UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

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

and

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

Plaintiffs,

v.

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

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

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

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

and

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

Defendants.

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

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SECOND AMENDED COMPLAINT
FOR DECLARATORY AND INJUNCTIVE RELIEF

This case concerns the lawful scope of the 340B Drug Pricing Program ("340B Program" or "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 (adding section 340B to the Public Health Service Act). Under the 340B statute, pharmaceutical manufacturers "must" offer steep discounts on their products to certain "covered entities." 42 U.S.C. § 256b(a)(1); *see also id.* § 256b(a)(4), (b)(1); *id.* § 1396r-8(a)(1), (5). And while manufacturers are not formally required to participate in the Program, they have little practical choice but to "opt in[]": "Manufacturers' eligibility to participate in State Medicaid [and federal Medicare] programs"—which not only "touch[] the lives of nearly all Americans," *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019), but make up a significant portion of manufacturers' annual revenues—"is conditioned on their" participation in the Program. *Astra U.S.A., Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

Cognizant of the constitutional limits on forcing private parties to effectively subsidize other private parties, Congress made clear in the 340B statute that only "covered entities"—a narrowly circumscribed class that Congress defined to be limited to 15 specifically enumerated types of non-profit healthcare providers—could demand these steep discounts. Entities not included on Congress's list of covered entities, such as for-profit hospitals or big businesses like Walgreens and CVS (the latter of which are referred to in this context as "contract pharmacies"), had no legal basis to demand to receive prescription medications or other product from manufacturers at 340B prices. *See* 42 U.S.C. § 256b(a)(4).

Yet the government claims that things are different now. Even though nothing about the statutory limitation regarding covered entities has changed, the U.S. Department of Health and Human Services ("HHS") Office of the General Counsel ("OGC") "released an advisory opinion"

on December 30, 2020, "concluding that drug manufacturers are required to deliver discounts under the 340B Drug Pricing Program [ ] on covered outpatient drugs when contract pharmacies are acting as agents of 340B covered entities." U.S. Dep't of Health and Human Servs., *HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies* (Dec. 30, 2020), https://bit.ly/38Qh0lB; *see* U.S. Dep't of Health & Human Servs. Office of the General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies under the 340B Program*, at 1 (Dec. 30, 2020) ("December 30 Decision") ("We conclude" that "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***" whenever a contract pharmacy acts as a covered entity's "agent." (emphasis added)), https://bit.ly/357nqfk.

That is no small matter. Unlike the 15 types of entities Congress enumerated in the statute, contract pharmacies do not exist to serve vulnerable populations, and they rarely pass along any 340B price savings to the patients who purchase 340B drugs. *See* U.S. Gov't Accountability Office ("GAO"), *Discount Drug Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480 ("2018 GAO Report"), at 10-13 (June 2018), https://bit.ly/3kJ7eGa; Aaron Vandervelde et al., *For-Profit Pharmacy Participation in the 340B Program*, at 3 (Oct. 2020), https://bit.ly/2XryAY5. Indeed, when Defendant the Health Resources and Services Administration ("HRSA"), which administers the Program, first allowed covered entities to enter into an unlimited number of contract pharmacy arrangements for 340B drugs back in 2010 (but did not require manufacturers to honor those arrangements, because nothing in the statute authorizes the government to impose such a requirement), contract pharmacies began "generat[ing] revenue" ***to the tune of hundreds of millions of dollars per year*** by perverting the Program simply by "purchas[ing] covered outpatient drugs at the 340B Program price for all

eligible patients regardless of the patients' income or insurance status" and "receiving reimbursement from patients' insurance that may exceed the 340B prices paid for the drugs." GAO, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108, at 5 (Dec. 2019), https://bit.ly/34Vj6zK.

Against this backdrop, and consistent with the plain text and clear purpose of the statute, Plaintiffs Eli Lilly and Company and Lilly USA, LLC (together, "Lilly") announced last summer that it would cease to offer 340B discounts to contract pharmacies on three formulations of its drug Cialis®. Lilly later expanded this new distribution model to include all of its prescription drug products—except when a covered entity lacks an in-house pharmacy. In that limited circumstance, where an outside pharmacy is necessary for a covered entity to dispense covered outpatient drugs to patients, Lilly will permit the covered entity to designate one outside contract pharmacy to receive and dispense 340B product to 340B-eligible patients. To be clear: Lilly still offers full 340B discounts to ***all*** entities eligible for them, and Lilly will continue to ensure that patients are able to receive 340B product even when a covered entity cannot dispense drugs itself. Lilly's new distribution plan is thus not only a necessary bulwark against contract pharmacy abuses (and a more-than-reasonable response to limit exposure to the raft of penalties the statute authorizes), but is consistent with the plain text and the original intent of the 340B statute.

Yet when Lilly announced that it would no longer allow an unlimited number of contract pharmacies to demand discounts, Defendants threatened Lilly with sanctions. And they have now made good on those threats: Defendants have jettisoned their prior, longstanding, and nonbinding guidance that contract pharmacy arrangements are permissible but not enforceable on pain of penalty in favor of a new, binding decision under which manufacturers like Lilly must offer full 340B discounts to an unlimited number of contract pharmacies on all covered outpatient drugs. If

a manufacturer refuses, Defendants say it will face massive penalties of up to $5,000 per occurrence, plus the potential revocation of the manufacturer's ability to participate in and receive reimbursements under the pervasive Medicare and Medicaid programs.

Worse, Defendants propose to adjudicate manufacturers' liability under this made-up statutory regime using unconstitutional, unlawful, and arbitrary procedures. Although the goal of the 340B Program was to provide financial support to hospitals and clinics that serve vulnerable populations, Congress did not appropriate federal funds for that purpose; instead, it coerced pharmaceutical manufacturers to effectively subsidize covered entities via the 340B Program as a condition of participating in Medicare Part B and Medicaid. Congress's decision to set up a taxpayer-to-taxpayer system has had a number of downstream consequences, including creating a lax regulatory environment ripe for for-profit contract pharmacies like CVS and Walgreens to siphon huge sums of money from the Program by partnering with covered entities and engaging in arbitrage. The decision also ensured that, eventually, 340B disputes between these taxpayers would arise. Hence, Congress instructed HHS in 2010 to establish an administrative dispute resolution ("ADR") procedure to hear 340B disputes between manufacturers and covered entities. But just as Defendants HHS and HRSA have flouted the clear limitations on their authority vis-à-vis contract pharmacies, they flouted that clear statutory command to establish ADR protocols: Although Congress instructed HHS to establish ADR procedures within 180 days, it took HHS nearly six ***years*** to promulgate a Notice of Proposed Rulemaking ("NPRM") suggesting ADR procedures and seek public comment—and even then, the NPRM did not last long; recognizing the host of problems with the belatedly proposed rule, HHS withdrew it altogether in 2017.

After ignoring congressional instructions regarding ADR for nearly a decade, HHS finally acted. Yet instead of issuing a new NPRM or giving any consideration to the concerns that led it

to withdraw the original NRPM in the first place, the agency rushed an ADR regulation out the door at the twilight of the Trump Administration as a panicked response to covered-entity-initiated litigation pressure. In particular, HHS simply blew the dust off its long-ago-withdrawn rule; pretended that the withdrawn NPRM has been alive the whole time; changed the rule in important ways; and then carried it into immediate effect—all without giving regulated parties any opportunity for public comment. *See* 340B Drug Pricing Program; Administrative Dispute Resolution Regulation, 85 Fed. Reg. 80,632-01 (Dec. 14, 2020) ("ADR Rule"). That is precisely the sort of unlawful agency gamesmanship that federal courts exist to police.

And if the ADR Rule's procedural history is bad (which it is), its substance is worse. First, it violates the Appointments Clause of Article II of the U.S. Constitution. The ADR Rule installs Executive Branch employees on ADR panels and gives them the power to adjudicate disputes between private parties and to issue "binding" judgments for money damages. No superior Executive official has any power to review these employees' decrees or remove them from an ADR panel except for cause, thus making the employees principal Executive officers, and making their non-Presidential appointment contrary to Article II. Second, the ADR Rule confers on ADR panels the power to issue final judgments for money damages and equitable relief to resolve private rights—authority reserved to Article III courts. As a result, the ADR Rule is contrary to the Constitution, or, at a minimum, it exceeds Congress's statutory authorization for agency action.

The ADR Rule is also arbitrary and capricious under the Administrative Procedure Act ("APA"). In comments to the NPRM, a number of manufacturers raised concerns about the agency's refusal to at least utilize an independent administrative law judge ("ALJ") to perform quintessentially adjudicatory tasks. The final ADR Rule not only arbitrarily and capriciously rejects that suggestion, it exacerbates the problem, expanding the panels' powers to include money

judgments and equitable relief (neither of which is in the original NPRM), providing that the panels' decisions will be "precedential" in future cases, and allowing covered entities' agents and trade associations (neither of which has any entitlement to 340B discounts under the statute) to bring ADR panel claims for money damages against manufacturers.

To make matters worse, one of the "judges" of these would-be "courts" is the HHS General Counsel, which is the Office that issued the December 30 Decision (mis-)interpreting the 340B statute to require manufacturers to provide discounts to contract pharmacies whenever the latter act as a covered entity's "agent." As a result, when confronted with the question of whether a manufacturer can and/or should be subjected to penalties for not offering 340B discounts to for-profit contract pharmacies, the Executive Branch employees who comprise the ADR panels will not apply their expertise in administering a pharmacy benefit program, but rather will apply common law principles of agency to adjudge the legal nature of the relationship between covered entities and contract pharmacies like CVS. That is a task for an Article III judge, not a bureaucrat. It also confirms that, as a result of the agencies' recent and final actions, the 340B Program writ large has been fundamentally transformed from a system designed to subsidize nonprofit healthcare providers that serve vulnerable patients into an unlawful and unconstitutional forced wealth transfer backstopped by an unlawful and unconstitutional administrative tribunal.

Subsequently, in a May 17, 2021 letter, Defendant Diana Espinosa ordered Lilly comply with Defendants' interpretation of the statute and demanded that Lilly reimburse all instances it did not provide 340B discounts for contract pharmacy transactions. This letter constitutes additional final agency action, determining that Lilly is in violation of the government's interpretation of the statute, and threatening the imposition of serious civil penalties. *See U.S. Army Corps of Eng. v. Hawkes*, 136 S. Ct. 1807, 1815 (2016) ("As we have long held, parties need

not await enforcement proceedings before challenging final agency action where such proceedings carry the risk of 'serious criminal and civil penalties.'"). The letter is an unlawful agency decision, not only departing from the agency's settled interpretation of the statute that had been in place at least prior to the December 30 Decision, but also departing from the rationale the agency relied on just five months before in its December 30 Decision.

Lilly therefore brings this action seeking an order: (1) declaring that the substantive obligation imposed in the December 30 Decision and May 17 Letter violates the APA because it violates the Constitution, is in excess of statutory authority, was issued without following proper procedure, and is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law; (2) declaring that Lilly is not required and cannot be required to provide 340B discounts to contract pharmacies (including on covered outpatient drugs acquired by contract pharmacies to replenish drugs that were dispensed to purported patients of 340B covered entities, and drugs not purchased by covered entities); (3) enjoining enforcement of the December 30 Decision, the May 17 Letter, and all actions by Defendants inconsistent with that declaratory relief; (4) declaring that the ADR Rule violates the APA because it violates the Constitution, is in excess of statutory authority, was issued without following proper procedure, and is arbitrary, capricious, an abuse of discretion, and not otherwise in accordance with law; and (5) enjoining implementation of the ADR Rule.

THE PARTIES

1. Plaintiff Eli Lilly and Company is a publicly traded pharmaceutical company organized and existing under the laws of the State of Indiana and headquartered in Indianapolis, Indiana. Eli Lilly and Company participates in the 340B Program.

2. Plaintiff Lilly USA, LLC is a wholly owned subsidiary of Eli Lilly and Company existing under the laws of the State of Indiana and headquartered in Indianapolis, Indiana.

3. Defendant HHS is an executive branch department in the United States government headquartered in the District of Columbia. HHS oversees the activities of HRSA.

4. Defendant Xavier Becerra sued in his official capacity only, is the Secretary of HHS, and is substituted as a party pursuant to Federal Rule of Civil Procedure 25(d). His official address is in the District of Columbia. Secretary Becerra has ultimate responsibility for oversight of the activities of HRSA, including with regard to the administration of the 340B Program and the actions complained of herein.

5. Defendant Daniel J. Barry, sued in his official capacity only, is the Acting General Counsel of HHS. His official address is in the District of Columbia. Mr. Barry oversees the Office of General Counsel, which publishes final legal decisions on behalf of the agency.

6. Defendant HRSA is an administrative agency within HHS and is responsible for administering the 340B Program. HRSA is headquartered in Rockville, Maryland.

7. Defendant Diana Espinosa, sued in her official capacity only, is the Acting Administrator of HRSA, and is substituted as a party pursuant to Federal Rule of Civil Procedure 25(d). Her official address is in Rockville, Maryland. Acting Administrator Espinosa is directly responsible for the administration of the 340B Program and the actions complained of herein. Acting Administrator Espinosa, among his other duties, has ultimate responsibility for the Office of Pharmacy Affairs ("OPA") in HRSA, which is headed by Rear Admiral Krista M. Pedley of the Public Health Service. OPA is involved directly in the administration of the 340B Program, as a constituent part of HRSA.

JURISDICTION AND VENUE

8. Lilly brings this action under the APA, 5 U.S.C. §§ 701–706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201–2202.

9. The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

10. Venue is proper because, among other things, Lilly resides in this judicial district and "no real property is involved in the action." 28 U.S.C. § 1391(e)(1).

11. This Court may grant injunctive and declaratory relief pursuant to 5 U.S.C. §§ 701–706 and 28 U.S.C. §§ 2201–2202.

FACTS

I. Congress Created The 340B Program To Help Vulnerable And Low-Income Patients

12. Congress established the 340B Program, named for the statutory provision authorizing it in the Veterans Health Care Act of 1992, *see* Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act), to "reduce pharmaceutical costs for safety-net medical providers and the indigent populations they serve." Connor J. Baer, *Drugs for the Indigent: A Proposal to Revise the 340B Drug Pricing Program*, 57 WM. & MARY L. REV. 637, 638 (2015); *see* H.R. Rep. No. 102-384 (II), at 12 (1992) (The 340B Program "provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to large numbers of uninsured Americans."). The point of the 340B Program, in other words, was to "create[] a low-cost source of pharmaceutical medication for the indigent patients themselves." Baer, *supra*, at 638.

13. Although participation in the 340B Program is formally optional, *see Astra*, 563 U.S. at 117-18, manufacturers have no real choice but to opt in: Manufacturers cannot receive coverage or reimbursement for their products under Medicaid and Medicare Part B unless they participate in the 340B Program. 42 U.S.C. § 1396r-8(a)(1), (5).

14. Manufacturers "opt into" the 340B Program by signing a form contract with HHS "for covered drugs purchased by 340B entities." *Astra*, 563 U.S. at 113, 117. That form contract is known as the Pharmaceutical Pricing Agreement ("PPA"). *Id.* at 117.

15. A PPA is not an ordinary contract. PPAs are entirely composed by HHS, they "have no negotiable terms," and they "simply incorporate statutory obligations and record the manufacturers' agreement to abide by them." *Id.* at 118. "The statutory and contractual obligations, in short, are one and the same." *Id.*

16. The government may terminate a PPA if it determines that a manufacturer has failed to comply with its obligations. *See* 42 U.S.C. 1396r-8(b)(4)(B)(v); 61 Fed. Reg. 65,406, 65,412–65,413 (Dec. 12, 1996); PPA §§ IV(c), VI(c).

17. Under the 340B statute and the terms of the PPA, any manufacturer that participates 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). Only "covered entities"—a class of non-profit healthcare organizations the 340B statute defines in painstaking detail—are eligible to participate in the Program and receive these discounts for prescription drugs.

18. The 340B statute exhaustively defines "covered entities." The statutory definition enumerates 15 categories of "covered entities" (*e.g.*, "A black lung clinic receiving funds under section 937(a) of title 30"), but not the specific eligible entities themselves (*e.g.*, the Philadelphia Black Lung Clinic). *See id.* § 256b(a)(4).

19. Consistent with the 340B Program's overriding goal of helping vulnerable and low-income patients acquire lower-cost access to life-saving medicines, the statute defines "covered entities" to include only organizations that naturally, and often predominantly, serve low-income individuals. For instance, Federally Qualified Health Centers, children's hospitals, rural hospitals, and other clinics serving vulnerable populations are all specifically defined as "covered entities"

eligible to enroll and participate in the 340B Program. *Id.*; *see also Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820 (D.C. Cir. 2020).

20. The statute further makes clear that entities ***not*** on the list—*e.g.*, for-profit hospitals, and commercial businesses such as "contract pharmacies" that profit off manufacturer discounts—are not entitled to receive medications from manufacturers at 340B discounted prices. 42 U.S.C. § 256b(a)(4).

21. Pursuant to the 340B statute and the terms of the PPA, HRSA publishes on its website a list of specific qualifying "covered entities," which it updates quarterly. *See* 42 U.S.C. § 256b(a)(9); PPA § III.(a). HRSA treats the quarterly list as definitive and binding on manufacturers. *See* 82 Fed. Reg. 1,210, 1,227 (Jan. 5, 2017).

22. Covered entities pay significantly discounted prices for "covered outpatient drugs," a category which includes most drugs used on an outpatient basis, according to a prescribed statutory formula. *See* 42 U.S.C. § 256b(a)(1), (a)(4), (b)(1). The 340B price is calculated by determining the difference between the manufacturer's Average Manufacturer Price and its Medicaid rebate amount, as determined under the Medicaid Drug Rebate Program statute, codified at Section 1927 of the Social Security Act. *Id.* § 256b(a)(1)-(2) & (b). The resulting prices, known as the 340B "ceiling prices," are significantly lower than what other purchasers would pay for the same product and can even be as low as one penny per pill or per milligram. Covered entities are then able to turn around and bill patients or insurers the drug's full price, pocketing the difference.

23. The 340B statute delegates oversight and enforcement responsibilities to HHS. In addition to requiring HHS to notify manufacturers of the identity of covered entities, *see id.* § 256b(a)(9), the statute authorizes HHS to monitor unlawful drug diversion by covered entities

and to audit covered entities and manufacturers, *see id.* § 256b(d)(1)(B)(vi). HHS has delegated 340B oversight and enforcement to HRSA, one of the defendants in this suit.

24. That authority empowers HRSA to evaluate manufacturer compliance with Program requirements, and it may impose civil monetary penalties ("CMPs") on manufacturers that knowingly and intentionally charge covered entities more than the statutory 340B ceiling price for covered outpatient drugs. In particular, HRSA may impose CMPs of more than $5,000 "for each instance of overcharging" a covered entity. 85 Fed. Reg. 2,869, 2,873 (Jan. 17, 2020); *see* 42 C.F.R. § 10.11(a); 42 U.S.C. § 256b(d)(1)(B)(vi).

25. In addition to limiting the universe of covered entities, Congress also prohibited covered entities from causing "duplicate discounts or rebates," which means they may not request both a 340B discount and a Medicaid rebate for the same drug. 42 U.S.C. § 256b(a)(5)(A).

26. And to help ensure that covered entities and others do not inappropriately benefit from the opportunity of 340B price arbitrage, Congress further forbade any "covered entity" from engaging in "diversion," *i.e.*, "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). In other words, covered entities may not transfer or sell the discounted drugs to any person or entity except their own patients. The 340B statute does not extend this diversion prohibition to manufacturers—thereby ensuring that if a covered entity lacks an in-house pharmacy through which it can dispense medicines itself, manufacturers may lawfully opt to deliver discounted product to a dispensing pharmacy of the covered entity's choosing (as Lilly has always done and continues, in a more limited fashion, to do still today).

27. There are two potential forms of diversion at play when covered entities use contract pharmacies. First, diversion occurs when the covered entities transfer or sell discounted

drugs to any person or entity except their own patients—*i.e.*, to the contract pharmacies. Second, diversion occurs when covered entities (or contract pharmacies) transfer or sell discounted drugs to patients who are not eligible to receive drugs at discounted prices pursuant to 340B. In other words, contract pharmacy arrangements, which instruct wholesalers to honor 340B prices to for-profit commercial pharmacies, may be (or at least result in) 340B discounted product being diverted—*i.e.*, "otherwise transfer[red]" to another person or entity in violation of the statute.

II. The 340B Statute Neither Requires Manufacturers To Offer Discounts To For-Profit Contract Pharmacies Nor Empowers HHS/HRSA To Impose Such A Requirement

28. The 340B statute contemplates that manufacturers will provide covered outpatient drugs at 340B discounted prices ***only*** to covered entities.

29. Nothing in the statute allows, let alone mandates, the use of contract pharmacies or that manufacturers respect an unlimited number of covered entity – contract pharmacy relationships. In fact, the opposite is true.

30. Section 340B's plain language limits a manufacturer's obligation to offer 340B prices to "each covered entity." 42 U.S.C. § 256b(a)(1); *see id.* (authorizing the HHS Secretary (and thus HRSA) to "require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price").

31. A contract pharmacy, however, is not a covered entity.

32. The 340B statute defines the term "covered entity" in exhaustive detail. In 42 U.S.C. § 256b(a)(4)—titled "'Covered entity' defined"—Congress defined the term as "an entity that meets the requirements described in paragraph (5)," which prohibits diversion and duplicate discounts, "and ***is*** one of the following":

> (A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act).

(B) An entity receiving a grant under section 256a of this title.

(C) A family planning project receiving a grant or contract under section 300 of this title.

(D) An entity receiving a grant under subpart II of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.

(F) A black lung clinic receiving funds under section 937(a) of title 30.

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act.

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act.

(J) Any entity receiving assistance under subchapter XXIV (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act that—

> (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this subchapter;
>
> (ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

> (iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.
>
> (M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.
>
> (N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).
>
> (O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.

33. The 340B statute thus lists 15 different types of entities that can qualify as "covered entities" for purposes of the 340B Program. Contract pharmacies do not make the list.

34. Furthermore, neither the 340B statute nor any other provision of law confers upon Defendants authority to require manufacturers to provide discounts to contract pharmacies through any exception process or carve out through a "safe harbor" for unlisted covered entities, or by claiming that contract pharmacies act as the "agents" of covered entities. That means Defendants have no such authority: As creatures of statute, agencies like HHS and HRSA have no valid power to act "unless and until Congress confers power upon [them]." *Wabash Valley Power Ass'n, Inc. v. Rural Electrification Admin.*, 988 F.2d 1480, 1486 (7th Cir. 1993) (quoting *La. Public Service Comm'n v. FCC*, 476 U.S. 355, 374 (1986)). Congress has not granted any such authority here.

35. Nor does the 340B statute permit Defendants to obligate manufacturers to offer discounts to contract pharmacies based on the theory that the latter are merely acting as "agents" of covered entities. To be sure, the statute contemplates that various entities that themselves are

not covered entities may effectively step in the shoes of a covered entity in certain, limited circumstances. *See, e.g.*, 42 U.S.C. § 256b(d)(3)(B)(vi) (referring separately to three types of agents, including "associations or organizations representing the interests of [ ] covered entities," rather than simply calling them "covered entities"); *id.* § 256b(d)(1)(B)(v) (same vis-à-vis "wholesalers"); *id*. § 256b(d)(2)(B)(iv) (same vis-à-vis "distributors"). But contract pharmacies are not among them. Contract pharmacies are obviously not wholesalers and distributors (they are retailers). And they are equally not "associations or organizations representing the interests of [ ] covered entities." That latter category encompasses trade associations and the like that lobby and litigate on behalf of covered entities and their interests; it does not include for-profit commercial enterprises that are publicly traded and that represent their own pecuniary interests above all else.

36. Nor did Congress delegate any discretionary or rulemaking authority to add to or subtract from the list of entities that manufacturers are required to treat as "covered entities" under the Program, or to impose a requirement that manufacturers offer 340B discounts to "associations or organizations representing the interests of [ ] covered entities" on pain of penalty. To the contrary, Congress specifically limited HRSA's authority to undertake rulemaking in the 340B Program to three specific areas: (1) the establishment of an administrative dispute resolution process; (2) the issuance of precisely defined standards of methodology for calculation of ceiling prices; and (3) the imposition of monetary civil sanctions, *see Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014) ("*Orphan Drug I*"), the latter of which is specifically and deliberately limited to instances of overcharging ***covered entities themselves***, not any agents thereof, *see* 42 U.S.C. § 256b(d)(1)(B)(vi)(II)-(III).

37. In short, HRSA has no authority to create exceptions to the statutory limitation that only the explicitly enumerated "covered entities" may receive 340B discounts. Only Congress

holds that power. Any agency determination to the contrary is in excess of its statutory authority and contrary to law. 5 U.S.C. § 706(2)(A); *see FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000) (An agency "may not exercise its authority in a manner that is inconsistent with the administrative structure that Congress enacted." (internal quotation marks omitted)).

III. Despite These Statutory Limitations, HRSA Issued Guidance Permitting The Use Of Contract Pharmacies In 1996 And Then Expanded That Permission In 2010, But Stopped Short Of Requiring Manufacturers To Offer Contract Pharmacies Discounts

38. Until 1996, covered entities purchased and dispensed 340B drugs exclusively through in-house pharmacies.

39. In 1996, HRSA issued guidance allowing "contract pharmacies"—typically large, commercial, for-profit entities—to sign agreements with covered entities to dispense covered outpatient drugs in connection with the 340B Program. 61 Fed. Reg. 43,549 (Aug. 23, 1996).

40. This initial allowance for contract pharmacies, which are not themselves covered entities, was narrow: Only covered entities without an in-house pharmacy could contract with contract pharmacies to dispense 340B drugs to the covered entity's patients—and even then, each covered entity could contract with just a single contract pharmacy.

41. The 1996 guidance made clear that HRSA itself recognized that it lacks authority to expand or contract the universe of covered entities. *See id.* at 43,550.

42. In issuing the 1996 guidance, moreover, HRSA intentionally chose not to follow the notice-and-comment requirements of the APA. *See* 5 U.S.C. § 553(b), (c). That was because, in HRSA's view, the guidance amounted merely to an interpretive rule that "create[d] no new law and create[d] no new rights or duties." 61 Fed. Reg. at 43,550. *Compare, e.g.*, *Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015) ("Interpretive rules do not have the force and effect of law and are not accorded that weight in the adjudicatory process." (internal quotation marks and citation omitted)), *with, e.g.*, *Metro. Sch. Dist. v. Davila*, 969 F.2d 485, 489 (7th Cir. 1992)

(legislative rules "create new law, rights, or duties," and must proceed through notice and comment).

43. In short, HRSA's 1996 allowance for contract pharmacies created no new obligations on manufacturers that do not arise from the statute itself, and it did not require (or even purport to require) manufacturers to deliver 340B discounted product to contract pharmacies; the guidance merely presents HRSA's view that it would not enforce against covered entities in the event they engaged contract pharmacies in limited and highly controlled situations.

44. The lay of the land from 1996 to 2010 was thus largely consonant with the Program's aims: In the ordinary course, only covered entities—which, again, uniformly are nonprofit healthcare providers that serve large numbers or proportions of vulnerable patients, not shareholders—could receive 340B discounted drugs from manufacturers. But if a covered entity lacked an in-house pharmacy, it could contract with one (but only one) nearby pharmacy to dispense 340B discounted drugs to its patients, near or far.

45. That all changed in 2010, when HRSA issued new guidance significantly expanding covered entities' ability to contract with outside, for-profit pharmacies. *See* 75 Fed. Reg. 10,272 (Mar. 5, 2010).

46. This 2010 guidance allows all covered entities, not just those without an in-house pharmacy, to contract with commercial pharmacies to dispense 340B discounted drugs. It further allows covered entities to enter into an unlimited number of such arrangements with an unlimited number of contract pharmacies—whether the pharmacy is across the street or across the country.

47. As in 1996, HRSA styled the 2010 guidance as an interpretive rule, did not go through the notice-and-comment procedures, and made clear that the guidance imposed no

obligations. *Id.* at 10,274; *see also id.* at 10,273 (2010 guidance "neither imposes additional burdens upon manufacturers, nor creates any new rights for covered entities under the law").

48. The 2010 guidance has radically altered—and undermined—the 340B Program. No longer is it a program designed to improve access to drugs among vulnerable patient populations; instead, the Program has become a massive profit engine for large businesses such as Walgreens, CVS, and other for-profit commercial enterprises.

49. In the first seven years following HRSA's relaxation of the rules, the GAO reported a 1,438% increase in the number of contract pharmacy arrangements, from 1,300 in 2010 to nearly 20,000 in 2017. 2018 GAO Report at 2. A more recent study reported an even greater, ***4,228%*** increase between 2010 and today. Vandervelde et al., *supra*, at 4. And according to HRSA's own figures, there are now tens of thousands of contract pharmacy locations across the country and more than 190,000 arrangements between contract pharmacies and covered entities. *See* HRSA, OPA 340B OPAIS, *340B Contract Pharmacy Database*, https://bit.ly/3nLdX3X (last visited May 25, 2021). That is a remarkable figure, particularly given that HRSA's online 340B Covered Entity Database lists only about 50,000 covered entity locations in the entire Program. *See id.*

Source: https://www.drugchannels.net/2019/07/walgreens-cvs-and-walmart-lead-25000.html.

50. Some covered entities use staggering numbers of contract pharmacies to dispense 340B Program drugs. In 2017, for example, the GAO reported that a single covered entity used as many as 439 distinct contract pharmacies—meaning each of those 439 pharmacies would seek

drugs from manufacturers at the 340B prices. 2018 GAO Report at 18. Covered entities also used contract pharmacies that were ***thousands of miles*** away. *Id*. at 22; *see also id.* at 23 n.38 ("The maximum distance across all covered entities was for a disproportionate share hospital located in Connecticut that contracted with a pharmacy in Hawaii.").

51. This dramatic expansion of the use of contract pharmacies cannot be explained by an increase in the number of covered entities; as of April 2020, the number of arrangements between contract pharmacies and covered entities far exceeds the number of covered entities eligible to receive 340B discounted product.[1] Instead, the "enormous growth in 340B contract pharmacy arrangements seems to boil down to a single factor: outsized profit margins" for pharmacies and covered entities. Vandervelde et al., *supra*, at 4; *see also* 2018 GAO Report at 23 n.38 (noting that the government's "340B database does not provide information on why a covered entity may choose to contract with a pharmacy that is located a long distance away").

IV. Contract Pharmacies Have Repeatedly And Consistently Abused The 340B Program

52. The massive expansion of the 340B Program since 2010 has created a number of program integrity concerns that neither HRSA nor Congress has addressed, despite persistent calls from drug manufacturers and other industry stakeholders.

A. Contract Pharmacies Are Not Required to Pass on 340B Discounted Prices to Patients—And they Rarely Do, Leaving Patients to Pay Full Price

53. In addition to transforming the 340B Program from a mechanism for increasing low-income Americans' access to medicines into one enriching for-profit pharmacies, the 2010 guidance has created profound program integrity concerns, enabling (and arguably encouraging) practices the 340B statute expressly prohibits—namely, drug diversion and duplicate discounts.

[1] Lilly respectfully requests that this Court take notice of the documents cited herein (*i.e.*, the government reports and published news sources), as their contents cannot reasonably be disputed and their accuracy can be readily determined. *See* Fed. R. Evid. 201.

See Vandervelde et al., *supra*, at 4 ("The 2010 guidance created an opportunity for sophisticated, for-profit pharmacy chains to realize larger margins than they otherwise could.").

54. For example, in the Medicare Part B context, government reports have found that covered entities typically paid between 20 and 50 percent below the average sales price for prescription drugs. *See, e.g.*, 85 Fed. Reg. 48,772, 48,886 (Aug. 12, 2020) (the "typical acquisition cost … under the [Medicare Hospital Outpatient Prospective Payment System] is … 34.7 percent" lower than the average sales price). Yet when they dispensed the drugs, they received the full reimbursement from Medicare. GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), https://bit.ly/3q3yG4p. In other words, covered entities with in-house pharmacies have generated considerable revenue via the 340B Program even without contract pharmacies.

55. That transfer of value from manufacturers to covered entities—all non-profit healthcare providers—is one thing. It is quite another for the government to force manufacturers to allow for-profit pharmacy chains like Walgreens and CVS to get in on the action. *See* 2018 GAO Report at 20 (75% of 340B contract pharmacies are commercial chain pharmacies). The five biggest retail chains (including, *e.g.*, CVS and Walgreens) together represent 60% of 340B contract pharmacies, but only 35% of pharmacies nationwide. *Id.* at 21.

56. Yet, under the current model, that is precisely what is happening. Like covered entities, contract pharmacies pay significantly discounted prices, known as ceiling prices, on outpatient drugs when they act on covered entities' behalf. Contract pharmacies are also permitted to—and typically do—bill the patient's third-party insurer or otherwise charge the patient out of pocket, thereby generating profits from the substantial difference between the low acquisition price mandated by the 340B statute and the higher reimbursement value of the drug. The covered entity

then pockets this "spread" and typically pays the contract pharmacy either a pre-negotiated fee or a share of the spread for each covered outpatient drug dispensed.

57. What that means in practice is simple, but pernicious: Contract pharmacies can use covered entities to secure huge discounts on pharmaceuticals, but then turn around and charge patients full price, and kick back some part of the difference to the covered entity—capturing a nontrivial portion of the discounts intended to benefit vulnerable patient populations in the process.

58. Under the current model, contract pharmacies therefore may purchase prescription drugs at these same steep discounts from the manufacturer list prices (in some cases, as low as one penny), but then turn around and sell them for the full list price. *See* 85 Fed. Reg. at 48,888.

59. Contract pharmacies unsurprisingly have profited greatly from this arrangement. "The average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent, compared with just 22 percent for non-340B medicines dispensed through independent pharmacies." Vandervelde et al., *supra*, at 3; *see also* Raymond James, *340B Pharmacy Follow Up—Less Than $1.4B but Still Yuge*, at 1 (Sept. 9, 2020) (Walgreens generated profits "in the hundreds of millions" through 340B contract pharmacy arrangements). A recent industry analysis found that covered entities and their contract pharmacies generated ***more than $13 billion in estimated profits*** from 340B purchased medicines in 2018 alone. Vandervelde et al., *supra*, at 7. While the 340B Program was "originally intended to provide healthcare services to indigent populations," "more than half of all profits realized by the 27,000 340B contract pharmacies participating in the 340B [P]rogram today are concentrated in just four companies," all of which are for-profit entities that are under no obligation to—and typically do not—pass on any portion of the discounts they receive to the patients the 340B Program is designed to help. *Id.*

60. Despite the 340B Program's objective of providing affordable drugs to underserved patients, contract pharmacies are not even required to "pass along" to patients the spread between the discounted acquisition prices from manufacturers and the reimbursement paid by an insurer (or the price charged to the uninsured patient). Nor are there any restrictions or reporting requirements related to how or even if the contract pharmacy redirects this 340B savings to benefit low-income or underserved patients in other ways. In other words, any entity obtaining 340B discounts—including a contract pharmacy—may decide to keep the full savings without ever passing the discounts along to any patient it serves. Without any reporting requirements to HRSA or otherwise, contract pharmacies can freely direct fungible money generated from the 340B Program savings to any cause without accountability, including their own bottom line.

61. These are not hypothetical concerns. Government reports show that "large numbers of low-income patients" that Congress intended to benefit from the 340B Program do not receive the substantial discounts on drugs dispensed through contract pharmacies. H.R. Rep. No. 102-384, at 10. For example, in response to a 2018 GAO survey, 45 percent of covered entities admitted they do not pass along ***any*** discount to ***any*** patients that use ***any*** of their contract pharmacies. 2018 GAO Report at 30. Nor is there reason to believe the remaining 55 percent does. The GAO specifically noted that the remaining surveyed entities using contract pharmacies may only provide discounts to patients in limited cases. *Id.* By contrast, it noted that 17 of 23 covered entities that used in-house pharmacies—instead of contract pharmacies—reported offering discounts to their patients. *Id.*

62. Add it all up, and a program designed to benefit needy American patients has become a mechanism for multiplying large, for-profit pharmacy chains' profit margins while exposing manufacturers to greater risk of duplicate discounts, diversion and potential penalties.

For instead of reinvesting the profits they generate from the 340B Program to expand access to affordable prescription drugs, contract pharmacies simply pocket the money.

63. Many businesses are not even trying to hide what they are doing; some covered entities contract with hundreds of different commercial pharmacies that are located up to 5,000 miles away. Such faraway contract pharmacies rarely, if ever, actually dispense discounted drugs to needy patients; they simply engage in arbitrage, as they are under no obligation to pass on discounts to patients. It is little wonder, then, that a recent *New England Journal of Medicine* study found that covered entities' "[f]inancial gains" under the 340B Program post-2010 "have not been associated with clear evidence of expanded care or lower mortality among low-income patients." Sunita Desai & J. Michael McWilliams, *Consequences of the 340B Drug Pricing Program*, 378 N. ENGL. J. MED. 539, 539 (Feb. 8, 2018); *see also* 2018 GAO Report at 10.

64. Even members of Congress have elevated concerns about for-profit, retail pharmacy chains taking advantage of the 340B Program to turn enormous profits. In July 2013, for example, U.S. Senator Chuck Grassley sent a letter to Walgreens CEO Gregory Wasson detailing concerns about Walgreens' 5,400 contract pharmacy locations and demanding information such as a "summary of all profits generated as a result of participating in the 340B [P]rogram as a contract pharmacy." *See* Ltr. from U.S. Sen. C. Grassley to G. Wasson (July 31, 2013), https://bit.ly/3rFSE6N. The letter reported that Walgreens employees projected dispensing 340B discounted drugs through Walgreens contract pharmacies would "add a ***minimum of $250 million***" in revenue over a 5-year period. *Id.* (emphasis added).

65. Those projections were accurate—if anything, they understated the amount the pharmacies stood to make. A September 2020 analysis by an investment bank confirmed that Walgreens had generated profits through 340B contract pharmacy arrangements "***in the hundreds***

of millions." *See* Raymond James, *supra* (emphasis added). This is why Walgreens' October 15, 2020 10-K regulatory filing reported that any pricing changes "in connection with the federal 340B drug pricing program[] could ***significantly reduce our profitability***." *See* Walgreens Boots Alliance, Inc., Form 10-K, at 23 (Oct. 15, 2020), https://bit.ly/2MoLX9d (emphasis added).

66. Uninsured patients also suffer from this contract pharmacy abuse. The HHS Office of Inspector General ("OIG") found that many contract pharmacies do not offer 340B discounted prices to uninsured patients. HHS-OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, at 2 (Feb. 2014), https://bit.ly/2LwZrzl. As a result, "uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies." *Id.*; *see also* Desai & McWilliams, *supra*, at 539 (340B-related "[f]inancial gains" post-2010 "have not been associated with clear evidence of expanded care or lower mortality among low-income patients.").

B. Contract Pharmacy Arrangements Flout the 340B Statute's Explicit Prohibitions on Diversion and Duplicate Discounts

67. In addition to capturing as profits the price savings intended to benefit patients in need for price assistance on life-saving prescription medicines, contract pharmacy arrangements have also led to diversion and duplicate discounts. As described above, contract pharmacy arrangements arguably constitute diversion *per se*. But even if the transfer of discounted drugs from a covered entity to a contract pharmacy (*i.e.*, an entity that is not the covered entity's own patients) is not diversion *per se*, contract pharmacy arrangements increase the incidence of a second and no less troublesome form of diversion in all events. Contract pharmacies fill prescriptions for both 340B and non-340B patients, and many contract pharmacies do not determine eligibility until weeks after the patient receives her prescription, meaning contract

pharmacies can improperly claim discounts for ineligible patients. In other words, they claim 340B discount prices for drugs provided to patients not eligible under the 340B Program.

68. Since 2010, government agency reports have disclosed shocking numbers of 340B violations by contract pharmacies, including violations of the prohibition on drug diversion to ineligible patients and the prohibition on "duplicate discounts"—*i.e.*, where the entity buying the drug from the manufacturer makes the manufacturer pay both a 340B discount and a Medicaid rebate on the same utilization, *see* 42 U.S.C. § 256b(a)(5)(A). *See, e.g.*, GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, But Federal Oversight Needs Improvement*, GAO-11-836 ("2011 GAO Report"), at 28 (Sept. 2011) ("Operating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in house pharmacies."), https://bit.ly/2JvWKgJ.

69. In 2018, as the number of contract pharmacies burgeoned without any government oversight, the HHS OIG acknowledged before Congress that it had "identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements." HHS OIG Testimony, *Examining Oversight Reports on the 340B Drug Pricing Program, Testimony of Ann Maxwell, Assistant Inspector Gen. for Evaluation and Inspections, OIG Before the U.S. S. Comm. on Health, Educ., Labor, and Pensions*, at 5 (May 15, 2018), https://bit.ly/3lCv4Uj. That same HHS OIG testimony revealed that certain contract pharmacies unlawfully diverted drugs through their uncontrolled inventory management practices: "many contract pharmacies dispense drugs to all of ***their*** customers—340B-eligible or otherwise—from ***their regular inventory***." *Id*. at 6 (emphases added).

70. Another GAO report found that two-thirds of 340B diversion violations uncovered in HRSA audits "involved drugs distributed at contract pharmacies." 2018 GAO Report at 44.

71. Publicly available HRSA audits underscore pervasive compliance issues involving contract pharmacies. HRSA audits routinely uncover dozens of instances of unlawful 340B drug diversions, despite HRSA auditing fewer than 200 entities per year:

Fiscal Year	Entity Audits	Entities with Contract Pharmacy Adverse Findings (All)	Entities with Contract Pharmacy Adverse Findings (Diversion)
2013	94	32	21
2014	99	51	38
2015	201	92	64
2016	200	81	68
2017	199	83	63
2018	200	63	43
2019	199	30	20

Source: HRSA, *340B Program Integrity, Audits of Covered Entity Results* (Apr. 2020), https://bit.ly/38MxknH.

C. The Government Has Utterly Failed to Rectify These Abuses

72. These marked shifts away from the 340B Program's intended goals come as no surprise to industry players, who vociferously objected to HRSA's 2010 expansion.

73. When HRSA issued the 2010 guidance that allowed covered entities to enter into an unlimited number of contract pharmacy arrangements, industry stakeholders expressed concern that the guidance expanding distribution to an unlimited number of contract pharmacies—entities never mentioned in the statute—was unlawful and unauthorized under the 340B statute.

74. Stakeholders also expressed concern that expanding the Program to allow covered entities to enter into an unlimited number of arrangements with commercial contract pharmacies would cause program integrity issues, increasing the risk of the already-widespread noncompliance with the statute's requirements for covered entities and prohibitions on drug diversion and duplicate discounts, and that the financial incentives related to participating in the

340B Program, coupled with HRSA's proposal to permit unlimited contract pharmacy relationships, would inevitably cause for-profit contract pharmacies to dominate the Program. As one commenter put it, HRSA's "guidelines do not adequately describe safeguards that will combat drug diversion and duplicate discounts." 75 Fed. Reg. at 10,273.

75. The government was, and remains, well aware of the abuses the contract pharmacy model has precipitated. *See, e.g.*, *id.* (noting but waiving away such concerns); Exhibit ("Exh.") A (Ltr. from Reps. Larry Bucshon, M.D., & Brad Wenstrup, D.P.M., to The Honorable Alex M. Azar, II (Oct. 15, 2020)) ("We have received reports that covered entities and/or their contract pharmacies are able to charge uninsured and potentially under-insured individuals mark-ups on prescriptions [sic] drugs" and "that patients in the 340B program, including the uninsured, can—and often do—bill cash-paying patients the 'usual and customary' pharmacy price plus a dispensing fee."); *see also, e.g.*, 2018 GAO Report at 44 (approximately two-thirds of diversion "involved drugs distributed at contract pharmacies"); HHS OIG Testimony, *supra*, at 5 (OIG "identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements"); H. Energy & Commerce Committee, *Review of the 340B Drug Pricing Program*, at 75 (Jan. 20, 2018) (HRSA's guidance "has led to concerns about whether the money is truly devoted to improving patient care"), https://bit.ly/3pyqNUk; 2011 GAO Report at 28 (contract pharmacy model "creates more opportunities for drug diversion compared to in-house pharmacies").

76. Yet HRSA and HHS have completely ignored these realities—and the text of the 340B statute—for a decade now, thus allowing for-profit pharmacy chains to come to represent a disproportionate share of this contract pharmacy expansion. *See* 2018 GAO Report at 21; *see also* GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*,

GAO-21-107 ("2020 GAO Report"), at 15-16 (Dec. 2020) (noting that HRSA stopped auditing contract pharmacies "because the 340B statute does not address contract pharmacy use" and thus provides no standard against which to audit contract pharmacies' abuses), https://bit.ly/3hfFVD8.

V. Lilly Introduced Distribution Plans Designed To Curb Contract Pharmacy Abuses Consistent With The 340B Statute

77. Against this backdrop, Lilly introduced a new distribution program that complies with the 340B statute's text and purpose and would curb the abuses the 2010 guidance unleashed.

78. Effective July 1, 2020, Lilly instructed its wholesalers to provide 340B discounts exclusively to covered entities and their child sites—and not to contract pharmacies—for certain formulations of Cialis® (tadalafil). Lilly limited its July 2020 plan to those Cialis® products indicated for erectile dysfunction and for which a generic formulation was available. The Cialis® distribution plan included an exception for covered entities that do not have an in-house pharmacy, permitting them to designate one contract pharmacy location as eligible to receive 340B discounts.

79. In August 2020, after rolling out the transition for Cialis® products, Lilly extended its distribution plan to all of Lilly's covered outpatient drugs under the 340B Program.

80. Reflecting Lilly's commitment to the original goal of the Program, however, Lilly is continuing to allow covered entities that lack an in-house pharmacy to designate a single contract pharmacy at which 340B medicines may be dispensed, and Lilly also allows contract pharmacies that are wholly owned by a covered entity to access 340B-priced product. Lilly also recently began to allow covered entities with an in-house pharmacy that does not dispense retail products to designate a single retail contract pharmacy. As these accommodations make clear, Lilly fully intends to continue to work flexibly with all stakeholders to refine its distribution plan as needed.

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

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

83. The Executive Order echoes key concerns that many stakeholders, including government entities and officials, have expressed about the 340B Program—namely, that "one penny per unit … steep [340B] discounts … are not always passed through to low-income Americans at the point of sale," and that "[t]hose with low-incomes can be exposed to high insulin and injectable epinephrine prices, as they often do not benefit from discounts negotiated by insurers or the Federal or State governments." Exec. Order No. 13,937, 85 Fed. Reg. 45,755 (July 29, 2020) (ordering HHS to ensure that future grants available to Federally Qualified Health Centers, one type of 340B covered entity, be conditioned on making insulin and injectable epinephrine available to patients at the 340B-discounted price). In other words, contract pharmacies failed to pass along 340B discounts even though they purchased insulin products at ***one penny*** per milliliter.

