patients, it was essential for them to access 340B pricing," (*id.* at 43,549), HHS issued non-binding guidance in 1996, stating that "[i]t would defeat the purpose of the 340B program if these covered entities [without in-house pharmacies] could not use their affiliated pharmacies in order to participate," because "[o]therwise, they would be faced with the untenable dilemma of having either to expend precious resources to develop their own in-house pharmacies (which for many would be impossible) or forego participation in the program altogether." *Id.* at 43,550. This 1996 Guidance thus advised that "[i]t has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price," regardless of whether the covered entity directs that the 340B drugs be shipped for handling and dispensing to a contract pharmacy. *Id.* at 43,549. In other words, "[i]f the [covered] entity directs the drug shipment to its contract pharmacy," that practice does not "exempt[] the manufacturer from statutory compliance." *Id.* at 43,549.

HHS further advised that limiting covered entities' access to 340B discounts only to those operating an in-house pharmacy would not be "within the interest of the covered entities, [or] the patients they serve, [or] consistent with the intent of the law." *Id.* at 43,550. The 1996 Guidance therefore explicitly provided that permitting the use of contract pharmacies does not constitute an unauthorized expansion of the 340B Program

because "[t]he statute is silent as to permissible drug distribution systems," and contains "no requirement for a covered entity to purchase drugs directly from the manufacturer or to dispense drugs itself." *Id.* at 43,549. Instead, "[i]t is clear that Congress envisioned that various types of drug delivery systems would be used to meet the needs of the very diversified group of 340B covered entities." *Id.* The 1996 Guidance counseled that covered entities could, if they chose, use "one pharmacy contractor per entity" to dispense 340B drugs. *Id.* at 43,555. The 1996 Guidance also clarified that it "create[d] no new rights or duties" under the 340B Program. *Id.* 43,550.

HHS's 2010 Advisory Opinion Regarding Contract Pharmacies

The 1996 Guidance addressed the use of only a single contract pharmacy. Fourteen years later, in 2010, HHS issued supplemental non-binding guidance specifying that covered entities were not necessarily limited to a single contract pharmacy, but were free to contract with as many pharmacies as they chose, even if they also operated an in-house pharmacy. *See* Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 75 Fed. Reg. 10,272-01 (Mar. 5, 2010) (hereinafter "2010 Guidance"). After issuing notice and soliciting comments, HHS opined that "[i]t would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements by covered entities," and that, because "some patients currently face transportation barriers or other obstacles that limit their ability to fill their prescriptions," more widespread use of contract pharmacies "would permit covered entities to more effectively utilize the 340B program and create wider patient access." *Id.* at 10,273.

The 2010 Guidance, in an effort to prevent unlawful duplicate discounts and the diversion of 340B drugs, included the following "essential elements" for transactions involving contract pharmacies: the "covered entity will purchase the drug, maintain title to the drug and assume responsibility for establishing its price"; "[a] 'ship to, bill to' procedure [will be] used in which the covered entity purchases the drug; the manufacturer/wholesaler must bill the covered entity … but ship[] the drug directly to the contract pharmacy"; "[b]oth the covered entity and the contract pharmacy are aware of the potential for civil or criminal penalties" for violations; and both the covered entity and contract pharmacy must maintain auditable records, track prescriptions, and verify patient eligibility. *Id.* at 10,278. The 2010 Guidance further stated that the covered entity was responsible for ensuring adherence to the 340B Program requirements and could lose eligibility if violations were to occur. *Id.*

The 2010 Guidance also provided that, "if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price," regardless of whether the covered entity "directs the drug shipment to its contract pharmacy." *Id.* HHS represented that the 2010 Guidance did not constitute "substantive rulemaking under the APA" because it merely interpreted the 340B statute "to create a working framework for its interpretation" and imposed no "additional burdens upon manufacturers, nor create[d] any new rights for covered entities under the law." *Id.*

Following issuance of the 2010 Guidance, no pharmaceutical manufacturer, trade association, or other similar entity filed suit to challenge its requirements or effect.

Defendants' Claimed Lack of Authority to Enforce Contract Pharmacy Arrangements

According to Lilly, at no time between 1992, when the 340B program began, and 2020, did Defendants initiate any enforcement action against any manufacturer that declined to deliver discounted drugs to contract pharmacies or refused to deal with an unlimited number of contract pharmacy arrangements.[3] In fact, in 2020, Defendants represented on several occasions that the agency did not possess legal authority to undertake such enforcement action. For example, on June 11, 2020, HRSA informed Lilly that the 1996 and 2010 "contract pharmacy advice" was not "binding" on manufacturers. VLTR_7590. HRSA also represented in a 340B-focused article in July 2020 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). On more than a few occasions during 2020, Defendants also informed covered entities that, although "HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacies," it "has only limited ability to issue enforceable regulations" in light of what was described as a lack of "authority" to make such a

[3] We note, however, that it is not clear how many, if any, drug manufacturers might have taken such actions prior to 2020.

demand. VLTR_3272, VLTR_3285, VLTR_4194. Accordingly, prior to late 2020, covered entities and contract pharmacies would have "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.

Lilly's Decision to Restrict Shipment of 340B Drugs to Contract Pharmacies

For approximately ten years, Lilly (and apparently every other pharmaceutical manufacturer participating in the 340B Program) followed the guidance set forth in the HHS's 2010 Advisory Opinion by shipping 340B drugs purchased by covered entities to the covered entities' designated contract pharmacies when and as requested to do so. However, in July 2020, Lilly determined, and so notified HHS, that with certain caveats it would no longer offer 340B pricing throughout contract pharmacy arrangements for one of its drugs—Cialis, a drug prescribed to treat erectile dysfunction. In that communication to HHS, Lilly also proposed that HHS rescind its 2010 Guidance on the use of contract pharmacies to dispense drugs purchased by 340B covered entities, even though Lilly had never filed a legal challenge to the 2010 Guidance and had been complying with its requirements for approximately ten years.

Approximately one month thereafter, on August 19, 2020, in response to what Lilly maintains were documented and widespread abuses of the 340B Program that had been increasing over the years since HHS issued its 2010 guidance permitting covered entities to utilize an unlimited number of contract pharmacies to dispense 340B drugs, Lilly publicly announced that it was "discontinu[ing] its practice of voluntarily honoring

requests for 340B 'contract pharmacies' for orders on all Lilly products." Am. Comp. Exh. F (August 19, 2020 Letter from Lilly to HRSA); *see also* Exh. G (notifying covered entities that they "will not be eligible to purchase [Lilly] products at the 340B ceiling price for shipment to a contract pharmacy"). However, Lilly promised to continue to honor orders by covered entities to ship 340B drugs to contract pharmacies in two instances: (1) where the covered entity lacks an in-house pharmacy and thus needs to partner with an outside pharmacy to dispense outpatient drugs; and (2) where the covered entity wholly owns the outside pharmacy and thus can assure the pharmacy's compliance with the 340B Program.[4] In cases where a covered entity lacks an in-house pharmacy and otherwise participates in contract pharmacy arrangements, we understand Lilly to require the covered entity to submit additional paperwork designating a single contract pharmacy for delivery and to engage in a process through which Lilly determines the eligibility of that contract pharmacy.

HRSA's August 2020 Violation Letter

In response to Lilly's newly announced policy, on August 26, 2020, HRSA notified Lilly in writing that the agency was "considering whether your new proposed policy constitutes a violation of section 340B and whether sanctions apply," including, "but [] not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi). Violation Letter Administrative Record ("VLTR") at 7627. In this letter, HRSA disputed

[4] Lilly is not restricting insulin to a single contract pharmacy, but only if insurance is not billed for the insulin, no markup or dispensing fee is charged to the patient, and the covered entity provides Lilly detailed information demonstrating compliance with these conditions.

Lilly's claim that its "plan did not give rise to an enforceable violation of the 340B statute," and warned Lilly that its newly imposed restrictions "would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," while "restrict[ing] access" for "underserved and vulnerable populations" in the midst of the COVID-19 global pandemic. *Id.* HRSA notified Lilly that the agency was "continu[ing] to examine whether Lilly's actions amount to attempts to circumvent th[e] statutory requirement by inappropriately restricting access to 340B drugs." *Id.*

Despite these warnings and concerns from HRSA, beginning in September 2020 and continuing through the present, Lilly has restricted access to 340B discounts through contract-pharmacy arrangements in the manner outlined in its August 19, 2020 notice to HHS. We are informed that several other global pharmaceutical manufacturers, including Sanofi-Aventis, AstraZeneca, and Novartis, followed suit, imposing, with certain modifications, similar restrictions on covered entities' use of contract pharmacies. In response to these actions, several covered entities have filed lawsuits against HHS,[5] seeking to compel HHS, *inter alia*, to reverse the drug manufacturers' unilateral changes in policies regarding contract pharmacies.

HHS's General Counsel's December 2020 Advisory Opinion

On December 30, 2020, following the filings of lawsuits against Defendants in various federal district courts around the country by covered entities and contract pharmacies challenging the drug manufacturers' unilateral restrictions on their

[5] *See, e.g., Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Oct. 9, 2020); *Am. Hosp. Ass'n v. HHS*, No. 20-cv-8806 (N.D. Cal. Dec. 11, 2020).

participation in the 340B Program, HHS's General Counsel issued an Advisory Opinion stating in part "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 the covered entity no more than the 340B ceiling price for those drugs." HHS Gen. Counsel, Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program ("2020 Advisory Opinion") at 1, *available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf (last visited March 9, 2021). The 2020 Advisory Opinion further opined that "the core requirement of the 340B statute … is that manufacturers must 'offer' covered outpatient drugs at or below the ceiling price for 'purchase by' covered entities" and that "[t]his fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs." *Id.* at 2.

The 2020 Advisory Opinion by HHS's General Counsel highlights the fact that covered entities had relied on contract pharmacies for decades for the distribution of these drugs and that the system is compatible with Congressional intent because "the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations," which are "the poster children of providers that one would expect to lack an in-house pharmacy." *Id.* at 4. The 2020 Advisory Opinion anchors HHS's interpretation in the statute itself, according to the General Counsel, and therefore no rulemaking was required, and no expansion of the 340B Program had been effectuated because Congress, in formulating the 340B

procedures, did not permit drug manufacturers to specifically condition access to discounted drugs on covered entities' operation of an in-house pharmacy to take physical delivery of drug purchases. *Id.* at 2–4.

Initiation of the Instant Litigation and Similar Lawsuits

Approximately two weeks following the issuance of the 2020 Advisory Opinion, on January 12, 2021, Lilly filed the instant lawsuit challenging its interpretation(s). That same day, two other pharmaceutical manufacturers, Sanofi-Aventis and AstraZeneca, filed similar federal lawsuits. *See Sanofi-Aventis*, No. 3:21-cv-634 (D.N.J. Jan 12, 2021); *AstraZeneca*, No. 1:21-cv-27 (D. Del. Jan. 12, 2021). Within a matter of a few days, two more pharmaceutical companies, Novo Nordisk and PhRMA, filed similar suits. *See Novo Nordisk v. Azar*, No. 21-cv-00806-FLW (D.N.J. Jan. 15, 2021); *PhRMA v. Cochran*, No. 8:21-cv-198-GLR (D. Md. Jan. 22, 2021).

HRSA's May 2021 Enforcement Letter

Following the issuance of the 2020 Advisory Opinion, Defendants took no other immediate enforcement action against either Lilly, or, to our knowledge, any of the other drug manufacturers, based on the pharmaceutical companies' unilateral changes in their contract pharmacy distribution policies. However, based at least in part on pressure on Congress generated by the covered entities and contract pharmacies objecting to Defendants' lack of enforcement, Congress pressed Defendants to act. On May 12, 2021, HHS Secretary Becerra, in testimony regarding the 340B Program before the U.S. House of Representatives, assured Congress that action would be taken, saying, "We are on this one. … Everyone has to follow the law."

Five days later, on May 17, 2021, HRSA issued a 340B-violation letter (the "May 17 Letter") notifying Lilly that, after a comprehensive and months' long review of Lilly's contract pharmacy policy, "HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute." May 17, 2021 Letter. The May 17 Letter instructed Lilly to "immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements" and to "credit or refund all covered entities for overcharges that have resulted from Lilly's policy." *Id.*

The May 17 Letter reminded Lilly that it had "signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum" and was "bound by the terms of the PPA." *Id.* Citing the statute, the May 17 Letter reiterated the requirement that Lilly must offer covered entities 340B drugs at or below the applicable ceiling price if such drug is made available to any other purchaser at any price, an obligation that "is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs" to its patients, and asserted that "[n]othing in the 340B statute grants a manufacturer the right to place conditions on its fulfillment of its statutory obligation to offer 340B pricing on covered outpatient drugs purchased by covered entities." *Id.*

The May 17 Letter contained a final warning to Lilly that its "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies" would "result in CMPs [civil monetary penalties]" in addition to repayment unless HHS is satisfied with "Lilly's willingness to comply with" HRSA's view of its "obligations under section 340B." *Id.* Lilly was directed to provide, within days, "an update on its plan to restart

selling, without restriction, covered inpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements," on the basis of which information HHS would "determine whether CMPs are warranted based on Lilly's willingness to comply with its obligations under 340B(a)(1)."[6] *Id.*

Lilly sent a written response to HHS explaining that it believes its policy fully complies with the text, structure, and purpose of the 340B statute. *See* Dkt. 115, 115-1. Lilly has therefore continued to apply its contract pharmacy policy per its August 2020 announcement. Plaintiffs recently informed the Court that, in a letter dated September 22, 2021, HRSA wrote to inform them that, "[g]iven Lilly's continued refusal to comply, HRSA has referred this issue to the HHS Office of the Inspector General (OIG) in accordance with the 340B Program Ceiling Price and Civil Monetary Penalties Final Rule." Dkt. 143-1.

