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.

ALEX M. AZAR II, in his official capacity as 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,

THOMAS J. ENGELS, in his official capacity as 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.

Civil Action No. 1:21-cv-81

Document Electronically Filed

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

At issue in this case is the lawful scope of the 340B Drug Pricing Program ("340B Program"), which Congress created in 1992 to expand low-income Americans' access to affordable prescription medicines. *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602(a), 106 Stat. 4943, 4967 (adding section 340B to the Public Health Service Act) ("340B Statute"). 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 340B Program, they have little practical choice but to "opt in[]": "Manufacturers' eligibility to participate in State Medicaid [and federal Medicare] programs," which "touch[] the lives of nearly all Americans," *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019), and contribute a significant portion of manufacturers' annual revenues, "is conditioned on their" participation in the 340B Program and "entry into [Pharmaceutical Pricing Agreements] for covered drugs purchased by 340B entities." *Astra U.S.A., Inc. v. Santa Clara Cnty.*, 563 U.S. 110, 113 (2011).

Under the original terms of the 340B Program, and cognizant of the constitutional limits on forcing private parties to effectively subsidize other private parties, Congress provided that only "covered entities"—a narrowly circumscribed class of non-profit healthcare providers that Congress defined to be limited to 15 discrete and specifically enumerated types of entities that serve low-income and/or vulnerable populations—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 as "contract pharmacies"—had no legal basis to demand to receive medications from manufacturers at 340B discounted prices. *See* 42 U.S.C. § 256b(a)(4).

But that has all changed now. On December 30, 2020, the U.S. Department of Health and Human Services ("HHS") Office of the General Counsel "released an advisory opinion concluding that drug manufacturers are required to deliver discounts under the 340B Drug Pricing Program (340B 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 predominantly 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. When Defendants HHS and the Health Resources and Services Administration ("HRSA") 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), contract pharmacies began "generat[ing] revenue" ***to the tune of hundreds of millions of dollars per year*** by perverting the 340B 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 products—except when a covered entity lacks an in-house pharmacy, in which case an outside pharmacy is necessary to dispense covered drugs, and in which case Lilly will permit the covered entity to designate one contract pharmacy to receive and dispense 340B product.

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 of the 340B Program, 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 first threatened Lilly with sanctions and now have made good on those threats: They have jettisoned their prior nonbinding guidance that contract pharmacy arrangements are permissible but not enforceable and replaced that guidance with a new, binding decision under which manufacturers like Lilly must offer full 340B discounts to contract pharmacies on all covered drugs, lest they 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.

Lilly therefore brings this action seeking an order (1) declaring that the December 30 Decision violates the Administrative Procedure Act because it 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; (2) declaring that Lilly is not required to offer 340B discounts to contract pharmacies; and (3) enjoining enforcement of the December 30 Decision and all actions by Defendants inconsistent with that declaratory relief.

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 Alex M. Azar II, sued in his official capacity only, is the Secretary of HHS. His official address is in the District of Columbia. Secretary Azar 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 Thomas J. Engels, sued in his official capacity only, is the Administrator of HRSA. His official address is in Rockville, Maryland. Administrator Engels is directly responsible for the administration of the 340B Program and the actions complained of herein. Administrator Engels, 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 Administrative Procedure Act ("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, known as the Pharmaceutical Pricing Agreement ("PPA"), with HHS. *Astra*, 563 U.S. 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 up to $5,883 "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 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 (and frequently do) 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. The 340B 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 Congress did not delegate any discretionary or rulemaking authority to HRSA 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.

36. To the contrary, Congress 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), the latter of which is specifically 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 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.

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).