84. These voluntary measures by Lilly are consistent with other patient-focused programs Lilly has initiated to help patients reduce out-of-pocket expenses, particularly uninsured patients, senior citizens covered by Medicare Part D, and patients with high-deductible plans.

85. For instance, Lilly provides automatic discounts at retail pharmacies to any patient with commercial insurance, capping monthly insulin costs at $95. Lilly also distributes three non-branded insulins with a list price 50 percent lower than brand name alternatives and donates insulin for distribution at free clinics for qualifying patients with demonstrated financial need. In 2019, Lilly's insulin affordability solutions helped up to 20,000 patients per month, decreasing patients' out-of-pocket spending by 65 percent on average. And Lilly expanded its patient affordability options for insulin last year to respond to the financial consequences of COVID-19, announcing in April 2020 that both uninsured and commercial-insurance patients can purchase a prescription of certain Lilly insulin products for $35 a month through the Lilly Insulin Value Program. Lilly also recently began participating in the CMS Innovation Center's Medicare Part D insulin cost sharing program, making affordable insulin available for patients covered by Medicare Part D.

86. Early in the pandemic, Lilly developed, at its own expense, a highly accurate COVID-19 test that it administered for free to front-line healthcare workers and first responders in Indiana. Lilly has also devised and made available ventilator splitters that allowed ventilators to serve two patients at once. In addition, Lilly has invested hundreds of millions of dollars developing COVID-19 treatments—including two monoclonal antibody treatments already in human trials and two other molecules to treat COVID-19-induced acute respiratory distress syndrome—and recently received emergency use authorization for two COVID-19 treatments.

87. Lilly also donates substantial sums to the Lilly Cares program, an independent 501(c)(3) that provides up to a one-year supply of Lilly medications for free to low-income patients with no insurance, Medicare Part D, and in some instances commercial insurance.

VI. HRSA First Approves Lilly's Distribution Plan, But Then—After Telling The Public It Lacks Authority To Do So—Threatens Sanctions In Response To Lilly's Attempt To Comply With Section 340B And To Halt Contract Pharmacy Diversion

A. HRSA Repeatedly Confirms that the 1996 and 2010 Contract Pharmacy Guidance Are "Not Legally Enforceable"

88. Lilly was transparent with the government about its distribution plans, informing the government of both the initial Cialis® plan and the later expanded plan.

89. Lilly first notified HRSA in May 2020 that it intended to implement the Cialis® distribution plan effective July 1, 2020. *See* Exh. B. Lilly explained to HRSA that it did "not believe 340B-priced purchases for contract pharmacies are consistent with or required by" the 340B statute, and it accordingly would "no longer honor contract pharmacy-related requests" for the three Cialis® formulations "[u]nless HRSA objects and states that it believes [Lilly's] proposed discontinuation of voluntary contract pharmacy 340B discounts is unlawful, providing [Lilly] the reasons for its conclusions." *Id.* at 1-2.

90. HRSA responded on June 11, 2020, that "contract pharmacies" "are not independent covered entities" and that its "contract pharmacy advice" was "guidance" and "not binding regulations." Exh. C at 1-2. To be clear: HRSA did not state that Lilly's Cialis® distribution plan was unlawful or identify any statutory provision that it violated.

91. Lilly followed up with HRSA on June 16, 2020, thanking HRSA for "confirming" that the agency's contract pharmacy guidance "does not impose binding obligations on manufacturers" requiring them to offer 340B discounts to contract pharmacies. Exh. D at 2-3. Lilly also pointed out that, in HRSA's June 11 response, the agency "did not say that [Lilly is] prohibited from moving forward" or "that [Lilly's] proposed action would, in fact, violate the statute." Lilly thus asked HRSA to correct any misinterpretation by Lilly on that score. *Id.* at 2.

92. HRSA responded to Lilly on June 18, 2020. Far from stating that Lilly had misunderstood HRSA's position, HRSA confirmed that it "look[ed] forward to receiving" Lilly's manufacturer notice announcing its Cialis® distribution plan for posting on the HRSA website. *Id.* at 1-2. For the second time, HRSA failed to identify any statutory provision that Lilly's distribution plan violated and did not assert that the distribution plan was in any way unlawful.

93. On June 26, 2020, Lilly provided the published notice relating to its Cialis distribution plan, and again invited HRSA to raise any questions or concerns that it might have. *See id.* at 1. HRSA responded on June 29, 2020, stating that it did not have any further questions at this time; HRSA then posted Lilly's notice to covered entities on its 340B Program website on July 1, 2020, without objection. *See* HRSA, *Manufacturer Notices to Covered Entities* (July 2020) (linking to *Limited Distribution Plan Notice for Cialis® (tadalafil) Erectile Dysfunction NDCs*, https://bit.ly/3n3DaWS), https://bit.ly/3hzDOua.

94. Days later, a 340B-focused publication, the *340B Report*, published an article quoting HRSA's reaction to Lilly's Cialis® distribution program and confirming that its 2010 Contract Pharmacy Guidance was non-binding, this time describing it as "not legally enforceable":

> The 2010 guidance is still in effect. However, guidance is not legally enforceable. Regarding the 340B Program's guidance documents, HRSA's current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute.

Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020), https://bit.ly/2X0I1xe. And far from asserting that Lilly's conduct was unlawful, the article stated that "[i]t appears now that HHS and HRSA have concluded that Lilly cannot be compelled to provide 340B discounts on drugs dispensed by contract pharmacies." *Id.* Lilly came to the same conclusion based on its communications with the agency.

95. Thereafter, on July 16, 2020, 340B Coalition (a trade association for 340B hospitals) and certain other 340B covered entity stakeholders wrote to Defendant Azar, asking him to declare that Lilly's Cialis® distribution program violated the 340B statute—specifically, that it violated the requirement that manufacturers "offer ***each covered entity***" no more than the ceiling price for all "covered outpatient drugs." *See* 42 U.S.C. § 256b(a)(1) (emphasis added).

96. In response to that intervention, Lilly sent a letter to Defendant HHS the next day, describing its communications with HRSA and explaining why Lilly's distribution plan complies with the 340B statute. Exh. E. HHS did not respond to Lilly for over two months (as discussed below), and even then, never stated that Lilly's distribution plan would violate the 340B statute.

B. HRSA and HHS Suddenly Change Course, Threatening Lilly with Sanctions

97. On August 19, 2020, with the transition for the Cialis® products underway, Lilly informed HRSA that it would extend its new distribution plan to include all of Lilly's covered outpatient drugs under the 340B Program (*i.e.*, not just Cialis), by "discontinu[ing] [its] practice of voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products." Lilly explained that HRSA had already confirmed that the 2010 Contract Pharmacy guidance was non-binding when discussing the plan for Cialis® and "the legal analyses performed previously by HRSA and Lilly apply equally here." Exh. F at 1. And as with its Cialis® program, Lilly provided HRSA an opportunity to object to Lilly's plan and, if it did, to explain its reasoning by August 31, 2020. *See id.* Lilly also provided HRSA with an updated Limited Distribution Plan Notice for posting on the agency's manufacturer notices website on September 1, 2020, the effective date of Lilly's new distribution plan. *See* Exh. G.

98. On August 26, 2020, HRSA sent Lilly a letter (Exh. H) purporting to respond not only to Lilly's August 19 expansion letter, but also to the original Cialis® program letter dated

May 18, 2020—even though correspondence for that initial program had ended more than a month earlier with HRSA stating that the agency did not have any further questions, *see* Exhs. A, B.

99. Although HRSA and HHS had previously declined to state that Lilly's conduct was unlawful despite at least four opportunities to do so, HRSA threatened that Lilly could be subject to sanctions if it followed through with its expanded distribution plan. Specifically, in its August 26 response to Lilly, HRSA stated that it was "considering whether your new proposed policy constitutes a violation of section 340B and whether sanctions apply," including, but "not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." Exh. H at 1.

100. Given the significance of HRSA's threat, which carried the prospect of subjecting Lilly to CMPs—not to mention the potential revocation of Lilly's PPA and thus ability to participate in and receive reimbursements pursuant to Medicare Part B and Medicaid—Lilly responded to HRSA the next day (August 27, 2020). *See* Exh. I. In its August 27 letter, Lilly reiterated its position that its distribution program was entirely lawful under the plain text and original understanding of the 340B statute. *See id.* at 1. Lilly also highlighted the imminent harm resulting from HRSA's "threats of sanctions," which were transparently designed to force Lilly to acquiesce to HRSA's position. *Id.* Lilly accordingly requested that HRSA "confirm by August 31st that nothing in the 340B Statute prohibits the Cialis Limited Distribution Plan or an expansion of that plan," and that if HRSA believed there was a "violation of the statute, [to] please identify with specificity the agency's grounds for that position." *Id.*

101. HRSA neither responded nor posted Lilly's updated notice on its website. Instead, on September 2, 2020, it released a new public statement to the *340B Report* reiterating its threat. HRSA stated to the *340B Report* that it was "considering whether manufacturer policies, ***including Lilly's***, violate the 340B statute and whether sanctions may apply." Bronwyn Mixter, *HRSA is*

Investigating Whether Manufacturer Policies to Restrict 340B Pricing at Contract Pharmacies Violates Statute, 340B Report (Sept. 2, 2020) (emphasis added), https://bit.ly/3aWgZPT.

102. In light of these threats, Lilly reached out to HHS on September 8, 2020, seeking "confirmation that HHS is not considering, and will not consider, sanctions against Lilly in response to Lilly's stated plan to discontinue providing 340B discounts to contract pharmacies." Exh. J at 1; *see also id.* at 1-5.

103. HHS responded nearly two weeks later on September 21, 2020. *See* Exh. K. HHS did not state that Lilly's distribution plan was unlawful. *See id.* Nor did it identify a single statutory provision that the plan violates. *See id.* Nevertheless, HHS declined to state that neither HRSA nor HHS was considering sanctions against Lilly. *See id.* And rather than defusing HRSA's threats of sanctions against Lilly, HHS issued a threat of its own, telling Lilly to "bear in mind" that a private "qui tam False Claims Act" action (which carries the potential of huge damages) is a "potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors." *Id.* at 2.

104. HHS immediately posted this threat on its public website. *See* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf (last visited May 25, 2021). After that public posting, many covered entities reached out to Lilly to demand that Lilly reverse its distribution plan and offer full 340B discounts to all contract pharmacies. HRSA still did not post Lilly's updated manufacturer notice on its 340B website.

105. On December 9, 2020, HRSA sent a letter to the CEO of 340B Health, a group that represents covered entities, regarding the modified distribution programs of Lilly and other manufacturers, stating that it was "continuing to review the various proposals and whether these actions by manufacturers violate the 340B statute and whether sanctions may apply." Exh. L at 1.

HRSA added that it was "working closely with each impacted covered entity," "actively investigating the matter in order to make a final determination as to any potential action." *Id.* at 2. HRSA still did not post Lilly's updated notice on its 340B website (and has not to this day).

106. In early- and mid-December 2020, the GAO reported that HRSA acknowledged that "the 340B statute does not address contract pharmacy use," 2020 GAO Report at 16, and counsel for HHS and HRSA described movements to compel "participation through contract pharmacies" as improper attempts to foist "wholesale changes to an agency program" on the government, *see* Defs.' Mot. to Dismiss for Lack of Jurisdiction 19-20, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Dec. 14, 2020), Dkt. 41.

VII. HRSA Issues A Final Decision Concluding, Contrary To The Text And Purpose Of The Statute, That Manufacturers Must Offer 340B Discounts To An Unlimited Number Of Contract Pharmacies Whenever Covered Entities Ask

107. On December 30, 2020, Defendants resolved any doubt about their position on the issue. They did so by issuing a decision making clear that they now (incorrectly) "conclude" that "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****"* whenever a contract pharmacy acts as a covered entity's "agent." December 30 Decision at 1 (emphasis added); *see also HHS Releases Advisory Opinion Clarifying that 340B Discounts Apply to Contract Pharmacies* (Dec. 30, 2020) (noting that HHS "has clarified that drug manufacturers must provide 340B discounts when a contract pharmacy is acting as an agent of a covered entity, providing services on behalf of the covered entity"), https://bit.ly/38Qh0lB.

108. In issuing that decision, Defendants acknowledged that they are not "authorized to add requirements to the [340B statute]." December 30 Decision at 2.

109. Defendants further recognized that "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***." *Id.* at 2 (emphasis added). (Recall that Lilly in fact is continuing to offer all covered outpatient drugs to covered entities at or below the ceiling price, and has always done so.)

110. Defendants nonetheless "conclude[d]"—for the first time, and in contrast to every other pronouncement HRSA and HHS had previously made on the subject—that "the plain text of the statute" ***requires*** manufacturers participating in the 340B Program to offer discounts to contract pharmacies whenever a covered entity is the one that placed the order for the drugs. *Id.* at 3.

111. Defendants' cursory textual analysis began from the "understand[ing]" that the 340B Program functions as follows in practice: "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." *Id.*

112. Defendants then concluded that, under the 340B statute, "[t]he situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant" to the statutory obligation to charge no more than the ceiling price. *Id.*

113. That was the sum-total of Defendants' textual analysis. Defendants did not address the fact that Congress exhaustively enumerated 15 types of entities as "covered entities" and specifically limited that class to non-profit healthcare providers, or that the 340B statute authorizes HHS and HRSA to impose CMPs for "each instance" that a manufacturer "knowingly and intentionally" overcharges "a covered entity," 42 U.S.C. § 256b(d)(1)(B)(vi)(II)-(III), ***not*** "a covered entity or its non-in-house pharmacy" or "a covered entity and its contract pharmacy." And they likewise nowhere reconciled their conclusion with the fact that the statute unambiguously distinguishes between "covered entities" and agents—*i.e.*, "associations or organizations representing the interests of [] covered entities," "wholesalers," and "distributors." *See id.*

§ 256b(d)(1)(B)(v), (2)(B)(iii), (3)(B)(vi). Nor did they reconcile this novel interpretation, which ***requires*** manufacturers to offer 340B discounts to an unlimited number of contract pharmacies, with the position they had taken for approximately fifteen years (and had reiterated mere months before) that the guidance allegedly creating this "obligation" is "legally unenforceable."

114. Nor did Defendants acknowledge, let alone defend against, the severe constitutional concerns raised by a requirement that one set of private parties (manufacturers) offer another set of for-profit private parties (contract pharmacies) massive discounts on pain of having their ability to participate in and be reimbursed under Medicare Part B and Medicaid. *See Kelo v. City of New London*, 545 U.S. 469, 477 (2005) ("[I]t has long been accepted that the sovereign may not take the property of A for the sole purpose of transferring it to another private party B.").

115. Instead of tackling any of these arguments head-on, Defendants simply waived them away as bad-faith "attempt[s] to circumvent section 340B's procedures for resolving disputes between manufacturers and covered entities." December 30 Decision at 5.

116. Defendants spent the majority of the Decision rejecting "[t]he argument that [because] the statute also evinces a purpose to prevent drug diversion or duplicate discounting, [it] therefore prohibits contract-pharmacy arrangements." *Id.* at 3 n.2; *see id.* at 4-7. Notably, however, Defendants did not dispute that contract pharmacy arrangements have multiplied the incidence of diversion and duplicate discounting exponentially. Nor could they: Defendants had previously recognized that fact many times. *See, e.g.*, Kenneth Yood, *Maneuvers on the 340B Drug Pricing Program Battlefield: Duplicate Discounts and Contract Pharmacies*, Healthcare Law Blog (Sept. 29, 2020) ("In a 2011 GAO report, … the GAO concluded that the 'increased use of the 340B program by contract pharmacies and hospitals may result in greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants self-policing to

oversee the program'"; and "[i]n a 2014 OIG report, … the OIG found that contract pharmacies create 'complications' in preventing diversion and duplicate discounts."), https://bit.ly/3bsQ0fh.

117. Defendants made no mention of the fact that their decision to mandate that manufacturers provide an unlimited number of contract pharmacies with 340B-priced drugs forces manufacturers like Lilly either to transfer their property, in the form of the prescription medicines they manufacture, to for-profit entities at a devastating financial loss, or to choose not to and suffer the economic equivalent of the death penalty by losing their ability to participate in and be reimbursed under critical federal healthcare programs. *See Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 606 (2013) ("Our precedents … forbid[] the government from engaging in 'out-and-out … extortion' that would thwart the Fifth Amendment" by coercing individuals into relinquishing their property without proper "just compensation." (third alteration in original) (quoting *Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 837 (1987))).

118. Nor did Defendants refute that the two mechanisms contract pharmacies use in capturing 340B discounts intended only for covered entities both necessarily effect a prohibited diversion of 340B-discounted drugs to the contract pharmacy. In fact, the Decision does not mention this concern at all, instead brushing it aside via a reductive purpose analysis that cannot be squared either with the text of the statute or with the reality of how the Program operates. But these diversions mechanisms that Defendants ignored illustrate how the contract pharmacy system is ripe for abuse. First, under the "retroactive replenishment" model, contract pharmacies do not segregate 340B inventory from non-340B inventory; rather, they have ***their own stock*** of inventory, purport to track dispensed prescriptions to the patients of 340B covered entities with which they have contracts, and then supposedly ***retroactively*** seek to "replenish" product at 340B pricing. For those prescriptions, they secure—through an entirely retrospective process—

replacement product at 340B pricing when the covered entity places an order with instructions to ship directly to the contract pharmacy. *See* Alliance for Integrity and Reform of 340B, *The Impact of Growth in 340B Contract Pharmacy Arrangements*, at 1 (July 2014) ("data indicates that neither the pharmacy nor the patient know that the transaction is '340B' at the point of sale"), https://bit.ly/3mRQ4YR; Nat'l Council for Prescription Drug Programs, *340 Information Exchange Reference Guide*, at 8-9 (June 2019), https://bit.ly/2JJVtCY. The 340B product, once transferred to a contract pharmacy, is then sold by the contract pharmacy in its own name to its own patients. Second, under the "physical inventory" system, the product is transferred directly from the wholesaler to the contract pharmacy, the latter of which sells it to a customer who appears at its counter. Under this model, the covered entity never takes possession of the product. Because both models entail the use of a "ship-to/bill-to" arrangement where covered entities purchase 340B drugs with instructions to ship directly to the contract pharmacy, an action to mandate that manufacturers honor requests for 340B discounts for contract pharmacy transactions would result in statutorily prohibited diversion of 340B-discounted product to independent commercial actors that are not covered entities or patients of covered entities, in violation of the 340B statute.

VIII. The Congressional Mandate, Demise, and Sudden Resurrection of the ADR Rule

A. Congress Amends the 340B Statute to Require Defendants to Establish an ADR Procedure within 180 Days

119. Congress amended the 340B statute in March 2010 as part of the Patient Protection and Affordable Care Act ("ACA"), Pub. L. No. 111-148, § 7102(a), 124 Stat. 119 (2010).

120. Most relevant here, the ACA amendments required Defendant HHS to promulgate regulations establishing an ADR process for resolving 340B price disputes between covered entities and manufacturers. *See id.*, 124 Stat. at 826-27 (codified at 42 U.S.C. § 256b(d)(3)).

121. The ADR regulations were to be promulgated within 180 days of enactment:

> Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions.

Id.

122. The ACA amendments further instructed that these "[r]egulations promulgated by the Secretary" must "designate or establish a decision-making official or body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered outpatient drugs in excess of the ceiling price … and claims by manufacturers that violations of [statutory prohibitions on conduct like diversion] have occurred." *Id.* (codified at 42 U.S.C. § 256b(d)(3)(B)(i)).

123. The statute further directed that "[t]he administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.*, 124 Stat. at 827 (codified at 42 U.S.C. § 256b(d)(3)(C)).

124. The statute does not explicitly authorize any official of the Executive Branch to review, overturn, or modify the judgment of an ADR panel.

B. HHS Belatedly Proposes, then Withdraws, the ADR Rule

125. Congress's 180-day deadline came and went. It was not until August 12, 2016—nearly six years after the ACA's enactment—that Defendants issued a Notice of Proposed Rulemaking ("NPRM") suggesting ADR procedures. *See* 81 Fed. Reg. 53,381-01 (Aug. 12, 2016).

126. That NPRM proposed to resolve ADR claims through three-member panels "chosen from a roster of eligible individuals alternating from claim to claim, and one ex-officio, non-voting member chosen from the staff of [HHS's Office of Pharmacy Affairs]." *Id.* at 53,382. Panel members would be "Federal employees (e.g., employees of [the Centers for Medicare & Medicaid Services, or CMS] or the U.S. Department of Veterans Affairs) with demonstrated expertise or familiarity with the 340B Program." *Id.*

127. Importantly, ADR panelists would be appointed by the HHS Secretary, and could only be removed from an ADR panel "for cause." *Id.* The only "for cause" removal scenario contemplated by the notice, moreover, was a conflict of interest. *Id.*

128. The NPRM proposed specific procedures for the adjudication of disputes brought before the ADR panels and suggested that covered entities and manufacturers would have three years to file a "written claim" to be resolved through the ADR process. *Id.* at 53,383. The NPRM specified that the ADR panel's decisions would "be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* The NPRM did not provide for any appeals process for these binding decisions. In fact, it provided no opportunity for the Secretary to oversee, review, or in any way alter an ADR panel decision.

129. The NPRM did not specify any specific remedies that ADR panels might impose, requiring only that "the final agency decision letter also be submitted to [HRSA's Healthcare Systems Bureau] to take enforcement action or apply sanctions, as appropriate." *Id.*

130. Lilly filed timely comments objecting to the proposed rule on October 11, 2016. *See* Exh. M. In particular, Lilly argued that HHS should (like many other administrative agencies) employ a neutral and disinterested adjudicator such as an ALJ. *See id.* at 8-10. Lilly reasoned that "the inclusion of an 'ex-officio, non-voting' HRSA employee undermines the guarantee that there would be a true separation of the regulatory and adjudicative functions" of the agencies. *Id.* at 9. The use of an ALJ, in contrast, would not pose this risk. Lilly further worried that nothing guaranteed that the ex-officio member would limit itself to giving purely technical advice, but would likely also "have some responsibility for HRSA rule making, investigation, and prosecution." *Id.* at 10. Finally, Lilly noted that "by virtue of his or her well-developed views on how the program 'should' work … and his or her greater sophistication with the subject matter," the ex-officio member could exert undue influence over the panel. *Id.* In sum:

> Since that panel would be comprised of individuals who work at HRSA and/or other federal agencies, those individual[s] are likely to bring their policy predilections to bear. That is, they are more likely than an ALJ to interpret regulations based on what they, themselves, 'intended' for the regulation to mean or how it was 'intended' to apply, irrespective of whether stakeholders could have divined this intent or whether the evidence presented supported such an outcome.

Id. at 11-12.

131. Lilly also raised concerns that the rule would be biased against manufacturers if Defendants did not first update the guidelines used for auditing a covered entity. The 340B statute requires a manufacturer to complete an audit prior to filing a claim that a covered entity has engaged in diversion or duplicate discounts. *See* 42 U.S.C. § 256b(d)(3)(B)(i). Lilly explained that, based on its own experiences, the auditing guidelines imposed numerous burdensome and costly requirements on manufacturers that did not serve to facilitate the audit. As Lilly noted, "[t]he bureaucratic effort and expense imposed by the 1996 Audit Guidelines makes it untenable,

except in the most egregious cases, for Lilly to conduct additional audits." Exh. M at 5. Defendants' failure to update the guidelines would mean that manufacturers would be disproportionately disfavored in the ADR process, as covered entities could more easily access and use the process compared to manufacturers.

132. After the close of the notice-and-comment period, the ADR began appearing on the Unified Agenda of Federal Regulatory and Deregulatory Actions ("Unified Agenda"), a semiannual compilation of information about federal regulations under agency development. On August 1, 2017, however, the rule was summarily withdrawn from the Unified Agenda without explanation. *See* Office of Mgmt. & Budget, *RIN: 0906-AA90: 340B Drug Pricing Program; Administrative Dispute Resolution Process*, https://bit.ly/3biRMPH.

133. Three years passed, with no indication from HHS or HRSA that the ADR rulemaking remained pending. The NPRM never appeared again on the Unified Agenda, nor did the agency publish a new NPRM in the Federal Register.

134. In fact, on March 12, 2020, a HRSA official told *The 340B Report* that Defendants had no plans to issue an ADR rule. According to the official, "[i]t would be challenging to put forth rulemaking on a dispute resolution process when many of the issues that would arise for dispute are only outlined in guidance" that Defendants understood to be legally unenforceable. Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B Report (Mar. 12, 2020), https://bit.ly/3651i5z.

C. Under Litigation Pressure, HHS Suddenly Resurrects and Implements the Previously Withdrawn Proposed Rule

135. On October 9, 2020, Ryan White Clinics for 340B Access and two affiliated 340B-covered entities filed a lawsuit in the United States District Court for the District of Columbia,

seeking to compel Defendants to promulgate the long-overdue ADR rules. *See* Compl. ¶¶ 99-100, *Ryan White Clinics for 340B Access v. Azar*, No. 20-cv-2906 (D.D.C. Oct. 9, 2020), Dkt. 1.

136. Two months after that lawsuit was initiated—and despite having withdrawn the NPRM and having publicly stated that it had no intention of promulgating a rule establishing an ADR process until after Congress further amended the 340B statutory scheme—HRSA suddenly published a final rule on December 14, 2020, without giving the public opportunity for notice and comment. *See* 85 Fed. Reg. 80,632-01 (Dec. 14, 2020).

137. The ADR Rule does not purport to invoke any statutory ground for excusing notice and comment (because there is none). Instead, it simply pretends that the agency had not, years earlier, withdrawn its NPRM, and then proceeds to alter and finalize its original proposal without further public input. *See id.* at 80,633 (claiming that the NPRM was not ***really*** withdrawn, just frozen by Presidential action). But that explanation is demonstrably false. First, the memorandum to which the agency refers ***on its face*** is inapplicable to the ADR Rule: That memorandum explicitly excluded "regulations subject to statutory … deadlines," Reince Priebus, Asst. to the President and Chief of Staff, *Memorandum for the Heads of Executive Departments and Agencies*, (Jan. 20, 2017), https://bit.ly/2KIutnM, which obviously includes the ADR Rule, notwithstanding the agency's defiance of Congress's 180-day deadline. Second, the agency's contemporaneous actions demonstrate that it itself believed the memorandum inapplicable: The memorandum ordered agencies to remove pending regulations to which it ***did*** apply "immediately," *id.*, but Defendants did not remove the ADR NPRM from the Unified Agenda for another eight months. And third, although regulatory actions retain the same Regulatory Identification Number ("RIN") throughout the entire rulemaking process, the final Rule was designated with a different RIN than the NPRM. *Compare* 81 Fed. Reg. 53,381, *with* 85 Fed. Reg. 80,632.

138. Ignoring the obligation to solicit public comment in a lawful and orderly way, the ADR Rule proceeds to finalize specific procedures for the resolution of disputes. It establishes a Board of "at least six members appointed by the Secretary": two each from HRSA, CMS, and the HHS OGC, plus one non-voting ex-officio member from OPA. 85 Fed. Reg. at 80,634. Each three-person ADR panel would consist of one member drawn from each voting group. *Id.*

139. The ADR Rule makes no provision for any Board member's removal from the ***Board***, providing only that individual panel members can be removed from a ***panel*** "for cause." *Id.* Like the NPRM, the final rule lists "a conflict of interest" as the only grounds for panel removal. *Id.*

140. In issuing the final rule, Defendants recognized that commenters had raised concerns that such a system would result in biased decisionmaking. But they cursorily brushed these concerns aside. According to the Rule, the ADR panels "are uniquely situated to handle the complexities of the 340B Program and related disputes," and the ex-officio "OPA staff member would not exercise undue influence over the three voting members." *Id.* at 80,634-35.

141. The Rule also made important changes regarding the remedies available to covered entities. Although the NPRM said nothing about the subject, the ADR Rule now provides that ADR panels can resolve claims for "money damages," as well as other unspecified "equitable relief" sought by disgruntled litigants. *Id.* at 80,633.

142. Furthermore, the ADR Rule empowers panels to function like federal courts. It expressly grants panel members "significant discretion" in their adjudicative functions. *Id.* at 80,635. A panel may "determine, in its own discretion, the most efficient and practical form of the ADR proceeding." *Id.* at 80,645. It may require "submission of additional information," and it has discretion to choose from an array of formidable sanctions if it concludes that its instructions

were inadequately complied with. *See id.*; 42 C.F.R. § 10.22(c) (permitting ADR panels to "[p]reclude a party from presenting or contesting a particular issue" or even enter judgment as a sanction). It has "discretion in admitting evidence and testimony" during the arbitration and may apply the Federal Rules of Civil Procedure and Federal Rules of Evidence. *Id.* at 80,641; *see* 42 C.F.R. § 10.23. It even has the discretion to issue whatever "additional instructions as may be necessary or desirable governing the conduct of ADR proceedings." 85 Fed. Reg. at 80,639; 42 C.F.R. § 10.21. Finally, ADR panel decisions "will" be based only and entirely on the panel's independent "review and evaluation of the evidence" and the governing law. 42 C.F.R. § 10.24(b).

143. The Rule also states that "[e]ach 340B ADR Panel will necessarily have jurisdiction to resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim." 85 Fed. Reg. at 80,636. And, even more notable, it imbues ADR panels with the authority to issue binding, precedential, and self-executing judgments. In a stark departure from the NPRM, the Rule now provides that ADR panel decisions are both "binding" on the parties and "precedential" for purposes of future adjudications. *Id.* at 80,634; 42 C.F.R. § 10.20. The regulation provides that the ADR panel's decision "constitutes a final agency decision that is precedential and binding on the parties involved unless invalidated by an order of a court of competent jurisdiction." 42 C.F.R. § 10.24(d).

144. Adding insult to injury, the ADR Rule insulates ADR panel judgments from any review by a superior (much less Senate-confirmed) Executive Branch official. Indeed, when expressly addressing comments concerning the earlier NPRM noting the need for an internal

appeals process, the Rule stated that such a process was not "necessary given that an aggrieved party has a right to seek judicial review." 85 Fed. Reg. at 80,641.

145. Nor does the ADR Rule purport to authorize any particular standard of judicial review. It does not, for instance, authorize *de novo* review in Article III courts of the private money judgments and equitable injunctions the ADR panelists are authorized to issue. Instead, it says only that review would be available under the APA and that "[t]he form of judicial review for ADR panel decisions is beyond the scope of this final rule." *Id.* at 80,642.

IX. HRSA Doubles Down On Its December 30 Decision By Issuing A New Ultimatum Requiring Lilly to Fall In Line Immediately or Risk Massive Penalties

146. Lilly filed this lawsuit on January 12, 2021, seeking to set the December 30 Decision aside as ultra vires under the statutory text, violative of the constitution, irregularly promulgated without notice and comment, and substantively arbitrary and capricious. Compl. for Decl. & Inj. Relief (Jan. 12, 2021), Dkt. 1. Lilly filed an amended complaint two weeks later, adding claims challenging HHS's ADR Rule on similar grounds. *See* First Amended Compl. for Decl. & Inj. Relief ¶¶ 211-63 (Jan. 25, 2021), Dkt. 17. Lilly simultaneously filed a motion preliminarily enjoin the ADR Rule, *see* Pls.' Mot. for Prelim. Inj. (Jan. 25, 2021), Dkt. 18, which the Court granted after full briefing and oral argument, *see* Order Granting Pls.' Mot. for Prelim. Inj. (Mar. 16, 2021) ("ADR PI Op."), Dkt. 81. The Court found that Defendants' actions before belatedly promulgating the ADR Rule were "duplicitous[] and misleading—the antithesis of fair notice under the APA," and, "[a]ccordingly," concluded "that Plaintiffs have established with a fair likelihood of success that Defendants violated notice-and-comment rulemaking requirements under the APA" in promulgating the ADR Rule. *Id.* at 23. The Court found that Lilly would "suffer irreparable injury for which there is no adequate remedy of law" by virtue of having been "'depriv[ed] of a procedural protection to which [Lilly is] entitled.'" *Id.* at 23, 25 (first alteration

in original) (quoting *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 94 (D.C. Cir. 2002)); *see also id.* at 25-26 ("[I]f the ADR Rule were permitted to go into effect and was later determined to have been promulgated without an adequate, fair opportunity for advance notice and comment, Plaintiffs would be deprived of their right, under the APA, to provide meaningful input into the agency's decision at a time when it is most likely to be carefully considered, a harm which the Court would be unable to fully remedy after the fact."). And the Court found that "the balance of harms and the public interest factors weigh in favor of Plaintiffs." *Id.* at 27. The Court therefore entered an order preliminarily enjoining Defendants "from implementing or enforcing [the ADR Rule] against Plaintiffs" "until further order of this Court." Prelim. Inj. (Mar. 16, 2021), Dkt. 82.

147. The lawsuit then proceeded to dispositive briefing on Lilly's claims, including the central issue of whether the 340B statute permits HHS to require Lilly to provide its products to contract pharmacies at the steeply-discounted 340B prices under any circumstances. On May 17, 2021, in the middle of the agreed-upon dispositive motion briefing on this and other claims and almost nine months after the government purportedly began its alleged "review" of Lilly's distribution plan, *see* Dkt. 85, Defendant Diana Espinosa sent a Lilly executive (not its counsel) an extraordinary demand letter. *See* Exh. P ("May 17 Letter").

148. The May 17 Letter announced that "HRSA has determined that Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute," and demands that "Lilly must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements" and must "credit or refund all covered entities for overcharges that have resulted from Lilly's policy." *Id.* at 1-2. The Letter then goes on to levy a number of threats, both open and veiled, against Lilly. The letter reminds Lilly that it

"signed a Pharmaceutical Pricing Agreement (PPA) and PPA addendum" and that "Lilly is bound by the terms of the PPA." *Id.* at 1.

149. The letter goes on to warn that "[c]ontinued failure to provide the 340B price to covered entities utilizing contract pharmacies" will "result in CMPs" (which "would be in addition to repayment") unless Defendant HHS is sufficiently satisfied with "Lilly's willingness to comply with" HRSA's unilaterally imposed view of Lilly's "obligations under section 340B." *Id.* at 1-2. And it concludes by "request[ing]" (*i.e.*, demanding) "that Lilly provide an update on its plan to restart selling, without restriction, covered outpatient drugs at the 340B price to covered entities that dispense medications through contract pharmacy arrangements by June 1, 2021." *Id.* at 2.

150. Unaccountably, the May 17 Letter's explanation for its demands differs from the attempted justifications the government has given for the December 30 Decision, not only in the Decision itself, but also in the summary judgment brief it filed in this case less than a month earlier. The May 17 Letter makes no mention of the "agency" theory set out in the Decision and proffered by the government in its briefing in this case. Nor does it cite the "purchased by" language also relied on in the December 30 Decision and by the government in briefing. *See* MTD/MSJ 22-25. Instead, the May 17 Letter relies solely on the "must offer" language added to the 340B statute by the 2010 Affordable Care Act, *see* Pub. L. No. 111-148, Title VII, § 7102(b), 124 Stat. 119, 827 (Mar. 23, 2010). *See* Exh. P at 1 (relying on the statutory requirement 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'"). By apparently jettisoning the agency theory, the Letter takes an ***even more extreme*** position than the December 30 Decision—purporting to require Lilly to deliver discounted drugs to contract pharmacies, period, whether they act as the covered entities' agents or not. *See id.* at 1-2. The Letter does not

acknowledge in any way that it encapsulates a different view than the December 30 decision, let alone any explanation for its changed position.

151. But the May 17 Letter marked more than a seismic shift in the explanation for the government's approach; it also fundamentally changed ***who*** would be deciding whether Lilly was required to offer 340B prices to contract pharmacies. At oral argument on Lilly's January 25 motion for preliminary injunction, the government's unequivocal position was that although "the agency has determined that covered entities have a right generally to use contract pharmacy arrangements, the agency has not passed on the specifics of Lilly's new policy, ***because that belongs in the ADR***." Tr. of Feb. 26 Oral Arg. (Exh. Q), at 76:24–77:3 (emphasis added).

X. Defendants' Final Agency Action, The Harm To Lilly, And The Need To File Suit

152. Lilly challenges "final agency action" within the meaning of 5 U.S.C. § 704.

153. To constitute final agency action, a decision "must [1] mark the 'consummation' of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature" and "[2] be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *W. Ill. Home Health Care, Inc. v. Herman*, 150 F.3d 659, 662 (7th Cir. 1998) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)); *see also, e.g.*, *Sackett v. EPA*, 566 U.S. 120, 126-27 (2012) (EPA order constituted final agency action immediately challengeable in federal court, even though it included a proviso inviting regulated parties to "engage in informal discussion of [its] terms and requirements" with the EPA and purported to be non-final, because "'legal consequences'" flowed from the order's "issuance" and the order marked "the 'consummation' of the [agency's] decisionmaking process" (quoting *Bennett*, 520 U.S. at 178)).

154. The December 30 Decision, the May 17 Letter, and the ADR Rule each independently constitute final agency action, as set forth below. Taken together, moreover, they represent a naked and unlawful attempt to accomplish through the back door that which they

cannot do via rulemaking—namely, forcing manufacturers to offer discounts to an unlimited number of for-profit contract pharmacies.

A. The December 30 Decision Constitutes Final Agency Action

155. The December 30 Decision represents the consummation of Defendants' mature decisionmaking process on this issue. This is not an issue Defendants only recently began considering; as the 1996 and 2010 guidance documents as well as the correspondence with Lilly and other manufacturers from last year reflect, Defendants have been evaluating this issue for some time now. Defendants' decision to conclude, once and for all, that manufacturers must offer 340B discounts to contract pharmacies, is the culmination of years' worth of consideration.

156. The December 30 Decision just as plainly determines rights and obligations from which legal consequences will inevitably flow—thereby creating an imminent threat of harm to Lilly. Indeed, Lilly has already begun to receive threats from covered entities in light of the December 30 Decision. *See, e.g.*, Exh. N (Ltr. from Univ. of Wash. Med. Ctr. and Harborview Med. Ctr. to Eli Lilly and Company (Jan. 6, 2021)) ("In light of the [December 30 Decision] your continued denial of 340B pricing [to contract pharmacies] puts Lilly's PPA and reimbursement under the Medicaid and Medicare Part B programs at risk, and subjects Lilly to civil monetary penalties for each overcharge or denied purchase.").

157. Simply put, Defendants' view that manufacturers ***must offer*** 340B discounts to contract pharmacies, on pain of severe penalties and consequences, is now fully operational. *See W. Ill. Home Health*, 150 F.3d at 763 (a letter from the Department of Labor was final agency action because "[l]egal consequences flow from it, both with respect to [plaintiffs'] obligations to their employees and with respect to [their] vulnerability to penalties should they disregard [it]").

158. Furthermore, Defendants have put Lilly to the "painful choice" of either complying with the incorrect "obligation[s]" that result from Defendants' mistaken interpretation of the 340B

statute or "risking the possibility of an enforcement action at an uncertain point in the future." *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 43 (D.D.C. 2015) (quoting *CSI Aviation Servs., Inc. v. U.S. Dep't of Transp.*, 637 F.3d 408, 412 (D.C. Cir. 2011)); *see also Abbott Labs. v. Gardner*, 387 U.S. 136, 153 (1967) (finding agency action fit for judicial review where "continued use of material which [plaintiffs] believe in good faith meets the statutory requirements, but which clearly does not meet the regulation of the Commissioner[,] … would risk serious criminal and civil penalties"), *abrogated on other grounds*, *Califano v. Sanders*, 430 U.S. 99 (1977). Under the December 30 Decision, if Lilly does not comply with the purported "obligat[ion]" to offer 340B prices to contract pharmacies, it may be subject to allegations of overcharging and even CMPs pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi), which exposes manufacturers to civil penalties of up to $5,000 "***for each instance*** of overcharging a covered entity." (Emphasis added.) That is not a far-off possibility, either: A few months before the December 30 Decision was published, HRSA told Lilly that its distribution plan could subject Lilly to sanctions "includ[ing] civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi)." Exh. H at 1. Given the 25,000-plus contract pharmacy locations nationwide and the 190,000-plus arrangements between contract pharmacies and covered entities, Lilly's decision to remain faithful to the plain text of the statute could thus have astronomically detrimental financial consequences.

159. And given Defendants' authority to terminate Lilly's PPA if they determine that Lilly has failed to comply with the 340B statute's obligations, a decision by Lilly not to acquiesce to the new obligations reflected in the December 30 Decision would jeopardize Lilly's participation in the Program altogether—as the Attorney General of Connecticut, who "led a bipartisan coalition of attorneys general urging [HHS] to hold accountable drug manufacturers," has already recognized. *See* Office of the Atty. Gen., *Attorney General Tong Leads Coalition of*

Attorneys General in Important Win on Prescription Drugs (Dec. 31, 2020) (recognizing that the December 30 Decision "puts a tremendous amount of pressure on drug companies"), https://bit.ly/356wuB0. That is no small matter. Termination of Lilly's PPA would be devastating to Lilly's business, as it would prohibit Lilly from receiving coverage and reimbursement for pharmaceutical products under Medicaid and Medicare Part B. Given the enormous size and importance of those federal programs, continuing participation in them is functionally necessary for Lilly (or any manufacturer) to be viable. *See, e.g.*, August 2020 Medicaid & CHIP Enrollment Data Highlights, Medicaid.gov (70 million people receive Medicaid), https://bit.ly/3rRO8SX; Nat'l Comm'n to Preserve Soc. Sec. & Medicare, *Number of People Receiving Medicare* (2019) (56 million people receive Medicare Part B), https://bit.ly/3olIG8D; *see also Allina Health*, 139 S. Ct. at 1808 ("One way or another, Medicare touches the lives of nearly all Americans."). Defendants have thus left Lilly in the untenable position of offering 340B discounts that are not required by the statute or else face crippling financial sanctions simply for asserting its right to comply with the obligations in the statute. *See, e.g., Brown & Williamson Tobacco Corp. v. FTC*, 710 F.2d 1165, 1172 (6th Cir. 1983); *A. O. Smith Corp. v. FTC*, 530 F.2d 515, 524 (3d Cir. 1976).

160. In short, the December 30 Decision—backed by the threat of massive sanctions—imposes "direct and immediate" burdens on Lilly, *Abbott Labs.*, 387 U.S. at 152, and is therefore final agency action subject to immediate review. "To hold otherwise would open a path for the defendants to substitute informal [advisory opinion]-writing for the formal process of notice and comment rulemaking. Perhaps more important, to hold otherwise would insulate the [December 30 Decision] from effective judicial review unless and until an affected party is willing to act contrary to [Defendants'] stated position and to risk severe civil … penalties." *Novelty, Inc. v. Tandy*, 2006 WL 2375485, at *1 (S.D. Ind. Aug. 15, 2006); *see id.* (holding that "one of a series

of letters" from the Drug Enforcement Agency constituted final agency action even though the agency did not follow "formal procedures" in promulgating it). It therefore warrants immediate review, and any delay in addressing this dispute would be manifestly inappropriate, as "'[e]ach day [it] wait[s] for the agency to drop the hammer," Lilly risks "accru[ing]" significant penalties ***plus*** losing its eligibility for Medicare and Medicaid programs. *See Sackett*, 566 U.S. at 127.

161. The need for immediate review is all the more acute given that the December 30 Decision does more than put Lilly to the choice between severe penalties and complying with the regulation: It effectuates an unconstitutional taking of property by forcing Lilly to transfer property in the form of its drugs to private, for-profit entities, not for the benefit of the public, but solely so that those for-profit entities can increase their profit margins. The Fifth Amendment expressly forbids such a regime. *See Kelo*, 545 U.S. at 477; U.S. Const. amend. V.

162. Moreover, the revenues Lilly generates pursuant to the 340B Program constitute personal property that cannot be taken by the government without just compensation. *See Horne v. Dep't of Agriculture*, 576 U.S. 350, 358 (2015).

163. It is also black-letter constitutional law that the government may not condition a benefit, such as participating in Medicare Part B and Medicaid, on the relinquishment of a constitutional right. *Koontz*, 570 U.S. at 604. Yet the December 30 Decision does precisely this: In order to receive reimbursement and coverage from the federal government—the nation's largest insurance provider that provides health insurance to hundreds of millions of individuals—the December 30 Decision forces Lilly to forego billions of dollars in revenue generated by its participation in the 340B Program.

164. The May 17 Letter confirms that HRSA views the December 30 opinion as final agency action. The agency went from merely threatening to level CMPs against manufacturers

that stray from the new interpretation of the statute to acting on that threat. The Letter explicitly finds that "Lilly's actions have resulted in overcharges and are in direct violation of the 340B statute," and stated that Lilly was subject to CMPs for failing to provide 340B prices to all covered entities. Exh. P at 1-2. The letter also stated that Lilly must "credit or refund all covered entities for overcharges that have resulted from Lilly's policy." *Id.* at 1. This letter enforces the final agency determination of its interpretation of the 340B statute announced in the December 30 opinion, and confirms that the decision was the consummation of agency decision-making and that Lilly was required to comply with the new legal obligations announced at the time of that decision.

B. Even if the December 30 Decision Did Not Constitute Final Agency Action, The May 17 Letter Does Constitute Final Agency Action

165. Even if the December 30 Decision were not a final agency action—and it is—the May 17 Letter certainly is one. Far from being "merely tentative or interlocutory [in] nature," *W. Ill. Home Health*, 150 F.3d at 662, the May 17 Letter unambiguously constitutes the consummation of the agency's decision process. In no uncertain terms, it proclaims: "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." Exh. P at 1.

166. By the same token, the Letter is also a decision by which "rights or obligations have been determined" and "legal consequences will flow," *W. Ill. Home Health*, 150 F.3d at 662: it states that "Lilly must immediately begin offering its covered outpatient drugs at the 340B ceiling price to covered entities through their contract pharmacy arrangements" or else suffer "CMPs as described in the CMP final rule." Exh. P at 2. Just like the December 30 Decision, the May 17 Letter forces Lilly to choose—this time with a strict deadline and an individualized threat—between complying with Defendants' mistaken interpretation of the 340B statute or suffering

massive penalties, and even termination from the 340B Program. *See, e.g.*, *Gardner*, 387 U.S. at 153. Further, for the first time, the agency has announced that manufacturers have an obligation to provide 340B discounts to *all* contract pharmacies, not just those that are common law agents of a covered entity, *and* it relies on statutory language that was enacted after 2010. There is therefore no argument that the view announced in the May 17 Letter embodies a previous position held by the agency, but rather it announces new legal obligations for manufacturers.

