BEFORE THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ADMINISTRATIVE DISPUTE RESOLUTION PANEL

NATIONAL ASSOCIATION OF COMMUNITY HEALTH CENTERS 7501 Wisconsin Ave Suite 1100W Bethesda, MD 20814, *Petitioner*, v. ELI LILLY AND COMPANY Lilly Corporate Center 893 Delaware Street Indianapolis, IN 46225, and SANOFI-AVENTIS U.S. LLC 55 Corporate Drive Bridgewater, NJ 08807 and ASTRAZENECA PLC AstraZeneca 1800 Concord Pike Wilmington, DE 19803, *Respondents*.	Petition No: 210112-2

PETITION FOR DECLARATORY AND INJUNCTIVE RELIEF

Petitioner, National Association of Community Health Centers ("NACHC"), as an association and authorized representative of its Federally-qualified health center ("FQHC") members, brings this action for equitable relief under Section 340B of the Public Health Service ("PHS") Act, 42 U.S.C. § 256b, pursuant to and in compliance with the procedures set forth in 42

C.F.R. § 10.21, and alleges as follows:

NATURE OF ACTION

1. Petitioner seeks equitable relief to remedy ongoing and unlawful overcharging activity by drug manufacturers Eli Lilly and Company, Sanofi-Aventis U.S. LLC, and AstraZeneca PLC—collectively, "the drug manufacturers"—each of which, as described more fully below, recently restricted FQHC covered entity access to covered outpatient drugs at federal 340B drug discount program ("340B" or "340B Program") pricing by refusing to offer covered outpatient drugs for FQHC covered entity purchase at or below the applicable ceiling price whenever the FQHC covered entity will dispense the drugs to its patients through contract pharmacy arrangements.

2. The drug manufacturers' actions constitute unlawful overcharging and a clear violation of both the 340B statute and the binding pharmaceutical pricing agreements ("PPAs") between manufacturers and the United States Department of the Health and Human Services ("HHS") that statute requires. The 340B statute, codified at 42 U.S.C. § 256b, and the PPAs (which simply incorporate 340B statutory requirements) require that manufacturers "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price." 42 U.S.C. § 256b(a)(1). The drug manufacturers cannot impose their own unilateral conditions or restrictions on this unequivocal statutory requirement.

3. FQHC covered entities are statutorily required to provide "pharmaceutical services as may be appropriate for particular centers" and authorized to provide those services either through their own staff, through "contracts or cooperative arrangements" with other entities, or through a combination of the two approaches. 42 U.S.C. § 254b(a)(1), (b)(1)(A)(i)(V).

4. HHS has long recognized that FQHCs are statutorily afforded the flexibility to provide pharmacy services to their patients through contractual arrangements with private pharmacies, instead of—or in addition to—doing so through an in-house pharmacy owned by the health center. Indeed, in response to the recent, unilateral drug manufacturer actions underlying this claim, HHS—through its Office of General Counsel (OGC)—issued an advisory opinion which forcefully reiterates and reinforces the agency's longstanding position.

5. The drug manufacturers have acted strikingly similarly, if not in concert, to limit the FQHC covered entities' ability to purchase drugs at 340B pricing when those drugs will be dispensed to eligible FQHC patients via contracted pharmacies. The drug manufacturers' actions, taken close in time, form part of the same series of transactions or occurrences, and the ADR panel's resolution of Petitioner's joint claims against each manufacturer will involve common issues of law and fact—namely whether prohibited overcharging in violation of the 340B statute results from the drug manufacturers' refusal to provide covered outpatient drugs at the 340B ceiling price to FQHC covered entities for drugs dispensed to such entities' patients via contract pharmacies. Accordingly, joinder of the drug manufacturers in this single action is appropriate under Rule 20(a)(2) of the Federal Rules of Civil Procedure and the 340B statute, which provides that claims "shall be resolved fairly, efficiently, and expeditiously." 42 U.S.C. § 256b(d)(3)(B)(ii); 42 C.F.R. § 10.21(e)(4).

PARTIES

6. Petitioner is a national, nonprofit corporation whose primary objective is to further—through extensive education, training, and advocacy—the mission and purpose of FQHCs. The FQHCs represented herein play a vital role in our nation's health care safety-net by providing primary and other health care and related services—including pharmaceutical services—to

medically underserved populations throughout the nation and its territories, regardless of any individual patient's insurance status or ability to pay for such services. FQHCs have been recognized as 340B Program covered entities since the 340B Program's 1992 inception.