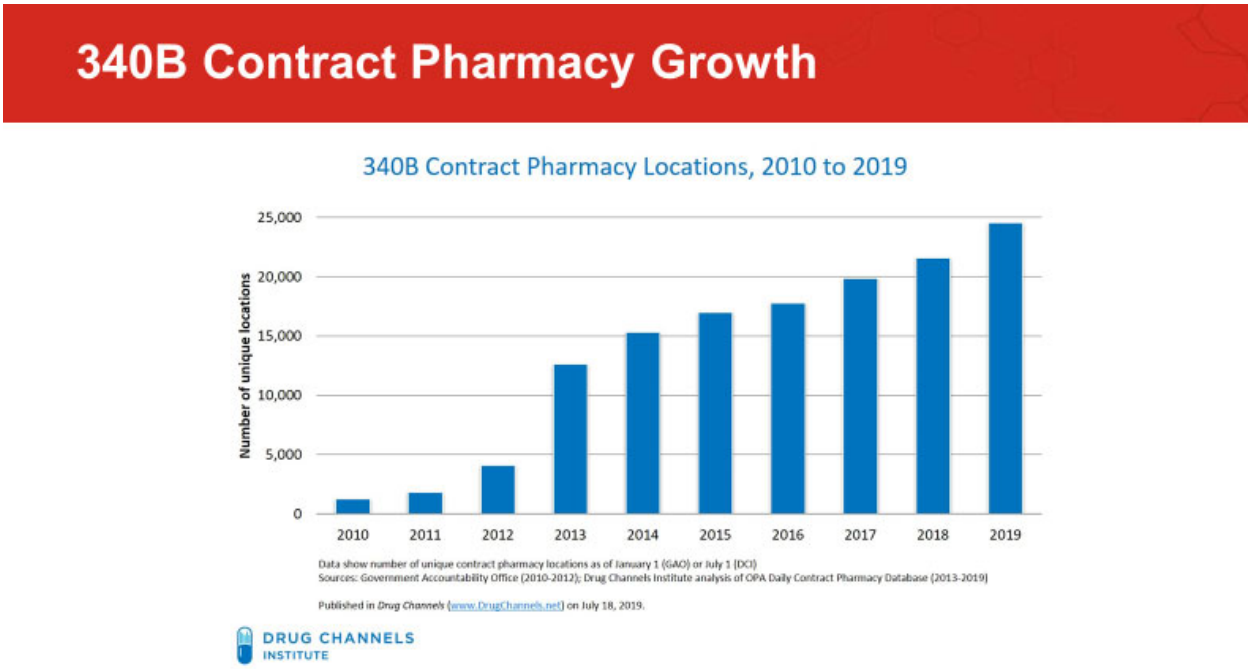
46. This 2010 guidance allows all covered entities, not just those without an in-house pharmacy, to contract with commercial pharmacies to dispense 340B discounted drugs. It further

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.

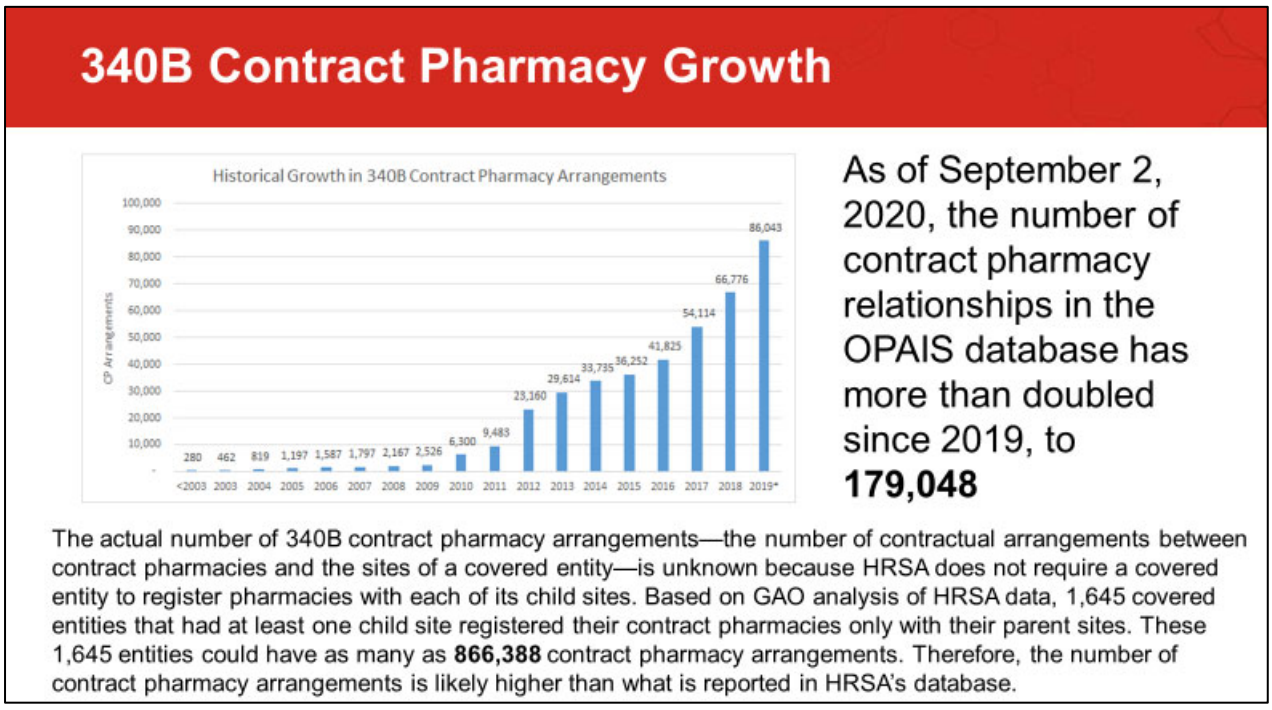
47. As in 1996, HRSA styled the 2010 guidance as an interpretive rule, did not go through the notice-and-comment procedures, and made clear that the guidance imposed no obligations. *Id.* at 10,274; *see also id.* at 10,273 (2010 guidance "neither imposes additional burdens upon manufacturers, nor creates 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 intended to improve access to much-needed drugs among vulnerable patient populations; instead, the Program has become a massive profit-making endeavor 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.