167. Indeed, the Supreme Court has already explained why "compliance orders" like the May 17 Letter constitute final agency action. In *Sackett v. EPA*, 566 U.S. 120 (2012), the EPA sent the Sacketts a letter concluding that the Sacketts' home-building efforts "constitute[d] a violation of" a federal statute. *Id.* at 125. On the basis of that violation, the EPA demanded that the Sacketts "immediately" comply with their purported statutory obligations. *Id.* The Court unanimously concluded that this letter constituted final agency action. The letter set out the Sacketts' purported "legal obligation" under statute, "expose[d] the Sacketts to double penalties in a future enforcement proceeding," and was "not subject to further Agency review." *Id.* at 126-27.

168. So too here. The May 17 Letter captures the agency's "determin[ation] that Lilly's actions … are in direct violation of the 340B statute," and holds itself out as the culmination of the agency's "review" and "analysis." Exh. P at 1. While the May 17 Letter may be the start of the agency's review for purposes of penalties, under *Sackett* it is immediately challengeable because it represents a determination by the agency of Lilly's obligations, and also precisely because of the fact that legal consequences can now follow from that decision. Indeed, the May 17 Letter expressly requires that Lilly "immediately" fall in line with its purported "340B statutory obligations." *Id.* at 2. And it expressly threatens that a failure to comply exposes Lilly to penalties. *See id.* ("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."). Further, just as in *Sackett*, "each day [Lilly] wait[s] for the Agency to drop the hammer," *Sackett*, 566 U.S. at 127, they run the risk of accruing additional penalties if it continues to follow its current pricing policy regarding contract pharmacies. The May 17 Letter is a *Sackett* redux, and therefore inarguably constitutes final agency action.

169. Indeed, it is apparent that, under the government's view, Lilly's decision to assert its rights ***in this lawsuit***—rather than immediately capitulate—could be a basis for civil monetary penalties under the 340B Statute, which are supposed to be available under the Statute only for knowing and willful violations. *See* 42 U.S.C. § 256b(d)(1)(B)(vi)(II).

C. The ADR Rule Constitutes Final Agency Action

170. The ADR Rule, codified at 42 C.F.R. §§ 10.20–10.24, became effective on January 13, 2021. *See* 85 Fed. Reg. at 80,632.

171. There is no doubt that Lilly will be subject to proceedings conducted under the ADR Rule; in fact, ADR petitions against Lilly have already been filed.

172. Nor is there any doubt that the petitions will continue to roll in. First, ADR proceedings are the exclusive remedial scheme for claims between covered entities and manufacturers. *See Astra*, 563 U.S. at 121-22. Second, many covered entities have been engaged in active litigation against HHS in an effort to force the agency to implement ADR rules so that those entities can make claims against manufacturers including Lilly. *See, e.g.*, Compl. 24, *Nat'l Assoc. of Comm'y Health Ctrs. v. Azar*, No. 1:20-cv-03032 (D.D.C. Oct. 21, 2020), Dkt. 1 (alleging that the plaintiff there would have submitted a claim through the ADR process "[h]ad the Secretary implemented" it). Third, covered entities have already sent Lilly letters threatening them with ADR-panel-issued damages if it does not acquiesce to their (and now HHS's) view that it

must offer full 340B discounts to for-profit contract pharmacies. Finally, after the Rule became effective, covered entities immediately began to file petitions, seeking all forms of relief—including ***preliminary injunctions*** nowhere contemplated in the statute—relying on the December 30 Decision as their central authority.

173. As Lilly has explained above and as it alleges further below, the 340B statute does not empower Defendants to require manufacturers like Lilly to offer product or allow purchases at 340B discounted prices to contract pharmacies. The term "covered entity" is defined in exhaustive detail to include fifteen very specific types of entities that predominantly provide services to low-income patients, 42 U.S.C. § 256b(a)(4); contract pharmacies, which typically are large and lucrative commercial, corporate pharmacies such as Walgreens and CVS, are mentioned nowhere on this list, *see id.* Moreover, Congress limited HRSA's authority to undertake rulemaking in the 340B Program to three specific areas: (1) establishing of an ADR process; (2) issuing standards for calculating ceiling prices; and (3) imposing monetary civil sanctions, *see Orphan Drug I*, 43 F. Supp. 3d at 41, the latter of which is expressly limited to instances of overcharging covered entities themselves, ***not their agents***, *see* 42 U.S.C. § 256b(d)(1)(B)(vi)(II)-(III).

174. Remarkably, however, one set of ADR panel judges, the OGC, ***has already staked out a position on Lilly's challenge***. *See* December 30 Decision.

175. As explained below, the ADR Rule to which Lilly is now subject is unconstitutional, unauthorized by statute, procedurally improper, and arbitrary and capricious. Lilly is therefore "suffering [a] legal wrong because of agency action" and "adversely affected or aggrieved by agency action," and is therefore "entitled to judicial review thereof." 5 U.S.C. § 702.

CLAIMS FOR RELIEF

I. Claims Regarding The December 30 Decision

COUNT I
(Violation of the Administrative Procedure Act
Failure to Provide Notice and Comment)

176. Lilly re-alleges and incorporates the allegations in all of the preceding paragraphs of this Complaint.

177. The Declaratory Judgment Act provides that, in a case of actual controversy within its jurisdiction, a United States court may declare the rights and other legal relations of any interested party seeking such declaration. 28 U.S.C. § 2201(a).

178. The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

179. The APA also provides that "final agency action for which there is no other adequate remedy in a court" is "subject to judicial review." *Id.* § 704.

180. The APA further provides that a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be … without observance of procedure required by law." *Id.* § 706(2)(D).

181. The December 30 Decision constitutes "final agency action for which there is no other adequate remedy," *id.* § 704, and Lilly has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile.

182. The APA defines a "rule" to include any "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law." *Id.* § 551(4).

183. To issue a valid rule, an agency "shall [ ] publish[]" "[g]eneral notice of proposed rule making" "in the Federal Register," and shall include in that notice "either the terms or

substance of the proposed rule or a description of the subjects and issues involved." *Id.* § 553(b)(3).

184. This notice requirement applies to all rules except "interpretive rules, general statements of policy, or rules of agency organization, procedure, or practice," and applies unless the agency "for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." *Id.* § 553(b)(A)-(B).

185. After providing notice of a proposed rule, the agency shall then "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* § 553(c).

186. Because the December 30 Decision definitively "conclude[s]" that manufacturers must provide contract pharmacies with 340B prices, it is plainly an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law." *Id.* § 551(4). It therefore constitutes a "rule" under the APA.

187. The December 30 Decision is not exempt from the APA notice-and-comment requirement under 5 U.S.C. § 553(b)(A), because it is not an "interpretative rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice." It is instead a legislative rule: The December 30 Decision creates rights and obligations on manufacturers with which they must comply, on pain of civil sanction and expulsion from the 340B Program.

188. Indeed, given the existence of the 1996 and 2010 contract pharmacy guidance, as well as HRSA's other repeated insistences that neither of those guidance documents create enforceable obligations, the ***only*** logical explanation for the December 30 Decision is that Defendants wanted to create and did create enforceable obligations under the 340B statute.

189. Defendants thus needed to comply with the APA's notice-and-comment procedures in order to (attempt to) enshrine these new obligations.

190. Yet Defendants nevertheless failed to provide public notice of their proposed action before issuing the December 30 Decision, and failed to provide the public any opportunity to comment on that proposed action.

191. The December 30 Decision was accordingly issued "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

COUNT II
(Violation of the Administrative Procedure Act
Exceeding Statutory Authority)

192. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

193. Under the APA, a reviewing court shall "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

194. The 340B statute does not confer on Defendants the authority to require drug manufacturers, on pain of penalty, to offer drugs to contract pharmacies at 340B prices, as contract pharmacies are not covered entities and Defendants have no authority to require manufacturers to offer discounts to any other type of entity. *See Pharm. Research & Mfrs. of Am.*, 43 F. Supp. 3d at 31, 39-40.

195. The 340B statute obligates manufacturers to offer drugs to covered entities—a defined term that does not include contract pharmacies. 42 U.S.C. § 256b(a)(1). And because Congress listed the entities intended to participate in the 340B Program in the definition of covered entity, the addition of contract pharmacies as a new category of recipients of covered outpatient drugs at 340B discount prices is prohibited. *See, e.g.*, *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1061 (D.C. Cir. 1995) ("[M]ention of one thing implies exclusion of another thing.").

196. Similarly, Defendants have no authority to create, through guidance or otherwise, an exception to the prohibition on diversion to any entity that is not a patient of the 340B covered entity under the statute.

197. Defendants likewise have no authority to broaden the scope of the 340B statute to effectively expand the statutory term "covered entities" and extend it to contract pharmacies, as they have now purported to do in the December 30 Decision.

198. Rather, HRSA possesses limited, circumscribed authority in only three areas: (1) the establishment of an administrative dispute resolution process; (2) the issuance of precisely defined standards of methodology for calculation of ceiling prices; and (3) the imposition of monetary civil sanctions. *See Pharm. Research & Mfrs. of Am.*, 43 F. Supp. 3d at 41 (vacating a rule that fell outside HRSA's regulatory authority).

199. Accordingly, the December 30 Decision is "in excess of statutory jurisdiction, authority, or limitations" and must be set aside. 5 U.S.C. § 706(2)(C).

COUNT III
(Violation of the Administrative Procedure Act
Arbitrary and Capricious Agency Action)

200. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

201. Under the APA, a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

202. Agency action is arbitrary and capricious if the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "Normally, an agency rule would be arbitrary

and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

203. Any change to an agency's policy must also be adequately explained. The agency must "display awareness that it ***is*** changing position," "show that there are good reasons for the new policy," and be aware that longstanding policies may have "engendered serious reliance interests that must be taken into account." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). "[A]n unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016) (citation and alterations omitted).

204. The December 30 Decision is arbitrary and capricious because Defendants did not consider the relevant factors. *See Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977); *Am. Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 241 (D.C. Cir. 2008). Indeed, Defendants entirely failed to give adequate consideration to the text of the 340B statute, which precludes Defendants from imposing an obligation on manufacturers to offer discounts to any entity other than the 15 classes of covered entities Congress specifically enumerated.

205. The December 30 Decision is also arbitrary and capricious because Defendants gave no indication that they gave any, let alone sufficient, consideration to the myriad and far-ranging abuses contract pharmacy arrangements have facilitated.

206. Furthermore, Defendants' application of their misguided view of the statute to mandate that Lilly offer 340B discounts for contract pharmacy transactions enables covered entity

diversion that is expressly prohibited by the 340B statute. *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."). Specifically, contract pharmacy transactions result in covered entities selling or otherwise transferring covered outpatient drugs to entities that are not "patients" of the covered entity. Use of contract pharmacies necessarily involves a prohibited "transfer" of 340B discounted product to a non-340B covered entity, the contract pharmacy.

207. Finally, the December 30 Decision is arbitrary and capricious because Defendants did not even attempt to reconcile the "obligation" enshrined in it with their earlier pronouncements that manufacturers were under no legally enforceable obligation to offer 340B prices to contract pharmacies. The December 30 Decision thus arbitrarily and capriciously fails to explain Defendants' change in policy.

COUNT IV
(Violation of the Administrative Procedure Act
Contrary to the Fifth Amendment to and Article I of the U.S. Constitution)

208. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

209. The APA provides that a reviewing court shall "hold unlawful and set aside agency action, found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

210. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend V.

211. The Takings Clause is not limited to instances where the government physically appropriates property for its own use through eminent domain. Rather, a taking can occur through legislation and regulation that sufficiently deprives a user of his property rights. *Squires-Cannon*

v. Forest Preserve Dist., 897 F.3d 797, 798 (7th Cir. 2018). As the Supreme Court has long recognized, "while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking." *Penn. Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922); *see also, e.g.*, *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 537 (2005); *Squires-Cannon*, 897 F.3d at 798.

212. The Takings Clause extends to both real and personal property. "The Government has a categorical duty to pay just compensation when it takes your car, just as when it takes your home." *Horne*, 576 U.S. at 358. Confiscatory regulations that mandate the transfer of personal property from one private party to another private party therefore amount to an unconstitutional taking with or without just compensation. *Id.*; *see E. Enters. v. Apfel*, 524 U.S. 498, 529 (1998).

213. A taking may be found based on "several factors," including "the economic impact of the regulation, its interference with reasonable investment backed expectations, and the character of the governmental action." *Kaiser Aetna v. United States*, 444 U.S. 164, 175 (1979). However, takings claims are inherently fact-intensive, and the ultimate question is whether the government has "forc[ed] some people alone to bear public burdens, which, in all fairness and justice, should be borne by the public as a whole." *Davon, Inc. v. Shalala*, 75 F.3d 1114, 1127 (7th Cir. 1996) (quoting *Armstrong v. United States*, 364 U.S. 40, 49 (1960)).

214. Defendants' decision to mandate that Lilly provide contract pharmacies with 340B-priced drugs is an exceedingly clear example of such a confiscatory regulation. In no uncertain terms, it forces Lilly to transfer its property, in the form of the drugs it manufactures, to contract pharmacies at a devastating financial loss. *See E. Enters.*, 524 U.S. at 529 (plurality op.) (evaluating economic impact as a prime factor for assessing whether a taking has occurred); *Penn Central Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978) (similar).

215. Under the December 30 Decision, which forces Lilly to offer discounts to an ever-growing number of contract pharmacies, Lilly stands to lose significant sums of money in both the short and long terms. The requirement reflected in December 30 Decision that Lilly offer discounts to contract pharmacies, on pain of severe penalty, is therefore unconstitutional, as "the 'power to regulate is not a power to destroy.'" *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 769 (1968) (quoting *Stone v. Farmers' Loan & Tr. Co.*, 116 U.S. 307, 331 (1886)); *accord, e.g.*, *Ames v. Union Pac. Ry.*, 64 F. 165, 186-89 (C.C.D. Neb. 1894) (Brewer, J.).

216. Defendants' December 30 Decision is especially galling—and constitutionally suspect—because it does not seek to use the confiscated property for a public use, as required by the Fifth Amendment. *See Horne*, 576 U.S. at 371. Rather, it forces Lilly and other manufacturers to transfer their property ***to other private entities***, many (if not most) of which are large and lucrative corporate pharmacies such as Walgreens and CVS, so that such entities can maximize their profits. The conclusion that manufacturers must offer discounts on all covered outpatient drugs to an unlimited number of contract pharmacies thus amounts to no more than "a naked transfer of property from private party *A* to *B* solely for *B*'s private use and benefit." *Carole Media LLC v. N.J. Transit Corp.*, 550 F.3d 302, 311 (3d Cir. 2008).

217. Such a regulation cannot be reconciled with the Fifth Amendment. "[I]t has long been accepted that the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation." *Kelo*, 545 U.S. at 477; *see also Calder v. Bull*, 3 U.S. (3 Dall.) 386, 388 (1798) (op. of Chase, J.) (the legislature has no power to enact "a law that takes property from A. and gives it to B."); *Reagan v. Farmers' Loan & Tr. Co.*, 154 U.S. 362, 399, 410 (1894) (similar). Indeed, such private takings are always unconstitutional, "since [n]o amount of compensation can authorize such action." *Lingle*, 544 U.S.

at 543; *see also Coniston Corp. v. Vill. of Hoffman Estates*, 844 F.2d 461, 464 (7th Cir. 1988). As "[a] purely private taking," the December 30 Decision "serve[s] no legitimate purpose of government" and is therefore "void." *Haw. Housing Auth. v. Midkiff*, 467 U.S., 229, 245 (1984). Accordingly, it must be set aside pursuant to the APA as "contrary to constitutional right." 5 U.S.C. § 706(2)(B).

218. Nor can the December 30 Decision be justified if only considered prospectively. Even if the December 30 Decision applies only to sales made in 2021 and afterward, it would still raise serious constitutional concerns given the sheer magnitude of Medicaid and Medicare Part B, participation in which Congress has made contingent on participation in the 340B Program (and thus on offering covered outpatient drugs to all covered entities at no more than the ceiling price established pursuant to the 340B statute). *See Elrod v. Burns*, 427 U.S. 347, 361 (1976) (plurality op.) ("The denial of a public benefit may not be used by the government for the purpose of creating an incentive enabling it to achieve what it may not command directly.").

219. The unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up" to obtain a benefit, such as the ability to participate in a government program. *Koontz*, 570 U.S. at 604; *see also Libertarian Party of Ind. v. Packard*, 741 F.2d 981, 988 (7th Cir. 1984) ("The 'unconstitutional conditions' doctrine is premised on the notion that what a government cannot compel, it should not be able to coerce."). This includes the rights to retain one's own personal (or business) property unless properly taken by the government. *See Dolan v. City of Tigard*, 512 U.S. 374, 385 (1994); *Nollan*, 483 U.S. at 837. The doctrine accordingly "forbid[s] the government from engaging in 'out-and-out … extortion' that would thwart the Fifth Amendment" by coercing private parties, on

pain of losing a government benefit, into relinquishing their property without proper compensation. *Koontz*, 570 U.S. at 606 (alteration in original) (quoting *Nollan*, 483 U.S. at 837).

220. The December 30 Decision effectively forces manufacturers to provide steep discounts to an endless number of for-profit contract pharmacies—even though the latter rarely, if ever, pass along the 340B discounts to the patients whom the Program is designed to serve—or else forego billions of dollars in revenues pursuant to Medicaid and Medicare Part B.

221. The December 30 Decision thus imposes a previously nonexistent condition that directly contravenes the unconstitutional conditions doctrine. Indeed, it has all the hallmarks of an "[e]xtortionate demand[]." *Id.* at 605. If Lilly wishes to continue participating in Medicaid, it must forfeit its constitutional "right not to have property taken without just compensation," *id.* at 607, and agree to provide 340B prices to limitless contract pharmacies. If it refuses, Lilly would become unable to contract with one of the largest insurance programs in the country, under which approximately 70 million Americans receive insurance. *Cf. NFIB v. Sebelius*, 567 U.S. 519, 581 (2012) (striking down use of Spending Power because "the financial 'inducement' Congress [ ] chose[] is much more than 'relatively mild encouragement'—it is a gun to the head").

222. At the very least, the broad reading of the 340B statute that is required in order for the December 30 Decision to be within Defendants' statutory authority raises serious constitutional concerns. In effect, by eviscerating the "covered entity" requirement, it would give Defendants the ability to confiscate property from private drug manufacturers whenever it sees fit, and to grant rights to that property to whomever it sees fit. The canon of constitutional avoidance weighs heavily against such a reading. *See, e.g.*, *INS v. St. Cyr*, 533 U.S. 289, 299-300 (2001).

II. Claims Regarding The ADR Rule

COUNT V
(Violation of the Administrative Procedure Act
Contrary to Article II of the U.S. Constitution)

223. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

224. The APA provides that a reviewing court shall "hold unlawful and set aside agency action, found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

225. The Appointments Clause of the U.S. Constitution provides:

> [The President] shall nominate, and by and with the Advice and Consent of the Senate, shall appoint … Officers of the United States, whose Appointments are not herein otherwise provided for, and which shall be established by Law: but the Congress may by Law vest the Appointment of such inferior Officers, as they think proper, in the President alone, in the Courts of Law, or in the Heads of Departments.

U.S. Const. art. II, § 2, cl. 2.

226. The Appointments Clause "is among the significant structural safeguards of the constitutional scheme." *Edmond v. United States*, 520 U.S. 651, 659 (1997). "By vesting the President with the exclusive power to select the principal (noninferior) officers of the United States, the Appointments Clause prevents congressional encroachment upon the Executive and Judicial Branches." *Id.* Although it may be administratively convenient for Congress to permit other persons to appoint officers, "that convenience was deemed to outweigh the benefits of the more cumbersome procedure only with respect to the appointment of 'inferior Officers.'" *Id.* at 661.

227. The Appointments Clause applies to "Officers of the United States." U.S. Const. art. II, § 2, cl. 2. To be an "officer," an individual must have "continuing and permanent" duties

and must "exercise[e] significant authority pursuant to the laws of the United States." *Lucia v. SEC*, 138 S. Ct. 2044, 2051 (2018). In the agency adjudication context, an individual is an officer when she can "take testimony, conduct trials, rule on the admissibility of evidence, and have the power to enforce compliance with discovery orders." *Id.* at 2052 (quoting *Freytag v. Comm'r of Internal Rev.*, 501 U.S. 868, 881-82 (1991)).

228. That description fits ADR panel members to a T. Just like the administrative law judges in *Lucia* and the special tax judges in *Freytag*, 340B ADR panelists have "significant discretion" to "take testimony, conduct trials, rule on the admissibility of evidence, and have the power to enforce compliance with discovery orders." *Lucia*, 138 S. Ct. at 2051 (quoting *Freytag*, 501 U.S. at 881-82); *see* 42 C.F.R. § 10.23 (permitting ADR panel to "conduct an evidentiary hearing when there are material facts in dispute"); *id.* § 10.22(b)-(c) (permitting ADR panel to "request additional information from either party" and sanction noncompliance); *see also* 85 Fed. Reg. at 80,641 (noting that the ADR Rule "allow[s] the 340B ADR Panel discretion in admitting evidence and testimony during the course of a proceeding"). Furthermore, the ADR Rule does not place any time limitation on panelists' service, with the result that their duties are "continuing and permanent." *Lucia*, 138 S. Ct. at 2051. And ADR panel decisions are "final agency decisions, binding on the parties, and precedential." 85 Fed. Reg. at 80,642; *see* 42 C.F.R. § 10.24(d). ADR panelists are thus Article II officers under a straightforward application of Supreme Court caselaw.

229. They are just as clearly ***principal*** officers. Once an individual has been identified as an officer, "the starting place for assessing the constitutionality of an officer's appointment is determining to which class the officer belongs." *Ass'n of Am. R.R. v. U.S. Dep't of Transp.*, 821 F.3d 19, 38 (D.C. Cir. 2016). If the officer is principal, but was not appointed by the President with advice and consent of the Senate, her appointment violates the Constitution. *Id.* So it is here.

230. The Supreme Court has ***never*** found an agency adjudicative officer to be inferior when—as here—her decisions were not reviewable by a superior executive officer. *See generally Edmond*, 520 U.S. at 662-63 (Because "[w]hether one is an 'inferior' officer depends on whether he has a superior," it is "evident that 'inferior officers' are officers whose work is directed and supervised at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate."). And unlike the (inferior-officer) judges of the Court of Criminal Appeals in *Edmond* or the (inferior-officer) members of the Public Company Accounting Oversight Board in *Free Enterprise Fund v. Public Co. Accounting Oversight Board*, 561 U.S. 477 (2010), ADR panel decisions ***are not subject to review by any superior executive official***. Indeed, ADR panelists—***and only ADR panelists***—have authority to "make precedential and binding final agency decisions regarding claims filed by covered entities and manufacturers." 42 C.F.R. § 10.20. *Compare id.*, *with Free Enter. Fund*, 561 U.S. at 486 (Board members are inferior officers because their actions are "subject to [SEC] approval and alteration"), *and Edmond*, 520 U.S. at 664-65 (CCA judges are inferior officers because they have no power to render final decisions on behalf of the U.S. "unless permitted to do so by other Executive officers"). ADR panel members are thus principal executive officers under a straightforward application of Supreme Court caselaw.

231. And because the ADR Rule permits these principal-officer panelists to hold office without nomination by the President and approval by the Senate, their appointment is unconstitutional under the Appointments Clause. Indeed, the lack of "any procedure by which [an agency] arbitrator's decision is reviewable by the [relevant agency]" ***is alone sufficient*** to render the arbitrator unconstitutionally appointed. *Ass'n of Am R.R*, 821 F.3d at 39. "Without providing

for the arbitrator's direction or supervision by principal officers, [the challenged statute] impermissibly vests power to appoint an arbitrator in the [relevant agency]." *Id.*

232. The ADR Rule's protection of ADR panelists from at-will removal only serves to confirm their status as superior officers. The Supreme Court has placed great weight on whether the officer in question was removable at will, as "[t]he power to remove officers … is a powerful tool for control." *Edmond*, 520 U.S. at 664; *see also Free Enter. Fund*, 561 U.S. at 510 ("Given that the Commission is properly viewed … as possessing the power to remove Board members at will, and given the Commission's other oversight authority, we have no hesitation in concluding that under *Edmond* the Board members are inferior officers …."). ADR panelists are not removable at will. Under 42 C.F.R. § 10.20(a)(1)(ii), a panelist can be "[r]emove[d] … from a 340B ADR Panel" only "for cause." Indeed, it is unclear whether members of the 340B ADR Board can be removed from that body ***at all***; no provision governs such a removal. That HHS lacks this "powerful tool for control" over 340B ADR panelists illustrates the reality that their decisions are not "directed and supervised … by others who were appointed by Presidential nomination with the advice and consent of the Senate." *Edmond*, 520 U.S. at 663-64.

233. Accordingly, because 340B ADR panelists are principal officers but were not appointed by the President with advice and consent of the Senate, the ADR Rule is unlawful as "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

234. These very principles are currently under consideration by the United States Supreme Court on a writ of certiorari. In *Arthrex, Inc. v. Smith & Nephew, Inc.*, the Federal Circuit concluded that "[t]he lack of any presidentially-appointed officer who can review, vacate, or correct decisions by APJs [administrative patent judges] combined with [a] limited removal power" makes those judges "principal officers." 941 F.3d 1320, 1335 (Fed. Cir. 2019), *pets. for*

reh'g en banc denied, 953 F.3d 760 (Fed. Cir. 2020). Because APJs were not appointed by the President with the Senate's advice and consent, the Federal Circuit held their appointments were unconstitutional. *See id.* The Federal Circuit concluded, in the context of the specific statute at issue there, that the APJs could be converted into inferior officers (thus curing the constitutional defect), by severing the statute's removal provision. *Id.* at 1338. The Supreme Court granted certiorari on both conclusions. *See Smith & Nephew, Inc. v. Arthrex, Inc.*, 2020 WL 6037207 (U.S. Oct. 13, 2020). Oral argument is set for March 1, 2021. While the conclusion that APJs as originally constituted were principal officers is undoubtedly correct, the remedial conclusion is not: No Presidential appointee must (or even may) review APJ decisions even as severed, which means that APJs—like ADR panelists—remain principal officers.

COUNT VI
(Violation of the Administrative Procedure Act
Contrary to Article III of the U.S. Constitution)

235. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

236. The Constitution vests the judicial power of the United States "in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish." U.S. Const. art. III, § 1. And "[w]hen a suit is made of the stuff of the traditional actions at common law tried by the courts at Westminster in 1789, and is brought within the bounds of federal jurisdiction, the responsibility for deciding that suit rests with Article III judges in Article III courts." *Stern v. Marshall*, 564 U.S. 462, 484 (2011) (citation and quotation marks omitted). Resolving "the mundane as well as the glamorous, matters of common law and statute as well as constitutional law, issues of fact as well as issues of law" is constitutionally assigned "to the Judiciary." *Id.* (quotation marks omitted). As a result, a statute or regulation violates Article III if it "confer[s] the Government's 'judicial Power' on entities outside Article III." *Id.*

237. Article III protects the rights of private litigants and the rule of law by ensuring that those who resolve their disputes do so without influence from the Executive. It provides that judges "shall hold their Offices during good Behaviour, and [who] shall, at stated Times, receive for their Services a Compensation, which shall not be diminished during their Continuance in Office." U.S. Const. art. III, § 1. This structural feature is an indispensable means by which the Constitution secures impartial adjudication and individual liberty, as it creates "in a body of judges insulated from majoritarian pressures and thus able to enforce [federal law] without fear of reprisal or public rebuke." *United States v. Raddatz*, 447 U.S. 667, 704 (1980) (Marshall, J., dissenting).

238. Since the earliest days of the Republic, the Supreme Court has understood that the adjudication of private rights must be overseen by Article III courts, and Article III courts alone. *See, e.g.*, *Stern*, 564 U.S. at 484; *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284 (1856); *see also* Caleb Nelson, *Adjudication in the Political Branches*, 107 COLUM. L. REV. 559, 569 (2007). Whether a statute or regulation conferring adjudicatory authority on a non–Article III tribunal is constitutional thus depends in considerable part on whether the adjudication involves "public rights" or "private rights": Congress may "assign adjudication of public rights to entities other than Article III courts," *Oil States Energy Servs., LLC v. Greene's Energy Group, LLC*, 138 S. Ct. 1365, 1374 (2018), but it may not do so with "private rights," *N. Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 70 (1982) (plurality op.).

239. Rights to private property are a fundamental part of "the stuff of the traditional actions at common law tried by the courts at Westminster in 1789," *N. Pipeline*, 458 U.S. at 90 (Rehnquist, J., concurring in the judgment), and they therefore must be adjudicated by Article III courts. Courts, commentators, and legislatures have always understood that "[t]he legislative power … cannot directly reach the property or vested rights of the citizen, by providing for their

forfeiture or transfer to another, without trial and judgment in the courts." *Newland v. Marsh*, 19 Ill. 376, 382 (1857); *see also* Theodore Sedgwick, *A Treatise on the Rules Which Govern the Interpretation and Application of Statutory and Constitutional Law* 676 (N.Y., J.S. Voorhies ed., 1857) (all have "the right to judicial procedure, investigation, and determination, whenever life, liberty, or property is attacked"); Nelson, *supra*, at 601 (early-twentieth-century statutes "drew a sharp distinction between administrative orders calling for the payment of money (which could be enforced only through suits in district court that proceeded 'like other civil suits for damages' and in which [agencies'] underlying findings were simply '*prima facie* evidence"' and other administrative orders (as to which [such] underlying findings, 'if supported by substantial evidence,' were to be 'conclusive unless … clearly … arbitrary or capricious'" (citation omitted)).

240. The ADR Rule flagrantly violates these basic principles. By enabling panels to mandate that Lilly transfer its property in the form of its drugs to covered entities often at an extreme financial loss to Lilly (and others), and by enabling those panels to enforce such decisions through binding money judgments, the ADR Rule empowers ADR panels to determine "the liability of one individual to another under the law as defined." *N. Pipeline*, 458 U.S. at 69-70 (quoting *Crowell v. Benson*, 285 U.S. 22, 51 (1932)); *see also Stern*, 564 U.S. at 494. The ADR Rule therefore unconstitutionally permits Executive Branch employees not only to adjudicate claims for money damages or equitable relief brought by one private party to obtain another's property without paying for its value, but to issue ***self-executing judgments*** on those claims.

241. Nor is this a case in which a non–Article III adjudication of private rights may be permissible because a federal court "retain[s] supervisory authority over the process." *Wellness Int'l Network, Ltd. v. Sharif*, 135 S. Ct. 1932, 1944 (2015); *see, e.g.*, *Peretz v. United States*, 501 U.S. 923, 937 (1991) (magistrate judges do not violate Article III because the district court can

remove a magistrate judge and "the entire process takes place under the district court's total control and jurisdiction" (citation omitted)); *Sharif*, 135 S. Ct. at 1944-45 (same with bankruptcy court judges). Judicial review is only available through the APA, 85 Fed. Reg. at 80,641, which provides for substantial evidence review of agency action, *see* 5 U.S.C. § 706(2)(E). This deferential review does not suffice. *See CFTC v. Schor*, 478 U.S. 833, 853 (1985) (noting that the "more deferential standard [of review] in *Northern Pipeline*" meant that the federal courts did not exert constitutionally sufficient control under that regime).

242. Moreover, ADR panels "exercise[] the range of jurisdiction and powers normally vested only in Article III courts," which further undermines federal courts' control and further underscores the Article III violation. *See id.* at 850. As described above, ADR panels have authority to award money judgments, issue equitable remedies, take evidence and hear testimony, apply the Federal Rules of Civil Procedure and Evidence, impose sanctions, issue precedential and binding decisions, and decide ancillary legal issues. And, again, ADR panels' binding and precedential money judgments appear to be self-executing. That makes the ADR process quite unlike most other administrative review schemes, which require litigants to apply to a federal court for enforcement of an order. *See, e.g.*, 7 U.S.C. § 18(d)(1); 29 U.S.C. § 1401(b)(2); *see also Schor*, 478 U.S. at 753 ("CFTC orders, like those of the agency in *Crowell*, but unlike those of the bankruptcy courts under the 1978 Act, are enforceable only by order of the district court.").

243. The ADR Rule accordingly violates Article III of the Constitution and should be set aside as contrary to law.

COUNT VII
(Violation of the Administrative Procedure Act
Exceeding Statutory Authority)

244. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

245. Under the APA, a reviewing court shall "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

246. As explained above, the ADR Rule violates both Article II and Article III of the U.S. Constitution. The Court can also invalidate the ADR Rule, however, as contrary to law under the APA, since Congress is presumed not to authorize violations of the Constitution.

247. For example, the 340B statute itself does not authorize ADR panels to issue decrees concerning "money damages" or "equitable relief" between private parties. It says only that the agency may "promulgate regulations to establish and implement an administrative process[,] … including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions." 42 U.S.C. § 256b(d)(3). Yet the statutory term "appropriate procedures for the provision of remedies" is general and not self-defining; it does not specify ***what*** remedies are to be made available by the ADR regulations—only that they be "appropriate." And an unconstitutional regulation cannot be an appropriate one.

248. Accordingly, the ADR Rule is "in excess of statutory jurisdiction, authority, or limitations" and must be set aside. 5 U.S.C. § 706(2)(C).

249. Or, at the very least, the Court should construe the statute not to authorize remedies, such as private money judgments or equitable relief between private parties, that would render the statutory scheme unconstitutional. *See, e.g.*, *INS v. St. Cyr*, 533 U.S. 289, 299-300 (2001); *United States v. Orona-Ibarra*, 831 F.3d 867, 875-76 (7th Cir. 2016).

COUNT VIII
(Violation of the Administrative Procedure Act
Failure to Provide Notice and Comment)

250. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this complaint.

251. The APA provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." 5 U.S.C. § 702.

252. The APA further provides that a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be … without observance of procedure required by law." *Id.* § 706(2)(D).

253. To issue a valid legislative rule (such as the ADR Rule), an agency must comply with the APA's rigorous notice-and-comment procedures. *See id.* § 553(b).

254. Defendants did not do so in promulgating the ADR Rule.

255. That Defendants provided notice-and-comment through the 2016 NPRM does not absolve their failure to do so in 2020. That is because Defendants ***withdrew the NPRM*** on August 1, 2017, and took no subsequent action on the rule before announcing that it was being resurrected with significant changes. The decision to withdraw had black-letter consequences, as it put regulated parties on notice that, rather than intending on continuing with the rulemaking process, the agencies had "[chosen] the status quo" of non-regulation. *Ctr. for Auto Safety v NHTSA*, 710 F.2d 842, 746 (D.C. Cir 1983); *cf. Cierco v. Lew*, 190 F. Supp. 3d 16, 25 (D.D.C. 2016) (withdrawal of NPRM left challenger to notice with no relief), *aff'd on other grounds sub nom. Cierco v. Mnuchin*, 857 F.3d 407 (D.C. Cir. 2017). Put another way, if the purpose of notice-and-comment is "to put interested parties on notice that Administrative rulemaking in certain areas is about to take place," *Nat'l Tour Brokers Ass'n v. United States*, 591 F.2d 896, 989 (D.C. Cir. 1978), the withdrawal put regulated parties on notice that rulemaking would ***not*** occur. Thus, in order to promulgate an ADR rule, Defendants needed to engage in notice and comment again.

256. That is all the more true given that, in the intervening four years, much changed about the 340B Program and stakeholder understandings and expectations, such that the comments provided and agency considerations would have been different in 2020 than they were in 2016. As the Pharmaceutical Research and Manufacturers of America ("PhRMA"), which represents the country's leading biopharmaceutical researchers and biotechnology companies, explained in its recent petition for rulemaking, the 340B Program has become increasingly and unsustainably plagued by material compliance issues over the past few years. *See* Exh. O; *see also* GAO, *HHS Uses Multiple Mechanisms to Help Ensure Compliance with 340B Requirements*, No. GAO-21-107 (Dec. 14, 2020) (admitting that HRSA lacks sufficient enforcement authority to deal with contract pharmacy abuses of the Program). Yet defendants took precisely none of that into account when they dusted off the old NPRM and issued an altered version of it late last year.

257. While Defendants stated in the ADR Rule that the NPRM was not actually withdrawn, that position is unpersuasive, inadequately explained, and nakedly pretextual. According to Defendants, they merely froze the proposal pursuant to President Trump's regulatory freeze memorandum. But that argument is facially and fundamentally flawed: On its face, the memorandum does not apply to rules promulgated to meet statutory deadlines, such as the ADR rule. In any event, had Defendants believed (wrongly) that the memorandum did apply to their NPRM, they would have withdrawn that NPRM "immediately," as the memorandum directed; in reality, however, they did not. That is the end of the matter: Courts are not required to defer to agency explanations where "the evidence tells a story that does not match the explanation the [agency] gave for [its] decision." *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2018).

258. That Defendants' explanation is pretextual becomes all the more clear when it is juxtaposed with Defendants' own actions, which confirm beyond doubt that the NPRM was indeed

withdrawn. Defendants withdrew the rule from the Unified Agenda in August 2017 and did not relist the NPRM on the agenda until the finalized rule appeared. *See* Office of Info. & Reg. Affairs: Reginfo.gov, *Final Rule: RIN 0906-AB26* (Fall 2020), https://bit.ly/39cOomV. Meanwhile, Defendants HRSA ***expressly told the public*** that it had no intention of publishing an ADR in the near future. These actions not only underscore that the rule announced in the NRPM was withdrawn, but also confirm that Defendants' actions in the lead-up to the eleventh-hour promulgation put manufacturers on notice that no rulemaking would imminently take place.

259. Finally, the agency's withdrawal is further evidenced by the fact that the NPRM and the final rule have different RINs. The NPRM, published at 81 Fed. Reg. 53,381, has a RIN of 0906-AA90. The final Rule, however, has a RIN of 0906-AB26. A RIN is given to a regulatory action when that action is entered into the rulemaking database, and a regulatory action retains the same RIN throughout the entire rulemaking process so that interested parties can monitor its progress. On information and belief, if the rule had not been withdrawn, then the ADR Rule and NPRM would have matching RINs. But they do not, confirming that the NPRM was withdrawn.

260. Because Defendants did not proceed through notice-and-comment rulemaking after the NPRM's withdrawal, as the APA required, the final ADR Rule must be set aside.

261. In any event, the agency never provided affected parties with the opportunity to comment on several provisions that appear in the ADR Rule but that were absent from, and do not logically grow from, the original NPRM. The NPRM did not mention, let alone elaborate upon, any suggestion that the agency intended to give ADR panels the authority to issue binding judgments for money damages, the as-yet-unspecified equitable relief mentioned in the Final Rule, or that their decisions would be "precedential." Thus, even if the NPRM had not been withdrawn,

the ADR Rule would violate the APA's notice-and-comment requirement because the final rule is not a "logical outgrowth" of the NPRM.

262. A final rule is a "logical outgrowth" of a proposed rule only if interested parties "'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period." *Ne. Md. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004). "If a 'final rule deviates too sharply from the proposal, affected parties will be deprived of notice and an opportunity to respond to the proposal,'" and the agency accordingly must undergo notice-and-comment again. *Public Citizen, Inc. v. Mineta*, 427 F. Supp. 2d 7 (D.D.C. 2006) (quoting *AFL-CIO v. Donovan*, 757 F.2d 330, 338 (D.C. Cir. 1985)). For the reasons explained above, the addition of these provisions concerning ADR panels' power to issue money-judgment and equitable decrees, and the decision to ascribe them precedential force, raise important questions of constitutional and statutory interpretation about which the public had no opportunity to present its views. None of these provisions grows out of the NPRM's original language—and indeed, the final Rule ***does not even acknowledge that this language is new***, much less provide a reasoned explanation for its inclusion. Accordingly, because no manufacturer could "divine [the Agency's] unspoken thoughts" on this issue, *Ariz. Pub. Serv. Co. v. EPA*, 211 F.3d 1280, 1299 (D.C. Cir. 2000) (citation omitted), the Rule is not a logical outgrowth, and further invalid.

COUNT IX
(Violation of the Administrative Procedure Act
Arbitrary and Capricious Agency Action)

263. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

264. Under the APA, a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

265. Agency action is arbitrary and capricious if the agency fails to "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted). "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.*

266. The ADR Rule is substantively arbitrary and capricious in several respects.

267. As an initial matter, the Rule fails to account for changed legal circumstances in the years since it withdrew the rule (or, at the very least, since the notice-and-comment period ended). Since notice and comment ended nearly four years ago, not only has the Supreme Court clarified its Appointments Clause jurisprudence, but it recently granted certiorari on an issue nearly identical to the one presented in this complaint, *i.e.*, whether Article II officers with a suite of powers and functions very similar to ADR panelists are principal officers whose non-Presidential appointment violates the Constitution. *See United States v. Arthrex Inc.*, 141 S. Ct. 549, *cert. granted* (U.S. Oct. 13, 2020) (No. 19-1434). If the Court answers that question in the affirmative, then the ADR Rule cannot stand. But even without a definitive ruling from the Court, the ADR Rule still does not pass muster because it does not contain any explanation, let alone a reasoned one, as to how the ADR process comports with the changed legal landscape after *Lucia*. *See, e.g.*,

Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2384 (2020) (an agency is "susceptible to claims that the rules were arbitrary and capricious for failing to consider an important aspect of the problem" if its rules do not account for legal developments).

268. The same is true with respect to the Article III concerns raised herein. The ADR Rule does not even acknowledge, let alone attempt to justify, how a process that affords Executive Branch employees full adjudicative powers, including the ability to exercise common-law interpretive authority and the power to issue binding money judgments or equitable relief touching private property, without being subject to an Article III court's plenary control, could be constitutional. Here, too, the agency has failed to grapple with an important aspect of the problem.

269. These are hardly the only examples of the agency's reliance on a stale record. PhRMA's petition for rulemaking (Exh. O) raised a host of concerns with the Program that had come to the fore in the intervening four years. Yet Defendants did not even acknowledge PhRMA's petition or the concerns PhRMA had raised. That failure to consider new information shows the ADR Rule is not "based on a consideration of the relevant factors and [that] there has been a clear error of judgment." *Nader v. FCC*, 520 F.2d 182, 192 (D.C. Cir. 1975) (quoting *Citizens to Preserve Overton Park v. Volpe*, 410 U.S. 402, 416 (1971)); *see NRDC v. Herrington*, 768 F.2d 1355, 1408 (D.C. Cir. 1985) ("Whether or not DOE acted reasonably in issuing rules in 1982 and 1983 based on 1980 information, we think it would be patently unreasonable for DOE to begin further proceedings in the last half of 1985 based on data half a decade old.").

270. The Rule is likewise arbitrary and capricious because Defendants failed to explain the reasons for choosing the structure for administrative dispute resolution established by the Rule. As manufacturers explained in comment letters, the ADR panel would likely be staffed by many of the same individuals responsible for creation and implementation of HRSA policy. Because

these individuals serve in other administrative functions, they are likely to hold biases, policy positions, or other objectives outside of the limited facts of the dispute at issue. There are virtually no safeguards under the Rule to limit these individuals from bringing their subjective views to bear in the ADR process. The ex-officio OPA member only compounds these risks with its potential to exert undue influence over the panel. Defendants' back-of-the-hand response that manufacturers should simply accept Defendants' say-so that no bias would exist falls far short of reasoned decisionmaking. *See, e.g.*, *FBME Bank Ltd. v. Lew*, 209 F. Supp. 3d 299, 333 (D.D.C. 2016) ("failing to respond to a comment rises to the level of arbitrariness if it 'demonstrates that the agency's decision was not based on a consideration of the relevant factors'" (citation omitted)); *see also* Kent H. Barnett, *Why Bias Challenges to Administrative Adjudication Should Succeed*, 81 MO. L. REV. 1023 (2016) (agency employees exhibit significant bias compared to ALJs).

271. The agency's choice of ADR panelists instead of more independent ALJs is both unreasonable and unreasonably explained. The agency claims that the panel structure is reasonable because it allows relevant government officials to draw on their expertise. But the lion's share of what panelists do—*i.e.*, hearing evidence, making credibility determinations, applying and interpreting the Federal Rules of Evidence and Civil Procedure, and even imposing sanctions—is far more analogous to common-law judging and ***has nothing whatsoever to do*** with specialized agency expertise. The ADR Rule provides that ADR panels will "resolve all issues underlying any claim or defense, including, by way of example, those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim." 85 Fed. Reg. at 80,636. They are the tasks of judges, familiar to ALJs who likely have the professional competence, experience, and independence to conduct an impartial adjudication. Besides that,

ADR panel rulings are "precedential" under the Rule, *see* 42 C.F.R. § 10.24(d), meaning that subsequent panels are supposed to uphold a body of existing administrative case law (again, a quintessentially judicial task) rather than adapt or alter decisionmaking based on accreted expertise. There is, in short, no fit between the problem of whom to appoint as adjudicators and the agency's solution of appointing non-neutral agency employees instead of professional judges.

272. In truth, the agency's evident reason for conferring vast adjudicatory power on non-neutral employees rather than professional judges is to come as close as possible to circumventing the agency's lack of any rulemaking authority under the 340B statute. *See Orphan Drug I*, 43 F. Supp. 28. Defendants have no statutory authority to define covered entities to include contract pharmacies, as they have recognized repeatedly over the course of two decades. *See, e.g.*, Tom Mirga, *HRSA Says its 340B Contract Pharmacy Guidance Is Not Legally Enforceable*, 340B Report (July 9, 2020); 75 Fed. Reg. at 10,273; 61 Fed. Reg. at 43,550. Indeed, it was this very lack of regulatory authority that, a mere eight months before issuing the Final Rule, led an HHS official to state that the agency could not promulgate an ADR rule. Tom Mirga, *HRSA: 340B Dispute Resolution Will Stay on Hold Until We Get Broader Regulatory Authority*, 340B Report (Mar. 12, 2020), https://bit.ly/3651i5z. Now, however, under the provisions of the ADR Rule, agency employees who ***cannot*** issue a rulemaking to effectuate their policy views can instead issue a "precedential" decision to set a prospective rule of decision for ADR panels.