7. Petitioner brings this joint claim, as defined in 42 C.F.R. § 10.3 and authorized under 42 C.F.R. § 10.21(e), on behalf of its FQHC covered entity members listed in Exhibit A. Each FQHC covered entity so listed could, on its own, bring claims against one or more of the drug manufacturers for the equitable relief sought, has authorized NACHC to bring this joint claim on its behalf, and otherwise meets applicable regulatory requirements for bringing this joint claim.

8. Eli Lilly and Company ("Lilly") is a publicly traded pharmaceutical manufacturer and participant in the 340B Program. Lilly is organized under the laws of the State of Indiana and headquartered in Indianapolis, Indiana.

9. Sanofi-Aventis U.S. LLC ("Sanofi") is a pharmaceutical manufacturer and participant in the 340B Program. Sanofi is headquartered in Bridgewater Township, New Jersey.

10. AstraZeneca PLC ("AstraZeneca") is a limited partnership biopharmaceutical manufacturer and participant in the 340B Program. AstraZeneca is organized under the laws of the State of Delaware with its principal place of business in Wilmington, Delaware.

JURISDICTION

11. This panel has jurisdiction over Petitioner's claims because, in accordance with the requirements of 42 C.F.R. §§ 10.3 and 10.21: (1) the claims are based on the drug manufacturers' unlawful overcharging activity, in particular their efforts to limit FQHC covered entities' ability to purchase covered outpatient drugs at or below 340B ceiling prices, and (2) the equitable relief sought will likely have a value of more than $25,000 for each joint claimant FQHC covered entity

member of NACHC during the twelve-month period after the 340B ADR Panel's final agency decision.

ALLEGATIONS

I. The 340B Program

12. The 340B Program exists to assist covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102–384(II), at 12 (1992). Under the 340B Program, drug manufacturers who wish to have their products covered by Medicare and Medicaid must provide covered outpatient drugs at a discount to covered entities.

13. Such covered entities, defined at 42 U.S.C. § 256b(a)(4), include, at subsection (a)(4)(1), "Federally-qualified health center[s] (as defined in section 1905(*l*)(2)(B) of the Social Security Act [42 U.S.C. 1396d(*l*)(2)(B)])."

14. For more than 20 years—from 1996 until mid-2020 when the prohibited overcharging activity leading to this Petition began—drug manufacturers, either directly or through wholesale distributors, have shipped FQHC-purchased covered outpatient drugs to FQHCs' contract pharmacies, i.e. third-party pharmacies with which FQHCs contract to dispense drugs to FQHC patients. All but a handful of the hundreds of manufacturers participating in the 340B Program under PPAs continue to do so.

15. Section 340B, at 42 U.S.C. § 256b(a)(1), requires HHS to "enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." Per that same statutory subsection, "[e]ach such agreement . . . shall require that the manufacturer offer each covered entity covered outpatient drugs for purchase at or

below the applicable ceiling price if such drug is made available to any other purchaser at any price." That agreement is the PPA.

16. As HHS recently made clear through its Office of General Counsel ("OGC"), the statute HHS is authorized to implement is unambiguous in obligating drug manufacturers to sell covered outpatient drugs to covered entities at or below applicable ceiling prices regardless of whether the drugs are distributed through a covered entity's in-house or contract pharmacies:

> [T]he core requirement of the 340B statute, as also reflected in the PPA and [PPA] Addendum, is that manufacturers must "offer" covered outpatient drugs at or below the ceiling price for "purchase by" covered entities. This fundamental requirement is not qualified, restricted, or dependent on how the covered entity chooses to distribute the covered outpatient drugs. All that is required is that the discounted drug be "purchased by" a covered entity. In this setting, neither the agency nor a private actor is authorized by section 340B to add requirements to the statute. . . . It is difficult to envision a less ambiguous phrase [than "purchased by"] and no amount of linguistic gymnastics can ordain otherwise. . . . The situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant.

HHS Office of General Counsel, *Advisory Opinion 20-06 on Contract Pharmacies Under the 340B Program* at 2 (Dec. 30, 2020). This Advisory Opinion is attached as Exhibit B.

17. The December 30, 2020 OGC Advisory Opinion was written in response to the unlawful overcharging activity underlying this Petition.