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.

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

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

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

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

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

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

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

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

59. Contract pharmacies unsurprisingly have profited greatly from this arrangement. "The average profit margin on 340B medicines commonly dispensed through contract pharmacies is an estimated 72 percent, compared with just 22 percent for non-340B medicines dispensed through independent pharmacies." Vandervelde et al., *supra*, at 3; *see also* Raymond James, *340B Pharmacy Follow Up—Less Than $1.4B but Still Yuge*, at 1 (Sept. 9, 2020) (Walgreens generated profits "in the hundreds of millions" through 340B contract pharmacy arrangements).

60. And instead of reinvesting those savings to expand access to affordable prescription drugs, contract pharmacies simply pocket a portion of the savings on each drug dispensed.

61. It gets worse. 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.

62. 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.*

63. Likewise, 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.*

64. 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.

65. 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.

66. 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).

67. Those projections were accurate. A September 2020 analysis by an investment bank confirmed that Walgreens 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).

68. 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

69. 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 increase the incidence of a second form of diversion: contract pharmacies claiming 340B discount prices for drugs provided to patients not eligible under the 340B Program. 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.

70. 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.

71. 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).

72. 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.

73. 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

74. 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.

75. 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 340B Statute—was unlawful and unauthorized under the 340B Statute.

76. 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 340B 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.

77. 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").

78. 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

79. 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.

80. 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.

81. 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.

82. 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 recently began to allow contract pharmacies that are wholly owned by a covered entity to access 340B-priced product. Lilly fully intends to continue to work flexibly with all stakeholders to refine its distribution plan as needed.

83. 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.

84. 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.

85. 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.

86. 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.

87. 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.

88. 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.

89. 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"

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

91. 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.

92. 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.

93. 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.

94. 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.

95. 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.

96. 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.

97. 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).

98. 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

99. 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.

100. 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.

101. 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.

102. 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.*

103. 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.

104. 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.

105. 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.

106. 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 (and has not to this day).

107. 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).

108. 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.

109. 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.

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

111. 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.)

112. 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.

113. 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.*

114. 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.*

115. 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 340B Statute unambiguously distinguishes between "covered entities" on the one hand and agents—*i.e.*, "associations or organizations representing the interests of [] covered entities," "wholesalers," and "distributors"—on the other. *See id.* § 256b(d)(1)(B)(v), (2)(B)(iii), (3)(B)(vi). Finally, they did not reconcile how this novel interpretation, which ***requires*** manufacturers to offer 340B discounts to an unlimited number of contract pharmacies, can be squared with the position that Defendants had taken for approximately fifteen years (and that they had reiterated mere months before) that the guidance allegedly creating this "obligation" is "legally unenforceable."

116. 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.").

117. 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.

118. 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.

119. 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))).

120. 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 at all. But these mechanisms only 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 covered entity never takes possession of the product. The contract pharmacy then sells the product to a customer who appears at its counter.

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

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

122. 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)).

123. 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.

124. 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. M (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.").

125. 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]").

126. 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.

127. 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).

128. 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.

129. 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.

130. 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).

131. 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.

CLAIMS FOR RELIEF

COUNT I

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

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

133. 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).

134. 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.

135. 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.

136. 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).

137. The December 30 Decision constitutes "final agency action[s] 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.

138. 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).

139. 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).

140. 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).

141. 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).

142. 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.

143. 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.

144. 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.

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

146. 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.

147. 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)

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

149. 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).

150. The 340B Statute does not confer on Defendants the authority to require drug manufacturers, on pain of penalty, to provide drugs subject to pricing under the 340B Statute to contract pharmacies, as contract pharmacies are not covered entities as defined by the 340B Statute and the statute does not authorize Defendants 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.

151. 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.").

152. 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 340B Statute.

153. 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.

154. 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).

155. 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)

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

157. 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).

158. 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.*

159. 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).

160. 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.

161. 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.

162. 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.

163. 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 U.S. Constitution)

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

165. 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).

166. 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.

167. 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.

168. 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).

169. 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)).

170. 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).

171. 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.).

172. 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).

173. 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).

174. 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.").

175. 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).

176. 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.

177. 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").

178. 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).

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

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

Dated: January 12, 2021

Respectfully submitted,

s/*Andrea Roberts Pierson*

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* Application for *pro hac vice* forthcoming

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CERTIFICATE OF SERVICE

I hereby certify that on **January 12, 2021**, a copy of the foregoing was filed electronically. Service of this filing will be made on all ECF-registered counsel by operation of the court's electronic filing system. Parties may access this filing through the court's system.

/s/ Andrea Roberts Pierson