Investigation That Led to May 17, 2021 Letter

As referenced above, following Lilly's August 2020 announcement regarding its contract pharmacy policy, Defendants informed Lilly that it planned to undertake a review of that policy to determine whether it violated the 340B statute. Defendants described their conclusions from that review and evaluative process in the May 17 Letter,

[6] Plaintiffs sought a temporary restraining order enjoining enforcement of the May 17 Letter, which, following a hearing, the Court orally denied on May 27, 2021. That denial was based primarily on Plaintiffs' failure to establish that they were likely to suffer irreparable harm if the request were denied. The Court did, however, extend the deadline within which Lilly was required to respond to the May 17 Letter by supplying the requested information.

noting that their review actually commenced months prior to the issuance of the 2020 Advisory Opinion.

The administrative record filed in this case spans more than 8,000 pages and consists of some 6,000-plus pages of complaints from covered entities regarding alleged overcharges. Defendants' May 17 Letter does not identify any specific covered-entity complaints which formed the basis of HRSA's determination, but certain complaints from covered entities and other stakeholders were cited as a part of Defendants' investigation, including the following:

- Beverly Hospital reported that "manufacturer(s) [are] deliberately refusing [the] 340B Price," explaining that restrictions had forced it to pay "WAC [wholesale acquisition cost] for [340B] contract pharmacy orders," which is the highest commercial rate.[7] VLTR_1460–61. The complaint included a spreadsheet showing specific transactions in which the hospital claims the 340B ceiling price was denied and subjected it to WAC costs on Lilly's medications of up to $3,683 per unit, which resulted in $126,508 in lost 340B savings, in October 2020. VLTR_1463. In December 2020, Beverly Hospital again alerted HRSA in writing that Lilly was "deliberately withholding 340B pricing," as illustrated on an accompanying spreadsheet showing numerous Lilly medications where the hospital was charged in amounts exceeding $3,000 per unit, far above the ceiling price, resulting in a loss of more than $70,000 in 340B savings for that month. VLTR_1464–68.

- The University of Utah Health reported that it "has been unable to purchase Eli Lilly products at the 340B ceiling price for delivery to its contract pharmacy," which, the University explained, "is contrary to the 340B statute … and the Pharmaceutical Price Agreement (PPA) Lilly has entered with HRSA." VLTR_5831. According to the University, "Lilly has removed the 340B pricing … [s]o when a [covered entity] replenishes a

[7] The 340B ceiling price is statutorily protected information: 42 U.S.C. § 256b(d)(1)(B)(iii); thus, it is redacted in the administrative record, as well as are other figures that would allow the ceiling price for any particular drug to be easily calculated. We understand the claim to be undisputed, however, that the ceiling prices for medications referenced herein are only a fraction of the WAC prices.

drug on the 340B account for a contract pharmacy, they are actually charged the WAC price. We were charged $3597.83 for a package when the 340B ceiling price is" much higher. VLTR_5834. Shortly thereafter, the University filed another complaint stating it "purchased 2 packages of NDC 00002840001 on 9/17/2020 [and was] charged $4597.83 per package when the ceiling price is" significantly lower. VLTR_5844. The University was charged similar prices again on September 25, 2020. VLTR_5852.

- St. Joseph Medical Center submitted a complaint with an actual invoice attached, showing that it was charged the "WAC pricing" for 340B-covered drugs after the "manufacturer ceased to provide 340B pricing suddenly." VLTR_1837, VLTR_1842. The invoice shows that the drugs were ordered and paid for by St. Joseph but shipped to Franciscan Pharmacy Tacoma and that Lilly charged $326 for one of the drugs and $274 for another, both of which are far above the statutory ceiling price. VLTR_1842.

- A covered entity hospital in South Dakota reported that, when it tried to purchase drugs through its existing wholesaler, "[s]ome accounts had the NDC [drug identifier] taken off the catalog," meaning that the drug was no longer available for purchase by the covered entity, while "some accounts had a WAC[] price listed." VLTR_1373. The covered entity stated that, "[t]he purchases that were made were done on the 340B account in what we feel was WAC[] pricing" and confirmed that it did in fact place orders and pay the WAC cost for those drugs. *Id.*

- Another covered entity included a screenshot from its ordering system showing that all formulations of Humalog, a Lilly insulin product, were marked as "Ineligible" for purchase on its 340B account." VLTR_1590. That community health center reported that it "is forced to pay WAC for these products if purchased for a contract pharmacy" to dispense and included a screenshot showing that it paid up to $763 per unit for Lilly insulin, (VLTR_1593, VLTR_1597), which should be provided to covered entities at "one-penny-per-milliliter prices." Compl. ¶ 82.

- A critical-access hospital in Nebraska documented numerous instances where it paid prices far above the 340B ceiling price for Lilly drugs, including instances where it paid $326, $339, $551, and $797 for Lilly insulin. VLTR_3110, VLTR_3116–17, VLTR_3119–20, VLTR_3122–23, VLTR_3125–26. The hospital stated that, "[a]s far as [it was] aware," those prices reflect "the WAC price," even though the orders were placed and paid for on its 340B account and the sales "counted as a 340B transaction as [they] met all criteria to be 340B." VLTR_3154.

- Blue Ridge Medical Center reported that "Eli Lilly is blocking 340B prices for their drugs ordered by [the medical center] that are shipped to my contract pharmacies. I am forced to pay WAC for those products for my contract pharmacies." VLTR_1607. Likewise, a family clinic included with its complaint an email from its wholesaler confirming that, under Lilly's policy, a "covered entity pays WAC if the pharmacy" where its purchases are shipped "is not the Eli Lilly approved pharmacy." RVLTR_3300. Lancaster Health Center notified the agency that Lilly is "refusing to fulfill orders (for any of their manufactured products) placed by [the] covered entity and shipped to my contract pharmacies at 340B prices. I am forced to pay WAC for these products" and that Lilly "refus[es] to ship my orders to my contract pharmacies." VLTR_3303, VLTR_3314–15. The Chief Executive of Windrose Health Network reported to HRSA in March 2021 that, "Eli Lilly is blocking 340B prices for their drugs ordered by [the] covered entity that are shipped to my contract pharmacies. I am forced to pay WAC for these products."[8] VLTR_6645–46.

- HRSA also gathered evidence from tribal leaders in multiple states detailing the harm 340B restrictions were inflicting on income-disadvantaged tribal members and underfunded rural health clinics, including one tribe that reported that its pharmacy bill has more than doubled, that it is "not financially feasible for the tribe to operate its own pharmacy," and that it had paid more than $3,400 for roughly 100 pills, which it described as "[un]sustainable costs." VLTR_7894, VLTR_7898.

- Representatives from Avita Pharmacy, a national chain that contracts almost exclusively with and dispenses for covered entities, reported that each of its 270 covered-entity clients, 98% of which do not operate their own pharmacies, were being denied 340B pricing and thus stand to lose millions of dollars in lost revenue. VLTR_7891–92. The representatives expressed concern that the changes "will lead to imminent harm to patients and possible site closures," and that some health centers were forced to charge $300 for insulin that had been dispensed for as little as $0. *Id.*

[8] The administrative record is replete with complaints from numerous covered entities repeating this message nearly verbatim—"I am forced to pay WAC [wholesale acquisition cost] for [the drugs] for my contract pharmacies"—which we have not individually referenced here.

Based on Defendants' investigation and their evaluation of this evidence[9] as well as a review of Lilly's explanations for its policy, HRSA concluded that Lilly's policy regarding contract pharmacies violates the 340B statute, prompting the issuance of the May 17 Letter. The specific complaints were never disclosed to Lilly nor was Lilly invited to respond prior to the issuance of the May 17 Letter.

Withdrawal of the December 2020 Advisory Opinion

Approximately one month following the issuance of the May 17 Letter, on June 16, 2021, the Honorable Leonard P. Stark, Chief Judge of the United States District Court for the District of Delaware, issued a memorandum opinion in a companion 340B case, *AstraZeneca Pharmaceuticals LP v. Becerra*, C.A. No. 21-27-LPS, 2021 WL 2458063 (D. Del. June 16, 2021), denying the defendants' motion to dismiss AstraZeneca's APA challenge to the December 2020 Advisory Opinion. Judge Stark ruled that the district court had jurisdiction to consider AstraZeneca's claim, and that, contrary to the agency's contention, the position outlined in the Advisory Opinion was neither compelled by the unambiguous text of the 340B statute nor the sole reasonable interpretation of the statute; thus, "[b]ecause the Opinion wrongly determines that purportedly unambiguous statutory language mandates its conclusion regarding covered entities' permissible use of an

[9] According to HRSA, in issuing its May 17 Letter, the agency also considered an abundance of other evidence that we have not specifically included in this factual recitation, such as evidence regarding the importance of contract pharmacy arrangements for covered entities, even for those that also operate an in-house pharmacy, the impact Lilly's restrictions have had on insulin patients in particular, and the significant financial impact Lilly's restrictions have had on covered entities, much of which is also addressed in the *amicus* briefs. Because we have not relied on this evidence specifically in determining whether the May 17 Letter violates the APA, we do not recount it here in detail.

unlimited number of contract pharmacies, the Opinion is legally flawed." *Id.* at *8. Judge Stark's judgment of June 30, 2021 set aside and vacated the Advisory Opinion on grounds that it was arbitrary and capricious in violation of the APA for the reasons set forth in the June 16 Order.

On June 18, 2021, two days following Judge Stark's order in *AstraZeneca*, HHS's Office of General Counsel issued a "Notice of Withdrawal" of the 2020 Advisory Opinion, stating that, effective that date, the Advisory Opinion was being "voluntarily withdrawn." The notice states that HHS's Office of General Counsel "disagree[s] with the decision of the District Court in *AstraZeneca Pharmaceuticals*," but, "in the interest of avoiding confusion and unnecessary litigation," it was withdrawing the opinion. The notice explicitly states that the withdrawal does not impact HRSA's enforcement efforts as set forth in the May 17 Letter because "HRSA's enforcement process operated independently from the issuance of the Opinion, and operates independently from the Opinion's withdrawal." Dkt. 119-1.

Currently Pending Motions

Against the backdrop of this prolix procedural history, we turn to address Defendants' Motion to Dismiss, or, in the alternative, for Summary Judgment, filed on April 19, 2021, and Plaintiffs' Cross Motion for Summary Judgment [Dkt. 89] and Motion for Preliminary Injunction [Dkt. 94], filed on May 10, 2021 and May 20, 2021, respectively, on which oral argument was conducted on July 30, 2021. We have carefully considered the administrative record, the parties' extensive briefing of these issues as well as the briefs submitted by several *amici curiae*.

Legal Analysis

I. Applicable Legal Standards

A. The Administrative Procedures Act

Plaintiffs allege that the 2020 Advisory Opinion and the May 17 Letter constitute final agency actions and as such each is unconstitutional and violative of the APA. The APA "sets forth the full extent of judicial authority to review executive agency action for procedural correctness." *F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 513 (2009) (citation omitted). The standard of review under the APA "is a narrow one," and the plaintiff bears the burden of proof. *See Sierra Club v. Marita*, 46 F.3d 606, 619 (7th Cir. 1995). Where, as here, a plaintiff seeks to set aside agency action, he or she must show that the action was "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," "contrary to constitutional right, power, privilege, or immunity," "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law." 5 U.S.C. § 706(2)(A), (B), (C), (D). The purpose of APA review is limited; the courts' role in screening for "arbitrary" or "capricious" actions is to "insist that an agency examine the relevant data and articulate a satisfactory explanation for its action." *F.C.C.*, 556 U.S. at 513 (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). A court does not "substitute its judgment for that of the agency," and should "uphold a decision of less than ideal clarity if the agency's path may be reasonably discerned." *Id.* at 513-14 (citation omitted).

B. Motion to Dismiss Standard

Defendants seek the dismissal of Plaintiffs' APA claims based on the Advisory Opinion, pursuant to Federal Rule of Civil Procedure 12(b)(6), alleging the APA claims fail to state claims upon which relief can be granted. In this procedural context, the Court accepts as true all well-pled factual allegations in the complaint and draws all ensuing inferences in favor of the non-movant. *Lake v. Neal*, 585 F.3d 1059, 1060 (7th Cir. 2009). Nevertheless, the complaint must "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests," and its "[f]actual allegations must . . . raise a right to relief above the speculative level." *Pisciotta v. Old Nat'l Bancorp*, 499 F.3d 629, 633 (7th Cir. 2007) (quotation marks and citations omitted). The complaint must therefore include "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); *see* Fed. R. Civ. P. 8(a)(2). Stated otherwise, a facially plausible complaint is one which permits "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

C. Summary Judgment Standard

Summary judgment is appropriate where there are no genuine disputes of material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). A court must grant a motion for summary judgment if it appears that no reasonable trier of fact could find in favor of the nonmovant on the basis of the designated admissible evidence. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). We neither weigh the evidence nor evaluate

the credibility of witnesses, id. at 255, but view the facts and the reasonable inferences flowing from them in the light most favorable to the nonmovant. *McConnell v. McKillip*, 573 F. Supp. 2d 1090, 1097 (S.D. Ind. 2008).