273. The rule is also arbitrary and capricious because it fails to address Lilly's (and other manufacturers') concerns regarding Defendants' outdated and burdensome auditing guidelines. Though the Final Rule acknowledged that numerous commenters had raised this issue, it gave them short shrift, in a conclusory manner and without explanation that "updated manufacturer audit guidelines" are not "needed to finalize the ADR process" and that ADR panels can

"determine when there have been statutory violations concerning overcharges, diversion, and duplicate discounts." 85 Fed. Reg. at 80,633. This sort of *ipse dixit* response to serious comments striking at the heart of the fairness and unbiased nature of the ADR process does not satisfy arbitrary-and-capricious review. *See Perez v. Mortg. Bankers Ass'n*, 575 U.S. 92, 97 (2015) ("An agency must consider and respond to significant comments received during the period for public comment."); *see also, e.g.*, *Transmission Agency of N. Cal. v. FERC*, 628 F.3d 538, 543-44 (D.C. Cir. 2010) (noting that an agency "must respond to objections and address contrary evidence in more than a cursory fashion."); *NorAm Gas Transmission Co. v. FERC*, 148 F.3d 1158, 1165 (D.C. Cir. 1998) ("[T]he Commission's dismissive treatment of [an] objection, which was hardly a response at all, was not the product of a reasoned decisionmaking process.").

274. Finally, Defendants' failure to make any adjustments in the wake of their three-year silence renders the rule arbitrary and capricious. Both the NPRM and the ADR Rule provide that a covered entity has three years to bring a claim. So as things currently stand, a covered entity has the ability to seek redress for claims occurring throughout the entire three-year period that the Rule was withdrawn, during which time manufacturers ordered their businesses under the understanding that no formalized ADR process was imminent. At the very least, the Rule should have considered and implemented timeframes that reflect the manifest unfairness of subjecting parties to binding money judgments when they had no reason to expect that such liability would arise.

275. For all of these reasons, the ADR Rule is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" and must be set aside. 5 U.S.C. § 706(2)(A).

III. Claims Regarding the May 17 Letter

COUNT X
(Violation of the Administrative Procedure Act Exceeding Statutory Authority)

276. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

277. Under the APA, a reviewing court shall "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

278. The 340B statute does not confer on Defendants the authority to require Lilly, on pain of penalty, to offer drugs to contract pharmacies at 340B prices, as contract pharmacies are not covered entities and Defendants have no authority to require manufacturers to offer discounts to any other type of entity. *See Pharm. Research & Mfrs. of Am.*, 43 F. Supp. 3d at 31, 39-40. Indeed. the 340B statute is does not include a "broad, expansive rulemaking authority[,]" but rather is a "specific grant[] of authority" that simply does not extend so far as to allow HHS to require manufacturers to give discounts to any entity apart from a statutorily defined covered entity. *See id.*

279. The 340B statute obligates manufacturers to offer drugs to covered entities—a defined term that does not include contract pharmacies. 42 U.S.C. § 256b(a)(1). And because Congress listed the entities intended to participate in the 340B Program in the definition of covered entity, the addition of contract pharmacies as a new category of recipients of covered outpatient drugs at 340B discount prices is prohibited. *See, e.g.*, *Ethyl Corp.*, 51 F.3d at 1061 ("[M]ention of one thing implies exclusion of another thing.").

280. Similarly, Defendants have no authority to create, through guidance and certainly not through an enforcement action, an exception to the prohibition on diversion to any entity that is not a patient of the 340B covered entity under the statute.

281. Defendants likewise have no authority to broaden the scope of the 340B statute to effectively expand the statutory term "covered entities" and extend it to contract pharmacies or to transactions in which covered entities do not themselves "purchase" covered outpatient drugs, as they purport to do in the May 17 Letter.

282. Accordingly, the May 17 Letter is "in excess of statutory jurisdiction, authority, or limitations" and must be set aside. 5 U.S.C. § 706(2)(C).

COUNT XI
(Violation of the Administrative Procedure Act
Contrary to the Fifth Amendment to and Article I of the U.S. Constitution)

283. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

284. The APA provides that a reviewing court shall "hold unlawful and set aside agency action, found to be … contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

285. The Takings Clause of the Fifth Amendment provides: "[N]or shall private property be taken for public use, without just compensation." U.S. Const. amend V.

286. The Takings Clause is not limited to instances where the government physically appropriates property for its own use through eminent domain. Rather, a taking can occur through legislation and regulation that sufficiently deprives a user of his property rights. *Squires-Cannon*, 897 F.3d at 798. As the Supreme Court has long recognized, "while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking." *Penn. Coal Co.*, 260 U.S. at 415; *see also, e.g.*, *Lingle*, 544 U.S. at 537; *Squires-Cannon*, 897 F.3d at 798.

287. The Takings Clause extends to both real and personal property. "The Government has a categorical duty to pay just compensation when it takes your car, just as when it takes your home." *Horne*, 576 U.S. at 358. Confiscatory regulations that mandate the transfer of personal

property from one private party to another private party therefore amount to an unconstitutional taking with or without just compensation. *Id.*; *see E. Enters.*, 524 U.S. at 529.

288. A taking may be found based on "several factors," including "the economic impact of the regulation, its interference with reasonable investment backed expectations, and the character of the governmental action." *Kaiser Aetna*, 444 U.S. at 175. However, takings claims are inherently fact-intensive, and the ultimate question is whether the government has "forc[ed] some people alone to bear public burdens, which, in all fairness and justice, should be borne by the public as a whole." *Davon*, 75 F.3d at 1127 (quoting *Armstrong*, 364 U.S. at 49).

289. Defendants' decision to mandate that Lilly provide contract pharmacies with 340B-priced drugs, or to require reimbursements for transactions in which covered outpatient drugs are not "purchased" by covered entities, is an exceedingly clear example of such a confiscatory regulation. In no uncertain terms, it forces Lilly to transfer its property, in the form of the drugs it manufactures, to contract pharmacies at a devastating financial loss. *See E. Enters.*, 524 U.S. at 529 (plurality op.) (evaluating economic impact as a prime factor for assessing whether a taking has occurred); *Penn Central Transp. Co.*, 438 U.S. at 124 (similar).

290. Under the May 17 Letter, which forces Lilly to offer discounts to an ever-growing number of contract pharmacies, Lilly stands to lose significant sums of money in both the short and long terms. The requirement reflected in the Letter that Lilly offer discounts to contract pharmacies, on pain of severe penalty, is therefore unconstitutional, as "the 'power to regulate is not a power to destroy.'" *In re Permian Basin Area Rate Cases*, 390 U.S. at 769 (quoting *Stone*, 116 U.S. at 331); *accord, e.g.*, *Ames*, 64 F. at 186-89 (Brewer, J.).

291. The May 17 Letter is especially galling—and constitutionally suspect—because it does not seek to use the confiscated property for a public use, as required by the Fifth Amendment.

See Horne, 576 U.S. at 371. Rather, it forces Lilly and other manufacturers to transfer their property ***to other private entities***, many (if not most) of which are large and lucrative corporate pharmacies such as Walgreens and CVS, so that such entities can maximize their profits. The conclusion that manufacturers must offer discounts on all covered outpatient drugs to an unlimited number of contract pharmacies thus amounts to no more than "a naked transfer of property from private party *A* to *B* solely for *B*'s private use and benefit." *Carole Media*, 550 F.3d at 311.

292. Such a regulation cannot be reconciled with the Fifth Amendment. "[I]t has long been accepted that the sovereign may not take the property of *A* for the sole purpose of transferring it to another private party *B*, even though *A* is paid just compensation." *Kelo*, 545 U.S. at 477; *see also Calder*, 3 U.S. (3 Dall.) at 388 (op. of Chase, J.) (the legislature has no power to enact "a law that takes property from A. and gives it to B"); *Reagan*, 154 U.S. at 399, 410 (similar). Indeed, such private takings are always unconstitutional, "since [n]o amount of compensation can authorize such action." *Lingle*, 544 U.S. at 543; *see also Coniston Corp.*, 844 F.2d at 464. As "[a] purely private taking," the May 17 Letter "serve[s] no legitimate purpose of government" and is therefore "void." *Midkiff*, 467 U.S. at 245. Accordingly, it must be set aside pursuant to the APA as "contrary to constitutional right." 5 U.S.C. § 706(2)(B).

293. Nor can the May 17 Letter be justified if only considered prospectively. Even if the Letter applies only to sales made in 2021 and afterward, it would still raise serious constitutional concerns given the sheer magnitude of Medicaid and Medicare Part B, participation in which Congress has made contingent on participation in the 340B Program (and thus on offering covered outpatient drugs to all covered entities at no more than the ceiling price established pursuant to the 340B statute). *See Elrod*, 427 U.S. at 361 (plurality op.) ("The denial of a public

benefit may not be used by the government for the purpose of creating an incentive enabling it to achieve what it may not command directly.").

294. The unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up" to obtain a benefit, such as the ability to participate in a government program. *Koontz*, 570 U.S. at 604; *see also Packard*, 741 F.2d at 988 ("The 'unconstitutional conditions' doctrine is premised on the notion that what a government cannot compel, it should not be able to coerce."). This includes the rights to retain one's own personal (or business) property unless properly taken by the government. *See Dolan*, 512 U.S. at 385; *Nollan*, 483 U.S. at 837. The doctrine accordingly "forbid[s] the government from engaging in 'out-and-out … extortion' that would thwart the Fifth Amendment" by coercing private parties, on pain of losing a government benefit, into relinquishing their property without proper compensation. *Koontz*, 570 U.S. at 606 (alteration in original) (quoting *Nollan*, 483 U.S. at 837).

295. The May 17 Letter effectively forces Lilly to provide steep discounts to an endless number of for-profit contract pharmacies—even though the latter rarely, if ever, pass along the 340B discounts to the patients whom the Program is designed to serve—or else forego huge amounts of revenue pursuant to Medicaid and Medicare Part B.

296. The May 17 Letter thus imposes a previously nonexistent condition that directly contravenes the unconstitutional conditions doctrine. Indeed, it has all the hallmarks of an "[e]xtortionate demand[]." *Id.* at 605. If Lilly wishes to continue participating in Medicaid, it must forfeit its constitutional "right not to have property taken without just compensation," *id.* at 607, and agree to provide 340B prices to limitless contract pharmacies. If it refuses, Lilly would become unable to contract with one of the largest insurance programs in the country, under which

approximately 70 million Americans receive insurance. *Cf. NFIB*, 567 U.S. at 581 (striking down use of Spending Power because "the financial 'inducement' Congress [ ] chose[] is much more than 'relatively mild encouragement'—it is a gun to the head").

297. At the very least, the broad reading of the 340B statute that is required in order for the May 17 Letter to be within Defendants' statutory authority raises serious constitutional concerns. In effect, by eviscerating the "covered entity" requirement, it would give Defendants the ability to confiscate property from private drug manufacturers whenever it sees fit, and to grant rights to that property to whomever it sees fit. The canon of constitutional avoidance weighs heavily against such a reading. *See, e.g.*, *St. Cyr*, 533 U.S. at 299-300.

COUNT XII
(Violation of the Administrative Procedure Act
Arbitrary and Capricious Agency Action)

298. Lilly re-alleges and incorporates the allegations in the preceding paragraphs of this Complaint.

299. Under the APA, a reviewing court shall "hold unlawful and set aside agency action, findings, and conclusions found to be … arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

300. The May 17 Letter is arbitrary and capricious for all of the same reasons that the December 30 Decision is arbitrary and capricious. The letter does not even attempt to reconcile this newfound obligation with the text of the statute; does not acknowledge, let alone sufficiently address, the myriad and far-ranging abuses contract pharmacy arrangements have facilitated; and is fundamentally incompatible with the government's earlier pronouncements that manufacturers were under no legally enforceable obligation to offer 340B prices to contract pharmacies

301. But the May 17 letter is arbitrary and capricious in several additional ways. First, Defendants did not even attempt to reconcile its reasoning—and its extension of the purported

obligations it imposes beyond contract pharmacies allegedly acting as "agents" of covered entities—with the December 30 Decision. The May 17 Letter conspicuously makes no mention of the "agency" theory the government had defended and relied on in its brief before this Court filed only 28 days before HRSA sent the May 17 Letter. This violates the fundamental premise of administrative law that an administrative agency must at least demonstrate awareness that it is changing its position. *See Fox Television Stations, Inc.*, 556 U.S. at 515; *Encino Motorcars,* 136 S. Ct. at 2126. HRSA failed to even acknowledge that it had previously advanced an "agency" theory justifying Lilly's purported obligations to provide 340B discounts to contract pharmacy transactions or that the May 17 Letter drops the previously announced "agency" limitation, much less explain the reasoning behind this change. The May 17 Letter therefore arbitrarily and capriciously fails to explain Defendants' change in policy.

302. The May 17 Letter is also arbitrary and capricious because it was not "both reasonable and reasonably explained." *Multicultural Media, Telecom & Internet Council v. Fed. Commc'ns Comm'n*, 873 F.3d 932, 937 (D.C. Cir. 2017). The May 17 Letter, like the December 30 Decision, relies on the statutory provision stating that a manufacturer "shall … offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." Exh. P at 1 (quoting section 340B(a)(1) of the Public Health Service Act, Pub. L. No. 102-585, Title VI, § 602(a), 106 Stat. 4943, 4967 (1992)). It also claims that manufacturers have been under this obligation since the agency first issued its 1996 guidance on contract pharmacies. *Id.* Yet Defendants ***never*** explain how the statutory "must offer" language could have created this obligation when it was not added to the statute until 2010. Nor does the Letter account for Defendants' multiple prior pronouncements that they lack authority to impose any such obligation on manufacturers. Such a

failure to offer even a plausible explanation of its statutory construction, or to explain (let alone account for) Defendants' abrupt change in position, is arbitrary and capricious.

COUNT XIII
(Violation of the Administrative Procedure Act
Failure to Provide Notice and Comment)

303. Lilly re-alleges and incorporates the allegations in all of the preceding paragraphs of this Complaint.

304. Under the APA, a reviewing court shall "hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

305. The May 17 Letter constitutes "final agency action for which there is no other adequate remedy," *id.* § 704, and Lilly has exhausted all of its available administrative remedies and/or pursuit of any further administrative remedies would be futile. *See Sackett*, 566 U.S. at 125–27.

306. The May 17 Letter definitively "determine[s]" that Lilly "must immediately begin offering its covered outpatient drugs at the 340B ceiling price" to contract pharmacy purchases, and not just covered entity purchases. Exh. P at 1-2. It plainly embodies a legislative rule under the APA because it is an "agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law." 5 U.S.C. § 706(2)(C). It therefore constitutes a legislative rule under the APA, because it creates and announces obligations with which Lilly must comply, on pain of "CMP[s] not to exceed $5,000 for each instance of overcharging" and expulsion from the 340B Program. Exh. P at 2.

307. To determine whether an agency has issued a legislative rule, courts inquire into the effect of the rule on the agency itself and on regulated parties. No matter how labeled, agency action is a legislative rule if it has binding effect—*i.e.*, it has not "genuinely [left] the agency … free to exercise discretion" and instead binds the agency to a particular legal policy position.

Clarian Health W., LLC v. Hargan, 878 F.3d 346, 357 (D.C. Cir. 2017); *see also, e.g., U.S. Tel. Ass'n v. FCC*, 28 F.3d 1232, 1234 (D.C. Cir. 1994). Where "[a]n agency action … purports to impose legally binding obligations or prohibitions on regulated parties" and "violations of those obligations or requirements" "would be the basis for an enforcement action," it "is a legislative rule." *Nat'l Min. Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014).

308. HHS and HRSA insisted throughout 2020 in multiple public statements that neither the 1996 nor 2010 contract pharmacy guidance created enforceable obligations that could form the basis of an enforcement action against a manufacturer that declined to provide 340B discounts on contract pharmacy sales. The May 17 Letter, by contrast, clearly creates enforceable obligations under the 340B statute—either comply by June 1 or risk CMPs and other sanctions—and it clearly operates from the premise that Lilly is bound to comply with the position announced in this letter.

309. Defendants needed to comply with the APA's notice-and-comment procedures in order to (attempt to) enshrine these new obligations. Because they did not do so before issuing either the December 30 Decision or the May 17 Letter, the May 17 Letter was improperly promulgated, as Defendants nevertheless failed to provide public notice of their proposed action before issuing the May 17 Letter, and failed to provide the public any opportunity to comment on that proposed action.

310. The May 17 Letter was accordingly issued "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

PRAYER FOR RELIEF

Lilly respectfully prays that this Court:

a. issue an order and judgment declaring that Defendants violated the APA in issuing the December 30 Decision and May 17 Letter because the December 30 Decision and May 17 Letter were issued without following proper procedure; are in excess of statutory authority; violate

the Constitution; and are arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law;

b. issue an order and judgment declaring that Defendants lack the authority to require Lilly to offer or give 340B discounts to contract pharmacies or on purchases made by contract pharmacies;

c. preliminarily and permanently enjoin implementation and/or enforcement of the December 30 Decision and May 17 Letter;

d. issue an order and judgment declaring that Defendants violated the APA in issuing the ADR Rule because the ADR Rule was issued without following proper procedure; is in excess of statutory authority; violates the Constitution; and is arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law;

e. preliminarily and permanently enjoin implementation and/or enforcement of the ADR Rule;

f. award Lilly costs and reasonable attorneys' fees, as appropriate; and

g. grant any other relief the Court deems just and appropriate.

Dated: May 27, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on **May 27, 2021,** a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

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

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA

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

and

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

Plaintiffs,

v.

XAVIER BECERRA,
in his official capacity as Secretary of HHS
Office of the Secretary
200 Independence Avenue, SW
Washington, D.C. 20201,

DANIEL J. BARRY,
in his official capacity
as Acting General Counsel of HHS
Office of the General Counsel
200 Independence Avenue, SW
Washington, D.C. 20201,

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

DIANA ESPINOSA,
in her official capacity
as Acting Administrator of HRSA
5600 Fishers Lane
Rockville, Maryland 20852,

and

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

Defendants.[1]

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

Document Electronically Filed

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

SECOND AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

INDEX OF EXHIBITS

EXHIBIT	DESCRIPTION
Exhibit A	2020-10-15 Letter to Azar re 340B
Exhibit B	2020-05-18 Lilly Letter to HRSA
Exhibit C	2020-06-11 HRSA Email to Lilly
Exhibit D	2020-06-26 HRSA - Lilly Email Exchange
Exhibit E	2020-07-17 Lilly Letter to HHS
Exhibit F	2020-08-19 Lilly Letter to HRSA
Exhibit G	Limited Distribution Plan Notice for Lilly Products September 2020
Exhibit H	2020-08-26 HRSA Letter to Lilly
Exhibit I	2020-08-27 Lilly Response to HRSA
Exhibit J	2020-09-08 Lilly Letter to HHS
Exhibit K	2020-09-21 HHS Letter to Lilly
Exhibit L	2020-12-09 HRSA Letter
Exhibit M	2016-10-11 Lilly NPRM comments
Exhibit N	2021-01-06 Letter from UWMC to Lilly
Exhibit O	2020-11-24 PhRMA Petition for 340B ADR Rulemaking
Exhibit P	2021-05-17 HRSA Letter to Lilly
Exhibit Q	2021-02-26 Hearing Transcript Excerpt

Exhibit A

Congress of the United States
House of Representatives
Washington, DC 20515

October 15, 2020

The Honorable Alex M. Azar, II
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

We write to you with growing concerns over the 340B Drug Pricing Program. While we are grateful for HHS' rapid response to the public health emergency and appreciate the critical work of safety net hospitals to ensure vulnerable patients have continued access to needed care during this time, we find it important to seek clarity on how to further improve the 340B program in order to protect these vulnerable patients.

As you know, Congress created the 340B program in 1992 to assist federal grantees and safety net hospitals that serve large numbers of uninsured or otherwise vulnerable patients. At the time, Congress recognized that covered entities "provide direct clinical care to large numbers of uninsured Americans."[1]

We believe the program was intended to help uninsured or vulnerable patients gain better access to prescription medicines and to reduce federal costs. Since then, some entities, while aiming "to stretch scarce federal resources," have exposed vulnerable patients to higher out-of-pocket prices for prescription drugs. These expansions have come in the form of hospitals acquiring community practices and converting them into child sites and by expanding their contract pharmacy network size and geographies. In both cases, there is limited evidence to show these hospital 340B expansions are directly benefiting patients.

The original purpose of contract pharmacy arrangements was to help small clinics who did not have their own in-house pharmacy, and these grantees continue to use contract pharmacies to support their patients in ways that adhere to the spirit of the program. However, a policy change in 2010 allowed all 340B entities – including large non-profit hospitals – to have an unrestricted number of contract pharmacies. As a result, an ecosystem of profit-driven vendors, consultants, and large pharmacy chains are now taking advantage of a program that was intended to serve vulnerable patients.

On October 9, 2020, House Energy and Commerce Committee Republican Leader Greg Walden (R-OR) and Senate Health, Education, Labor and Pensions (HELP) Committee Chairman Lamar Alexander (R-TN) called for input on how to improve the 340B program. As we consider how to

[1] H.R. Rept. 102-384(II), (1992)

improve the program and ensure that it remains sustainable and viable for the long term, we would appreciate your expertise and insights on several topics. Please consult with the Administrator of HRSA or the Director of the Office of Pharmacy Affairs (OPA) to provide answers to the following questions:

1. Pharmacy Mark-Ups to Uninsured Patients and Patients in the Deductible Phase

We have received reports that covered entities and/or their contract pharmacies are able to charge uninsured and potentially under-insured individuals mark-ups on prescriptions drugs. For example, a recent Executive Order indicates that many insulins and epi-pens are available for pennies per milliliter (mL) but that patients in the 340B program, including the uninsured, can – and often do – bill cash-paying patients the "usual and customary" pharmacy price plus a dispensing fee.[2]

Can you confirm that this practice is commonplace in the 340B program? If there are exceptions, please describe how patients can benefit from 340B discounts at the point-of-sale and provide an estimate of the frequency with which such patient savings occur.

2. The Impact of the 340B program on State Medicaid Programs

As you know, the statute contains an absolute prohibition against manufacturers providing a 340B discount and paying a Medicaid rebate on the same unit of a drug.[3] This prohibition applies to both fee-for-service Medicaid utilization and on utilization through Medicaid Managed Care Organizations (MMCOs). 340B covered entities interpret the Medicaid statute to give them a right to the 340B discount that is superior to a State Medicaid program's right to the rebate. This dynamic has compelled states to carve-in all Medicaid prescription drug utilization to the fee-for-service benefit.[4],[5]

Does a covered entity's claim to the 340B discount take priority over the Medicaid program's claim to rebate on MMCO utilization? How much Medicaid rebate revenue is lost to 340B covered entities? What has HRSA, OPA or the Department done to curtail duplicate discounts on MMCO utilization?

3. Other Distortions to the Market for Prescription Drugs

Studies have identified other potentially unintended consequences of the 340B program, for example, instances of higher prescribing rates of branded products over generics at 340B covered entities,[6] shifting patients to less convenient or more costly sites of care, and "underpricing" in the 340B program contributing to increases in list prices.[7]

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[2] Exec. Order No. **13937**, 2020.

[3] 42 U.S.C. § 256b(a)(5)(B).

[4] New York Education, Labor, Housing and Family Assistance budget for the 2020-2021 fiscal year, S.7506B. (2020); California Exec Order N-01-19, 2019; North Dakota Health and Human Services Appropriation, S. 2012, 66th Legislative Assembly. (2019).

[5] Kaiser Family Foundation How State Medicaid Programs are Managing Prescription Drug Costs, April 2020.

[6] Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, June 2015.

[7] "HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs." Federal Register 83 FR 22692 (May 16, 2018). Pg. 37.

What, if any, possible distortionary effects to the market for prescription drugs has HHS observed? What is HHS doing to address these unintended consequences, including higher cost to the Medicare program through site of care shift?

4. Regulatory Authority

In a 2018 Energy and Commerce investigative report on the 340B program, the committee found that HRSA lacks sufficient authority to adequately oversee the program and clarify program requirements. The report suggests that HRSA needs more regulatory authority to promote compliance and ensure program integrity.

Using specific examples, when has HRSA's regulatory authority been challenged? What specific areas of the program are most in need of additional regulatory authority to allow the agency to provide meaningful oversight of the program?

5. Administrative Authority of Contract Pharmacy Agreements

HRSA has appropriately acknowledged that it may not enforce its contract pharmacy guidance.[8] At the same time, the agency has suggested that, if it were granted rulemaking authority, it would have the means to do so,[9] despite the fact that the 340B statute nowhere contemplates contract pharmacy arrangements.

How could a grant of rulemaking authority overcome the fact that there is no text in the 340B statute that can be reasonably interpreted to provide for contract pharmacy arrangements? Does HRSA agree that it is the domain of Congress to determine whether to alter the parameters of the 340B program to provide for contract pharmacy arrangements? If not, why not?

We look forward to your prompt attention to this matter and answers to our questions.

Sincerely,

Larry Bucshon, M.D.
Member of Congress

Brad Wenstrup, D.P.M.
Member of Congress

[8] See, e.g., Tom Mirga, HRSA Says Its 340B Contract Pharmacy Guidance Is Not Legally Enforceable, 340B Report (Jul. 9, 2020) (available at https://340breport.substack.com/p/hrsa-says-its-340b-contract-pharmacy) (quoting HRSA as stating, "The 2010 [contract pharmacy] guidance is still in effect. However, guidance is not legally enforceable.").

[9] *Id.*

Exhibit B

Lilly USA, LLC

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By E-mail (KPedley@hrsa.gov)

May 18, 2020

Rear Admiral Krista M. Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

RE: Availability of 340B-Priced Cialis® (tadalafil) Erectile Dysfunction Presentations to Contract Pharmacies

Dear RADM Pedley:

Eli Lilly and Company (Lilly) is writing to inform the Health Resources and Services Administration (HRSA) that, effective July 1, 2020, we are instructing wholesalers to discontinue our practice of voluntarily honoring requests for 340B "contract pharmacies" for orders of certain Cialis® (tadalafil) presentations. Unless HRSA objects and states that it believes our proposed discontinuation of voluntary contract pharmacy 340B discounts is unlawful, providing us the reasons for its conclusions, Lilly will no longer honor contract pharmacy-related requests for 340B-priced purchases of the following products after that date: Cialis 10mg (00002-4463-30), Cialis 20 mg (00002-4464-30), and Cialis 2.5mg (00002-4465-34). In addition, and as discussed further below, Lilly is formally challenging HRSA's quarterly listings, which include contract pharmacy listings, pursuant to Section IV(b) of the Pharmaceutical Pricing Agreement (PPA). Under the PPA, we believe HRSA is obligated to respond to this letter.[1]

The presentations of Cialis at issue here are indicated solely for erectile dysfunction and are all available as generic formulations.[2] We are prepared to provide a public letter for posting on the HRSA website describing our discontinuation of voluntary contract pharmacy discounts.

7We believe this action is prudent, reasonable and lawful, particularly in light of the substantial and ongoing expansion of contract pharmacy participation in the 340B program and the now overwhelming evidence demonstrating that contract pharmacy transactions result in 340B duplicate discounts and diversion. Based on these concerns, coupled with the risk that contract pharmacy transactions may be considered a basis a Civil Money Penalties or subject to onerous repayment obligations, Lilly feels compelled to take this action at this time.

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[1] PPA § IV(b).

[2] In prior correspondence to HRSA, we articulated and explained our position, based on applicable statutory provisions, that presentations of Cialis that are indicated solely for erectile dysfunction are not "covered outpatient drugs" for purposes of the Medicaid Drug Rebate Program or the 340B Program and, thus, are not subject to the 340B ceiling price. *See* Lilly Letter to HRSA RE: CIALIS® (TADALAFIL) 340B CEILING PRICING (Mar. 17, 2015). Although we disagree with HRSA's assessment of the concerns we raised in that correspondence, we do not assert it as a basis at this time for our decision to cease voluntarily providing 340B discounts in connection with contract pharmacy purchases.

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We explain, below, why Lilly does not believe 340B-priced purchases for contract pharmacies are consistent with or required by 42 U.S.C. § 256b (Section 340B). HRSA's 340B contract pharmacy guidance, 75 Fed. Reg. 10,272 (Mar. 5, 2010) (Contract Pharmacy Guidance), is inconsistent with the plain language of the statute and has resulted in systematic violations of the core requirements of Section 340B, as reflected in numerous audits and government reports. Further, developments after the issuance of the Contract Pharmacy Guidance demonstrate that the continued, wholesale adoption of the Contract Pharmacy Guidance is deeply flawed as a matter of public policy, both because HRSA has not considered subsequent statutory and regulatory developments and because the Contract Pharmacy Guidance is itself inconsistent with other guidance issued by HRSA. Most fundamentally, however, the Contract Pharmacy Guidance is both procedurally and substantively unlawful. We request that HRSA inform Lilly by June 17, 2020 if it objects to Lilly's proposed course of action.

Specifically, Lilly believes it has discretion to decline Section 340B contract pharmacy orders for at least the following reasons:

1. **Contract Pharmacy Arrangements Violate the Statutory Prohibition Against Diversion.**

The 340B statute is clear: "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***."[3] HRSA's Contract Pharmacy Guidance is inconsistent with this straightforward prohibition. In particular, the Contract Pharmacy Guidance, by its terms, requires the transfer of a drug to a legal person (typically a for-profit pharmacy) that is not a "covered entity" or a "patient."[4]

Clearly, a contract pharmacy is not a "covered entity." The plain language of Section 340B limits a manufacturer's obligation to offer 340B prices to "each covered entity."[5] In defining the term "covered entity," the statute states that it is "an entity" that "is one" of the specified entity types. Contract pharmacies are clearly not one of those "types."

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[3] 42 U.S.C. § 256b(a)(5)(B) (emphasis added).

[4] The term "person" under Section 340B includes legal entities as well as individuals. "Under the Dictionary Act, 'the wor[d] "person" . . . include[s] corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.'" *Burwell v. Hobby Lobby Stores, Inc*., 134 S. Ct. 2751, 2768 (2014); *see also FCC v. AT&T Inc*., 562 U.S. 397, 404-05 (2011) ("We have no doubt that 'person,' in a legal setting, often refers to artificial entities. The Dictionary Act makes that clear"); *Al Fayed v. CIA*, 229 F. 3d 272, 274 (D.C. Cir. 2000); *Soup, Inc. v. FTC*, 449 F. 2d 1142, 1143 (D.C. Cir. 1971) (per curiam) ("On the contrary, the statutory guidelines for the interpretation of Congressional acts, 1 U.S.C. § 1 (1970), make clear that the term "person" should ordinarily be taken to "include corporations * * * as well as individuals."). Moreover, here, the statutory "context" of Section 340B likewise confirms that the term "person" in the subsection prohibiting the "re[sale] or . . . transfer" of drugs under Section 340B "to a person who is not a patient of the entity" makes unlawful the "resale" or "transfer" of drugs under Section 340B to any non-patient of a covered entity, which necessarily includes ineligible "legal entities" as well as "individuals." 42 U.S.C. § 256b(a)(5)(B). Otherwise, "covered entities" could circumvent the prohibition against the resale or transfer of such drugs by simply transferring them to third party corporations on a wholesale basis. Such a reading would fundamentally undermine the program as designed by Congress and would be entirely inconsistent with the statutory scheme as a whole.

[5] 42 U.S.C. § 256b(a)(1).

Because the entities that Congress expected to participate in the program are listed, specifically, in the definition of "covered entity," the addition of contract pharmacies as a new category of recipients of covered outpatient drugs at 340B discount prices is prohibited.[6] The interpretive canon *expressio unius est exclusio alterius* requires that enumerated statutory lists must be read to exclude entities not expressly included.[7] Accordingly, by permitting contract pharmacies to participate in the program, we are concerned HRSA has exceeded its authority under Section 340B.[8]

HRSA has argued in the past, without statutory support, that contract pharmacies should receive 340B-discounted product because they should be deemed "agents" of covered entities.[9] We do not agree with the premise that contract pharmacies act as "agents" to covered entities. Further, the plain language of the statute forecloses this argument. The statute specifically limits a manufacturer's obligation to offer 340B discounted prices to "each covered entity," not to "each covered entity and its agents." The plain language of the statute defines the term "covered entity" to only mean "an entity" that "is one" of certain specified types. An agent of a covered entity is not the "entity" that "is one of the specified types."

Indeed, the statute *separately* refers repeatedly to numerous agents of different 340B program participants and principals, showing clearly that a reference to the principal is not a reference to the agent. For instance, the statute separately and distinctly refers to "covered entities" and agents of those covered entities, such as "associations or organizations representing the interests of such covered entities."[10] In fact, Section 340B separately refers to other participants and their agents repeatedly.[11]

The plain language of a statute must be read in context.[12] Here, the context shows that Congress identified when the 340B program applied to covered entities and various third parties, including those representing covered entities. Where, as here, Congress referred separately to principals and agents, when included, there is no basis to contend that references to covered entities include contract pharmacies.

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[6] *Id.* § 256b(a)(4).

[7] *See*, *e.g.*, *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1061 (D.C. Cir. 1995) ("[M]ention of one thing implies the exclusion of another thing"); *accord Independent Ins. Agents of America, Inc. v. Hawke*, 211 F. 3d 638, 644 (D.C. Cir. 2000); *American Methyl Corp. v. EPA*, 749 F.2d 826, 835-36 (D.C. Cir. 1984).

[8] This is especially true where contract pharmacies act as both "340B program administrator" and "340B contract pharmacy" for a given entity, suggesting that it is the for-profit commercial pharmacy that is the true beneficiary of the program and the 340B entity is effectively "renting out" its eligibility. https://www.walgreens.com/businesssolutions/payer/340BComplete.jsp.

[9] *See, e.g.*, 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) (stating "[t]he contract pharmacy would act as an agent of the covered entity").

[10] 42 U.S.C. § 256b(d)(3)(B)(vi) (separately referring to "covered entities" and an agent of those covered entities, "associations or organizations representing the interests of such covered entities").

[11] 42 U.S.C. § 256b(d)(1)(B)(v) (referring separately to "wholesalers" contracted with manufacturers); *id*. § 256b(d)(2)(B)(iii) (referencing "distributors"); *id*. § 256b(d)(3)(B)(iii) (separately referring to manufacturers and "third parties" subject to discovery).

[12] *See Bell Atlantic Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997) ("[T]extual analysis is a language game played on a field known as 'context.' The literal language of a provision taken out of context cannot provide conclusive proof of congressional intent, any more than a word can have meaning without context to illuminate its use. In short, 'the meaning of statutory language, plain or not, depends on context.'").

Congress's intent is all the more clear here. Congress has, over the course of 28 years, amended the 340B statute no fewer than four times, adding four types of covered entities through those amendments. Despite that, Congress has never chosen to recognize or codify HRSA's contract pharmacy guidance or the Agency's position that contract pharmacies may serve as "agents" of covered entities for purposes of 340B discounts.

Given, for all the reasons described above, that a contract pharmacy is not a covered entity, it is equally clear that by the very nature of the way contract pharmacies operate, their use necessarily involves a prohibited "transfer" of 340B discounted product to a non-340B covered entity, the contract pharmacy. As HRSA knows, contract pharmacies are dependent on virtual inventories and retrospective replenishment. These mechanisms necessarily involve a "transfer" of drug products to the contract pharmacies.

Under the "virtual inventory" systems and "retroactive replenishment" models that contract pharmacies use, the contract pharmacies do not segregate 340B inventory from non-340B inventory; rather, they have their own stock of inventory, purport to track dispensed prescriptions through a "virtual" inventory, and then supposedly *retroactively* seek to "replenish" product at 340B pricing for purchases allegedly determined—sometimes weeks or months after they are filled—to have been 340B-eligible. In other words, contract pharmacies dispense drugs *from their own stock*, and then determine later which prescriptions they will assert were 340B-eligible. For those prescriptions, they request—through an entirely retrospective process—replacement product at 340B pricing. The 340B product, which should only be dispensed to 340B patients, is then used, in reality, for non-340B patients.

Thus, these contract pharmacy operations necessarily constitute the transfer of 340B-discounted drugs to non-patients of the covered entity and, accordingly, are statutorily prohibited diversion. Agency guidance and interpretations are invalid and unlawful when they are inconsistent with the controlling statute.[13]

Indeed, the prohibited transfer of 340B product to non-340B patients under the replenishment model is not even consistent with HRSA's own guidance – in addition to its violating the statute. HRSA's "bill to/ship to" requirements are included in the Contract Pharmacy Guidance.[14] Under the "bill to/ship to" model required by HRSA, the covered entity should pay for the product to be used for 340B patients and the manufacturer may be directed to "ship to" the contract pharmacy.[15] Although we believe that this guidance is itself inconsistent with the statute, contract pharmacy transactions cannot be said to comply even with HRSA's existing guidance.

2. The Contract Pharmacy Guidance Is Unlawful, Ultra Vires, and Beyond HRSA's Statutory Authority.

The Contract Pharmacy Guidance results in direct harm to Lilly. By listing contract pharmacies among the entities eligible to obtain product priced at a Section 340B discount, HRSA applies this

[13] *See, e.g.*, *Gonzales v. Oregon*, 546 U.S. 243, 269-75 (2006) (invalidating an interpretive rule regulating medical practice on grounds that the agency interpretation was inconsistent with the controlling statute); *PhRMA v. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 54 (D.D.C. 2015) (invalidating HRSA's orphan drug exclusion "interpretive rule" because it was contrary to the language of Section 340B).
[14] *See* 75 Fed. Reg. at 10,277.
[15] *Id*.

Contract Pharmacy Guidance to Lilly, each quarter.[16] Unless HRSA rescinds the Contract Pharmacy Guidance or clarifies that it permits, but does not obligate, manufacturers to honor contract pharmacy orders, then those quarterly listings will continue to purport to obligate Lilly to provide Section 340B discounts to contract pharmacies, contrary to the statute. For the reasons cited in this letter, Lilly is formally challenging HRSA's quarterly listings pursuant to Section IV(b) of the Pharmaceutical Pricing Agreement (PPA).[17] Under the PPA, HRSA is obligated to respond.[18]

As a result of HRSA's actions, Lilly suffers injury and risk of loss when it provides, as dictated by HRSA, Section 340B discounts to entities that are not entitled to them. Indeed, as described below, the unlawful expansion of Section 340B through the Contract Pharmacy Guidance results in diversion of Section 340B drug sales, duplicate discounts in violation of Congress's commands in Section 340B, and other harm to State and Federal healthcare programs.[19]

To state the basis for our challenge under Section IV(b) of the PPA in greater detail, we believe that the Contract Pharmacy Guidance is ultra vires, beyond HRSA's statutory authority, and issued in violation of the Administrative Procedure Act (APA). The Guidance was not authorized under one of the defined areas for which Congress delegated rulemaking authority to HRSA. In addition, the quarterly listings and underlying Guidance, to the extent they should be interpreted as mandating 340B discounts on contract pharmacy transactions, represent a substantive change in the rights and obligations of affected parties, which HRSA has failed to promulgate by regulation, in violation of the APA. Finally, the guidance and any assertion or enforcement of its purported requirements is incompatible with the President's recent Executive Order and the Department of Justice's Brand Memorandum.

HRSA failed to comply with the APA's requirements for adopting substantive rules when it issued the Contract Pharmacy Guidance. The Contract Pharmacy Guidance is a "substantive," i.e., "legislative," rule because, as a result of it, HRSA "create[d] new law, rights or duties" for regulated parties under the 340B program.[20] Indeed, the Contract Pharmacy Guidance had a substantial "legal effect" on Lilly and other regulated entities because the expansion of Section 340B to include contract pharmacies imposed legal obligations, risks, and burdens on drug manufacturers, as well as on covered entities and contract pharmacies.[21] Thus, despite the label of a "guidance" document and the agency's assertion that the guidance does not create new rights or obligations for regulated

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[16] *See* Pharmaceutical Pricing Agreement, § III(a) ("Pursuant to the requirements under section 340B of the [Public Health Service] Act, the Secretary agrees to the following: (a) to make available a list of covered entities on the HRSA, Office of Pharmacy Affairs web site (http://www.bphc.hrsa.gov/opa/), or otherwise, for access by participating Manufacturers, covered entities, State Medicaid agencies, and the general public. This information will be updated, to the extent practicable, on a quarterly basis"), *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf.

[17] *See id*. § IV(b) ("The Manufacturer may challenge the presence of an entity on the list of eligible entities issued by the Secretary.")

[18] *Id.*

[19] *See* 42 U.S.C. § 256b(a)(5)(A) ("Prohibiting duplicate discounts or rebates"); *id.* § 256b(a)(5)(B) ("Prohibiting resale of drugs").

[20] *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc); *see also Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 653 F.3d 1, 6-7 (D.C. Cir. 2011) ("The practical question inherent in the distinction between legislative and interpretive regulations is whether the new rule effects a substantive regulatory change to the statutory or regulatory regime.").

[21] *See PhRMA v. HHS*, 43 F. Supp. 3d at 46 (explaining that agency action is substantive rule where it affects "legal rights").

parties, *see* 75 Fed. Reg. at 10,273, the "guidance" was clearly a substantive rule. The massive growth in the number of contract pharmacies, the corresponding increase in 340B sales attributable to those purchases, and the evidence of diversion and duplicate discounts all underscore the substantive purpose and effect of the "guidance."[22] The fact that these transactions can also serve as a basis for Civil Money Penalties and/or require manufacturer repayments are further evidence that guidance has a substantive purpose and effect.

HRSA, however, did not comply with the procedural requirements that the APA imposes for substantive regulations.[23] In the Contract Pharmacy Guidance, HRSA acknowledged that it was not undertaking the procedure required for a legislative rule, asserting incorrectly that the regulatory action being taken was "exempt from notice and comment rulemaking under the APA."[24]

HRSA did not proceed through a substantive rulemaking, because it could not do so; it had and has no such authority. In *Pharm. Research & Mfrs. of Am. v. Dep't of Health & Human Servs*., 43 F. Supp. 3d 28 (D.D.C. 2014), the district court struck down a regulation adopted by HRSA that purported to implement a statutory provision. In that case, the district court held that HHS lacked authority to engage in such rulemaking. *Id.* at 31, 39. The court explained that HHS's authority to adopt regulations with respect to the 340B program was limited to discrete areas expressly specified in the 340B statute, and the court held that HRSA's limited regulatory authority did not extend to regulations interpreting or implementing the relevant provisions of Section 340B. Thereafter, the district court rejected HHS's effort to readopt the same policy as an interpretive rule. *See also Pharm. Research & Mfrs. of Am. v. Dep't of Health & Human Servs.,* 131 F. Supp. 3d 31 (D.D.C. 2015). Under this precedent, HHS lacks statutory authority to implement the Contract Pharmacy Guidance as it was not issued based on the limited authority provided by Congress.

Executive Order 13891 (Oct. 9, 2019), confirms that HRSA cannot impose substantive obligations on regulated parties through the Contract Pharmacy Guidance and HRSA's retention of the guidance violates the Order. Section 2 of the Executive Order 13891 explains that an agency may not regulate "the public without following the rulemaking procedures of the APA," and that "[e]ven when accompanied by a disclaimer that [the guidance] is non-binding, a guidance document issued by an agency may carry the implicit threat of enforcement action if the regulated public does not comply." In response, the Executive Order directs, among other things, that "it is the policy of the executive branch, to the extent consistent with applicable law, to require that agencies treat guidance documents as non-binding both in law and in practice . . . ."

Additionally, the Department of Justice likewise has confirmed that agency guidance documents may not be used to coerce regulated parties like Lilly into taking action or refraining from taking action beyond what is required by the terms of the applicable law or lawful regulation. *See* Rachel Brand, Associate Attorney General, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases at 1 (Jan. 25, 2018) ("Brand Memo"). Under the Brand Memo, (1) "Guidance documents cannot create binding requirements that do not already exist by statute or regulation," (2) "the Department may not use enforcement authority to effectively convert agency guidance documents into binding rules," and (3) "noncompliance with guidance documents [should not be used as] a basis for proving violations of applicable law in [affirmative civil enforcement] cases." *Id.* at 2.

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[22] *See* notes 31-32, *supra.*
[23] *See* 5 U.S.C. § 553(b), (c) (setting forth agency obligations for notice-and-comment rulemaking).
[24] 75 Fed. Reg. at 10,273.

In some instances, HRSA representatives have sought to justify its authority to issue the Contract Pharmacy Guidance by stating that Section 340B does not prohibit these arrangements. That analysis ignores, however, that an agency may only exercise authority affirmatively granted by Congress. An unbroken line of D.C. Circuit Court of Appeals cases has steadfastly rejected the notion of "presuming" statutory authority because there is no express statutory prohibition against it.[25] This argument inverts the appropriate analysis. The question is not did Congress prohibit the Agency from taking an action; the question is did Congress specifically authorize that action.

3. The Contract Pharmacy Guidance Should Not Be Relied Upon or Enforced Because It Has Been Shown To Be Inconsistent with the Premise Upon Which It Was Issued.

When HRSA issued guidance permitting covered entities to enter into multiple contract pharmacy arrangements, with no numerical or geographical limitations, it rejected stakeholder concerns that unlimited contract pharmacy arrangements would necessarily result in diversion or statutorily prohibited Medicaid duplicate discounts.[26] In proposing the guidance, HRSA expressly asserted that, "[t]o date, there has been no evidence of drug diversion or duplicate manufacturer's discounts on 340B drugs" related to various contract pharmacy arrangements.[27] But, just as stakeholders feared and predicted, the available evidence makes clear that, as more and more prescriptions have been dispensed through contract pharmacies, diversion and duplicate discounts have resulted. We also are concerned that the breadth of penalties under the CMP Rule, under which HRSA may seek to assess a penalty of up to $5,000 per "instance of overcharge," would be vastly and unlawfully expanded by the inappropriate application of the Contract Pharmacy Guidance.

There are many reasons why the premise for the Guidance—HRSA's assumption that contract pharmacies would not lead to diversion and duplicate discounts—has failed. Unlike in-house pharmacies, contract pharmacies do not possess or have access to the records of the covered entity's patients sufficient to make a "patient" determination (even under the 1996 standards which are often themselves not followed by covered entities[28] or contract pharmacies[29]). Often "patient"

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[25] *See*, *e.g.*, *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) (rejecting as "entirely untenable under well-established case law" the argument "that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency"); *ExxonMobil Gas Mktg. Co. v. FERC*, 297 F.3d 1071, 1088 (D.C. Cir. 2002) ("We have repeatedly admonished federal agencies that jurisdiction may not be presumed based solely on the fact that there is not an express withholding of jurisdiction."); *Nat'l Mining Ass'n v. U.S. Dep't of Interior*, 105 F.3d 691, 695 (D.C. Cir. 1997) (rejecting the "extreme position" that "because Congress did not specifically preclude" an agency action, the court "should defer to [the agency's] interpretation of the statute"); *Am. Petroleum Inst. v. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995) ("[W]e will not presume a delegation of power based solely on the fact that there is not an express withholding of that power."); *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) ("We refuse ... to presume a delegation of power merely because Congress has not expressly withheld such power.").