18. The view espoused in that Advisory Opinion is not novel; it reiterates the longstanding and well-settled concept that covered entities, including FQHCs, have the common law right to contract with third-parties to provide services on their behalf, as HHS recognized in 1996, reiterated in 2010, and reaffirmed in the 2020 Advisory Opinion.

19. HHS has repeatedly made clear that contract pharmacy arrangements are a consistent and necessary outgrowth of the FQHC program's authorizing statute, Section 330 of the PHS Act, *codified at* 42 U.S.C. § 254b *et seq.*, which requires FQHCs to provide pharmacy services and which permits the provision of such services through "contracts or cooperative

arrangements" with other entities. As HHS OGC noted in its 2020 Advisory Opinion: "the [340B] Program is aimed at benefiting providers that are small, remote, resource-limited, receiving federal assistance, or serving disadvantaged populations. . . . These are the poster children of providers that one would expect to lack an in-house pharmacy." *Id.* at 4.

20. HHS is not alone in interpreting the plain language of a plainly written statue to obligate the drug manufacturers to offer covered entities drugs at 340B pricing regardless of whether those drugs are dispensed in-house or through a contract pharmacy arrangement. On September 14, 2020, numerous Members of Congress, weighing in on the drug manufacturer's "series of actions to restrict federally required 340B drug discounts for eligible health care organizations/covered entities"—i.e. the actions underlying this Petition—wrote:

> the 340B statute requires manufacturers wishing to participate in Medicaid and Medicare Part B to "offer each covered entity covered outpatient drugs for purchase at or below the applicable ceiling price." *There are no provisions in the statute that allow manufacturers to set conditions or otherwise impede a provider's ability to access 340B discounts.*

Letter from Members of Congress to Alex M. Azar II, Secretary, U.S. Dep't Health & Human Servs. at 1, Exhibit C (Sept. 14, 2020) (emphasis added). The letter, directed to the HHS Secretary, strongly condemned the unlawful overcharging activity at issue here, noting that "[t]he recent actions undermine the intended purpose of the 340B Drug Pricing Program. The Department of Health and Human Services (HHS) must take immediate action to stop these companies from either denying or limiting access to 340B pricing to hospitals, health centers, and clinics participating in 340B." *Id.* at 1.

II. FQHC Participation in the 340B Program

21. The FQHC covered entities on whose behalf Petitioner brings this action, as indicated in Exhibit A, purchase covered outpatient drugs from some or all of the drug manufacturers

named in this Petition. Certain of the covered entities regular purchases—where applicable provider and patient eligibility elements are satisfied—qualify for 340B discount pricing.

22. The FQHC covered entities represented herein utilize contract pharmacy arrangements to fulfill some or all of their patients' pharmaceutical dispensing needs, including the dispensing of drugs eligible for 340B discount pricing.

23. Under their agreements with contract pharmacies, the covered entities (either directly or through a third-party administrator) order and pay for the 340B drugs and direct the shipment of those drugs from the manufacturer (or wholesaler) to the contract pharmacy.

24. As Congress intended, the FQHC covered entities' participation in the 340B Program generates both savings and revenue at no cost to taxpayers: savings are realized when an FQHC covered entity pays the ceiling price for a particular drug provided to an uninsured or underinsured patient; revenue is generated on the spread between the ceiling price and any reimbursement at or above that price from third-party payers including the Medicare Program, Medicaid managed care organizations, or patients' private insurance carriers.

25. Section 330 of the PHS Act obligates the FQHC covered entities to use any non-grant or program income—e.g. revenue generated through public or private reimbursement for services—in furtherance of their health care safety-net mission. See 42 U.S.C. §§ 254b(e)(5)(A) (defining non-grant funds as "state, local, and other operational funding provided to the center" and "fees, premiums, and third-party reimbursements . . . the center may . . . receive for its operations"), (D) (mandating that non-grant funds be used to further center's project objectives).

III. The Drug Manufacturers' Unlawful Overcharging

A. Lilly

26. Beginning in or around the second half of 2020, the drug manufacturers threatened—and then imposed—significant limitations on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable 340B ceiling prices. The prohibited overcharging actions of each of the three named drug manufacturers are as follows:

27. On or about July 1, 2020, Lilly posted a notice on HHS's designated 340B Program webpage informing 340B covered entities that, effective immediately, it would no longer fulfill covered entities' purchases for multiple formulations of the drug Cialis at 340B pricing for dispensing through the covered entities' contract pharmacies. *See* Limited Distribution Plan Notice for Cialis, Exhibit D.