Cases arising under the APA are typically resolved by summary judgment on the basis of the administrative record compiled by the agency. *See Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744-45 (1985). "The factfinding capacity of the district court is thus typically unnecessary to judicial review of agency decisionmaking …. [C]ourts are to decide, on the basis of the record the agency provides, whether the action passes muster under the appropriate APA standard of review." *Id.* at 744. Here, faced with cross motions for summary judgment, we therefore will address and resolve the claims raised by Plaintiffs without necessity of either an evidentiary hearing or trial on the merits. *See Cronin v. USDA*, 919 F.2d 439, 445 (7th Cir. 1990).

II. Discussion

It is undisputed that the 340B Program being administered today is vastly more expansive than that implemented when the program was first enacted by Congress in 1992. That growth is tied in no small way to the steady growth of the nation's healthcare safety net system such that today significantly more patients rely on this network of service providers than ever before.[10] The broadly-based need for such care and related

[10] Counsel for Plaintiffs has represented to the Court that the 340B Program is now the second largest federal drug distribution/financing program, involving 30 billion discounted purchases each year, which constitutes nearly ten percent of overall pharmaceutical sales in the U.S.

essential healthcare services, including prescription medications, is clear, expansive and a demand made even more critical by the current global pandemic.

As discussed previously, one method by which covered entities make 340B drugs more accessible to their patients is through arrangements with contract pharmacies. Reliance on such arrangements was a common practice at the time the 340B statute was enacted, though "[t]he statute [was] silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *AstraZeneca Pharms. LP*, 2021 WL 2458063, at *9. Recognizing that such arrangements were both commonplace, and, for a vast majority of covered entities, a necessary aspect of their process for effectively dispensing 340B drugs to their patients, HRSA advised covered entities in its 1996 Guidance that, if a covered entity did not operate its own in-house pharmacy, it was authorized to contract with a single outside pharmacy to effectively dispense 340B drugs.

A single outside pharmacy to serve as the exclusive pipeline for 340B drugs dispensed by a covered entity soon proved inadequate to the demand. As the number of covered entities grew, the number of outside pharmacies to distribute 340B drugs contracted by those covered entities also significantly increased. Indeed in 2010, HRSA issued Guidance authorizing covered entities to contract with not just a single outside pharmacy, but with an unlimited number of such entities, without restriction as to the size or nature of the geographic area served by the covered entity. Plaintiffs maintain that the greatly expanded program permitted contract pharmacies participating in the 340B Program to dramatically alter the nature of the program from that created when the

originating statute was enacted. At the outset of the program, Plaintiffs explain, the covered entity interfaced directly with a contract pharmacy to supply sufficient inventory to meet the demands of 340B patients. Today, the typical dispensing process requires covered entities and contract pharmacies to submit to a "replenishment model", whereby a contract pharmacy dispenses the drug to a patient, after which, assuming the patient has been identified as eligible for 340B savings based on a 340B-tailored software program, the covered entity receives notice that it is allowed to place a 340B order with the manufacturer to "replenish" the contract pharmacy's supply of the previously dispensed drug, which the manufacturer then ships to the contract pharmacy for retention in its neutral inventory.[11]

It requires almost no imagination to appreciate how, with the significant expansion of the 340B Program and the proliferation of contract pharmacy arrangements, more opportunities for abuse within the system have arisen. Plaintiffs criticize the government for its alleged failure to recognize and remedy the hardships and unfairnesses that have resulted from the expansion on drug manufacturers who participate in the 340B Program and have had to absorb the brunt of these costs and abuses. Without sufficient oversight

[11] The "replenishment model" consist of three main steps: First, the contract pharmacy dispenses a drug to a patient and 340B-tailored software programs operated under the oversight of the covered entity subsequently determine whether the patient is eligible for 340B savings. Second, once the software determines that a sufficient number of 340B-eligible dispenses have accumulated to reach a pre-set packages size, the software notifies the covered entity that it may place an order on its 340B account for that amount of 340B drugs to replenish the contract pharmacy's stock. Third, the covered entity is billed for the purchase and the replenishment drugs are shipped to the contract pharmacy, where they are placed in neutral inventory. Pedley Decl. ¶ 10.

by the government of the covered entities' contract pharmacy arrangements and/or enforcement of the statutory prohibitions against diversion and duplicate discounting, the manufacturers, they say, are at the mercy of a system run amok. HRSA's explanation for its lack of monitoring and/or enforcement of the 340B statute with regard to contract pharmacy arrangements, according to Plaintiffs, directly conflicts with HHS's General Counsel's Advisory Opinion and HRSA's rationale behind the May 17 Letter. Against this backdrop, Plaintiffs have brought their challenges to these agency actions under the APA.

Plaintiffs specifically allege that both the December 2020 Advisory Opinion by HHS's General Counsel and the agency's May 17 Letter are unconstitutional final agency actions which violate the APA, in the following respects: (1) notice and comment procedures were not followed; (2) the actions taken exceeded the agency's statutory authority; (3) the actions taken are arbitrary and capricious; and (4) the actions taken are contrary to the Fifth Amendment's Takings Clause and Article I of the United States Constitution. We address each of these challenges below.

A. December 2020 Advisory Opinion

1. Mootness

As referenced above, HHS's Office of General Counsel withdrew the December 2020 Advisory Opinion on June 18, 2021, which Defendants contend renders moot Plaintiffs' challenges to the Advisory Opinion. We are not persuaded by this argument. "A defendant's voluntary cessation of challenged conduct does not necessarily render a case moot." *Freedom From Religion Found., Inc. v. Concord Cmty. Schs.*, 885 F.3d

1038, 1051 (7th Cir. 2018) (citing *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982)). A case becomes moot only "if events make it 'absolutely clear that the allegedly wrongful behavior could not reasonably be expected to recur.'" *Id.* (quoting *United States v. Concentrated Phosphate Export Ass'n*, 393 U.S. 199, 203 (1968)). "The party asserting mootness bears the 'heavy' burden of proof on this 'stringent' standard." *Id.* (quoting *Friends of the Earth, Inc. v. Laidlow Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 189 (2000)).

Defendants' claim of mootness falls well short of this definition. HHS's withdrawal does not include any indication that the agency has fully and for all time (in the context of this case at least) abandoned the position laid out in the December 2020 Advisory Opinion. Its withdrawal simply notes the agency's "disagreement" with the reasoning set forth in Judge Stark's recent opinion in *AstraZeneca Pharmaceuticals*, which held in favor of the drug manufacturer on the claims challenging the Advisory Opinion, noting that the Advisory Opinion was withdrawn by the government only to "avoid[] confusion and unnecessary litigation"; in fact, enforcement efforts directed toward drug manufacturers' policies regarding contract pharmacies will likely continue. Dkt. 119-1. Accordingly, it is not at all clear that the agency's "allegedly wrongful behavior could not reasonably be expected to recur," which makes Plaintiffs' claims challenging the Advisory Opinion far from moot. We shall thus address them in that light.

2. Defendants' Motion to Dismiss

Defendants seek the dismissal of Plaintiffs' APA claims challenging the Advisory Opinion on two grounds: first, that the Advisory Opinion does not constitute final agency action and is therefore not reviewable by the Court; and second, that Plaintiffs' legal challenge to the Advisory Opinion is untimely. For the following reasons, we again find neither argument persuasive.

For an agency's action to be deemed final and thus judicially reviewable, "the action must mark the consummation of the agency's decisionmaking process," meaning, it cannot be "of a merely tentative or interlocutory nature;" "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (internal quotation marks and citations omitted).

Plaintiffs contend that the Advisory Opinion does, in fact, mark the culmination of the agency's decisionmaking process regarding manufacturers' delivery obligations in relation to covered entities that utilize contract pharmacy arrangements. The Advisory Opinion states 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 drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." VLTR_8048 (emphasis added). In addition, the Opinion provides that "manufacturers *may not* refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies." VLTR_8055 (emphasis added). The Advisory Opinion asserts that the "*plain meaning*"

of the statute "*requires* manufacturers to sell covered drugs to covered entities at or below the ceiling price, independent of whether the entity opts to use contract pharmacies to dispense the drugs." VLTR_8049 (emphasis added). These provisions clearly represent "a definitive pronouncement of [agency] policy," *Home Builders Ass'n of Greater Chi. v. United States Army Corps of Engineers*, 335 F.3d 607, 615 (7th Cir. 2003), and advance an interpretation the agency "believes is the only permissible interpretation of the statute." *California Cmties. Against Toxics v. EPA*, 934 F.3d 627, 636 (D.C. Cir. 2019) (emphasis removed). Accordingly, the first element of "final agency action" is satisfied.

As for the second requirement, the mandatory language utilized in the Advisory Opinion purports to "determine" manufacturers' "obligations" under the 340B statute with regard to their dealings with covered entities utilizing contract pharmacies to dispense 340B drugs. As Plaintiffs note, the directives set out in the Advisory Opinion have legal consequences, particularly under the recently issued ADR procedures, which warn that drug manufacturers' "fail[ure] to heed the determination" carries "the risk of significant criminal and civil penalties." *Id.* at 637.

Defendants' defense of the Advisory Opinion focuses on what they maintain is nothing more than a restatement of the position espoused by the agency since at least the time of the issuance of the 2010 Guidance, allowing covered entities to enter into "complex arrangements" that include contracts with "multiple pharmacies" and expressly providing that "[u]nder section 340B, if a covered entity using contract pharmacy services requests to purchase a covered outpatient drug from a participating

manufacturer, the statute directs the manufacturer to sell the drug at a price not to exceed the statutory 340B discount price." 75 Fed. Reg. at 10,277. Thus, according to Defendants, the Advisory Opinion neither asserted any legal obligations nor imposed any penalties or consequences apart from those in the statute itself.

Defendants' arguments would carry more weight if, prior to the issuance of the Advisory Opinion, the agency had not indicated on several occasions that its enforcement powers were limited and that it lacked authority to "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); *accord Am. Hosp. Ass'n v. Dep't of Health & Human Servs.*, No. 4:20-cv-08806-YGR, 2021 WL 616323, at *3 (N.D. Cal. Feb. 17, 2021) (quoting HRSA email). The Advisory Opinion thus directly conflicts with this interpretation of the agency's limited authority. Defendants' argument that the Opinion "did little but restate what [Lilly] already knew," is belied by this history. Dkt. 88 at 15. Moreover, as recognized by Judge Stark in *AstraZeneca Pharmaceuticals*, to the extent the Advisory Opinion relies on the "shall … offer" provision of the 340B statute, it necessarily "treads new ground" since that language was not added to the statute until after the agency issued the 2010 Guidance. 2021 WL 2458063, at *5 (internal quotation marks and citation omitted). The Advisory Opinion therefore satisfies the second requirement for "final agency action," making it reviewable by the Court. The motion to dismiss on this ground is unavailing.

Defendants' parallel contention that Plaintiffs' challenge to the Advisory Opinion is nothing more than "an untimely collateral attack on the agency's consistent, twenty-

five-year statutory interpretation," (Dkt. 88 at 19), and therefore must be dismissed on statute of limitations grounds, fares no better. This argument is premised on the same mischaracterization of the Advisory Opinion we have addressed and rejected above, to wit, that it plows no new ground and simply restates the agency's view previously expressed in the 2010 Guidance. We find that description disingenuous, adopting our prior reasoning and rejecting the accuracy of this conclusion. Accordingly, Defendants' motion to dismiss Plaintiffs' APA claims related to the Advisory Opinion is denied.

3. Cross-Motions for Summary Judgment

In reviewing Plaintiffs' APA challenges to the Advisory Opinion, HHS's General Counsel wrote 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 drugs to those contract pharmacies and to charge the covered entity no more than the 340B ceiling price for those drugs." VLTR_8076–77. The General Counsel also wrote that "the situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant." VLTR_8050. According to the Opinion, "manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies," VLTR_8055, and the "plain meaning" of the statute "requires manufacturers to sell covered drugs to covered entities at or below the ceiling price, independent of whether the entity opts to use contract pharmacies to dispense the drugs." VLTR_8049.

In reading the Advisory Opinion as a whole, it is clear that drug manufacturers' obligations under the government's interpretation of the 340B statute include their

honoring the ceiling price when selling to covered entities, regardless of the drug distribution model they utilize, and in line with Judge Starks' framing in *AstraZeneca Pharmaceuticals*, unambiguously requiring drug manufacturers *to deliver* 340B drugs to an unlimited number of contract pharmacies, if acting as "agents" of the covered entity. This is true despite the statute's silence both as to covered entities' entitlement to utilize unlimited contract pharmacy arrangements and as to any delivery obligations imposed on drug manufacturers. As Judge Stark, in rejecting this interpretation of the 340B statutory language, it "simply cannot bear the weight that the government places on it." 2021 WL 2458063, at *9.