[26] 75 Fed. Reg. at 10,273, 10,274 (noting comments raising concerns about diversion by contract pharmacies).

[27] 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007).

[28] *See, e.g.*, *Genesis HealthCare v. Azar* No.:4-19-cv-1531-RBH (D.S.C. Dec. 18, 2019).

[29] *See, e.g.*, GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018) (discussing "identified noncompliance at contract pharmacies," including diversion findings in HRSA audits), *available at* https://www.gao.gov/assets/700/692697.pdf; OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014), at 1-2 ("We found that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways. . . . In some cases, these different methods lead to differing determinations of 340B eligibility

determinations are adjudicated by contract pharmacies hastily, and/or inconsistently with 340B program standards, on the back end, after insufficient coordination with covered entities and consistent with an improper financial incentive to mischaracterize commercial customers as 340B "patients." Sprawling contract pharmacy networks are major sources of prohibited diversion, despite covered entities' obligations to police and oversee their contract pharmacy relationships.

Oversight agencies, including the Government Accountability Office (GAO) and Health and Human Services Office of Inspector General (HHS OIG), as well as Congressional committees, have all noted that the increased use of contract pharmacies has created substantial drug diversion and duplicate discount issues, problems, and violations. For example:

- 2011 GAO Report: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement: GAO concluded that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." GAO further noted the "[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program".[30]

- 2014 HHS OIG Report: Contract Pharmacy Arrangements in the 340B Program: In 2014, HHS OIG reported that contract pharmacies create "complications" in preventing diversion because "some covered entities that do dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts." OEI-05-13-00431, at 1–2, *see also id*. at 16. HHS OIG also concluded, quite troublingly, that findings of noncompliance did not lead to HRSA terminating the covered entities' permission to use multiple pharmacy arrangements. *Id*. at 7, 9–15.

- 2018 HHS OIG Testimony: Examining Oversight Reports on the 340B Drug Pricing Program: In its testimony, OIG stated that it "has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements." OIG Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions (May 15, 2018), at 5. OIG further stated that "many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory."

- 2018 GAO Report: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement: In this report, GAO concluded that "[t]he *identified noncompliance* at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."[31] For example, GAO found that approximately two-thirds (66 percent) of diversion findings in HRSA audits (from FY 2012 to FY 2017, based on results posted to HRSA's website as of February 2018), "involved drugs distributed at contract pharmacies."[32]

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across covered entities. That is, two covered entities may categorize similar prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) in their contract pharmacy arrangements."), *available at* https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[30] GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836: Published: Sep 23, 2011. Publicly Released: Sep 23, 2011. https://www.gao.gov/products/GAO-11-836 (emphasis added).

[31] GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 44 (June 2018), GAO-18-480, *available at* https://www.gao.gov/assets/700/692697.pdf (emphasis added).

[32] *Id.* at 44 & n. 64.

Despite this significant conclusion, GAO further noted that "the number of contract pharmacy oversight findings may be limited by the fact that officials from HRSA's contractor said that its auditors rely on verbal responses from entity officials about any internal review or self-audits conducted by the entity."[33]

- 2018 House Energy and Commerce Committee Report: Review of the 340B Drug Pricing Program: In 2018, the House Energy and Commerce Committee issued a report echoing the findings of HHS OIG, concluding that contract pharmacy arrangements lead to diversion of 340B drugs. The committee's review of HRSA's audit files revealed that many covered entities have engaged in diversion. Further, in one quarter of the audit files reviewed by committee staff, HRSA recommended that the covered entity improve its oversight of their contract pharmacy arrangement to prevent diversion of 340B drugs at the contract pharmacy. *See* H. Comm. on Energy & Commerce, at 39. The Committee emphasized its concerns by recommending that "[a]ll covered entities should perform independent audits of their contract pharmacies at regular intervals to ensure 340B program compliance." *Id*. at 76. The Committee endorsed auditing by manufacturers to stem unlawful diversions, underscoring how HRSA's limiting the actions that a manufacturer may take to police compliance undermines the program's integrity.

Publicly available audit statistics published by HRSA support these concerns. Notably:

Fiscal Year	Entity Audits	Entities with Contract Pharmacy Adverse Findings (All)	Entities with Contract Pharmacy Adverse Findings (Diversion)
2013	94	31	19
2014	104	45	34
2015	200	92	71
2016	200	77	61
2017	199	81	69
2018	200	64	42
2019	187	52	33

Finally, Lilly's own data demonstrate that contract pharmacies are a frequent source of noncompliance.

- 2013-2020 Analysis of Covered Entity and Contract Pharmacy Self-Disclosures: Over the past seven years, Lilly has received 125 disclosures in which contract pharmacy noncompliance was reported, involving either or both duplicate discounts and diversion.

- 2019 Contract Pharmacy Managed Medicaid Duplicate Discount Review: In 2019, Lilly engaged Kalderos, a third-party, to review Managed Medicaid rebate requests from five states (CA, LA, FL, TX and NJ) to identify instances of duplicate 340B discounts for selected covered entities from 2014 to 2018. Kalderos identified approximately $12.4M worth of duplicate discounts related to contract pharmacy utilization in connection with just this small sample.

[33] *Id.* at 44.

The statutory prohibitions against diversion and duplicate discounts are absolute and central to the program. HRSA should not—and manufacturers ought not to be required to—accept, year after year, report after report, and audit after audit, the ongoing violations of the Section 340B prohibitions against diversion and duplicate rebates involving contract pharmacies. Compelling evidence—including in government reports and congressional oversight hearings—demonstrate that the rampant growth of 340B transactions processed at or through contract pharmacies is an intractable problem. We believe that HRSA should, as a consequence, clarify, at a minimum, that manufacturers are not obligated to honor contract pharmacy-related orders for 340B-priced product.

4. The Contract Pharmacy Guidance Should Not Be Relied Upon or Enforced Because It Harms Other Federal and State Healthcare Programs.

There are also various ways in which the 340B Program in general, and contract pharmacies specifically, interfere with other federal healthcare programs.

Lilly has identified, as noted in greater detail above, widespread duplicate Medicaid discounts. Similarly, in January 2020, the Centers for Medicare & Medicaid Services (CMS) acknowledged the problem and noted that the burden of identifying duplicate discounts for contract pharmacy utilization falls onto the states:

> CMS is also aware that some states face challenges with avoiding duplicate discounts on 340B drugs dispensed by 340B contract pharmacies. Contract pharmacies may be unable to prospectively identify claims for 340B purchased drugs before billing states, because the prescriptions are not generally identified as 340B at the point of sale by the 340B covered entity. Collectively, states are responsible for retrospectively identifying claims, which is time consuming, often requires employing the services of contractors, and can be rather complex given the involvement of the number of contract pharmacies.[34]

The administrative burden placed on states and manufacturers to identify and resolve disputes because of the opaque and unreliable nature of contract pharmacy data is costly and time consuming. Moreover, because these disputed Medicaid rebates must be held in abeyance, states are denied Medicaid rebate payments pending resolution of these disputes, a process that can take years.

For example, concerns have been raised about diversion and the fact that contract pharmacies reduce Medicaid rebate payments to California's Medicaid program, Medi-Cal. As a consequence, these concerns have prompted the state's Legislative Analysts to consider whether lawmakers should prohibit or limit the dispensing of 340B drugs to Medi-Cal enrollees at contract pharmacies. The California Governor's 2018-2019 budget proposal sought to eliminate the use of 340B discounts in Medi-Cal and cited challenges in administering the federal Medicaid drug rebate program in conjunction with the 340B program (preventing prohibited duplicate discounts after the fact).[35] Our understanding is that consideration of the proposed prohibition is continuing.

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[34] CMCS Informational Bulletin, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid (Jan. 8, 2020).

[35] The 2018-19 Budget: The Governor's Medi-Cal Proposal for the 340B Drug Pricing Program (Mar. 22, 2018), available at https://lao.ca.gov/reports/2018/3790/medi-cal-340B-032118.pdf.

In addition, with respect to the Medicare Part D program, we note that a 2019 HHS OIG report regarding Medicare Part D Rebates for Prescriptions filled at 340B Contract Pharmacies found that , for just a sample of claims (554,549 reviewed in 2014), manufacturers would have paid rebates of up to $74.7 million more to Part D if those claims had not been 340B eligible. This occurs because manufacturers, under their contracts with Part D plan sponsors, typically are not responsible for Part D rebates on 340B-discounted utilization.[36]

The risks and costs of contract pharmacy business practices to Federal and State healthcare programs further underscore why the Contract Pharmacy Guidance should be rescinded now or, at a minimum, why HRSA should publicly acknowledge that manufacturers have discretion to not follow that Guidance.

5. The Contract Pharmacy Guidance Should Not Be Relied Upon or Enforced Because It Conflicts with Other HRSA Guidance And Does Not Consider Subsequent Developments.

The Contract Pharmacy Guidance was published on March 5, 2010.[37] Although HRSA stated that it considered whether the Contract Pharmacy Guidance imposed additional burdens on manufacturers, HRSA could not have evaluated the impact of the Guidance in light of the Affordable Care Act (ACA), enacted on March 23, 2010, which fundamentally increased the burdens associated with this Guidance.

The ACA included a number of new provisions that subject manufacturers to potential liability for Civil Monetary Penalties (CMPSs) and a "repayment" obligation for mis-stated 340B ceiling prices. By expanding the purchases subject to 340B discount prices, the Contract Pharmacy Guidance imposed additional burdens as a consequence of the ACA provisions. These additional burdens were not contemplated or considered by HRSA when it adopted the Contract Pharmacy Guidance. Since HRSA has not evaluated the Contract Pharmacy Guidance in light of the ACA or the 340B CMP Rule, which became effective January 1, 2019, the Guidance should be rescinded.

HRSA should also rescind the Contract Pharmacy Guidance because it conflicts with other guidance issued by HRSA. Specifically, the Contract Pharmacy Guidance conflicts with both the guidance requiring 340B discounts to be asserted at the time of purchase and the "bill to/ship to" guidance. It is arbitrary and capricious for HRSA to maintain, without explanation, program requirements that are mutually inconsistent.[38]

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[36] A recent settlement also illustrates concerns related to the impact on the Medicare Part D Program. In November 2019, Jewish Hospital and St. Mary's Healthcare Inc., doing business as Pharmacy Plus and Pharmacy Plus Specialty, paid $10 million to settle claims that they overbilled Medicare Part D plans. *See* DOJ, *Kentucky Hospital to Pay over $10 Million to Resolve False Claims Act Allegations* (Nov. 20, 2019), *available at* https://www.justice.gov/opa/pr/kentucky-hospital-pay-over-10-million-resolve-false-claims-act-allegations. The whistleblower complaint in that case included allegations related to a hospital and health center's participation in the 340B program and, in particular, alleged that patients with third party insurance—"frequently including Medicare Part D payers—often paid many multiples of the price paid by 'cash' payers for the same medication." *See United States ex rel. Stone v. Jewish Hosp. & St. Mary's Healthcare, Inc., et al.*, Civil Action No. 3:17-294 (W.D. Ky.). Amended Complaint at 29.

[37] 75 Fed. Reg. 10,272 (March 5, 2010).

[38] *NCTA v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (highlighting that agency is obligated to explain inconsistency in practice under the APA).

We do not believe there is any argument that the contract pharmacy "replenishment" models are consistent with other HRSA guidance. HRSA has clearly said that 340B covered entities "are responsible for requesting 340B pricing at the time of the original purchase."[39] The operation of 340B contract pharmacies contradicts that guidance.

In relevant part, the guidance provides:

> Does HRSA authorize covered entities to retroactively change a previous quarters' transactions from a non-340B transaction into a 340B price transaction . . . ?
>
> HRSA does not authorize covered entities to reclassify a purchase as 340B eligible after the fact. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase. . . .[40]

Despite a clear prohibition on covered entities against reclassifying transactions after the time of purchase, this is exactly how contract pharmacies operate. There are multiple reports and audits that document that contract pharmacy purchases are "replenishment" orders, wherein a contract pharmacy does not assert the 340B price at the time that the product is actually dispensed to the purported 340B patient that receives that product. The assertion of a 340B price comes only many days or weeks or months later.[41] It is illogical that a covered entity would not be permitted to undertake such re-characterizations but that contract pharmacies, on behalf of themselves and/or covered entities, would be.

As discussed earlier in this letter, the contract pharmacy replenishment models also conflict with HRSA "bill to/ship to" guidance, which is explicitly incorporated into the Contract Pharmacy Guidance. These multiple conflicts constitute additional reasons that the Contract Pharmacy Guidance should not be seen as creating a mandate. Indeed, in our view, the Guidance should be rescinded or, at a minimum, clarified to confirm that manufacturers have discretion to not follow it.

* * *

We designate this letter as confidential, proprietary, and reflective of trade secrets. This letter contains confidential commercial and financial information within the meaning of the Freedom of Information Act (FOIA),[42] the relevant Federal criminal statute,[43] the FOIA regulations,[44] and other applicable laws, regulations, or policies. Specifically, this information is subject to exemption from

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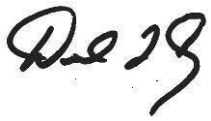
[39] *See* HRSA/OPA 340B FAQs, *at* https://www.hrsa.gov/opa/faqs/index.html (last visited April 21, 2020). HRSA, in its guidance, seems to hold out an exception to this rule where a covered entity notifies a manufacturer and secures the agreement of the manufacturer to the reclassification. Covered entities provide no such notice of contract pharmacy reclassifications, and Lilly would not, in any event, agree to them, as they are contrary to the statute for all the reasons discussed in this letter.
[40] HRSA/OPA 340B FAQs, *at* https://www.hrsa.gov/opa/faqs/index.html (last visited April 21, 2020).
[41] *See, e.g.*, OIG Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions (May 15, 2018); 80 Fed. Reg. 52,300, 52,308 (Aug. 28, 2015).
[42] 5 U.S.C. § 552.
[43] 18 U.S.C. § 1905.
[44] 17 C.F.R. § 200.83.

mandatory disclosure under Exemption 4 of FOIA,[45] and any other exemption applicable by law. Accordingly, we expect this letter and the documents contemplated by this letter will be kept in a non-public file and that HRSA will deny access to them by any unauthorized third person or entity. We also hereby request that your Office, department, and all constituent agencies provide notice to us of any request under FOIA for, or intended FOIA disclosure of, such information, records, or materials. This request is made pursuant to 5 U.S.C. §§ 552(b)(4), (6) & (7); 45 C.F.R. §§ 5.65(d), 5.67 & 5.68; Executive Order 12600; and Attorney General Ashcroft FOIA Memorandum (Oct. 12, 2001), *available at* http://www.justice.gov/archive/oip/foiapost/2001foiapost19.htm. Lilly also requests that reasonably prompt notice be provided to Lilly, at the contact information provided below, of any request by a third party for discovery of this letter, or of any proposal or apparent intention by a third party or your Office, department, or any constituent agency to enter this letter in the public record. We request that such notice be provided reasonably in advance of satisfying any such discovery request or, to the extent possible, that Lilly be enabled to seek confidential treatment of the letter or to seek relief in an appropriate court. These requests do not expire.

Please feel free to contact me at derek.asay@lilly.com directly if you have any questions or need any additional information. Thank you for your attention to this very important matter.

Sincerely,



Derek L. Asay
Senior Director, Government Strategy, Lilly USA

cc: Josh O'Harra, Assistant General Counsel, Eli Lilly and Company

[45] 5 U.S.C. § 552(b)(4).

Exhibit C

From: HRSA 340B Audit
To: Derek L Asay
Cc: Josh Tomas O"Harra
Subject: [EXTERNAL] Response to Derek L Asay - Eli Lilly USA - 00002 - Availability of Cialis-Tadalafil - 06-11-2020
Date: Thursday, June 11, 2020 1:34:09 PM
Attachments: image001.png

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

Mr. Derek L. Asay
Senior Director, Government Strategy
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Dr. Siegel:

The Health Resources and Services Administration (HRSA) is responding to Lilly USA's (Lilly) May 18, 2020, correspondence regarding contract pharmacies in the 340B Drug Pricing Program (340B Program). Many of the arguments advanced in Lilly's letter are not persuasive, and we do not address the arguments here. Our primary point is the importance for manufacturers to observe the guidance so that the program can meet its statutory objectives. Contract pharmacies, which are only a mode for dispensing 340B drugs and not independent covered entities, serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Therefore, HRSA strongly encourages Lilly to reconsider its decision to discontinue contract pharmacy 340B discounts.

Many health centers and other safety net organizations receiving HRSA grants do not have an in-house pharmacy and are able to participate in the 340B Program only through a contract pharmacy. Lilly's position, especially if expanded to other drugs, would have the effect of denying underserved and vulnerable populations served by these covered entities access to 340B discounted drugs. This result would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute. [1] Even for those covered entities with in-house pharmacies, Lilly's refusal to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point obtaining their prescriptions.

While HRSA has published contract pharmacy advice in guidance, rather than through binding regulations, HRSA strongly encourages Lilly to reconsider its position. Lilly's refusal to sell 340B priced drugs to covered entities through contract pharmacy arrangements would have a significant negative impact on the nation's safety net, especially at a time when the health care community is under great pressure to address the current COVID-19 pandemic. We note that the contract pharmacy guidance was issued only after notice and public comment, and that stakeholders had the opportunity to address any concerns about the scope of the guidance before its final adoption.

Lilly indicated in its letter that it considers its letter to be "confidential and proprietary not subject to release or disclosure under FOIA or otherwise." HRSA fails to see any confidential

or proprietary information in the letter. If Lilly believes that portions of its correspondence are confidential or proprietary, please respond with an explanation and reference to the specific portions of the letter that Lilly believes are confidential and proprietary.

Sincerely,

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
Email: 340baudit@hrsa.gov

cc: Josh O'Harra, Assistant General Counsel, Eli Lilly and Company

---

[1] The intent of the 340B Program is to permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. (See: [1] See: H.R. REP No. 102-384(II), at 12 (1992) (Conf. Report).

Exhibit D

From: Derek L Asay
To: Pedley, Krista (HRSA)
Cc: Josh Tomas O"Harra
Subject: RE: Response to Derek L Asay - Eli Lilly USA - 00002 - Availability of Cialis-Tadalafil - 06-11-2020
Date: Friday, June 26, 2020 1:43:57 PM
Attachments: image001.png
Limited Distribution Plan Notice for Cialis July 2020.pdf

Dear RADM Pedley,

As a follow-up to my email below, attached is the posting for publication on the HRSA manufacturer website, to be posted on July 1 but not before. We have provided this posting in an effort to reduce the number of calls or questions HRSA receives on this topic. You will note that we incorporated your suggestion to accommodate covered entities without an in-house pharmacy.

Please let me know if you have any questions.

Thank you
Derek

Derek L. Asay
Senior Director, Government Strategy
Managed Healthcare Services
Lilly USA, LLC
Office: 317-651-0785
Mobile: 908-268-8720
Email: derek.asay@lilly.com | Web: http://www.lilly.com
<image001.jpg>
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From: Pedley, Krista (HRSA) <KPedley@hrsa.gov>
Sent: Thursday, June 18, 2020 5:22 PM
To: Derek L Asay <asay_derek_l@lilly.com>
Cc: Josh Tomas O'Harra <oharra_josh_t@lilly.com>
Subject: [EXTERNAL] RE: Response to Derek L Asay - Eli Lilly USA - 00002 - Availability of Cialis-Tadalafil - 06-11-2020

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening attachments.

Hello and thank you for your response.

HRSA would like to apologize for the error in addressing the letter to someone that does not work for Lilly. HRSA would like to confirm that information has not been shared with any external parties.

Thank you and we look forward to receiving the letter you mention in the email below.

Krista M. Pedley, PharmD, MS
RADM, USPHS

Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, 13N182
Rockville, MD 20857
ph: 301-443-5294
kpedley@hrsa.gov

From: Derek L Asay <asay_derek_l@lilly.com>
Sent: Tuesday, June 16, 2020 7:42 PM
To: HRSA 340B Audit <340baudit@hrsa.gov>; Pedley, Krista (HRSA) <KPedley@hrsa.gov>
Cc: Josh Tomas O'Harra <oharra_josh_t@lilly.com>
Subject: RE: Response to Derek L Asay - Eli Lilly USA - 00002 - Availability of Cialis-Tadalafil - 06-11-2020

Confidential and Proprietary
Not Subject to Release or Disclosure Under FOIA or Otherwise

Dear RADM Pedley,

Thank you for your timely response to Lilly's May 18 letter and for confirming that the contract pharmacy guidance published by HRSA is advice and not a regulation, and thus does not impose binding obligations on manufacturers. Although HRSA encourages Lilly to reconsider, you do not say that we are prohibited from moving forward. And while you express concern about the intent behind the enactment of the 340B statute you do not state that our proposed action would, in fact, violate the statute.

Of course, we take your policy concerns and advice seriously and will explore options for permitting covered entities without in-house pharmacies to identify a contract pharmacy to which Lilly would permit shipment, as a voluntary matter, provided the entity has an actual contract in place with the pharmacy as well as meaningful controls to prevent diversion and duplicate discounts.

As we noted in our letter, we plan to submit a posting for publication on the HRSA manufacturer website to reduce the number of calls or questions HRSA receives on this topic. Since we may yet revise that posting to incorporate your suggestion that we consider accommodating entities without an in-house pharmacy, we will send that shortly and under separate cover. We are considering taking this step as a voluntary matter.

Please permit me to address some other concerns and statements made in your reply.

First, regarding your concern about timing and the ongoing COVID-19 pandemic, Lilly is very much part of the healthcare community dedicated to eradicating COVID-19. We have invested hundreds of millions of dollars developing COVID-19 treatments, including developing two monoclonal antibody treatments already in human trials and testing two other molecules (including one in Phase III) for treatment of COVID-19 induced acute respiratory distress syndrome.

Also, early in the pandemic, Lilly developed at its own expense a highly accurate COVID-19 test and administered these tests for free to front-line healthcare workers and first responders in Indiana. Our process engineers also devised and made available ventilator splitters that allowed ventilators to function on two patients at once.

To respond to the economic consequences of COVID-19, Lilly has also expanded its patient affordability options. For example, we recently announced that anyone who has commercial insurance, or no insurance, can purchase their monthly prescription of Lilly insulin for $35 through the Lilly Insulin Value Program.

To fund the unanticipated innovation needed during this time, we are focused on placing resources to the highest and best use.

Second, you indicated a concern that limiting distribution of erectile dysfunction drugs would deny, "underserved and vulnerable populations served by [...] covered entities access to 340B discounted drugs." The implication is that patients benefit directly from the 340B price. Of course, that is not typically true, particularly with 340B contract pharmacy prescriptions. Instead, contract pharmacies are allowed to generate excessive profits on these products (in some cases charging vulnerable and uninsured patients mark ups of more than 20,000%). We, in turn, make copay cards and patient support programs available in order to ensure, directly, that patients are able to access drugs at an affordable cost. Because of limitations in the structure of the 340B program itself, neither contract pharmacies nor covered entities are under any obligation to use their profits to actually provide services to underserved or vulnerable patients populations.

Particularly in connection with Cialis, which is indicated only for erectile dysfunction and for which numerous generic products are available, we do not believe the decision to provide 340B pricing to covered entities—but not to 340B contract pharmacies—would "deny[] underserved and vulnerable populations . . . access to 340B discounted drugs" or that it would "undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute," as stated in your response dated June 11. Any and all covered entities enrolled and participating in the 340B program will continue to have access to 340B pricing for these products.

Please note we consider this letter and our prior letter, in its entirety, to be subject to FOIA exemption (b)(4). 5 U.S.C. § 552(b)(4) (explaining that FOIA does not apply to "trade secrets and commercial or financial information"). The manner in which we plan to or may distribute our product is commercially sensitive information. The plan that we have communicated is not public and constitutes a trade secret.

As you know from our earlier engagement with HRSA regarding the three NDCs addressed in our May 18 letter, penny-priced Cialis for erectile dysfunction is particularly susceptible to fraudulent "buy ins" by covered entities. This underscores the sensitive nature of the commercial information contained in our May 18 letter and in this email reply. Please let us know if you have already shared part or all of the contents or substance of our May 18 communication externally. We note your response to us was erroneously addressed to someone named "Dr. Seigel", who is not an individual at Lilly. We are concerned that this suggests that HRSA potentially may have been in contact with others regarding our confidential trade secrets.

Again, we appreciate your response. If we have misunderstood your reply in any manner, please inform us immediately, as we will be moving forward soon.

Kind regards,
Derek

Derek L. Asay
Senior Director, Government Strategy
Managed Healthcare Services
Lilly USA, LLC
Office: 317-651-0785
Mobile: 908-268-8720
Email: derek.asay@lilly.com | Web: http://www.lilly.com

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From: HRSA 340B Audit <340baudit@hrsa.gov>

Sent: Thursday, June 11, 2020 2:34 PM

To: Derek L Asay <asay_derek_l@lilly.com>

Cc: Josh Tomas O'Harra <oharra_josh_t@lilly.com>

Subject: [EXTERNAL] Response to Derek L Asay - Eli Lilly USA - 00002 - Availability of Cialis-Tadalafil - 06-11-2020

EXTERNAL EMAIL: Use caution before replying, clicking links, and opening

attachments.

Mr. Derek L. Asay
Senior Director, Government Strategy
Lilly USA, LLC
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Dr. Siegel:

The Health Resources and Services Administration (HRSA) is responding to Lilly USA's (Lilly) May 18, 2020, correspondence regarding contract pharmacies in the 340B Drug Pricing Program (340B Program). Many of the arguments advanced in Lilly's letter are not persuasive, and we do not address the arguments here. Our primary point is the importance for manufacturers to observe the guidance so that the program can meet its statutory objectives. Contract pharmacies, which are only a mode for dispensing 340B drugs and not independent covered entities, serve a vital function in covered entities' ability to serve underserved and vulnerable populations. Therefore, HRSA strongly encourages Lilly to reconsider its decision to discontinue contract pharmacy 340B discounts.

Many health centers and other safety net organizations receiving HRSA grants do not have an in-house pharmacy and are able to participate in the 340B Program only through a contract pharmacy. Lilly's position, especially if expanded to other drugs, would have the effect of denying underserved and vulnerable populations served by these covered entities access to 340B discounted drugs. This result would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute. [1] Even for those covered entities with in-house pharmacies, Lilly's refusal to honor contract pharmacy orders would have the effect of significantly limiting access to 340B discounted drugs for many underserved and vulnerable populations who may reside in geographically isolated areas and rely on a contract pharmacy as a critical point obtaining their prescriptions.

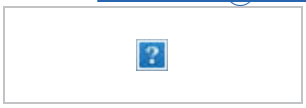
While HRSA has published contract pharmacy advice in guidance, rather than through binding regulations, HRSA strongly encourages Lilly to reconsider its position. Lilly's refusal to sell 340B priced drugs to covered entities through contract pharmacy arrangements would have a significant negative impact on the nation's safety net, especially at a time when the health care community is under great pressure to address the current COVID-19 pandemic. We note that the contract pharmacy guidance was issued only after notice and public comment, and that stakeholders had the opportunity to address any concerns about the scope of the guidance before its final adoption.

Lilly indicated in its letter that it considers its letter to be "confidential and proprietary not subject to release or disclosure under FOIA or otherwise." HRSA fails to see any confidential or proprietary information in the letter. If Lilly believes that portions of its correspondence are confidential or proprietary, please respond with an explanation and reference to the specific portions of the letter that Lilly believes are confidential and proprietary.

Sincerely,

Krista M. Pedley, PharmD, MS

RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
Email: 340baudit@hrsa.gov



cc: Josh O'Harra, Assistant General Counsel, Eli Lilly and Company

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[1] The intent of the 340B Program is to permit covered entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. (See: [1] See: H.R. REP No. 102-384(II), at 12 (1992) (Conf. Report).

Exhibit E

July 17, 2020

BY E-MAIL

Lilly USA, LLC

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Eric Hargan, Esq.
Deputy Secretary of Health and Human Services
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Robert Charrow, Esq.
General Counsel
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

RE: 340B Contract Pharmacy Guidance

Dear Messrs. Hargan and Charrow,

On behalf of Eli Lilly and Company (Lilly), I am writing in response to communications submitted to Secretary Azar regarding Lilly's limited distribution program for Cialis (tadalafil) erectile dysfunction products.[1,2] Under that program, 340B covered entities and child sites receive 340B priced Cialis, but contract pharmacies do not unless an entity lacks an in-house pharmacy, in which case Lilly would voluntarily honor a contract pharmacy relationship. Our decision was arrived at after engagement between Lilly and the Health Resources and Services Administration (HRSA). We request a virtual meeting to discuss this matter with you at your earliest convenience and to identify options for avoiding costly and unnecessary litigation.

I. Background

On July 1, Lilly implemented a program, through wholesalers, to decline 340B contract pharmacy requests to acquire erectile dysfunction (ED) formulations of Cialis at the 340B ceiling price. The rationale for this decision was submitted to HRSA for prior review on May 18, 2020. See Attachment 1. On June 11, HRSA responded by stating that the Contract Pharmacy Guidance (75 Fed. Reg. 10,272 (Mar. 5, 2010)) is "advice" and is not binding on Lilly. HRSA encouraged Lilly to honor the guidance, citing a concern, *inter alia*, that some covered entities lacked an in-house pharmacy. Lilly responded to that communication on June 16 and, in deference to HRSA's concern, revised its proposal to accommodate entities without pharmacies. We submitted public notice of the program for review and posting by HRSA on June 26. We expect that HRSA fully reviewed the issue and its response with HHS before HRSA communicated its final determination to Lilly.

HRSA's determination that the contract pharmacy guidance is not legally binding, coupled with the fact the covered entities and child sites continue to have access to 340B priced product, ensures that Lilly is in compliance with the "must offer" provision and all other relevant aspects of the 340B statute. Lilly has and will continue to offer 340B price product to all 340B covered entities.

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[1] Michelle Stein, "340B Coalition To HHS: Stop Efforts By Lilly, Merck To Limit Discounts," Inside Health Policy. (July 16, 2020).

[2] We have addressed this communication to you because we understand that Secretary Azar has recused himself from matters regarding Eli Lilly and Company.

II. Implications for Federal Healthcare Programs and Patients

HHS is well acquainted with the 340B Program and its impact on the federal program finances.

Medicare Part B: In the 2018 Outpatient Prospective Payment (OPPS) rule, HHS attempted to adjust Medicare Part B reimbursement to 340B providers in acknowledgement of the fact that the standard reimbursement amount, Average Sales Price (ASP) plus 6% (4.3% during sequestration) results in excessive reimbursement on product acquired at a 340B prices and incentives for 340B covered entities to furnish higher priced products in higher cost settings.[3] 340B providers sued HHS to block this rule, as well as other Medicare cost-containment efforts intended to curtail excessive profiteering by hospitals at Medicare's expense.[4]

Medicare Part D: In 2019, the HHS OIG issued a report regarding Medicare Part D Rebates for Prescriptions filled at 340B Contract Pharmacies and found that, for just a sample of claims (554,549 reviewed in 2014), manufacturers would have paid rebates of up to $74.7 million more to Part D if those claims had not been 340B eligible. This occurs because manufacturers, under their contracts with Part D plan sponsors, typically are not responsible for Part D rebates on 340B-discounted utilization.[5] Moreover, as in the Part B context, the opportunity for a significant profit on 340B drugs, has led providers to steer patients to 340B sites of care or 340B product. These discounts covered by the definition of "negotiated price," causing Part D plans to reimburse 340B providers at rates well above their acquisition costs, sometimes fraudulently.[6]

Medicaid: In 2010, lobbyists for 340B covered entities were successful in inserting language in the Medicaid Drug Rebate statute to ensure that the right of 340B covered entities to receive discounts is superior to the right of Medicaid to receive rebates in the context of managed Medicaid utilization. This little noted provision reads:

> (j) Exemption of organized health care settings
>
> (1) Covered outpatient drugs are not subject to the requirements of this section [the Medicaid Drug Rebate statute] if such drugs are—
> (A) dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1396b(m) of this title; and
>
> (B) subject to discounts under section 256b [340B] of this title.

---

[3] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 59216 (Dec. 14, 2017).
[4] See, e.g., "Hospitals Sue HHS Over Negotiated Price Disclosure Rule," citing suits over site neutral payments and 340B payments. https://www.modernhealthcare.com/payment/hospitals-sue-hhs-over-negotiated-price-disclosure-rule (Dec. 4, 2019).
[5] HHS OIG, "Medicare Part D Rebates for Prescriptions Filled at 340B Contract Pharmacies," Report No. A-03-16-00002 (July 2019).
[6] *See* DOJ, *Kentucky Hospital to Pay over $10 Million to Resolve False Claims Act Allegations* (Nov. 20, 2019), *available at* https: //www.justice.gov/opa/pr/kentucky-hospital-pay-over-10-million-resolve-false-claims-act-allegations. (Alleging, for a 340B hospital and health center, that "Medicare Part D payers—often paid many multiples of the price paid by 'cash' payers for the same medication.") *See United States ex rel. Stone v. Jewish Hosp. & St. Mary's Healthcare, Inc., et al.*, Civil Action No. 3:17-294 (W.D. Ky.). Amended Complaint at 29.

42 U.S.C. 1396r-8(j) (brackets added). Given that nearly 70% of Medicaid beneficiaries are enrolled in a managed Medicaid plan, this provision likely results in either billions of dollars being siphoned away from Medicaid or hundreds of millions of dollars in duplicate discounts.[7]

Finally, Lilly conducted a patient survey to ensure that individual or uninsured patient out-of-pocket expenses would not be impacted. Based on that analysis, we believe that it continues to be the case the vast majority of patients only benefit indirectly from 340B profits generated by contract pharmacy utilization. There is no evidence that contract pharmacies are able to identify 340B patients at time of dispense nor are the 340B discounts extended, in whole or in part, to these patients.

III. Lilly's Proposal: Rescind the 2010 Contract Pharmacy Guidance

HHS has been asked by 340B Health and others to deem Lilly's Cialis distribution program a violation of the "must offer" provision. Were HHS to endorse this view, the Agency would be converting the Contract Pharmacy Guidance from an interpretive rule into a statement of law. The result would effectively render a nonbinding sub-regulatory guidance into a binding legislative rule in violation of the Administrative Procedures Act (APA). Any such pronouncement would also be a clear consummation of the Agency's decision-making process, immediately susceptible to a legal challenge.

If HHS takes no action and permits the HRSA interpretation to stand, 340B Health will likely either sue the Agency for withholding action it deems required or sue Lilly under a theory yet developed. In either case, HHS will be drawn into the matter as the underlying validity of the Contract Pharmacy Guidance is litigated.

To avoid litigation, we propose that HHS immediately rescind the Contract Pharmacy Guidance and, if HHS believes there is a statutory basis, to re-issue it as a formal regulation pursuant to notice and comment rulemaking. While we may question HHS's basis for asserting such authority, we believe that this would at least be procedurally consistent with the APA and consistent with recent Executive Orders (13,891 and 13,892) that (1) prohibit treating noncompliance with guidance as a violation unless there is a clear violation of statute or regulations and (2) require agencies to review their guidance documents and to withdraw those that lack the force and effect of law.

***

Lilly has profound concerns about the explosive growth of the 340B program and the lack of oversight and control over contract pharmacies in general. Simply put, it is not sustainable and manufacturers seeking to continue participating in the Medicaid Drug Rebate Program may be pushed out by the unchecked growth in 340B. Please contact me at hakim_anat@lilly.com to arrange for a time to meet to discuss this important issue.

Sincerely,

Anat Hakim
General Counsel, Eli Lilly and Company

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[7] Elizabeth Hinton, et al, 10 Things to Know about Medicaid Managed Care, (Dec. 16, 2019) https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-managed-care/

Attachment 1: Lilly's May 18, 2020 Letter to HRSA

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By E-mail (KPedley@hrsa.gov)

May 18, 2020

Rear Admiral Krista M. Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

RE: Availability of 340B-Priced Cialis® (tadalafil) Erectile Dysfunction Presentations to Contract Pharmacies

Dear RADM Pedley:

Eli Lilly and Company (Lilly) is writing to inform the Health Resources and Services Administration (HRSA) that, effective July 1, 2020, we are instructing wholesalers to discontinue our practice of voluntarily honoring requests for 340B "contract pharmacies" for orders of certain Cialis® (tadalafil) presentations. Unless HRSA objects and states that it believes our proposed discontinuation of voluntary contract pharmacy 340B discounts is unlawful, providing us the reasons for its conclusions, Lilly will no longer honor contract pharmacy-related requests for 340B-priced purchases of the following products after that date: Cialis 10mg (00002-4463-30), Cialis 20 mg (00002-4464-30), and Cialis 2.5mg (00002-4465-34). In addition, and as discussed further below, Lilly is formally challenging HRSA's quarterly listings, which include contract pharmacy listings, pursuant to Section IV(b) of the Pharmaceutical Pricing Agreement (PPA). Under the PPA, we believe HRSA is obligated to respond to this letter.[1]

The presentations of Cialis at issue here are indicated solely for erectile dysfunction and are all available as generic formulations.[2] We are prepared to provide a public letter for posting on the HRSA website describing our discontinuation of voluntary contract pharmacy discounts.

7We believe this action is prudent, reasonable and lawful, particularly in light of the substantial and ongoing expansion of contract pharmacy participation in the 340B program and the now overwhelming evidence demonstrating that contract pharmacy transactions result in 340B duplicate discounts and diversion. Based on these concerns, coupled with the risk that contract pharmacy transactions may be considered a basis a Civil Money Penalties or subject to onerous repayment obligations, Lilly feels compelled to take this action at this time.

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[1] PPA § IV(b).

[2] In prior correspondence to HRSA, we articulated and explained our position, based on applicable statutory provisions, that presentations of Cialis that are indicated solely for erectile dysfunction are not "covered outpatient drugs" for purposes of the Medicaid Drug Rebate Program or the 340B Program and, thus, are not subject to the 340B ceiling price. *See* Lilly Letter to HRSA RE: CIALIS® (TADALAFIL) 340B CEILING PRICING (Mar. 17, 2015). Although we disagree with HRSA's assessment of the concerns we raised in that correspondence, we do not assert it as a basis at this time for our decision to cease voluntarily providing 340B discounts in connection with contract pharmacy purchases.

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We explain, below, why Lilly does not believe 340B-priced purchases for contract pharmacies are consistent with or required by 42 U.S.C. § 256b (Section 340B). HRSA's 340B contract pharmacy guidance, 75 Fed. Reg. 10,272 (Mar. 5, 2010) (Contract Pharmacy Guidance), is inconsistent with the plain language of the statute and has resulted in systematic violations of the core requirements of Section 340B, as reflected in numerous audits and government reports. Further, developments after the issuance of the Contract Pharmacy Guidance demonstrate that the continued, wholesale adoption of the Contract Pharmacy Guidance is deeply flawed as a matter of public policy, both because HRSA has not considered subsequent statutory and regulatory developments and because the Contract Pharmacy Guidance is itself inconsistent with other guidance issued by HRSA. Most fundamentally, however, the Contract Pharmacy Guidance is both procedurally and substantively unlawful. We request that HRSA inform Lilly by June 17, 2020 if it objects to Lilly's proposed course of action.

Specifically, Lilly believes it has discretion to decline Section 340B contract pharmacy orders for at least the following reasons:

1. **Contract Pharmacy Arrangements Violate the Statutory Prohibition Against Diversion.**

The 340B statute is clear: "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***."[3] HRSA's Contract Pharmacy Guidance is inconsistent with this straightforward prohibition. In particular, the Contract Pharmacy Guidance, by its terms, requires the transfer of a drug to a legal person (typically a for-profit pharmacy) that is not a "covered entity" or a "patient."[4]

Clearly, a contract pharmacy is not a "covered entity." The plain language of Section 340B limits a manufacturer's obligation to offer 340B prices to "each covered entity."[5] In defining the term "covered entity," the statute states that it is "an entity" that "is one" of the specified entity types. Contract pharmacies are clearly not one of those "types."

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[3] 42 U.S.C. § 256b(a)(5)(B) (emphasis added).

[4] The term "person" under Section 340B includes legal entities as well as individuals. "Under the Dictionary Act, 'the wor[d] "person" . . . include[s] corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as individuals.'" *Burwell v. Hobby Lobby Stores, Inc*., 134 S. Ct. 2751, 2768 (2014); *see also FCC v. AT&T Inc*., 562 U.S. 397, 404-05 (2011) ("We have no doubt that 'person,' in a legal setting, often refers to artificial entities. The Dictionary Act makes that clear"); *Al Fayed v. CIA*, 229 F. 3d 272, 274 (D.C. Cir. 2000); *Soup, Inc. v. FTC*, 449 F. 2d 1142, 1143 (D.C. Cir. 1971) (per curiam) ("On the contrary, the statutory guidelines for the interpretation of Congressional acts, 1 U.S.C. § 1 (1970), make clear that the term "person" should ordinarily be taken to "include corporations * * * as well as individuals."). Moreover, here, the statutory "context" of Section 340B likewise confirms that the term "person" in the subsection prohibiting the "re[sale] or . . . transfer" of drugs under Section 340B "to a person who is not a patient of the entity" makes unlawful the "resale" or "transfer" of drugs under Section 340B to any non-patient of a covered entity, which necessarily includes ineligible "legal entities" as well as "individuals." 42 U.S.C. § 256b(a)(5)(B). Otherwise, "covered entities" could circumvent the prohibition against the resale or transfer of such drugs by simply transferring them to third party corporations on a wholesale basis. Such a reading would fundamentally undermine the program as designed by Congress and would be entirely inconsistent with the statutory scheme as a whole.

[5] 42 U.S.C. § 256b(a)(1).

Because the entities that Congress expected to participate in the program are listed, specifically, in the definition of "covered entity," the addition of contract pharmacies as a new category of recipients of covered outpatient drugs at 340B discount prices is prohibited.[6] The interpretive canon *expressio unius est exclusio alterius* requires that enumerated statutory lists must be read to exclude entities not expressly included.[7] Accordingly, by permitting contract pharmacies to participate in the program, we are concerned HRSA has exceeded its authority under Section 340B.[8]

HRSA has argued in the past, without statutory support, that contract pharmacies should receive 340B-discounted product because they should be deemed "agents" of covered entities.[9] We do not agree with the premise that contract pharmacies act as "agents" to covered entities. Further, the plain language of the statute forecloses this argument. The statute specifically limits a manufacturer's obligation to offer 340B discounted prices to "each covered entity," not to "each covered entity and its agents." The plain language of the statute defines the term "covered entity" to only mean "an entity" that "is one" of certain specified types. An agent of a covered entity is not the "entity" that "is one of the specified types."

Indeed, the statute *separately* refers repeatedly to numerous agents of different 340B program participants and principals, showing clearly that a reference to the principal is not a reference to the agent. For instance, the statute separately and distinctly refers to "covered entities" and agents of those covered entities, such as "associations or organizations representing the interests of such covered entities."[10] In fact, Section 340B separately refers to other participants and their agents repeatedly.[11]

The plain language of a statute must be read in context.[12] Here, the context shows that Congress identified when the 340B program applied to covered entities and various third parties, including those representing covered entities. Where, as here, Congress referred separately to principals and agents, when included, there is no basis to contend that references to covered entities include contract pharmacies.

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[6] *Id.* § 256b(a)(4).

[7] *See*, *e.g., Ethyl Corp. v. EPA*, 51 F.3d 1053, 1061 (D.C. Cir. 1995) ("[M]ention of one thing implies the exclusion of another thing"); *accord Independent Ins. Agents of America, Inc. v. Hawke*, 211 F. 3d 638, 644 (D.C. Cir. 2000); *American Methyl Corp. v. EPA*, 749 F.2d 826, 835-36 (D.C. Cir. 1984).

[8] This is especially true where contract pharmacies act as both "340B program administrator" and "340B contract pharmacy" for a given entity, suggesting that it is the for-profit commercial pharmacy that is the true beneficiary of the program and the 340B entity is effectively "renting out" its eligibility. https://www.walgreens.com/businesssolutions/payer/340BComplete.jsp.

[9] *See, e.g.*, 61 Fed. Reg. 43549, 43550 (Aug. 23, 1996) (stating "[t]he contract pharmacy would act as an agent of the covered entity").

[10] 42 U.S.C. § 256b(d)(3)(B)(vi) (separately referring to "covered entities" and an agent of those covered entities, "associations or organizations representing the interests of such covered entities").

[11] 42 U.S.C. § 256b(d)(1)(B)(v) (referring separately to "wholesalers" contracted with manufacturers); *id*. § 256b(d)(2)(B)(iii) (referencing "distributors"); *id*. § 256b(d)(3)(B)(iii) (separately referring to manufacturers and "third parties" subject to discovery).

[12] *See Bell Atlantic Tel. Cos. v. FCC*, 131 F.3d 1044, 1047 (D.C. Cir. 1997) ("[T]extual analysis is a language game played on a field known as 'context.' The literal language of a provision taken out of context cannot provide conclusive proof of congressional intent, any more than a word can have meaning without context to illuminate its use. In short, 'the meaning of statutory language, plain or not, depends on context.'").

Congress's intent is all the more clear here. Congress has, over the course of 28 years, amended the 340B statute no fewer than four times, adding four types of covered entities through those amendments. Despite that, Congress has never chosen to recognize or codify HRSA's contract pharmacy guidance or the Agency's position that contract pharmacies may serve as "agents" of covered entities for purposes of 340B discounts.

Given, for all the reasons described above, that a contract pharmacy is not a covered entity, it is equally clear that by the very nature of the way contract pharmacies operate, their use necessarily involves a prohibited "transfer" of 340B discounted product to a non-340B covered entity, the contract pharmacy. As HRSA knows, contract pharmacies are dependent on virtual inventories and retrospective replenishment. These mechanisms necessarily involve a "transfer" of drug products to the contract pharmacies.

Under the "virtual inventory" systems and "retroactive replenishment" models that contract pharmacies use, the contract pharmacies do not segregate 340B inventory from non-340B inventory; rather, they have their own stock of inventory, purport to track dispensed prescriptions through a "virtual" inventory, and then supposedly *retroactively* seek to "replenish" product at 340B pricing for purchases allegedly determined—sometimes weeks or months after they are filled—to have been 340B-eligible. In other words, contract pharmacies dispense drugs *from their own stock*, and then determine later which prescriptions they will assert were 340B-eligible. For those prescriptions, they request—through an entirely retrospective process—replacement product at 340B pricing. The 340B product, which should only be dispensed to 340B patients, is then used, in reality, for non-340B patients.

