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.

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

ROBERT P. CHARROW, in his official capacity as 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 ESPINOZA, 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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FIRST 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.

That brings us to now. 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.

Lilly therefore brings this action seeking an order: (1) declaring that the December 30 Decision 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 to offer 340B discounts to contract pharmacies; (3) enjoining enforcement of the December 30 Decision 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 Norris Cochran, sued in his official capacity only, is the Acting 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. Acting Secretary Cochran 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 Robert P. Charrow, sued in his official capacity only, is the General Counsel of HHS. His official address is in the District of Columbia. Mr. Charrow 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 Espinoza, 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 Espinoza is directly

responsible for the administration of the 340B Program and the actions complained of herein. Acting Administrator Espinoza, 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* 42 U.S.C. § 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 Jan.

12, 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.

[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.

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

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. *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 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 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 Jan. 12, 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. Defendants' Final Agency Action, The Harm To Lilly, And The Need To File Suit

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

147. 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, 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)).

148. The December 30 Decision 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

149. The December 30 Decision plainly 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.

150. 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.").

151. 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]").

152. 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.

153. 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).

154. 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.

155. 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.

156. 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).

157. 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.

B. The ADR Rule Constitutes Final Agency Action

158. 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.

159. 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.

160. 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.

161. 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).

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

163. 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)

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

165. 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).

166. 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.

167. 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.

168. 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).

169. 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.

170. 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).

171. 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).

172. 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).

173. 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).

174. 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.

175. 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.

176. 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.

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

178. 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.

179. 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)

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

181. 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).

182. 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.

183. 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.").

184. 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.

185. 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.

186. 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).

187. 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)

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

189. 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).

190. 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.*

191. 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).

192. 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.

193. 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.

194. 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.

195. 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)

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

197. 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).

198. 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.

199. 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.

200. 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).

201. 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)).

202. 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 opinion) (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).

203. 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.).

204. 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).

205. 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 Dall. 386, 388 (1798) (opinion 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).

206. 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

opinion) ("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.").

207. 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).

208. 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.

209. 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").

210. 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)

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

212. 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).

213. 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.

214. 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.

215. 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)).

216. 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.

217. 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.

218. 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.

219. 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.*

220. 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.

221. 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).

222. 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)

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

224. 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.*

225. 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).

226. 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 opinion).

227. 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)).

228. 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.

229. 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).

230. 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.").

231. 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)

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

233. 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).

234. 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.

235. 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.

236. 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).

237. 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)

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

239. 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.

240. 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).

241. 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).

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

243. 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.

244. 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.

245. 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).

246. 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.

247. 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.

248. 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.

249. 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.

250. 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)

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

252. 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).

253. 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.*

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

255. 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).

256. 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.

257. 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.").

258. 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).

259. 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.

260. 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.

261. 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.").

262. 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.

263. 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).

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 because the December 30 Decision 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;

b. issue an order and judgment declaring that it would be entirely lawful for Lilly not to offer 340B price discounts to contract pharmacies;

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

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: January 25, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on **January 25, 2021**, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system. I further certify that copies will be mailed by U.S. mail to the following addresses:

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Washington D.C. 20201

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

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

United States Attorney General
United States Department of Justice
950 Pennsylvania Ave, N.W.
Washington, DC 20530

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

/s/ Andrea Roberts Pierson
Andrea Roberts Pierson

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

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.

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

ROBERT P. CHARROW, in his official capacity as 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 ESPINOZA, 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

Document Electronically Filed

AMENDED COMPLAINT
INDEX OF EXHIBITS

EXHIBIT	DESCRIPTION
Exhibit A	10.15.2020 – HHS 340B Letter Signed
Exhibit B	2020-05-18 – Lilly Letter to HRSA 340B Contract Pharmacy Cialis
Exhibit C	2020-06-11 – Response to Derek L Asay - Eli Lilly USA
Exhibit D	2020-06-26 – HRSA Email re Lilly Manufacturer Notice
Exhibit E	2020-07-17 – Lilly Letter to HHS
Exhibit F	2020-08-19 – Lilly Letter to HRSA 340B Contract Pharmacy Portfolio
Exhibit G	Limited Distribution Plan Notice for Lilly Products Sept 2020
Exhibit H	2020-08-26 Response to Derek Asay - Eli Lilly
Exhibit I	2020-08-27 Lilly Response to RADM Pedley
Exhibit J	2020-09-08 Lilly Letter to HHS
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Exhibit L	2020-12-09 HRSA Response Letter
Exhibit M	2021-01-06 Lilly Letter re Advisory Opinion-c

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.

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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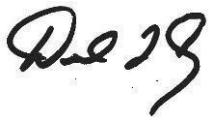
[39] *See* HRSA/OPA 340B FAQs, *at* https://www.hrsa.gov/opa/faqs/index.html (last visited April 21, 2020). HRSA, in its guidance, seems to hold out an exception to this rule where a covered entity notifies a manufacturer and secures the agreement of the manufacturer to the reclassification. Covered 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

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 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>

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

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

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

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.

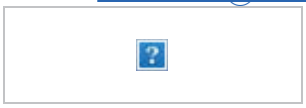
While HRSA has published contract pharmacy advice in guidance, rather than through binding regulations, HRSA strongly encourages Lilly to reconsider its position. Lilly's refusal to sell 340B priced drugs to covered entities through contract pharmacy arrangements would have a significant negative impact 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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Department of Health and Human Services
200 Independence Avenue SW
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General Counsel
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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

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.

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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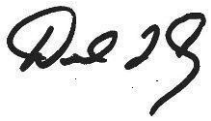
[39] *See* HRSA/OPA 340B FAQs, *at* https://www.hrsa.gov/opa/faqs/index.html (last visited April 21, 2020). HRSA, in its guidance, seems to hold out an exception to this rule where a covered entity notifies a manufacturer and secures the agreement of the manufacturer to the reclassification. Covered 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

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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.

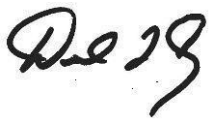
Lilly shares the Administration's goal of ensuring that 340B patients should directly benefit from the significant 340B discounts on Lilly insulins. Lilly will provide quarterly reports (or more frequently, if requested) regarding covered entity use of the two exceptions provided for under our policy.

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.

***

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.

****

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

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

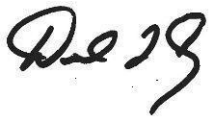
We do not take threats of sanctions lightly. Nor do we appreciate the gamesmanship you appear to be engaged in—threatening potential sanctions if Lilly does not voluntarily acquiesce, but failing to take a position on how or why the 340B statute would be violated, in an attempt to avoid finality (and 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.

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

Exhibit J

Lilly USA, LLC

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www.lilly.com

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

POLSINELLI

1000 Second Avenue, Suite 3500, Seattle, WA 98104 • (206) 393-5400

January 6, 2021

Jessica M. Andrade
206.393.5422
206.299.9423 Fax
jessica.andrade@polsinelli.com

Via Email

Eli Lilly & Company
340B@lilly.com

Derek Asay
Senior Director, Government Strategy, Federal Accounts & Quality
asay_derek_l@lilly.com

Heather Dixson
Director, Government Price Reporting
dixson_heather_a@lilly.com

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