We share these reservations as to the government's claims as set forth in *AstraZeneca Pharmaceuticals,* namely that the Advisory Opinion is "legally flawed" in its "'unjustified assumption' that Congress imposed [Counsel's] interpretation as a statutory requirement." *Id.* at *11. In such cases, agency action "must be declared invalid, even though the agency might be able to adopt the [interpretation] 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 an interpretation was required. *Prill v. N.L.R.B.*, 755 F.2d 941, 948 (D.C. Cir. 1985) (quoting *FCC v. RCA Commc'ns*, 346 U.S. 86, 96 (1953)).

We therefore conclude that the Advisory Opinion must be vacated on the grounds that it reflects an arbitrary and capricious agency action. However, no order of remand is necessary, given HHS's voluntary withdrawal of it. Plaintiffs' motion for summary judgment on Count III of the Second Amended Complaint is therefore granted and

Defendants' cross motion is denied. The parties' cross motions for summary judgment on all other APA claims related to the Advisory Opinion (Counts I, II, and IV) are denied without prejudice.

B. May 17 Letter

We turn next to address the May 17 Letter. Plaintiffs maintain that, having found the Advisory Opinion violative of the APA, we must reach the same conclusion as to the May 17 Letter. We do not share that view. Unlike the Advisory Opinion, HRSA's determination in the May 17 Letter does not rely on a general, overarching requirement on behalf of manufacturers to deliver 340B drugs to an unlimited number of contract pharmacies. Rather, the Letter is limited to the finding that Lilly's unilaterally adopted policy, whereby it will offer 340B pricing to all covered entities only so long as the 340B drugs ordered by the covered entity are shipped to an in-house or wholly-owned pharmacy or to a single designated contract pharmacy approved by Lilly, violates both the requirements set forth in the 340B statute and Lilly's PPA. Lilly is obligated to honor the 340B price for drugs purchased by covered entities and offer 340B pricing to covered entities on any drug that it sells to any other purchaser. Whether this specific agency finding in the May 17 Letter is lawful under the APA is the issue before us here.

Plaintiffs contend, and both sides agree, that the May 17 Letter constitutes a final agency action. Plaintiffs assert that it is both procedurally and substantively lacking under the APA for the reasons that it was issued without following proper notice and comment procedure, it exceeds the agency's statutory authority, it violates the United States Constitution, and it is arbitrary and capricious and an abuse of discretion and

otherwise not in accordance with law. We address these summary judgment claims in turn below.

1. Notice and Comment

We first address Plaintiffs' contention that the May 17 Letter is procedurally defective under the APA because required notice and comment procedures were not followed. It is well-established, however, that "[t]he APA does not require administrative agencies to follow notice and comment procedures in all situations." *Metro. Sch. Dist. of Wayne Twp., Marion Cnty., Ind. v. Davila*, 969 F.2d 485, 488 (7th Cir. 1992). Rather, "Section 553(b)(3)(A) specifically excludes 'interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice,' from notice and comment procedures." *Id.* at 488–89. While the Seventh Circuit has recognized the distinction between interpretive rules, which are exempt from notice and comment procedures, and legislative rules, which require such procedures, the Court has conceded that the distinction "is admittedly far from crystal-clear." *Id.* at 489 (quotation marks and citation omitted). Upon careful review, we conclude that the May 17 Letter is interpretive, not legislative, and therefore not subject to notice and comment requirements under the APA.

The "starting point" in our analysis of whether a rule is interpretive "is the agency's characterization of the rule," which, while not determinative "is a relevant factor." *Id.* (citations omitted). "An interpretive rule simply states what the administrative agency thinks the [underlying] statute means, and only reminds affected parties of existing duties." *Id.* (citations omitted); *see also Dismas Charities, Inc. v. U.S.*

Dep't of Justice, 401 F.3d 666 (6th Cir. 2005) ("[A] pure legal determination of what the applicable law already is does not require notice and comment under APA § 553(b)."). Moreover, where a rule is "based on specific statutory provisions … and its validity stands or falls on the correctness of the agency's interpretation of the statute" it is "clear the rule is an interpretive one." *Id.* at 492.

Here, the May 17 Letter clearly reflects an interpretation of the 340B statute. *See* Dkt. 94-1 ("HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute."). The agency then supports this conclusion that Lilly's contract-pharmacy restrictions have resulted in unlawful overcharges by citing to the language of specific statutory provisions, and the validity of the agency's conclusion stands or falls on the correctness of its interpretation of the statute. Although the May 17 Letter clearly addresses the scope of Plaintiffs' duties and obligations under the 340B statute, an action "affecting rights and obligations is not *ipso facto* legislative." *Davila*, 969 F.2d at 493. For these reasons, we hold that the May 17 Letter is an interpretive rule that is exempt from notice and comment and thus not violative of the APA on these procedural grounds.

2. Exceeds Statutory Authority/Contrary to Law

Plaintiffs next claim that the May 17 Letter violates the APA because its assertions are contrary to law and exceed the agency's statutory authority by requiring Lilly, on pain of penalty, to do the following: (1) to offer drugs to contract pharmacies at 340B prices, thereby creating an exception to the statutory prohibition on diversion and effectively

expanding the statutory definition of "covered entities" to include contract pharmacies, and (2) to require Lilly to offer 340B discounts for transactions in which covered entities do not actually "purchase" covered outpatient drugs.

In response, Defendants maintain that the May 17 Letter neither exceeds the agency's statutory authority nor is contrary to law because the agency, duly tasked with administering the 340B program, correctly determined that Lilly's unilaterally adopted policy, pursuant to which it will ship 340B drugs only to covered entities at in-house and wholly-owned pharmacies, or, if the covered entity does not operate an in-house pharmacy, to a single contract pharmacy designated by the covered entity, has resulted in overcharges to covered entities in violation of its obligations under the 340B statute and its PPA.

In evaluating agency actions under the APA, courts must "hold unlawful and set aside" any that are "not in accordance with the law" or "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(d). "No matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always, simply, *whether the agency has stayed within the bounds of its statutory authority*." *City of Arlington, Tex. v. F.C.C.*, 569 U.S. 290, 297 (2013) (emphasis in original). In the case before us, there is no dispute between the parties that HRSA operates within its statutory authority in auditing drug manufacturers in an effort to ensure compliance with 340B pricing requirements. In determining whether the May 17 Letter is valid, Lilly's policy must be contrary to the 340B statute.

Thus, the question here is whether HRSA correctly concluded that Lilly's contract pharmacy restrictions violated the statutory prohibition on overcharging covered entities. Resolution of this issue turns on the interpretation of the 340B statute.

In engaging in statutory interpretation, the first issue "always, is the question whether Congress had directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Chevron, U.S.A, Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984). "[I]t is elementary that no deference is due to agency interpretations at odds with the plain language of the statute itself." *Smith v. City of Jackson*, 544 U.S. 228, 266 (2005) (O'Connor, J., concurring) (internal quotation marks and citation omitted).

If the statute is deemed ambiguous with respect to the specific issue, however, the level of deference afforded to the agency's interpretation varies. *United States v. Mead Corp.*, 533 U.S. 218, 227–31 (2001). Here, Defendants concede that, if the Court determines the 340B statute to be ambiguous, the agency's statutory interpretation is entitled to, at most, the level of deference outlined in *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). *Skidmore* deference directs that, the agency's interpretation is "'entitled to respect'—but only to the extent that [it has the] 'power to persuade.'" *Arobelidze v. Holder*, 653 F.3d 513, 520 (7th Cir. 2011) (quoting *Bailey v. Pregis Innovative Packaging, Inc.*, 600 F.3d 748, 751 (7th Cir. 2010)). In applying *Skidmore* deference to an agency's interpretation, courts consider "the thoroughness evident in [the agency's]

consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Id.* (quoting *Skidmore*, 323 U.S. at 140).

Applying these principles, we begin with an examination of the plain language of the statute at issue, that is, "the text of the statute." *United States v. All Funds on Deposit with R.J. O'Brien & Assocs.*, 783 F.3d 607, 622 (7th Cir. 2015). Courts "must presume that a legislature says in a statute what it means and means in a statute what it says there." *United States v. Rosenbohm*, 564 F.3d 820, 823 (7th Cir. 2009) (quotation marks and citation omitted). If the language of a statute is "clear and unambiguous," it "must ordinarily be regarded as conclusive," absent any "clearly expressed legislative intent to the contrary." *Id.* (quotation marks and citation omitted). "The plainness or ambiguity of statutory language is determined by reference to the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil, Co.*, 519 U.S. 337, 341 (1997) (citations omitted).

The May 17 Letter relies on the text of section 340B(a)(1) as support for its determination that Lilly's policy has resulted in drug overcharges in violation of the law. By statute, the HHS Secretary is required to "enter into an agreement with each manufacturer of outpatient drugs under which the amount required to be paid … to the manufacturer for covered outpatient drugs … does not exceed" the applicable ceiling price 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."[12] The May 17 Letter also references the fact that manufacturers that have signed a PPA and PPA addendum, as Lilly has, are required by the terms of the PPA to comply with these statutory requirements.

The 340B statute is silent as to contract pharmacy arrangements and drug manufacturers' *delivery* obligations. Plaintiffs argue that, because the plain statutory language does not impose any delivery obligation on the manufacturer and does not dictate any other aspect of the manufacturer's offer beyond the price or require Lilly to offer anything to or through contract pharmacies, Lilly is under no obligation to deliver 340B drugs to whatever destination a covered entity may command. Lilly maintains that its policy of both directly and through wholesalers, "offer[ing] each covered entity" the right to "purchase" "at or below the applicable ceiling price" all "covered outpatient drugs" that Lilly produces comports with its statutory obligations. By merely refusing to *deliver* the drugs to more than one location, it is not acting beyond the unambiguous dictates of the statute. Thus, according to Lilly, the May 17 Letter is contrary to law because HRSA's determination that Lilly's policy violates the 340B statute, necessarily

[12] Plaintiffs claim that the government's defense of the May 17 Letter cannot rest on the "purchased by" provision of the 340B statute because HRSA does not rely on that provision in the letter, and 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). It is true that the May 17 letter nowhere quotes the "purchased by" provision, but it does provide that HRSA determined that Lilly's policy violates Section 340B(a)(1) and its PPA, both of which contain the "purchased by" requirement in addition to the "shall … offer" provision. In any event, we think we are on solid ground in interpreting the "shall … offer" provision in context with the "purchased by" provision, given that case law makes clear that the meaning of statutory language is determined not only by reference to the text itself, but also "the specific context in which that language is used, and the broader context of the statute as a whole." *Robinson*, 519 U.S. at 341.

reads into that provision a delivery requirement that does not appear in the text of the statute.

Plaintiffs argue that their construction of the statute best aligns with the ordinary meaning of the word "offer," which does not include any obligation to "deliver" a product to someone other than the purchaser. *See Black's Law Dictionary* (11th ed. 2019) (defining "offer" as: "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."). Relying on these definitions, Plaintiffs contend that the mere fact that a seller must "offer" goods to a particular buyer at a particular price imposes no obligations on where or how the seller must ship the good. Any construction of the term "offer" which incorporates a delivery requirement does not align with or reflect the plain meaning of that term.

We accept that, "[a] fundamental canon of statutory construction instructs that in the absence of statutory definition, we [are to] give terms their ordinary meaning." *Bass v. Stolper, Koritzinsky, Brewster & Neider, S.C.*, 111 F.3d 1322, 1325 (7th Cir. 1997). However, we must "interpret the relevant words, not in vacuum, but with reference to the statutory context, structure, history, and purpose," *Abramski v. United States*, 573 U.S. 169, 179 (2014) (citation omitted), because "it is a fundamental principle of statutory construction (and, indeed, of language itself) that the meaning of a word cannot be determined in isolation, but must be drawn from the context in which it is used." *Textron*

Lycoming Reciprocating Engine Div., Avco Corp. v. United Auto., Aerospace & Agric. Implement Workers of Am., Int'l Union and Its Local 787, 523 U.S. 653, 657 (1998) (quotation marks and citation omitted).

Defendants fault Plaintiffs' construction of the term "offer" as violative of this statutory canon based on their isolating a single word in the statute and interpreting it out of context, since the statute clearly requires drug manufacturers not simply to *offer*, but also to *sell* discounted drugs to covered entities. According to Defendants, when read as a whole, the unambiguous statutory requirements reflect Congress's clear intent, in enacting the 340B statute, to create a comprehensive drug distribution scheme to enable safety net providers to purchase the identified 340B drugs in a manner that ensures access to the discounted medications. Congress in no way intended to allow regulated entities to unilaterally erect barriers—such as Lilly's delivery restrictions—the effect of which frustrate the overarching purpose of the program based on a rationale that such restrictions are not explicitly prohibited by the plain language of the statute. Defendants stress that nothing in the statutory text supports the view that manufacturers' obligations are qualified, restricted, or dependent on the manner in which the covered entity chooses to distribute the covered outpatient drugs nor is a manufacturer otherwise permitted to condition its performance under the statute on such an interpretation.