Thus, these contract pharmacy operations necessarily constitute the transfer of 340B-discounted drugs to non-patients of the covered entity and, accordingly, are statutorily prohibited diversion. Agency guidance and interpretations are invalid and unlawful when they are inconsistent with the controlling statute.[13]

Indeed, the prohibited transfer of 340B product to non-340B patients under the replenishment model is not even consistent with HRSA's own guidance – in addition to its violating the statute. HRSA's "bill to/ship to" requirements are included in the Contract Pharmacy Guidance.[14] Under the "bill to/ship to" model required by HRSA, the covered entity should pay for the product to be used for 340B patients and the manufacturer may be directed to "ship to" the contract pharmacy.[15] Although we believe that this guidance is itself inconsistent with the statute, contract pharmacy transactions cannot be said to comply even with HRSA's existing guidance.

2. The Contract Pharmacy Guidance Is Unlawful, Ultra Vires, and Beyond HRSA's Statutory Authority.

The Contract Pharmacy Guidance results in direct harm to Lilly. By listing contract pharmacies among the entities eligible to obtain product priced at a Section 340B discount, HRSA applies this

[13] *See, e.g.*, *Gonzales v. Oregon*, 546 U.S. 243, 269-75 (2006) (invalidating an interpretive rule regulating medical practice on grounds that the agency interpretation was inconsistent with the controlling statute); *PhRMA v. Dep't of Health & Human Servs.*, 138 F. Supp. 3d 31, 54 (D.D.C. 2015) (invalidating HRSA's orphan drug exclusion "interpretive rule" because it was contrary to the language of Section 340B).
[14] *See* 75 Fed. Reg. at 10,277.
[15] *Id*.

Contract Pharmacy Guidance to Lilly, each quarter.[16] Unless HRSA rescinds the Contract Pharmacy Guidance or clarifies that it permits, but does not obligate, manufacturers to honor contract pharmacy orders, then those quarterly listings will continue to purport to obligate Lilly to provide Section 340B discounts to contract pharmacies, contrary to the statute. For the reasons cited in this letter, Lilly is formally challenging HRSA's quarterly listings pursuant to Section IV(b) of the Pharmaceutical Pricing Agreement (PPA).[17] Under the PPA, HRSA is obligated to respond.[18]

As a result of HRSA's actions, Lilly suffers injury and risk of loss when it provides, as dictated by HRSA, Section 340B discounts to entities that are not entitled to them. Indeed, as described below, the unlawful expansion of Section 340B through the Contract Pharmacy Guidance results in diversion of Section 340B drug sales, duplicate discounts in violation of Congress's commands in Section 340B, and other harm to State and Federal healthcare programs.[19]

To state the basis for our challenge under Section IV(b) of the PPA in greater detail, we believe that the Contract Pharmacy Guidance is ultra vires, beyond HRSA's statutory authority, and issued in violation of the Administrative Procedure Act (APA). The Guidance was not authorized under one of the defined areas for which Congress delegated rulemaking authority to HRSA. In addition, the quarterly listings and underlying Guidance, to the extent they should be interpreted as mandating 340B discounts on contract pharmacy transactions, represent a substantive change in the rights and obligations of affected parties, which HRSA has failed to promulgate by regulation, in violation of the APA. Finally, the guidance and any assertion or enforcement of its purported requirements is incompatible with the President's recent Executive Order and the Department of Justice's Brand Memorandum.

HRSA failed to comply with the APA's requirements for adopting substantive rules when it issued the Contract Pharmacy Guidance. The Contract Pharmacy Guidance is a "substantive," i.e., "legislative," rule because, as a result of it, HRSA "create[d] new law, rights or duties" for regulated parties under the 340B program.[20] Indeed, the Contract Pharmacy Guidance had a substantial "legal effect" on Lilly and other regulated entities because the expansion of Section 340B to include contract pharmacies imposed legal obligations, risks, and burdens on drug manufacturers, as well as on covered entities and contract pharmacies.[21] Thus, despite the label of a "guidance" document and the agency's assertion that the guidance does not create new rights or obligations for regulated

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[16] *See* Pharmaceutical Pricing Agreement, § III(a) ("Pursuant to the requirements under section 340B of the [Public Health Service] Act, the Secretary agrees to the following: (a) to make available a list of covered entities on the HRSA, Office of Pharmacy Affairs web site (http://www.bphc.hrsa.gov/opa/), or otherwise, for access by participating Manufacturers, covered entities, State Medicaid agencies, and the general public. This information will be updated, to the extent practicable, on a quarterly basis"), *available at* https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/pharmaceutical-pricing-agreement-example.pdf.

[17] *See id*. § IV(b) ("The Manufacturer may challenge the presence of an entity on the list of eligible entities issued by the Secretary.")

[18] *Id.*

[19] *See* 42 U.S.C. § 256b(a)(5)(A) ("Prohibiting duplicate discounts or rebates"); *id.* § 256b(a)(5)(B) ("Prohibiting resale of drugs").

[20] *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984) (en banc); *see also Elec. Privacy Info. Ctr. v. U.S. Dep't of Homeland Sec.*, 653 F.3d 1, 6-7 (D.C. Cir. 2011) ("The practical question inherent in the distinction between legislative and interpretive regulations is whether the new rule effects a substantive regulatory change to the statutory or regulatory regime.").

[21] *See PhRMA v. HHS*, 43 F. Supp. 3d at 46 (explaining that agency action is substantive rule where it affects "legal rights").

parties, *see* 75 Fed. Reg. at 10,273, the "guidance" was clearly a substantive rule. The massive growth in the number of contract pharmacies, the corresponding increase in 340B sales attributable to those purchases, and the evidence of diversion and duplicate discounts all underscore the substantive purpose and effect of the "guidance."[22] The fact that these transactions can also serve as a basis for Civil Money Penalties and/or require manufacturer repayments are further evidence that guidance has a substantive purpose and effect.

HRSA, however, did not comply with the procedural requirements that the APA imposes for substantive regulations.[23] In the Contract Pharmacy Guidance, HRSA acknowledged that it was not undertaking the procedure required for a legislative rule, asserting incorrectly that the regulatory action being taken was "exempt from notice and comment rulemaking under the APA."[24]

HRSA did not proceed through a substantive rulemaking, because it could not do so; it had and has no such authority. In *Pharm. Research & Mfrs. of Am. v. Dep't of Health & Human Servs*., 43 F. Supp. 3d 28 (D.D.C. 2014), the district court struck down a regulation adopted by HRSA that purported to implement a statutory provision. In that case, the district court held that HHS lacked authority to engage in such rulemaking. *Id.* at 31, 39. The court explained that HHS's authority to adopt regulations with respect to the 340B program was limited to discrete areas expressly specified in the 340B statute, and the court held that HRSA's limited regulatory authority did not extend to regulations interpreting or implementing the relevant provisions of Section 340B. Thereafter, the district court rejected HHS's effort to readopt the same policy as an interpretive rule. *See also Pharm. Research & Mfrs. of Am. v. Dep't of Health & Human Servs.,* 131 F. Supp. 3d 31 (D.D.C. 2015). Under this precedent, HHS lacks statutory authority to implement the Contract Pharmacy Guidance as it was not issued based on the limited authority provided by Congress.

Executive Order 13891 (Oct. 9, 2019), confirms that HRSA cannot impose substantive obligations on regulated parties through the Contract Pharmacy Guidance and HRSA's retention of the guidance violates the Order. Section 2 of the Executive Order 13891 explains that an agency may not regulate "the public without following the rulemaking procedures of the APA," and that "[e]ven when accompanied by a disclaimer that [the guidance] is non-binding, a guidance document issued by an agency may carry the implicit threat of enforcement action if the regulated public does not comply." In response, the Executive Order directs, among other things, that "it is the policy of the executive branch, to the extent consistent with applicable law, to require that agencies treat guidance documents as non-binding both in law and in practice . . . ."

Additionally, the Department of Justice likewise has confirmed that agency guidance documents may not be used to coerce regulated parties like Lilly into taking action or refraining from taking action beyond what is required by the terms of the applicable law or lawful regulation. *See* Rachel Brand, Associate Attorney General, Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases at 1 (Jan. 25, 2018) ("Brand Memo"). Under the Brand Memo, (1) "Guidance documents cannot create binding requirements that do not already exist by statute or regulation," (2) "the Department may not use enforcement authority to effectively convert agency guidance documents into binding rules," and (3) "noncompliance with guidance documents [should not be used as] a basis for proving violations of applicable law in [affirmative civil enforcement] cases." *Id.* at 2.

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[22] *See* notes 31-32, *supra.*
[23] *See* 5 U.S.C. § 553(b), (c) (setting forth agency obligations for notice-and-comment rulemaking).
[24] 75 Fed. Reg. at 10,273.

In some instances, HRSA representatives have sought to justify its authority to issue the Contract Pharmacy Guidance by stating that Section 340B does not prohibit these arrangements. That analysis ignores, however, that an agency may only exercise authority affirmatively granted by Congress. An unbroken line of D.C. Circuit Court of Appeals cases has steadfastly rejected the notion of "presuming" statutory authority because there is no express statutory prohibition against it.[25] This argument inverts the appropriate analysis. The question is not did Congress prohibit the Agency from taking an action; the question is did Congress specifically authorize that action.

3. The Contract Pharmacy Guidance Should Not Be Relied Upon or Enforced Because It Has Been Shown To Be Inconsistent with the Premise Upon Which It Was Issued.

When HRSA issued guidance permitting covered entities to enter into multiple contract pharmacy arrangements, with no numerical or geographical limitations, it rejected stakeholder concerns that unlimited contract pharmacy arrangements would necessarily result in diversion or statutorily prohibited Medicaid duplicate discounts.[26] In proposing the guidance, HRSA expressly asserted that, "[t]o date, there has been no evidence of drug diversion or duplicate manufacturer's discounts on 340B drugs" related to various contract pharmacy arrangements.[27] But, just as stakeholders feared and predicted, the available evidence makes clear that, as more and more prescriptions have been dispensed through contract pharmacies, diversion and duplicate discounts have resulted. We also are concerned that the breadth of penalties under the CMP Rule, under which HRSA may seek to assess a penalty of up to $5,000 per "instance of overcharge," would be vastly and unlawfully expanded by the inappropriate application of the Contract Pharmacy Guidance.

There are many reasons why the premise for the Guidance—HRSA's assumption that contract pharmacies would not lead to diversion and duplicate discounts—has failed. Unlike in-house pharmacies, contract pharmacies do not possess or have access to the records of the covered entity's patients sufficient to make a "patient" determination (even under the 1996 standards which are often themselves not followed by covered entities[28] or contract pharmacies[29]). Often "patient"

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[25] *See*, *e.g.*, *Aid Ass'n for Lutherans v. USPS*, 321 F.3d 1166, 1174 (D.C. Cir. 2003) (rejecting as "entirely untenable under well-established case law" the argument "that the disputed regulations are permissible because the statute does not expressly foreclose the construction advanced by the agency"); *ExxonMobil Gas Mktg. Co. v. FERC*, 297 F.3d 1071, 1088 (D.C. Cir. 2002) ("We have repeatedly admonished federal agencies that jurisdiction may not be presumed based solely on the fact that there is not an express withholding of jurisdiction."); *Nat'l Mining Ass'n v. U.S. Dep't of Interior*, 105 F.3d 691, 695 (D.C. Cir. 1997) (rejecting the "extreme position" that "because Congress did not specifically preclude" an agency action, the court "should defer to [the agency's] interpretation of the statute"); *Am. Petroleum Inst. v. EPA*, 52 F.3d 1113, 1120 (D.C. Cir. 1995) ("[W]e will not presume a delegation of power based solely on the fact that there is not an express withholding of that power."); *Ethyl Corp. v. EPA*, 51 F.3d 1053, 1060 (D.C. Cir. 1995) ("We refuse ... to presume a delegation of power merely because Congress has not expressly withheld such power.").

[26] 75 Fed. Reg. at 10,273, 10,274 (noting comments raising concerns about diversion by contract pharmacies).

[27] 72 Fed. Reg. 1540, 1540 (Jan. 12, 2007).

[28] *See, e.g.*, *Genesis HealthCare v. Azar* No.:4-19-cv-1531-RBH (D.S.C. Dec. 18, 2019).

[29] *See, e.g.*, GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018) (discussing "identified noncompliance at contract pharmacies," including diversion findings in HRSA audits), *available at* https://www.gao.gov/assets/700/692697.pdf; OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014), at 1-2 ("We found that contract pharmacy arrangements create complications in preventing diversion, and that covered entities are addressing these complications in different ways. . . . In some cases, these different methods lead to differing determinations of 340B eligibility

determinations are adjudicated by contract pharmacies hastily, and/or inconsistently with 340B program standards, on the back end, after insufficient coordination with covered entities and consistent with an improper financial incentive to mischaracterize commercial customers as 340B "patients." Sprawling contract pharmacy networks are major sources of prohibited diversion, despite covered entities' obligations to police and oversee their contract pharmacy relationships.

Oversight agencies, including the Government Accountability Office (GAO) and Health and Human Services Office of Inspector General (HHS OIG), as well as Congressional committees, have all noted that the increased use of contract pharmacies has created substantial drug diversion and duplicate discount issues, problems, and violations. For example:

- 2011 GAO Report: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement: GAO concluded that "[o]perating the 340B program in contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies." GAO further noted the "[i]ncreased use of the 340B program by contract pharmacies and hospitals may result in a greater risk of drug diversion, further heightening concerns about HRSA's reliance on participants' self-policing to oversee the program".[30]

- 2014 HHS OIG Report: Contract Pharmacy Arrangements in the 340B Program: In 2014, HHS OIG reported that contract pharmacies create "complications" in preventing diversion because "some covered entities that do dispense 340B-purchased drugs to Medicaid beneficiaries through their contract pharmacies did not report a method to avoid duplicate discounts." OEI-05-13-00431, at 1–2, *see also id*. at 16. HHS OIG also concluded, quite troublingly, that findings of noncompliance did not lead to HRSA terminating the covered entities' permission to use multiple pharmacy arrangements. *Id*. at 7, 9–15.

- 2018 HHS OIG Testimony: Examining Oversight Reports on the 340B Drug Pricing Program: In its testimony, OIG stated that it "has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements." OIG Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions (May 15, 2018), at 5. OIG further stated that "many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory."

- 2018 GAO Report: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement: In this report, GAO concluded that "[t]he *identified noncompliance* at contract pharmacies raises questions about the effectiveness of covered entities' current oversight practices."[31] For example, GAO found that approximately two-thirds (66 percent) of diversion findings in HRSA audits (from FY 2012 to FY 2017, based on results posted to HRSA's website as of February 2018), "involved drugs distributed at contract pharmacies."[32]

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across covered entities. That is, two covered entities may categorize similar prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) in their contract pharmacy arrangements."), *available at* https://oig.hhs.gov/oei/reports/oei-05-13-00431.pdf.

[30] GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836: Published: Sep 23, 2011. Publicly Released: Sep 23, 2011. https://www.gao.gov/products/GAO-11-836 (emphasis added).

[31] GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, at 44 (June 2018), GAO-18-480, *available at* https://www.gao.gov/assets/700/692697.pdf (emphasis added).

[32] *Id.* at 44 & n. 64.

Despite this significant conclusion, GAO further noted that "the number of contract pharmacy oversight findings may be limited by the fact that officials from HRSA's contractor said that its auditors rely on verbal responses from entity officials about any internal review or self-audits conducted by the entity."[33]

- 2018 House Energy and Commerce Committee Report: Review of the 340B Drug Pricing Program: In 2018, the House Energy and Commerce Committee issued a report echoing the findings of HHS OIG, concluding that contract pharmacy arrangements lead to diversion of 340B drugs. The committee's review of HRSA's audit files revealed that many covered entities have engaged in diversion. Further, in one quarter of the audit files reviewed by committee staff, HRSA recommended that the covered entity improve its oversight of their contract pharmacy arrangement to prevent diversion of 340B drugs at the contract pharmacy. *See* H. Comm. on Energy & Commerce, at 39. The Committee emphasized its concerns by recommending that "[a]ll covered entities should perform independent audits of their contract pharmacies at regular intervals to ensure 340B program compliance." *Id*. at 76. The Committee endorsed auditing by manufacturers to stem unlawful diversions, underscoring how HRSA's limiting the actions that a manufacturer may take to police compliance undermines the program's integrity.

Publicly available audit statistics published by HRSA support these concerns. Notably:

Fiscal Year	Entity Audits	Entities with Contract Pharmacy Adverse Findings (All)	Entities with Contract Pharmacy Adverse Findings (Diversion)
2013	94	31	19
2014	104	45	34
2015	200	92	71
2016	200	77	61
2017	199	81	69
2018	200	64	42
2019	187	52	33

Finally, Lilly's own data demonstrate that contract pharmacies are a frequent source of noncompliance.

- 2013-2020 Analysis of Covered Entity and Contract Pharmacy Self-Disclosures: Over the past seven years, Lilly has received 125 disclosures in which contract pharmacy noncompliance was reported, involving either or both duplicate discounts and diversion.

- 2019 Contract Pharmacy Managed Medicaid Duplicate Discount Review: In 2019, Lilly engaged Kalderos, a third-party, to review Managed Medicaid rebate requests from five states (CA, LA, FL, TX and NJ) to identify instances of duplicate 340B discounts for selected covered entities from 2014 to 2018. Kalderos identified approximately $12.4M worth of duplicate discounts related to contract pharmacy utilization in connection with just this small sample.

[33] *Id.* at 44.

The statutory prohibitions against diversion and duplicate discounts are absolute and central to the program. HRSA should not—and manufacturers ought not to be required to—accept, year after year, report after report, and audit after audit, the ongoing violations of the Section 340B prohibitions against diversion and duplicate rebates involving contract pharmacies. Compelling evidence—including in government reports and congressional oversight hearings—demonstrate that the rampant growth of 340B transactions processed at or through contract pharmacies is an intractable problem. We believe that HRSA should, as a consequence, clarify, at a minimum, that manufacturers are not obligated to honor contract pharmacy-related orders for 340B-priced product.

4. The Contract Pharmacy Guidance Should Not Be Relied Upon or Enforced Because It Harms Other Federal and State Healthcare Programs.

There are also various ways in which the 340B Program in general, and contract pharmacies specifically, interfere with other federal healthcare programs.

Lilly has identified, as noted in greater detail above, widespread duplicate Medicaid discounts. Similarly, in January 2020, the Centers for Medicare & Medicaid Services (CMS) acknowledged the problem and noted that the burden of identifying duplicate discounts for contract pharmacy utilization falls onto the states:

> CMS is also aware that some states face challenges with avoiding duplicate discounts on 340B drugs dispensed by 340B contract pharmacies. Contract pharmacies may be unable to prospectively identify claims for 340B purchased drugs before billing states, because the prescriptions are not generally identified as 340B at the point of sale by the 340B covered entity. Collectively, states are responsible for retrospectively identifying claims, which is time consuming, often requires employing the services of contractors, and can be rather complex given the involvement of the number of contract pharmacies.[34]

The administrative burden placed on states and manufacturers to identify and resolve disputes because of the opaque and unreliable nature of contract pharmacy data is costly and time consuming. Moreover, because these disputed Medicaid rebates must be held in abeyance, states are denied Medicaid rebate payments pending resolution of these disputes, a process that can take years.

For example, concerns have been raised about diversion and the fact that contract pharmacies reduce Medicaid rebate payments to California's Medicaid program, Medi-Cal. As a consequence, these concerns have prompted the state's Legislative Analysts to consider whether lawmakers should prohibit or limit the dispensing of 340B drugs to Medi-Cal enrollees at contract pharmacies. The California Governor's 2018-2019 budget proposal sought to eliminate the use of 340B discounts in Medi-Cal and cited challenges in administering the federal Medicaid drug rebate program in conjunction with the 340B program (preventing prohibited duplicate discounts after the fact).[35] Our understanding is that consideration of the proposed prohibition is continuing.

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[34] CMCS Informational Bulletin, Best Practices for Avoiding 340B Duplicate Discounts in Medicaid (Jan. 8, 2020).

[35] The 2018-19 Budget: The Governor's Medi-Cal Proposal for the 340B Drug Pricing Program (Mar. 22, 2018), available at https://lao.ca.gov/reports/2018/3790/medi-cal-340B-032118.pdf.

In addition, with respect to the Medicare Part D program, we note that a 2019 HHS OIG report regarding Medicare Part D Rebates for Prescriptions filled at 340B Contract Pharmacies found that , for just a sample of claims (554,549 reviewed in 2014), manufacturers would have paid rebates of up to $74.7 million more to Part D if those claims had not been 340B eligible. This occurs because manufacturers, under their contracts with Part D plan sponsors, typically are not responsible for Part D rebates on 340B-discounted utilization.[36]

The risks and costs of contract pharmacy business practices to Federal and State healthcare programs further underscore why the Contract Pharmacy Guidance should be rescinded now or, at a minimum, why HRSA should publicly acknowledge that manufacturers have discretion to not follow that Guidance.

5. The Contract Pharmacy Guidance Should Not Be Relied Upon or Enforced Because It Conflicts with Other HRSA Guidance And Does Not Consider Subsequent Developments.

The Contract Pharmacy Guidance was published on March 5, 2010.[37] Although HRSA stated that it considered whether the Contract Pharmacy Guidance imposed additional burdens on manufacturers, HRSA could not have evaluated the impact of the Guidance in light of the Affordable Care Act (ACA), enacted on March 23, 2010, which fundamentally increased the burdens associated with this Guidance.

The ACA included a number of new provisions that subject manufacturers to potential liability for Civil Monetary Penalties (CMPSs) and a "repayment" obligation for mis-stated 340B ceiling prices. By expanding the purchases subject to 340B discount prices, the Contract Pharmacy Guidance imposed additional burdens as a consequence of the ACA provisions. These additional burdens were not contemplated or considered by HRSA when it adopted the Contract Pharmacy Guidance. Since HRSA has not evaluated the Contract Pharmacy Guidance in light of the ACA or the 340B CMP Rule, which became effective January 1, 2019, the Guidance should be rescinded.

HRSA should also rescind the Contract Pharmacy Guidance because it conflicts with other guidance issued by HRSA. Specifically, the Contract Pharmacy Guidance conflicts with both the guidance requiring 340B discounts to be asserted at the time of purchase and the "bill to/ship to" guidance. It is arbitrary and capricious for HRSA to maintain, without explanation, program requirements that are mutually inconsistent.[38]

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[36] A recent settlement also illustrates concerns related to the impact on the Medicare Part D Program. In November 2019, Jewish Hospital and St. Mary's Healthcare Inc., doing business as Pharmacy Plus and Pharmacy Plus Specialty, paid $10 million to settle claims that they overbilled Medicare Part D plans. *See* DOJ, *Kentucky Hospital to Pay over $10 Million to Resolve False Claims Act Allegations* (Nov. 20, 2019), *available at* https://www.justice.gov/opa/pr/kentucky-hospital-pay-over-10-million-resolve-false-claims-act-allegations. The whistleblower complaint in that case included allegations related to a hospital and health center's participation in the 340B program and, in particular, alleged that patients with third party insurance—"frequently including Medicare Part D payers—often paid many multiples of the price paid by 'cash' payers for the same medication." *See United States ex rel. Stone v. Jewish Hosp. & St. Mary's Healthcare, Inc., et al.*, Civil Action No. 3:17-294 (W.D. Ky.). Amended Complaint at 29.

[37] 75 Fed. Reg. 10,272 (March 5, 2010).

[38] *NCTA v. Brand X Internet Servs.*, 545 U.S. 967, 981 (2005) (highlighting that agency is obligated to explain inconsistency in practice under the APA).

We do not believe there is any argument that the contract pharmacy "replenishment" models are consistent with other HRSA guidance. HRSA has clearly said that 340B covered entities "are responsible for requesting 340B pricing at the time of the original purchase."[39] The operation of 340B contract pharmacies contradicts that guidance.

In relevant part, the guidance provides:

> Does HRSA authorize covered entities to retroactively change a previous quarters' transactions from a non-340B transaction into a 340B price transaction . . . ?
>
> HRSA does not authorize covered entities to reclassify a purchase as 340B eligible after the fact. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase. . . .[40]

Despite a clear prohibition on covered entities against reclassifying transactions after the time of purchase, this is exactly how contract pharmacies operate. There are multiple reports and audits that document that contract pharmacy purchases are "replenishment" orders, wherein a contract pharmacy does not assert the 340B price at the time that the product is actually dispensed to the purported 340B patient that receives that product. The assertion of a 340B price comes only many days or weeks or months later.[41] It is illogical that a covered entity would not be permitted to undertake such re-characterizations but that contract pharmacies, on behalf of themselves and/or covered entities, would be.

As discussed earlier in this letter, the contract pharmacy replenishment models also conflict with HRSA "bill to/ship to" guidance, which is explicitly incorporated into the Contract Pharmacy Guidance. These multiple conflicts constitute additional reasons that the Contract Pharmacy Guidance should not be seen as creating a mandate. Indeed, in our view, the Guidance should be rescinded or, at a minimum, clarified to confirm that manufacturers have discretion to not follow it.

* * *

We designate this letter as confidential, proprietary, and reflective of trade secrets. This letter contains confidential commercial and financial information within the meaning of the Freedom of Information Act (FOIA),[42] the relevant Federal criminal statute,[43] the FOIA regulations,[44] and other applicable laws, regulations, or policies. Specifically, this information is subject to exemption from

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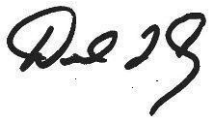
[39] *See* HRSA/OPA 340B FAQs, *at* https://www.hrsa.gov/opa/faqs/index.html (last visited April 21, 2020). HRSA, in its guidance, seems to hold out an exception to this rule where a covered entity notifies a manufacturer and secures the agreement of the manufacturer to the reclassification. Covered entities provide no such notice of contract pharmacy reclassifications, and Lilly would not, in any event, agree to them, as they are contrary to the statute for all the reasons discussed in this letter.
[40] HRSA/OPA 340B FAQs, *at* https://www.hrsa.gov/opa/faqs/index.html (last visited April 21, 2020).
[41] *See, e.g.*, OIG Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions (May 15, 2018); 80 Fed. Reg. 52,300, 52,308 (Aug. 28, 2015).
[42] 5 U.S.C. § 552.
[43] 18 U.S.C. § 1905.
[44] 17 C.F.R. § 200.83.

mandatory disclosure under Exemption 4 of FOIA,[45] and any other exemption applicable by law. Accordingly, we expect this letter and the documents contemplated by this letter will be kept in a non-public file and that HRSA will deny access to them by any unauthorized third person or entity. We also hereby request that your Office, department, and all constituent agencies provide notice to us of any request under FOIA for, or intended FOIA disclosure of, such information, records, or materials. This request is made pursuant to 5 U.S.C. §§ 552(b)(4), (6) & (7); 45 C.F.R. §§ 5.65(d), 5.67 & 5.68; Executive Order 12600; and Attorney General Ashcroft FOIA Memorandum (Oct. 12, 2001), *available at* http://www.justice.gov/archive/oip/foiapost/2001foiapost19.htm. Lilly also requests that reasonably prompt notice be provided to Lilly, at the contact information provided below, of any request by a third party for discovery of this letter, or of any proposal or apparent intention by a third party or your Office, department, or any constituent agency to enter this letter in the public record. We request that such notice be provided reasonably in advance of satisfying any such discovery request or, to the extent possible, that Lilly be enabled to seek confidential treatment of the letter or to seek relief in an appropriate court. These requests do not expire.

Please feel free to contact me at derek.asay@lilly.com directly if you have any questions or need any additional information. Thank you for your attention to this very important matter.

Sincerely,



Derek L. Asay
Senior Director, Government Strategy, Lilly USA

cc: Josh O'Harra, Assistant General Counsel, Eli Lilly and Company

[45] 5 U.S.C. § 552(b)(4).

Exhibit F

Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

By E-mail (KPedley@hrsa.gov)

August 19, 2020

Rear Admiral Krista M. Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

RE: Availability of 340B-Priced Products to Contract Pharmacies

Dear RADM Pedley:

Eli Lilly and Company (Lilly) is writing to inform the Health Resources and Services Administration (HRSA) that, effective September 1, we have instructed wholesalers to discontinue our practice of voluntarily honoring requests for 340B "contract pharmacies" for orders on all Lilly products except where Lilly has approved an exception that (1) a covered entity does not have an in-house pharmacy and/or (2) for certain insulins, if the 340B discounted price is passed on to the patient. Unless HRSA objects and states that it believes our proposed discontinuation of voluntary contract pharmacy 340B discounts is unlawful by August 31, providing us the reasons for its conclusions, Lilly will no longer honor contract pharmacy-related requests for Lilly products (labeler codes 00002, 00777, and 66173), subject to the exceptions above.

As we explained in our May 18, 2020 letter to you, we believe this action is prudent, reasonable and lawful, particularly in light of the substantial and ongoing expansion of contract pharmacy participation in the 340B program and the now overwhelming evidence demonstrating that contract pharmacy transactions result in 340B duplicate discounts and diversion. Based on these concerns, coupled with the risk that contract pharmacy transactions may be incorrectly considered a basis for Civil Money Penalties or incorrectly subject us to onerous repayment obligations, Lilly feels compelled to take this additional action at this time.

In discussing our plan with respect to the Cialis products, HRSA concluded that its Contract Pharmacy Guidances were non-binding and that our plan did not give rise to any enforceable violation of the 340B statute. Indeed, in our view, contract pharmacy transactions constitute prohibited diversion and lead to duplicate discounts in violation of the statute. We believe that the legal analyses performed previously by HRSA and Lilly apply equally here.

I. The Insulin Exception and Lilly's Commitment to Transparency with HRSA

On July 24, the President signed Executive Order 13,937, "Access to Affordable Life-saving Medications." That order instructs the Secretary of Health and Human Services (HHS) to condition federal grant eligibility for federally qualified health centers (FQHCs) on an FQHC's commitment to pass on the 340B ceiling price to vulnerable patients. Lilly supports this goal. As the Executive Order states, insulin is a critical and lifesaving medication and many insulins "are subject to the

'penny pricing' policy when distributed to FQHCs, meaning FQHCs may purchase the drug at a price of one penny per unit of measure. These steep discounts, however, are not always passed through to low-income Americans at the point of sale. Those with low-incomes can be exposed to high insulin and injectable epinephrine prices…."

We applaud the Administration's concern with how discounts provided by pharmaceutical manufacturers are consumed by intermediaries and are not passed on to patients. And, unlike the Administration, which is legally more constrained than a manufacturer who voluntarily seeks to extend the 340B price through a contract pharmacy, Lilly can apply this HHS policy more broadly.

To that end, and for the reasons set forth below, Lilly will grant an exception to our contract pharmacy limited distribution program for certain Lilly insulin products (NDCs attached) to any 340B contract pharmacy that agrees to the following:

- Any and all 340B eligible patients will be able to acquire their Lilly insulins through the contract pharmacy at the 340B price (typically $.03 per 3 mL pen or $.10 per 10 mL vial) at the point-of-sale.

    - Rationale: This is consistent with the approach set forth in the recent Executive Order. We appreciate that most contract pharmacies currently may not identify 340B eligible patients at that point-of-sale, choosing instead to identify these patients retrospectively. However, retroactive determinations are inconsistent with HRSA's expectations in both 1996 and 2010 Contract Pharmacy Guidance documents. Both of those guidances suggested that the following "contract provisions" be included in the agreements with the contract pharmacy:

> The pharmacy will dispense Covered drugs only in the following circumstances: (a) Upon presentation of a prescription bearing the covered entity's name, the eligible patient's name, a designation that the patient is an eligible patient of the covered entity, and the signature of a legally qualified health care provider affiliated with the covered entity; or (b) receipt of a prescription ordered by telephone or other means of electronic transmission that is permitted by State or local law on behalf of an eligible patient by a legally qualified health care provider affiliated with the covered entity who states that the prescription is for an eligible patient.[1]

While we agree these guidances are not legally binding, we assume that HRSA based its position, at least in part, on the fact that identification of 340B patients at the point-of-sale was, and remains, a critical safeguard to prevent duplicate discounts and diversion. It appears that covered entities and contract pharmacies have ignored this expectation from the outset. Given the growth in contract pharmacies and the well-documented non-compliance referenced in our May 18, 2020 letter, we believe that this is a reasonable condition to qualify for the insulin exception.

[1] 61 Fed. Reg. 43553 (Aug. 23, 1996) and 75 Fed. Reg. 10279 (Mar. 5, 2010); as we also noted in our May 18 letter, HRSA has elsewhere advised against covered entities retroactively reclassifying. *See* HRSA/OPA 340B FAQs, *at* https://www.hrsa.gov/opa/faqs/index.html (last visited August 11, 2020).

- Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing or any administration fee for the Lilly insulin.
    - Rationale: Just as Lilly does not seek to recoup the cost to manufacture or distribute penny priced insulins when they are sold to 340B covered entities, covered entities and their contract pharmacies seeking to obtain this exception we would expect covered entities and contract pharmacies to be willing to dispense the product free of charge.
- No insurer or payer is billed for the Lilly insulin dispensed.
    - Rationale: To avoid overcharges by 340B entities to federal or commercial payers, as well as to facilitate the avoidance of duplicative Medicaid rebates claims, Lilly believes that no third party should be billed for insulins dispensed under this exception.
- The covered entity provides claim-level detail (CLD) for their contract pharmacy(s) to Lilly so that we can validate that the foregoing conditions have been satisfied.
    - Rationale: Several other manufacturers have recently started requesting or requiring CLD from covered entities for their contract pharmacies. As these data should be both readily available and sufficient to confirm that the terms of our voluntary exception have been met, Lilly would seek this documentation.

Lilly shares the Administration's goal of ensuring that 340B patients should directly benefit from the significant 340B discounts on Lilly insulins. Lilly will provide quarterly reports (or more frequently, if requested) regarding covered entity use of the two exceptions provided for under our policy.

Attached please find an updated Limited Distribution Notice for posting on the manufacturer notices website on September 1, 2020. Please note that this updated notice is intended to replace the Cialis Limited Distribution Notice which was effective July 1, 2020. If you have questions or comments related to this proposed notice, please do not hesitate to contact me.

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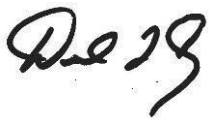
Please feel free to contact me at derek.asay@lilly.com directly if you have any questions or need any additional information. Thank you for your attention to this very important matter.

Sincerely,



Derek L. Asay
Sr. Director, Government Strategy

Exhibit G

Limited Distribution Plan Notice for Eli Lilly and Company Products

This notice provides information to 340B eligible covered entities seeking to purchase any product manufactured or distributed by Eli Lilly and Company or its subsidiaries and affiliates (labeler codes 00002, 00077, and 66713).Effective September 1, 2020, Lilly is limiting distribution of all 340B ceiling priced product directly to covered entities and their child sites only. Covered Entities will not be eligible to purchase Eli Lilly and Company products at the 340B ceiling price for shipment to a contract pharmacy.

Covered entities that do not have an in-house pharmacy may contact 340B@lilly.com regarding the exception process to designate a contract pharmacy location.

Special Exception for Insulins: Contract Pharmacies that Pass on 340B Discounts

Consistent with the spirit of Executive Order 13,937, "Access to Affordable Life-saving Medications" (July 24, 2020), Lilly will grant an exception to the limited distribution program described above for Lilly insulin products (NDCs attached) subject to a 340B covered entity and their contract pharmacys' ability to ensure that the following conditions are met:

- Any and all 340B eligible patients will be able to acquire their Lilly insulins through the contract pharmacy at the 340B price (typically $.03 per 3 mL pen or $.10 per 10 mL vial) at the point-of-sale;

- Neither the covered entity nor the contract pharmacy marks-up or otherwise charges a dispensing fee for the Lilly insulin;

- No insurer or payer is billed for the Lilly insulin dispensed; and,

- The covered entity provides claim-level detail (CLD) demonstrating satisfaction of these terms and conditions.

Lilly shares the goal of ensuring that 340B patients directly benefit from the significant 340B discounts on Lilly insulins.

To take advantage of this exception for insulins contact 340B@lilly.com. Please be prepared to submit documentation demonstrating that the conditions set forth above will be satisfied. Lilly is committed to compliance with the 340B statute and to responsible distribution of its products. If you have any questions regarding this notice please contact Lilly at 340B@lilly.com.

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Special Exception for Insulins:
Contract Pharmacies that Pass on 340B Discounts Applicable NDCs

NDC	Brand Name	Product Description
00002-7510-01	HUMALOG	HUMALOG 100UCD 10.000000 MML
00002-7510-17	HUMALOG	HUMALOG 100UCD 3 MILLILITER
00002-7516-59	HUMALOG	HUMALOG CARTRIDGE 100UCD 15.000000 MML
00002-7714-59	HUMALOG	HUMALOG JR KWIKPEN 100UCD 15 MILLILITER
00002-8799-59	HUMALOG	HUMALOG KWIKPEN 100UCD 15 MILLILITER
00002-7511-01	HUMALOG	HUMALOG MIX 75/25 100UCD 10 MILLILITER
00002-7512-01	HUMALOG	HUMALOG MIX50/50 100UCD 10 MILLILITER
00002-8798-59	HUMALOG	HUMALOG MIX50/50 KWIKPEN 100UCD 15 MILLILITER
00002-8797-59	HUMALOG	HUMALOG MIX75/25 KWIKPEN 100UCD 15 MILLILITER
00002-8824-27	HUMULIN R U500	HUMULIN 500 UCD 6.000000 MILLILITER
00002-8501-01	HUMULIN R U500	HUMULIN R 500UCD 20 MILLILITER
00002-7737-01	INSULIN LISPRO	INSULIN LISPRO 100 UCD 10.000000MILLILITER
00002-7752-05	INSULIN LISPRO	INSULIN LISPRO KWIKPEN JR 100UCD 15 MILLILITER
00002-8222-59	INSULIN LISPRO	INSULIN LISPRO KWIKPEN 100UCD 15.000000 MILLILITER
00002-8233-05	INSULIN LISPRO	INSULIN LISPROMIX75/25 KWIKPEN 100UCD 15 MILLILITER
66733-0773-01	INSULIN LISPRO	INSULIN LISPRO 100 UCD 10.000000 MILLILITER
66733-0822-59	INSULIN LISPRO	INSULIN LISPRO 100 UCD 15.000000 MILLILITER

Exhibit H

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

August 26, 2020

Mr. Derek L. Asay
Senior Director, Government Strategy
Lilly USA, LLC
Lilly Corporate Center
893 Delaware St
Indianapolis, Indiana 46285

Dear Mr. Asay:

This is in response to your letters of May 18, 2020, and August 19, 2020. In your May 18 letter, you indicated the Lilly USA ("Lilly") would cease selling the drug Cialis at the section 340B ceiling price to pharmacies operating under contract with a covered entity unless the covered entity lacked an in-house pharmacy, in which case Lilly would offer the ceiling price to one contract pharmacy. In your August 19 letter, you indicated that Lilly was planning to extend this policy to all of its drugs.

HRSA is considering whether your new proposed policy constitutes a violation of section 340B and whether sanctions apply. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to 42 U.S.C. § 256b(d)(1)(B)(vi).

Lilly claims that HRSA concluded that Lilly's plan "did not give rise to any enforceable violation of the 340B statute." That is not correct. In fact, in HRSA's response letter dated June 11, 2020, HRSA expressed its concern that the plan would undermine the entire 340B Program and the Congressional intent behind enactment of the 340B statute. HRSA encouraged Lilly to reconsider its decision to restrict access to 340B drugs and HRSA warned Lilly of the plan's impact on underserved and vulnerable populations.

Under 42 U.S.C. § 256b(a)(1), manufacturers must offer covered entities outpatient drugs at specified prices. HRSA continues to examine whether Lilly's actions amount to attempts to circumvent that statutory requirement by inappropriately restricting access to 340B drugs for at least some covered entities.

We understand that Lilly's rationale is its concern that distribution to contract pharmacies can lead to duplicate discounts and diversion. To the extent that Lilly has evidence of specific duplicate-discount and diversion violations, please share that evidence, including the alleged covered entities and drugs involved.

HRSA will respond to your other requests as quickly as possible. However, given the urgent demands of the COVID-19 pandemic and other demands, HRSA may not be in a position to respond by your requested date.

Sincerely,

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration

Exhibit I

Lilly USA, LLC

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www.lilly.com

By E-mail (KPedley@hrsa.gov)

August 27, 2020

Rear Admiral Krista M. Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

RE: Response to Derek Asay - Eli Lilly - 08-26-2020

Dear RADM Pedley:

We are troubled by the tone and substance of your response. As we now understand it, HRSA is, and has been for over three (3) months, considering whether to apply sanctions, including possible civil monetary penalties, against Lilly.

As an initial matter, nothing in the Contract Pharmacy Guidance is binding on manufacturers such as Lilly, as HRSA has repeatedly made clear. To the extent you now mean to suggest otherwise, that would be inconsistent with your prior statements to Lilly, 340B Health and to the media. More fundamentally, HRSA has still failed to identify a specific violation of the 340B statute resulting from the Cialis Limited Distribution Plan or an expansion of that plan—and with good reason, there is none. As HRSA knows well, we are continuing to offer all covered entities – and their child sites – access to 340B discounts. That is all the statute requires.

We do not take threats of sanctions lightly. Nor do we appreciate the gamesmanship you appear to be engaged in—threatening potential sanctions if Lilly does not voluntarily acquiesce, but failing to take a position on how or why the 340B statute would be violated, in an attempt to avoid finality (and with it, judicial review).

We ask that you confirm by August 31st that nothing in the 340B statute prohibits the Cialis Limited Distribution Plan or an expansion of that plan. If it is the agency's position that there is a violation of the statute, then please identify with specificity the agency's grounds for that position.

In terms of providing evidence of diversion and duplicate discounts, we believe our May 18 letter adequately addresses that issue. In short, contract pharmacy relationships constitute per se diversion; in the alternative, HRSA's ample audit record, the 125 self-disclosures to Lilly, and the findings by HHS OIG and GAO should be sufficient to put you on notice that diversion and duplicate discounts are widespread.

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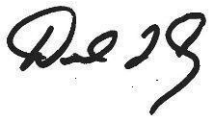
NOT SUBJECT TO RELEASE OR DISCLOSURE UNDER FOIA OR OTHERWISE

I look forward to hearing from you soon. Thank you in advance for your prompt attention to this request.

Sincerely,



Derek L. Asay
Sr. Director, Government Strategy

CONFIDENTIAL AND PROPRIETARY
NOT SUBJECT TO RELEASE OR DISCLOSURE UNDER FOIA OR OTHERWISE

Exhibit J

Lilly USA, LLC

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September 8, 2020

BY E-MAIL

Eric D. Hargan, Esq.
Deputy Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Robert Charrow, Esq.
General Counsel
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

RE: 340B Contract Pharmacy Guidance Update

Dear Deputy Secretary Hargan and General Counsel Charrow:

Further to our letter of July 17, 2020, and in light of Administrator Paul J. Ray's August 31 Memorandum for the Deputy Secretaries of Executive Agencies and Departments, I am writing to request a virtual meeting with you and confirmation that HHS is not considering, and will not consider, sanctions against Lilly in response to Lilly's stated plan to discontinue providing 340B discounts to contract pharmacies.

I. HRSA Approved Lilly's Efforts To Halt Contract Pharmacy Diversion, But Then Threatened Lilly With Sanctions.

Effective July 1, 2020, Lilly instructed its wholesalers to discontinue providing 340B discounts to contract pharmacies for certain formulations of Cialis® (tadalafil). As Lilly explained to the Health Resources and Services Administration (HRSA) back in May of this year, providing 340B discounts to contract pharmacies is neither consistent with nor required by Section 340B of the Public Health Service Act, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967–71 (1992).

When Lilly first explained its position, HRSA identified nothing unlawful or improper about it. In fact, HRSA responded by confirming that "contract pharmacies" "are not independent covered entities" under the 340B statute, and that HRSA's "contract pharmacy advice"—the 2010 Contract Pharmacy Guidance—constituted mere "guidance," and "not binding regulations." Consistent with that view, HRSA did not state that Lilly's Cialis® limited distribution plan was unlawful. Lilly followed up with HRSA on June 16, 2020, outlining its understanding that HRSA "did not say that [Lilly is] prohibited from moving forward" or

"that [Lilly's] proposed action would, in fact, violate the statute," and asking HRSA to correct any misinterpretation by Lilly. HRSA never suggested that Lilly had somehow misunderstood HRSA's position on the issue. Instead, when it wrote back to Lilly on June 18, 2020, HRSA stated merely that it "look[ed] forward to receiving" Lilly's manufacturer notice announcing its Cialis® limited distribution plan for posting on the HRSA website.

Consistent with HRSA's instructions, Lilly provided the published notice on June 26, 2020, and again invited HRSA to raise any questions it might have. HRSA responded on June 29, 2020, stating it did "not have any further questions at this time." HRSA thereafter posted Lilly's notice on its 340B Program website on July 1, 2020, without any further objection. Days later, HRSA again confirmed publicly that the 2010 Contract Pharmacy Guidance is not binding, telling the *340B Report* publication that "guidance is not legally enforceable."

On August 19, 2020, with the transition for the Cialis® products underway, Lilly informed HRSA that it would extend its approach to all of Lilly's covered outpatient drugs under the 340B Program by "discontinu[ing] [its] practice of voluntarily honoring requests for 340B 'contract pharmacies' for orders on all Lilly products." Lilly also explained that it was voluntarily creating a new exception for insulin patients under the expansion, whereby a covered entity could use a contract pharmacy so long as the contract pharmacy provided the entire 340B discount to the insulin patient. Lilly also notified HRSA of its plan to extend the exception for a single contract pharmacy relationship for covered entities that have no in-house pharmacy.

Lilly based this insulin exception on an Executive Order the President issued on July 24, 2020, instructing HHS to ensure that future grants available to Federally Qualified Health Centers (FQHCs) be conditioned on making insulin and injectable epinephrine available to patients at the 340B-discounted price. *See* Executive Order on Access to Affordable Life-saving Medications (July 24, 2020), available at https://www.whitehouse.gov/presidential-actions/executive-order-access-affordable-life-saving-medications/. The Executive Order echoes key concerns that many stakeholders have expressed about the 340B program—namely, that "steep [340B] discounts … are not always passed through to low-income Americans at the point of sale," and that "[t]hose with low-incomes can be exposed to high insulin and injectable epinephrine prices, as they often do not benefit from discounts negotiated by insurers or the Federal or State governments." *Id.*

Lilly closed its August 19 letter by (1) reiterating that, in its prior correspondence regarding the plan for Cialis®, HRSA had confirmed that the 2010 Contract Pharmacy Guidance was non-binding; and (2) emphasizing that "the legal analyses performed previously by HRSA and Lilly apply equally here." As it had when it provided notice of its Cialis® program, Lilly also provided HRSA an opportunity to object to Lilly's plan and to explain its reasoning by August 31, 2020.