On or about September 2, 2020, Lilly disseminated another notice (which HHS declined to post on its webpage) informing the covered entities that, effective the day prior, it would no longer fulfill covered entities' purchases for *any* of its covered outpatient drugs at 340B pricing to be dispensed to FQHC patients through any contract pharmacies of a covered entity. Lilly's notice indicated it would provide an exception for certain insulin products. *See* Limited Distribution Plan Notice for Eli Lilly & Co. Prods., Exhibit F; *see also* Letter from Robert P. Charrow, General Counsel, U.S. Dep't of Health & Human Servs., to Anat Hakim, Senior Vice President and General Counsel, Eli Lilly & Co. (Sept. 21, 2020), https://www.hrsa.gov/sites/default/files/hrsa/opa/pdf/hhs-eli-lilly-letter.pdf, Exhibit E (expressing grave concern and refusing to endorse Lilly's actions). The limited insulin exception has proved infeasible.

28. Lilly's near total restriction on the FQHC covered entities' ability to purchase Lilly drugs at 340B pricing is an overcharge as defined in 42 C.F.R. § 10.21(c)(1), i.e. a "limit[ation on]

the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." It is also exactly the sort of "knowing and intentional" overcharging HHS called out in its civil monetary penalty regulations at 42 CFR § 10.11(b).

29. A list of NDCs impacted by Lilly's overcharging is attached as Exhibit I.

B. Sanofi

30. On or around July, 2020 Sanofi announced that, effective October 1, 2020, Sanofi would no longer permit covered entities to purchase covered outpatient drugs at or below 340B ceiling prices for dispensing through the entities' contract pharmacies unless the covered entities submit claims data to Sanofi through third-party software vendor Second Sight Solutions. *See* Sanofi Letter Re: 340B Program Integrity Initiative, Exhibit H.

31. Sanofi claims publicly that it needs this data to identify and prevent duplicate discounts, but has no legal right to demand this information or condition its statutory obligation to offer covered outpatient drugs to covered entities at or below 340B ceiling prices on compliance with its demands. HHS has long made clear that the 340B statute does not permit manufacturers to impose any conditions on covered entities, including by, for example, conditioning the offer of 340B discounts on a covered entity's assurance of compliance with 340B Program requirements. *See, e.g.*, Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25110 (May 13, 1994); HRSA, 340B Drug Pricing Program, Manufacturer Resources, https://www.hrsa.gov/opa/manufacturers/indExhibithtml (*last accessed* Jan. 13, 2021); HRSA, 340B Drug Pricing Program Notice No. 2011-1.1 (May 23, 2012), https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/nondiscrimination05232012.pdf.

32. Sanofi's conditioning of the FQHC covered entities' ability to purchase its drugs at 340B pricing on participation in unsanctioned data sharing is an unlawful overcharge—i.e. a limitation on the covered entities' ability to purchase Sanofi drugs at or below applicable ceiling prices—as defined in 42 C.F.R. § 10.21(c)(1). Like Lilly's conduct, it too is the sort of overcharging HHS referenced in 42 CFR § 10.11(b).

33. A list of NDCs impacted by Sanofi's overcharging is attached as Exhibit K.

C. AstraZeneca

34. In or around August 2020, AstraZeneca informed the covered entities that, effective October 1, 2020, it would no longer ship covered entities' purchases of 340B discounted drugs to the entities' contract pharmacies. AstraZeneca followed through on its threat, with a limited exception for covered entities that lack any other pharmacy outlet to designate one single contract pharmacy per covered entity. *See* AstraZeneca Letter Re: 340B Contract Pharmacy Pricing (Aug. 17, 2020), Exhibit G.

35. AstraZeneca's "exception" concedes that it is refusing to make its covered outpatient drugs available to FQHC covered entities at or below 340B ceiling prices based on its unilateral decision as to whether a covered entity's use of contract pharmacies is permissible under the 340B Program. This documented action meets the definition of an overcharge included in 42 C.F.R. § 10.21(c)(1)—it is a "limit[ation on] the covered entity's ability to purchase covered outpatient drugs at or below the 340B ceiling price." Like the other manufacturers' actions, it too is the sort of overcharging HHS referenced in 42 CFR § 10.11(b).