Defendants maintain that HRSA correctly determined, "[a]fter review of [Lilly's] policy and an analysis of the complaints HRSA [] received from covered entities," Dkt. 94-1, that Lilly's policy of limiting the delivery of 340B drugs to only a covered entity's

in-house pharmacy and/or to one contract pharmacy identified by the covered entity violates the the 340B statute and the requirements of its PPA. To buttress their conclusion, Defendants highlight the administrative record, which, they say, is replete with complaints received from covered entities that Lilly's policy has caused 340B prices to be removed from covered entities' contract pharmacy accounts, whether orders were placed/received directly from Lilly or its wholesalers. As a result, those prices are no longer available to covered entities unless the covered entity ships to an in-house pharmacy or submits paperwork to Lilly designating a single contract pharmacy for shipment, and many covered entities have had to pay amounts above the ceiling price for 340B drugs.

This is the finding set out in the May 17 Letter, to wit, that Lilly's policy has resulted in overcharges in violation of its obligations under the 340B statute its PPA to "ensure that the 340B ceiling price is available to all covered entities," because Lilly places extra-statutory conditions on its "offer" that have prevented covered entities from accessing 340B pricing and have instead required them to pay much higher wholesale acquisition costs to purchase 340B drugs. This policy, according to Defendants, runs afoul of Lilly's obligation under the "shall … offer" provision "to provide the same opportunity for 340B covered entities and non-340B purchasers to purchase covered outpatient drugs," as reflected in the May 17 Letter, because Lilly's policy prevents covered entities from accessing discounted drugs through the same wholesale channels where drugs are made available for full-price purchase and also because it imposes

shipment and delivery conditions on 340B purchases that it does not impose on non-340B purchases.

In drafting the 340B statute, Congress clearly utilized broad, generalized language that "is silent as to the role contract pharmacies may play in connection with covered entities' purchases of 340B drugs." *AstraZeneca Pharms.*, 2021 WL 2458063, at *9. The breadth of the statutory language does not prevent a court from determining whether actions by an agency or a regulated entity contravene Congressional intent. Having previously ruled that the statute was not accurately reflected in HHS's General Counsel's Advisory Opinion's conclusion that drug manufacturers are required to deliver 340B drugs to an unlimited number of contract pharmacies, we determined that Plaintiffs' construction of the "shall … offer" provision swung too far in the opposite direction. By relying solely on the statute's silence, drug manufacturers would be authorized to unilaterally impose a wide variety of restrictions on their offers, the effect of which would assuredly render 340B drugs inaccessible to many covered entities.[13]

The Supreme Court recently held that there is no "such thing as a 'canon of donut holes,' in which Congress's failure to speak directly to a specific case that falls within a

[13] As Defendants argue, Lilly's refusal to deliver 340B drugs to more than one contract pharmacy often renders hollow its "offer" to sell. Because these are prescription drugs, some of which cover controlled substances, they can be shipped only to locations that provide the proper legal infrastructure, including state licensing, DEA registration, staff pharmacists, etc., to accept delivery of, and dispense, pharmaceuticals. Many covered entities do not have the capacity or authority to handle their own dispensing or to take delivery of Lilly's medications, even for those that do, covered entities often serve vulnerable populations scattered over large geographic areas, making it impossible for all patients to fill their prescriptions each month on-site or in a single contract pharmacy location. *E.g.*, VLTR_7260–61.

more general statutory rule creates a tacit exception. Instead, when Congress chooses not to include any exceptions to a broad rule, courts apply the broad rule." *Bostock v. Clayton Cnty.*, 140 S.Ct. 1731, 1747 (2020). Defendants therefore challenge Plaintiff's construction of the statute on this basis as reading into the statutory text an exception to the "shall … offer" and "purchased by" provisions for covered entities utilizing multiple contract pharmacies. That interpretation does not align with the Supreme Court's pronouncement in *Bostock*, say Defendants.

We share Defendants view here: in analyzing and interpreting the 340B statute, we must construe the terms in context, with an eye to "the specific context in which that language is used," including other provisions of the statute. *Robinson*, 519 U.S. at 341. What is clear is that, since its enactment, the 340B statute has required drug manufacturers to honor their PPAs as to the amount covered entities can be required to pay for 340B drugs, which cannot exceed the ceiling prices. Plaintiffs' construction of the "shall … offer" provision to authorize its refusal to honor the 340B price for covered entities' purchases based solely on delivery location or dispensing mechanism, thereby requiring covered entities to pay WAC prices for covered outpatient drugs if they do not operate an in-house pharmacy or fail to designate a single contract pharmacy Lilly approves for shipment, directly conflicts with the statutory requirement otherwise.

Congress's use of broad language in enacting this statute and specifically omitting any mention of where 340B drugs are to be delivered does not leave room for drug manufacturers to unilaterally condition or control the availability of their 340B pricing to

a particular delivery location of their choosing such that covered entities are prevented from accessing 340B pricing and required to purchase covered outpatient drugs at WAC prices. The fairest and most reasonable interpretation of the 340B statute would not authorize drug manufacturers to impose unilateral restrictions on the distribution of the drugs that "would frustrate Congress' manifest purpose" in enacting the statute. *United States v. Hayes*, 555 U.S. 415, 426–27 (2009).

Plaintiffs focus their characterization of the sales of 340B drugs to covered entities utilizing contract pharmacy arrangements as not actually being "purchases by" covered entities. Instead, they constitute diversion, which the statute elsewhere prohibits. It makes no sense, argue Plaintiffs, to interpret the "shall … offer" provision in a manner that mandates the same kind of diversion that the statute otherwise prohibits. Even Plaintiffs assert, however, that only contract pharmacies "engage in diversion at outsize rates," not that every contract pharmacy arrangement results in diversion. Dkt. 129 at 21. And there is no evidence establishing that every covered entity working with multiple contract pharmacies uses the "replenishment model" to order 340B drugs, which is the sole method of purchase that Plaintiffs have claimed constitutes diversion.[14] We are not persuaded, therefore, by Plaintiffs' contention that construing the 340B statute in the

[14] We note also that it is beyond the Court's purview to determine whether purchases made using the replenishment model constitute diversion as Congress explicitly required manufacturers to address diversion and duplicate-discounting concerns in the ADR process and to audit covered entities before availing themselves of the ADR process. 42 U.S.C. § 256b(d)(3)(B)(iv). While the lawfulness of the ADR process promulgated by Defendants is a separate issue in this litigation that, as discussed above, will be addressed at a later date, there can be no dispute that Congress mandated that any concerns regarding diversion be addressed first through ADR procedures, not in federal litigation.

manner Defendants posit "mandate[s] the same kind of diversion the statute elsewhere prohibits." *Id.* at 20.

Plaintiffs further contend that Defendants' construction of the statute, which Plaintiffs describe as imposing an unlimited delivery obligation on drug manufacturers that appears nowhere in the plain language of the statute, would violate the "no-elephants-in-mouseholes canon," which recognizes the rule that "Congress 'does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions.'" *Bostock*, 140 S.Ct. at 1753 (quoting *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001)). We repeat: we do not agree with Plaintiffs' premise that to uphold the agency's determination set forth in the May 17 Letter, we must interpret the 340B statute to require drug manufacturers to deliver to an unlimited number of contract pharmacies. Nevertheless, we acknowledge, as Plaintiffs emphasize, that the demand for 340B drugs and the prevalence of contract pharmacies has exploded in a way that Congress likely did not imagine either when the statute was first enacted in 1992 or when the "shall … offer" language was added to the statute in 2010. That said, the evidence before us establishes that reliance on outside pharmacies by covered entities was, even at the time of the statute's enactment, known to Congress as a common business practice; thus, by choosing to use broad language to define obligations and entitlements under the statute, Congress "virtually guaranteed that unexpected applications would emerge over time." *Id.* Accordingly, the "elephant" that is the greatly enhanced role of contract pharmacies in

the 340B program "has never hidden in a mousehole; it has been standing before us all along." *Id.*

Given the expansion of the 340B program and the vast proliferation of contract pharmacy arrangements since Congress's most recent amendments to the 340B statute, Congress may at some point choose to amend the statute to directly address these issues. But that is for Congress to determine; drug manufacturers may not usurp the role through unilateral extra-statutory restrictions. *See Patriotic Veterans, Inc. v. Indiana*, 736 F.3d 1041, 1047 (7th Cir. 2013) ("If Congress determines later that the plain language of the statute does not accurately reflect the true intent of Congress, it is for Congress to amend the statute).

Construing the 340B statute not to permit drug manufacturers to impose extra-statutory conditions on covered entities' access to discounted medications is not only a permissible construction, but, in our view, the construction that best aligns with congressional intent.[15] Accordingly, we hold that the May 17 Letter, which determined that Lilly's policy under which it delivers drugs to only one location per covered entity

[15] Having used the tools of statutory interpretation to arrive at what we believe is the appropriate and correct interpretation of the 340B statute, we need not discuss whether the agency's interpretation is entitled to *Skidmore* deference, apply the rule of lenity, or consider the statute's legislative history. We do note, however, that the 340B statute's legislative history is consistent with our holding. In 1992, Congress considered but removed from the statute a provision that would have restricted 340B-discounted sales to drugs "purchased and dispensed by, or under a contract entered into for on-site pharmaceutical services with" a covered entity. *See* S. Rep. No. 102-259, at 1–2. The fact that Congress once considered but rejected restricting covered entities' choice of dispensing mechanism in a manner consistent with Plaintiffs' position supports our statutory interpretation. *See Lomax v. Ortiz-Marquez*, 140 S. Ct. 1721, 1725 (2020) ("[T]his Court may not narrow a provision's reach by inserting words Congress chose to omit.").

and otherwise charges covered entities prices high above the ceiling price for covered outpatient drugs resulted in violations of the 340B statute's prohibition against overcharging, neither exceeds the agency's statutory authority nor is contrary to law.

3. Takings Clause/Unconditional Condition

Plaintiffs claim that interpreting the 340B statute in the manner championed by Defendants renders the May 17 Letter unconstitutional and violative of the APA because it effects a *per se* taking in violation of the Fifth Amendment to the United States Constitution. Under the Takings Clause of the Fifth Amendment, "private property" shall not "be taken for public use, without just compensation." U.S.CONST. amend. V. Specifically, Plaintiffs argue that the May 17 Letter effects a purely private taking of their property by forcing Lilly to transfer its drugs to contract pharmacies solely to serve those entities' private interests, and that, by requiring Lilly to succumb to a private taking of property to obtain coverage of its drugs under federal health-insurance programs, the May 17 Letter imposes an unconstitutional condition on a valuable government benefit. Compl. ¶¶ 289–96.

We are not persuaded by Plaintiffs' argument, however, primarily due to the fact that they have voluntarily chosen to participate in the 340B program and are thus free to terminate their participation if and when they may choose to do so. Such "voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation …." *Southeast Arkansas Hospice, Inc. v. Burwell*, 815 F.3d 448, 450 (8th Cir. 2016) (quoting

Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare, 742 F.2d 442, 446 (8th Cir. 1984); *accord St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 875–76 (7th Cir. 1983) (per curiam); *see also Ruckelshaus v. Monsato Co.*, 467 U.S. 986, 1007 (1984) (rejecting an unconstitutional-conditions challenge to a condition on a valuable government benefit (i.e., voluntary exchange of proprietary information in exchange for a license to sell a product) on grounds that if the plaintiff "is aware of the conditions" under which the property is relinquished and "the conditions are rationally related to a Government interest," the "voluntary" relinquishment of the property "in exchange for the economic advantages" of the benefit, "can hardly be called a taking."). We concede that in withdrawing from the 340B program Lilly would no longer receive coverage or reimbursement for its products under Medicaid and Medicare Part B, which would result in a significant financial impact for Lilly, but "economic hardship is not equivalent to legal compulsion for purposes of takings analysis." *Garelick v. Sullivan*, 987 F.2d 913, 917 (2d Cir. 1993); *see also Minnesota Ass'n of Health Care Facilities, Inc.*, 742 F.2d at 446 (holding that a "strong financial inducement to participate" in a regulated program does not render such participation involuntary).

For these reasons, we are not persuaded by Plaintiffs' claim that the government's position set forth in the May 17 Letter cannot be reconciled with the Takings Clause.[16] Plaintiffs have made clear their frustration with the government's lack of oversight over

[16] We note that Plaintiffs' takings-related arguments are potentially more persuasive when applied to the Advisory Opinion's interpretation of the 340B statute. However, as discussed above, the interpretation relied upon in the May 17 Letter is distinct from and less expansive than that espoused in the Advisory Opinion.

covered entities' dealings with contract pharmacies, which has forced Lilly and other drug manufacturers to absorb the financial impact of any such abuses of the 340B system, but we "conclude that the Takings Clause of the Fifth Amendment is not the proper vehicle for altering this harsh reality." *Baker Cnty. Med. Servs., Inc. v. United States Atty. Gen.*, 763 F.3d 1274, 1280 (11th Cir. 2014). "As is so often the case, [Lilly's] most effective remedy may lie with Congress rather than the courts." *Id.*

4. Arbitrary and Capricious

Finally, Plaintiffs maintain that, even if not contrary to law, the May 17 Letter is invalid under the APA because the position it espouses is arbitrary and capricious. A careful review of the May 17 Letter reveals its failure to acknowledge, never mind explain HRSA's change in position regarding its authority to enforce potential violations of the 340B statute connected to contract pharmacy arrangements. The May 17 Letter thus must be vacated and set aside as arbitrary and capricious and the issues outlined therein remanded to the agency.