On August 26, 2020, HRSA responded by threatening Lilly with potential sanctions, including "civil monetary penalties pursuant to 42 U.S.C. § 256(d)(1)(B)(vi)," if Lilly implemented its limited distribution plan. Equally troubling, HRSA's August 26 threat

letter purported to respond not just to Lilly's August 19 letter, but also to the original Cialis® program letter from back in May, even though HRSA's correspondence for that initial program ended *more than a month earlier* with it stating it did "not have any further questions."

Lilly is extremely troubled by this response. Given the seriousness of HRSA's threat, Lilly responded within a day to reiterate its position that the limited distribution program for Cialis® and the planned expansion of that program to other covered outpatient drugs did not violate the 340B Statute. Lilly also highlighted the imminent harm resulting from HRSA's "threats of sanctions" designed to force Lilly to acquiesce to HRSA's position. Lilly thus requested that HRSA "confirm by August 31st that nothing in the 340B statute prohibits the Cialis Limited Distribution Plan or an expansion of that plan," and that if HRSA believes that there is a "violation of the statute, then please identify with specificity the agency's grounds for that position."

Despite the urgency of the situation, HRSA has not responded directly to Lilly's letter. Instead, HRSA went to the media to reiterate its threat, telling the *340B Health* publication it was "considering whether manufacturer policies, *including Lilly's*, violate the 340B statute and whether sanctions may apply."

II. Any Effort To Sanction Lilly For Discontinuing Its Practice Of Honoring 340B Discounts For Contract Pharmacies Is Inconsistent With The 340B Statute Itself And Would Run Afoul Of Administrator Ray's August 31 Memorandum.

On August 31, 2020, the Administrator of the Office of Information and Regulatory Affairs (OIRA) issued a memorandum to the Deputy Secretaries of Executive Agencies and Departments outlining "best practices" for agencies and departments. Any effort to impose sanctions on Lilly in response to Lilly's limited distribution plan not only would exceed agency authority under the 340B statute but would flout the letter and the spirit of Administrator Ray's recent memorandum.

First, consistent with our constitutional separation of powers, the August 31 Memorandum makes clear that "[t]he Government should bear the burden of proving an alleged violation of law" and should not require regulated entities "to prove a negative to prevent liability and enforcement consequences in the absence of statutory standards requiring otherwise." That alone suffices to preclude any effort to impose sanctions on Lilly in response to Lilly's limited distribution plan. After all, despite being given ample notice of Lilly's plan and multiple opportunities to state that Lilly's plan would violate any statutory standard, HRSA spent months *acceding to Lilly's position* that ceasing to provide 340B discounts for contract pharmacies is entirely lawful. For good reason: the plain text and structure of the 340B statute confirm that HRSA has no authority to require manufacturers to provide 340B discounts to contract pharmacies. The statute enumerates 15 different categories of entities that can qualify as "covered entities" eligible for discounts under the 340B Program—but contract pharmacies explicitly *do not make the list*. *See* 42 U.S.C. § 256b(a)(4)(A)–(O). To bring an enforcement action against Lilly would thus seek to

impose penalties for violating a statutory standard that does not exist and would turn the separation-of-powers principles animating this first "best practice" on their head.

Second, under the August 31 Memorandum, "[p]enalties should be proportionate, transparent, and imposed in adherence to consistent standards and only as authorized by law." The only consistent and transparent standard HRSA articulated here, however, is one wholly incompatible with bringing an enforcement action against Lilly. Throughout 2020, HRSA left no doubt that contract pharmacies are *not* covered entities under the 340B statute, and made equally clear that any guidance instructing otherwise was "not binding" on regulated entities. Nor could it have reasonably argued otherwise. Again, the 340B statute painstakingly enumerates 15 categories of entities that are eligible for 340B discounts, and conspicuously omits contract pharmacies. The only potential argument HRSA could make in support of its recent threat is that there is no express statutory prohibition against requiring manufacturers to provide discounts to contract pharmacies. But that argument would turn basic principles of administrative law upside down, and violate decades of D.C. Circuit precedent making clear that an administrative agency may not presume authority from the lack of an express prohibition, particularly when (as here) the statute authorizing a practice does so in a carefully reticulated and limited manner.

Third, the August 31 Memorandum mandates that "[a]dministrative enforcement … be prompt and fair" and requires agencies to take account of "estoppel … principles," and it clarifies that "[l]iability should be imposed only for violations of statutes or duly issued regulations, after notice and an opportunity to respond." Any enforcement action here would violate those commands at every turn. Lilly spent months informing HRSA of its plans. Lilly implored HRSA in May, June, and July to tell Lilly if it believed that the limited distribution plan ran afoul of the 340B statute (or some other provision). In response, HRSA spent months signalling that it agreed with Lilly that the 340B statute did not obligate Lilly to provide 340B discounts to contract pharmacies. If HRSA believed that Lilly's limited distribution plan was unlawful, it was incumbent on it to inform Lilly of that view in May in response to Lilly's initial correspondence; or in June, in response to any of Lilly's multiple letters; or even in July, in response to Lilly's further correspondence. Instead, HRSA told Lilly that contract pharmacies are not covered entities and that any agency guidance to the contrary did not constitute binding regulations.

In light of that failure to give any indication that it saw a legal problem in Lilly's plan, HRSA's recent threat not only flouts basic notions of estoppel and fair play, but constitutes the worst kind of surprise: an eleventh-hour threat of massive sanctions based on nothing more than "the desire to compel capitulation." For while HRSA spent all of summer 2020 acceding to Lilly's *legal* position that HRSA lacks the authority to compel Lilly to provide 340B discounts to contract pharmacies, it has simultaneously made clear its *policy opposition* to Lilly's plan. Yet executive agencies are not allowed to substitute their policy judgment for the clearly expressed will of Congress. And they are certainly not entitled to use threats of sanctions to try to strong-arm regulated entities into bending to their will.

I therefore respectfully request a virtual meeting to discuss this matter with you and to identify options for avoiding costly and unnecessary litigation. I also request that you confirm that HHS is not considering, and will not consider, any sanctions against Lilly for its decision to cease honoring 340B discount requests by contract pharmacies. I look forward to hearing back from you by September 15, 2020.

* * *

We designate this letter as confidential, proprietary, and reflective of trade secrets. This letter contains confidential commercial and financial information within the meaning of the Freedom of Information Act (FOIA), *see* 5 U.S.C. § 552, the relevant federal criminal statute, *see* 18 U.S.C. § 1905, the FOIA regulations, *see, e.g.*, 17 C.F.R. § 200.83, and other applicable laws, regulations, or policies. Specifically, this information is subject to exemption from mandatory disclosure under Exemption 4 of FOIA, 5 U.S.C. § 552(b)(4), and any other exemption applicable by law. Accordingly, we expect this letter will be kept in a non-public file, and that HHS will deny access to them by any unauthorized third person or entity. We also hereby request that your office, department, and all constituent agencies provide notice to us of any request under FOIA for, or intended FOIA disclosure of, such information, records, or materials. This request is made pursuant to 5 U.S.C. §§ 552(b)(4), (6) & (7); 45 C.F.R. §§ 5.65(d), 5.67 & 5.68; Executive Order 12600; and Attorney General Ashcroft FOIA Memorandum (Oct. 12, 2001). Lilly also requests that reasonably prompt notice be provided to Lilly, at the contact information provided below, of any request by a third party for discovery of this letter, or of any proposal or apparent intention by a third party or your office, department, or any constituent agency to enter this letter in the public record. We request that such notice be provided reasonably in advance of satisfying any such discovery request or, to the extent possible, that Lilly be enabled to seek confidential treatment of the letter or to seek relief in an appropriate court. These requests do not expire.

Please feel free to contact me at hakim_anat@lilly.com directly if you have any questions or need any additional information. Thank you for your attention to this very important matter.

Sincerely,

Anat Hakim
Senior Vice President and General Counsel
Eli Lilly and Company

cc: Shawn O'Neill, Vice President, Government Affairs, Eli Lilly and Company

Exhibit K

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

September 21, 2020

Anat Hakim
Senior Vice President and General Counsel
Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285

Dear Ms. Hakim:

I am responding to your September 8, 2020 letter to the Deputy Secretary and me. In that letter, you requested a pre-enforcement advisory opinion ("AO") as to whether Lilly's new unilateral policy involving the 340B program would subject Lilly to sanctions. Under that policy, Lilly will cease extending 340B pricing to pharmacies under contract with covered entities, unless the covered entity lacks an in-house pharmacy.[1] In such a case, Lilly will extend 340B pricing to only one designated contract pharmacy. As we understand it, Lilly has already implemented that policy for Cialis and has since extended the same policy for its other covered outpatient drugs.

As we have indicated in earlier correspondence, although the Health Resources and Services Administration ("HRSA") has significant initial concerns with Lilly's new policy, it continues to review that policy and has yet to make a final determination as to any potential action. Correspondingly, Lilly cannot and should not view the absence of any questions from the government as somehow endorsing Lilly's policy especially when this Department is leading the government's response to the COVID-19 pandemic.

In the interim, we have four concerns with your letters that do not relate to the legal propriety of your unilateral price increases.

First, Lilly sought to unilaterally impose an artificial deadline on HRSA's decision-making when it asserted in its May 18, 2020, letter to HRSA that unless it heard from HRSA to the contrary by June 30, 2020, it would assume that HRSA had no objections to its price restructuring for Cialis and would implement the same on July 1. Lilly imposed a similar set of deadlines for the rest of its drugs, indicating in its August 19, 2020 letter to HRSA that unless Lilly heard to the contrary by August 31, 2020, it would begin charging higher prices to pharmacies under contract with covered entities serving the disadvantaged on September 1. Lilly cannot and should not seek to impose such deadlines on the government's deliberations—especially when HRSA is playing a pivotal role in responding to an unprecedented pandemic. Nor is Lilly entitled to know the substance of those ongoing deliberations.

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[1] In addition to the September 8 letter from you, Lilly has submitted four other letters with respect to its proposal to scrap 340B pricing to contract pharmacies—dated August 27, 2020, August 19, 2020, July 17, 2020, and May 18, 2020.

Second, Lilly's decision to interpret HRSA's responses as tantamount to definitive agency agreement with Lilly's position is incorrect. As noted above, HRSA is still evaluating how to proceed.

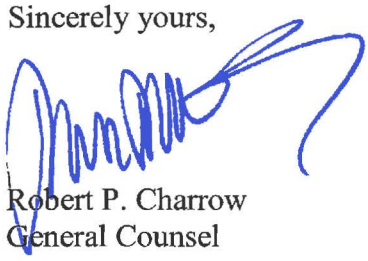
Third, Lilly's designation of its letters of September 8 and May 18 as exempt from disclosure under FOIA Exemptions 4, 6, and 7 and containing trade secrets under 18 U.S.C. § 1905 is fundamentally in error. Exemption 4 covers trade secrets and commercial confidential information. Lilly's legal position is neither. Moreover, we could find nothing in any of your letters that qualifies as either a trade secret or commercial confidential information. Exemption 6 relates to "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." We could find nothing in any of the Lilly letters that would qualify for this exemption. Exemption 7 relates to law-enforcement records. It is unclear why Lilly believes that Exemption 7 applies.

Fourth, we believe that the timing of your pricing changes is, at the very least, insensitive to the recent state of the economy. Although the economy is rebounding at a record rate, the unemployment and under-employment rates are still temporarily higher than at the beginning of the year due to COVID-19. Many Americans and many small businesses have had difficulty making ends meet. Lilly, on the other hand, seems to be enjoying an outstanding year. The price of Lilly's stock has increased by more than 11 percent since January 1, 2020, reflecting, among other things, the fact that your company's comprehensive income jumped from $1.414 billion during the second quarter of 2019 to $1.615 billion for the second quarter of 2020, an increase of more than 14 percent.

In contrast, during this same period, most health care providers, many of which are covered entities under section 340B, were struggling financially and requiring federal assistance from the Provider Relief Fund established by the CARES Act. Many continue to struggle and depend on emergency taxpayer assistance. It is against this backdrop that you are effectively increasing the prices of 10 mg and 20 mg Cialis by more than 500,000 percent and have done the same for other drugs in your portfolio.

In your letter, you noted that at least one covered entity has been the subject of a *qui tam* False Claims Act suit arising, in part, out of the 340B program. *See* Letter to the Deputy Secretary from Ms. Hakim (Lilly) at 2 n.6 (July 17, 2020); Letter to Rear Admiral Pedley from Mr. Asay (Lilly) at 11 n.36 (May 18, 2020). Please bear in mind that a similar suit against Lilly is a potential consequence in the event that Lilly knowingly violates a material condition of the program that results in over-charges to grantees and contractors.

Sincerely yours,



Robert P. Charrow
General Counsel

Exhibit L

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857
Office of Pharmacy Affairs

December 9, 2020

Ms. Maureen Testoni
President and Chief Executive Officer
340B Health
1101 15th Street, NW, Suite 910
Washington, DC 20005

Dear Ms. Testoni:

Secretary Azar asked me to thank you for your letter regarding recent actions by several drug manufacturers impacting covered entities that participate in the 340B Drug Pricing Program (340B Program).

Your letter raises concerns about specific actions that limit access to 340B drugs. For example, Eli Lilly USA (Lilly) is no longer providing 340B discounts on several of its drug products to covered entities through contract pharmacy arrangements. Several other manufacturers have also announced plans not to sell 340B drugs to contract pharmacies, while others are limiting sales by requiring specific data requirements or selling drug products only after a covered entity has demonstrated 340B compliance.

The Health Resources and Services Administration (HRSA) is continuing to review the various proposals and whether these actions by manufacturers violate the 340B statute and whether sanctions may apply. Under section 340B(a)(1) of the Public Health Service Act (PHSA), a manufacturer participating in the 340B Program must offer its covered outpatient drugs for purchase at or below the 340B ceiling price. Those sanctions could include, but are not limited to, civil monetary penalties pursuant to section 340B (d)(1)(B)(vi) of the PHSA. In a letter to Lilly posted on the 340B website, the U.S. Department of Health and Human Services reiterates its concern with actions such as those Lilly is taking.[1]

The 340B statute does not specify the mode by which 340B drugs may be dispensed. HRSA believes contract pharmacies serve a vital function in covered entities' ability to serve underserved and vulnerable populations, particularly as many covered entities do not operate in-house pharmacies.

[1] See: https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf

HRSA believes that manufacturers that refuse to honor contract pharmacy orders could limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions. To this end, HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements.

Some covered entities have reached out to HRSA expressing concern that they are unable to receive the 340B ceiling price on certain drug products due to these recent actions. HRSA is working closely with each impacted covered entity and is actively investigating the matter in order to make a final determination as to any potential action.

Sincerely,

Krista M. Pedley, PharmD, MS
RADM, USPHS
Assistant Surgeon General
Director, Office of Pharmacy Affairs
Health Resources and Services Administration

Exhibit M

Lilly USA, LLC

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By Federal eRulemaking Portal (http://www.regulations.gov)

October 11, 2016

Captain Krista M. Pedley
Director, Office of Pharmacy Affairs (OPA)
Health Resources and Services Administration (HRSA)
5600 Fishers Lane
Parklawn Building, Mail Stop 10C-03
Rockville, MD 20857

RE: 340B Drug Pricing Program; Administrative Dispute Resolution (ADR) Process Proposed Rule (RIN 0906–AA90)

Dear Capt. Pedley:

Eli Lilly and Company (Lilly) appreciates the opportunity to submit the following comments on the above-captioned Notice of Proposed Rulemaking (the Proposed Rule) issued on April 19, 2016.[1] Lilly is one of the country's leading innovation-driven, research-based pharmaceutical and biotechnology corporations. Our company is devoted to seeking answers for some of the world's most urgent medical needs through discovery and development of breakthrough medicines and technologies and through the health information we offer. Ultimately, our goal is to develop products that save and improve patients' lives.

Lilly is concerned that the proposed ADR process is profoundly flawed and designed to disadvantage manufacturers. Our primary concerns are two-fold: (1) the claims submission requirements are grossly disproportionate; and (2) the ADR Panel is a not able to provide due process or competent review.

In order for manufacturers to meaningfully opportunity assert claims under the ADR process, HRSA must rescind or revise its 1996 Audit Guidelines.[2] Since an audit is the gatekeeper to a manufacturer's ability to submit a claim, it is important for HRSA to recognize how lopsided those guidelines make the claim submission process. Table 1 below compares, side-by-side, the administrative barriers for covered entities and manufacturer.

Table 1: Required Steps Necessary to Submit an ADR Claim	
Covered Entity	**Manufacturer**
Identify Possible Overpayment. Review data in Ceiling Price Reporting system maintained by HRSA and populated by manufacturers. Compare reported prices to invoice prices.	**Identify Possible Non-Compliance**. Manufacturers have no readily available automated tools for monitoring duplicate discounts or diversion. The rules and practices employed by covered entities are diverse and opaque, while duplicate discounts in the Managed Medicaid context and the proliferation of Contract Pharmacy arrangements have grown and exacerbated this opacity.
Communicate with Manufacturers	**Communicate with Covered Entity**
Engage in Good Faith Dispute Resolution	**Engage in Good Faith Dispute Resolution (Round 1)**
Submit ADR Claim	**Evaluate Case, Obtain Internal Approvals to Conduct Audit**
	Provide Formal Notice of Audit to Entity. The manufacturer shall notify the covered entity in writing

[1] *340B Drug Pricing Program; Administrative Dispute Resolution*, *Notice of Proposed Rulemaking.* 81 Fed. Reg. 53381 (August 12, 2016).
[2] *Health Resources and Services Administration Manufacturer Audit Guidelines and Dispute Resolution Process 0905–ZA–19*. 61 Fed. Reg. 65406 (December 12, 1996).

	when it believes the covered entity has violated provisions of section 340B.
	Engaged in Formal Good Faith Dispute Resolution (Round 2).The manufacturer and the covered entity shall have at least 30 days from the date of notification to attempt in good faith to resolve the matter.
	Develop and Submit to HRSA Evidence of "Reasonable Cause"
	Await "Reasonable Cause" Review By HRSA. The Department will review the documentation submitted to determine if reasonable cause exists. If the Department finds that there is reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, the Department will not intervene. In cases where the Department determines that the audit shall be performed by the Government, the Department will so advise the manufacturer and the covered entity within 15 days of receipt of the audit work plan.
	Seek, Interview and Engage Independent Auditor
	Submit Audit Work Plan to HRSA. The manufacturer must file an audit work plan with the Department. The manufacturer must set forth a clear description of why it has reasonable cause to believe that a violation of section 340B(a)(5) (A) or (B) has occurred, along with sufficient facts and evidence in support of the belief. In addition, the manufacturer shall provide copies of any documents supporting its claims.
	Await HRSA Review of Audit Workplan. Upon receipt of the manufacturer's audit work plan, the Department, in consultation with an appropriate audit component, will review the manufacturer's proposed workplan. As requested by GAS, the audit workplan shall describe in detail the following: (1). audit objectives (what the audit is to accomplish), scope (type of data to be reviewed, systems and procedures to be examined, officials of the covered entity to be interviewed, and expected time frame for the audit), and methodology (processes used to gather and analyze data and to provide evidence to reach conclusions and recommendations); (2). skill and knowledge of the audit organization's personnel to staff the assignment, their supervision, and the intended use of consultants, experts, and specialists; (3). tests and procedures to be used to assess the covered entity's system of internal controls; (4). procedures to be used to determine the amounts to be questioned should violations of section 340B(a)(5) (A) and (B) be discovered; and (5). procedures to be used to protect patient confidentiality and proprietary information.
	Submit Revision(s) to Audit Workplan
	Await HRSA Review of Revisions to Audit Workplan
	Provide Notice to Covered Entity of Audit. The covered entity will have at least 15 days to prepare for the audit.
	Work with Covered Entity to Find Time for On-Site Audit (Auditor)
	Conduct the Audit (Auditor). This involves at least the following steps:
	1. Review the covered entity's policies and procedures regarding the procurement, inventory, distribution, dispensing, and billing for covered outpatient drugs.
	2. Obtain an understanding of internal controls applicable to the policies and procedures identified above (step a) when necessary to satisfy the audit objectives.
	3. Review the covered entity's policies and procedures to prevent the resale or transfer of drugs to a person or persons who are not patients of the covered entity.
	4. Test compliance with the policies and procedures identified above (step c) when necessary to satisfy the audit objectives.
	5. Review the covered entity's records of drug procurement and distribution and test whether the covered entity obtained a discount only for those programs authorized to receive discounts by section 340B of the PHS Act.
	6. Where the manufacturer's auditors conclude that there has been a violation of the requirements of section 340B(a)(5) (A) or (B), identify (1) the procedures or lack of adherence to existing procedures which caused the violation, (2) the dollar amounts involved, and (3) the time period in which the violation occurred.
	7. Following completion of the audit field work, provide an oral briefing of the audit findings to the covered entity to ensure a full understanding of the facts.
	Draft Audit Report (Auditor). At the completion of the audit, the auditors must prepare an audit report in accordance with reporting standards for performance audits of the GAS. The manufacturer shall submit the audit report to the covered entity.
	Review Audit Report. The manufacturer will review the audit findings.
	Await Covered Entity Review of Audit Report. The covered entity shall provide its response to the manufacturer on the audit report's findings and recommendations within 30 days from the date of receipt of the audit report. When the covered entity agrees with the audit report's findings and recommendations either in full or in part, the covered entity shall include in its response to the manufacturer a description of the actions planned or taken to address the audit findings and recommendations. When the covered entity does not agree with the audit report's findings and recommendations, the covered entity shall provide its rationale for the disagreement to the manufacturer.
	Submit Copies to HRSA and HHS OIG. The manufacturer shall also submit copies of the audit report to the Department.
	Good Faith Dispute Resolution (Round 3). Engage in discussions with Covered Entity related to repayment pursuant to Audit findings.
	Submit ADR Claim

It is particularly inequitable and unreasonable that manufacturers would face such significant obstacles to submitting a claim where there is no evidence that manufacturers have engaged in widespread violation of program rules. To date, HRSA has committed only one audit of a manufacturer and issued no findings of noncompliance. On the other hand, HRSA has conducted multiple audits of covered entities has identified the following evidence of widespread noncompliance: In 2012, of 51 audits, 32 (63%) involved adverse findings; in 2013, of 94 audits 73 (78%) involved adverse findings; in 2014, of 99 audits, 80 (81%) involved adverse findings; in 2015, of 200 audits, 155 (77.5%) involved adverse findings; so far in 2016, of 87 audits, 55 (63%) involved adverse findings.[3]

Lilly, of course, commends HRSA for its audit efforts but respectfully disagrees that these findings support the implementation of a system designed to make it easier for covered entities – who have demonstrated serious compliance deficiencies – to assert claims against manufacturers, who have no similarly established record of flouting program rules. Accordingly, we offer the following comments on the Proposed Rule.

I. HRSA Should Implement the Affordable Care Act's (ACA) Provisions in Careful Order.

As we stated in our comments to the Proposed Civil Money Penalties rule, Lilly sincerely believes that the sound foundation for any coherent regulatory framework, especially one that has been so significantly revised in recent years, is to proceed in a careful order with new rules and obligations, recognizing that several of these rules are interrelated and that changes to one part of the program can have significant implications for compliance with another part of the program. HRSA might also consider aligning effective dates across various rules and guidance documents to ensure that there are no unintended instances of non-compliance based on piece-meal implementation.

Lilly continues to believe the most logical order would be the order we suggested in our August 17, 2015 letter. We would add, however, a couple minor additional points for your consideration, notably that HRSA should update its 1996 manufacturer audit guidelines, which are out of date and include conflicting guidance on dispute resolution. In order:

- **Step 1:** *Amend the Pharmaceutical Pricing Agreement (PPA) to Implement the Manufacturer Reporting, Ceiling Price Clarification, and "Must Offer" Provisions of 42 U.S.C. § 256b(a).*

We think this is a logical first step and an important acknowledgement that the PPA is still a critical component in the statutory scheme.

- **Step 2**: *Finalize the Information Collection Request (ICR) and Gain Experience with Administering the Ceiling Price Reporting System.*

HRSA is presently in the midst of obtaining authorization from the Office of Management and Budget (OMB) to engage in new information collection activities from manufacturers. *80 Fed.*

[3] Internal calculations based on HRSA data posted at http://www.hrsa.gov/opa/programintegrity/index.html (last visited October 1, 2016).

Reg. 22207 (Apr. 21, 2015). Lilly agrees that this process is appropriate and we applaud HRSA for inviting stakeholder input and following the processes established by HHS prior to imposing new data collection requirements on manufacturers.

Still, HRSA has not yet published final specifications regarding the scope of data that will be collected in connection with the ceiling price reporting system. HRSA has also not yet issued a proposed rule, let alone a final rule, establishing the data collection requirements. Absent completion of the price reporting rulemaking, the entire repayment regime upon which the pending CMP regulations and the instant ADR proposed regulations are predicated does not make sense.

Since the data derived from this system will invariably play a substantial role in the ADR process, it is absolutely essential that this system be both functional and well understood prior to implementing an ADR process.

- **Step 3:** *Establish the Mechanism for Administering Refunds*

The 340B statute requires HRSA to establish "procedures for manufacturers to issue refunds to covered entities in the event there is an overcharge by the manufacturers" and requires "[t]he development of a mechanism by which appropriate credits and refund are issued to covered entities." *42 U.S.C. §§ 256b(d)(1)(B)(ii) and (iv)(II)*. HRSA has not yet done this. Even once HRSA has built and deployed the price reporting system, the agency should expect some "growing pains" associated with the creation of an entirely new database. Moreover, HRSA has only established the framework for reporting and the penalties for non-compliance, it has not yet provided any guidance or mechanism for facilitating refunds. Judging by our operational experiences with the Medicaid Drug Data and Reporting (DDR) system, Lilly knows that a data reporting system will never be "perfect." Still, it would be hasty to establish final rules related to repayment and penalties before HRSA has even established, let alone resolved major "kinks" in, the repayment procedures.

As a practical matter, the mechanism for administering refunds will be integral to the ADR process. For example, if HRSA has established a fair and orderly mechanism for refunds, then covered entities and manufacturers will have less need to invoke the ADR process in the first instance. If HRSA fails to establish a fair and functional mechanism, then the opposite is likely to be true: covered entities and manufacturers will rush to invoke the ADR because neither will know when, whether or how a refund might be processed.

- **Step 4:** *Update and Revise the 1996 Audit Guidelines*

Since HRSA is proposing that a manufacturer must conduct an audit of a covered entity in order to avail itself of the ADR process, HRSA should, at a minimum, revise this process. As must be abundantly clear to HRSA, the ADR statutory provisions were drafted with considerable input from lobbyists representing covered entities. These biased provisions compound audit procedures designed by HRSA to be maximally burdensome to manufacturers. As Table 1 demonstrates, the audit process and HRSA's proposed implementation of the ADR provisions render manufacturers essentially shut out of the ADR process. For this reason, and those identified below, HRSA should significantly revise the 1996 Audit Guidelines.

A. <u>This Rulemaking Renders the 1996 Audit Guidelines, Reaffirmed in 2011, Out of Date and Confusing.</u>

The 1996 Audit Guidelines were developed during the infancy of the 340B program. At that time, regulators had no idea how frequent manufacturer audits were likely to be or whether those audits would be invasive and burdensome to covered entities. In the more than 20 years since those guidelines have been final, HRSA must agree that manufacturer audits are exceedingly rare and that the agency overcompensated for concerns that covered entities would be burdened by frequent and onerous manufacturer audits. Accordingly, the time is ripe for HRSA to reconsider those guidelines.

First, as a threshold matter, HRSA should acknowledge that the dispute resolution process developed and published in the 1996 Audit Guidelines are inconsistent with the proposed ADR process. Specifically, there is a section in those guidelines called "Dispute Resolution Process." That process is different than the process in the ADR. As a matter of good regulatory practice, HRSA should formally rescind the 1996 Dispute Resolution Process to avoid confusion.

Second, HRSA should carefully analyze its own experience with manufacturer audits and determine which aspects of these guidelines are reasonable and necessary and which are overly burdensome and extraneous.

Lilly has direct experience here. We were among the first manufacturers to undertake covered entity audits. These audits (and there were only a few) were conducted in 2012, suggesting that for more than 17 years, no manufacturer audits were conducted at all.

We found the experience burdensome, costly and ultimately pointless, despite the fact that all three audits surfaced widespread instances diversion and duplicate discounting. The bureaucratic effort and expense imposed by the 1996 Audit Guidelines makes it untenable, except in the most egregious cases, for Lilly to conduct additional audits. We believe this is inconsistent with the intent of the statute and a bad public policy outcome, as it shifts more of the oversight burden to HRSA.

Moreover, the ability for covered entities to shrug off manufacturer findings and to refuse manufacturer requests for recoupment renders the entire exercise futile. As HRSA is aware, one of the entities Lilly audited in 2012 has, to date, only paid a small portion the amount the independent auditor adjudged was due. HRSA has provided no support to Lilly in resolving the outstanding issues and the covered entities has faced no sanction from HRSA related to its disregard of the audit findings.

B. <u>The 1996 Audit Guidelines' Requirement to Engage an Independent Third-Party Auditor Is Not Permitted by Statute, Required by Government Audit Standards, and Is Unnecessarily Burdensome In Light of the ADR Process.</u>

There is no statutory basis for HRSA's requirement that a manufacturer engage an independent third-party auditor. In fact, the plain reading of the statute is that a manufacturer, itself, may audit covered entities. The statute states:

> (C) Auditing.—A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

HRSA's 1996 Audit Guidelines go well beyond establishing procedures with respect to "number, duration, and scope" of audits. They add a requirement that manufacturer audits be conducted in accordance with the Generally Accepted Government Auditing Standards (GAGAS). That requirement appears nowhere in the statute and HRSA's authority to impose such a requirement is dubious. HRSA also imposes a "good cause" requirement which, similarly, does not appear in the statute.

Moreover, HRSA has misinterpreted (or, at a minimum, failed to update) its understanding of what is required by the GAGAS. For example, HRSA assumes that the "independence" requirement under GAGAS imposes a requirement on manufacturers to hire external auditors. The audit guidelines state:

> The manufacturer's auditor shall be an independent public accountant employed by the manufacturer to perform the audit. The auditor has an ethical and legal responsibility to perform a quality audit in accordance with Government Auditing Standards, Current Revision, developed by the Comptroller General of the United States.

61 Fed. Reg. 65409 (Dec. 12, 1996). The requirement to hire an independent public accountant is not an actual requirement under GAGAS. According to GAGAS, safeguards to independence can be achieved via safeguards for independence. These safeguards include:

> 3.17 Examples of safeguards include:
>
> a. consulting an independent third party, such as a professional organization, a professional regulatory body, or another auditor;
>
> b. involving another audit organization to perform or reperform part of the audit;
>
> c. having a professional staff member who was not a member of the audit team review the work performed; and

d. removing an individual from an audit team when that individual's financial or other interests or relationships pose a threat to independence.

GAO-12-331G Government Auditing Standards at 33. Importantly, these requirements permit federal agencies to conduct audits using internal staff, provided safeguards for independence exist.

C. <u>The 1996 Audit Guidelines Never Addressed Manufacturer Joint Audits, Though The Proposed ADR Suggests the Manufacturers May Consolidate Claims.</u>

HRSA made no effort to identify instances where multiple manufacturers could jointly audit covered entities. The 1996 Audit Guidelines state: "[w]hen specific allegations involving the drugs of more than one manufacturer have been made concerning an entity's compliance with section 340B(a)(5) (A) and (B), the Department will determine whether an audit should be performed by the (1) Government or (2) the manufacturer." *61 Fed. Reg. 65409 (Dec. 12, 1996)*. However, the ADR Proposed Rule appears to suggest that there may be instances where manufacturers could consolidate claims. We believe the ability for manufacturers to consolidate claims is illusory, since HRSA has never established guidelines for joint audits by manufacturers.

For these reasons, Lilly respectfully requests withdrawal and republication of the 1996 Audit Guidelines.

- **Step 5:** *Establish the Requirements for Manufacturer Compliance, Covered Entity Compliance and the Administrative Dispute Resolution Process Simultaneously.*

Lilly supports HRSA's adherence to Congress's intent to create a single ADR process that would govern both manufacturers and covered entities. As you know, the statute calls for a single, unitary decision-making official or body that would review claims related to overcharges as well as instances of covered entity non-compliance. *42 U.S.C. § 256b(d)(3)(b)(i)*. Lilly provides specific comments in Section II-VI of this letter, below, related to the recently proposed ADR process, but generally supports HRSA's effort to establish a unitary process for manufacturers and covered entities.

- **Step 6:** *Implement the CMP Rules for Manufacturers*

Section 42 U.S.C. § 256b clearly compels the establishment of CMPs for certain instances of manufacturer non-compliance with 340B requirements. HRSA should and must implement these pursuant to regulation and Lilly does not seek to avoid its obligations under the program. However, given the serious and punitive nature of CMPs, HRSA must take care to implement CMPs in a fair and rational manner.

Irrespective of the timing with which HRSA finalizes the CMP rule, we offer the following comments on the Proposed Rule.

II. Definitions (Proposed 42 C.F.R. § 10.3)

A. HRSA Should Improve the Definition of Administrative Dispute Resolution Process Through a Minor Correction.

It is a small point, but Lilly believes there is a drafting error in the definition of "Administrative Dispute Resolution process" that mischaracterizes which entity is "purchasing" drugs at the 340B price. See the strikethrough and proposed amendment below:

> *Administrative Dispute Resolution (ADR) process* means a process used to resolve claims by covered entities that may have been overcharged for 340B drugs purchased ~~by~~ **[from]** manufacturers, and claims by manufacturers of 340B drugs, after a manufacturer has conducted an audit of a covered entity, that a covered entity may have violated the prohibitions against duplicate discounts or diversion.

B. HRSA Should Delete the Definition of "Administrative Dispute Resolution Panel"

As Lilly describes below, HRSA should professionalize and standardize the ADR process by utilizing an Administrative Law Judge. Since Lilly does not support the concept of an ADR Panel, it respectfully urges deletion of this definition and recommends replacing it with a designation that the decision making body be comprised of an ALJ.

III. 340B Administrative Dispute Resolution Panel (Proposed 42 C.F.R. § 10.20)

Lilly opposes the establishment of an Administrative Dispute Resolution Panel as proposed by 42 C.R.F. § 10.20 and urges HRSA to consider implementation of an Administrative Law Judge (ALJ) and quasi-judicial mechanism instead. We believe this is both consistent with the demands of due process and more likely to result in an efficient process.

A. The Proposed ADR Procedures Fail to Provide Due Process.

The ADR Panel is an adjudicative body. Agencies that seek to establish adjudicative administrative procedures must do so in a manner that ensures due process. This requirement is enshrined in both the Constitution and federal law. *U.S. Const. Amds. 5 and 14; 5 U.S.C. § 554*.

In the context of administrative adjudication, the basic elements of due process are:

- An unbiased tribunal;
- Notice of the proposed action and the grounds asserted for it;
- An opportunity to present reasons why the proposed action should not be taken;
- The right to call witnesses;
- The right to know evidence against oneself;
- The right to have a decision based exclusively on the evidence presented;
- The right to counsel;
- The making of a record;

- The availability of a statement of reasons for the decision;
- Public attendance; and
- Judicial review.[4]

Evaluated under these standards, HRSA's proposals fall short, especially with respect to the process afforded manufacturers.

1. Bias: The ADR Panel Will Not Be an Unbiased Tribunal.

The 340B statute requires the Secretary to "designate or establish a decision-making official or body within the Department of Health and Human Services" to resolve certain claims filed by covered entities or manufacturers. *42 U.S.C. § 256b(d)(3)(B)(1)*. HRSA proposes to establish a Panel with three members chosen from a list of eligible individuals and alternating from claim to claim and one ex-officio, non-voting member chosen from the HRSA Office of Pharmacy Affairs (OPA) staff who will facilitate the review process. The voting members of the Panel would be comprised of Federal employees – the Proposed Rule cites "employees of CMS or the U.S. Department of Veterans Affairs" as examples – "with demonstrated expertise and familiarity with the 340B Program." HRSA also proposed to require disclosure of any conflicts of interest, which it defines as "(1) Financial interest in a party involved, a subsidiary of a party involved, or in the claim before the 340B ADR Panel; (2) Family or close relation to a party involved; and (3) Current or former business or employment relation to a party."

Despite the appearance of objectivity, Lilly is concerned that this panel would not – in fact – be unbiased. First, the inclusion of an "ex-officio, non-voting" HRSA employee undermines the guarantee that there would be a true separation of the regulatory and adjudicative functions.

Manufacturers have good cause to skeptical of the objectivity of HRSA employees. The agency's strong biases against manufacturers are obvious. Comments submitted by the Pharmaceutical Research and Manufacturers of America (PhRMA) in connection with just the CMP Proposed Rule highlight the agency's predisposition toward disadvantaging manufacturers. PhRMA provides the following examples in that context[5]:

- Where the proposed rule could have established a process for routine restatements and refund procedures (as it is statutorily obligated to do), it suggests instead that -- notwithstanding the lack of any ground rules concerning refund procedures -- "overcharges" due to restatements potentially could trigger civil monetary penalties against manufacturers;

- Where HRSA could have proposed a reasonable, non-confiscatory ceiling price in instances where the calculation yields a zero price, it proposes the most punitive price possible (one penny);

[4] Harry Friendly, *"Some Kind of Hearing,"* 123 Up. L. Rev. 1267 (1975).
[5] Comment Letter from the Pharmaceutical Research and Manufacturers of America (PhRMA) submitted in response to 340B Drug Pricing Program Ceiling Price and Manufacturer Civil Monetary Penalties Regulation; RIN 0906-AA89. (August 17, 2015) at 3.

- Where HRSA could have permitted manufacturers to forego offering a 340B ceiling price for a product in its launch quarter (which usually is a partial quarter) where there are no AMPs or URAs to calculate a ceiling price, it proposes to impose an unexplained retroactive pricing requirement;

- Where HRSA could have proposed fair and reasonable procedures for handling mistakes and routine true-ups, it proposes an unfair and statutorily unauthorized approach that would deny manufacturers an ability to offset;

- Where HRSA could have proposed a definition of "instance" that relates to conduct within a manufacturer's knowledge and control, it proposes a definition so broad that it essentially would nullify the "knowingly" and "intentionally" requirement Congress required, and create the potential for grossly excessive CMP liability; and

- Where HRSA could have proposed to implement the 340B law's "must offer" provision in accordance with an amendment to the PPA (as it is required to do), instead it seeks to use the term "Instance of overcharging" as the mechanism for creating new substantive obligations.

HRSA's conduct during multiple rounds of litigation related to the eligibility of Orphan Drugs is also fairly suggestive of a bias against manufacturers and for covered entities.

Against this backdrop, it is difficult for manufacturers to trust that the ex-officio HRSA staff member will be truly impartial. HRSA may intend for this person to be a mere technical resource to the voting members intended to answer questions related to program operation, but there is no guarantee that the ex-officio member would so limit their role. In fact, it is likely the ex-officio member would have some responsibility for HRSA rule making, investigation, and prosecution. Furthermore, this individual, by virtue of his or her well-developed views on how the program "should" work would and his or her greater sophistication with the subject matter would likely be the most influential member of the panel.

Second, the individuals who would comprise the voting members of the panel are unlikely to possess the requisite familiarity with the program. These individuals would be required to adjudicate mixed issues of law and fact. The statute has only been scantly litigated, suggesting a limited judicial gloss on the legal issues. Moreover, many of the legal issues the panel would need to consider are only now emerging. In addition to the instant rulemaking, HRSA is in the process of implementing CMP rules, the PPA Addendum, and an Omnibus Guidance. All of these are new and regulations are challenging for experienced practitioners with deep program expertise. One can only imagine how difficult the rules will be for the odd staff member from another federal agency who has to balance *ad hoc* service on some other agency's panel with his or her own daily obligations. Layer on top of this the fact that the 340B program has grown in size and complexity. Concepts like "contract pharmacies," "replenishment," "split billing software," "accumulators," and the like render it almost a certainty that the panel members will be ill-equipped to provide meaningful rulings.

2. Notice: Covered Entities Will Have Clear Notice of Any Potential Claim and The Grounds Asserted for It, But Manufacturers Will Not.

There is a tremendous asymmetry in the degree and timing of notice under the proposed ADR procedures. Under the proposed rule, manufacturers may only invoke the ADR process against a covered entity upon completion of an audit by that manufacturer. This means the entity subject to the ADR claim would have had notice of the potential claim at the following points: (1) initial notice under the 1996 Audit Guidelines; (2) during the thirty (30) day pendency of good faith discussions prior to a submission of "good cause" to HRSA for approval to conduct the audit; (3) for the period it takes HRSA to evaluate the "good cause" request; (4) during the audit; and, (5) after audit is completed and for the period of time during which the entity may review and comment on the auditor's finding. Again, we direct your attention to Table 1, above.

Manufacturers, by contrast, will have no advance notice and will be provided retroactive notification within the three (3) business days of the claim being submitted. Moreover, the elements contained in this notice are vague and leave broad discretion to the entities. HRSA proposes only to required that the covered entity provide HHS a "summary of the documents submitted as part of the claim" rather than the documents themselves. Contrast this "summary" with the robust audit report that manufacturers must submit to covered entities. Aside from being completely lopsided, such a highly summarized document deprives manufacturers a meaningful opportunity to respond.

3. Presentation of Evidence: The Procedures for the Presentation and Evaluation of Evidence Are Insufficient.

Several of due process requirements related to the presentation of evidence are absent from HRSA's proposed ADR procedures. For example, there is no right to call witnesses or examine witnesses. The fact that the ADR Panel is supposed to evaluate the claim without any form and oral evidence is bewildering. Also, because covered entities need only provide a "summary" of the documents being relied upon, there is no meaningful right for manufacturers or the panel to know or adjudge the evidence that would support a covered entity's claim.

Lilly has significant concerns with these shortcomings. With respect to the complete lack of any physical presentation of witnesses or evidence, there is no ability for the tribunal to evaluate credibility. Moreover, the reliability and probative worth of written submissions is an inadequate substitute for oral presentation because they do not provide an effective means the parties to communicate their cases to the decision makers or for decision makers to ask questions.

Lilly's own experience with the back-and-forth paperwork connected to covered entity audits underscores how ill-suited the presentation of the mere written exchange of positions and facts is to the complete evaluation of the issues likely to be presented by a claim.

Moreover, Lilly is concerned that the due process demand that a decision be rendered solely on the evidence presented is threated by the proposed ADR Panel. Since that panel would be comprised of individuals who work at HRSA and/or other federal agencies, those individual are likely to bring their policy predilections to bear. That is, they are more likely than an ALJ to interpret regulations based on what they, themselves, "intended" for the regulation to mean or how

it was "intended" to apply, irrespective of whether stakeholders could have divined this intent or whether the evidence presented supported such an outcome.

4. Public Attendance: There is No Right to Public Attendance

HRSA's proposed ADR process contemplates that all decision-making would be conducted behind closed doors. Aside from the obvious lack of openness and transparency, this "behind-the-curtain" approach to dispute resolution eliminates any possibility for those subject to a claim to know whether the adjudication is subject to abuse or bias.

5. The Right to Counsel

There is no bar on the right to counsel. Accordingly, Lilly has no concern on this point.

6. The Making of a Record, the Availability of a Statement of Reasons for the Decision and Judicial Review.

Again, Lilly believes the ADR Panel would result in the making of at least some sort of record, though it is unclear how robust this record would be. We also acknowledge that the proposed "decision letter" is likely to provide for a statement of the reasons for the decision and HRSA has contemplated judicial review. We do not believe these aspects of due process are necessarily threatened.

B. HRSA Should Implement a Hearing Presided Over by and Administrative Law Judge (ALJ).

We believe the formality of a quasi-judicial proceeding with a hearing officer or ALJ would be much more fair, predictable, professional, transparent and appropriate than the relatively *ad hoc* and secretive process proposed by HRSA. ALJ's set the gold standard for agency adjudications as they generally act like true judges; their only job is to hear cases and they usually receive no *ex parte* staff assistance. Furthermore, they develop specialized expertise, enjoy substantial *de facto* and *de jure* independence, and have a highly independent mind-set. They know how to hear testimony, find the facts, apply the law, exercise discretion, apply precedent, and draft decision memoranda in a manner a reviewing court could readily review.

Lilly urges HRSA to survey other agencies and to review options for formal rulemaking through agency adjudication.[6]

Specifically, Lilly believes this alternative have the following benefits:

1. Due Process. As set forth above, we believe a hearing presided over by an ALJ would satisfy the due process requirements under federal law and the U.S. Constitution.

2. Objectivity and Separation of Functions. HRSA's proposed ADR Panel would likely be comprised of many of the same individuals responsible for creation and implementation of HRSA policy. Because these individuals serve in other

[6] We would specifically direct HRSA to consider modeling their ADR Process on the Drug Enforcement Agency's (DEA's) Show Cause and Hearing procedures set forth at 21 C.F.R. §§ 1301.37-46.

administrative functions, they are likely to have biases, position, or other objectives outside of the limited facts of the dispute at issue. There are basically no safeguards under the proposed ADR Panel to limit these individuals from brining their subjective views to bear in the ADR process. Moreover, these individuals would be less apt to apply objective interpretations to the regulations as their role in drafting them would mean they could interpret regulations based on what they, themselves, intended for the regulation to mean, irrespective of whether that was clear to external stakeholders. This could make the ADR process a means of retroactively applying new policies that HRSA is developing on the spot, rather than a faithful application of existing policies.

D. Ability and Training. Most ALJs are lawyers or are trained by the Administrative Conference of the United States with skills designed to fairly and professionally resolve administrative disputes. These professionals are accustomed to evaluating precedent, applying it or creating it when appropriate, reviewing mixed issues of law and fact, evaluating credibility, and drafting decisions or recommendations in manner that is easily understandable to reviewing courts.

E. Efficiency. An ALJ would be full-time dedicated resource responsible for the 340B ADR process, not an agglomeration of individuals appointed on an *ad hoc* basis and balancing their ADR Panel responsibilities against their daily work demands. Moreover, ALJ's who apply the same routine over and over will be able to handle procedural matters more expeditiously. Finally, their abilities to find fact and apply law will save on judicial resources in the event a dispute is appealed to a court.