36. A list of NDCs impacted by AstraZeneca's overcharging is attached as Exhibit J.

IV. Harm to the FQHC Covered Entities

37. The drug manufacturers' ongoing and unlawful overcharging activities have caused and will continue to cause significant financial and other harms to the FQHC covered entities—and their patients—so long as the manufacturers' limitations on the entities' purchases continue.

38. The differential between the non-discounted "wholesale acquisition cost" ("WAC") and 340B ceiling price for affected drugs can be enormous, even for commonly prescribed drugs such as insulin, osteoporosis treatments, and asthma inhalers.

39. As just one example of the magnitude of the manufacturer's overcharging, the WAC for the Lilly osteoporosis treatment Forteo is approximately $3,663.39 per unit, while the 340B price is $0.02, resulting in an approximate overcharge of $3,663.37 for each unit of Forteo that Lilly refuses to offer the FQHC covered entities at 340B pricing. A sample of WAC/340B price comparisons is attached as Exhibit L to further illustrate the value of the drug manufacturers' sweeping restrictions on covered entity purchasing.

40. The cumulative financial harm to the FQHC covered entities caused by each drug manufacturer, taken separately, will far surpass the *de minimus* regulatory threshold for equitable relief—namely, an impact on the covered entity with an estimated value of $25,000 or more in the twelve months following the 340B ADR Panel's resolution of the claim.

41. Indeed, several of the FQHC covered entities on whose behalf Petitioner brings this joint claim anticipate that the equitable relief sought—i.e. the restoration of the covered entities' access to Lilly, Sanofi, and AstraZeneca drugs at applicable 340B pricing for dispensing to their patients at contract pharmacies—will have a far greater value than the estimated prospective threshold in 42 C.F.R. § 10.21(b).

42. Covered entity patients also stand to be harmed by cuts to non-reimbursable services that FQHCs currently support with funds generated through 340B Program participation.

These services—which may be drastically reduced or eliminated entirely due the drug manufacturers' refusal to offer their drugs at 340B pricing—include, for example, medication therapy management, behavioral health care, dental services, vaccinations, case management and care coordination services, translation/interpretation services for patients with limited English language ability, and transportation assistance that enables patients to reach their health care appointments.

COUNT ONE: LILLY

43. The allegations contained in paragraphs 1–44 above are re-alleged and incorporated by reference herein.

44. By refusing to allow the FQHC covered entities to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, Lilly has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS, it "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."

COUNT TWO: SANOFI

45. The allegations contained in paragraphs 1–44 above are re-alleged and incorporated by reference herein.

46. By placing restrictions and conditions on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, Sanofi has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS,

it "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."

COUNT THREE: ASTRAZENECA

47. The allegations contained in paragraphs 1–44 above are re-alleged and incorporated by reference herein.

48. By restricting the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices where those drugs will be dispensed to eligible patients via contract pharmacies, AstraZeneca has violated and continues to violate the requirement in 42 U.S.C. § 256b(a)(1) that, per its statutorily-mandated PPA with HHS, it "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."

REQUEST FOR RELIEF

Petitioner respectfully requests equitable relief as follows:

1. Declare that each FQHC covered entity is entitled to purchase the drug manufacturers' covered outpatient drugs at 340B pricing to be dispensed to eligible patients through each covered entity's contract pharmacies.

2. Declare that Lilly, by restricting the FQHC covered entities' ability to purchase Lilly drugs at or below applicable ceiling prices, as described in paragraphs 27–28 herein, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

3. Declare that Sanofi, by restricting the covered entities' ability to purchase Sanofi drugs at or below 340B ceiling prices unless the covered entities' submit claims data to Sanofi

through a third-party vendor, as described in paragraphs 31–32 herein, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

4. Declare that AstraZeneca, by restricting the FQHC covered entities' ability to purchase Lilly drugs at or below applicable ceiling prices, as described in paragraphs 35–36 herein, overcharged and continues to overcharge the FQHC covered entities in violation of 42 U.S.C. § 256b(a)(1).

5. Order the drug manufacturers to comply with 42 U.S.C. § 256b(a)(1) and the terms of their PPAs by removing all manufacturer-imposed qualifications, limitations, conditions, or restrictions on the FQHC covered entities' ability to purchase covered outpatient drugs at or below applicable ceiling prices.

6. Order such other equitable relief as the Panel deems just and proper.

Dated: January 13, 2021

Respectfully submitted,

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