The legal underpinnings of this ruling are clear. Under the APA, when an agency changes its existing position on a particular issue, it "must at least 'display awareness that it is changing position' and 'show that there are good reasons for the new policy.'" *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (quoting *Fox Television Stations, Inc.*, 556 U.S. at 515). In addition, "[i]n explaining its changed position, an agency must also be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Id.* (quoting *Fox Television Stations,*

Inc., 556 U.S. at 515). "In such cases it is not that further justification is demanded by the mere fact of policy change; but that a reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy." *Id.* (quoting *Fox Television Stations, Inc.*, 556 U.S. at 515–16). Thus, "an [u]nexplained inconsistency' in agency policy is 'a reason for holding an interpretation to be an arbitrary and capricious change from agency practice.'" *Id.* (quoting *Nat'l Cable & Telecommunications Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005)).

HRSA contends that the May 17 Letter reflects its view that Lilly's policy violates the 340B statute, which is the position that the agency "has made plain, consistently since the issuance of its 1996 contract pharmacy guidance, that the 340B statute requires manufacturers to honor [covered entities'] purchases regardless of the dispensing mechanism." Dkt. 94-1. We accept that the agency has consistently espoused the view in non-binding guidance that drug manufacturers must comply with their obligations under the 340B statute regardless of the manner in which the covered entity chooses to dispense the drugs and must accommodate all contract pharmacy arrangements that the government permits. However, its exponential expansion of "what covered entities ***may*** do" with regard to contract pharmacy arrangements over the years, "has consequently changed what drug manufacturers ***must*** do." *AstraZeneca Pharms.*, 2021 WL 2458063, at *7 (emphasis in original).

Prior to December 2020, the agency consistently represented that its interpretation set forth in the 1996 and 2010 Guidance regarding contract pharmacy use was non-

binding and further, that the agency had limited authority to issue enforceable regulations regarding contract pharmacy arrangements. Specifically, in June 2020, in response to Lilly's announcement of its contract pharmacy policy, HRSA informed Lilly in writing that its prior "contract pharmacy advice" was not "binding" on manufacturers. VLTR_7590. Approximately one month later, in July 2020, HRSA publicly shared this view, explaining to a 340B-focused publication that "[t]he 2010 guidance … is not legally enforceable," and that the agency could enforce only direct violations of the statute, but 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).

Throughout 2020, the agency continued to inform covered entities that, although "HRSA continues to strongly encourage manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements," it lacked "comprehensive regulatory authority" to "issue enforceable regulations to ensure clarity in program requirements …." *E.g.*, VLTR_3272, VLTR_3285, VLTR_4194; *see also Am. Hosp. Ass'n*, 2021 WL 616323, at *3 (quoting July 8, 2020 email from HRSA Communications Director Martin Kramer recognizing that, while the agency strongly encouraged manufacturers to sell 340B drugs to covered entities through contract pharmacy arrangements, "HRSA's current authority to enforce certain 340B policies … is limited"). As a result, in communications with HRSA, covered entities and contract pharmacies recognized that it was HRSA's view that it "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." VTLR_3283.

HRSA not only espoused the view that it lacked enforcement authority regarding contract pharmacy use, but also applied that view in practice in addressing covered entity compliance. Plaintiffs cite a December 2020 GAO report which states that HRSA declined in certain instances in 2019 to address the problem of covered entity statutory compliance via their contract pharmacy partners in part because, in HRSA's 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 ("GAO Report"), at 15–16, gao.gov/assets/gao-21-107.pdf; *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.").

The agency's view regarding the non-binding nature of its position that drug manufacturers should sell 340B drugs through contract pharmacy arrangements dramatically changed in December 2020, however, with the issuance of HHS General Counsel's[17] Advisory Opinion, which for the first time provided that participating manufacturers are obligated by statute to provide 340B discounts to covered entities

[17] HHS regulations provide that the HHS general counsel's office "[s]upervises all legal activities of the Department and its operating agencies," and "[f]urnishes all legal services and advice to … all offices, branches, or units of the Department in connection with the operation 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).

through contract pharmacy arrangements "to the extent" that a contract pharmacy is acting as an agent of the covered entity. VLTR_8048. Even after the issuance of the Advisory Opinion, Defendants' counsel represented to the Court at a February 26, 2021 hearing on Lilly's motion for a preliminary injunction to enjoin the ADR Rule that, "while the agency has determined that covered entities have a right generally to use contract pharmacy arrangements, the agency has not passed on the specifics of Lilly's new policy, because that belongs in the ADR" and "if the panel determines that Lilly's policy does not comply with the statute, it can refer its decision to HRSA for enforcement action," at which point HRSA considers "whether to impose penalties, sanctions, to refer the decision to the OIG for civil monetary penalties." Dkt. 72 at 76–77.

Less than three months thereafter, in the May 17 Letter, HRSA issued its final determination on the precise issue that counsel for Defendants had represented to the Court belonged in the ADR, to wit, whether Lilly's policy complied with the 340B statute. The May 17 Letter does not reference or explain HRSA's about-face regarding the agency's authority to compel drug manufacturers to offer 340B pricing to covered entities dispensing drugs through contract pharmacies and to enforce Lilly's failure to do so. The Advisory Opinion issued by HHS's General Counsel approximately five months prior relies on the theory that "covered entity and contract pharmacy are not distinct, but function as principal-agent" and thus "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 the

covered entity no more than the 340B ceiling price for those drugs." However, the May 17 Letter nowhere references the reasoning behind this opinion or explains HRSA's subsequent decision to abandon that view, despite the fact that the Advisory Opinion had at that point not yet been withdrawn by HHS.

Defendants argue that the May 17 Letter is not inconsistent with HRSA's previously expressed position regarding the enforceability of contract pharmacy arrangements for the reason that the May 17 Letter lays out its determination that Lilly was acting in direct violation of statutory requirements, which the agency has always maintained is within its scope of authority to enforce. This conclusion by the agency—that Lilly's policy, under which it does not sell 340B discounted drugs to covered entities dispensing drugs through more than one contract pharmacy, making it a clear violation of the statute—clearly conflicts with HRSA's representations to the GAO just a year before that declined to pursue potential compliance issues involving covered entities' dealings with contract pharmacies because "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 Report at 15–16.

Given the well-established principle that 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 Cnty. v. Wolf*, 962 F.3d 208, 230 (7th Cir. 2020) (quotation marks and citation omitted)) and because HRSA has failed even to acknowledge any change in its position regarding its ability to take enforcement

action related to drug manufacturers' dealings with covered entities through contract pharmacy arrangements, much less provide "good reasons" for such change, the determinations in the May 17 Letter are arbitrary and capricious and must be set aside and vacated and the issues remanded to the agency as actions violative of the APA.

III. Conclusion

While we have most assuredly crafted the most careful judgments of which we are capable with respect to the challenging issues raised by the parties in this litigation, we do not presume to have a full, integrated understanding of the way(s) in which the 340B program should properly and fairly be administered going forward in a way that attempts to reflect the dramatically altered healthcare landscape in which the regulated parties now operate. We do not know, for example, why the agency said for so long that it was not able to enforce its view of drug manufacturers' obligations under the statute in the context of contract pharmacy arrangements and then suddenly changed tack and said it was able to enforce these requirements. We cannot divine whether Congress intended for drug manufacturers to have unlimited delivery obligations under the statute, untethered to the particular covered entity's actual distribution needs. We have no insight into why there is apparently so much reluctance to promulgate a holistic legislative proposal to bring clarity to the scope of the regulated parties' obligations and entitlements under the statute with regard to contract pharmacy arrangements rather than engage in piecemeal interpretations and after the fact patchwork characterizing the history of the agency's attempts to manage this program. What we have come to see, however, is that the 340B

program can no longer be held together and implemented fairly for all concerned with non-binding interpretive guidelines and mixed, sometimes inconsistent messaging by the agency regarding the source and extent of its authority to enforce statutory compliance in the area of contract pharmacies.

In performing our analysis and reaching the conclusions recorded here, we have decided only the issues presented to us in this case. In doing so, we sought to understand and explain and apply the appropriate legal principles within the boundaries of justiciability. We are not authorized or qualified to go beyond this role by presuming to speak for Congress, the agency, the regulated entities, or other federal district courts assessing similar but distinct policies of other drug manufacturers. For the reasons detailed above, we have determined that, though the 340B statute does not unambiguously require drug manufacturers to deliver drugs to an unlimited number of contract pharmacies as the Advisory Opinion would require, the statute, correctly construed, does not permit drug manufacturers, such as Lilly, to impose unilateral extra-statutory restrictions on its offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements. Thus, the May 17 Letter advancing the conclusion that Lilly's policy resulted in overcharges in violation of the 340B statute is not contrary to law or in excess of the agency's statutory authority nor is it unconstitutional or issued in violation of the APA's notice and comment procedures.

However, despite the agency's assertion that it has consistently advanced the view that drug manufacturers must comply with the 340B statutory requirements regardless of

the drug dispensing system used by covered entities, at the same time it has espoused the conflicting view that the agency does not have authority to issue binding regulations regarding contract pharmacies and operated with only limited enforcement authority with regard to its contract pharmacy guidance and that determining whether Lilly's policy complied with the statute was an issue that must be decided in the ADR process. Because the May 17 Letter fails to acknowledge or explain the agency's changed position(s) with regard to its authority to enforce statutory compliance when the alleged violation is entangled with a regulated entity's failure to comply with the agency's non-binding contract pharmacy guidance, we hold that it is arbitrary and capricious and thus violative of the APA.

In line with these findings and conclusions:

- Defendants' Motion to Dismiss as to Plaintiffs' APA claims challenging the Advisory Opinion issued by General Counsel of HHS on December 30, 2020 is DENIED.
- Plaintiffs' Motion for Summary Judgment on their claim that the Advisory Opinion is arbitrary and capricious and thus violates the APA (Count III) is GRANTED and Defendants' Cross-Motion for Summary Judgment on that claim is correspondingly DENIED.
- The parties' cross-motions on Plaintiffs' remaining APA claims challenging the Advisory Opinion on grounds that it was issued without following notice and comment procedures (Count I), exceeds the agency's statutory authority (Count II),

and violative of the Fifth Amendment's Takings Clause and Article I of the United States Constitution (Count IV), are DENIED WITHOUT PREJUDICE.

- Plaintiffs' Motion for Summary Judgment on their APA claims challenging the May 17 Letter on grounds that it is contrary to law or in excess of statutory authority (Count X), violative of the Fifth Amendment's Takings Clause and Article I of the United States Constitution (Count XI), and issued without following notice and comment procedures (Count XIII) is DENIED and Defendants' Cross Motion for Summary Judgment is correspondingly GRANTED as to these claims.
- Plaintiffs' Motion for Summary Judgment as to their claim that the May 17 Letter is arbitrary and capricious in violation of the APA (Count XII) is GRANTED and Defendants' Cross Motion for Summary Judgment is DENIED.

Having found that the 2020 Advisory Opinion and the May 17 Letter are both arbitrary and capricious actions that violate the APA, we hereby SET ASIDE and VACATE these agency actions and REMAND the May 17 Letter to the agency for further consideration/action consistent with the opinions explicated here. Although agency actions invalidated as arbitrary and capricious are typically remanded to the agency for further consideration, *Florida Power & Light Co. v. Lorion*, 470 U.S. 729 (1985), because the agency has already withdrawn the Advisory Opinion, no remand of that agency action is necessary.

The Court is making the requisite finding pursuant to Federal Rule of Civil Procedure 54(b) that there is no just reason for delay; thus, partial final judgment shall issue on Counts III and X–XIII to allow the parties to decide whether to seek expedited appellate review of these issues. The Court will address the parties' cross-motions for summary judgment as to Plaintiffs' APA claims challenging the ADR Rule (Counts V, VI, VII, VIII, and IX) in due course.

IT IS SO ORDERED.

Date: 10/29/2021

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al. Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al. Defendants.	)	No. 1:21-cv-00081-SEB-MJD

PARTIAL FINAL JUDGMENT

The Court, having on this day granted summary judgment in favor of Plaintiffs on Counts III and XII and in favor of Defendants on Counts X, XI, and XIII, finds, pursuant to Federal Rule of Civil Procedure 54(b), that there is no just reason for delay.

Accordingly, partial final judgment is hereby entered in favor of Defendants and against Plaintiffs on Counts X, XI, and XIII and in favor of Plaintiffs and against Defendants on Counts III and XII. HHS's General Counsel's December 30, 2020 Advisory Opinion and HRSA's May 17, 2021 Enforcement Letter are hereby SET ASIDE and VACATED and HRSA's May 17, 2021 Enforcement Letter is REMANDED to the agency.