F. Transparency. ALJ's can open their hearings to the public, but deliberate in private in a manner than is vastly more transparent than the proposed ADR Panel process.

IV. Claims (Proposed 42 C.F.R. § 10.21)

Lilly respectfully requests that this section not be finalized, as we believe the agency should engage in further rulemaking necessary to implement the ADR process by employing an ALJ. In the event HRSA rejects this request, Lilly supports, as an alternative position, the comments submitted by its trade association, PhRMA.

V. Covered Entity Information Requests (Proposed 42 C.F.R. § 10.22)

Lilly respectfully requests that this section not be finalized, as we believe the agency should engage in further rulemaking necessary to implement the ADR process by employing an ALJ. In the event HRSA rejects this request, Lilly supports, as an alternative position, the comments submitted by its trade association, PhRMA.

VI. Final Agency Decision (Proposed 42 C.F.R. § 10.23)

Lilly respectfully requests that this section not be finalized, as we believe the agency should engage in further rulemaking necessary to implement the ADR process by employing an ALJ. Should HRSA reject this request, we offer the following comments.

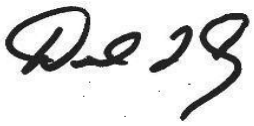
The "Final Agency Decision" provisions in the Proposed Rule actually encompass the both the decision process and the evaluation process. As noted above, there is no process for oral presentation of the issues nor is their opportunity for credibility determinations based on in-person interactions. HRSA proposes simply to rely on paper filings and written responses to a draft decision. As we note above, Lilly has significant concerns with these shortcomings. With respect to the complete lack of any physical presentation of witnesses or evidence, there is no ability for the tribunal to evaluate credibility. Moreover, the reliability and probative worth of written submissions is an inadequate substitute for oral presentation because they do not provide an effective means the parties to communicate their cases to the decision maker(s).

HRSA also proposes that the 340B ADR Panel's final agency decision letter will be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction in accordance with section 340B(d)(3)(C) of the PHSA. We agree that this is a correct reading of the statute, but believe it underscores the need to create a robust record, since a reviewing will likely give at least some deference to the agency.

*****

Lilly appreciates the opportunity to comment in response to this re-opened NPRM. We look forward to continuing to work with HRSA to ensure orderly and efficient administration of the 340B drug discount program. Please feel free to contact Derek Asay at derek.asay@lilly.com directly if you have any questions or need any additional information. Thank you for your attention to this very important matter.

Sincerely,



Derek L. Asay
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Exhibit N

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Re: **HHS Advisory Opinion 20-06**

Dear Mr. Asay and Ms. Dixson:

On behalf of University of Washington Medical Center ("UWMC") and Harborview Medical Center ("HMC") (collectively, "UW Medicine Hospitals"), we write with regard to your continued policies unlawfully restricting covered entities' ability to purchase covered outpatient drugs at 340B prices through contract pharmacies. UW Medicine Hospitals have previously reached out with regard to the unlawfulness of your policy, under both statutory and regulatory provisions, and the negative impact your policy is having on UW Medicine Hospitals and their patients, especially during the fight against COVID-19.

Since the time of our original correspondence, the Department of Health and Human Services ("HHS") has issued Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program.[1] This Advisory Opinion makes clear, as UW Medicine Hospitals' previous correspondence has explained, 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." Further, the Advisory Opinion outlines that the statutory language, the Pharmaceutical Pricing Agreement ("PPA"), and the purpose and the history of the 340B Program all support this conclusion. In light of the Advisory Opinion your continued denial

[1] *Available at* https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

POLSINELLI

of 340B pricing puts Lilly's PPA and reimbursement under the Medicaid and Medicare Part B programs at risk, and subjects Lilly to civil monetary penalties for each overcharge or denied purchase.

Given the Advisory Opinion and the numerous other indications from both government and industry authorities that your policy with regard to contract pharmacies is unlawful and harmful to covered entities, we ask that you revoke your policy effective immediately. We also ask that you reverse any transactions where you have charged UW Medicine Hospitals above the applicable ceiling price for 340B covered outpatient drugs, and compensate UW Medicine Hospitals for its losses otherwise incurred in being blocked from purchasing covered outpatient drugs at 340B pricing through its contract pharmacies.

It is UW Medicine Hospitals' intent to seek reimbursement of these losses through administrative action, including applicable fees and costs, should you not reverse your policy. Given the negative impacts of your policy and the need to seek administrative relief, we would appreciate your swift response by January 14, 2021.

Sincerely,

Jessica Andrade

Jessica M. Andrade

JMA:jma

Exhibit O

PhRMA
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PETITION FOR RULEMAKING REGARDING AN ADMINISTRATIVE DISPUTE RESOLUTION PROCESS FOR THE 340B DRUG PRICING PROGRAM

(RIN 0906–AA90 and RIN 0906–AB26)

Pursuant to 5 U.S.C. §§ 553(e), 555(b), and 555(e), submitted to:

THE HEALTH RESOURCES AND SERVICES ADMINISTRATION
THE UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES

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November 24, 2020

Pharmaceutical Research and Manufacturers of America, Petitioner

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STATEMENT OF PETITIONER

The Pharmaceutical Research and Manufacturers of America ("PhRMA") hereby petitions the Secretary of the Department of Health and Human Services "HHS"), and the Administrator of the Health Resources and Services Administration ("HRSA"), as well as the Director of HRSA's Office of Pharmacy Affairs ("OPA"), to issue a new proposed rule establishing an administrative dispute-resolution ("ADR") procedure for participants in the 340B Drug Pricing Program. PhRMA supports the goal of the 340B program, which is to make prescription drugs more accessible to uninsured or vulnerable patients. But, as PhRMA explains in detail below, there is significant new evidence that the 340B program is plagued by abuses that are undermining that goal and HRSA has been unwilling to hold covered entities accountable for those abuses. *Genesis Health Care v. Azar*, No. 4;19-cv-1531-RBH (D. S.C. Dec. 18, 2019). Accordingly, as part of this petition, PhRMA reiterates its prior requests that HRSA include a precise definition of "patient" as well as practical audit procedures. Both elements are essential to an efficient ADR process, which is in turn critical to maintaining the integrity of the 340B program and ensuring that the program achieves its intended purpose.

It has been more than four years since HRSA previously proposed an ADR rule in 2016, only to abandon it in 2017. As a result of recent litigation against HHS for failing to issue an ADR rule, an ADR final rule has been sent to the White House Office of Management and Budget ("OMB") Office of Information and Regulatory Affairs ("OIRA") for review, https://www.reginfo.gov/public/do/eoReviewSearch (last visited Nov. 22, 2020), and it appears HRSA plans to complete its rulemaking without affording affected parties adequate opportunity to comment on the material changes that have occurred in the 340B program's operation since the close of the 2016 comment period. Rushing to publish an abandoned ADR rule based on dated comments is plainly inconsistent with the Administrative Procedure Act ("APA"). The four year-old record before HRSA is stale, and does not reflect the explosive growth in contract pharmacies, which are not mentioned in the 340B statute and stem from non-binding guidance, and the corresponding increase in diversion and other abuses that have occurred since 2016, as documented by the HHS Inspector General, Congress and the Government Accountability Office, among others. HRSA cannot engage in the reasoned and non-arbitrary decisionmaking that the APA requires based on a record that is plainly past its useful life. HRSA must therefore open a new comment period to ensure that the ADR rule it promulgates will promote the purposes of the 340B program as it currently exists, not as reflected in the now-stale record it assembled in 2016.

It is of course indisputable that an ADR rule is required by law. See 42 U.S.C. § 256b(d)(3). But the agency also has an obligation to ensure that the ADR rule protects the 340B program's integrity, which in turn ensures that the program

benefits the patients Congress intended it to serve. To achieve these goals, the ADR rule must rest upon a more precise definition of "patient" under the 340B program. It must also be based on practical audit procedures, so manufacturers can meaningfully access the ADR process, which Congress designed to help HRSA resolve claims of unlawful diversion and duplicate discounts left unresolved after good faith negotiations between the parties. PhRMA and others provided comments on these and other issues in the 2016 ADR rulemaking. In addition, PhRMA has sought clarity and precision in the patient definition for many years in repeated comments to HHS and in response to Congress. *See, e.g.*, PhRMA, Comment Letter on Proposed 340B Program Omnibus Guidance Published by the Health Resources and Services Administration (HRSA) (Oct. 27, 2015), https://bit.ly/3nXZq55; PhRMA, Comment Letter on HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (July 16, 2018), https://bit.ly/366NRTr; PhRMA, Comment Letter in Response to Senator Lamar Alexander and Congressman Greg Walden's Request for Input on Modernizing 340B Drug Pricing Program (Oct. 30, 2020), https://onphr.ma/2VbZ12Z. But the need and justifications for PhRMA's earlier requests and proposals have become much clearer in light of significant events and trends reflecting how the 340B program now functions in the real world.

Specifically, significant new evidence has emerged since 2016 reflecting serious problems in the 340B program, including diversion of drugs, duplicate discounts, and other abuses by covered entities that exploit the lack of a "patient" definition. The increase in these abuses has occurred in tandem with an explosive growth in arrangements between covered entities and contract pharmacies—arrangements that create market-distorting incentives, to the detriment of both the 340B program and patient care. HRSA cannot simply rush ahead with its previous 2016 proposal without reopening the record in order to consider those changes.

Accordingly, HRSA should instead issue a new proposed rule and open a new comment period pursuant to 5 U.S.C. § 552(e) so stakeholders have the opportunity to comment on the proposed rule and provide fresh evidence on critical program issues. At the very least, HRSA should re-open the comment period on its prior proposed rule for 60 days, to allow stakeholders to submit comments regarding the new evidence and issues that have arisen since that rule was abandoned, and HRSA should revise the proposed rule in response to these issues. After years of inaction, HRSA should not rush to finalize its deeply flawed proposed rule in order to avoid responding to lawsuits. Doing so will simply compound the legal deficiencies in the 2016 proposed rule and make it more vulnerable to legal challenges under the APA.

STATEMENT OF INTEREST

PhRMA is a voluntary, non-profit organization representing the nation's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to lead longer, healthier, and more productive lives. PhRMA is committed to advancing public policies that

support innovative medical research, yield progress for patients today, and provide hope for new treatments and cures in the future. To advance these goals, PhRMA serves as the pharmaceutical industry's principal public policy advocate before Congress, regulatory agencies, and the courts.

PhRMA supports the goals of the 340B program, which Congress enacted to help make prescription drugs more accessible to uninsured or otherwise vulnerable patients. PhRMA submits this petition to ensure that HRSA appropriately addresses the serious issues with the current operation of the program, so that in future years the program can be strong, sustainable, and administered fairly and consistently with the 340B statute. This petition incorporates by reference the comments previously submitted by PhRMA in response to the agency's 2016 proposed ADR rule, see PhRMA, Comment Letter on Proposed Rule for Administrative Dispute published by the Health Resources and Services Administration (HRSA) (Oct. 11, 2016), https://bit.ly/3pVnrvA, and 2015 proposed omnibus guidance, see PhRMA, Comment Letter on Proposed 340B Program Omnibus Guidance Published by the Health Resources and Services Administration (HRSA) (Oct. 27, 2015), https://bit.ly/3nXZq55.

BACKGROUND

Congress established the 340B program in 1992 to improve access to essential medications for certain poor, uninsured, and otherwise vulnerable patient groups. *See* H. Rep. No. 102-384 (II), at 11-13 (1992); *see also* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act). Under the program, drug manufacturers as a condition of participating in Medicaid must charge no more than a deeply discounted "ceiling price" to specified "covered entities" on certain outpatient prescription drugs. 42 U.S.C. § 256b(a)(4).

Congress recognized that this program needed limits to ensure that the typically steep manufacturer discounts on drugs reached the covered entities listed in the 340B statute. It therefore wrote two crucial safeguards into the 340B statute to protect against abuse and to ensure that the program serves its intended public purpose. Among other things, the statute prohibits "duplicate-discounts," sales on which a manufacturer is charged both a 340B discount and a Medicaid Drug Rebate Program rebate. *See* 42 U.S.C. § 256b(a)(5)(A). In addition, the statute's "anti-diversion" provision prohibits covered entities from "resell[ing] or otherwise transfer[ing]" 340B drugs to anyone "who is not a patient of the [covered] entity." *Id.* § 256b(a)(5)(B).

Congress amended the 340B program in 2010 as part of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act. *See* Patient Protection and Affordable Care Act of 2010 § 7102, Pub. L. No. 111-148, 124 Stat. 119, 826–27 (Mar. 23, 2010); Health Care and Education Reconciliation Act of

2010 § 2302, Pub. L. No. 111-152, 124 Stat. 1029, 1082–83 (Mar. 30, 2010) (collectively, the Affordable Care Act ("ACA")). As part of those 2010 amendments, Congress directed the agency to improve covered entity compliance with the program's anti-diversion and duplicate-discount prohibitions. *See* 42 U.S.C. § 256b(d)(2)(A). Congress also instructed the agency to establish and implement "an administrative process for the resolution of claims by covered entities that they have been overcharged for drugs purchased under [the 340B program], and [of] claims by manufacturers" that covered entities have generated duplicate discounts or allowed 340B covered drugs to be transferred to non-patients. 42 U.S.C. § 256b(d)(3)(A). HRSA was to establish this ADR process "not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act [March 23, 2010]." *Id.*

On September 20, 2010, HRSA published an advance notice of proposed rulemaking regarding the ADR process. *See 340B Drug Pricing Program Administrative Dispute Resolution*, 75 Fed. Reg. 57,233, 57,233 (Sept. 20, 2010). On August 12, 2016, HRSA issued a notice of proposed rulemaking, *340B Drug Pricing Program; Administrative Dispute Resolution Process*, 81 Fed. Reg. 53,381 (Aug. 12, 2016). In October 2016, PhRMA and other organizations submitted comments demonstrating that the rule HRSA proposed was inadequate, unlawful, and contrary to the statute's requirements. *See* OMB, 340B Drug Pricing Program; *Administrative Dispute Resolution Process*, RIN 0906-AA90, https://bit.ly/2HBbCJK. Not surprisingly, the flawed proposed rule was abandoned on August 1, 2017. *See* OMB/OIRA, Unified Agenda, Summary of Regulatory Action for RIN-0906-AA90 (Spring 2017), https://bit.ly/3q1t37o (reflecting that the ADR proposed rule was abandoned on August 1, 2017).

Recently, two lawsuits were filed against the agency in federal district court for the District of Columbia. *Ryan White Clinics for 340B Access, et al. v. Azar, et al.*, No. 20-cv-2906, ECF No. 1 (D.D.C. Oct. 9, 2020); *Nat'l Ass'n of Cmty. Health Ctrs. v. Azar & U.S. Dep't of Health & Hum. Servs.*, No. 20-cv-3032, ECF No. 1 (D.D.C. Oct. 21, 2020). Each lawsuit seeks, among other things, a writ of mandamus ordering the agency to promulgate an ADR rule, on the ground that the statutory deadline has passed, and the agency has unreasonably delayed taking action. Apparently in response to these lawsuits, HRSA has sent a 340B ADR final rule to OMB for review and approval.

REASONS FOR NEW ADR RULEMAKING AND COMMENT PERIOD

PhRMA files this petition to express its deep concern with HRSA's apparent plan to finalize the abandoned 2016 proposed rule without considering both the changes in circumstances in the years since the prior comment period, and the numerous deficiencies with the proposed rule outlined in the prior comments. Among other things, the proposed rule cannot be issued without a clear and adequate definition of "patient" and appropriate audit guidelines in place. HRSA should instead develop a new proposed rule, or at least re-open the comment period for the

ADR proposed rule, to account for material new developments relevant to any ADR process.

A. Changed Circumstances and New Evidence Since 2016 Require a New Comment Period.

As a threshold matter, finalizing the 2016 proposed rule rather than undertaking a new notice-and-comment rulemaking proceeding would not satisfy the requirements of the APA. There is no good cause to dispense with the APA's notice-and-comment requirements; the agency's apparent desire to avoid litigating the recently-filed suits does not justify a last-minute rush to finalize a flawed proposal after years of inaction. *See, e.g., Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93-95 (D.C. Cir. 2012) (holding agency lacked "good cause" for promulgating emergency interim rule because notice and comment was not impracticable or unnecessary); *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 754-55 (D.C. Cir. 2001) (similar).

Nor does the 2016 comment period on the proposed rule obviate the need for a notice-and-comment proceeding here. "[T]he life of [a notice and comment] record is not infinite." *Mobil Oil Corp. v. U.S. EPA*, 35 F.3d 579, 585 (D.C. Cir. 1994). Rather, where "new information relevant to the agency's decisionmaking" has "come to light after the original notice and comment proceedings," the APA requires a new comment period, so that impacted stakeholders can present this new information, and the agency can fairly consider it and alter the proposed rule as needed. *Id.* That is particularly the case here, given the new evidence of problems that has come to light in the years since the close of the comment period in 2016 and abandonment of the ADR rule in 2017.

Here, changes in circumstances and new evidence demonstrate that the prior 2016 comment period is past its "useful life." *Id.* Since 2016, Congress, independent agencies, and even HRSA have compiled evidence that the 340B program is rife with compliance abuses. The most significant change in the 340B program since 2016 has been the dramatic increase in the number of covered entities and the use of contract pharmacies, which has corresponded with a dramatic increase in unlawful drug diversion and duplicate discounts, as well as other new for-profit entities.

- The 340B program continues to experience explosive growth, tripling in size since 2014, with little change in regulatory oversight to keep pace with this rapidly evolving program. According to a 2018 GAO Report, the number of contract pharmacies increased from about 1,300 in 2010 to nearly 20,000 in 2017. GAO, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480 (June 2018), https://bit.ly/3kZYAD7.

- As of October 2020, there apparently are approximately 25,000 unique contract pharmacy locations across the country and more than 170,000 arrangements between contract pharmacies and 340B covered entities. *See* HRSA, 340B

Contract Pharmacy Database, https://bit.ly/39qpNNp (last visited Nov. 22, 2020).

- Starting in 2016, a new pattern of vertically integrated specialty pharmacy enrollments emerged. In January 2016, there were 1,473 contract pharmacy arrangements between 340B covered entities and these vertically integrated specialty pharmacies. By April 2020, this count had grown to 16,293—a 1,006 percent increase in four years. *See* Berkeley Research Group, *For-Profit Pharmacy Participation in the 340B Program* (October 2020), https://bit.ly/2KzNFDD; *see also* Sunita Desai & J. Michael Williams, *Consequences of the 340B Drug Pricing Program*, N. Engl. J. Med. (Feb. 8, 2018), https://bit.ly/362pcz5.

This unchecked program growth has been reported in the years that followed the close of the comment period to the ADR proposed rule. For example, the House Energy and Commerce Committee has found that "the number of participating unique covered entities has grown from 3,200 in 2011…to 12,722 in October 2017." H. Comm. on Energy & Commerce, Review of the 340B Drug Pricing Program, 114th Cong., at 44 (Jan. 10, 2018) ["2018 House Report"]. The 2018 House Report went on to state that: "As of October 1, 2017, 42,029 registered covered entity sites were participating in the 340B program, including 12,722 covered entity (parent) sites and 29,307 associated (child) sites." *Id.* at 13. As a result, the sale of discounted 340B drugs has exploded beyond any measure that Congress contemplated. *See* Adam J. Fein, *New HRSA Data: 340B Program Reached $29.9 Billion in 2019; Now Over 8% of Drug* Sales, Drug Channels (June 9, 2020) ["2020 Drug Channels Report"]. By 2019, discounted drugs purchased through the 340B program accounted for at least 8% of the total U.S. drug market, amassing $29.9 billion in sales that year, an "astonishing" 23% increase over sales in 2018. *See* 2020 Drug Channels Report (noting that "the 340B program is now almost as large as the Medicaid program's outpatient drug sales").

Similarly, the rapid growth in the number of commercial contract pharmacies participating in the 340B program—from 1,256 in 2010 to more than 27,928 in 2020—has occurred since the 2016 comment period closed. *See* Adam. J. Fein *A Primer on 340B Contract Pharmacies and Medicaid Duplicate Discounts (video)*, Drug Channels (Oct. 22, 2020); *see also* Adam J. Fein, *Walgreens and CVS Top the 28,000 Pharmacies Profiting from the 340B Program. Will the Unregulated Party End?*, Drug Channels (July 14, 2020). OIG flagged this problematic unchecked growth in 2018 congressional testimony, where OIG noted that it had "identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements." HHS OIG Testimony: Examining Oversight Reports on the 340B Drug Pricing Program, Testimony Before the U.S. Senate Committee on Health, Education, Labor, and Pensions (May 15, 2018), at 5.

The explosive growth in the number of covered entities and contract pharmacies has not resulted in any guaranteed benefit to patients but instead has coincided with significant increases in diversion of 340B drugs. In 2018, the House Energy and Commerce Committee found that nearly half—and in some years more than half—of audited covered entities unlawfully sold or transferred 340B drugs to nonpatients. *See* 2018 House Report at 38 (noting that audit information from 2012 through 2016 shows that nearly half of audited covered entities were involved in unlawful diversions to non-patients). Likewise, in 2020 and 2018, the GAO concluded that the sharp growth in contract pharmacy arrangements sharply increased the risk of both duplicate discounts and unlawful diversion. *See* GAO, GAO-20-212, *340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement* (Jan. 2020) ["2020 GAO Report"]; *see also* GAO, GAO-18-480, *Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement* (June 2018) ["2018 GAO Report"]. For example, GAO found that approximately two-thirds of diversion findings in HRSA audits "involved drugs distributed at contract pharmacies." *Id.*; *see* HHS, HRSA, *Program Integrity: FY18 Audit Results*. Similar results were posted for Fiscal Year 2019, with numerous audits identifying instances of diversion and duplicate discounts as a result of the use of contract pharmacies. Equally troubling, HRSA does not terminate covered entities when there are findings of noncompliance. For instance, in one case where HRSA initially concluded that a covered entity had violated 340B requirements, the lack of a clear definition of "patient" hampered its enforcement efforts, and ultimately both the enforcement measures and audits were withdrawn. *Genesis Health Care v. Azar*, No. 4;19-cv-1531-RBH (D. S.C. Dec. 18, 2019).

Unlike in-house pharmacies, contract pharmacies do not possess and do not have access to the records of the covered entity's patients. *See* Examining Oversight Reports on the 340B Drug Pricing Program: Hearing Before the S. Comm. on Health, Education, Labor, and Pensions, 115th Cong. 6 (May 15, 2018) (statement of Ann Maxwell, Assistant Inspector General, Office of Evaluation and Inspections, HHS OIG) ("Retail contract pharmacies often have no way to distinguish a 340B patient from any other customer filling a prescription at their stores."); *see also* Examining HRSA's Oversight of the 340B Drug Pricing Program: Hearing Before the Subcomm. on Oversight and Investigations of H. Comm on Energy and Commerce, 115th Cong. (July 18, 2017) (Statement of Erin Bliss, Assistant Inspector General, Office of Evaluation and Inspections, HHS OIG).

While the growth in covered entities and contract pharmacies has coincided with growth in diversion and duplicate discounts, it has not resulted in benefits to the low income and vulnerable patients the program is intended to help. Indeed, HRSA imposes no requirement on covered entities to share 340B discounts with their patients, nor does the agency require contract pharmacy arrangements to ensure that 340B patients receive any portion of the 340B discounts. Instead, covered entities are permitted to keep all of the revenue for 340B discounts if they choose to do so, or even to share it with contract pharmacies.

Troublingly, government reports have found that many covered entities do, in fact, fail to pass on any portion of the 340B discount to their patients, even as they share a portion of the discounts with their commercial entity, for-profit contract pharmacies. *See, e.g.,* 2018 GAO Report at 30, https://bit.ly/3kZYAD7 (finding that, of 55 covered entities that responded to a questionnaire, only 30 stated that they provide low-income, uninsured patients with discounts on 340B drugs dispensed at some or all of their contract pharmacies, and that 25 said they do not offer 340B discounts to patients at their contract pharmacies); 2018 House Report, at 32–34 (finding that contract pharmacies typically not only charge a dispensing fee for their role in distributing covered outpatient drugs, but also ensure that they receive a share of the revenue that the covered entity receives through the 340B-discounted price).

To the contrary, the 340B program's "good intentions have been overwhelmed by middlemen that pocket discounts while forcing patients, employers, and the Medicare program to pay more for prescription drugs." Ltr. from Adam J. Fein to the Hon. Lamar Alexander and the Hon. Greg Walden (Oct. 30, 2020). And among other things, contract pharmacies often fail to extend 340B pricing to the low income or uninsured patients to whom they dispense, instead siphoning manufacturer discounts from covered entities in the form of "spread-splitting" and service fees. *See* Adam J. Fein, *The Federal Program that Keeps Insulin Prices High*, Wall St. J. (Sept. 10, 2020); *see also* PhRMA, *New Analysis Shows Contract Pharmacies Financially Gain from 340B Program with No Clear Benefit to Patients*, Press Release (Oct. 8, 2020). *See, e.g.*, 2018 GAO Report at 30, https://bit.ly/3kZYAD7; HHS OIG, *Memorandum Report: Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431 (Feb. 2014), https://bit.ly/2UZSCaM.

In addition, new studies show that the amount of charitable care provided by covered entities has *decreased*. Evidence published in 2019 shows that, between 2013 and 2017, the total value of uncompensated care (as a proxy for charity care) is estimated to have declined from $46.8 billion to $38.4 billion. *See* Adam. J. Fein, *340B Program Purchases Reach $24.3 Billion—7%+ of the Pharma Market—As Hospitals' Charity Care Flatlines*, Drug Channels (May 14, 2019) ["2019 Drug Channels Report"] (noting that uncompensated care as a percentage of total expenses has hit a historic low, declining from 5.9% in 2013 to 4.0% in 2017).

Covered entities are also directing more resources to wealthier and better insured individuals—specifically, they are charging full price for the drugs that the entities themselves receive at a deep discount. *See* Rena M. Conti, *The 340B Drug Discount Program: Hospitals Generate Profits By Expanding To Reach More Affluent Communities*, Health Affairs (Oct. 2014), https://bit.ly/2J5qvok. Many covered entities have acquired distant child sites in affluent communities to turn previously independent physician offices and clinics into 340B sites, expanding their opportunities to dispense discounted 340B drugs to commercially insured patients

(and non-eligible individuals). In addition, and ironically, this shift often causes government and private payors to pay *more* in reimbursement (hardly "stretching scarce federal resources"). *See* Peter B. Bach & Raina H. Jain, *Physician's Office and Hospital Outpatient Setting in Oncology: It's About Prices, Not Use*, J. of Oncol. Pract. Volume 13 Issue, 1 (Jan. 2017). These increased costs are also borne by patients with coinsurance obligations when based off a non-discounted price, not the deeply discounted 340B price.

Further, in the Medicare Part B context, government reports—and rulemaking from HHS/CMS itself—have found and emphasized the extent to which 340B program discounts result in significant financial losses for the Medicare program. For example, government reports and rulemaking from HHS/CMS have demonstrated that hospitals participating in the 340B Program typically paid between 20 percent and 50 percent *below* the average sales price (ASP) that is used as a metric for Medicare Part B reimbursement of most prescription drugs when they acquired Part B drugs—but, they received the full reimbursement from Medicare. *See* GAO, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442 (June 2015), https://bit.ly/3fx8Npu; *see also* CMS, Hospital Outpatient Prospective Payment System Proposed Rule Calendar Year 2021, 85 Fed. Reg. 48,772, 48,886 (Aug. 12, 2020) ("We estimate that the typical acquisition cost for 340B drugs for hospitals paid under the [Medicare Hospital Outpatient Prospective Payment System] is ASP minus 34.7 percent"). *See also Am. Hosp. Ass'n v. Azar* (D.C. Cir. July 31, 2020), slip op. at 6 (noting the "large gap between the amount a 340B hospital would spend to acquire a [prescription drug] and the higher amount Medicare would reimburse that hospital. The gap ranged from 25% to 55% of the cost of the drug"). Indeed, HHS and CMS acknowledged, in the rulemaking for the Medicare Part B program, that this hospital outpatient reimbursement gap "allow[ed] [340B] providers to generate significant profits when they administer[ed] Part B drugs," 82 Fed. Reg. 52,356, 52,494 (Nov. 13, 2017)—at the expense of the Medicare program. The government prevailed earlier this year in the D.C. Circuit in litigation that hospitals brought to challenge cuts the agency made in these 340B hospital reimbursement rates. *See Am. Hosp. Ass'n v. Azar*, *supra*. And, further reflecting the agency's efforts to address the 340B program's negative impact on Medicare, CMS has proposed to continue and potentially even increase these 340B hospital reimbursement cuts under Part B going forward. *See* 85 Fed. Reg. at 48,886.

The unchecked expansion of the 340B program has also resulted in increased treatment costs. Indeed, the 340B program drives care away from less expensive physician office settings into more expensive hospital settings:

> [M]edical-benefit drug costs for these patients in the hospital outpatient setting cost more than twice as much as in the physician office setting. Due to these types of price differences,

> the hospital outpatient setting is typically the highest-cost setting for administration of medical benefit drugs.

Aaron Vandervelde & Eleanor Blalock, *Site of Care Shift for Physician-Administered Drug Therapies*, Berkeley Research Group, 3 (Oct. 2017). Likewise, the 2018 House Report provided another illustrative example, noting that in Atlanta, "after Northside acquired Atlanta Cancer Care in 2013, the out of pocket cost of treatment for one patient rose from $20 to $212, a more than 1000 percent increase." 2018 House Report, at 68.

Several government entities have raised concerns about market distortions caused by the program's expansion. The 2018 House Report noted that the 340B program is affecting "market dynamics" in ways that "should be concerning to everyone focused on improving patient care":

> The committee has been unable to determine at this time how frequent or widespread such dynamics may be. However, the sincere concerns expressed by numerous health care providers who have witnessed these challenges suggest there may be at least some negative consequences of market dynamics associated with the 340B program. Given the widespread agreement between all covered entities that the aim of the 340B program is to assist these entities in providing care to patients, first-person reports of negative patient impacts or patient harm should be concerning to everyone focused on improving patient care.

2018 House Report, at 68. HHS, OIG, and GAO have identified unchecked program growth as an area of significant concern because of the unknown consequences in the shifts in behavior. *See* GAO, *Drug Discount Program: Update on Agency Efforts to Improve 340B Program Oversight, Testimony Before H. Comm. on Energy & Commerce*, 113th Cong., 1–3 (July 18, 2017) (statement of Debra A. Draper, Director, Health Care, GAO).

The foregoing is not an exhaustive recitation of the problems and new evidence that has arisen in the 340B program since 2016. These examples, however, are more than sufficient to show that stakeholders should be afforded the opportunity to supplement the record to ensure that any final ADR rule can take account of, and address, these material developments in the 340B program. Due to the changed circumstances since the 2016 comment period, it would violate the APA for HRSA to finalize the abandoned proposed rule without taking into proper consideration the new evidence, and making the necessary alterations to the proposed ADR process to address these problems.

B. The Abandoned 2016 Proposed Rule Cannot Be Finalized.

To survive review under the APA's arbitrary and capricious standard, the agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). An agency determination is arbitrary and capricious if it is not "based on a consideration of the relevant factors," "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency," or "there has been a clear error of judgment." *Id.*; *see also, e.g., Whitaker v. Thompson*, 248 F. Supp. 2d 1, 13 (D.D.C. 2002) ("[T]he basic finding upon which the [agency] rests its decision . . . is unreasonable because it is not supported by an overall review of the available evidence . . . .").

Here, the agency's 2016 proposed rule was invalid at the outset because it did not include "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii). That directive reinforces the agency's obligation to "provide for improvements in compliance by covered entities . . . in order to prevent diversion and violations" of the statutory prohibition on duplicate discounts. *Id.* § 256b(2)(A). To satisfy those obligations, the agency needs to adopt a precise patient definition and audit procedures. The impacts of these deficiencies have only become more pronounced, as unchecked abuses in the program have grown. The agency cannot continue to turn a blind eye to evidence of the explosive growth in the 340B program and the abuses that growth has spawned since the close of the 2016 comment period. This new evidence underscores the need to implement a patient definition that has undergone adequate notice-and-comment rulemaking and to eliminate the restrictions manufacturers face in accessing the ADR process, so that key participants in the program can use the ADR process to resolve claims in a fair, efficient, and timely manner.

To be effective, all participants in a dispute resolution process—including those who administer it—must understand the governing standards, including the definition of patient and appropriate audit procedures. Leaving the development of key elements of these standards to case-by-case decision-making is the antithesis of an efficient system. It is also inconsistent with the statutory requirement that the agency "*shall*" establish "procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii) (emphasis added). In many cases, a dispute between a covered entity and a manufacturer turns on whether the recipient of the 340B drug is a patient entitled to receive that drug under the statute. Accordingly, the ADR process cannot possibly be efficient and expeditious until the agency has adopted a clear and adequate definition of the statutory term "patient."

Likewise, the 2016 proposed rule was promulgated without the fair and adequate audit procedures necessary to investigate diversion and duplicate discount

violations. These audit procedures are critically important for manufacturers because an audit is the gateway to the ADR process, as it is a required prerequisite under the statute and provides a basis for asserting that the covered entity has violated the diversion or duplicate-discount prohibitions. *See* 42 U.S.C. § 256b(d)(3)(A), (B)(iv). Limitations in the current audit guidelines prevent manufacturers from availing themselves of a process HRSA has said should be "fair, efficient, and [facilitate] timely resolution of claims." 81 Fed. Reg. 53381, 53385 (Aug. 12, 2016).

For these reasons, the agency must take into account new evidence as part of a new notice and comment rulemaking process to protect the program's integrity and stakeholder rights under the APA.

PROPOSED PATIENT DEFINITION AND AUDIT PROCEDURES

Before finalizing an ADR rule, consistent with our prior comments, and in light of the new evidence, the agency should provide a notice and comment period that (i) allows stakeholders to comment on the definition of "patient" and key policies and terms necessary to ensure a meaningful, fair, and effective dispute-resolution process, and (ii) provides clear manufacturer audit procedures for investigating and adjudicating disputes, including claims that a covered entity has diverted discounted drugs to nonpatients.

A. The Agency Should Adopt a Definition of "Patient" to Ensure That the Dispute-Resolution Process is Meaningful and Promotes the Integrity of the 340B Program.

Nearly 30 years ago, HRSA issued a "patient" definition. HRSA, *Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility*, 61 Fed. Reg. 55,156 (October 24, 1996). According to that notice, an "individual is a 'patient' of a covered entity . . . if:

> " 1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;
>
> 2. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and
>
> 3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center

> look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement."

61 Fed. Reg. at 55,157. The definition excludes anyone who receives no other health care from the covered entity other than "the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting." *Id*. at 55,158.

The 1996 notice was inadequate to ensure program integrity because the definition lacked needed clarity and specificity. HRSA and other government agencies such as GAO have recognized some of these problems. For example, GAO has stated that "HRSA's current guidance on the definition of a 340B patient is sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for purposes of 340B" and that this has "raised concerns that the guidance will be interpreted too broadly." GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836, at 22 (Sept. 2011); *see also* HRSA, Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of "Patient," 72 Fed. Reg. 1543, 1544 (reflecting HRSA's own statement that "it is possible that some 340B covered entities may have interpreted the definition [under the 1996 'patient' definition guidance] too broadly, resulting in the potential for diversion of medications purchased under the 340B Program"). GAO further noted that, "[a]s a result of the lack of specificity in the guidance, [HRSA] has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care." GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept. 2011). Since putting forward the 1996 guidance, the agency has on two separate occasions proposed a new patient definition. *See* 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007); 80 Fed. Reg. 52,300, 52,306 (Aug. 28, 2015). Yet the agency did not finalize either proposal, and they are no longer being actively considered.

The agency should therefore adopt a definition for when an individual is a patient of a covered entity, on a prescription-by-prescription and order-by-order basis. The following six requirements were largely proposed by HRSA in 2015 and are necessary to protect the 340B program's integrity and to ensure that the program serves its lawful public purposes. Below each of these we offer additional improvements to bring needed clarity to the definition.

(1) *The individual receives a health care service at a covered entity site that is registered for the 340B Program and listed on the public 340B database.*

An individual must receive a health care service from a covered entity, and the covered entity must be medically responsible for the care provided to the individual. An individual who sees a physician in a private practice that is not listed on the public 340B database or at any other non-340B site of the covered entity, even as follow-up to care provided at a covered entity, would not be eligible to receive drugs obtained under the 340B Program for the services provided at these non-340B sites or for prescriptions that originate from the services provided at these non-340B sites.

An individual is not considered a patient of the covered entity if the individual's health care that results in the administration or prescription of a covered outpatient drug is provided by another health care organization that has an affiliation arrangement with the covered entity, even if the covered entity has access to the affiliated organization's records, unless the organization with the affiliation arrangement is itself registered under the 340B Program and listed on the public 340B database. Access to an individual's records by a covered entity, by itself, does not make the individual a patient of the covered entity. Merely having a drug dispensed from a contract pharmacy of a covered entity is also not sufficient to establish or renew a patient relationship between an individual and a covered entity.

(2) *The individual receives an in-person*[1] *health care service from a health care provider who is either employed by the covered entity or who is an independent contractor of the covered entity, and in either case the covered entity is authorized to bill for services on behalf of the provider, the provider is listed on the covered entity's Medicare cost report, the provider has direct oversight of the individual's care as it relates to any covered outpatient drug, and the covered entity has responsibility for the care provided.*

Faculty practice arrangements and established residency, internship, locum tenens, and volunteer health care provider programs are examples of covered-entity-provider relationships that could meet this standard, provided all other requirements of those arrangements are also met. The fact that a provider has privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by that provider is a patient of the covered entity for purposes of the

[1] PhRMA supports an appropriately tailored exception to the "in-person" requirement for public health emergencies such as the COVID-19 pandemic.

340B Program. Instead, when an employee or independent contractor provides health care services to an individual on behalf of the covered entity, the covered entity must be responsible for the care provided in order for the individual to qualify as a patient of the covered entity. For the covered entity to be responsible for the care provided, the employee or individual contractor must assign their right to bill and collect payment for services to the covered entity.

If a patient is referred from a covered entity for care at an outside provider that is unaffiliated with the covered entity within the meaning of this section, and receives a prescription from that outside provider, the prescribed drug would not be eligible for a 340B discount at the covered entity. When an individual receives care at several entities, for the individual to be considered a patient of the covered entity with respect to a particular prescription, the prescription must originate during the healthcare service provided at the covered entity, and not at another entity, and should be written by a provider employed by (or as an independent contractor to) the covered entity or by a provider appropriately affiliated with the covered entity, within the meaning and restrictions of this section.

There may be narrow circumstances where a non-hospital entity is 340B-eligible as a result of a HRSA grant that requires it to operate a medical home model of care or otherwise coordinate the care of certain patient populations. In those circumstances, ensuring that patients served by the grantee are referred to other providers as appropriate and closely coordinating with those providers are central to the grantee's ability to fulfill its grant obligations. In those limited circumstances, an individual may qualify as a patient of the covered entity if the grantee refers its patient to a provider for medical services or treatment and the prescription is written by the provider, as long as the grantee takes steps to ensure that only one covered entity seeks a 340B discount on any given prescription.

(3) The individual receives a drug that is directly related to, and is ordered or prescribed by the covered entity provider as a result of, the service described in (2). An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug.

An individual qualifies as a patient of a covered entity if the health care service received at the covered entity results in a drug order or prescription for the individual being written by a provider employed by (or as an independent contractor to) the covered entity. An individual

does not qualify as a patient of the covered entity if the covered entity's only relationship to the individual is the dispensing or infusion of a drug. The dispensing of or infusion of a drug alone, without a covered entity provider-to-patient encounter involving the provision of a health care service, does not qualify an individual as a patient for purposes of the 340B Program.

(4) The individual receives a health care service that is consistent with the covered entity's scope of grant, project, or contract.

Individuals qualify as patients of a covered entity only if they are receiving health care at a covered entity site from a covered entity provider that is consistent with the health care service or range of services for which the covered entity is 340B-eligible. In the case of a covered entity with 340B eligibility based on receipt of a Federal grant, project, designation or contract, the services provided to the individual must be consistent with the health care service or range of services designated in the Federal grant, project, designation, or contract. In the case of a hospital that is 340B-eligible because it has a contract with a state or local government to care for low-income individuals ineligible for Medicare or Medicaid, the services provided to the individual must be provided within the scope of that contract.

If an individual is receiving services from a child site of a covered entity and the child site's scope of grant, project, or contract is more limited than that of the parent site, the individual will qualify as a patient of the covered entity only if he or she is receiving health care at the child site that is consistent with the health care service or range of services properly delegated to the child site.

(5) The individual is classified as an outpatient when the covered outpatient drug is ordered, prescribed, and dispensed, with the patient's classification status determined by how the services for the patient are billed to and paid by the insurer or third-party payor.

An individual cannot qualify as a patient of the covered entity if his or her care is not properly classified as outpatient. An individual is considered an outpatient for purposes of the 340B Program if his or her health care service is billed as "outpatient" to the individual's insurance or third-party payor (e.g., Medicare or private insurance), and his or her health care service is paid by the individual's insurance or a third-party payor as an outpatient service. Covered entities should maintain auditable records documenting any changes in patient status due to insurer or third-party payor determinations.

A covered entity may not fill "discharge prescriptions" with 340B drugs. A "discharge prescription" does not, however, include prescriptions filled by non-hospital grantees that are responsible for managing the care of the individual both before admission and after discharge.

The outpatient status of individuals who are self-pay, uninsured, or whose care is provided by the hospital covered entity's charity care program, would be determined by the covered entity's documented, auditable policies and procedures. Covered entities would therefore be expected to have clearly defined policies and procedures that they follow to classify individuals consistently as either inpatient or outpatient. Most policies and procedures of covered entities should classify an individual as inpatient or outpatient based on how the services have been billed to Medicare or another third-party payor.

(6) The individual has an ongoing relationship with the covered entity such that the covered entity maintains, owns, controls, and possesses auditable health care records sufficient to demonstrate that the covered entity has an ongoing provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition is met for each 340B drug.

An individual qualifies as a patient of the covered entity if he or she has an established, ongoing relationship with the covered entity such that the covered entity maintains, owns, controls, and possesses auditable health care records that demonstrate that the covered entity has a provider-to-patient relationship with the individual for the health care service that results in the order or prescription and that the covered entity retains responsibility for care that results in every 340B drug ordered, dispensed, or prescribed to the individual.

HRSA's 2007 proposed clarification also provided that the covered entity must have "ongoing responsibility" for "the outpatient health care service that results in the use of (or prescription for) 340B drugs," and that "[t]o demonstrate the necessary retention of ongoing responsibility for the health care it is expected that, at a minimum, the covered entity will provide health care to the individual in the [340B hospital] or the qualified provider-based facility of the [hospital] within 12 months after the time of the referral." This 12-month standard is reasonable and appropriate. Thus, we recommend that HRSA specify that the 340B provider/patient relationship may begin with an individual's first visit to a covered entity (provided all other elements of the patient definition are met), but that this relationship will end if the individual does not visit the covered entity within 12 months following the visit that resulted in the 340B prescription.

B. The Agency Should Adopt Improved Audit Procedures Necessary to Ensure that the Dispute-Resolution Process is Meaningful and Promotes the Integrity of the 340B Program.

The agency should also adopt improved audit procedures so that manufacturers can reasonably and fairly complete the audits of covered entities that are required in order for manufacturers to access the ADR process. Unfortunately, the existing audit guidelines make manufacturer audits costly and difficult. The result is an arbitrary, one-sided system that drastically exceeds the Agency's authority and unduly limits manufacturers from auditing the abuses that are undermining the integrity of the 340B program and fueling market distortions.

HRSA recognized these unfair barriers to manufacturer audits when it issued an advanced notice of proposed rulemaking in 2010. At that time, the agency requested comments on how make its audit procedures more useful to manufacturers, given that they rarely utilize it. *See* 75 Fed. Reg. at 57,235. In line with that request, PhRMA has provided comments on an audit process that would revise and improve HRSA's existing audit procedures in several respects. *See* PhRMA, Comment Letter on Proposed Rule for Administrative Dispute published by the Health Resources and Services Administration (HRSA) (Oct. 11, 2016), https://bit.ly/3pVnrvA; *see* PhRMA, Comment Letter on Proposed 340B Program Omnibus Guidance Published by the Health Resources and Services Administration (HRSA) (Oct. 27, 2015), https://bit.ly/3nXZq55. Implemented together, PhRMA's proposed improvements will promote manufacturers' use of the audit process to redress program violations. That should help curb the abuses and harmful effects of the program discussed above.

CONCLUSION

For the foregoing reasons, HRSA should issue a new proposed rule and then, after receiving and considering comments, promulgate a final rule establishing an ADR procedure for participants in the 340B Drug Pricing Program. *See* 5 U.S.C. § 552(e). In the alternative and at a minimum, HRSA should re-open the comment period of the ADR rulemaking for at least 60 days.

Exhibit P

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

May 17, 2021

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

Dear Mr. Asay:

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

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

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

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

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

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

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

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

Thank you for your commitment to the 340B Program.

Sincerely,

Diana Espinosa

Diana Espinosa
Acting Administrator

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

Exhibit Q

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

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

Before the Honorable
SARAH EVANS BARKER, JUDGE

OFFICIAL REPORTER'S TRANSCRIPT OF
MOTION FOR PRELIMINARY INJUNCTION

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

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

A P P E A R A N C E S

For Eli Lilly:

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appeal right under the APA any place in your website or your formulation of the ADR Rules, right? Is that right?

MS. TALMOR: No, Your Honor.

THE COURT: You have? You have referenced that?

MS. TALMOR: Yes, Your Honor.

THE COURT: Appeals would be processed through the APA?

MS. TALMOR: Yes, Your Honor. Appeals would be processed through the APA.

THE COURT: Where does it say that?

MS. TALMOR: 42 U.S.C. 256(B)3(A), when it provides that the secretary shall establish a decision-making official or body that has the authority to issue final decisions, that does create a principal-officer as Lilly portrayed. That should be that the entity charged with reviewing 340B program violations is authorized to issue a final agency action reviewable under the APA. It's both in the statute and it's in the rule.

The rule also states that the decision will be final agency action reviewable under the APA. In fact, in its motion, I was a bit perplexed because Lilly complained that the rule only authorizes APA review. The statute authorizes APA review. The rule confirms that the statute authorizes APA review, and HHS could not authorize anything else. HHS can't authorize to do anything.

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

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

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

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

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

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

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