Date: 10/29/2021

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

Roger A.G. Sharpe, Clerk

BY: _____
Deputy Clerk, U.S. District Court

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al. Plaintiffs, v. UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al. Defendants.	)	No. 1:21-cv-00081-SEB-MJD

AMENDED PARTIAL FINAL JUDGMENT[1]

The Court, having this day granted summary judgment in favor of Plaintiffs on Counts III and XII, and in favor of Defendants on Counts X, XI, and XIII, finds, pursuant to Federal Rule of Civil Procedure 54(b), that there is no just reason for delay. The Court therefore hereby enters partial final judgment in favor of Defendants and against Plaintiffs on Counts X, XI, and XIII, and in favor of Plaintiffs and against Defendants on Counts III and XII.

Accordingly, the Court enters declaratory judgment as follows:

(1) HHS's General Counsel's December 30, 2020 Advisory Opinion is arbitrary and capricious under 5 U.S.C. § 706;

(2) HRSA's May 17, 2021 Enforcement Letter is arbitrary and capricious under 5 U.S.C. § 706;

[1] Pursuant to the Seventh Circuit's April 8, 2022 directive [Dkt. 155], we are entering this amended judgment "declaring specifically and separately the respective rights of the parties," *nunc pro tunc* to October 29, 2021.

(3) HRSA's May 17, 2021 Enforcement Letter does not violate the notice-and-comment requirements of 5 U.S.C. § 553;

(4) HRSA's May 17, 2021 Enforcement Letter does not exceed statutory authority under 5 U.S.C. § 706 because 42 U.S.C. § 256b, correctly construed, does not permit drug manufacturers, such as Plaintiffs, to impose unilateral extra-statutory restrictions on their offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements;

(5) HRSA's May 17, 2021 Enforcement Letter is not a taking under the Fifth Amendment's Takings Clause; and

(6) HRSA's May 17, 2021 Enforcement Letter is not an unconstitutional condition on the receipt of benefits.

HHS's General Counsel's December 30, 2020 Advisory Opinion and HRSA's May 17, 2021 Enforcement Letter are hereby SET ASIDE and VACATED, and HRSA's May 17, 2021 Enforcement Letter is REMANDED for further action as Defendants may determine consistent with these rulings.

Date: 4/14/2022

SARAH EVANS BARKER, JUDGE
United States District Court
Southern District of Indiana

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AMERICA'S ESSENTIAL HOSPITALS

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CERTIFICATE OF COMPLIANCE WITH CIRCUIT RULE 30(d)

Pursuant to 7th Circuit Rule 30(d), counsel certifies that all materials required by 7th Circuit Rule 30(a) and (b) are included in the appendix.

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

Nos. 21-3128 & 21-3405

In The United States Court of Appeals for the Seventh Circuit

ELI LILLY AND COMPANY and LILLY USA, LLC,
Plaintiffs-Appellants-Cross-Appellees,

v.

XAVIER BECERRA, DANIEL J. BARRY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, DIANA ESPINOSA, AND HEALTH RESOURCES AND SERVICES ADMINISTRATION
Defendants-Appellees-Cross-Appellants.

On Appeal from the United States District Court
for the Southern District of Indiana, Indianapolis Division
Case No. 1:21-cv-00081-SEB-MJD
Honorable Sarah Evans Barker

APPENDIX FOR PLAINTIFFS-APPELLANTS

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Counsel for Appellants

May 25, 2022

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VIOLATION LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Resources and Services Administration

Rockville, MD 20857

May 17, 2021

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

Dear Mr. Asay:

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

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

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

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

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

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

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

HRSA requests that Lilly provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by **June 1, 2021**, to 340Bpricing@hrsa.gov.

Thank you for your commitment to the 340B Program.

Sincerely,

/Diana Espinosa/

Diana Espinosa
Acting Administrator

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

Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

The General Counsel
Washington, D.C. 20201

ADVISORY OPINION 20-06 ON CONTRACT PHARMACIES UNDER THE 340B PROGRAM
DECEMBER 30, 2020

The 340B Program, established by section 340B of the Public Health Service Act ("PHSA"), 42 U.S.C. § 256b, imposes limitations on the prices manufacturers may charge for medications sold to specified health care facilities, referred to as "covered entities." Those facilities include public hospitals and community health centers, many of which provide safety-net services to the poor. The 340B Program requires drug manufacturers, as a condition of coverage of their products under Medicaid (*see* Social Security Act ("SSA") § 1902(a)(54)) and Medicare Part B (*see, e.g.*, SSA §§ 1842(o)(1), 1847A), to agree to sell their covered outpatient drugs to covered entities at no more than the statutorily-set "ceiling price." *See* SSA § 1927(a)(1).

Many covered entities enter into written agreements with pharmacies ("contract pharmacies") to distribute their covered outpatient drugs to the entities' patients. Under those agreements, the covered entity orders and pays for the 340B drugs, which are then shipped from the manufacturer to the contract pharmacy. Although the contact pharmacy has physical possession of the drug, it has been purchased by the covered entity.

Recently, certain drug manufacturers participating in the 340B Program are declining to distribute covered outpatient drugs through contract pharmacies at the ceiling price.

The Office of the General Counsel ("OGC") has received numerous requests from both manufacturers and covered entities to address whether it is proper for a drug manufacturer participating in the 340B Program to refuse to provide covered outpatient drugs at the 340B ceiling price to a covered entity for drugs distributed at the entity's contract pharmacies. For the reasons set forth below, we conclude 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 the covered entity no more than the 340B ceiling price for those drugs.

I. Analysis

A. The Plain Meaning of Section 340B Requires Manufacturers to Sell Covered Drugs to Covered Entities at or Below the Ceiling Price, Independent of Whether the Entity Opts to Use Contract Pharmacies to Dispense the Drugs

"[O]ur inquiry begins with the statutory text, and ends there as well if the text is unambiguous." *BedRoc Ltd., LLC v. United States*, 541 U.S. 176, 183 (2004). Section 340B of the PHSA, entitled "Limitation on prices of drugs purchased by covered entities," states, in relevant part, that "[t]he 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]." 42 U.S.C. § 256b(a)(1) (emphasis supplied). Furthermore, "[e]ach such agreement . . . 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." *Id.* As a result, the obligations placed on manufacturers by 340B are set out in a Pharmaceutical Pricing Agreement ("PPA") between the Secretary and the respective manufacturer. *See generally Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110 (2011) (describing role of PPAs in 340B Program). The exemplar PPA provides, in pertinent part, as follows:

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following: (a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to [the ceiling price].

PPA § II(a). The exemplar PPA Addendum provides that a "[m]anufacturer 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." PPA Addendum ¶ 2.

Thus, the core requirement of the 340B statute, as also reflected in the PPA and Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity. In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute. *See Radovich v. Nat'l Football League*, 352 U.S. 445, 454 (1957) ("Congress itself has placed the private antitrust litigant in a most favorable position . . . . In the face of such a policy this Court should not add requirements to burden the private litigant beyond what is specifically set forth by Congress in those laws."); *Financial Planning Ass'n v. SEC,* 482 F.3d 481 (D.C. Cir. 2007); *Baker v. Bell Textron, Inc.*, 2020 WL 5513431, at *4 (N.D. Tex. 2020) ("The Court will not add requirements to the law that Congress could have included but did not.").

It is against this backdrop that we examine the 340B phrase "purchased by." It is difficult to envision a less ambiguous phrase and no amount of linguistic gymnastics can ordain otherwise. The Court recently cautioned against seeing ambiguity where none exists. For

example, a regulation must be "genuinely ambiguous" before resorting to deference. *Kisor v. Wilkie*, ___U.S.___, 139 S.Ct. 2400, 2415 (2019). Here, as we understand it, the medications at issue are sold by the manufacturer to the covered entity; the covered entity takes title and the covered entity pays the manufacturer either directly or through the manufacturer's distributor. In either event, the arrangement between the manufacturer and covered entity is a straightforward "sale" which "consists of the passing of title from the seller [drug manufacturer] to the buyer [covered entity] for a price." Uniform Commercial Code (U.C.C.) § 2-106.[1] A "buyer" is, by definition, a "purchaser." BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "buyer" as "[s]omeone who makes a purchase"). The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant. *See* U.C.C. § 2-401(2) ("Unless otherwise explicitly agreed 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 . . . ").

Given the lack of ambiguity in the plain text of the statute, the above analysis is dispositive. *Bostock v. Clayton Cty.*, ___U.S.___, 140 S. Ct. 1731, 1739 (2020) ("[W]hen the meaning of the statute's terms is plain, our job is at an end."). This straightforward textual interpretation, aside from dutifully reflecting the plain meaning of the statute, has the added benefit of comporting with the statute's purpose and history.

B. The Purpose and History of the 340B Program Reflect the Provision's Plain Meaning

1. Contract Pharmacies Have Been an Integral Part of the 340B Program Since Its Outset

The 340B Program was created to allow covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rept. No. 102–384(II), at 12 (1992). As the Health Resources and Services Administration ("HRSA")—the agency primarily responsible for administering the 340B Program—has explained in prior guidance, a substantial number of covered entities are practically constrained to rely on contract pharmacies to access the 340B Program; if manufacturers can simply shut off this means of access, the Program's effectiveness will be greatly diminished. *See Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services*, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996); *see also Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (proposed Feb. 6, 2019) (OIG proposed rule discussing distribution of pharmaceuticals).[2]

[1] The U.C.C. can be used for statutory construction, even if it does not directly apply. *See Comm'r of Internal Revenue v. Brown*, 380 U.S. 563, 571 (1965) (interpreting provision of the Internal Revenue Code by pointing to U.C.C. as support for the "ordinary sense" of the word "sale").

[2] The argument that the statute also evinces a purpose to prevent drug diversion or duplicate discounting, and therefore prohibits contract-pharmacy arrangements, is not persuasive. That is like arguing that the main purpose of federal healthcare programs are their antifraud provisions. In the absence of the core 340B discount mechanism, there would be no need for the duplicate-discount or diversion provisions.

This is particularly pertinent given that at the outset of the 340B Program only approximately 500 out of 11,500 covered entities (less than 5 percent) used in-house pharmacies. *See* 61 Fed. Reg. at 43,550. This is not surprising: the Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations. *See, e.g.*, 42 U.S.C. § 256b(a)(4) (defining covered entities); *Astra USA*, 563 U.S. at 113. These are the poster children of providers that one would expect to lack an in-house pharmacy. To champion a policy, ungrounded in the language of the statute, that would foreclose 340B discounts to 95 percent of covered entities and foreclose discounts to the neediest of this cohort is inconsistent with purpose of the Program and common sense. Had Congress intended to reach such a bizarre result, it would have used language affirmatively precluding the use of contract pharmacies as arms in the distribution channel, but it did not. *Doe v. Hesketh*, 828 F.3d 159, 167 (3d Cir. 2016) (the result is "so bizarre that Congress could not have intended it").

2. The Department's Longstanding Interpretation of Section 340B Reflects the Plain Language of the Section by Recognizing the Use of Contract Pharmacies

The Department's longstanding interpretation of the statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used. In 1996, HRSA issued the aforementioned guidance and stated, "[i]t has been the Department's position that if a covered entity using contract pharmacy services requests to purchase a covered drug from a participating manufacturer, the statute directs the manufacturer to sell the drug at the discounted price." 61 Fed. Reg. at 43,549. HRSA's assertion cannot be attacked as impermissible legislative rulemaking,[3] because the guidance only sought to "explain the statutory language by clarifying the meaning given by the Department to particular words or phrases"—it "create[d] no new law and create[d] no new rights or duties" not otherwise present in the statute. *See id.* at 43,550. HRSA reaffirmed its interpretation of the statute in guidance issued in 2010. *See* HRSA, *Notice Regarding 340B Drug Pricing Program–Contract Pharmacy Services*, 75 Fed. Reg. 10,272 (Mar. 5, 2010).

The Department's consistent position over the past 24-plus years would factor into a court's interpretation of the statute. Courts defer to agency expertise in the interpretation of statutes, especially where they govern complex administrative regimes. *See, e.g.*, *United States v. Mead Corp.*, 533 U.S. 218, 227–28 (2001). Conversely, a court would be skeptical of an abrupt about-face. *See, e.g.*, *Wyeth v. Levine*, 555 U.S. 555, 577–81 (2009). Courts may also look to agency implementation and the actions of regulated parties to determine the meaning of a statute. *See, e.g.*, *S.D. Warren Co. v. Me. Bd. of Env't Prot.*, 547 U.S. 370, 377–78 (2006) (even though relevant agencies had not "formally settled the definition, or even set out agency reasoning," the "administrative usage of [the disputed term] in this way confirm[ed the Court's]

[3] *See, generally*, *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) ("Within section 340B, Congress specifically authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the 'regulatory issuance' of precisely defined standards of methodology for calculation of ceiling prices, and (3) the imposition of monetary civil sanctions."); *Pharm. Rsch. and Mfrs. of Am. v. U.S. Dep't of Health and Human Servs.*, 138 F. Supp. 3d 31, 39 (D.D.C. 2015) (even if "HHS lacks the authority to promulgate the rule as a binding statement of law, HHS is not forbidden altogether from proffering its interpretation of the statute").

understanding"); *Bd. of the Trs. of Leland Stanford Jr. Univ. v. Roche Molecular Sys.*, 563 U.S. 776, 792–93 (2011) ("[I]t is worth noting that our construction of the [statute in question] is reflected in the common practice among parties operating under the Act."). Here, contract-pharmacy arrangements have been utilized, and honored by manufacturers, since 1996 and earlier.[4]

C. Manufacturers' Rationale for Precluding the Use of Contract Pharmacies Is Not Supported by the Language of the Statute and Leads to Absurd Results

The primary rationale offered for cutting off contract pharmacies—that such arrangements lead to a heightened risk of diversion and duplicate discounts—makes clear that manufacturers are attempting to circumvent section 340B's procedures for resolving disputes between manufacturers and covered entities. *See, e.g.*, *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1984) ("In ascertaining the plain meaning of the statute, the court must look to the particular statutory language at issue, as well as the language and design of the statute as a whole.") (emphasis supplied). Not surprisingly, the manufacturers have been unable to point to any language in the statute that would support this hobbling interpretation. If a manufacturer is concerned that a covered entity has engaged in duplicate discounting or diversion, *see* 42 U.S.C. § 256b(a)(5)(A), (B), it must (1) conduct an audit, and (2) submit the claim to the administrative dispute resolution ("ADR") process, *see* §256b(d)(3)(A). The PPA even provides that a covered entity's failure to comply with the audit requirement does not "relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of the Act and the Agreement." PPA § IV(d). Moreover, the Department specifically rejected this reasoning when issuing regulations regarding the calculation of the 340B ceiling price. In responding to a comment regarding perceived 340B violations, HRSA stated "[m]anufacturers cannot condition sale of a 340B drug at the 340B ceiling price because they have concerns or specific evidence of possible non-compliance by a covered entity." *340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation*, 82 Fed. Reg. 1210, 1223 (Jan. 5, 2017). In addition, "[m]anufacturers that suspect diversion are encouraged to work in good faith with the covered entity, conduct an audit per the current audit guidelines, or contact HHS directly." *Id.* Certain manufacturers' newfound and unilateral refusal to sell drugs through contract pharmacies is at odds with the structure and intended operation of the statute.[5]

[4] The fact that Congress has not amended the 340B statute to expressly exclude contract-pharmacy arrangements from coverage can be read as supporting the agency's longstanding construction. *See* Valerie C. Brannon, Cong. Rsch. Serv., R45153, *Statutory Interpretation: Theories, Tools, and Trends* 63 (2018) (discussing "presumption of legislative acquiescence").

[5] For 24-plus years, manufacturers have offered the ceiling price to covered entities using contract-pharmacy distribution. To the extent manufacturers now have sincere concerns about diversion or duplicate discounting, the 340B statute speaks directly to how they should proceed. *See also 340B Drug Pricing Program; Administrative Dispute Resolution Regulation*, 85 Fed. Reg. 80,632, 80,633 (Dec. 14, 2020) ("The purpose of the ADR process is to resolve . . . claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHSA, that a covered entity has violated the prohibition on diversion or duplicate discounts."). Manufacturers who shut off contract-pharmacy access may have also skipped over any effort to resolve disputes with covered entities in "good faith." PPA § IV(a)(1) ("If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A) . . . [t]he Manufacturer shall attempt in good faith to resolve the matter with the covered entity."); 85 Fed. Reg. at 80,633 ("Historically, HHS has

Relatedly, it has also been argued that the use of contract pharmacies is inconsistent with the 340B statute's prohibition on diversion of discount drugs. We start with the basic proposition that subsection (a)(5)(B) was intended to prohibit the diversion of 340B drugs. *See* 42 U.S.C. § 256b(a)(5)(B) ("With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity."). According to one court, the 340B Program places a "ban on 'diversion,' *i.e.*, a requirement that covered entities refrain from reselling or otherwise transferring covered drugs to non–340B entities[.]" *Cty. of Santa Clara v. Astra USA, Inc.*, 257 F.R.D. 207, 211–12 (N.D. Cal. 2009), *vacated on other grounds*, *Astra USA,* 563 U.S. 110; *see also* 85 Fed. Reg. at 80,636 (subsection (a)(5)(B) prohibits diversion).

Diversion means that, on net, covered outpatient drugs end up in the hands of persons who are not patients of the covered entity. The movement of drugs purchased by the covered entity and ultimately dispensed to the patient by a contract pharmacy can involve complex inventory models. Whether diversion occurs, however, should be independent of the inventory-accounting model contemplated by the agreement between the contract pharmacy and the covered entity. *See Toyota Motor Sales, U.S.A., Inc. v. United States,* 35 Ct. Int'l Trade 1205 (2011) (noting that inventory-accounting methods are authorized to determine tariffs and drawbacks); *Sears, Roebuck & Co. v. King County*, 487 P.2d 221, 223, 5 Wash. App. 273, 276 (1971) (for tax purposes "identification by any reasonable and reliable [inventory-accounting] method [is proper], rather than by a strict tracing method.").

The notion that the legitimate transfer of drugs to contract pharmacies so that they can be dispensed to patients of the covered entity constitutes diversion not only ignores the realities of accounting, but also that the covered entity and contract pharmacy are not distinct, but function as principal-agent. As explained, the covered entity remains the purchaser whether it chooses to have discount drugs distributed through an in-house pharmacy or a contract pharmacy. *See also* 61 Fed. Reg. at 43,550 ("The mechanism does not in any way extend this pricing to entities which do not meet program eligibility."); *id.* (agreeing that "[a]s a general rule, a person or entity privileged to perform an act may appoint an agent to perform the act unless contrary to public policy or an agreement requiring personal performance") (citing Restatement (Second) of Agency § 17 (Am. L. Inst. 1995)); *id.* ("The contract pharmacy would act as an agent of the covered entity, in that it would not resell a prescription drug but rather distribute the drug on behalf of the covered entity. This situation is akin to a covered entity having its own pharmacy."); *id.* at 43,552 (under "bill to/ship to" arrangement contemplated in guidance, "[t]he contract pharmacy does not purchase the drug. Title to the drugs passes to the covered entity" and "the manufacturer is still selling to the covered entities"); *cf. Abramski v. United States*, 573 U.S. 169, 186 (2014) ("[t]he individual who sends a straw [purchaser] to a gun store to buy a firearm is transacting with the dealer, in every way but the most formal" such that "straw arrangements are not a part of the secondary market, separate and apart from the dealer's sale") (emphasis in original).[6]

encouraged manufacturers and covered entities to work with each other to attempt to resolve disputes in good faith.").

[6] Similar reasoning still applies under the so-called "replenishment" model, where the contract pharmacy dispenses medications from a general inventory to the covered entity's patient and "replenishes" its general

In addition, the argument that use of contract pharmacies constitutes an illicit "transfer" leads to absurd results. For instance, if a covered entity uses a courier service to send discount drugs to its patient, this, too, would be appear to be an illegal "transfer" to the shipper. Any arrangement that did not involve a physical hand-off from the employee of a covered entity to the patient him or herself could be an unauthorized "transfer" under the 340B statute. To avoid such absurdities, and under the canon of *noscitur a sociis*,[7] the phrase "otherwise transfer" must be interpreted in conjunction with the word "resell" and the title of that specific provision ("Prohibiting resale of drugs") (emphasis supplied).[8]

This conclusion is reinforced by an understanding of the practical realities of drug distribution. Such distribution often functions through intermediaries. For example, covered entities often purchase 340B discounted drugs from wholesalers, not directly from manufacturers. And yet, the obligations of § 256b(a) are placed on manufacturers. If it were correct that distribution to any entity other than a covered entity freed the manufacturer from the obligation to charge no more than the ceiling price, then there would be no firm basis for the wholesalers to charge-back discounts to the manufacturer. Large portions of the current 340B Program would seem to turn on solely manufacturers' voluntary choice to offer the ceiling price,

inventory with discount medications purchased by the covered entity. The inventory commingling (drugs purchased by covered entity(ies) under the auspices of 340B, commingled with what the contract pharmacy might otherwise have) does not change the analysis. *Cf. Martin Marietta Corp. v. N.J. Nat'l Bank*, 612 F.2d 745, 749 (3d Cir. 1979) ("identification" of goods for purposes of U.C.C. § 2-501 not broken even if "seller removes some of the fungibles and later replaces them . . . because such conduct is quite natural with fungibles and cannot be taken as an intent to negate the buyer's interest in the goods"); *Apex Oil Co. v. Belcher Co. of N.Y., Inc.*, 855 F.2d 997, 1,003–05 (2d Cir. 1988) ("[W]here fungible goods are concerned, identification is not always an irrevocable act and does not foreclose the possibility of substitution."); *Matter of Bevill, Bresler & Schulman Asset Mgmt. Corp.*, 67 B.R. 557, 588 (D.N.J. 1986) (under U.C.C. § 9-207, "a secured party is allowed to commingle fungible collateral, including certain types of securities, and may sell the collateral and replace it with instruments which are equivalent in kind and value without breaching his duty to exercise reasonable care in the custody and preservation of the pledged collateral"). Nor does the ordering of events. If the contract pharmacy's dispensing of the drugs is event "A" and the contract pharmacy's receipt of the drugs is event "B," the ordering of events does not matter if repeated over time. Whether the series looks like ...BABABA... or ...ABABAB... is simply a function of the reference timeframe. In sum, where the contract pharmacy is replenished by the covered entity and dispenses to the covered entity's patients on a rolling basis, it is still true that the covered entity's patients are receiving the covered entity's drugs—they are not re-sold or "otherwise transfer[red]" to the contract pharmacy.

It also bears mention that the replenishment inventory model is currently an integral part of many patient assistance programs operated by drug manufacturers. *See, e.g.*, *Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623, 70,624 (Nov. 22, 2005); Merck & Co., Inc. *For Health Care Professionals*, MERCK HELPS, https://www.merckhelps.com/HCPs.aspx (last visited Dec. 21, 2020); Pfizer, Inc., *The Pfizer Institutional Patient Assistance Program (IPAP) At-a-Glance* (April 2019), https://www.pfizerrxpathways.com/sites/default/files/attachment/PP-PAT-USA1032%20RxPathways_IPAP_Factsheet%202019.pdf (last visited Dec. 21, 2020).

[7] "[W]e rely on the principle of *noscitur a sociis*—a word is known by the company it keeps—to avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Yates v. United States*, 574 U.S. 528, 543 (2015) (plurality op.) (quotes omitted).

[8] An exact delineation of the scope of the phrase "otherwise transfer" is beyond the scope of the Advisory Opinion. The point here is simply that the phrase must have some limiting principle to avoid sweeping in innocuous conduct that is inevitable in the functioning of the 340B Program.

not a statutory mandate. Thus, manufacturers may not refuse to offer the ceiling price to covered entities, even where the latter use distribution systems involving contract pharmacies.

II. Conclusion and Limitations

For these reasons, the Office of the General Counsel concludes that covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients.[9]

This Advisory Opinion may be supplemented or modified by the Office of the General Counsel. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.[10] It is not a final agency action or a final order, and it does not have the force or effect of law.

Robert Charrow

Robert P. Charrow
General Counsel
December 30, 2020

[9] This Advisory Opinion is limited to interpretation of the 340B statutory requirements in general and does not opine on the legality of any specific contract-pharmacy model, under either the 340B statute or other laws that may apply (such as the anti-kickback statute, 42 U.S.C. § 1320a-7b).

[10] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647–48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]"); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).

HHS Notice of Withdrawal

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Office of the General Counsel
Washington, D.C. 20201

NOTICE OF WITHDRAWAL
JUNE 18, 2021

Withdrawing Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program (issued December 30, 2020)

The Office of the General Counsel (OGC) is withdrawing Advisory Opinion 20-06 (Opinion) in light of ongoing confusion about the scope and impact of the Opinion.

The Opinion has been challenged in lawsuits brought by various drug manufacturers. *See AstraZeneca Pharma. LP v. Becerra et al.*, 21-cv-27 (D. Del.); *Eli Lilly and Co. et al. v. Becerra et al.*, 21-cv-81 (S.D. Ind.); *Sanofi-Aventis U.S. LLC v. HHS et al.*, 21-cv-634 (D.N.J.); *Novo Nordisk Inc. et al. v. HHS et al.* (D.N.J.). The Opinion was never intended to do what plaintiffs in those suits allege: to create new, binding obligations on plaintiffs or to serve as the predicate for enforcement against those plaintiffs. As stated in the Opinion, it was meant to "set forth the current views of [OGC]" on the proper interpretation of the statute without "the force or effect of law." Opinion at 8.

OGC maintains that the Opinion was not intended to impose new, binding obligations on regulated entities, and we respectfully disagree with the decision of the District Court in *AstraZeneca Pharmaceuticals*. However, in the interest of avoiding confusion and unnecessary litigation, OGC withdraws the Opinion.

OGC notes that its withdrawal of the Opinion does not impact the ongoing efforts of the Health Resources and Services Administration (HRSA) to enforce the obligations that 42 U.S.C. § 256b places on drug manufacturers, including HRSA's May 17, 2021 violation letters concerning restrictions placed on contract pharmacy arrangements. HRSA's enforcement process operated independently from the issuance of the Opinion, and operates independently from the Opinion's withdrawal.

Daniel J. Barry
Acting General Counsel